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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

FAT 41'018/A

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

FAT 41'018/A

1. APPLICANT

Ciba-Geigy Australia Ltd, 235 Settlement Rd, Thomastown, Victoria, 3074

2. IDENTITY OF THE CHEMICAL

FAT 41'018/A is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, spectral data, composition of the dye and the commercial product Cibacron Yellow C-2R, exact amount to be imported and the number of sites at which the notified chemical will be used have been exempted from publication in the Full Public Report and the Summary Report.

Trade names: FAT 41'018/A (the commercial product to be imported is called Cibacron Yellow C-2R or Cibacron Yellow DER 7459 and contains an anti-dusting agent, a dispersing agent, inorganic salts and a buffering agent)

Method of detection and determination:

A high performance liquid chromatographic method has been developed by the notifier and UV/VIS, NMR and IR spectra were submitted.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Red/Brown powder
Melting Point:	Decomposes above 216°C but does not melt
Density:	1790 kg/m^3 at 20°C
Water Solubility:	> 650 g/L at room temperature
Fat Solubility:	0.1 - 1.1X10^{-4} g/kg at 37°C
Partition Co-efficient (n-octanol/water) log $P_{O/W}$:	$\leq$ -7

Hydrolysis as a function of pH: pH 4: Half-lives of 9, 28 and 93 hours (estimated) at 50°C, 37°C and 25°C respectively;

pH 7: A decrease in concentration of <10% was observed after 5 days;

pH 9: Half-lives of 4, 12 and 6500 hours (estimated) at 80°C, 70°C and 25°C.

Adsorption/Desorption:

Soil	Composition	Adsorption (%)	Desorption (%)
I[a]	pH 4.0, 6.0% clay, 1.4% organic matter	100	0
II[b]	pH 7.5, 13.6% clay	53	
III[c]	pH 6.6, 12.1% clay	89	6.1

[a] strong silty sand [b] strong sandy loam [c] weak sandy loam

Dissociation Constants
pKa: 5.9 and 8.9 at 20°C

Surface Tension: 70.7 nM/m at 20°C and 0.99 g/L

Flammability: Not highly flammable. The substance could not be ignited with a gas burner. Not auto-flammable to 420°C.

Explosive Properties: Not explosive following thermal or mechanical stress

Particle size distribution: 4.7% < 60µm
0.3% < 10µm

4. PURITY OF THE CHEMICAL

Degree of purity: 57.7%

Impurities: A number of impurities related to the notified chemical have been identified and there are also a number of high molecular weight (> 1000) organic unknowns. No toxicity data is available on the individual impurities. However, the substance with a typical impurity profile has been used in the toxicity studies (section 9 below). Non-hazardous impurities at > 1% are inorganic salts at < 5%.

5. INDUSTRIAL USE

The notified substance will be used for the colouring of cellulosic textiles by the cold pad-batch method.

The amount of FAT 41' 018/A expected to be imported is less than 20 tonnes per year in the first 5 years.

6. OCCUPATIONAL EXPOSURE

Following importation, some repacking may be necessary at the notifier's warehouse. This is done under local exhaust ventilation and less than 100 kg will be repacked per year on not more than 10 days for 15-20 minutes on each day.

FAT 41' 018/A is to be applied by the pad-batch method. It is expected to be used in several dyehouses employing about 30-40 employees in total.

About 2 dye-weighers per dyehouse are expected to weigh 1.16 kg on 4-5 occasions per day, 120 days per year. Each weighing is expected to take no more than 15 minutes and is expected to be carried out under local exhaust ventilation.

Dissolution of the dye takes place in an enclosed vat. The dye solution (500 litres) is pumped through closed lines to a tank at the padding mangle where about 50 - 100 litres are fed by gravity to a trough. The cloth is led through the trough using a tape or lead cloth (the operator does not touch the liquor) and is squeezed to a consistent liquor pick-up. The cloth is run until a full roll is built up which is then covered with plastic by the operator.

