File No: NA/397

Date:June 1996

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Direct Yellow 169 FAT 40'403

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act), and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health and Family Services

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the hours of 10.00 a.m. and 12.00 noon and 2.00 p.m. and 4.00 p.m. each week day except on public holidays.

For Enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 577-9466 **FAX (61) (02) 577-9465**

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Direct Yellow 169 FAT 40’403

1. APPLICANT

Ciba-Geigy Australia Pty Ltd of 235 Settlement Road THOMASTOWN VICTORIA 3074 has submitted a standard notification statement for an assessment certificate for Direct Yellow 169 FAT 40’403.

2. IDENTITY OF THE CHEMICAL

Direct Yellow 169 FAT 40’403 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, molecular weight, spectral data and exact details of import volume and sites where the chemical will be used have been exempted from publication in the Full Public Report and the Summary Report.

Other names:	Fat 40'403; Disazo Yellow SCR 905; Direct Yellow 169
Trade name:	the commercial product to be marketed in Australia will be known as Pergasol Yellow RN liquid/Solophenyl Yellow AGL liquid and powder and will contain FAT 40'403 and certain adjuvants to improve application
Method of detection and determination:	UV/Vis, IR and NMR spectra

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	orange powder with nil odour, commercial form is either a liquid or powder (antidusting type formulation)
Melting point:	none to 573 K
Density:	1.53 g/ml at 22°C
Vapour pressure:	not available
Water solubility:	> 155000 mg/L at 20°C

Partition co-efficient (n-octanol/water):	log P_{ow} < -2.05 at pH 6.9 and 25°C
Hydrolysis as a function of pH:	$T_{1/2}$ at pH 4.0 > 1 year $T_{1/2}$ at pH 7.0 > 1 year $T_{1/2}$ at pH 9.0 > 1 year
Adsorption/desorption:	not available
Dissociation constant:	not available
Flash point:	not applicable
Flammability limits:	not highly flammable
Autoignition temperature:	not available
Explosive properties:	not explosive
Reactivity/stability:	no thermal effect up to 150°C, with and without air
Surface tension (aqueous solution):	70.0 - 71.2 mN/M at 10 g/L
Fat solubility:	≤ 0.05 mg/100g at 37ºC
Particle size distribution:	163 μm (median), 97% > 20μm

Comments on Physico-Chemical Properties

Although highly soluble, the dye is expected to have superior fixation properties (supported by colorimetric tests) to paper that will resist leaching by water. Product fastness tests have also been carried out, which indicate the dye is resistant to extraction.

Adsorption/desorption tests were not performed, but the high water solubility and low partition coefficient suggest the chemical will not readily adsorb to soils.

A dissociation constant was not determined. As a sodium salt however, the dye is expected to be highly dissociated, and exhibit typical acidity.

4. PURITY OF THE CHEMICAL

Degree of purity:	85.6% (typical)
Toxic or hazardous impurities:	unsulphonated primary aromatic amines were not detectable as impurities: detection limit of 10 mg/kg

Non-hazardous impurities
(> 1% by weight):

Chemical Name	*CAS No.*	*Weight %*
unidentified coloured byproducts1,2,3,5,6,7		6.4
water	7732-18-5	8.5
sodium		4.8

Additives/Adjuvants: none; additives and adjuvants may be included only in the commercial version, not in the notified substance

5. USE, VOLUME AND FORMULATION

The notified substance will not be manufactured in Australia. Imports will be in the form of ready-to-sell, 1000 L international bulk containers (IBCs) for the liquid form or 30 kg plastic lined cartons for the powdered form. Some repacking for the purposes of supplying samples or material for mill trials may be required. It is estimated that less than 200 L will need to be repacked each year, and simply involves, in the case of the liquid formulation, the transfer of liquid from one container to another. This will occur at Ciba's Thomastown (Victoria) warehouse.

