File No: **NA/81**

27 October 1992

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

TINUVIN 123 (TK12382)

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

TINUVIN 123

1. APPLICANT

Ciba-Geigy Australia Ltd, 140 Bungaree Road, Pendle Hill NSW 2145.

2. IDENTITY OF THE CHEMICAL

Chemical name: bis (1-octyloxy-2,2,6,-tetramethyl-4-piperidyl) sebacate.

Trade name: Tinuvin 123

Other name(s): TK12382
GL 123

Chemical Abstracts Service (CAS) Registry No.: 129757-67-1

Molecualar Formulae:

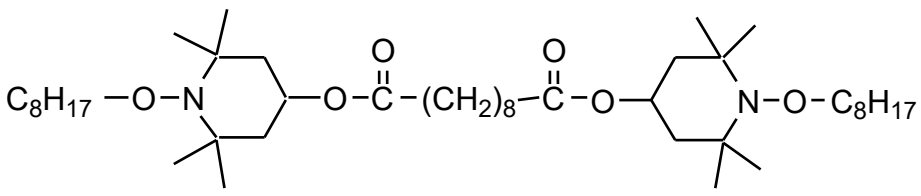
Tinuvin 123 is a mixture of a number of chemical entities, of which there are two principal components:

$C_{44}H_{84}N_2O_6$ (major product)

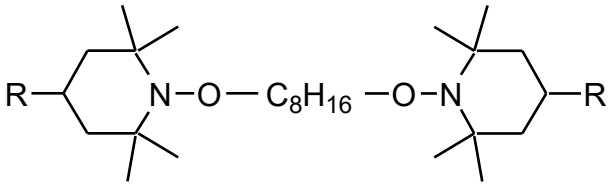
$C_{80}H_{150}N_4O_{12}$ (minor product)

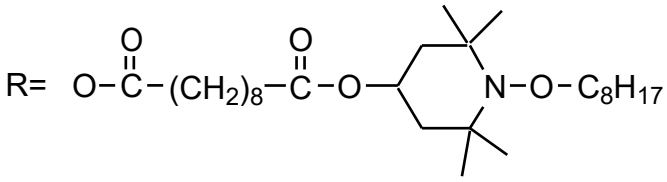
Structural Formulae:

Major product



Minor Product





Method of detection and determination:

Molecular Weight: 737 (major product)
1,360 (minor product)

Dangerous Goods Identity

Method of detection and determination:

- High Pressure Liquid Chromatography (HPLC).
- Ultraviolet/Visible Spectroscopy (UV-Vis).
- Infra Red Spectroscopy (IR)
- Nuclear magnetic Resonance (NMR)

Spectral data:

- **UV-Vis** (max) [nm] 196.6 e(l mol^{-1} cm^{-1}] 2960

- **IR:** major absorption bands for identification at 2920 cm^{-1}, 1730 cm^{-1}, 1460 cm^{-1}, 1370 cm^{-1}, 1360 cm^{-1}, 1170 cm^{-1},

  NMR: was provided for assessment

3. PHYSICAL AND CHEMICAL PROPERTIES

All tests for physical and chemical properties were conducted in accordance with EEC directives and/or OECD technical guidelines and/or ISO standard methods.

Appearance at 20°C and 101.3 kPa:	Yellow-amber coloured viscous liquid.
Odour:	Slight ethereal.
Glass-transition temperature:	-50.5 °C.
Specific Gravity:	0.97 at 20 °C.
Vapour Pressure:	0.00036 Pa at 25 °C (extrapolated).
Water Solubility:	Below detection limit (below 0.006 g/L at 20°C).
Fat Solubility:	Fully miscible (above 10 g/100 g fat at 37 °C).
Partition Co-efficient: (n-octanol/water)	log P_{OW}< 10.
Hydrolysis as a function of pH:	Not determined owing to the low solubility of the chemical.
Adsorption/Desorption:	Not determined. In view of its hydrophobicity, Tinuvin 123 can be expected to be immobile in soils.
Dissociation Constant:	Not determined as chemical is not soluble in water, has a high molecular weight and does not contain easily dissociated groups.
Flash Point:	95 °C (closed cup).
Flammability Limits:	combustible.
Combustion products:	water, oxides of carbon and nitrogen.
Autoignition Temperature:	280 °C
Explosive Properties:	not explosive, as tested with flame or shock.

