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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

FAT 45'162/A

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

FAT 45'162/A

1. APPLICANT

Ciba-Geigy Australia Ltd of 235 Settlement Road, Thomastown VIC 3074 have submitted a Standard Notification for FAT 45'162/A.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, FAT 45'162/A, is considered to be non-hazardous. Therefore, the chemical identity, spectral data, composition, import volume and the number and identity of sites have been exempted from publication in the Full Public Report and the Summary Report.

Other names: FAT 45'162/A
Reactive Yellow AE 3800

Method of detection and determination:

FAT 45'162/A can be determined quantitatively by HPLC. The impurities may be determined by atomic absorption spectroscopy, fluorosensitive titration, X-ray fluorescence, ion chromatography and flame ionisation detection.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Red brown powder
Odour:	None
Melting Point:	> 300°C
Density:	1650 kg/m^3 at 20°C
Vapour Pressure:	1.1 x 10^{-29} Pa at 25°C (estimated)
Water Solubility:	Ú225 g/L at 20°C, pH 7.4
Fat Solubility:	< 0.05 mg/100g fat at 37°C
Partition Co-efficient (n-octanol/water) log P_{ow}:	<-6.0

Hydrolysis as a function of pH:

pH	Temperature [°C]	Rate Constant [second^{-1}]	Half Life Time t´ [hours]
4	50	1.059	18.2
4	39	0.444	43.3
4	25*	0.134	143.5
7	25*		> 1 year
9	50	0.327	59.0
9	60	1.132	17.1
9	70	3.657	5.3
9	25*	0.010	1906.9

* calculated result

Adsorption/Desorption: Not provided

Dissociation Constant pKa**:** 2.58 and 6.39 at 20°C

Flash Point: Not provided

Flammability Limits: Not flammable

Combustion Products: Not provided

Decomposition Temperature: Not provided

Decomposition Products: Not provided

Autoignition Temperature: > 400°C

Explosive Properties: Not explosive by thermal or mechanical stress

Reactivity/Stability: Not oxidizing

Particle size distribution:

< 2	µm	0.0 %
2 - 5	µm	0.1 %
5 - 10	µm	0.5 %
10 - 20	µm	1.4 %
20 - 50	µm	5.3 %
50 - 63	µm	1.9 %
63 - 250	µm	61.1 %
> 250	µm	29.5 %

Surface Tension: 74.6 mN/m at 0.974 g/L (not a surfactant).

Comments: The test for soil adsorption-desorption was not performed. The notifier claims that results for substances of similar molecular weight, structure, functional groups, water solubility, and partition coefficient suggest that the dye would exhibit "very strong adsorption on strongly silty sand and weak sandy loam". This is possible since a study of some dyes has shown that these chemicals sorb to sediment (1). However, the degree to which they will absorb to soils in the Australian environment is unknown, and with their high solubility, low Pow, and low fat solubility, it would tend to indicate low absorption. The compound's hydrolytic stability indicated that it would be stable only at a neutral pH. The octanol/water partition coefficient was very low with all the test substance remaining in the water phase. The chemical is considered not to be surface active (by EEC definition, a chemical has surface activity when the surface tension is less than 60 mN.m^{-1}).

4. PURITY OF THE CHEMICAL

Degree of purity: typically 66%

Additives/Adjuvants: None in the notified chemical

5. INDUSTRIAL USE

FAT 45'162/A will be used as a cellulose textile dye using exhaust dye methods. It will be used in several city and country locations, mainly in NSW and Victoria.

6. OCCUPATIONAL EXPOSURE

FAT 45'162/A will be imported as a red brown powder in sturdy antistatically lined drums. It will be distributed to 12 dye houses for use.

Up to 12 employees per site may potentially be exposed to FAT 45'162/A but eight of these workers will only be using the dye in closed systems. Four batch operators weigh out the dye powder, usually under local exhaust ventilation, and add it to the blending vessel. Each batch operator weighs out approximately 2.0 kg five times during the day on 125 days per year. Ciba-Geigy have estimated a "worst case" exposure to these workers of 0.0029 mg/kg bw/day.

