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June 1999

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Solartex CEL

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Solartex CEL

1. APPLICANT

Ciba Speciality Chemicals Pty Ltd of 235 Settlement Road THOMASTOWN VICTORIA 3074 has submitted a standard notification statement in support of their application for an assessment certificate for Solartex CEL

2. IDENTITY OF THE CHEMICAL

Claims were made and accepted for the identity of the notified chemical to be exempt from publication in the Full Public Report. The data items were:

chemical name;
CAS number;
molecular and structural formulae;
molecular weight;
exact import volume;
customers; and
spectral data.

The notified chemical is not considered to be hazardous based on the nature of the chemical and the data provided.

Other Names:	FAT 75'700/A UV Absorber FFU 641 versuchsprodukt 4584 contains more than 70% of the notified chemical
Trade Name:	Solartex CEL (contains 20 - 50% of notified chemical by weight)
Method of Detection and Determination:	the notified chemical can be detected by infrared (IR) ultraviolet/visible (UV/Vis) and nuclear magnetic resonance (NMR) spectra

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	the notified chemical is a beige powder with no odour
Melting Point:	not detected up to 400°C
Density:	1690 kg/m^3 at 20°C
Vapour Pressure:	1.6 x 10^{-22} kPa at 25°C (estimated)
Water Solubility:	22 400 mg/L at 20°C
Partition Co-efficient (n-octanol/water):	log P_{ow} = -2 at 20°C
Hydrolysis as a Function of pH:	$T_{1/2}$ = 170 days at pH 4.0 $T_{1/2}$ = 8.75 days at pH 7.0 $T_{1/2}$ < 24 hours at pH 9.0
Adsorption/Desorption:	concentration at 4.99 mg/L on 5 g soil sample
Surface Tension:	63.9 mN/m at 1.1 g/L at 20ºC
Fat Solubility:	3.3 mg/L in octanol
Flammability Limits:	not flammable
Autoignition Temperature:	exotherm from 251°C; autoflammable at 314°C
Explosive Properties:	not explosive
Reactivity/Stability:	non oxidising
Particle Size Distribution:	< 63 µm = 24.17% 63 < 100 µm = 15.89% 100 < 200 µm = 39.20% ≥ 200 µm = 20.74% respirable fraction (< 7 microns) is considered to be less than 4%

Comments on Physico-Chemical Properties

Tests were performed according to OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice, 1981.

The very low vapour pressure of the notified chemical was estimated based on the calculated boiling point and using the Modified Watson Correlation.

Hydrolysis (vinylation) rates at 25°C for pH 4.0 and 9.0 were calculated using the Arrhenius Equation from results that were determined at 50°C. The notified chemical is considered to be relatively stable at pH 4.0 whilst relatively unstable at pH 7.0. The hydrolysis reaction at pH 9.0 will start immediately.

The partition coefficient of the notified chemical was estimated to be log K_{OW} < -4.9 by calculation using its saturation concentration in pure solvents. However, results obtained by the preliminary partitioning experiment indicated that the expected log K_{OW} was outside the range accessible to the flask shaking method. Therefore, it was estimated to be log K_{OW} < -2.

The adsorption/desorption study revealed a very strong adsorption to soil, and there was also limited desorption from these samples. Results indicate that the notified chemical would exhibit slight to low mobility in soils (McCall, *et al*, 1981), with less mobility expected in high organic carbon soils.

The molecular structure of the free acid was used for the estimation of the dissociation behaviour. The results indicate that reaction centers 1 and 2 will completely dissociate. It is noted that the presence of sulphonic acid functionalities (reaction centers 1 and 2) which are expected to be completely dissociated under environmental conditions

The notified chemical is not expected to be surface active. By definition, a chemical has surface activity when the surface tension is less than 60 mN/m (European Economic Community (EEC), 1992). The fat solubility was not determined. However, this is expected to be low due to the low solubility of the notified chemical in octanol (3.3 mg/L).

4. PURITY OF THE CHEMICAL

Degree of Purity:	79.9%
Toxic or Hazardous Impurities:	none
Impurities (> 1%)	sodium chloride 15.8% water 3%
Additives/Adjuvants:	none

Ingredients (of Solartex CEL):

Component	*CAS No.*	*Concentration*
Versuchsprodukt 4584	confidential	20-50%
Stabilising agent	confidential	30-70%
Anti-dusting agent	confidential	< 5%
Organic acid	confidential	< 5%
Water	772-18-5	9.1%

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia but will be imported in powder form as a 20% component of Solartex CEL, and will be used to brighten and protect cellulose textiles by UV-absorption at the surface. The notified chemical enables a high UPF (Ultraviolet Protection Factor) rating to be imparted to garments and other textiles. The treated cellulose will be used in domestic textiles for apparel and sheeting, and other commercial industrial use.

It is estimated up to 1 000 kg per annum of the notified chemical will be imported in the first three years. However there is a possibility that it may exceed 1 000 kg thereafter.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported into Australia in 25 kg polyethylene lined fibre board cartons. The total import volume will be transported by road to a Ciba warehouse at Thomastown for storage prior to transportation to the customer sites. It will be used in 4 large and 8 small dyehouses largely in NSW and Victoria and to a lesser extent in Tasmania and South Australia. Dye houses may use the commercial product on about 75 days each year. The notifier estimates some re-packing might be needed for the purpose of supplying samples and/or material for mill trials. Repacking will be carried out only at Ciba Speciality Chemicals at Thomastown.

Waterside Transport and Storage
For waterside, transport and warehouse workers, there is not expected to be any exposure to the notified chemical during storage and distribution, except in the event of a spill.

Repacking
Some repackaging of the powdered form of the product containing the notified chemical may be carried out by the notifier. An anti-dusting agent is included in the final product and the repacking processes will be conducted in a booth in which air flow is drawn away from the operator at a rate which ensures capture of particulates. The notifier has also previously stated that under the conditions employed at the notifier's site, workplace air monitoring

studies have shown that levels of similar anti-dusting products in the breathing zone are undetectable. The notifier must ensure that these protective measures are in place otherwise there is the possibility for dermal, inhalational and ocular exposure to occur during repacking. A maximum of 2 workers will be involved in packing less than 100 kg of the notified chemical for 15 to 20 minutes per day for less than 10 days per year. The notifier states that repackaging workers will wear overalls, safety glasses/face shields and impermeable gloves and where sufficient ventilation is not available suitable respiratory protection.

Batching operations
Workers may be exposed to the product containing the notified chemical during the preparation of the "application solution". The process involves manual transfer of non-dusting powdered end use product from the fibre board cartons into a weighing container under local exhaust ventilation and manual transfer to a open blending vessel (vat). Inhalational, dermal and ocular exposure may occur during transfer of this product from the cartons to the weighing vessel and to the vat. The powder is then immediately wetted and dispersed using high speed stirring and pumped into a side tank from which the dilute solution is pumped through a closed-metered system, to the application machine. Potential inhalational and dermal exposure exists in the dyehouse from the UV absorber in solution during high speed stirring due to generation of aerosols and in connecting and disconnecting hoses. Eye contact would be limited to accidents. The notifier states that it is recommended that workers attached to this facility use respiratory protection as a precautionary measure to avoid inhalation, together with safety glasses, impermeable gloves and overalls.

During the fixation phase, minimal worker exposure is expected during the automatic pumping of the application solution to an automated fixing machine. Large bolts of cloth to be fixed by the notified chemical will be passed through the machine. After fixing, the cloth is washed in a continuous multi-tank system and dried. Worker exposure to the diluted notified chemical is likely to occur during equipment cleaning or repair.

There is minimal opportunity for workers to be exposed to the notified chemical during continuous fixation, as the process is largely automated. Some dermal exposure may occur when the cloth is initially threaded through the pad trough. Once fixed with the notified chemical, the cloth is washed and dried. The operator does not come into contact with the impregnated cloth (which will be wet with pad liquor) unless there is an interruption of the process.