Viscosity:	2.9-3.1 Pa/s (20 °C) at shear rate 8.35-153 s^{-1} 0.59-0.62 Pa/s (40 °C) at shear rate 8.35-153 s^{-1}
Surface Tension: (aqueous solution)	4.7 - 59.8 mN/m (in a water emulsion containing 10 g/L Tinuvin 123 at 20 °C).
Reactivity/Stability:	Stable from room temperature to 150 °C.incompatible with oxidising agents

4. PURITY OF THE CHEMICAL

Main component (monomer):	65-85%
Main component (dimer):	5-20 %
Any other by-product: ≤	3.5 % per compound
Additives/Adjuvants:	none

5. INDUSTRIAL USES

Tinuvin 123 is a N-substituted hindered amine. These compounds find widespread use as heat and light stabilisers, oxidants and radical scavengers in polymer applications. As such, they are used in the manufacture of surface coatings, plastics and printing inks to counteract the effects of long term degradation to weather and sunlight.

Tinuvin 123 will be manufactured overseas and imported into Australia by the applicant, in "ready to sell packages". From information provided on the container label, these appear to be 200 L drums.

The chemical is to be used as an additive in paint manufacture. As paint production in Australia is by batch manufacture, it is proposed that Tinuvin 123 will be added to the paint during the final stages of production. The final concentration of Tinuvin 123 in paint will be in the order of 5 to 10 g/L.

It is anticipated that Tinuvin 123 containing paints will have mainly industrial applications, in vehicle painting and refinishing (cars, boats and aircraft) and in timber protection.

The projected import volume is below 10 tonnes a year for the first three years, 10 to 20 tonnes years in year 4, and 20 tonnes a year thereafter.

6. OCCUPATIONAL EXPOSURE

Occupational exposure to Tinuvin 123 is possible as part of four main activities:

. during import, transport and storage of Tinuvin 123, if containers leak or if spills occur. These are likely to be of low and irregular incidence, and are not considered to be a significant risk;

. during use of Tinuvin 123 in its addition to paint in its formulation. Inhalation is not a significant route of exposure, and skin and eye contact is the main risk;

. during use of paint containing a dilute concentration of Tinuvin 123. The number of "downstream" users of paints containing a dilute amount of Tinuvin 123 is likely to be large, although the hazard from the chemical will not be great;

. during disposal of Tinuvin 123, its containers, paint containing Tinuvin 123, or material otherwise contaminated with Tinuvin 123. As with spills and leaks, this is not considered a significant risk.

7. PUBLIC EXPOSURE

Public exposure to Tinuvin 123 is considered neglible, as:

. the product is not manufactured in Australia;

. there are limited opportunities for release to environment or food chains; and

. with a very low solubility, the possibility of significant groundwater contamination is remote.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

- Formulation, handling and disposal

Tinuvin 123 will be formulated at a level of 0.5% to 1.0% into surface coatings in a simple weighing and blending operation at a late stage in the manufacturing process. Incorporation of the stabiliser, either neat or predissolved in a hold—out portion of the coating solvent, can be carried out as the final formulation step, provided agitation is adequate to ensure complete and uniform mixing. For waterborne systems, addition with an organic co—solvent is recommended.

It is stated that formulation will not generate any waste stabiliser, but this appears unrealistic as process equipment must be routinely cleaned to prevent product contamination and maintain operational efficiency (2). Use of the new stabiliser in paint manufacture is expected to occur at 24 sites around Australia.

Incineration is the recommended method of disposal, and is therefore expected to be used for all wastes, after adsorption of liquids on inert material. The notifier has stated that metal drums used for transport of the stabiliser are expected to be washed (with rinsate incinerated) and recycled.

- Use

Tinuvin 123 is an aminoether derivative of the existing Hindered Amine Light Stabilisers (HALS), Tinuvin 770. Conventional HALS must undergo preliminary oxidation to aminoethers, and are thus subject to an induction period before they offer protection against radical degradation. The aminoethers are thought to terminate radical chains by reacting with peroxyradical intermediates to form unstable dialkylperoxides. Observed termination by-products tend to be alcohols, ketones or aldehydes. Reaction of aminoethers with alkylperoxyradicals leaves nitroxyl radicals which can react with alkyl radicals formed during photooxidation to regenerate aminoether stabilisers.

The main use for coatings containing Tinuvin 123 will be to

provide a high quality clear finish to new vehicles, including aircraft and trains, and will occur at 10—15 sites. In addition, at least 1000 spray painting workshops in the smash repair industry will use these coatings. Small quantities may be used in boats and for general timber protection, and another possible application may be to provide a clear finish over exterior signs.

The following three possible routes via which Tinuvin 123 may enter the environment are identified in the submission:

gradual weathering of coatings containing the notified substance;

discard of coated articles to landfill; and volatilisation during accelerated curing.

None of these routes is likely to give rise to significant environmental exposure to the free stabiliser, which is expected to remain encapsulated in paint matrices by virtue of its low vapour pressure and minimal water solubility. However, the most significant route for entry into the environment, disposal of paint sludge from spraying operations, is not addressed by the notifier.
Conventional liquid spray technology relies on air—pressurised sprayers and is usually conducted in a horizontal or downdraft spray booth (2). Transfer efficiencies are typically rather poor (in the order of 50%) and overspray in the air is often exhausted through an aqueous scrubber, which removes the waste paint as a sludge. Scrubber water tends to be recycled, and solids are drummed for disposal as hazardous waste, either through incineration or secure landfill.

8.2 Fate

The low vapour pressure and low water solubility of Tinuvin 123 is expected to restrict its mobility, such that it will tend to remain associated with the coatings in which it is formulated, and be encapsulated therein after curing. Significant exposure of air or water is not expected, with wastes expected to be either destroyed by incineration or consigned to landfill where they will remain immobile.

Ready biodegradability was investigated in a modified Sturm test at nominal concentrations (in presence of nonylphenolethoxylate) of 11.3 and 20 ppm. The amount of carbon dioxide evolved in 28

days did not differ significantly (20±1%) at the two concentrations, and the low rate of mineralisation indicates that Tinuvin 123 is not readily biodegradable. This result is characteristic of insoluble esters, which are, however, subject to relatively rapid primary degradation once they become dissolved in aquatic environments because of microbially initiated hydrolysis, and thus do not bioaccumulate.

9. EVALUATION OF TOXICOLOGICAL DATA

All toxicology tests were conducted in accordance with relevant OECD technical guidelines.

9.1 Acute Toxicity

Table 1: Summary of acute toxicity of Tinuvin 123

Test	Species	Outcome	Reference
Oral	Rat	LD_{50} above 2000 mg/kg.	(3)
Dermal	Rat	LD_{50} above 2000 mg/kg.	(4)
Skin Irritation	Rabbit	slightly irritating	(5)
Eye Irritation	Rabbit	slightly irritating	(6)
Skin Sensitisation	Guinea	not sensitising	(7)

9.1.1 Oral Toxicity (3)

A limit test was carried out in albino rats (Tif: RAi f (SPF)), initial body weight 177 to 205 g. The rats (5/sex/dose) were administered the test substance in a carboxymethylcellulose/polysorbate solution at a dose of 2000 mg/kg, and were observed for two weeks.

No deaths occurred during the two week observation period,

although common signs and symptoms of slight toxicity were observed (raised hair, hunched posture, exophthalmos, rapid breathing) for four to five days after dosing. No abnormal morphology was observed at necropsy.

9.1.2 Dermal Toxicity (4)

A limit test was carried out in albino rats (Tif: RAi f (SPF)), initial body weight 211 to 235 g. The undiluted test substance was applied to unshaved skin at a dose of 2000 mg/kg under a semi-occlusive dressing, and was left in contact for 24 hours.

No deaths occurred during the two week observation period, although common signs and symptoms of slight toxicity were observed (raised hair, abnormal body positions, ventral recumbency, rapid breathing) for four days after dosing. No abnormal morphology was observed at necropsy.

9.1.3 Inhalation Toxicity

This test was not conducted as Tinuvin 123 is a liquid with a low vapour pressure, and its viscosity is such that it is unlikely to form aerosol mists in use.

9.1.4 Skin Irritatioy (5)

Tinuvin 123 was tested for skin irritation/corrosion potential in three male albino New Zealand rabbits. The undiluted test substance (0.5 ml) was applied to shaved skin under a semi-occlusive bandage for four hours. Skin reactions at the site of application were evaluated at 1, 24, 48 an 72 hours and scored for redness (erythema) and swelling (oedema).

Slight redness of the skin was observed in all three animals after one hour, and one animal for over 72 hours. This skin reaction was fully reversible, and no skin redness was observed after seven days. According to standard scoring protocols at 24, 48 and 72 hours, Tinuvin 123 is classified as non-irritant and noncorrosive to the skin.

9.1.5 Eye Irritation (6)

Tinuvin 123 was tested for eye irritation/corrosion potential in three female albino New Zealand rabbits. The undiluted test substance (0.1 ml) was instilled into the conjunctival sac of the eye. Eye reactions were evaluated at 1, 24, 48 and 72 hours and

scored for conjunctival redness and chemosis, damage to the iris, and corneal opacity.

Slight conjunctival chemosis was observed in all three animals, but for no longer than 48 hours. Slight redness of the conjunctiva was also observed in all three animals after one hour, and two animals for over ten days. This eye reaction was fully reversible, and no conjunctival redness was observed after ten days. According to standard scoring protocols at 24, 48 and 72 hours, Tinuvin 123 is classified as non-irritant and noncorrosive to the eye.

9.1.6 Skin Sensitisation (7)

Tinuvin 123 was assessed for skin sensitisation potential in the albino guinea pig using the maximisation test. Twenty guinea pigs (10/sex) were used in the test. Induction was made in two phases, the first being three pairs of intradermal injections (0.1 ml of 5% in sesame oil) were made, the second being a week later by topical application of 0.4 g of 30% (0.12%) of the test chemical in vaseline under an occluded dressing for 48 hours. This dosing by intradermal and then topical application is a variation of the standard method, but is not critical. Challenge doses were administered two weeks later, again topically in vaseline, this time at 0.2 g of 10% (0.02 g) under an occluded dressing for 24 hours. Negative (adjuvant/vehicle) controls were also used. Positive controls were not used, although the study notes that the sensitivity of the strain is tested with known sensitisers every six months.

Skin reactions were evaluated after intradermal injection, 24 and 48 hours after removal of the dressing after challenge. At no stage were skin redness (erythema) or swelling (oedema) observed. Tinuvin 123 is not a skin sensitiser in guinea pigs.

9.2 Repeated Dose Toxicity (8)

Tinuvin 123 was tested in rats for repeated dose toxicity in a 28 day study. Eighty male and eighty female rats (Tif: RAIf (SPF)) were given daily doses of Tinuvin 123 by gavage at 0, 10, 100 or 1000 mg/kg for four weeks (20 sex/dose). Some of these animals were also observed for a further two weeks after the end of dosing to observe recovery from exposure.

No deaths occurred during the study, and there were no toxicologically significant differences in body weight, food consumption and water consumption across the dose groups. No compound related differences were observed in neurological investigations, organ weights, macroscopical examination or neuropathological examination. There was one finding in macroscopical examination, of a enlarged testis in a high dose group animal. This is noted to occur spontaneously in the strain of rat used, and is probably not compound related;

The following treatment related effects were observed;

. in haematology studies, where statistically significant dose related increases were found in prothrombin time in both sexes at 1000 mg/kg, and in males at 100 mg/kg;

. in blood chemistry studies, where statistically significant dose related increases were found in total bilirubin levels in both sexes at 1000 mg/kg, and in males at 100 mg/kg;

. in microscopical examination, there were a number of high dose effects noted, though the compound related effects of 1/5 (high dose) compared with 0/5 (other groups) in males (lung granuloma and myocardial lymphocytic infiltration), and females (lung lymphocytic infiltration) are difficult to evaluate. However, hepatic extramedullary haematopoiesis was observed in animals in all groups of animals at the end of dosing, and after two weeks recovery, suggesting the liver as a target organ of toxicity. The incidence and severity of this effect was significant in high dose males.