After 4 - 24 hours dye fixation, the cloth is washed through 4 - 8 wash tanks being pulled through by the previous batch or a lead cloth. The only handling involves sewing of the lead cloth. After washing, the cloth is free of unfixed dye and is dried prior to pick-up on a rotating beam.

7. PUBLIC EXPOSURE

There is low potential for public exposure to the dyestuff during transport and distribution and application of the dye is not expected to result in significant public exposure.

Disposal of waste notified chemical will be limited to traces remaining from the clean-up of any spill, trace residues in empty packaging and discharges to dyehouse effluent systems. Approximately 50% of notified chemical discharged into the dyehouse effluent system is expected to be retained in the sludge in biological effluent treatment works. There is low potential for public exposure resulting from disposal of the notified chemical.

Public exposure to dye on clothing and other products is expected to be negligible as the dye does not 'bleed' from cotton fabrics and therefore, transfer of dye to the skin is not expected to occur.

8. ENVIRONMENTAL EXPOSURE

. Release

Formulation, handling and disposal

No formulation will take place in Australia. Some re-packaging for the purposes of supplying samples or materials for mill trials may be required. This will occur at the Ciba warehouse, where measures to control possible spills are reported to be in place. Less than 100 kg per year would be expected to be re-packed.

Distribution to customers is expected to take place from one site only, where only small quantities are distributed to a restricted number of customers.

Waste dyes that may arise from spills, cleaning of ventilation filters or container residues will either be consigned to landfill or incineration. Incineration is the disposal method recommended, due to the high solubility of the substance.

Use

The dye will be imported in a ready to use form as a red-brown powder. It will be used to colour cellulosic textiles by the cold pad-batch methods. Dyehouses will be located in NSW, Victoria and Tasmania.

It is claimed that the dye has a high level of fixation to cellulosic fibres when applied using the pad-batch method (90% - 93%). Fixation curves are supplied to corroborate the fixation levels achieved, however, these reports are in German, and are not supplied as a certified translation.

Use of this dye is claimed to reduce the environmental impact of dyeing processes, as the cold pad-batch process has a very high fixation value, and the dye is expected to have a high fastness level. Dye not fixed to cloth will be discharged to wastewater at effluent treatment plants or sewers, depending on local requirements.

The calculated PEC for the receiving waters will typically range between 1 and 40 ppb (see page 11, Part A).

. Fate

The bulk of the dye will become chemically bound to fibre and in this state is not expected to impact on the environment.

Unfixed residues from dyeing operations will enter the aquatic environment following discharge from textile mills and subsequent treatment, during which they may be removed through degradation (chemical or biological) or sorption to sludge. Given the hydrolytic instability at pH 4 and pH 9 (although at 25°C at this pH, the chemical is fairly stable - half-life of 270 days approximately), the chemical could reasonably be expected to break down in the sludge. The high solubility of the chemical would mean that it would then be carried out of the sewage system in effluent. However, the

adsorption/desorption constant of this particular dye in soils similar to those that will be found in areas of dye use in Australia indicates that it will sorb to sediments quite strongly.

· Biodegradation

Cibacron Yellow CR-2 is not readily biodegradable (22% after 28 days) when the dye was tested using activated sludge from a domestic sewage plant according to OECD Test Guideline 301D and EEC directive 84/449 Part C.

· Bioaccumulation

The bioaccumulation potential of Cibacron Yellow CR-2 was not investigated because of the low partition co-efficient (log Pow = -7) and the lipid solubility (0.001 to 0.011 mg/100g fat simulant at 37°C). These features greatly reduce the potential for bioaccumulation, and such an omission is acceptable.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Fat 41'018/A

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD_{50} > 2000 mg/kg	1
Acute dermal toxicity	Rat	LD_{50} > 2000 mg/kg	2
Skin irritation	Rabbit	Non irritant	3
Eye irritation	Rabbit	Slight irritant	4
Skin sensitisation	Guinea pig	non-sensitiser	5

9.1.1 Oral Toxicity (1)

FAT 41'018/A in distilled water was administered to 5 male and 5 female Wistar rats by gavage at a dose level of 2000 mg/kg. No clinical signs or behavioural changes were noted during a 14 day observation period. All animals survived to the end of the observation period and no abnormalities were noted at post mortem on day 15.