Projected import volumes (tonnes) are from < 1 tonne to < 100 tonnes/annum:

The notified substance is a dye imported in ready-to-use liquid form (eg Pergasol Yellow RN/ Solophenyl Yellow AGL liquid) with a concentration of the notified chemical of 42.4%. The powdered form is imported in a ready to use antidusting formulation with the concentration of the notified chemical being 30-60%. These dyes are expected to replace other dyes currently in the marketplace, as these usually represent older technology with inherently lower rates of fixation.

The liquid formulation of the dye will be used mainly in paper mills. These are located in NSW, Victoria and Tasmania. It will be sold for the purpose of colouring paper and tissue paper. The commercial form of the substance is a liquid which will be dispensed directly from the sales container and incorporated into the paper dyeing stock.

A second minor use for the dye is as a textile dyestuff and the commercial form is a powder. It is anticipated that less than 1 tonne per year will be imported (800 kg in year 4).

6. OCCUPATIONAL EXPOSURE

The dye will be imported in two forms; the majority will be as a liquid formulation for paper dyeing and also as a powder for textile dyeing. Occupational exposure to both forms can occur through accidental release during transport and warehousing. The main area of occupational exposure will be during dyeing operations.

The major use of the notified chemical in Australia will be in paper dyeing. As the dye is in a liquid formulation dermal and oral exposure are the most probable occupational exposure routes. Inhalational exposure could occur if aerosols are formed, this may occur during paper forming operations. Only small quantities of dye are used, 50-100g of dye/tonne of paper, the low concentration will reduce exposure. The processes that occur in the paper dyeing/forming operations where exposure could occur are when the dye container as supplied to the paper mill is connected to the supply system, transferral via the metering pump to the dilution vessel and during transfer operations to the pulper vessel. The dilution occurs in a covered tank. Once diluted it is pumped in a closed system to the pulper. During this phase the machine operator is unlikely to come into contact with the solution. The processing of the pulp and solution occurs at the beater, refiner and machine chest. The dye is fixed to the paper fibres during calendering and drying. The process is largely automated and enclosed. 'Backwater' from the papermaking machine is constantly reused, as distinct from a constant loss system, further reducing exposure during papermaking. Occupational exposure during papermaking will be greatest for those operators connecting and disconnecting delivery/transfer hoses in paper mills. The probable exposure routes are likely to be exposed skin and the eyes. Exposure will occur for approximately 0.5 hr/day for 24 days a year. In total 91 staff employed as machine technicians and laboratory attendants can be potentially exposed to the notified chemical during papermaking. A further 60 staff may be exposed to the dyed paper during processing and packaging operations.

Ciba-Geigy may undertake some repackaging of the dye formulations. This will entail up to four staff being exposed for 1 hour/day for up to 12 days/year. Repackaging will be undertaken by staff trained in the transfer of hazardous substances.

In textile dyeing operations the powdered dye formulation, Solophenyl Yellow AGL will be supplied in the imported 30 kg plastic lined cartons direct. The dye is weighed and then usually mixed in a premix tank before being added to the dyebath. Inhalational and dermal exposure could occur during weighing and dissolution operations, the notifier has submitted a worse case exposure assessment based on an employee being exposed for 50 days a year (this only takes into account ambient exposure for the dye weigher as distinct from peak exposure levels). This gives an average daily exposure level of 0.001450 mg/kg.bw/day. To accurately establish safe levels and NOEL a longer term study (90 days) is usually required, the notifier submitted a 28 date feeding study in rats.

7. PUBLIC EXPOSURE

The notified chemical will be imported into Australia in 1000 L international bulk containers (liquid formulation) or in 30 kg plastic lined cartons (powder formulations). The formulations will be transported to Ciba's Thomastown (Victoria) and Pendle Hill (NSW) warehouses then distributed by road to manufacturers of paper and/or textiles. No public exposure to the notified chemical is expected to occur during its storage and distribution.

