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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Poly (maleic anhydride-methyl vinyl ether) by 1,9-decadiene

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Director

Chemicals Notification and Assessment

FULL PUBLIC REPORT

Poly (maleic anhydride-methyl vinyl ether) crosslinked by 1,9-decadiene

1. APPLICANT

ISP (Australasia) Pty Ltd, 73-77 Derby St, Silverwater NSW 2141.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, Poly (maleic anhydride-methyl vinyl ether) crosslinked by 1,9-decadiene, is considered to be non-hazardous. Therefore, the identity of the monomers and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Chemical name: Poly (maleic anhydride-methyl vinyl

ether) crosslinked by 1,9-decadiene

Chemical Abstracts Service

(CAS) Registry No.: 136392-67-1

Other names: PVM/MA Decadiene Crosspolymer/MA

copolymer crosslinked with 1,9-

DecadieneACV-4006

Trade name: Stabileze 06

Molecular formula: $[C_7H_8O_4)_X(C_{10}H_{18})(C_7H_8O_4)_V]_Z$

Structural formula:

Number-average molecular weight: >1,000,000 (based on network structure)

Maximum percentage of low
molecular weight species
(molecular weight < 1000): <0.8%</pre>

Method of detection and determination: Infra red spectroscopy; NMR spectroscopy; gas chromatography.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: white powder

Odour: mild, non specific

organic odour

Melting Point/Boiling Point: none, the polymer

decomposes before it

Specific Gravity/Density: 250 kg/m³

Water Solubility: insoluble (forms a gel)

Flash Point: none known to exist

Flammability Limits: polymer is not flammable

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Combustion Products:

Pyrolysis Products:

Decomposition Temperature:

Decomposition Products:

Explosive Properties: none known to exist

Reactivity/Stability: stable at room

temperature

Particle size distribution: <5 µm

Vapour pressure was not required as the polymer is a solid.

Values for partition co-efficient, hydrolysis as a function of pH, adsorption/desorption and dissociation constant are not relevant as the polymer is insoluble in water.

Autoignition temperature was not available as the polymer has no flash point.

No indication of hydrolysis has been given by the notifier on the ground that the polymer is insoluble in water. It should be noted that the structure of the notified polymer indicates prominent anhydride functionality which may normally be expected to be susceptible to hydrolysis. However, during the formulation stage a blend containing the notified polymer is neutralised under basic conditions with no apparent degradation of the polymer.

4. PURITY OF THE CHEMICAL

Degree of purity: >99%

Toxic or hazardous impurity/impurities:

(a) Chemical name: cyclohexane

Synonyms: hexahydrobenzene; hexamethylene;

CAS No.: 110-82-7

Weight percentage: 0.2

Toxic properties: Moderately toxic by ingestion rat

oral LD50 29820 mg/kg, mouse oral LD50 813 mg/kg; systemic irritant by inhalation and ingestion; skin irritant; mutagenic data (1). exposure standard TWA 300ppm (2).

(b) Chemical name: ethyl acetate

Synonyms: acetic ether; acetoxyethane; ethyl

acetic ester; ethyl ethanoate

CAS No.: 141-78-6

Weight percentage: 0.3

Toxic properties: Mildly toxic by ingestion (rat oral

 LD_{50} 5620 mg/kg); irritant to eye, skin and mucous membranes; systemic

irritant by inhalation; mildly narcotic; mutagenic data (1). exposure standard TWA 400ppm.

Non-hazardous impurity/impurities: none (> 1% by weight)

Maximum content of residual monomers: 0.7%

Additives/Adjuvants: negligible

5. <u>INDUSTRIAL USE</u>

The notified polymer will be imported as the white powder Stabileze 06 (containing >99% of notified polymer). It will be marketed to the cosmetics manufacturing industry as a thickener and stabiliser for gels, creams and lotions in hair care and skin care products. It is currently marketed in the USA, Holland, France, Germany, Spain, China, Singapore and Hong Kong. The notifier intends to import up to 10 tonnes per annum.

