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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

REACTIVE SCARLET RUE 56

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

REACTIVE SCARLET RUE 56

1. APPLICANT

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

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, Reactive Scarlet Rue 56 is not considered to be hazardous. Therefore, the chemical name, CAS No., molecular and structural formulae, molecular weight and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Other names: Reactive Scarlet Rue 56
FAT 45' 165/A

Trade name: CIBACRON Scarlet LS-2G (commercial product containing 73.1% Reactive Scarlet Rue 56)

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Red-brown powder.
Odour:	None
Point/ Melting Boiling Point:	> 300°C
Glass-transition Temperature:	not provided
Density:	1650 kg/m^3
Vapour Pressure:	negligible based on the high MW of the chemical
Water Solubility:	>83 g/L at 20°C
Fat Solubility:	< 0.05 mg/100 g at 37°C
Partition Co-efficient (n-octanol/water) log P_{ow}:	< -5
Surface Tension:	52.0 mN/m at 20°C

Hydrolysis as a function of pH:	- at pH 7: hydrolytically stable as < 10% hydrolysed at 50°C after 5 days, $t_{1/2}$ > year at 25°C (estimated) - pH 4: hydrolysis relatively fast at 25°C, $t_{1/2}$ = 2.4 days - at pH 9: hydrolysis relatively slow at 25°C, $t_{1/2}$ = 193 days
Adsorption/Desorption:	Not determined
Dissociation Constant pKa:	Not determined
Flash Point:	Not relevant
Flammability Limits:	Not carried out
Autoignition Temperature:	An exothermic reaction starting at 265°C. At 270°C, test substance increased to > 400°C (self ignition). Classified as autoinflammable.
Explosive Properties:	Not explosive by thermal, mechanical or frictional stresses
Reactivity/Stability:	Not determined
Particle size distribution:	range -<3 to 600 µm < 2 µm 0.5% 2-5 µm 2.5% 5-10 µm 4.6% 10-20 µm 6.1% 20-50 µm 8.4% 50-63 µm 1.3% 63-250 µm 49.3% > 250 µm 27.5%

Comments on physico-chemical properties:

Adsorption/desorption data were not provided because the method of use of the notified substance will not present opportunities for release in any significant amounts into the environment. The dye is expected to exhibit "very strong adsorption on strongly silty sand and weak sandy loam." This is possible since a study of highly sulphonated bis(azo) dyes has shown that these chemicals sorb to sediment (1) and the chemical is considered to be surface active (by EEC definition, for example, a chemical has surface activity when the surface tension is less than 60 mN/m). However, the degree to which they will adsorb to soils in the Australian environment is unknown, and with their high solubility, low P_{ow} and low fat solubility it would tend to indicate low absorption. The compound's hydrolytic stability indicates that it would be stable only at neutral to slightly alkaline pH. The half-life of 2.4 days at 25°C and pH 4 is considered fast, while the half-life of 193 days at 25°C and pH of 9 is considered slow.

The dissociation constant test was not performed as it is obvious that the chemical will dissociate in dilute solution from its structure, functional groups and by analogy with members of the same dye family already assessed.

4. PURITY OF THE CHEMICAL

This information is exempted from publication in the full public report.

5. INDUSTRIAL USE

FAT 45' 165/A will be imported in the dyestuff CIBACRON Scarlet LS-2G. It will be used for the purpose of colouring of cellulosic textiles by the exhaust dyeing method.

6. OCCUPATIONAL EXPOSURE

The dye will be transported to Australia by ship in sturdy containers with antistatic liners used for international transport. The commercial form is formulated to have anti-dusting properties. It will be distributed from two warehouses to the dyehouses. Exposure during road transport is possible but would be minimal taking into account the substantial packaging and the small amount of substance per package.

Repacking, if necessary, will be carried out using a down-flow booth. Less than 100 kg will be need to be repacked over 10 days/year for 15-20 min daily.