Only small quantities of the dye will be used in the manufacture of paper (50 to 100 g of dye /tonne of paper) and textiles (0.15 to 0.3% dye on weight of textile), and given that application processes are largely conducted in closed systems, no public exposure to the notified chemical is expected to occur.

Disposal of any waste notified chemical will be by incineration or to sewage. It has been estimated that up to 80% of the notified chemical will be collected as solid waste from effluent treatment systems. Further dilution of wastes containing the notified chemical on entry to water courses is expected to lead to extremely low exposure levels. There is minimal potential for public exposure to the notified chemical during its disposal.

Public exposure to the notified chemical as a result of contact with paper products is not expected to occur as no loss of the dye from the paper is expected. Textiles treated with the dye will be used in the manufacture of clothing articles, and although some transfer of dye to the skin could occur, exposure levels are expected to be low. In addition, given that the substance has a low fat solubility (< 0.5 mg/100 g fat simulant), it is unlikely that dermal absorption would occur.

8. ENVIRONMENTAL EXPOSURE

Release

The bulk of the dye will become chemically bound to paper fibres or textile, and in this state is not expected to impact on the environment. 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 (ie. the dyehouse biological effluent treatment works or the community sewage treatment plant).

The notified dye represents an improvement on other dyes due to its high affinity for paper and textile fibres. Assessment of fixation of the paper dye has been carried out by colorimetric methods based on depth of shade. These indicate that generally in the order of 98 - > 99% of the dye will be exhausted (range from 95 - > 99%). Recovery of lost dyestuff occurs through the mill effluent system from which it is recovered through a "save all" (50% of remaining dye in mill effluent) and clarifier process (further 25% recovery of dye in mill effluent). Addition of a flocculant to the clarifier can reduce this final amount by up to 80%. Therefore, with 95% exhaustion, 2.5% is left after the save all process, and 1.9% after the clarifier process which will be released to sewer. With the addition of a flocculant in the clarifier process, only around 0.5% of the product will be released to sewer.

The sludge may be further treated if the mill has a biological effluent treatment works, where chemical and biological degradation occurs. Otherwise the solid waste is usually incinerated or passed to landfill. Incineration will result in oxides of carbon, nitrogen and sulphur. Bulk containers are thoroughly rinsed with water to recover all of the product delivered to the mill. The rinsate is passed to the consuming process.

Fate

The OECD TG 301A test for ready biodegradability was carried out, and found that the substance was not readily biodegradable (0% after 28 days), but did not inhibit bacteria.

The substance has a high water solubility and low fat solubility. This together with a log P_{ow} = <-2.05 indicate that bioaccumulation is unlikely.

The dye normally released in water as effluent from the mill is expected to be the major environmental release. The dye (in its anionic form) has the potential to chelate to mineral sediment, containing such cations as Al^{3+} and Ca^{2+}.

Any dye which binds to sludge is expected to remain with the sludge, which would be disposed of by incineration or landfill. Instructions in the Material Safety Data Sheet (MSDS) sheet show incineration to be the preferred method to reduce potential leaching of the compound into the environment.

On entering the sewage treatment plant, unfixed residues may be removed through degradation. Residues that survive sewage treatment will enter freshwater or marine environments in solution, where aerobic conditions are anticipated. The low biodegradability in aerobic conditions and stability to hydrolysis, coupled with high water solubility suggest the compound may persist for long periods in the aquatic compartment. Although azo dyes are generally stable under aerobic conditions, highly sulphonated bis(azo) dyes have been shown to sorb to sediment, where they are susceptible to reductive degradation under the characteristically anaerobic conditions (1).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Direct Yellow 169 FAT 40'403

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5000 mg/kg	2
acute dermal toxicity	rat	LD_{50} > 2000 mg/kg	4
skin irritation	rabbit	non irritant	6
eye irritation	rabbit	non irritant	7
skin sensitisation	guinea pig	not sensitising	8