The steps involved in the textile dye process are weighing, addition of the dye to the blending vessels and transferring of the dye mixture to the dyeing equipment. The dye is dissolved in a vat before it is pumped to a tank from which it is dispensed to the dye machine. These processes all occur in closed systems. The fabric is fed into the dye machine and following dyeing the fabric is washed free of unfixed dye and dried. Exposure of workers during the dyeing process is not expected.

Repacking may also be performed at the warehouse prior to distribution. This is performed in a booth where down flow air is drawn away from the operators. A maximum of 100 kg of dye is anticipated to be repacked by two personnel for several hours each year.

7. PUBLIC EXPOSURE

The public is unlikely to be exposed to the chemical during the importation and commercial dyeing processes. After wash off and drying the reactive dye is strongly bound to the fibres, hence public exposure to the chemical is likely to be very low.

8. ENVIRONMENTAL EXPOSURE

. Release

The dyestuff will be used to colour cellulosic textiles by exhaust dyeing methods. The notifier indicates that the substance exhibits high levels of fixation using this technique. The remainder will be discharged with waste water to dyehouse effluent systems. The notified chemical is expected to replace other reactive dyestuffs in the market place, the latter, it is claimed, usually representing older technology with inherently lower rates of fixation.

No additional formulation will take place in Australia. Some re-packaging for the purposes of supplying samples or material for mill trials may occur. Waste dye that may arise from spills, cleaning of ventilation filters or container residues will be consigned to landfill or incineration.

. Fate

Transport, Storage and Disposal

The pigment will be transported in sturdy containers with antistatic liners used for international transport. Risks from accidental spillage appear small. The Material Safety Data Sheet (the 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.

Loss to the environment

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 dyehouse. Due to its high water solubility and its use in dyeing, however, the major potential loss to the environment is from the dye being released into the dyehouse effluent system (i.e. the dyehouse biological effluent treatment works or the community Sewage Treatment Plant) 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 a significant proportion of unfixed residue will remain in the aquatic compartment, and not degraded significantly, in spite of the relative alkalinity of the sewerage system. Furthermore, reactive dyes in general have been found not to adsorb to sludge in model systems (2).

Residues that survive sewage treatment will enter freshwater or marine environments in solution. Azo dyes are generally stable under aerobic conditions, but are susceptible to reductive degradation under the anaerobic conditions characteristic of sediment (3). Also, some azo dyes have been shown to sorb to sediment (1). Another possible route of entry of the dye into the sediment is by precipitation of its calcium salts, as several calcium salts of these dyes are known to be insoluble at modest concentrations (1). Degradation of such dyes in sediment water systems proceeded with a half-life of 2-16 days. Accordingly, no significant increase in dissolved concentrations over time is predicted, while residues bound to sediment are expected to undergo reductive degradation. However, apart from precipitation as the calcium salt, the hydrophilic nature of FAT 45' 162/A and its metabolites should limit the affinity for soil and sediment and thus the dye should remain mainly in the aquatic compartment.

The ability of the dyestuff to be biodegraded was tested using the EEC C4-E test (4). The test result (using nominal concentrations of 1 and 3 $mg.L^{-1}$) indicated no significant degradation of the dyestuff. The dyestuff was classified as ‘not readily biodegradable’. Inherent biodegradability is uncertain.

The bioaccumulation potential of FAT 45' 162/A was not investigated because of the very low partition coefficient (log P_{OW} = < -6) and lipid solubility (0.05 $mg.100\ g^{-1}$). Hydrophilic dyes with log P_{OW} < 3 have been shown not to bioaccumulate (3). Also, no bioaccumulation of the dyetuff is expected since its large molecular size is likely to inhibit membrane permeability and prevent uptake during exposure (5,6).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of FAT 45'162/A

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD_{50} > 2000 mg/kg	(7)
Acute dermal toxicity	Rat	LD_{50} > 2000 mg/kg	(8)
Skin Irritation	Rabbit	Non-irritant	(9)
Eye irritation	Rabbit	Slight irritant	(10)
Skin sensitisation	Guinea pig	Non-sensitiser	(11)

9.1.1 Oral Toxicity (7)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 401*.

Wistar rats (5 per sex) were administered by gavage a single dose of 2000 mg/kg FAT 45'162/A dissolved in water. Animals were observed for a period of 14 days after which necropsy was performed.

One female showed reduced weight gain during the second week of observation. No other clinical signs, deaths, macroscopic or body weight changes were observed in any animal.