Occupational exposure potential results primarily from batching operations in the preparation of dye-baths in dyehouses. The batching operation consists of weighing out the powder product and adding to the blending vessel under local exhaust ventilation.

Potential exposure exists in the dyehouse from the dye in solution. The potential is low because of the absence of aerosol production. Also the dye-baths are enclosed further minimizing exposure potential.

There is no evidence of dye loss fixed to fibre after wash-off and during drying or subsequent use in the dyed cellulose.

7. PUBLIC EXPOSURE

Under normal circumstances no public exposure to the notified chemical is expected to occur during its distribution to potential customers by road and rail.

No public exposure is expected to occur during its industrial use which will be conducted in a limited number of dyehouses under local exhaust ventilation or within a closed system. Disposal of the notified chemical wastes will be either by incineration or to sewerage. Any notified chemical in the treatment plant effluent is expected to be at a low concentration and will be subject to dilution in the community sewerage systems. Hence public exposure is expected to be minimal.

The public will be exposed to textiles treated with the notified chemical. However, since the estimated level in the textile is less than 1.5% of the weight of the cellulose, the chemical is not expected to present a public health problem. This conclusion can be supported since, due to its high molecular weight and low fat solubility, dermal absorption would not be expected to occur.

8. ENVIRONMENTAL EXPOSURE

. Release

The dyestuff will be used to colour cellulosic textiles by exhaust dyeing methods with a high fixation level. The remainder will be discharged with waste water to dyehouse effluent systems. The notified substance is expected to replace other reactive dyestuffs with lower rates of fixation (60-75%). The new technology also uses much less salt which gives both economic and environmental benefits.

Release will also be limited due to the use in a limited number of sites. The generation of waste is limited to traces remaining from the clean-up of any spill, trace residues in empty packaging and discharges to dyehouse effluents.

The bulk of the dye will become chemically bound to fibre and in this state is not expected to impact on the environment. Some minor losses to the environment might occur from ventilation of dusts to air or through spills at the warehouse, during transit, or at the warehouse. Due to its high water solubility, the major potential loss to the environment is from the dye being released into the dyehouse effluent system after washing the fabric free of unfixed dye.

Any unfixed residues, after entering the sewage works, may be removed through degradation (chemical or biological) or sorption to sludge. In view of the high water solubility, it is likely that significant proportion of unfixed residue will remain in the aquatic environment. Furthermore, reactive dyes in general have been found not to adsorb to sludge in model systems (2).

. Fate

The Material Safety Data Sheet (MSDS) gives directions for clean-up of minor spills, disposal of product and disposal of contaminated packaging. In the event of a minor spill, the MSDS states that the material should be damped down and deposited in a suitable container for disposal by landfill or incineration, and disposed of as a chemical waste. Also, the product could be incinerated, observing local regulations, and residues could be flushed away with water. Incineration, with excess air, where available could be preferable because of the high water solubility of the material.

While azo dyes are generally stable under aerobic conditions, they are susceptible to reductive degradation under the anaerobic conditions characteristic of sediment (3). Also, highly sulphonated bis(azo) dyes have been shown to adsorb to sediment (1). Dyestuff could also enter sediment by precipitation of the calcium salt, as several calcium salts of sulphonic dyes are known to be insoluble at modest concentrations (1). Degradation of such dyes in sediment water systems proceeded with a t1/2 of 2-16 days. Accordingly, no significant increase in dissolved concentrations over time is predicted. However, apart from precipitation as the calcium salt, the hydrophilic nature and low partition coefficient of FAT 45' 165/A and its sulphonated metabolites may limit the affinity for soil and sediment and thus the dye should remain mainly in the aquatic environment.

The ability of the dyestuff to be biodegraded was tested using the EEC C4-E test. The test result indicated no significant degradation of the dyestuff. Therefore, the dyestuff is classified as not readily biodegradable.