9.1.1 Oral Toxicity (2)

Species/strain:	rat, Wistar Han.
Number/sex of animals:	5/5
Observation period:	15 days
Method of administration:	gavage, distilled water, single dose of 5000 mg/kg bw
Clinical observations:	none
Mortality:	none
Morphological findings:	none
Test method:	based on OECD Guidelines for Testing Chemicals (3)
LD_{50}:	> 5000 mg/kg
Result:	low toxicity

9.1.2 Dermal Toxicity (4)

Species/strain:	rat, Wistar Han
Number/sex of animals:	5/5
Observation period:	14 days
Method of administration:	occluded patch to shaved skin; 24 hour exposure to 2000 mg/kg

Clinical observations: both sexes yellow discolouration, in males focal erythema up to day 6

Mortality: nil

Morphological findings: nil

Draize scores (5):

Time after treatment (days)	***Animal #***									
	1	***2***	***3***	***4***	***5***	***6***	***7***	***8***	***9***	***10***
Erythema	[i]									
2	*x	x	x	x	x	0	0	0	0	0
6	x	x	x	x	x	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0
Oedema										
2	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0

[i] see Attachment 1 for Draize scales

* absence or presence only, x indicates presence of effect

Test method: based on OECD Guidelines for Testing Chemicals (3)

Result: low toxicity, irritant in male rats

9.1.3 Inhalation Toxicity

No inhalation toxicity data was provided in the submission.

9.1.5 Skin Irritation (6)

Species/strain: New Zealand white rabbit

Number/sex of animals: 2 males/1 female

Observation period: 72 hours after removal of test article (0.5g/ animal)

Method of administration: under semi occlusive dressing for 4 hours

Draize scores (5):

Time after treatment (days)	***Animal #***					
	1	***2***	***3***	***4***	***5***	***6***
Erythema						
1	[i]0	0	0	0	0	0
3	0	0	0	0	0	0
Oedema						
1	0	0	0	0	0	0
3	0	0	0	0	0	0

[i] see Attachment 1 for Draize scales

Test method: based on OECD Guidelines for Testing Chemicals (3)

Result: not a skin irritant in rabbits

9.1.5 Eye Irritation (7)

Species/strain: New Zealand White rabbit

Number/sex of animals: 2 males/1 female

Observation period: 72 hours

Method of administration: 0.1 g (solid, particle size not specified) into conjunctival sac of one eye

Draize scores (5) of test eyes:

	Time after instillation					
Animal	**1 day**		**2 days**		**3 days**	
Cornea	**o[a]**	**a[b]**	**o[a]**	**a[b]**	**o[a]**	**a[b]**
1	[i]0	0	0	0	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0
Iris						
1	0		0		0	
2	0		0		0	
3	0		0		0	
Conjunctiva	**r[c]**	**c[d]**	**d[e]**	**r[c]**	**c[d]**	**d[e]**	**r[c]**	**c[d]**	**d[e]**
1	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0

[i] see Attachment 1 for Draize scales
[a] opacity [b] area [c] redness [d] chemosis [e] discharge

Test method: based on OECD Guidelines for Testing Chemicals (3)

Result: not an irritant

9.1.6 Skin Sensitisation (8)

Species/strain: Himalayan spotted guinea pig

Number of animals (M/F): 5/5

Induction procedure: three pairs of injections of 0.1 ml: FCA in water (1:1); 0.5% notified chemical in physiological saline; 0.5% notified chemical emulsified in physiological saline and Freund's Complete Adjuvant (FCA); topical induction: at day 6, 10% sodium lauryl sulphate in petrolatum followed 1 day later by 25% in petrolatum oil (saturated) 48 hours

Challenge procedure: challenge concentration of notified chemical (25%) in petrolatum oil.