It is concluded that the acute oral LD_{50} of FAT 41'018/A is greater than 2000 mg/kg.

9.1.2 Dermal Toxicity (2)

FAT 41'018/A in distilled water was applied to a clipped area of the backs of 5 male and 5 female Wistar rats under an occlusive dressing at a dose level of 2000 mg/kg. The cuff was removed after 24 hours and the test site was wiped free of residual test substance with a tissue moistened with tap water.

No mortality occurred during a 14 day study period. Lethargy was observed in 2 out of 5 males on day 1 and focal erythema (slight) was observed in 2 out of 5 males and 2 out of 5 females on days 2 or 3.

Macroscopic post mortem examination of the animals at termination revealed orange discolouration of the treated skin area.

It is concluded that the acute dermal LD_{50} of FAT 41'018/A is greater than 2000 mg/kg.

9.1.3 Skin Irritation (3)

FAT 41'018/A (0.5 g) was moistened with distilled water and applied under a semi-occlusive dressing to the intact skin of a shaved area on one flank of each of 3 male New Zealand White rabbits. The contralateral flank was similarly prepared but without test substance or vehicle. Four hours after the application, the dressing was removed and the remaining test substance removed using a tissue moistened with tap water and subsequently a dry tissue.

The only observable effect of application of the test substance was very slight erythema in one animal 1 day after exposure. No other erythema and no oedema was observed up to 7 days after removal of the dressing.

Although yellow/orange staining of the skin made scoring of erythema difficult on day 1, it can be concluded that FAT 41'018/A is non-irritating to rabbit skin.

9.1.5 Eye Irritation (4)

FAT 41'018/A (68 mg of powder) was instilled into the conjunctival sac of one eye of each of 3 male New Zealand White rabbits and the lids held closed for about 1 second. The contralateral eye of each animal remained untreated and served as the reference control.

At the 24 hour observation, a solution of 2% fluorescein in water (adjusted to pH 7.0) was instilled into both eyes of each animal to quantitatively determine corneal epithelial damage.

No effects on the iris or cornea were observed for any animal throughout the 7 day observation period.

Slight discharge was observed in one animal 24 hours after treatment. Conjunctival redness was observed in all animals although yellow discolouration made scoring difficult. Slight conjunctival redness (some blood vessels definitely injected) was observed for all animals at 1, 24, 48 and 72 hours after treatment. Obvious swelling (chemosis) with partial eversion of the lids was observed at one hour

in all animals and this had reduced to slight swelling by 24 hours and was not observed thereafter.

It can be concluded that FAT 41'018/A is slightly irritating to the rabbit eye.

9.1.6 Skin Sensitisation (5)

To assess the sensitisation potential of FAT 41'018/A in albino (Himalayan spotted) guinea pigs, the Maximisation test of B Magnusson and A B Kligman (1969) was used. Ten females were used as the control group and 20 females were used as the test group.

In a pretest with 6 animals, the maximally tolerated concentration of the test article by injection was judged to be 5% and a suitable non-irritant concentration for topical application was judged to be 25%. No primary irritant concentration could be established.

Main Study

Induction

Intradermal injections:
An area of dorsal skin from the scapular region was clipped free of hair. Three pairs of intradermal injections (0.1 ml/site) were made at the border of a 4 X 6 cm area in the clipped region as follows:

Test group:

1) Freund's complete adjuvant 50:50 with physiological saline

2) The test article, diluted to 5% with physiological saline

3) The test article diluted to 5% by emulsion in a 50:50 mixture of Freund's complete adjuvant and physiological saline

Control group:

1) Freund's complete adjuvant 50:50 with physiological saline

2) Physiological saline

3) Freund's complete adjuvant 50:50 with physiological saline

Epidermal applications:

At test day 7 and approximately 24 hours prior to the epidermal application, the scapular area was clipped, shaved free of hair and the test area was pretreated with 10% Sodium lauryl sulphate (SLS) in petrolatum oil because no primary irritation concentration could be determined in the corresponding pretest. The SLS was massaged into the skin with a glass rod without bandaging. This SLS concentration enhances sensitisation by provoking a mild inflammatory reaction.