The bioaccumulation of FAT 45'165A was not investigated because of the very low partition coefficient (log P_{ow} = < -5) and lipid solubility (0.05 mg/100 g). Hydrophilic dyes with log P_{ow} = < 3 have been shown not to bioaccumulate (3). Also the large molecular size of the notified chemical would tend to inhibit membrane permeability and uptake (4, 5).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of FAT 45' 165/A

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD_{50} > 2000 mg/kg	(6)
Acute dermal toxicity	Rat	LD_{50} > 2000 mg/kg	(7)
Skin Irritation	Rabbit	Slight skin irritant	(8)
Eye irritation	Rabbit	Slight eye irritant	(9)
Skin sensitisation	Guinea-pig	Not a skin sensitiser	(10)

9.1.1 Oral Toxicity (6)

This study was performed in accordance with OECD guideline No. 401 (11).

FAT 45' 165/A was administered to Wistar rats (5/sex/group) by oral gavage at a single dose of 2000 mg/kg. Clinical observations were made over 15 days. Necropsies were conducted at the end of the study. No mortalities occurred during the study. No clinical signs were noted and body weight gains were not affected by treatment. Necropsy on sacrificed animals revealed no significant macroscopic lesions.

The study indicated that FAT 45' 165/A had an oral LD_{50} > 2000 mg/kg.

9.1.2 Dermal Toxicity (7)

This study was performed in accordance with OECD guideline No. 402 (12).

FAT 45' 165/A was applied to the clipped backs of Wistar rats (5/sex/group) at a single dose of 2000 mg/kg, covered with a semi-occlusive dressing, over 24 h. Clinical observations were made over 15 days. Necropsies were conducted at the end of the study. No mortalities occurred during the study. No clinical signs were noted. Minor body weight losses (1 to 3%) were noted in 4 females. This was suggested to be due to the semi-occlusive dressing, to which females are more sensitive in response in relation to body weight than males. Necropsy on sacrificed animals revealed no significant macroscopic lesions.

The study indicated that FAT 45' 165/A had an oral LD_{50} > 2000 mg/kg.

9.1.3 Skin Irritation (8)

This study was performed in accordance with OECD guideline No. 404 (13).

A single dose of 0.5 g FAT 45' 165/A slightly moistened with bi-distilled water, was applied to the clipped dorsal skin (6 cm^2) of 3 New Zealand White rabbits (1 male/2 females). The area was covered by a semi-occlusive application and exposure time was 4 h. Skin reactions were assessed 1, 24, 48 and 72 hours after removal of the dressing.

No mortalities or clinical signs were noted during the study.

A slight red discolouration at the application sites did not prevent assessment.

Very slight erythema (in 2/3 animals; mean grade = 0.44 out of maximum of 4 over 24-72 hours) and no oedema were observed.

The primary irritation score for FAT 45' 165/A was therefore 0.44 (out of max. possible of 8.0). The results of the study indicate that FAT 45' 165/A is a slight skin irritant in rabbits.

9.1.4 Eye Irritation (9)

This study was performed in accordance with OECD guideline No. 405 (14).

A single dose of FAT 45' 165/A was instilled into the conjunctival sac of the left eye of each of 3 New Zealand White rabbits (1 male/2 females). The right eye served as the untreated control. The eyes were examined for ocular irritation 1, 24, 48 and 72 hours after application.

No mortalities or clinical signs were recorded during the study. No staining of the conjunctivae or cornea by the chemical was noted. No corrosion was observed. Slight oedema was observed in two animals (1/sex) up to 24 h. A primary irritation score of 0.22 was calculated (out of a max possible of 13).

Based upon the results of the study, FAT 45' 165/A is a slight eye irritant.

9.1.5 Skin Sensitisation (10)

This study was performed in accordance with OECD Guideline No. 406 (15).

The Magnusson-Kligman Maximisation Test (16) was used. The test animals used were female Himalayan white spotted guinea-pigs.