It is estimated that average number of workers potentially exposed per large dyehouse is 12, eight of these workers will be handling the notified chemical in solution in open vats or in closed systems. The notifier estimates workers potentially exposed in Australia, is approximately 72 but may increase to 144.

Some exposure may also occur during cleaning processes.

Workers may also come into contact with dry fabrics fixed by the notified chemical during packaging or manufacturing.

The notifier has included an estimate of inhalation exposure for a batch weigher in a large dyehouse using the notified chemical. In the calculation it is estimated that workers would weigh 20 kg of the dye per day over five weighings, during 0.5 h of the working day. The air borne concentration of dye is estimated at 3.5544 mg/m^3. Assuming a breathing rate of 1.25 m^3/hr, the above figures translate to a daily inhalation exposure of 0.4443 mg, or 0.0063 mg/kg bw/day for an average 70 kg worker.

7. PUBLIC EXPOSURE

Public exposure to the notified chemical will occur primarily through contact with clothes made from fabrics treated with the notified chemical to reduce UV penetration. The number of people potentially exposed will be limited only by the commercial success of the product. As notified chemical is a reactive dye with a high fixation rate and is water soluble when not fixed to the cloth, the level of unbound material in processed cloth is likely to be negligible despite prolonged direct contact with treated cloth.

The notified chemical is provided to dyehouses as a non dusting powder and applied to the cloth by a wet process. Dissemination of the notified chemical beyond the dyehouse environment, other than as finished fabric, will be limited predominantly to that contained in process water discharged to the sewer system. Public exposure to the notified chemical from its industrial use will therefore be negligible.

In the event of a transport accident the dispersion of notified chemical will be limited to that carried from the spill site as dust or in solution in wash water or rain. The other constituents of Solartex CEL (stabilising agent, 30-70%) are of low toxicological hazard and will not pose a fire hazard. Potential exposure from this source is likely to be low.

8. ENVIRONMENTAL EXPOSURE

Release

The bulk of the product will become chemically fixed to cellulose textiles, and in this state is not expected to impact on the environment. The substance is a reactive compound that binds covalently to the cotton fibre upon application. The result of fastness performance tests shows that a high fastness rating should be achieved (85-90%).

The major environmental exposure to the substance will come from the effluent discharge of dyehouses and waste water treatment systems. This release will consist mainly of the

hydrolysed derivative due to the alkaline nature of these systems (Ecological and Toxicological Association of the Dyestuffs Manufacturing Industry, 1991). Other releases will be limited to traces remaining from repacking operations and clean-up of spills, and from trace residues in empty packaging (estimated by *Environment Australia* at 0.1%, based on previous similar notifications by the notifier).

All clean up of spills and disposal of empty packaging should be carried out according to the instructions given in the Material Safety Data Sheet (MSDS).

Fate

The substance, including the hydrolysed derivative, normally released in water as effluent from the dyehouse is expected to be the major environmental exposure. The substance may either partition to sediment or stay in the aqueous compartment. Hobbs (Hobbs SJ, 1988) reports that reactive dyes have been found not to absorb to sludge in model systems. However, the adsorption/desorption results show that the chemical will undergo strong adsorption to soil/sediment, exhibiting only slight to low mobility. This indicates that the substance should be significantly removed through adsorption to sludge in the waste water treatment process. Any substance that binds to the sludge will be disposed of through incineration or landfill.

Residues that persist after sewage treatment from both city and country waste water treatment systems will enter aquatic environments in solution. Due to the alkaline nature of the dyehouse and waste water treatment systems, the majority of substance entering the environment will be in the hydrolysed form.

Incineration is the preferred option of disposal because of the high water solubility and potential mobility of the material. Incineration of the dye will produce oxides of carbon, nitrogen and sulfur, together with sodium salts in the ash with a small amount of hydrogen chloride. Disposal of the substance to landfill (at a secured site) is not recommended by the notifier. Empty product packaging should contain minimal residues of the notified chemical and will be disposed of as waste, presumably to a trade waste landfill site. The low mobility of the notified chemical indicates that it should not leach to groundwater.