At test day 8 a 2 X 4 cm patch of filter paper was saturated with the test article (25% in physiological saline) and placed over the injection sites of the test animals. The patch was covered with aluminium foil and firmly secured by an elastic plaster wrapped

around the trunk of the animal and secured with impervious adhesive tape. The dressings were left in place for approximately 48 hours. The epidermal application procedure described ensured intensive contact of the test article.

The guinea pigs of the control group were treated as described above with the omission of the test article (physiological saline only).

Reaction sites were assessed for erythema and oedema 24 and 48 hours after removal of the dressing.

Challenge:

The test and control guinea pigs were challenged 2 weeks after the epidermal induction application and were treated in the same way.

Hair was clipped and shaved on the left and right flank of each guinea pig. Two patches of filter paper were saturated with a non-irritant concentration of 25% (left flank) and the vehicle only (physiological saline applied to the right flank) using the same method as for the epidermal application. The dressings were removed approximately 24 hours later. The sites were assessed for erythema and oedema 24 and 48 hours after removal of the dressing.

After removal of the dressing the application site was depilated with a cream to clean the application site from staining produced by the test article.

Skin effects were observed after epidermal induction and challenge. These were:

Skin effects after induction:

In the control group erythema and oedema were observed in 2/10 animals after 24 and 48 hours.

In the test group discolouration by the test article masked erythema but oedema was observed in 5/20 animals after 24 hours.

Skin effects after challenge:

In the control group no positive reactions were evident after the challenge application whether treated with physiological saline or with the 25% test article solution.

In the test group 2/20 animals showed erythema reactions at 24 and 48 hours with the 25% solution of test substance but not with physiological saline.

It can be concluded that FAT 41'018/A is a non-sensitiser.

9.2 Repeated Dose Toxicity (6)

FAT 41'018/A was administered orally by gavage to SPF-bred Wistar male and female rats at dose levels of 0, 50, 200 or 1000 mg/kg/day for 28 days. The test substance was dissolved in distilled water. There were 10 male and 10 female rats in the 0 and 1000 mg/kg/day

dose groups and 5 rats of each sex in the other 2 dose groups. Five male and 5 female rats from each dose group were killed for necropsy after 28 days. The extra 5 male and 5 female rats in the 0 and 1000 mg/kg/day dose groups were held for a further 14 day treatment-free recovery period prior to necropsy.

There were no deaths and no clinical signs of reaction to treatment at any dose level. No test article related effects were noted on food consumption or body weight development of the animals.

Changes in the haematological data were considered to be incidental and of normal biological variation for rats of this strain and age.

For the clinical biochemical data certain statistically significant effects were noted in the high dose group (1000 mg/kg/day). These were an increase in bilirubin concentration by about 29% was ascribed to discolouration of the plasma with the test article. Increases of 29% for total cholesterol concentration in males, of 29% for triglycerides in females and of 19% for phospholipids in males were suggested to be within the limits of historical control data. However, as all parameters returned to normal after the 2 week treatment-free recovery period, it would appear that the effects on clinical biochemistry were treatment-related.

For the urinalysis data a deep yellow discolouration of the urine in all males and 2/10 females in the 1000 mg/kg/day dose group was considered to be related to the yellow-brown colour of the test article. At the end of the treatment-free recovery period, the discolouration was no longer observed. All other differences in the urinalysis parameters were considered to be incidental and of normal biological variation for rats of this strain and age.

