

File No: NA/118

Date: 2 February 1994

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Photopia Yellow AQ-G/WY413

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 Health, Housing, Local Government and Community Services.

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**Photopia Yellow AQ-G/WY413****1. APPLICANT**

Bonds, 56 Jones St, Wentworthville NSW 2145

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, Photopia Yellow AQ-G/WY413 is not considered to be hazardous. Therefore the details of chemical name, molecular and structural formula, CAS number, spectral data, molecular weight, purity, impurities and volume of import have been exempted from publication in the Full Public Report and the Summary Report.

Trade name: Photopia Yellow AQ-G/WY413

Method of detection and determination:

Separation and structure elucidation is by ultra-violet, infrared, nuclear magnetic resonance (NMR), and mass spectroscopy and high performance liquid chromatography. Data were consistent with the structure of the notified chemical.

3. PHYSICAL AND CHEMICAL PROPERTIES (1)

Appearance at 20°C and 101.3 kPa: Cream powder

Odour: Odourless

Melting Point/Boiling Point: Decomposes prior to melting and boiling even at reduced pressure.

Density: 1247.4 kg/m³ at 24°C

Vapour Pressure: 4.2 x 10⁻⁵ Pa at 25°C

Water Solubility:	$< 2 \times 10^{-4}$ g/L at 20°C
Fat Solubility:	1.54×10^3 mg/100 g at 37°C
Partition Co-efficient (n-octanol/water) $\log P_{O/W}$:	5.8 at 20°C
Hydrolysis as a function of pH:	Not provided
Adsorption/Desorption:	Not provided
Dissociation Constant	Not provided
Flash Point:	Not applicable
Flammability Limits:	Not highly flammable
Combustion Products:	Oxides of carbon
Pyrolysis Products:	Not provided
Decomposition Temperature:	Below 160°C
Decomposition Products:	Not provided.
Autoignition Temperature:	Did not show auto ignition below the temperature range in which it thermally decomposes.
Explosive Properties:	Did not explode as a result of impact, friction or flame.
Reactivity/Stability:	Does not have any oxidising properties.
Particle size distribution:	Majority of the substance is $> 45 \mu\text{m}$. A high proportion of the small fraction below this value is $< 10 \mu\text{m}$.

The substance was not soluble in water under the conditions of the tests applied. Therefore, solubility tests could not be conducted. The value given is the limit of detection by spectrophotometry. This is acceptable.

Hydrolysis tests were not conducted due to the low water solubility of the chemical and to the absence of hydrolysable groups in the structure. This is acceptable.

Adsorption/desorption tests were not performed due to the low solubility in water and relatively high P_{ow} of the chemical. This is acceptable. Relatively strong adsorption to soils may be expected.

There is no simple mode of chemical dissociation for this chemical.

4. PURITY OF THE CHEMICAL

Additives/Adjuvants: None

5. INDUSTRIAL USE

Photopia Yellow AQ-G/WY413 has been in use in Japan and the EEC and no adverse effects related to exposure have been reported.

Photopia Yellow AQ-G/WY413 is a photochromic dye that will be imported for use in the textile industry. It will be imported into Australia as a 3% component of a formulated paste known as Photopia Aqualite Ink. During use Photopia Aqualite Ink will make up 20% weight/fabric weight of a mixture which will dye fabrics. No reformulation will take place.

6. OCCUPATIONAL EXPOSURE

Photopia Aqualite Ink will be imported and transported in paper cartons of 20 kg net which have been packed in 100 kg iron drums. These will be repackaged on arrival in Australia. Contact during storage and transportation of the chemical is expected to be negligible.

The dyeing process involves 2-3 workers per factory at factories in Sydney and Wentworthville. During the dyeing process Photopia

Aqualite Ink paste containing Photopia Yellow AQ-G/WY413 is measured into a container and diluted with water and other dye solvents. After mixing for 10 minutes, the solution is automatically pumped into the colouring machine. Pre-treated fabric is added to the solution and the temperature is raised to 70°C by indirect hot water vapour. The dyeing is completed after 20-25 minutes and the process is concluded by rinsing and the addition of a softening agent.