Pretest

Pretest were performed to identify a maximally tolerated concentration of chemical for the induction phase of the test.

Based upon the results of these pretests, intradermal and epidermal induction doses of 5% FAT 45' 165/A in bi-distilled water and 10% in vaselinum album, respectively, were chosen. For the challenge, 1% and 0.5% dilutions of FAT 45' 165/A in vaselinum album were chosen.

Induction

On day 1, 20 guinea pigs were injected intradermally (on either side of a 4 x 6 cm clipped area of the dorsal scapular position) with a 1:1 (v/v) mixture of FCA and physiological saline, 5% w/v FAT 45' 165/A in bi-distilled water and 5% w/v Fat 45' 165/A in a 1:1 (v/v) mixture of FCA and physiological saline.

On day 8, after clipping the scapular region again, a filter paper patch saturated with Fat 45' 165/A (10% in vaselinum album) was applied over the injection sites and covered with dressing for 48 hours. Skin reactions were assessed by the Draize method 24 and 48 hours after patch removal.

Controls were treated identically with the omission of test article.

After intradermal induction there was no difference in response between control and test animals. After epidermal induction, red discolouration by the test article prevented determination of erythema but no oedema was present.

First Challenge

On day 22, filter paper patches saturated with test article at either 1% and 0.5% concentrations or vaselinum album vehicle alone were applied to the clipped left cranial flank, left caudal flank and right flanks, respectively, of each guinea pig, and occluded for 24 hours with dressing. The sites were then depilated to remove red staining by the test article and sensitisation reactions scored 24 and 48 hours after patch removal according to the Draize method. Controls were treated identically without the test article.

No positive reactions were noted in control or treated animals neither when treated with vaselinum album alone nor when treated with the test article at 1% and 0.5% in vaselinum album.

Second Challenge

On day 29 the second challenge was performed with the treatment procedure identical for test animals as described for the first challenge except the applications were made to the opposite flanks of the guinea pigs. The controls were treated with the vehicle alone applied to the left flank.

No positive reactions were noted in control or treated animals neither when treated with vaselinum album alone nor when treated with the test article at 1% and 0.5% in vaselinum album.

Other Data

No clinical signs related to treatment were observed during the study. Body weight gains were unaffected by treatment. Two deaths occurred during the study, one epidermal pretest animal and one test animal prior to the second challenge application. Neither death was attributed to treatment.

In conclusion, using the highest non-irritating concentration of FAT 45' 165/A ie. 1% for the challenge applications, the results of this study indicate that Fat 45' 165/A is not a skin sensitiser.

9.2 Repeated Dose Toxicity

9.2.1 28 Day Oral Toxicity Study in Rats (17)

This study was performed in accordance with OECD Guideline No. 407 (18). GLP and QA statements were provided.

Fat 45' 165/A was administered orally to Wistar rats (10/sex/group) at doses of 0, 50, 200 or 1000 mg/kg/day for 28 days. The vehicle was bi-distilled water. At termination of the study 5 animals/sex in the control and high dose (HD) groups were observed for a further 14 day treatment free recovery period while all other animals were necropsied on day 29.

No mortalities were recorded during the study. The only clinical sign observed was discolouration of faeces in all dose groups, which would be due to the colouration of the test article.

Miminal retardation of body weight gain was observed in MD and HD males throughout the study and HD females during the last two weeks of the study. MD and HD male body weights were 8-9% lower than controls at the end of treatment in comparison to being similar at the beginning of the study. During the recovery period body weight gains of HD males was comparable to that of controls. Though the body weight gains did not reach statistical significance, the effects were treatment related.

No ophthalmic abnormalities were noted during the study. Clinical chemistry, haematology and urinalysis results revealed no treatment-related effects.

Gross necropsy was unremarkable. Organ weights, organ to body weight and organ to brain weight ratios were within normal ranges.