6. OCCUPATIONAL EXPOSURE

Stabileze 06 will be transported from the dock to the ISP warehouse and from the warehouse to potential customers by road (truck) in steel or fibre drums of approximately 50kg. Potential customers (approximately 10) will be cosmetic and toiletry manufacturers, located principally in the suburbs of Sydney, Melbourne and Brisbane. The occupational exposure can only be estimated at this stage as there are no customers for Stabileze 06.

The total number of workers in the industry likely to be exposed to products containing Stabileze 06 is 170. These are expected to be storepersons (20), quality assurance personnel (20), plant operators (20), packers (100) and personnel involved in product development (20).

Storepersons will load, unload, store and transport sealed drums by forklift. Exposure of storepersons to Stabileze 06 will be negligible unless there is a spill.

Personnel involved in quality assurance (chemists, chemical technicians and laboratory assistants) will sample from drums and test material as supplied as well as test the manufactured cosmetics. Exposure will be approximately 2 hours/day, 12 times/year to raw material and 1-2 hours/day, 60 days/year to the cosmetics.

Plant operators will add and mix Stabileze 06 with other cosmetic ingredients to produce the cosmetic products (containing a maximum of 1% Stabileze 06). Weighing and addition of powder to mixing vessels will be by manual means. The process equipment used will be open head stainless steel tanks ranging in size from 100 L to 10,000 L; stirrers ranging from high speed impeller (1440 rpm) to slow speed sweep (~20rpm); and pumps (either lobe, diaphram, gear or air piston type). Cleaning will range from one worker with a scraper and hose to an elaborate "clean in place" system. Engineering controls will also vary at each plant depending on what is required, ranging from general ventilation to use of dust extractors. It is envisaged that the requirement for dust extraction will be minimal during addition as very little dust is formed, however it is expected that such engineering controls will be in force during weighing operations. Exposure to Stabileze 06 will be approximately 1 hour/day, 60 days/year, and will vary depending on the systems employed.

However, with adequate ventilation, inhalation of the polymer should be negligible.

Packers will fill and pack the manufactured cosmetics involving exposure for 8 hours/day, 60 days/year. However, these workers will only handle finished products containing a maximum of 1% Stabileze 06 and the notifier states that adequate ventilation will be available, therefore exposure to the notified polymer will be low.

Personnel involved in product development (chemists, chemical technicians and laboratory assistants) will be exposed to Stabileze 06 2 hours/day, 12 days/year during development of new cosmetic formulae.

7. PUBLIC EXPOSURE

Stabileze O6 is to be imported into Australia in steel or fibre drums and transported by truck from the dock to ISP warehouse, and from the warehouse to the customers who at this stage are identified as the cosmetic and toiletry industry. Public exposure to Stabileze O6 may occur accidentally during transportation of the material.

Stabileze O6 is intended for use as a thickening and stabilising agent in cosmetic products for skin and hair care, such as styling gels, moisturising creams and lotions, in which it is compounded with other ingredients. The skin and hair care products will contain Stabileze O6 at 1% or less by weight. By far the greatest means of exposure to Stabileze O6 will occur during the use of the cosmetic and toiletry products that contain Stabileze O6.

Unspent polymer will be disposed of to landfill or through the sewerage system where it is anticipated that the polymer will be precipitated in the solid sludge, and the dried sludge will be disposed of to landfill, spread on agricultural land or incinerated. Products of incineration are likely to be oxides of carbon and hydrogen.

8. ENVIRONMENTAL EXPOSURE

. Release

The polymer will be compounded into cosmetics by an estimated 10 cosmetics manufacturing companies in at least 3 major cities and is expected to be sold Australia-wide providing a wide environmental exposure of the substance. Given that cosmetics formulation involves use of maximum estimated import quantity of 10 tonnes per year of Stabileze 06, the average substance usage per site is expected to be 1000 kg per annum.

The notifier indicates that a typical manufacturing plant will produce a bulk batch (2000 kg) of hair gel or skin lotion on 100 days of the year. The expected total polymer wastage factor will be 0.5% from unused residues in the polymer containers, equipment washings and batch residues. Therefore, the expected daily waste polymer release will be 100 g. Further, it follows that a maximum of 10 kg of the polymer will be disposed of annually at a given site. These batch residues will be processed through a treatment system for separation of solids and oils and precipitated into sludge. The dried sludge is expected to be disposed of to landfill.

Stabileze 06 is intended for use in hair care and facial products and, as such, would be expected to be released to the environment via consumer use through washing the polymer from hair and face into the sewerage system.

Stabileze 06 is likely to strongly bind to the sludge/solids compartment of the sewerage system where it is expected to be incinerated, disposed of to landfill or spread onto agricultural land.

. Fate

Stabileze 06 is an insoluble polymer. Therefore leaching from landfill sites or agricultural land is not expected. Incineration of the notified substance will produce oxides of carbon.

Upon release to the environment in sewage effluent, the notified polymer would be expected to disperse and partition to sediment. The polymer is not expected to undergo biodegradation at significant rates. Whilst the anhydride functionality indicates

a susceptibility to hydrolysis the low solubility of the notified polymer would limit its biodegradation via this mechanism. Bioaccumulation of the polymer is unlikely due to its high molecular weight (>1000).

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicological data are not required for polymers with NAMW >1000 under the *Industrial Chemicals* (Notification and Assessment) Act 1989, as amended (the Act). However, the following data were submitted for evaluation.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Stabileze 06

Test	Species	Outcome	Reference
Oral	Rat	LD50: >5000mg/kg	3,4
Skin	Rabbit	slight irritant	5
Eye	Rabbit	slight irritant	6
Skin	Human	non-sensitising	7
Phototoxicity	Human	non-phototoxic	8
Photoallergy	Human	non-photoallergen	9

9.1.1 Oral Toxicity (3,4)

These studies were carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 401 (10).

In one study (3) a single dose of 1500mg/kg Stabileze 06 (as a 16.7% w/v suspension in corn oil) was administered by gavage to 10 (5 male and 5 female) Sprague-Dawley rats. These animals were observed for signs of toxicity and mortality for a period of 14 days. All animals appeared normal throughout the observation period except for one female which was intubated incorrectly. This animal was replaced on day 4 by another female rat which was

observed for the following 14 days. Upon necropsy at the conclusion of the observation periods no gross abnormalities were noted for all animals.

In a similar study (4) a single dose of 5000mg/kg Stabileze 06 (as a 1% gel) was administered to 5 male and 5 female Sprague-Dawley rats by gavage. All animals appeared normal throughout the 14 day observation period. Necropsy revealed no gross abnormalities for all animals.

Results of these studies indicate an oral acute LD $_{50}$ of >5000 mg/kg in rats for Stabileze 06.

9.1.2 Dermal Toxicity (Ref No:)

9.1.3 Inhalation Toxicity (Ref No:)

9.1.2 Skin Irritation (5)

This study was conducted in accordance with the *OECD Guidelines* for Testing of Chemicals No: 404 (11). However, it should be noted that the test did not include all the observation times recommended by these guidelines.

A single dose of 0.2 g of Stabileze 06 was applied occlusively to the clipped backs of six New Zealand white rabbits. A dose of 0.2 g was chosen for application as greater doses could not be completely covered by the occlusive patch due to the 'fluffy' nature of the test compound. One abraded and one intact site was treated on each animal for 24 hours. At the conclusion of the contact period the test sites were wiped with deionised water and examined for erythema and oedema. Observations were made at 24 hours (ie within 30-60 minutes after patch removal) and at 72 hours after application. Skin reactions were assessed according to the scoring system in (5). Very slight erythema was observed on two intact sites and three abraded at 24 hours. At 72 hours one rabbit had well defined erythema on an intact test site. None of the animals showed oedema formation over the observation period.

The results of this study suggest that Stabileze 06 is a slight irritant to skin at the concentration tested. However, these results are unexpected as Stabileze 06 is a high molecular weight

polymer (NAMW > 1,000,000) with only <0.8% low molecular weight species (< 1,000) and therefore is not expected to be percutaneously absorbed and cause irritation.

9.1.3 Eye Irritation (6)

This study was conducted in accordance with the OECD Guidelines for Testing of Chemicals No: 405 (12).

Six New Zealand white rabbits were employed in this study. A single dose of 100mg of Stabileze 06 was instilled into one eye of each animal while the other eye served as control. the animals had both treated and control eyes washed with tepid tap water 30 seconds after treatment for 1 minute. Eyes were examined at 1 hour and 1, 2, 3, 4 and 7 days following instillation of test compound. Ocular lesions were scored according to the Draize technique. In the unwashed group, all animals showed conjunctival irritation 1 hour after instillation, which persisted through day 1 in 3/3 animals. In the washed group, all animals showed conjunctival irritation 1 hour after instillation, 2 animals which persisted at the 1 day observation and 1 animal at the 2 day observation. No corneal opacity or iritis was noted during the observation period in either of the test groups.

According to the classification of Kay and Calandra described in (6), the results of this study suggest that Stabileze 06 is a slight irritant to the eye at the dose tested. However, these results are unexpected for this high molecular weight polymer.

9.1.4 Skin Sensitisation (7)

A total of 116 human subjects (22 male and 94 female) were empanelled for a repeated insult patch test. Of these, 109 (20 male and 89 female) completed the test. Subjects varied in age from 13 to 68 years.

Patch sites were cleansed with 70% isopropyl alcohol and approximately 0.2g of Stabileze 06 was applied to the patch sites on each subject. The test material was administered as a gel (2% solid in water).

Induction phase

A series of 9 induction patches were applied over a period of 3 weeks (on the days Monday, Wednesday and Friday) to the same test site on the left upper back of each subject. Each subject was instructed to keep the test site dry while the patch was in place and remove the patch 24 hours after each application. After each patch removal, skin reactions were scored according to the system described in (7) and recorded.

During the induction phase one subject exhibited intense erythema and oedema, two showed very faint or minimal erythema and three exhibited dryness.

Rest period

A period of 2 weeks followed the induction phase during which no applications were made. At the end of this period the original test sites were observed for any skin reactions and any reactions that were experienced by the subjects during this period were also noted.

No subjects exhibited any skin reactions during the rest period.

Challenge phase

A challenge patch was applied to the right upper back of each subject. The patch remained dry and in place for 24 hours, after which reactions were scored and recorded. Further observations were made 48 and 72 hours post-patching.

During the challenge phase only the subject exhibiting the greatest reaction at induction, showed any signs of erythema.

The results of this study suggest that Stabileze 06 is non-sensitising to human skin at the concentration tested.

9.2 Repeated Dose Toxicity (Ref No:)

9.1.5 Phototoxicity (8)

Ten subjects (3 male and 7 female) with fair skin, ranging in age from 30 to 64, were used in this study. The test material, Stabileze 06, was administered as a gel (2% solid in water).

The UV-A light source was from four F40BL fluorescent tubes delivering 0.22 Joules/cm 2 /min at a distance of 15 cm \pm 2 cm from the lamp to the skin sites. Irradiation was for 15 min giving a total dose of 3.3 Joules.

Test material was applied occlusively (0.2 g per patch) to both volar forearms of each subject. Subjects were instructed to keep the patch sites dry during a 24 hour test period. At the conclusion of this period the patches were removed and any reactions on the test sites scored and recorded.

Half the subjects then had their right forearm irradiated, the other half their left. Twenty-four and 48 hours after patch removal, reactions on the test sites were scored and recorded. Non-irradiated arms were protected from UV irradiation throughout the observation period.

Immediately after the 24 hour irradiation, one subject exhibited very faint or minimal erythema on the irradiated site. At 48 and 72 hours no skin reactions were observed on any of the irradiated contact sites. No skin reactions were observed on any of the non-irradiated (no test material) control sites over the entire study.

The results of this study suggest that Stabileze 06 does not induce contact dermal phototoxic responses in human skin at the concentration tested.

9.1.6 Photoallergy (9)

Thirty subjects (6 male and 24 female) with fair skin, ranging in age from 18 to 65, were used in this study. Two females did not complete the study. The test material, Stabileze 06, was administered as a gel (2% solid in water).

UV-A irradiation was from four F40BL fluorescent tubes delivering 0.22 Joules/cm 2 /min at a distance of 15 cm \pm 2 cm from the lamp to the skin sites. UV-A irradiation was for 15 min giving a total dose of 3.3 Joules.

UV-B irradiation was from a Solarium 300 delivering 1.2 mJoules/cm 2 /sec at a distance of 22 cm \pm 2 cm from the lamp to the skin sites. The duration of UV-B irradiation was based on each subject's skin type and Minimal Erythema Dose as determined on

the control arm prior to the first irradiation. Approximate doses were: 108 mJoules for skin that never tans, 126 mJoules for skin that tans minimally and 144 mJoules for skin that tans gradually.

Induction phase

Patches containing approximately 0.2 g of test material were applied to both volar forearms of each subject. These patches were applied every Monday and Thursday for the first 3 weeks for a total of six separate induction doses. Each patch remained in place for 24 hours and the subjects were instructed to keep the patches dry while in place.

One forearm was then irradiated (the right forearm for oddnumbered subjects and the left for even-numbered). The nonirradiated forearm was protected from UV irradiation throughout the test period. After the patches were removed the skin reactions at the test sites were scored and recorded.

Nine subjects exhibited erythema and/or oedema on irradiated treated sites, with one subject showing dryness. One subject exhibited minimal erythema on a non-irradiated treated site. Six of the subjects exhibited minimal erythema on non-treated irradiated sites, while one subject exhibited hypopigmentation. Both treated and untreated irradiated sites exhibited some degree of tanning.

Rest period

A period of two weeks followed the last induction dose during which no applications of test material were made. No reactions were reported on the original test sites during this period.

Challenge phase

After the rest period, the induction test sites were observed, and challenge patches applied to virgin sites on the volar forearms of each subject. Twenty-four hours after challenge dosing the patches were removed and the reactions on the test area scored and recorded. The designated forearm was then irradiated with UV-A, immediately observed and skin reactions scored and recorded. Further observations were made at 48 and 72 hours post-patching (24 and 48 hours post-irradiation).

One subject exhibited minimal erythema on a treated site 24 and 48 hours after irradiation. Non-irradiated and untreated sites showed no reactions during challenge.

The results of this study suggest that Stabileze 06 does not induce a contact dermal photoallergic response in human skin at the concentration tested.

9.2 Genotoxicity: Salmonella typhimurium Reverse Mutation Assay (13)

This study was conducted in accordance with the OECD Guidelines for Testing of Chemicals No: 471 (14).

Stabileze 06 at concentrations of 0, 100, 333, 667, 1000, 3330 and 5000 µg/plate was tested in two separate experiments for gene mutation according to the direct plate method using Salmonella typhimurium strains TA98, TA100, TA1535, TA1537 and TA1538, both in the presence and absence of microsomal activation. Each concentration was plated in triplicate for each experiment. TA100 containing plates in the second experiment were repeated due to an unusually high number of revertants in the vehicle control group (water). Positive controls used were 2-aminoanthracene, 2-nitrofluorene, sodium azide and ICR-191. No dose-dependent increases in revertant colonies were observed in any of the strains exposed to Stabileze 06. In contrast, the positive controls caused a significant increase in the number of revertant colonies observed.

Under the experimental conditions, Stabileze 06 is considered to be non-mutagenic in the *Salmonella typhimurium* reverse mutation assay.