The no observable effect level (NOEL), based on clinical findings of increases in prothrombin times and bilirubin levels in male animals, was 10 mg/kg/day. The NOEL for other effects was 100 mg/kg/day.

9.3 Genotoxicity

9.3.1 Point Mutations in Bacteria (9)

Tinuvin 123 was tested in two species of bacteria (*Salmonella typhimuium*, strains TA 98, TA 100, TA 1535 and TA 1537, and *Eschericia coli*, strain WP2uvrA). Nominal concentrations up to 5,000 ug/0.1 ml (50 g/L) were used, and none of these were

cytotoxic in TA 100*. There was no evidence of an increase in the number of revertants in any strain of bacteria at any concentration with or without microsomal activation. Positive controls produced the expected increase in the number of revertant colonies.

Under the conditions of this study, Tinuvin 123 did not appear to have any mutagenic activity in representative strains of *Salmonella typhimuium* or *Eschericia coli*.

9.3.2 Micronucleus in Mice (10)

Tinuvin 123 was tested in the mouse (Tif: MAGf (SPF)) micronucleus assay. Initially, a dose ranging study established that an intraperitoneally administered dose of 5,000 mg/kg of the test substance dissolved in arachis oil caused no deaths within three days: this dose was selected for use in the main assay.

Evaluation of bone marrow smears from treated animals (eight males and females) at 16, 24 and 48 hours after dosing showed no statistically significant increases in micronucleated polychromatic erythrocytes. Positive controls (cyclophosphamide) produced the expected increase in the number of micronucleated cells in polychromatic erythrocytes.

Under the conditions of this study, Tinuvin 123 did not appear to have any clastogenic activity in the micronucleus assay in the mouse.

9.4 Overall Assessment of Toxicological Data

Tinuvin 123 has low acute oral toxicity (LD_{50} in rats: > 2000 mg/kg) and low acute dermal toxicity (LD_{50} in rats: > 2000 mg/kg). Toxic effects noted in the dermal toxicity study suggest that Tinuvin 123 is absorbed through the skin. It is slightly irritating to the skin and eye, and it is not a skin sensitiser.

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*Although the test substance was dissolved in acetone prior use, some doubt must be expressed about the actual concentration of test substance in the medium, owing to its low solubility in water.

Repeated oral administration in rats for 28 days resulted in changes in some biochemical parameters at 100 mg/kg/day, and changes in the liver at 1000 mg/kg/day. Tinuvin 123 was not genotoxic when tested in *Salmonella typhimurium, Escheri ci a coil* or the mouse micronucleus test.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

A static acute toxicity study with zebrafish (Brachydanio rerio) indicated negligible toxicity (96 h LC5O > 58 ppm). The limiting value represents the highest concentration measured in test solutions with nominal concentrations upto 1000 ppm Tween 20).

No evidence of any significant toxicity was observed in a similar test using *Daphnia magna* (24 h EC5O = 83 ppm). Nominal and measured concentrations again differed widely, particularly as in this test no solubilising agents were used, either in the 1000 ppm stock solution or the test media. The EC5O is the concentration after 24 h in an aquarium nominally dosed at 320 ppm, in which the initial measured concentration exceeded 500 ppm.

Similar tests using activated sludge from sewage treatment plant and nominal concentrations did not reveal any inhibitory effect on respiration (3 h 1C20> 100 ppm).

Algal growth inhibition data were not submitted, but significant exposure appears unlikely in view of the low solubility and routes of disposal for waste products containing the substance.

11. ASSESSMENT OF ENVIRONMENTAL HAZARDS

Tinuvin 123 will represent a small proportion (<1%) of waste paint sludges consigned to landfill, and is expected to remain associated with such wastes. Significant contamination of the aquatic enviroment, where it appears relatively benign and non-persistent, is not expected, and hazard appears minimal

12 ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY

The physico—chemical properties of the chemical indicate that it will not pose a significant hazard to the safety of workers.

The toxicity profile of Tinuvin 123 reveals that Tinuvin 123 may be absorbed on skin contact. It is a likely skin and eye irritant. In spite of its negligible vapour pressure there is the possibility of a slight respiratory irritant problem in practice, due to mists containing the polymer generated during spray painting, using paints formulated with products containing the notified polymer. The 28 day repeated dose toxicity revealed changes in blood chemistry and the liver. However, there were no significant effects observed at a dose of 10 mg/kg/day. No adverse effects on humans have been reported from the use of this chemical overseas.

Under normal use conditions and correct handling procedures Tinuvin 123 is not expected to pose a significant health and safety hazard to the public and workers.

13. RECOMMENDATIONS

To minimise public and worker exposure to Tinuvin 123 the following guidelines and precautions should be observed:

- spray painting should be conducted in spray booths fitted with exhaust ventilation;
- if spray painting is carried out in the absence of spray booths are not used then appropriate respiratory protection which complies with Australian Standards (AS 1716—1991 (11)) should be worn.
- the workplace should be well ventilated;
- when direct contact with the chemical is possible, personal protective equipment which complies with Australian Standards should be worn such as splash proof goggles (AS 1336—1982 (12), AS 1337—1984 (13)) ; gloves (AS 2161—1978 (14)) and overalls (AS 3765.1—1990 (15));
- good work practices should be implemented to avoid splashes or spillages;
- good housekeeping and maintenance should be practised. Spillages should be dealt with promptly;
- absorbents should be used and then discarded;

- storage of the chemical should be in sealed robust containers away from sources of ignition; and
- a copy of the Material Safety Data Sheet should be easily accessible to all employees.

14 MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Tinuvin 123 (Attachment 1) was provided in Worksafe Australia format (16). This MSDS was provided by Ciba-Geigy Australia Ltd 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 Ciba-Geigy Australia Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of Decanedioic acid, bis (2,2,6, 6—tetramethyl-4-piperidenyl) -ester, reaction products with 1,1-dimethylethylhydroperoxide and octane 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. S.H. Yalkowsky, Residue Reviews, 1983, 85, 43
2. P.M. Randall, Journal of Hazardous Materials, 1992, 29, 275.
3. Acute oral toxicity in the rat: TK 13282 (CGL 123). No 894465, Data on file, Ciba—Geigy Ltd, Stein, Switzerland, 1989.
4. Acute dermal toxicity in the rat: TK 13282 (CGL 123). Test No 894468, as above, Ciba-Geigy Ltd, Stein, Switzerland, 1989.
5. Acute denial irritation/corrosion study in the rabbit: TK 13282 (CGL 123). Test No 894467, Ciba—Geigy Ltd, Stein, Switzerland, 1989.
6. Acute eye. irritation/corrosion study in the rabbit: TK 13282 (CGL 123). Test No 894466, Ciba—Geigy Ltd, Stein, Switzerland, 1989.

7. Skin sensitisation test in the guinea pig maximisation test: TK 13282 (CGL 123). Test No 894469, Ciba—Geigy Ltd, Stein, Switzerland, 1989.

8. Twenty eight days subacute oral toxicity in the rat gavage: TK 13282 (CGL 123). Test No 894470, Ciba—Geigy Ltd, Stein, Switzerland, 1991.
9. Samonella and Eschericia/liver-microsome test: TK 894472 (CGL 123). Test No 894472, Ciba—Geigy Ltd, Basle, Switzerland, 1990.

10. Micronucleus test, mouse: TK 894472 (CGL 123). Test No 894483, Ciba—Geigy Ltd, Basle, Switzerland, 1990.

11. Australian Standard 1716—1991, "Respiratory Protection", Standard Association of Australia Publ., 1991.
12. Australian Standard 1336—1982, "Eye Protection in the Industrial Environment", Standards Association of Australia Publ., Sydney, 1982.

13. Australian Standard 1337—1984, "Eye Protectors for Industrial Applications", Standard Association of Australia Publ., Sydney, 1984.

14. Australian Standard 2161-1978, "Industrial Safety Gloves and Mittens (excluding Electrical and Medical Cloves)", Standard Association of Australia Publ., Sydney, 1978.

15. Australia Standard 3765.1-1990, "Clothing for Protection against Hazardous Chemicals", Standard Association of Australia Publ., Sydney, 1990.

16. National Occupational Health and Safety Commission, *Guidance Note for the Completion of Material Safety Data Sheet,* 2nd. edition, AGPS, Canberra, 1990.