Histopathology revealed treatment-related effects in the stomach of primarily HD animals. These consisted of minimal to slight foveolar hyperplasia of the glandular mucosa (1 male and 4 females in HD) accompanied by higher incidence and severity of inflammatory cell infiltration in the HD animals. Additionally a minimal to slight degree of vacuolation was observed in 2 MD animals (1 male/1 female) and 4 HD animals (3 males/1 female). Foveolar hyperplasia and vacuolation were no longer in evidence in recovery animals.

In conclusion, the primary target organ for toxicity of FAT 45' 165/A was the gastric mucosa which was resolved during a recovery period.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assays (19)

This study was performed in accordance with OECD Guideline No. 471 and 472 (20, 21).

Strains used were *Salmonella typhimurium* strains TA 1535, TA 1537, TA 98 and TA 100 and *Escherichia coli* strains WP2 and WP2 *uvrA*. The assays were performed in two independent experiments both without and with metabolic activation. Each concentration including controls was tested in triplicate. The following concentrations were tested: 33.3, 100, 333.3, 1000, 2500 and 5000 μg/plate. Positive reference controls used were a) sodium azide, 4-nitro-o-phenylene-diamine and methyl methane sulfonate in the absence of metabolic inactivation and b) congo red and 2-aminoanthracene in the presence of metabolic activation.

Up to the highest investigated concentration no toxic effects were observed on growth of any strains either in the absence or presence of metabolic activation.

No increase in revertant colony numbers was observed for any of the strains at any dose level of FAT 45' 165/A used, in the absence or presence of metabolic activation.

The positive controls produced the expected responses.

In conclusion, under the conditions of these assays, FAT 45' 165/A did not induce point mutations by base pair changes or frameshifts in any of the four *Salmonella typhimurium* and two *Escherichia coli* strains used.

9.3.2 Chromosomal Aberrations in Chinese Hamster Ovary Cells (22)

This study was performed in accordance with OECD Guideline No. 473 (23).

Two independent experiments were carried out. The chromosomes were prepared 18 h and 28 h after initiation of treatment with FAT 45' 165/A formulated in DSMO. The exposure time was 4 h with metabolic activation and 18h and 28 h without metabolic activation. Cultures without metabolic activation were treated with 10, 30 or 100 μg/mL (experiment 1) or 10, 50 or 80 μg/mL (experiment 2) and harvested at 18 h (all concentrations) and 28 h (highest respective concentrations in experiments 1 and 2). Concentrations of 30, 100 or 300 μg/mL were incubated with metabolic activation (experiments 1 and 2) and harvested at 18 h (all concentrations) and 28 h (300 μg/ml only; experiments 1 and 2). All experiments were conducted in duplicate. One hundred metaphases per culture were scored for structural chromosomal aberrations. Positive

controls used were ethylmethanesulfonate without metabolic activation or cyclophosphamide with metabolic activation.

In both independent experiments, there was no biologically and statistically relevant increases in cells with structural aberrations after treatment with FAT 45' 165/A at both fixation intervals either with or without metabolic activation.

The positive control mutagens produced the expected responses.

In conclusion, under the assay conditions described, FAT 45' 165/A did not induce structural chromosomal aberrations.

9.4 Overall Assessment of Toxicological Data

Animal studies indicate that FAT 45' 165/A has low acute oral and dermal toxicity (LD_{50} > 2000 mg/kg). It was a mild skin and eye irritant, but according to the NOHSC 1008 criteria (24) it is not classified as an irritant. FAT 45' 165/A is not a skin sensitiser. It produced irritation of the gastric mucosa in rats at doses ≥ 200 mg/kg PO, which was readily resolved at the end of a 14 day recovery period. Overall, FAT 45'165/A had low toxicity.