9.3 Overall Assessment of Toxicological Data

Stabileze 06 has a low acute oral toxicity (oral LD50 in rats: >5000mg/kg). Animal tests suggest that Stabileze 06 is a slight skin and eye irritant. In human skin tests Stabileze 06 was found to be non-sensitising, non-phototoxic and produced no photoallergic reactions. A genotoxicity study indicates that Stabileze 06 is not mutagenic towards Salmonella typhimurium.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No aquatic toxicity data were provided, which is acceptable according to the Act, since the notified polymer has a number average molecular weight (NAMW) > 1000. Due to its high NAMW the polymer is not expected to cross biological membranes and will therefore be of low toxicity.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The polymer is unlikely to present a hazard to the environment at any stage of its use, whether it be when reformulated into cosmetic products (resulting in an estimated 10 kg per year per site of reformulation waste disposed of to landfill) or when consumers wash the polymer residue from their hair/face.

If the polymer remains suspended, a predicted environmental concentration (PEC) for the substance in sewage water throughout Australia can be estimated from the following assumptions: 10 tonne maximum annual use, an Australian population of 17 million and a daily per capita water usage volume of 150 L (i.e. national usage = 930.8 GL per annum). This provides a PEC of 10 ppb in sewage water which would be reduced to insignificant levels, likely to be in the ppt (parts per trillion) range, by precipitation or dilution in receiving waters.

The notified polymer is unlikely to present a hazard to aquatic organisms due to its low concentration in receiving waters and its expected low bioaccumulation potential.

12. <u>ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY</u> <u>EFFECTS</u>

Stabileze 06 has low acute oral toxicity and is a slight skin and eye irritant in animals. Human studies suggest that Stabileze 06 is not sensitising, phototoxic or photoallergenic. A genotoxicity study indicates that Stabileze 06 is not mutagenic towards Salmonella typhimurium. However, Stabileze 06 powder has a respirable particle size (<5µm) and therefore inhalation of the powder should be avoided. In a recent paper (15) the US EPA has reported that chronic inhalational exposure of rats to water absorbing, high molecular weight polymers (> 10,000 daltons) has

resulted in squamous cell carcinomas and bronchio-alveolar carcinomas at atmospheric concentrations as low as $0.2~\text{mg/m}^3$.

Stabileze 06 is stable at ambient temperature, is non-flammable, has no flash point and is not known to exhibit explosive properties. Therefore, it should not pose any significant risk to the safety of workers in the work environment.

Significant public exposure to the notified chemical is anticipated as it is to be marketed in cosmetic and toiletry products that are used frequently by the public.

Exposure to Stabileze 06 will occur principally via the dermal route, however due to the high molecular weight, the polymer is not likely to cross biological membranes and systemic levels are likely to be very low. Human data indicate that local toxicity is not anticipated. Furthermore, in view of the low levels of Stabileze 06 in cosmetic products, the potential hazard to the public is anticipated to be low.

Under correct handling procedures, it is unlikely that this chemical will pose a significant health or safety hazard to either the public or workers.

13. RECOMMENDATIONS

To minimise occupational exposure (and public/environmental if recommendations have been made by these agencies) to Stabileze 06, the following guidelines and precautions should be observed:

- . Inhalational exposure to the powder form of the polymer must be minimised.
- . Work practices should be undertaken to avoid the generation of dusts. If dust generation is unavoidable then local exhaust ventilation should be used. If engineering controls and work practices are insufficient to avoid dust generation, respiratory protective equipment which complies with Australian Standard 1715-1991 (16) should be worn.
- . To avoid exposure to Stabileze 06, or products containing large proportions of Stabileze 06, personal protective equipment should be used such as chemical-type goggles with face shield recommended to prevent eye contact (17) and

chemically resistant gloves (18) and protective clothing (16) to prevent skin contact.

- . Good work practices should be implemented to avoid splashing or spillages.
- . Good personal hygiene practices, such as washing of hands prior to eating food, should be observed.
- . A copy of the MSDS for products containing the notified chemical should be easily accessible to all employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Stabileze 06 was provided in Worksafe Australia format (19). This MSDS was provided by ISP (Australasia) Pty 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 ISP (Australasia) Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals* (Notification and Assessment) Act 1989 (the Act), secondary notification of Stabileze 06 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

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- 19. 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.