A few statistically significant increased values in organ weights were noted at the end of the treatment-free recovery period in the high dose (1000 mg/kg/day) animals - increased testes/body weight ratio in the male (1.17% vs 1.06%), increased liver weight (absolute (6.30 g vs 5.65 g) and liver/brain (333.35% vs 287.02%) weight ratio) and heart/brain (42.04% vs 38.54%) weight ratio in the females.

There were no test article-related abnormal findings at macroscopic examination.

For the microscopic findings, all high dose (1000 mg/kg/day) animals except one female had increased numbers of red/brown inclusions in the mucosa of the glandular part of the stomach. The inclusions were also present, in small numbers, in 3 control males and 2 control females. The toxicological significance of this finding is uncertain but is considered to be test article related. Also observed for the high dose (1000 mg/kg/day) animals was irregular deposits of pale brown pigment in the kidney tubules which were still present after the recovery period. This finding was considered to be test article related.

Target organs for toxicity were the GI tract and kidney.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium and Escherichia coli Reverse Mutation Assay (7)

FAT 41'018/A was assessed for its potential to induce gene mutations according to the pre-incubation test for azo dyes using *Salmonella typhimurium* strains TA 1535, TA 1537, TA 98 and TA 100 and the *Escherichia coli* strains WP 2 and WP2 *uvrA*.

The test substance was assayed in two independent experiments at doses of up to 5000 µg/plate with and without metabolic activation provided by Syrian hamster liver S9. At this concentration normal background growth was observed suggesting limited toxicity.

No substantial increases in revertant colony numbers of any of the five tester strains were observed following treatment with FAT 41'018/A at any dose level either in the presence or absence of metabolic activation.

The numbers of back mutants per plate in the negative controls were within the expected ranges for each of the bacterial strains used. Positive controls gave the expected responses and were:

Strain	Chemical	Liver S9
TA 1535	Sodium azide	-
	2-Aminoanthracene	+
TA 1537	4-Nitro-o-phenylene diamine	-
	2-Aminoanthracene	+
TA 98	4-Nitro-o-phenylene diamine	-
	Congo Red	+
TA 100	Sodium azide	-
	2-Aminoanthracene	+
WP2	Methyl methane sulphonate	-
	2-Aminoanthracene	+
WP2*uvrA*	Methyl methane sulphonate	-
	2-Aminoanthracene	+

It is concluded that the notified chemical is unlikely to induce mutations in *Salmonella typhimurium* and *Escherichia coli* and is, therefore, not genotoxic as measured by these assays.

9.3.2 Chromosomal Aberration Assay in Chinese Hamster Ovary (CHO) Cells (8)

FAT 41' 018/A was assessed for its potential to induce structural chromosomal aberrations in CHO cells *in vitro* in two independent experiments.

The chromosomes were prepared 24 hours (low, medium and high concentration range) and 30 hours (high concentration range) after the start of treatment with the test article. The treatment interval was 4 hours with metabolic activation, 24 and 30 hours without metabolic activation provided by rat liver S9.

Doses were chosen on the basis of the number of scorable metaphases obtainable up to a maximum of 5.0 mg/ml. The doses used were 0.10, 0.50 or 1.0 mg/ml for the 24 hour interval and without S9. For the 30 hour interval a dose of 0.50 mg/ml was used in one replicate and 1.0 mg/ml was used in the other. With S9 the doses used were 0.5, 2.5 or 5.0 mg/ml for the 24 hour interval and 5.0 mg/ml for the 30 hour interval.

In the two replicate experiments one statisically significant increase in the percentage of metaphases with chromosomal aberrations was observed at one time point. At a treament interval of 24 hours in the presence of S9, cells treated with 0.5 mg/ml test article exhibited 5.0% aberrations against 0.5% aberrations in the solvent control. However, because historical control data varies between 0 and 5.0%, this observation was not considered to be biologically significant.

It is concluded that FAT 41'018/A does not induce structural chromosomal aberrations in the CHO cell line.