Genotoxicity studies indicated that it had no mutagenic potential *in vitro*. No *in vivo* studies were performed.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The ecotoxicity studies were conducted using FAT 45' 165/A (≅ 65% purity) dissolved in water. Actual concentrations of test solutions in all tests remained > 90%, except for the respiration and biodegradability tests in which concentrations were not measured. The dye solution in the *Daphnia magna* test dehomogenized (i.e. separated into layers), although animals were observed to move through each of the different layers. The results in Table 2 were provided by the notifier.

Table 2 Ecotoxicity Test Results

Species	Test	Result (nominal concentration)
Carp (*Cyprinus carpio*)	96 h acute	LC_{50} > 100 mg/L; no deaths at highest concentration used
Water flea (*Daphnia magna*)	48 h acute	EC_{50} > 100 mg/L; no Daphnia were immobilized at highest concentration tested.
Algae (*Scenedesmus subspicatus*)	72 h growth	For growth inhibition (0-72 h): EC_{50} > 100 mg/L.
Activated Sludge	Respiration Inhibition Test	EC_{50} > 100 mg/L

The results show Fat 45' 165/A to be non-toxic to fish and daphnids. This is consistent with the water solubility and high MW of the substance.
The company performed a modified algae growth test to differentiate between reduced growth rate due to real toxic effects and those induced by an indirect physical effect i.e. light absorption by the coloured test solution. The influence of the notified chemical on respiration of activated sludge was tested under aerobic conditions according to EEC Directive 67/548 (amendment 87/302).

A concentration of > 100 mg/L caused no inhibition of bacterial respiration processes.

No fish bio-accumulation test was performed, based on the low fat solubility and low partition coefficient of FAT 45' 165/A.

In conclusion, the substance was not toxic to aquatic organisms and is not expected to bioaccumulate. The surface activity of the dye did not appear to have any significant effect on aquatic organisms under the test conditions.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

As noted above, significant quantities of dye will be discharged into the effluents. The notifier has claimed that the worst case scenario predicted environmental concentration (PEC) is 23 μg/L and the effluent is diluted by 10:1 in the receiving waters. Also, higher levels may be approached in a country dyehouse, on the mainland or during drought conditions.

Table 3 Estimation of Predicted Environmental Concentration

Process or dilution factor	City dyehouse	Country dyehouse 1	Country dyehouse 2
Effluent concentration in dye-specific wash-water	22.5 $mg.L^{-1}$	22.5 $mg.L^{-1}$	22.5 $mg.L^{-1}$
Dilution factor in dyehouse by other wash-waters	31:1 (2.5 $ML.d^{-1}$ effluent)	30:1 (2 $ML.d^{-1}$ effluent)	60:1 (2 - 4 $ML.d^{-1}$ effluent)
Influent concentration	0.703 $mg.L^{-1}$	0.725 $mg.L^{-1}$	0.369 $mg.L^{-1}$
Dilution factor in sewage treatment plant	100:1	3:1	2:1
Concentration balance in effluent from sewage treatment plant			
No removal of dye in sludge:	7 $\mu g.L^{-1}$	182 $\mu g.L^{-1}$	123 $\mu g.L^{-1}$
50% removal of dye in sludge:	3.5 $\mu g.L^{-1}$	91 $\mu g.L^{-1}$	62 $\mu g.L^{-1}$
Dilution factor in receiving waters	3:1 to 10:1	3:1	3:1
Predicted environmental concentration in receiving waters			
No removal of dye in sludge:	1.8 - 0.6 $\mu g.L^{-1}$	46 $\mu g.L^{-1}$	30 $\mu g.L^{-1}$
50% removal of dye in sludge:	0.9 - 0.3 $\mu g.L^{-1}$	23 $\mu g.L^{-1}$	15 $\mu g.L^{-1}$
Safety factor* for exposure of most sensitive aquatic organism (Algae, *Scenedesmus subspicatus*, for growth inhibition: E_BC_{10} = 1.22 $mg.L^{-1}$)	677-2033	27	41

* The safety factor is the highest PEC divided by the lowest NOEC (EC_{10} approximates the a NOEC)

The calculations in Table 3 are based on the internationally accepted assumption that 50% of the dyestuff is retained in sludge in the biological effluent treatment works. However, assuming that no dyestuff is retained in sludge (as shown for the study in reference 2) in the biological effluenttreatment works, then the worst case PEC is calculated to be 46 μg/L in effluent discharged from Country Dyehouse 1. Based on this most extreme scenario, the PEC of 46 μg/L gives a safety factor of 27 to algal species. Although the algal species is considered by the US EPA to be insensitive (25), the growth inhibition effect of the dye on algae was shown to be a function of decreased light intensity or change in light quality reaching the algae in the coloured media. However, the high water solubility of Fat 45' 165/A suggests that once released into the waterways, it would be quickly reduced to undetectable environmental levels.

The substance is not expected to reach the terrestial compartment in any significant amounts, nor have any impact on terrestial (soil) organisms.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

FAT 45' 165/A is stable at room temperature, is not flammable and has negligible vapour pressure. Its high MW would tend to minimize transmission through biological membranes. The Fat 45' 165/A powder has a particle size distribution where 3% is < 5 μm in size. The commercial product will be formulated to contain an anti-dusting agent to minimize inhalational exposure. As the notified chemical is not a sensitiser based upon the findings of the maximization test on the skin, inhalation of the powder is not considered to be a major concern.

The favourable toxicological profile: low acute oral and dermal toxicities in rats (> 2000 mg/kg), negative results in the skin and eye irritation studies and skin sensitisation in the maximization test, negative results in bacterial reverse-mutation and the *in vitro* chromosomal aberrations test on ovary cells of Chinese hamsters, all indicate a low hazard potential.

The notified chemical is not expected to bioaccumulate due to a low partition coefficient and a low fat solubility.

In view of the physico-chemical properties (dermal absorption not expected to occur), the toxicological profile and the likely low exposure through the use of enclosed systems, FAT 45' 165/A is not expected to present a significant occupational health risk.

The public will be exposed to textiles treated with the notified chemical. However, since the estimated level in the textile is less than 1.5% of the weight of the cellulose, the chemical is not expected to present a public health problem. This conclusion can be supported since, due to its high molecular weight and low fat solubility, dermal absorption would not be expected to occur.

13. RECOMMENDATIONS

To minimise occupational exposure to FAT 45' 165/A the following guidelines and precautions should be observed:

. If engineering controls and work practices are insufficient to reduce exposure to dye solutions containing FAT 45' 165/A to a safe level, the following personal protective equipment should be used:

  - respiratory protection conforming to Australian Standards (AS) 1715 (26) and 1716 (27),

- eye protection conforming to AS 1336 (28) and AS 1337 (29)
- impervious handgloves conforming to AS 2161 (30), and
- overalls (31)

. Good work practices should be implemented to avoid generation of dust.

. Good personal hygiene practices should be observed.

. A copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The attached MSDS for FAT 45' 165/A was provided in Worksafe Australia format (32).

This MSDS was provided by Ciba Geigy Australia Ltd. as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of Ciba Geigy Australia Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of FAT 45' 165/A 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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3. C-P Yen, T A Perenich and G L Baughman, Environmental Toxicology and Chemistry, 1991, **10,** 1009-1017.
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6. RCC Project 358830. Acute Oral Toxicity with Fat 45' 165/A in Rats. Research and Consulting Company Ltd., CH-4452 Itingen, Switzerland, 1993.
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10. RCC Project 358874. Contact Hypersensitivity to Fat 45' 165/A in Albino Guinea Pigs. Maximization Test. Research and Consulting Company Ltd., CH-4452 Itingen, Switzerland, 1993.

11. OECD Guidelines for Testing of Chemicals - Acute Oral Toxicity No. 401, 1981.

12. OECD Guidelines for Testing of Chemicals - Acute Dermal Toxicity No. 402, 1981.

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