Challenge outcome:

	Test animals		Control animals	
Challenge concentration	***24 hrs****	***48 hrs****	***24 hrs***	***48 hrs***
25%	**0/20	0/20	0/10	0/10

* time after patch removal
** number of animals exhibiting positive response

Test method: based on OECD Guidelines for Testing Chemicals (3)

Result: not a sensitiser

9.2 Repeated Dose Toxicity (9)

Species/strain: rat Wistar

Number/sex of animals (M/F): Group1, controls 10/10
Group 2, 50 mg/kg bw/day 5/5
Group 3, 200 mg/kg bw/day 5/5
Group 4A, 1000 mg/kg bw/day 10/10 toxicity testing
Group 4B, 1000 mg/kg bw/day 10/10 recovery testing

Method of administration: gavage, vehicle distilled water

Dose/Study duration: Group 4A, 1000 mg/kg bw/day for 28 days
Group 4B, 1000mg/kg bw/day for 28 days followed by 14 days recovery (no dose)

Clinical observations: no clinical signs of toxicity in any of the animals; in addition no significant variation in body weights or organ weights between controls and dosed animals

Clinical chemistry/Haematology/ Urinanalysis high dose males had statistically higher platelet counts than controls but still within 95% confidence limits; this group also had elevated uric acid, bilirubin and LDH levels and lower sodium and chloride levels; 7/10 high dose males had discoloured urine and low-grade bilirubinuria; effects were still apparent during 14 day recovery period; low dose animals showed no comparable treatment related effects

Histopathology: no treatment related effects

Test method:	based on OECD Guidelines for Testing Chemicals (3)
Result:	no effects noted in test animals dosed up to 200 mg/kg bw/day. At dose rates of 1000 mg/kg bw/day changes in clinical chemistry of blood and urine was evident in the majority of male rats

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (10)

Strains:	*Salmonella typhimurium* TA 98, TA 100, TA 1535, TA 1537, TA 1538 and *Escherichia coli* WP2
Concentration range:	10 - 5000 μg/ plate test article with or without rat liver S9
Test Method:	in accordance with OECD Guidelines for Testing Chemicals (4)
Result:	non-mutagenic in bacteria; positive controls showed a distinct increase in revertant colonies

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (11)

Species/strain:	NMRI mouse
Number and sex of animals:	42/42 (5/5 at 24h, 48h and 72h)
Doses:	5000 mg/kg
Method of administration:	orally, vehicle distilled water
Test method:	in accordance with OECD Guidelines for Testing Chemicals (4)
Result:	non mutagenic in test system at 5000 mg/kg

9.3.3 Chromosome Aberration Assay in Chinese Hamster V79 cells *in vitro* (12)

Doses:	cytotoxicity: 42-85700 µg/ml mutagenicity: 370-10000 µg/ml with and without metabolic activation
Method of administration:	In vitro study, cells maintained in Ham's F10 medium supplemented with foetal calf serum
Test method:	in accordance with OECD Guidelines for Testing Chemicals (4)
Result:	no cytotoxicity at maximum dose; no relevant increase in mutant frequencies with or without metabolic activation

9.3.4 *In vivo/in vitro* Unscheduled DNA Synthesis (UDS) in Rat Hepatocytes (13)

Species/strain:	Wistar rat
Number and sex of animals:	25 males
Doses:	10 ml/kg for either 4 or 16 hours
Method of administration:	test article formulated in double distilled water and administered orally; after either 4 or 16 hours primary hepatocyte cultures were established following sacrifice of the test animals; cultures exposed to ^{3}HTdR for 4 hours which is incorporated if UDS occurs
Test method:	In compliance with GLP; no OECD or EEC guidelines at time of test, based on methods referenced in test report
Result:	test article did not induce DNA damage leading to repair synthesis in the hepatocytes of the treated rats

9.4 Overall Assessment of Toxicological Data

The notified chemical had a low oral and dermal toxicity in rats of LD_{50} > 5000 mg/kg and LD_{50} > 2000 mg/kg respectively. It was noted that localised erythema was present in a number of the rats in the dermal toxicity study and at this dose (2000 mg/kg) was a skin irritant. The notified chemical was not a skin irritant in studies using rabbits at a dose of 0.5g/animal (approximates to 1800 mg/kg as rabbits weighed between 2.4-3.2 kg). In both studies the article was moistened with distilled water, however in the rat study the

treatment period was 24 hours whereas in the rabbit study the test article was only applied for 4 hours. The notified chemical was not an eye irritant in rabbits.