9.4 Overall Assessment of Toxicological Data

FAT 41'018/A is of low acute oral and dermal toxicity in rats, is not a skin irritant but is a slight eye irritant. The eye irritation may have resulted from mechanical damage by the powder inserted in the conjunctival sac of the test animals.

Some effects of repeated oral dosing of rats over 28 days on certain clinical biochemical parameters were observed at the highest dose tested of 1000 mg/kg/day. Also at the highest dose, some effects were observed at the cellular level in the stomach and in kidney tubules.

FAT 41'018/A is not a skin sensitiser in guinea pigs and is not genotoxic as judged by the results of assays for bacterial mutagenesis and induction of chromosomal aberrations in chinese hamster ovary cells *in vitro.*

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The ecotoxicity studies were conducted using technical grade Cibacron Yellow CR-2, and the following results were provided by the notifier.

Test	Species	Test Guideline	Result
96 hour Acute	*Cyprinus carpio* (Carp)	OECD No. 203 EEC Directive 84/449 No L251 C-1	LC_{50} > 1000 mg/L
Acute 48 h Immobilisation	*Daphnia magna*	OECD No. 202 EEC Directive 84/449 No. L251 C-2	EC_{50} = 556 mg/L NOEL = 320 mg/L
96 hour Static	*Scenedesmus subspicatus*	OECD No. 201 EEC Directive 67/548 OJEC L133 V31 Part C	EC_{50} for cell growth inhibition (E_BC50 : 0-96h) - 74 mg/L EC_{50} for growth rate reduction (E_RC_{50} : 24-96H) - 117 mg/L NOE_BC - 10 mg/L NOE_RC - 3.2 mg/L
Respiration Inhibition	Activated sludge (mixed bacterial culture)	OECD No. 209 EEC Directive 67/548 Part C NO. L133	EC_{50} > 100 mg/L
14 day Acute Static	*Eisenia foetida* (earthworm)	OECD No. 207	LC_{50} > 1000 mg/kg

Tests were conducted using nominal concentrations of the chemical. Final concentrations of test solutions were not found to depart significantly from the initial nominal concentrations (range 94% - 105%).

The above results show the dye to be practically non-toxic to bacteria, earthworms, mammals, fish and *Daphnia* and slightly toxic to the alga tested. This is consistent with the high water solubility and the high molecular weight. *Daphnia* reproduction tests were not conducted on the grounds that colouration of the test media may have inhibited reproduction, rendering the test inapplicable. This is acceptable. Colouration of the test media did occur during the Daphnia. immobilisation tests, but apparently did not prevent assessment of the *Daphnia* mobility.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

As noted above, up to 10% of the dye is not fixed in the pad-batch dyeing process and will be discharged to the effluent. The notifier

has calculated a worst case scenario Predicted Environmental Concentration for three proposed dyehouses. These are presented in detail below. Briefly, the examples include a city dyehouse, a country dyehouse and a Hunter River dye plant. Calculated PECs at a dilution rate of 3 : 1 in receiving waters, and assuming at concentration after 50% removal in sewage treatment plants are 1 µg/L, 5 µg/L, and 40 µg/L.

Calculation factor	**City**	**Country 1**	**Country 2**
Typical use of dye expected per day	5.2 kg	5.2 kg	16.7 kg
In wash water (at a fixation rate of 90%)	0.52 kg	0.52 kg	1.17 kg (given) 1.67 kg (calc. by CEPA)
Quantity of water used including wash-off	350, 000 L (at 100 L/kg)	350, 000 L (at 100 L/kg)	111, 300 (at 100 L/kg)
Effluent conc. in dye specific wash water	1.5 mg/L av.	1.5 mg/L av.	15.0 mg/L
Dilution in dyehouse by other wash water	5 : 1	-	5 : 1
Influent concentration	0.25 $mg.L^{-1}$	0.315 $mg.L^{-1}$	1.75 $mg.L^{-1}$
Dilution in sewage treatment plant	1 : 250	1 : 15	1 : 45
Balance in effluent after sewage treatment plant	0.005 mg/L at 50% removal	0.01 mg/L at 50% removal	0.88 mg/L at 50% removal
Dilution in receiving waters	3 : 1 to 10 : 1	3 : 1	3 : 1
Conc. (PEC) in receiving waters	1 µg/L at 3:1, ie. 1 ppb 0.5 µg/L at 10:1, ie 0.5 ppb	5 µg/L ie. 5 ppb	40 µg/L ie. 40 ppb