An industrial ventilation fan is intended to be used to remove steam but significant amounts of the Photopia Yellow AQ-G/WY413 will not be vaporised.

7. PUBLIC EXPOSURE

There is a low potential for public exposure to Photopia Yellow AQ-G/WY413 during manufacturing processes. The notified chemical will be in paste form, minimising the formation of dusts. Photopia Yellow AQ-G/WY413 is of low solubility in water and has a very low vapour pressure, so will not be discharged to the atmosphere during the dyeing process. Factory wastewater is to be treated with pigment precipitants, and the sedimented waste dyes are dehydrated by filter press to form a wet cake which can be disposed of by landfill or incineration. The public is therefore unlikely to be exposed to the notified chemical in effluent, recreational or drinking water.

Unfixed Photopia Yellow AQ-G/WY413 will not be available to the public. Although widespread contact will occur with the dyed fabric, by this stage the notified chemical will be irreversibly bound to the fibre, from which absorption should be negligible.

8. ENVIRONMENTAL EXPOSURE

. Release

The notifier states that the neat substance will not normally be discharged directly to the sewage system or aqueous environment. The notified substance has a minimum fixation degree of 98.8%, when applied in the prescribed manner (but this rate may drop to 60 - 70% at 50 % on the weight of fibre if conditions are varied) and is adhered by means of a fixing agent-resin (a report has been provided to support the amount of exhaustion of dye).

Release of unfixed dye to the sewers should therefore be negligible.

The dyes and pigments are disposed of at the colouring factories with the waste water which is treated in the water treatment area. This area employs the coagulation process which coagulates dyes and pigments in the water by the application of alum, for example.

The sedimented waste dyes and pigments are dehydrated by the filter press to form a wet cake. This is then transferred to the waste disposal area for disposal by landfill or incineration. Release of unfixed dye to the sewers should be negligible.

. **Fate**

The main environmental exposure to the dye would occur through the release of unfixed dye into effluent by textile factories using the dye.

The concentration of the notified substance in textile wastewater has been estimated as 0.72 ppm (report provided), which can only be a theoretical value, as it is above the solubility limit. The dye is expected to be associated with the wet cake from the water treatment process at the textile dyeing factories.

Incineration of the notified substance is unlikely to produce toxic compounds.

The notified substance is unlikely to leach from landfill due to its insolubility in water and relatively high log K_{OW} . The majority of the substance will be bound to cloth and will eventually be disposed of by landfill with other domestic refuse.

• **Biodegradation**

The notified chemical attained 6% degradation at 10 mg.L⁻¹ and 4% at 20 mg.L⁻¹ (2) (OECD TG 301B) during 28 days, and therefore cannot be considered as readily biodegradable.

- **Hydrolysis**

The notified chemical is unlikely to hydrolyse under environmental conditions due to its insolubility in water and the absence of hydrolysable groups in the structure.

- **Bioaccumulation**

The notified chemical has physico-chemical properties which indicate it has the potential to bioaccumulate; it is insoluble in water, has a log K_{OW} of 5.76 and a molecular weight of 334. However, exposure to aquatic organisms is likely to be low due to the dye's low concentration in waste water and its expected association with sludge at waste water treatment plants. Therefore, bioaccumulation from the proposed use is expected to be negligible.

9. **EVALUATION OF TOXICOLOGICAL DATA**

Under the *Industrial Chemicals (Notification and Assessment) Act, 1989* toxicity data are not required for chemicals manufactured or imported in volumes less than 1 tonne/year. However, the following studies were provided and have been assessed.