In a 28 day repeat dose study effects were noted at a dose rate of 1000 mg/kg in male rats. These effects were limited to variations in clinical chemistry and haematology with no treatment related effects noted on histopathological and clinical assessment. The effects were generally still apparent after the recovery period of 14 days following the dosing trial.

A diverse range of genotoxic studies gave negative results for the notified chemical. In a *Salmonella typhimurium* reverse mutation assay and a micronucleus assay in the bone marrow cells of the mouse the notified chemical was not mutagenic. In a study using chinese hamster V79 cells the notified chemical did not induce chromosome aberrations at levels in excess of the controls. In a further study using rats, the notified chemical at a dose rate of 10 ml/kg did not induce DNA damage leading to repair synthesis in the hepatocytes of the treated rats.

On the basis of the available toxicological information the notified chemical would not be classified as hazardous in accordance with the *Approved Criteria for Classifying Hazardous Substances* (14).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Table 1: Biological effects of FAT 40'403

Test	Species/system	Result
96 h Acute	zebra fish	96h LC_{50} > 1000 mg/L NOEC $\geq$ 1000 mg/L
48 h Acute	*Daphnia magna*	48h LC_{50} > 1000 mg/L NOEC $\geq$ 1000 mg/L
Algal growth inhibition	*Scenedesmus subspicatus*	72h NOEC > 1000 mg/L
Inhibitory concentration	activated sludge	3h IC_{50} > 100 mg/L

The acute toxicity to zebra fish was carried out according to OECD Guideline 203, with concentrations of aqueous FAT 40'403 solutions of 562 and 1000 ppm, and a control. No abnormal responses of the fish were observed.

The acute toxicity to *D. magna* was determined in a 48 h static test according to OECD 202. Only the nominal concentration of 1000 ppm and a control was tested.

The influence of the test chemical on the growth of green algae (*S. subspicatus*) was investigated according to OECD 201. The nominal concentrations tested were 0.1, 1.0, 10.0, 100 and 1000 ppm, and a control. Concentrations of 1.0 to 100 ppm

appeared to promote algal growth in relation to the control. In the concentration of 1000 ppm, the cell density was somewhat lower than in the control until 72 hours test duration, when from this point until the end of the test (96 h) the cell density increased to 169% of the cell density of the control. It is apparent that at low concentrations the notified chemical causes growth stimulation, initially at high concentrations growth was inhibited. At high concentrations the dye would decrease light penetration in the test solutions and could thus effect the algal photosynthetic activity.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The predicted environmental concentration (PEC) has been modelled based on the maximum potential import volume of 8 tonnes per annum; three sites of operation; 200 days of operation per year (as per the notifiers figures); 95% fixation rate. The fixation rate as per tests carried out on the notified substance are far better than the 95% figure, generally up around 98 - > 99%. For a worst case scenario however, the worst fixation rate of 95% will be used.

Table 2: Predicted Environmental Concentration.