It was concluded that the oral LD_{50} of FAT 45'162/A was > 2000 mg/kg.

9.1.2 Dermal Toxicity (8)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 402*.

Wistar rats (5 per sex) were administered FAT 45'162/A by dermal application.

On day one of the procedure the test substance was applied evenly to a portion of a shaved skin area. This was covered by a semi-occlusive dressing. FAT 45'162/A was diluted in water and animals received 4 ml of the substance at a dose of 2000 mg/kg. Twenty four hours after application the skin was washed and dried. The animals were then observed for a period of 14 days after which necropsy was performed.

No mortality or macroscopic abnormalities were observed during the study. The skin of all animals became yellow coloured and this persisted for the entire observation period. Two females lost weight (4.5 g and 8.9 g) in the first week of observation of the study and the female rats in general showed low weight gain.

It was concluded that the dermal LD_{50} of FAT 45'162/A to rats was > 2000 mg/kg.

9.1.4 Skin Irritation (9)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 404*.

New Zealand White rabbits (one male, two females) were administered a single dose of 0.5 g of FAT 45'162/A moistened with water by dermal application.

On day one of the procedure the test substance was applied to a portion of the shaved area and covered with a semi-occlusive dressing. The test substance remained on the skin for four hours after which time it was removed with lukewarm tap water. Animals were then observed at 1, 24, 48 and 72 hours after removal of the dressing.

All animals showed skin discolouration which persisted for 7 days and was said not to influence the evaluation of reactions. No animals exhibited erythema or oedema. Body weights were normal and no other clinical symptoms were observed.

FAT 45'162/A was concluded to be a non-irritant to the skin under the conditions of this study.

9.1.5 Eye Irritation (10)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 405.*

New Zealand White rabbits (three males) were administered a single dose of 0.1 g of FAT 45'162/A into the conjunctival sac of one eye. The other eye remained untreated and was used as a control. Animals were observed at 1, 24, 48 and 72 hours and 7 days after administration of FAT 45'162/A.

The conjunctivae were moderately reddened in one animal at 1 hour only and slightly reddened in the other two animals. The nictitating membrane was reddened and the sclera coloured yellow in all animals. These symptoms were absent by 48 or 72 hours. No other signs of treatment were evident.

No clinical signs of systemic toxicity were observed. Discolouration of the eyelid and hair occurred for the entire observation period, but this was not present in the cornea or conjunctivae.

FAT 45'162/A was concluded to be a slight irritant to the eye of the rabbit under the conditions of the study.

9.1.6 Skin Sensitisation (11)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 406*.

The test used was the guinea-pig maximisation test of Magnusson and Kligman (ref).

To determine the dose level for intradermal injection in the main study, 0.1 ml of a 5%, 3% and 1% solution of FAT 45'162/A in water were injected into the clipped flank of two Himalayan strain guinea-pigs. The resulting dermal reactions were assessed 24 hours later. Very slight oedema was present in both animals at all treatment levels 24 hours after bandage removal. Erythema could not be determined due to skin discolouration from the test substance. A concentration of 5% FAT 45'162/A was selected for intradermal induction.

To determine the dose level for topical induction and challenge in the main study 25%, 15%, 10% and 5% of FAT 45'162/A in vaseline was applied to the clipped and shaved flanks of four guinea pigs. Filter paper saturated with the test substance was applied to the skin under occlusive bandage. The dressings were removed after 24 hours and the hair depilated 21 hours later. Assessments were made 24 and 48 hours after removal of the bandage. No skin reactions were observed in any animal at any dose level. A 25% solution of FAT 45'162/A was chosen for induction study and 25% and 15% solutions for the challenge study.

Induction Study

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

On day 1 three pairs of intra-dermal injections (0.1 ml) were made into the clipped scapular region of each guinea-pig. The injected solutions were:

Freund's Complete Adjuvant (50:50) with physiological saline.
FAT 45'162/A diluted to 5% with water,
FAT 45'162/A diluted to 5% in saline and emulsified in a 50:50 mixture with Freund's Complete Adjuvant.

Control animals received the same treatment but without the test substance.

On day 7 the scapular region was clipped and shaved and treated with 10% sodium-lauryl-sulfate (SLS) to enhance a mild inflammatory reaction. On day 8 the areas of the injection sites were treated with an occlusive epidermal application of 25% FAT 45'162/A in vaseline in the same manner as described above for topical application. The bandage remained in place for 48 hours. Control animals were similarly treated but without the use of the test substance. The sites were evaluated 24 and 48 hours after removal of the bandages.

Challenge Study

Two weeks after the epidermal induction application, the test and control animals were challenged topically with FAT 45'162/A. Filter paper was saturated with 25% or 15% of FAT 45'162/A or with vaseline vehicle only. The test substance was applied to the left and right flanks of each guinea pig. The techniques used were the same as those described above. The bandages remained for 24 hours and assessment was made of the skin reactions at 24 and 48 hours after removal of the bandages. Hair was chemically depilated several hours prior to the 24 hour reading.

A second challenge was performed one week after the first challenge. Control animals were treated with the vaseline only. Test animals were treated on the previously untreated flank.

Results

After epidermal induction, one female showed very slight oedema when treated with 25% at both observation times; erythema could not be scored due to orange-red staining of the skin.

Following the first challenge, no positive reactions were observed in any of the treated animals. Following the second challenge one animal treated with 25% FAT 45'162/A showed slight erythema at 24 hours after treatment with 25% of the test article. Two animals showed slight erythema at 48 hours after treatment with 15% of the test article.

Body weights were not affected during the study and no toxic symptoms were observed in any animals.

In conclusion FAT 45'162/A is considered not to be a skin sensitiser in the guinea pig.

9.2 28 Day Repeated Dose Toxicity (12)

Groups of 10 rats (5 of each sex) of a Wistar-derived strain were treated orally by gavage, once daily, 7 days a week for 4 weeks. Animals received 0, 50, 200 or 1000 mg/kg/day of FAT 45'162/A dissolved in distilled water at 10 ml/kg. Animals were necropsied after the 28-day treatment period was over. In a recovery study 5 animals of each sex were treated with 0 or 1000 mg/kg and allowed a 14 day recovery period prior to necropsy being performed.

Body weights and food consumption of treated animals varied slightly but this could not be attributed to treatment. No treatment related deaths, clinical signs or changes in ophthalmic properties or urine

parameters were observed among any treatment group. No changes of significance occurred to haematological parameters or clinical biochemistry.

A small increase in the liver/body weight ratio in female rats occurred after 4 weeks. Non statistically significant dose dependent increases in the liver weight and liver /brain weight occurred in females after 4 weeks sample time. Non statistically significant dose dependent increases in the liver weight and liver/body weight occurred in males after 4 weeks sample time.

No macroscopic nor microscopic changes were observed that were unusual for the age and strain of rat used, or were more severe or frequent in the treated animals compared to the controls.

The results of this study suggest that administration of FAT 45'162/A to rats at up to 1000 mg/kg has little effect on the biological parameters measured. No changes were observed in animals treated with 200 mg/kg or less.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium and Escherichia coli Reverse Mutation Assay (13)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 471.*

FAT 45'162/A was tested in the reverse mutation assay on *S. typhimurium* strains TA98, TA100, TA1535 and TA1537, and *E. coli* strains WP2 and WP2*uvrA* in the presence or absence of hamster liver microsomal S9 activation. As a result of a preliminary study the concentrations selected for the main study were 0, 33.3, 100.0, 333.3, 1000, 2500 or 5000 µg FAT 45'162/A/plate dissolved in dimethylsulfoxide. Toxicity was evident at 5000 µg/plate in strain TA 98 but was not evident in any of the other strains. Positive controls used in the absence of activation were 4-nitro-o-phenylenediamine, sodium azide, and methyl methane sulfonate. 2-Aminoanthracene and Congo Red were used as the positive controls in experiments including the liver S9 mix.

Significant and dose-dependent increases in the number of revertant colonies of bacteria were recorded for *S. typhimurium* strain TA98 in the presence of S9 mix. Increases of 6 fold over the solvent control were observed. Increases were apparent from 100.0 to 1000.0 µg/plate, beyond which toxic effects of the test article had an impact on the result. All positive control substances produced marked increases in the number of revertant colonies within the anticipated range.

In conclusion, under the conditions of this experiment, FAT 45'162/A produced point mutations by frame shifts in the presence of metabolic activation with the *S. typhimurium* strain TA98.

9.3.3 Chromosomal Aberrations in Chinese Hamster Ovary Cells (14)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 473*.

FAT 45'162/A was investigated for its potential to cause chromosomal aberrations *in vitro* in the V79 line of cells from the Chinese hamster.

Preliminary experiments were performed in order to determine the toxicity of FAT 45'162/A to the cells. Cytotoxicity was observed in the absence and presence of rat liver S9 mix at 300 µg/plate and higher. The culture medium and solvent (water) were used as the negative controls; ethylmethanesulfonate (4.8 mM final concentration) and cyclophosphamide (3.3 µM final concentration) dissolved in nutrient medium were the positive controls utilised.

Two experiments were performed using cultures in the presence absence of S9 metabolic activation. A single cell suspension of V79 was prepared from 3 or 4 day-old exponentially growing stock. Cells were subsequently treated with FAT 45'162/A for 4 h with metabolic activation or 18h or 28 h without

metabolic activation. Chromosomes were prepared 18 h or 28 h after treatment. After 48 h (28 h preparation interval) and 55 h (18 h preparation interval) the cell medium of the 4-h treatment group was replaced by serum-free medium containing the test article and S9 mix. The cell medium of the 18 and 28 h treatment group was replaced by complete medium containing different concentrations of the test article without S9 mix. Low, medium and high concentrations of FAT 45'162/A were used for the 18 h fixation interval and high concentration for the 28 h fixation interval. Precipitation of the test article occurred at 300.0 µg/ml, with and without S9 mix thus limiting the concentrations available.

The mitotic indices were reduced to 60% after treatment with the highest dose in the absence of S9 at both fixation intervals in one experiment only. The index was reduced to 65% at the higher doses at both fixation levels in both experiments in the presence of S9. No increases in the rate of polyploid metaphases were observed compared to controls.

The chromosomal aberration rates on two occasions were significantly higher than the corresponding control values. This occurred at the highest dose at the 28 h fixation level without S9 in one experiment, and at the highest dose at the 28 h fixation level with S9 in one experiment. These results were not thought to be biologically significant due to the low (0%) aberration rate of the controls and the low aberration rate of the test substance being well within the historical control window.

No other aberration rates of the test compound were found to be significantly different to the control values.

In conclusion, FAT 45'162/A was found not to be a clastogen in the V79 Chinese hamster cell line under the conditions of the study.

9.3.3 Gene Mutation Assay in Chinese Hamster Ovary Cells (15)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 476*.

FAT 45'162/A was investigated for its potential to cause gene mutations *in vitro* to the HPRT (hypoxanthine-guanine phosphoribosyl transferase) locus in the V79 line of cells from the Chinese hamster.

Three independent experiments were performed with and without the addition of metabolic activation provided by S9. The culture medium and solvent (water) were used as the negative controls; ethylmethanesulfonate (4.8 mM final concentration) dissolved in nutrient medium and 7,12-dimethylbenz(a)anthracene (15.0 µM final concentration) dissolved in dimethylsulfoxide nutrient medium were the positive controls utilised. Experiments performed to determine the toxicity of FAT 45'162/A to the cells showed no toxicity up to and including the limit of solubility.

Concentrations of FAT 45'162/A from 10.0 to 1500.0 µg/ml were used. At least four concentrations per experiment were used. A single cell suspension of V79 was prepared from 3 or 4 day old exponentially growing stock. After 24 h the medium was replaced with serum free medium containing FAT 45'162/A, either with or without S9 mix. After a 4 h treatment time this medium was rinsed and replaced with complete medium. The cells were allowed to grow for 8 days prior to the termination of growth and the subsequent staining of the colonies. Forward mutation was indicated by the resistance of cells to 6-thioguanine which kills non mutated ($HPRT^+$) cells.

FAT 45'162/A did not produce an increase in mutant colony numbers. In contrast, both positive control substances caused a marked increase in the number of mutant colonies.

In conclusion it can be stated that under the conditions described in these experiments FAT 45'162/A did not cause gene mutations at the HPRT locus in V79 cells of the Chinese hamster.

9.4 Overall Assessment of Toxicological Data

FAT 45'162/A is non toxic via the oral and dermal routes to the rat with both LD_{50s} > 2000 mg/kg. It is a slight irritant to the eye and a non irritant to the skin of the rabbit. It is non sensitising to the skin of the guinea-pig. When rats were treated orally with up to 1000 mg/kg/day for 28 days only small changes to any of the measured parameters were observed. No effects were observed at doses of 200 mg/kg/day or less. FAT 45'162/A was found to be genotoxic *in vitro* to *Salmonella typhimurium* strain TA 98 in the presence of S9 mix, but not to other strains of the bacteria nor to *Escherichia coli*. Neither chromosomal aberrations nor gene mutations were induced in the V79 line of cells *in vitro* from the Chinese hamster.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The ecotoxicity studies were conducted using FAT 45' 162/A (~ 70% purity) dissolved in water. Actual concentrations of test solutions in all tests remained > 80%, except for the respiration and worm test in which concentrations were not measured. The results in Table 2 were provided by the notifier. The results show the pigment to be nontoxic to fish and daphnids which is consistent with the water solubility and high molecular weight of the substance.

An algae growth inhibition and rate reduction test gave a no-observed-effect-concentration for growth inhibition (NOE_BC) of 4 $mg.L^{-1}$ and a no-observed-effect-concentration for growth rate reduction (NOE_RC) of 9 $mg.L^{-1}$. Any change in growth may be due to a reduction in light intensity or change in light quality, and not necessarily due to the toxicity of the substance to algae. While any effect on algae growth due to colouration of the water might lead to an undesirable environmental impact, it was noted that algae cell growth did recover after 24 h.

Table 2. Ecotoxicity test results

Species	Test	Result (nominal concentrations)
Carp (*Cyprinus carpio*)	96 h acute	LC_{50} > 100 $mg.L^{-1}$
Water Flea (*Daphnia magna*)	48 h acute	EC_{50} > 100 $mg.L^{-1}$
Algae (*Scenedesmus subspicatus*)	72 h growth	For growth inhibition: E_BC_{50} > 100 $mg.L^{-1}$ and NOE_BC = 4 $mg.L^{-1}$ For growth rate reduction: E_RC_{50} > 100 $mg.L^{-1}$ and NOE_RC = 9 $mg.L^{-1}$
Earthworm (*Eisena foetida foetida*)	14 d acute	LC_{50} > 1000 $mg.kg^{-1}$ dry soil)
Activated Sludge	Respiration Inhibition Test	EC_{50} > 100 $mg.L^{-1}$ (30 min)

The influence of the dyestuff on respiration of activated sludge was tested under aerobic conditions according to EEC Directive 67/548 (amendment, 87/302). A concentration of >100 $mg.L^{-1}$ caused no inhibition of bacterial respiration processes.

The company also provided results from an ecotoxicity test (OECD Test Guideline 207) using an earthworm, (*Eisena foetida foetida*). No acute effects were observed at the highest nominal concentration of 1000 $mg.L^{-1}$.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

As noted above, significant quantities of dye will be discharged into effluent. The notifier has calculated that the worst case scenario predicted environmental concentration (PEC) is 28 $\mu g.L^{-1}$ and the effluent is diluted by 10:1 in the receiving waters at a country dyehouse. Also, higher levels may be approached in a country dyehouse, on the mainland, during drought conditions.

The calculations in Table 3 are based on the internationally acceptable 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 in the biological effluent treatment works (as shown for the study in reference 2), then the worst case PEC is calculated to be 56 $\mu g.L^{-1}$ dye in effluent discharged from a country dyehouse. Based on this most extreme scenario, the PEC of 56 $\mu g.L^{-1}$ gives a safety factor of 57. Although the algal species tested is considered by the US EPA to be insensitive (21), the growth inhibition effect of the dye on algae may be a function of decreased light intensity or change in light quality reaching the algae in the coloured media, and algae growth did recover after 24 h. In any event, the dye's high solubility suggests that once released to the waterways, dilution would be expected to swiftly reduce the environmental concentration to undetectable levels.

The substance is non-toxic to aquatic fauna, and is not expected to accumulate in sediment or to bioaccumulate. The substance is not expected to reach the terrestrial compartment in any significant amounts, nor have any impact on terrestrial (soil) organisms.

Table 3. Estimation of Predicted Environmental Concentration

Process or dilution factor	City dyehouse	Country dyehouse	Country dyehouse
Effluent concentration in dye-specific wash-water	10 $mg.L^{-1}$	10 $mg.L^{-1}$	10 $mg.L^{-1}$
Dilution factor in dyehouse by other wash-waters	10:1 (2.5 ML. d^{-1} effluent)	10:1 (2 ML. d^{-1} effluent)	10:1 (2 - 4 ML. d^{-1} effluent)
Influent concentration	0.91 $mg.L^{-1}$	0.91 $mg.L^{-1}$	0.48 $mg.L^{-1}$
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:	9 $\mu g.L^{-1}$	227 $\mu g.L^{-1}$	158 $\mu g.L^{-1}$
50% removal of dye in sludge:	4.5 $\mu g.L^{-1}$	114 $\mu g.L^{-1}$	79 $\mu g.L^{-1}$
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:	2 - 0.8 $\mu g.L^{-1}$	56 $\mu g.L^{-1}$	40 $\mu g.L^{-1}$
50% removal of dye in sludge:	1 - 0.4 $\mu g.L^{-1}$	28 $\mu g.L^{-1}$	20 $\mu g.L^{-1}$
Safety factor* for exposure of most sensitive aquatic organism (Algae, *Scenedesmus subspicatus*) **	1600 to 4000	57	80

* The safety factor is the highest PEC divided by the lowest NOEC

** for growth inhibition: NOE_BC = 3.2 $mg.L^{-1}$, LOE_BC = 7.2 $mg.L^{-1}$ actual concentrations)

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

FAT 45'162/A is a powder with a partition coefficient of < -6.0, low fat solubility (< 0.05 mg/100g) and a molecular weight > 1000 suggesting that it is unlikely to accumulate in biological tissue. It has a negligible vapour pressure and only 0.6% of the particles are in the respirable range of less than 10 µm. The potential for entering the lungs is therefore low, but inhalation of the powder should be avoided to avoid potential health affects.

FAT 45'162/A is likely to be of low oral and dermal toxicity in humans and have few irritation properties. The dye was found to be mutagenic towards one strain of *Salmonella typhimurium*. It was non mutagenic towards three other strains of the same bacteria and in two other *in vitro* mammalian tests. FAT 45'162/A was not classified as a mutagen according to the Hazardous Substances Criteria (22).

There is a limited amount of handling of the dye due to the use of closed systems. Local exhaust ventilation is normally used during weighing processes and down draft air systems and a booth is used when repackaging is necessary. It is likely that only 4 workers at each of 12 dye houses will be exposed directly to FAT 45'162/A during their work, and that the remaining workers will be using the dye in closed systems. Those exposed to FAT 45'162/A may make contact with the dissolved dye via skin or eye contact.

The public is unlikely to be exposed to the chemical during its importation and application to fibres by commercial dye houses. After wash off and drying the reactive dye is strongly bound to the fibres, and public exposure to the dye in textiles is therefore likely to be very low.

In conclusion, when used under the conditions described by the notifier, FAT 45'162/A presents a low risk to those working with the chemical and to the general public.

13. RECOMMENDATIONS

To minimise occupational exposure to FAT 45'162/A the following guidelines and precautions should be observed:

If engineering controls and work practices are insufficient to reduce exposure to a safe level, the following personal protective equipment should be used:

- respiratory protection conforming to Australian Standard AS 1715 (23) and AS 1716 (24);
- chemical-type goggles conforming to Australian Standard AS 1336 (25) and 1337 (26);
- impervious gloves conforming to Australian Standard AS 2161 (27); and
- protective clothing conforming to Australian Standards AS 3765.1 (28) or 3765.2 (29).

- good work practices should be implemented to avoid generation of dust and liquid spills.
- spills should be cleaned up promptly.
- good personal hygiene practices should be observed.
- a copy of the Material Safety Data Sheet for products containing the notified chemical should be easily accessible to all employees.

14. MATERIAL SAFETY DATA SHEET

The attached Material Safety Data Sheet (MSDS) for FAT 45'162/A was provided in Worksafe Australia format (31).

This MSDS was provided by Ciba-Geigy 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 Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of FAT 45'162/A shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

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