In all of the above cases, the PECs are far lower than the NOEAC for the most sensitive species tested, the alga (10 mg/L). The substance is not expected to bioaccumulate, given the low partition co-efficient and fat solubility.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The toxicological profile of FAT 41'018/A suggests that, unlike some other reactive dyes, it does not appear to be genotoxic and is not a skin sensitiser. Because it is a powder, FAT 41'018/A has the potential to enter the upper respiratory tract. However, again unlike some other reactive dyes, it is unlikely to be a respiratory sensitiser.

Because of the abovementioned effects of reactive dyes, dyehouses use local exhaust ventilation during weighing operations and the same will be the case for FAT 41'018/A.

FAT 41'018/A has a low potential for acute toxic effects such as acute oral or dermal toxicity and is unlikely to be a skin irritant. However, there is some potential for eye irritation possibly as a result of mechanical damage.

Some small effects of FAT 41'018/A on some clinical biochemistry values at a high dose in a 28-day repeated dose study in rats were noted. In addition, some microscopic effects were found in the stomach and kidneys.

FAT 41'018/A is very stable at room temperature and is safe to handle.

Exposure of workers to FAT 41'018/A is expected to be very low as the powder is weighed out under local exhaust ventilation and after dissolution of the dye, subsequent operations such as fixation and washing occur in open troughs with limited intervention by operators. Further, once attached to the cellulosic textiles, the dye is expected to remain fixed.

From the data presented, it would appear that FAT 41'018/A has a very limited risk of producing any adverse occupational health or safety effects.

As public exposure is expected to be minimal, the risk of adverse health effects is unlikely.

13. RECOMMENDATIONS

To minimise occupational exposure to FAT 41'018/A the following guidelines and precautions should be observed:

. local exhaust ventilation should be employed during weighing out of the notified chemical and the dust level should be maintained below Worksafe Australia's exposure standard for nuisance particulates of 10 mg/m3 (9);

. if engineering controls and work practices are insufficient to reduce exposure to FAT 41'018/A to a safe level, then personal protective devices which conform to and are used in accordance with Australian Standards (AS) for eye protection (AS 1336, AS 1337) (10,11), impermeable gloves (AS 2161) (12), protective clothing (AS 3765.1, 3765.2) (13,14) and respiratory protection (AS 1715) (15) should be worn;

. a copy of the Material Safety Data Sheet should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The attached Material Safety Data Sheets (MSDS) for FAT 41'018/A and Cibacron Yellow C-2R were provided in Worksafe Australia format (16).

These MSDS were provided by Ciba Geigy Australia Ltd as part of their notification statement. 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 41'018/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

1. *Assessment of Acute Oral Toxicity with FAT 41'018/A in the Rat*, data on file, Ciba-Geigy AG, Basle, Switzerland. Report - RCC project 336723, 1992.

2. *Assessment of Acute Dermal Toxicity with FAT 41'018/A in the Rat*, data on file, Ciba-Geigy AG, Basle, Switzerland. Report - RCC 336734, 1993.

3. *Primary Skin Irritation/Corrosion Study with FAT 41'018/A in the Rabbit (4-Hour Semi-Occlusive Application)*, data on file, Ciba-Geigy AG, Basle, Switzerland. Report - RCC 336745, 1993.

4. *Acute Eye Irritation/Corrosion Study with FAT 41'018/A in the Rabbit,* data on file, Ciba-Geigy AG, Basle, Switzerland. Report - RCC 336756, 1993.

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