Process (dilution factor)	City paper mill	Country paper mill
Typical dye use per day	13.34 kg	13.34 kg
Quantity in backwater	0.67 kg	0.67 kg
Backwater flow rate per day	2 ML	2 ML
Dye concentration in backwater	0.34 ppm	0.34 ppm
Dye concentration after "save all" step (50% removal)	0.17 ppm	0.17 ppm
Dye concentration after clarifier step (25% removal)	0.125 ppm	0.125 ppm
Dilution factor with effluent from other mill machines	a) 1 : 3	a) 1 : 3
Dilution factor in sewage treatment plant	b) 1 : 10	b) 1 : 3
Dye concentration in receiving waters i) "save all" and clarifier steps: ii) dilution within mill:	a) + b): 4.2 ppb b) only: 12.5 ppb	a) + b): 13.9 ppb b) only: 41.7 ppb

The figures provide the PEC for an absolute worst case situation which would occur without dilution in the mill from other paper making machines, and without the addition of a flocculant during the clarifier process. The above calculation shows in

this case, in a country area's receiving waters, the PEC is 41.7 ppb, several orders of magnitude below the most sensitive aquatic toxicity result.

A second worst case PEC for the textile use of the notified chemical of 5 ppb (country mill), using similar calculations as above, but with 800 kg of chemical is used at 4 mills, each operating 50 days per year, with a fixation rate of 98% (notifiers figures), is also several orders of magnitude below the the most sensitive aquatic toxicity result.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Occupational exposure during transport and warehousing will only occur in the event of an accident. Occupational exposure is most likely to occur during repackaging or at the site where the dye formulations will be used. The majority of the notified chemical will be imported as a liquid dye formulation for dyeing paper. A minor component of the import volume (< 1 tonne/annum) will be used for textile dyeing, the formulation for this use is a as a powder albeit with antidusting agents added to it. Repackaging of both the liquid and powdered formulations may occur at the notifier's premises. This will be undertaken by staff trained in the handling of hazardous substances; exposure will be limited to approximately 1 hour/day for up to 4 days/year.

The group most exposed during textile dyeing, where the powdered formulation is used, will be the dye weighers. Exposure through both inhalational and dermal pathways may occur. Exposure of employees during paper dyeing operations will be limited due to the low concentrations used in the paper dyeing process and the liquid form of the formulation. The group of paper mill employees who are likely to receive the highest levels of exposure are those involved in connecting and disconnecting delivery/transfer hoses. Exposure will occur for approximately 0.5 hr/day for 24 days/year.

Given that no loss of the notified chemical is expected to occur from treated paper, no public exposure is expected. Some public exposure to low levels of the notified chemical may occur as a result of wearing clothing made of textiles treated with the notified chemical. However, the high molecular weight and low fat solubility of the notified chemical suggests that dermal absorption is unlikely. There is negligible risk to public safety resulting from use of the notified chemical.

As the notified chemical has both low oral and dermal toxicity in rats, is not a skin or eye irritant in rabbits, is not a skin sensitiser in guinea pigs, and has a low genotoxic potential in a range of both *in vivo* and *in vitro* tests, risk through occupational exposure will be limited. On the basis of the available toxicological information the notified chemical would not be classified as hazardous according to the criteria of Worksafe Australia (14).

13. RECOMMENDATIONS

To minimise occupational exposure to Direct Yellow 169 FAT 40'403 the following guidelines and precautions should be observed:

- When handling the dye in powdered formulations, good general and local exhaust ventilation should be provided in weighing areas. Where this is not available then the appropriate respiratory device should be selected and used in accordance with Australian Standard/ New Zealand Standard (AS/ NZS) 1715 (15) and should conform to AS/NZS 1716 (16).

- Safe practices, as should be followed when handling any chemical formulation, should be adhered to - these include:

  - minimising spills, splashes and the mobilisation of dust;

  - practising good personal hygiene; and

  - practising good housekeeping and maintenance including bunding of large spills which should be cleaned up promptly with absorbents and put into containers for disposal.

  It is expected that, in the industrial environment, protective clothing conforming to and used in accordance with Australian Standard (AS) 2919 (17) and protective footwear conforming to Australian/New Zealand Standard (AS/NZS) 2210 (18) should be worn as a matter of course; in addition it is advisable that when handling chemical formulations containing the notified chemical to wear chemical-type goggles (selected and fitted according to AS1336 (19) and meeting the requirements of AS/NZS 1337 (20)), impermeable gloves (AS 2161) (21) should be worn to protect against unforseen circumstances.

- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (22).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical 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. C-P Yen, T A Perenich, G L Baughman. *Environmental Toxicology & Chemistry*, 1991 Vol 10, pp 1009 - 1017.

2. Ullmann L, Althaus P, Th. Janiak and Vogel O, 1990. *Acute oral toxicity study with FAT 40'403/A in rats*. Study No: 273881, project on file, RCC, Research and Consulting Company AG, Itingen, Switzerland.

3. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of Chemicals*, OECD, Paris, France.

5. Draize, J. H. 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US,* **49**.

6. Ullmann L, Porricello T and Th. Janiak, 1993. *Primary skin irritation study with FAT 40'403/A in rabbits*. Study No: 273903, project on file, RCC, Research and Consulting Company AG, Itingen, Switzerland.

7. Ullmann L, Porricello T and Th. Janiak, 1993. *Primary eye irritation study with FAT 40'403/A in rabbits*. Study No: 273914, project on file, RCC, Research and Consulting Company AG, Itingen, Switzerland.

8. Ullmann L, Kröling C, Lucini P, Th. Janiak, Horstmann R 1993. *Contact hypersensitivity to FAT 40'403/A in albino guinea pigs*. Study No: 273925, project on file, RCC, Research and Consulting Company AG, Füllinsdorf, Switzerland.

9. Decker U, Ullmann L, Althaus P, Th. Janiak, Biedermann K, Luetkemeier H and Vogel O, 1993. *Subacute 28-day oral toxicity (gavage) study with FAT 40'403/A in the rat*. Study No: 273936, project on file, RCC, Research and Consulting Company AG, Itingen, Switzerland.

10. Poth, A, 1992, *Salmonella typhimurium and Escherichia coli reverse mutation assay with FAT 40'403A*. Study No: 282014, project on file, CCR, Cytotest Cell Research (Rossdorf, Germany).

11. Volkner W, 1990, *Micronucleus assay in bone marrow cells of the mouse with FAT 40'403A*. Study No: 196391, project on file, CCR, Cytotest Cell Research (Rossdorf, Germany).

12. Geleick D, 1992*, Gene mutation test with chinese hamster V79 cells in vitro*. Study No: 925002, project on file, Ciba-Geigy Ltd, Basle Switzerland.

13. Fautz, R, 1991, *In vivo/in vitro unscheduled DNA synthesis in rat hepatocytes with FAT 40'403A*. Study No: 213502, project on file, CCR, Cytotest Cell Research (Rossdorf, Germany).

14. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)], Australian Government Publishing Service, Canberra.

15. Standards Australia, Standards New Zealand, 1994. *Australian/New Zealand Standard 1715 - 1994 Selection, Use and Maintenance of Respiratory Protective Devices.* Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ., Wellington, New Zealand.

16. Standards Australia/ Standards New Zealand, 1991. *Australian/New Zealand Standard 1716 - 1991 Respiratory Protective Devices.* Standards Association of Australia Publ., Sydney, Australia.

17. Standards Australia, 1987, *Australian Standard 2919 - 1987 Industrial Clothing,* Standards Association of Australia Publ., Sydney, Australia.

18. Standards Australia, Standards New Zealand 1994, *Australian/ New Zealand Standard 2210 - 1994 Occupational Protective Footwear, Part 1: Guide to Selection, Care and Use. Part 2: Specifications,* Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.

19. Australian Standard 1336-1982, *Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, 1982.

20. Australian Standard 1337-1984. *Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, 1984.

21. Australian Standard 2161-1978. *Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)*, Standards Association of Australia Publ., Sydney, 1978.

22. National Occupational Health and Safety Commission (1994). *National Code of Practice for the Completion of a Material Safety Data Sheets*, [NOHSC:2011(1994)], AGPS, Canberra.

Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe