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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

PF-310

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For Enquiries please contact the Administration Coordinator:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 565-9466 **FAX (61) (02) 565-9465**

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

PF-310

1. APPLICANT

Toshiba Australia Pty Ltd of Talavera Road, North Ryde NSW 2113.

2. IDENTITY OF THE CHEMICAL

PF-310 is corrosive to the eye. However, as the notified chemical is imported as a minor constituent of < 1% of a formulated product which is not, itself, hazardous according to Approved Criteria for Classifying Hazardous Substances (19). Therefore, the chemical name, CAS number, structural and molecular formulae, molecular weight, composition of the chemical, spectral data, specific use and the import volume have been exempted from publication in the Full Public Report and Summary Report.

Trade names: PF-310
FT-310

Other name: Ricoh FT Black Toner Type 8800

Molecular weight: < 1000

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Light yellow powder
Odour:	No appreciable odour
Melting Point:	> 400°C
Density:	1780 kg/m^3
Vapour Pressure:	0.012 kPa at 25°C
Water Solubility:	0.25 g/L at 20°C
Fat Solubility:	1.19 mg/100 g of standard fat HB 307 at 37°C
Partition Co-efficient (n-octanol/water) log $P_{O/W}$:	2.3 (estimated)
Hydrolysis as a function of pH:	At pH 7 the chemical is hydrolytically stable. At pH 4 and 9 after 144 hrs concentration is decreased by about 30%
Adsorption/Desorption:	Not provided
Dissociation Constant:	pKa of 4.08 at 20°C
Surface tension:	21.4 mN/m at 20°C (saturated solution)

Flash Point:	Could not be ignited
Flammability Limits:	Not flammable
Decomposition Temperature:	> 180°C
Autoignition Temperature:	Not auto-flammable
Explosive Properties:	Not explosive under the influence of flame, shock or friction
Reactivity:	Has no oxidising properties
Particle size:	Not provided

4. PURITY OF THE CHEMICAL

Degree of purity: 99.2% (99.0%-99.9%)

Toxic or hazardous impurity/impurities: None known

Non-hazardous impurity/impurities Total impurities 0.8%

Additives/Adjuvants: None

5. INDUSTRIAL USE

The chemical is to be used as a photocopier toner additive.

6. OCCUPATIONAL EXPOSURE

PF-310 will not be manufactured in Australia. The chemical will be imported as an ingredient of a formulated product in 1-2 kg ready to sell packages. The formulated product contains less than 1% of PF-310.

Workers likely to be exposed to PF-310 are:

. photocopier service engineers involved in the installation and maintenance of dry process photocopiers. Approximately 150-160 service engineers will be involved in these tasks in Australia and will be servicing many machines on a daily basis; and

. office workers who add toner to photocopiers *in situ* including workers involved in full time photocopying and machine upkeep.

The number and categories of workers exposed to the product in Australia will be large depending on the number of machines used and the amount of photocopying carried out on each machine. The product containing the chemical is contained in a cartridge thus minimising direct contact with the notified chemical.

7. PUBLIC EXPOSURE

The potential for public exposure to PF-310 is anticipated to be low. The notified chemical will be imported to Australia contained in a cartridge and public exposure may arise through contact with dust particles during maintenance of the photocopiers or through contact with residues on photocopied

paper. These are not regarded to be significant as in most cases (except for people employed for photocopying) the process of photocopying is carried out infrequently and the packaging of the product in cartridges will markedly reduce potential exposure.

The notified chemical and products containing it will be disposed of as domestic waste to landfill.

8. ENVIRONMENTAL EXPOSURE

. Release

As all formulations and packaging will be carried out overseas, there will be no risk of environmental exposure from these activities.

Toner is added to photocopiers as required. The contents of the entire packet is added to the machine, and the empty toner container is discarded. The product, its containers and materials contaminated with the chemical can be disposed of as domestic waste to landfill in accordance with local, State and Federal regulations. Waste materials from products containing PF-310 should not be burnt, owing to the presence of halogen atoms.

Apart from transport spills, or accidental spills when changing toner cartridges, no environmental release is expected as a result of normal use.

. Fate

The chemical is likely to arrive in a dispersed manner in landfill bound to waste paper. As such, it may biodegrade slowly when placed in the landfill.

Paper recycling is a growing industry in Australia. Wastepaper is repulped using a variety of alkalis, dispersing agents, wetting agents, water emulsifiable organic solvents and bleaching agents. These chemicals enhance fibre separation, ink detachment from the fibres, pulp brightness and whiteness of the paper. After pulping, the contaminants and the ink are separated from the fibres by pumping the stock through various heat, washing, screening, cleaning, flotation and dispersion stages. The notifier has provided no data on the likely behaviour of the chemical during the recycling process. The chemical may survive the above conditions, either remaining bound to the pulp or becoming associated with the sludge. In the latter case, the chemical may arrive in landfill, where it would be subject to low biodegradation. However, given the soluble nature of the chemical, a significant proportion may partition in the aquatic compartment.

When subjected to a modified Sturm test (OECD No 301B), biodegradation occurred at 10 mg/L (20%) and 20 mg/L (35%) over a 28 day period. Under the stringent conditions of this test, the substance cannot be classed as readily biodegradable, but should not be highly persistent.

No bioaccumulation data was provided on the grounds that such data is not required if the substance is readily biodegradable. Although PF-310 does not appear to be readily biodegradable, the small quantities to be imported and the relatively high water solubility mean that bioaccumulation is unlikely and the omission of such data is acceptable.

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 are evaluated below.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of PF-310

Species	Test	Outcome	Reference
Rat	Oral toxicity	LD_{50} > 5000 mg/kg	(1)
Rat	Dermal toxicity	LD_{50} > 2000 mg/kg	(3)
Rabbit	Skin irritation	Non-irritant	(5)
Rabbit	Eye Irritation	Corrosive	(7)
Guinea pig	Skin sensitisation	Non-sensitising	(9)

9.1.1 Oral Toxicity (1)

This study was carried out according to OECD Guidelines for Testing of Chemicals No: 401 (2).

Ten albino Wistar rats (5/sex) were selected for the study. PF-310 (99.2%) was administered by gavage at a purity of 99.2%. The animals received a dose of 5000 mg/kg.

No mortality occurred during the study period. All the rats had gained weight by day 14, rough coat was observed in all males,but on day 15 no other signs of toxicity were observed. Macroscopic examination at necropsy did not reveal any abnormalities due to PF-310.

The results of this study indicate that PF-310 has an oral LD_{50} > 5000 mg/kg in rats.

9.1.2 Dermal Toxicity (3)

This study was carried out in accordance with OECD Guidelines for Testing of Chemicals No: 402 (4).

A single dose of 2000 mg/kg of PF-310 was administered by occlusive application to the shaved backs of Wistar rats (5/sex) for 24 hours. The animals were observed for 14 days and were sacrificed and subjected to necropsy.

A gain in body weight was noted for all animals. Lethargy was observed in three males on days 1 and 2. No other toxic signs related to the chemical were noted. Erythema was observed at the site of application in two female rats from day 5 onwards. One of these females showed scales on the treated area between days 7 and 9. Macroscopic examination of the animals at post-mortem did not reveal any abnormalities.

The results of this study indicate that the dermal LD_{50} for PF-310 is >2000 mg/kg in rats.

9.1.3 Skin Irritation (5)

The study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No 404: (6)

A single dose of 0.5 g of PF-310 was administered by occlusive application to the intact skin of a shaved area on one flank of three New Zealand White rabbits. The other flank was similarly prepared

to act as a procedural control. Patches were applied to the unabraded area of the skin for four hours. The site of application was observed at approximately 60 mins, 24, 48 and 72 hours after removal of the patch.

Yellow staining of the treated skin by the test substance was observed. Very slight erythema was observed in 2/10 animals and slight oedema in one animal at the end of 60 mins. The skin irritation was reversed within 24 hours after exposure in all three animals. No symptoms of systemic toxicity were observed in the animals during the test period and no mortality occurred.

The results of this study indicate that PF-310 is a slight skin irritant in rabbits.

9.1.4 Eye Irritation (7)

The test was conducted in accordance with OECD Guidelines for Testing of Chemicals No: 405 (8).

PF-310 (100mg) was instilled into the conjunctival sac of one eye of each of three New Zealand White rabbits. The untreated eye served as the control. The eyes of each animal were examined 1, 24, 48 and 72 hours and 7, 14 and 21 days after instillation of the test substance. After the 24 hr observation a solution of 2% fluorescein was instilled into both eyes to quantitatively determine corneal epithelial damage. This procedure was repeated in all the animals on days 4, 8, 15 and 22. At the end of 1 hr, congestion, swelling and circumcorneal hyperaemia were observed in the iris of all three rabbits. PF-310 also caused redness and chemosis of the conjunctivae of the three rabbits. The injection of the iris was reversed within 21 days after instillation in 2/3 rabbits. The three animals showed translucent corneal opacity and neovascularisation, diffuse beefy redness of the conjunctivae and some discharge on day 22. Treatment of the eyes with 2% fluorescein revealed corneal epithelial damage in all three animals. No systemic symptoms were observed in the animals and no mortality occurred.

The results of this test indicate that PF-310 is corrosive to the eye in rabbits.

9.1.5 Skin Sensitisation (9)

This study was carried out in accordance with the OECD Guidelines for the Testing of Chemicals No 406: (10).

The test used was the guinea-pig maximisation test of Magnusson and Kligman (18). The skin reactions were assessed according to a four point scale. The sensitivity of the guinea-pig strain used was checked periodically with formaldehyde.

Preliminary Study

To determine the dose level for intradermal injection in the main study, four injections were made into the clipped shoulder region of one female albino guinea pig of the Himalayan strain at a concentration of 5% in distilled water. The dermal reactions were assessed 24 and 48 hours later.

Moderate erythema around a necrotic area was observed at the end of 24 hours. A concentration of 2.5% in physiological saline was then apparently arbitrarily used as the inducing dose in the main study.

To determine the dose level for topical induction in the main study, four animals were topically treated with 0.5 ml of a 50%, 25%, 10% and 5% concentration of PF-310 in distilled water by occlusive application. This procedure ensured intensive contact of PF-310 even though it is insoluble in the vehicle used. The reaction sites were assessed 24 and 48 hours after bandage removal. No erythema or necrosis was observed at the end of 24 or 48 hours.

The dose level selected for topical challenge in the main study was 50% w/w in distilled water.

Induction and Challenge Study

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

Three pairs of intra-dermal injections were made into the clipped scapular region of each guinea-pig. The injected solutions were: PF-310 dissolved to 2.5% w/w with physiological saline, Freund's Complete Adjuvant 50:50 with distilled water and 5% concentration of PF-310 emulsified in a 50:50 mixture of Freund's Complete Adjuvant. Seven days after the intra-dermal injections and prior to the epidermal application of PF-310 the intra-scapular area was treated with 10% Sodium-Dodecyl Sulphate (SDS) in petrolatum. This concentration of SDS enhances sensitisation by provoking a mild inflammatory reaction. Seven days after the SDS treatment 0.5 ml of a 50% solution of PF-310 was applied to the same region. The residual chemical was removed at the end of 48 hrs and reaction sites were assessed for erythema and oedema.

The animals in the control group were treated by epidermal and intradermal inductions with the omission of PF-310.

After induction, 11/20 animals showed well defined erythema while 9/20 had slight erythema after 48 hrs in the group receiving PF-310. Slight oedema was also observed in 8/20 animals.

Two weeks after the topical induction application the test and control animals were challenged topically using 0.5 ml of PF-310 at concentrations of 50%, 25% and 10% in distilled water and distilled water by occlusive application. The challenge sites were evaluated 24 and 48 hours after removal of the patches.

No skin reactions were seen in the control group after challenge exposure. In the experimental group 4/20 animals receiving 50% w/w PF-310 developed mild erythema. No reactions were seen in the animals receiving 25% or 10% concentrations of PF-310 and distilled water. No symptoms of systemic toxicity or mortality were observed in the animals during the study.

In the case of adjuvant-type test, an erythema response in at least 30% of the treated animals is considered to be positive. Therefore, the results of this study indicate that PF-310 is a moderate skin sensitiser at the highest concentration tested.

9.2 Repeated Dose Toxicity (11)

This study was carried out according to OECD Guidelines for Testing of Chemicals No: 407 (12)

A five day range finding study was performed with Wistar (rats/sex/group) at oral doses of 50, 200 or 1000 mg/kg/day for 28 days to provide a basis for selection of dose levels. No effects were observed at the highest dose, therefore, a high dose level of 1000 mg/kg/day was selected for a study of 28 days duration.

PF-310 in distilled water was administered by gavage, once daily, at doses of 0(control), 50, 200 or 1000 mg/kg/day to groups of SPF-bred Wistar rats (5/sex). The animals were treated for 28 days.

In rats receiving 1000 mg/kg/day of PF-310, a swollen appearance of the abdomen was seen in all animals from week 3 of treatment till termination. Two males and one female rat developed rales and laboured breathing. Excessive salivation was also noted in more than 75% of the animals receiving this dose. The body weights and food consumption of animals in this group were lower than controls over the four week treatment period.

In rats dosed with 200 mg/kg/day, excessive salivation was seen in 25% of the animals from day 9 onwards. Rales and laboured breathing was noted in one male and one female.

No toxic effects related to the chemical were noted in animals receiving 50 mg/kg/day. Body weights and food consumption of animals receiving 200 or 50 mg/kg/day were similar to controls.

Haematological and clinical parameters of treated rats did not show any difference from those of control rats.

Macroscopic examination at necropsy showed enlargement of the caecum, colon or the whole gastro-intestinal tract in all animals receiving 1000 mg/kg/day. Other findings in this group were pale kidneys, alopecia and a grey-white nodule in the fore-stomach. These were noted incidentally and not considered to exceed normal incidences of background variation. Absolute and relative organ weights of treated animals were in the same range as controls.

Rats dosed at 1000 mg/kg/day with enlarged caecums showed no histopathological lesions, however, one male rat had an inflammatory reaction in the caecum and colon. No microscopic changes were seen in animals receiving 200 or 50 mg/kg/day.

Enlarged gastro-intestinal areas could be attributed to gas accumulation and may be indicative of local or diffuse gastro-intestinal paralysis or change in the gut flora.

These data indicate that the gastro-intestinal tract is the target organ for toxicity of PF-310 following repeated oral dosing in rats.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (13)

This study was carried out according to the OECD Guidelines for Testing Chemicals No 471 (14)

Following a preliminary toxicity test the doses selected for the main study were 1, 3.3, 10, 33.3 and 100 µg/plate. *Salmonella typhimurium* strains TA 1535, TA 1537, TA 98 and TA 100, both in the presence and absence of metabolic activation provided by rat S9-mix were used. Positive controls used were sodium azide, 9-aminoacridine, daunomycin and methylmethanesulfonate. 2-Aminoanthracene was used as a positive control in experiments using S9.

In the study the test substance did not induce an increase in the revertant colony numbers per plate at any concentration tested with or without metabolic activation.

The results of this study indicate that PF-310 is not genotoxic towards *Salmonella typhimurium.*

9.3.2 Analysis of Metaphase Chromosomes (15)

This study was carried out according to the OECD Guidelines for Testing Chemicals No 473 (16).

Cultured human lymphocytes were exposed to 10, 33, 100 or 333 µg/ml of PF-310 for 2 hrs with or without S9 mix. After the 2 hr treatment, cells were rinsed and incubated for 21-23 hrs or 45-47 hrs. Mitotic activity was arrested by the addition of colchicine to the culture three hours before the end of the incubation. Mitomycin C (0.5 µg/ml) and cyclophosphamide (15 µg/ml) were used as positive controls. Cells were fixed, stained and examined for chromosomal aberrations.

Both in the presence and absence of S9-mix, PF-310 did not induce an increase in the number of cells with chromosomal aberrations.

The results of this study indicate that PF-310 is not clastogenic towards cultured human lymphocytes.

9.4 Overall Assessment of Toxicological Data

PF-310 exhibited a low acute oral toxicity (LD_{50}>5000 mg/kg) and a low acute dermal toxicity in rats (LD_{50} in rats >2000 mg/kg). PF-310 was not a skin irritant in rabbits, but was corrosive to the eye in rabbits. Skin sensitisation was not observed at a concentration of 50% in guinea pigs. PF-310 was not mutagenic towards *Salmonella typhimurium* and did not cause chromosomal aberrations *in vitro* in human lymphocytes.

In the 28 day repeated oral dose study in rats, PF-310 administration was associated with swollen appearance of the abdominal area, rales, laboured breathing and excessive salivation at 1000 mg/kg/day. There were no significant haematological changes. The target organ for toxicity was the gastro-intestinal tract.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Information has been submitted on ecotoxicology data, and whilst not required for this type of notification, the data have been summarised below.

Toxicological analyses were conducted in accordance with OECD and EEC guidelines in all cases, using static and semi-static conditions. The fish results are based on measured concentrations taken at the end of the test period, while the acute *Daphnia* results are based on nominal concentrations. By contrast, the measured concentration in the chronic *Daphnia* test has decreased significantly in the 48 hour renewal period.

Test	Species	Results
Acute Toxicity, 96 hour. Semi-static	Carp, *Cyprinus carpio*	24 hr LC_{50} = 2.4 mg/L 96 hr LC_{50} = 1.9 mg/L*
Acute Toxicity, 48 hour (Immobilisation)	*Daphnia magna*	24 hr EC_{50} = 7.94 mg/L 48 hr EC_{50} = 4.35 mg/L NOEL = 3.3 mg/L
Reproduction and Immobilisation (21 day)	*Daphnia magna*	EC_{50} = 1.0 < X < 3.2 mg/L LOEC = 1.0 mg/L NOEC = 0.32 mg/L
Acute Static (14 day)	Earthworm, *Eisenia andreii*	LC_{50} > 1000 mg/kg

* 100% mortality noted in concentrations above 3.2 ppm.

The above results indicate that the chemical is moderately toxic to aquatic organisms, but practically non-toxic to earthworms.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The low environmental exposure of the chemical as a result of normal use indicates that the overall environmental hazard should be negligible.

Spillage during transport or disposal of spilt material in landfills should represent very minor risk to the environment, as the concentration of PF-310 in the imported product is low. Accidental spillage of the chemical should result in negligible hazard as it will be marketed in small packages (cartridges) for direct filling into photocopier machines.

Environmental exposure to the notified substance could occur when paper containing the chemical is recycled or disposed of. Exposure of the aquatic compartment to effluents resulting from paper recycling could potentially occur, due to the relatively high water solubility of the chemical and its resistance to biodegradation. The moderate toxicity of this chemical to fish and other aquatic organisms could be of concern. However, the very small proportion of this chemical in the formulated product should mean that this risk will again be minimal, due to the expected very low environmental concentrations.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The estimated quantity of PF-310 to be imported into Australia is less than 1 tonne per year as an ingredient (<1% concentration) in a formulated product in robust sealed cartridges. The main occupational exposure to PF-310 is likely to be by skin and eye contact. Based on the results of the animal studies, the notified chemical has a low acute oral and dermal toxicity. PF-310 is not a skin irritant but is corrosive to the eye when tested in an undiluted form. However, as the notified chemical is imported as a minor constituent of a formulated product, it is not expected to be a risk to human health.

Any risk of worker exposure during storage and transport is unlikely.

Public exposure to the notified chemical is expected to be minimal as the product is contained in a cartridge.

13. RECOMMENDATIONS

To minimise occupational exposure to PF-310 the following guidelines and precautions should be observed:

. when changing toner cartridges containing the notified polymer, care should be taken to avoid exposure to the toner adhering to the plastic tape which seals the cartridge. Should exposure occur, the toner should be removed immediately by washing.

. good work practices should be implemented to avoid spillages;

. good personal hygiene should be observed; and

. a copy of the Material Safety Data Sheet (MSDS) for products containing PF-310 should be made easily accessible to workers.

14. MATERIAL SAFETY DATA SHEET

The MSDS for a product containing PF-310 (Attachment 1) was provided in Worksafe Australia format (17). The MSDS was provided by Gestetner Australia 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 Gestetner Australia Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of PF-310 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise and any submission for secondary notification may need to include test results on adsorption/desorption, and further details of environmental hazard and bioaccumulation. Details of the behaviour of the substance during and following paper recycling may also be required.

16. REFERENCES

1. *Assessment of Acute Oral Toxicity with PF-310 (FT-310) in the Rat*, Project 055722, data on file, RCC NOTOX, The Netherlands, April 1991.

2. OECD Guidelines for Testing of Chemicals - *Acute Oral Toxicity No: 401*, 1987

3. Assessment of Acute Dermal Toxicity with PF-310 (FT-310) in the Rat, Project 055733, data on file. RCC NOTOX, The Netherlands, April 1991.

4. OECD Guidelines for Testing of Chemicals - *Acute Dermal Toxicity No: 402, 1981.*

5. *Primary Skin Irritation/Corrosion Study with PF-310 (FT-310) in the Rabbit (4-Hour Semi-Occlusive Application),* Project 055744, data on file. RCC NOTOX, The Netherlands, April 1991.

6. OECD Guidelines for Testing of Chemicals - *Acute Dermal Irriatation/Corrosion No:404*, 1981.

7. *Acute Eye Irritation/Corrosion Study with PF-310 (FT-310) in the Rabbit,* Project 055755, data on file. RCC NOTOX, The Netherlands, May 1991.

8. OECD Guidelines for Testing of Chemicals -*Acute Eye Irritation/Corrosion No:405*, 1987.

9. *Assessment of Contact Hypersensitivity to PF-310 (FT-310) in the Albino Guinea Pig (Maximization Test),* Project 055766, data on file. RCC NOTOX, The Netherlands, , May 1991.

10. OECD Guidelines for Testing of Chemicals - *Skin Sensitisation No: 406*, 1981.

11. *Subacute 28-Day Oral Toxicity with PF-310 (FT-310) by Daily Gavage in the Rat*, Project 055777, data on file. RCC NOTOX, The Netherlands, May 1991.

12. OECD Guidelines for Testing of Chemicals - *Repeated Dose Oral Toxicity No: 407*, 1981.

13 *Evaluation of the Mutagenic Activity of PF-310 (FT-310) in the Ames Salmonella/Microsome Test (With Independent Repeat),* Project 055799, data on file. RCC NOTOX, The Netherlands, June 1991.

14 OECD Guidelines for Testing of Chemicals - *Samonella typhimurium, Reverse Mutation Assay No: 471*, 1983.

15. *Evaluation of the Ability of PF-310 (FT-310) to Induce Chromosome Aberrations in Cultured Peripheral Human Lymphocytes*, Project 055801, data on file. RCC NOTOX, The Netherlands, July 1991.

16. OECD Guidelines for Testing of Chemicals - *Genetic Toxicology: In Vitro Mammalian Cytogenetic Test No: 473*, 1983

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

18. "Allergic Contact Dermatitis in the Guinea-Pig: Identification of Contact Allergens" Magnusson B. Kligman A.M., 1970 published by C.C. Thomas, Springfield, Illinois, USA.

19. National Occupational Health and Safety Commission, *Approved Criteria for Classifying Hazardous Substances*, Australian Government Publishing Service Publ., Canberra, 1994.