9.1 **Acute Toxicity**

Table 1 Summary of the acute toxicity of Photopia Yellow AQ-G/WY413

Test	Species	Outcome	Ref
Oral	Rat	LD ₅₀ : > 2000 mg/kg	3
Dermal	Rat	LD ₅₀ : > 2000 mg/kg	4
Skin Irritation	Rabbit	Non-irritant	5
Eye Irritation	Rabbit	Non-irritant	6
Skin Sensitisation	Guinea-Pig	Non-sensitising	7

9.1.1 Oral Toxicity (Ref No:3)

This study was carried out in accordance with *OECD Guidelines for Testing of Chemicals No: 401*.

Ten Sprague-Dawley rats (5 male and 5 female) were administered 2000 mg/kg of test substance by gavage. The animals were observed for deaths and the incidence of behavioural and clinical abnormalities 1/2, 1, 2 and 4 hours after dosing and subsequently once daily for 14 days. At the end of 14 days the animals were killed and subjected to gross pathological examination.

There were no deaths or signs of systemic toxicity noted during the study. All animals showed expected gain in bodyweight. No abnormalities were noted at necropsy.

The results of this study indicate that Photopia Yellow AQ-G/WY413 has an acute oral LD₅₀ > 2000 mg/kg.

9.1.2 Dermal Toxicity (4)

This study was carried out in accordance with *OECD Guidelines for Testing of Chemicals No: 402*.

Ten Sprague-Dawley rats (5 male and 5 female) were administered a single dose of Photopia Yellow AQ-G/WY413 at 2000 mg/kg by semi-occlusive application to the shaved dorsal area for a period of 24 hours. The animals were observed 1/2, 1, 2 and 4 hours after dosing and subsequently once daily for 14 days prior to being killed for gross pathological examination. There were no deaths or signs of systemic toxicity during the study. Haemorrhage of the dermal capillaries at the treatment sites of three females was noted one day after dosing. This persisted in two females two days after dosing. No other signs of skin irritation were noted. All animals showed expected gain in bodyweight during the study. No abnormalities were noted at necropsy.

The results of this study indicate that the dermal LD₅₀ for Photopia Yellow AQ-G/WY413 is > 2000 mg/kg.

9.1.3 Skin Irritation (5)

This study was carried out in accordance with *OECD Guidelines for Testing of Chemicals No: 404*.

A single dose of 0.5 g of the chemical in 0.5 ml of distilled water was administered by semi-occlusive application to the clipped back of three New Zealand White strain rabbits. The patches were applied for 4 hours. The site of application was observed 1, 24, 48, and 72 hours after removal of the patch.

No erythema, oedema or necrosis was observed at the site of application in any of the animals.

The results of this study indicate that Photopia Yellow AQ-G/WY413 is a non-irritant to rabbit skin.

9.1.4 Eye Irritation (Ref No:6)

This study was carried out according to *OECD Guidelines for Testing of Chemicals No: 405*.

Three New Zealand White strain rabbits were used for the study. One hundred microlitres of Photopia Yellow AQ-G/WY413 was instilled into the conjunctival sac of three rabbits with the other eye being used as control. The eyes were examined 1, 24, 48 and 72 hours following treatment. One hour after instillation of the chemical, redness of the conjunctiva was observed in all three animals. Conjunctival swelling was observed in two of the animals. The iris showed congestion, swelling and circumcorneal injection but reacted to light in two of the animals. Discharge from the eyes was seen in two animals. There were no changes to the cornea. The effects were reversible as no adverse effects were seen at the end of 24 hours.

The results of this study indicate that Photopia Yellow AQ-G/WY413 is non-irritating to the rabbit eye.

9.1.5 Skin Sensitisation (Ref No:7)

The study was carried out in accordance with the *OECD Guidelines for testing of Chemicals No: 406*

The test used was the guinea-pig maximisation test of Magnusson and Kligman. The skin reactions were assessed according to a four point scale.

Preliminary study

To determine the dose level for intra-dermal injection in the main study, 1%, 5% or 10% w/v solutions of Photopia Yellow AQ-G/WY413 were injected into three albino Dunkin-Hartley guinea-pigs. A dose of 10% w/v in arachis oil was selected for intra-dermal induction in the main study as this was the highest concentration that did not cause local necrosis or ulceration.

To determine the dose level for topical induction in the main study, 2 guinea-pigs (intradermally injected with Freund's Complete Adjuvant nine days earlier) were treated with 50%, 25%, 10% and 5% w/w Photopia Yellow AQ-G/WY413 in arachis oil. The highest concentration producing mild to moderate dermal irritation after a 48 hour occlusive application, 50% w/w, was selected for topical induction in the main study.

The dose levels selected for topical challenge in the main study were 25% and 10% w/w.

Induction Study

Thirty albino guinea-pigs of the Dunkin-Hartley strain (20 test and 10 control animals) were used.

Three pairs of intra-dermal injections were made into the clipped inter-scapular region of each guinea-pig. The injected solutions were: Freund's Complete Adjuvant plus distilled water in the ratio 1:1, a 10% w/v dilution of Photopia Yellow AQ-G/WY413 in arachis oil and a 10% w/v dilution of Photopia Yellow AQ-G/WY413 in a 1:1 preparation of Freund's Complete Adjuvant plus arachis oil. One week later the same area was treated with an occlusive topical application of 50% w/v of Photopia Yellow AQ-G/WY413 for 48 hours. Control animals were similarly treated but without the use of the test substance. The sites were evaluated 1 and 24 hours after removal of the patches.

One hour following topical induction 10 of the 20 treated animals had mild scattered erythema while 10 had moderate erythema. Mild scattered erythema persisted in 5 animals at the end of 24 hours. No reactions were seen in the control animals.

Challenge Study

Two weeks after the topical induction application, the test and control animals were challenged topically using 10 or 25% Photopia Yellow AQ-G/WY413 in arachis oil by occlusive application, for 24 hours, at two different sites. The challenge sites were evaluated 24 and 48 hours after removal of the patches.

No skin reactions were observed in test or control animals 24 or 48 hours after challenge. Bodyweight gains in the test group were comparable to those observed in the control group.

The results of this study indicate that Photopia Yellow AQ-G/WY413 is not a skin sensitiser in guinea-pigs at the concentrations tested.

9.1.6 Evaluation For Weak Skin Irritancy By Microscopic Observation (8)

Data from a human skin irritation study was provided by the notifier and has been assessed. The test was based on "The Evaluation Method (Kawai's Method) of Skin Patch Tests Based on Microscopical Observation" (9). It is a non-OECD method.

The test was carried out on 20 healthy male and female volunteers. Seven patches of Aqualite Photopiacolor (mixture of Photopia Aqualite Ink Purple, Yellow and Blue) were applied to the volar surface of the forearm (four sites on the right arm and four on the left). One patch containing the negative control was also used. The control consisted of di(stearo amino ethylene)amide epichlorhydrin condensate. The patches were taken off after 24 hours. Macroscopic examination of the skin was done 30-60 mins after removal of patches for any signs of erythema. Following this, Susuki's universal microscopic printing method was used to prepare skin replicas from the sites of patch application for microscopic observation.

According to the degree of abnormal reaction observed, four ranks of judgement of skin irritancy may be given. These are described by the B score which is defined as the number of subjects who show deepened skin furrows from the control substance subtracted from the number of subjects who show the same reaction from the test substance.

- . Negative: No microscopic or macroscopic changes are observed, or the abnormal reaction is less severe than the reaction to the control substance.
- . Almost Negative: If B score is 2 or less.
- . Almost Positive: If B score is 3.
- . Positive: When B score is more than 4, or if one or more subjects show loss of the triangular configuration of the skin furrow pattern, or if there is any macroscopic inflammation.

In this study Aqualite Photopiacolor obtained a score of 2B (almost negative) and therefore the results indicate that it is a non-irritant to the skin.

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (Ref No:10)

This study was carried out in accordance with the *OECD Guidelines for Testing Chemicals No 471*.

Photopia Yellow AQ-G/WY413 was tested in two independent experiments. The dose range used in the preliminary study was 0, 312.5, 625, 1250, 2500 and 5000 µg/plate. The doses selected for the main study were 0, 8, 40, 200, 1000 and 5000 µg/plate. *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 both in the presence and absence of S9 mix were used. Positive controls used without activation were 9-aminoacridine, N-ethyl-N'-nitro-N-nitrosoguanidine, 4-nitro-o-phenylenediamine and 4-nitroquinoline-1-oxide. 2-Aminoanthracene and benzo(a)pyrene were used as positive controls in experiments using activated S9 mix.

No significant increases in the number of revertant colonies of bacteria were recorded for any of the strains of *Salmonella typhimurium* used, at any dose level of Photopia Yellow AQ-G/WY413, with or without metabolic activation. All positive controls produced marked increases in the number of revertant colonies within the normal range. The test substance caused no toxicity to the bacterial lawn at the concentrations used but did cause a precipitate at 5000 µg per plate.

The results indicate that Photopia Yellow AQ-G/WY413 is not genotoxic toward *Salmonella typhimurium*.

9.3 Overall Assessment of Toxicological Data

Photopia Yellow AQ-G/WY413 has low acute oral and dermal toxicity in the rat with LD_{50s} > 2000mg/kg. In a patch test on human skin Aqualite Photopiacolor containing Photopia Yellow AQ-G/WY413 elicited an "almost negative" reaction. The notified chemical is neither a skin nor eye irritant to the rabbit, nor a skin sensitiser in the guinea pig. It is not mutagenic towards *Salmonella typhimurium* either in the presence or absence of metabolic activation.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

As the notified chemical is a low volume chemical substance, it is not a requirement that environmental effect studies are submitted. However, the notifier has provided the following ecotoxicity results for Photopia Yellow AQ-G/WY413.

Test	Species	Result
Acute toxicity (11)	Fathead minnow	96h LC ₅₀ = 920 ppm NOEC = 500 ppm
Acute toxicity (11)	<i>Daphnia pulex</i>	48h LC ₅₀ = 73 ppm NOEC = 31.3 ppm
Acute toxicity (12)	<i>Daphnia magna</i>	NOEC ≤ 6 mg. L ⁻¹ (OECD TG)
Reproduction (13)	<i>Daphnia magna</i>	21d EC ₅₀ ≤ 100% satd.sln NOEC = 100% satd.sln
90d Early life stage (14)	Rainbow trout	90d LC ₅₀ ≤ 100% satd.sln NOEC = 100% satd.sln
Growth (15)	<i>Selenastrum capricornutum</i>	96h EC ₅₀ = 547 ppm
Growth inhibition (16)	<i>Selenastrum capricornutum</i>	96h EC ₅₀ ≤ 100% satd.sln NOEC = 100% satd.sln

The studies used US EPA guidelines except for the *Daphnia magna* acute toxicity test (OECD TG 202). The above results were based on nominal concentrations. In a number of the studies a saturated solution of the sample was used as it is not soluble in water. The saturated solution was prepared by adding 5 g test

material to 40 L of water, mixed for 24 hours and filtered. The saturated solution was then diluted with water to the desired test concentrations. At higher test concentrations there was marked precipitation of the test material approximately 30 minutes after the addition of solvent stock solutions to water.

The above results indicate that the notified substance is practically non-toxic to fish, algae, and is slightly toxic to *Daphnia*. No effects were apparent up to the limit of solubility.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The proposed use of Photopia Yellow AQ-G/WY413, a photochromic dye for use in the textile industry, is unlikely to present a significant environmental hazard as exposure to the aquatic environment is expected to be negligible. The majority of the notified substance will be bound to cloth and will eventually be disposed of by landfill with other domestic refuse. The notified substance in waste water from the textile factories is expected to be associated with the sludge at water treatment plants, following coagulation. Disposal of sludge by incineration and/or landfill is not expected to present a hazard to the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Skin or eye contact may occur during repackaging and during the initial dilution and mixing stage unless appropriate care is taken. Photopia Yellow AQ-G/WY413 is unlikely to pose an inhalation hazard as it is formulated in a paste, has a low vapour pressure (4.2×10^{-5} Pa) and has a particle size generally above 45µm, although a small proportion of the particles are less than 10 µm and therefore respirable.

Based on the results of animal studies, and a single study on the human skin, human exposure to Photopia Yellow AQ-G/WY413 is unlikely to cause eye irritation, irritation to the skin or sensitisation.

Under normal conditions of use, public exposure to unfixed Photopia Yellow AQ-G/WY413 is expected to be negligible, since it is intended for industrial application only. Public exposure to

the notified chemical will be limited to contact with dyed material from which it is unlikely to be absorbed.

13. RECOMMENDATIONS

To minimise occupational exposure to Photopia Yellow AQ-G/WY413 the following guidelines and precautions should be observed:

- . during the textile dyeing process, local exhaust ventilation should be used;
- . if engineering controls and work practices do not sufficiently reduce exposure to a safe level then the following personal protective equipment should be used:
 - rubber gloves which conform to the Australian Standard AS 2161 (17),
 - protective clothing including overalls and PVC apron which conform to the Australian Standard AS 3765 (18),
 - eye protection which conforms to Australian Standard AS 1337 (19).
- . The MSDS should be easily accessible to all employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Photopia Yellow AQ-G/WY413 was provided in Worksafe Australia format (20). The MSDS was provided by Bonds 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 Bonds.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of Photopia Yellow AQ-G/WY413 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. Secondary notification should also be made if the substance

is to be discharged directly to the sewage system or the aquatic environment without prior coagulation. No other specific conditions are prescribed.

16. **REFERENCES**

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- (2) Assessment of the ready biodegradability (modified Sturm test) of Photopia Yellow AQ-G/WY413. Project No: 482/4. Data on File. Safepharm Laboratories, Derby, U.K.
- (3) Photopia Yellow AQ-G/WY413: Acute Oral Toxicity (Limit Test) In The Rat. Project No: 461/1, 1992. Data on File. Safepharm Laboratories, Derby, U.K.
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- (9) Evaluation Method (Kawai's Method) of Skin Patch Tests Based on Microscopical Observation K.Kawai, Fragrance Journal 2:7 (pages not given) (1974)

- (10) Photopia Yellow AQ-G/WY413: Reverse Mutation Assay "Ames Test" Using *Salmonella Typhimurium*. Project No: 461/5. Data On File. Safepharm Laboratories, Derby, U.K.
- (11) Aquatic Toxicity Tests versus *Pimephales promelas* and *Daphnia pulex*, Photopia Aqualite Yellow AQ-G/WY413. Test Report No: 063848-3. Data on File. United States Testing Company, Inc., Biological Services, New Jersey, USA.
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- (14) Aquatic Toxicity Testing versus *Oncorhynchus mykiss*. Test Report No: 064427-1. Data on File. United States Testing Company, Inc., Biological Services, New Jersey, USA.
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- (16) Aquatic Toxicity versus *Selenastrum capricornutum*. Test Report No: 064427-5. Data on File. United States Testing Company, Inc., Biological Services, New Jersey, USA.
- (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 3765-1990: *Clothing for Protection Against General or Specific Chemicals*, Standards Association of Australia Publ., Sydney (1990).
- (19) Australian Standard 1337-1984: *Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney (1984).
- (20) National Occupational Health and Safety Commission, Guidance Note for the Completion of a Material Safety Data Sheet, 2nd. Edition, AGPS, Canberra, 1990.