No biochemical oxygen demand (0 mg O_2/L) was measured for the substance in the two flasks, when exposed to micro-organisms from a domestic sewage treatment plant over a period of 28 days. Therefore, the notified chemical was determined to be non-biodegradable (0%) according to the OECD Test Guideline 301F (Manometric Respirometry Test). No inhibition on the activity of the bacteria was observed in this test, which is consistent with the findings of the Activated Sludge - Respiration Inhibition Test (see *Environmental Effects* Section below).

However, the notified chemical was found to be inherently biodegradable over a 28-day exposure period when exposed to micro-organisms from a domestic waste water treatment plant, according to the OECD Test Guideline 302B (Zahn-Wellens/ EMPA Test). Expressed as percentage DOC removal, average biodegradation was 21% after 3 days, 44% after 10 days, 57% after 14 days, 70% after 21 days and 78% after 28 days.

Coupled to this biodegradability, the potential for bioaccumulation is also low due to the low calculated partition coefficient (log K_{OW} = -2), very high water solubility of the substance (22 g/L) and predicted low fat solubility (3.3 mg/L in octanol). Hydrophilic dyes with log K_{OW} < 3 have also been shown not to bioaccumulate (Yen CP, 1991).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of FAT 75'700/A (contains approximately 70% of the notified chemical)

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	> 2 000 mg/kg	(Arcelin G, 1996)
acute dermal toxicity	rat	> 2 000 mg/kg	(Schmid H, 1996)
skin irritation	rabbit	non-irritant	(Braun WH, 1996)
eye irritation	rabbit	slight irritant	(Braun WH, 1996))
skin sensitisation	guinea pig	non-sensitiser	(Acrelin G, 1996))

9.1.1 Oral Toxicity (Arcelin G, 1996)

Species/strain:	rat/Han Ibm: Wist
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	a single dose of 2 000 mg/kg administered by gavage; vehicle was bi-distilled water
Clinical observations:	no clinical signs of toxicity were observed during the observation period
Mortality:	none
Morphological findings:	no abnormalities detected
Test method:	OECD guidelines (Organisation for Economic Co-

	operation and Development, 1995-1996)
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Schmid H, 1996))

Species/strain:	rat/ Han Ibm: Wist
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	a dose of 2 000 mg/kg was applied to an intact skin site and covered with semi-occlusive dressing; after 24 hours the dressing and residual test material were removed
Clinical observations:	none
Mortality:	none
Morphological findings:	no abnormalities detected
Test method:	OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity (ref)

Not performed. The notifier states that the powdered product containing the notified chemical also contain anti-dusting agents, which will reduce the potential for exposure by this route.

9.1.4 Skin Irritation (Braun WH, 1996)

Species/strain:	rabbit/New Zealand White

Number/sex of animals:	one male and two femles
Observation period:	24, 48 and 72 hours after dose administration
Method of administration:	a dose of 0.5g was applied to 6 cm^2 of an intact skin site; the site was covered with semi-occlusive dressing; after 4 hours the dressing and the residual test material were removed
Test method:	similar to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	the notified chemical was non-irritating to the skin of rabbits

9.1.5 Eye Irritation (Braun WH, 1996)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	one male and two females
Observation period:	24, 48 and 72 hours after dose administration
Method of administration:	100 mg of the test substance was placed in the conjunctival sac of one eye of each rabbit whilst the contralateral eye of each rabbit served as the control

Draize scores (Draize JH, 1959) of unirrigated eyes:

	Time after instillation														
Animal	***1 hour***			***1 days***			***2 days***			***3 days***			***4 days***		
Cornea															
1	0[1]			0			0			0			-		
2	0			0			0			0			-		
3	0			0			0			0			-		
Iris															
1	0			0			0			0			-		
2	0			0			0			0			-		
3	0			0			0			0			-		
Conjunctiva	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***
1	1	1	+	1	0	0	0	0	0	0	0	0	-	-	-
2	2	2	±	1	0	0	1	0	0	0	0	0	-	-	-
3	2	1	±	1	0	0	1	0	0	0	0	0	-	-	-

[1] see Attachment 1 for Draize scales
[r] redness [c] chemosis [d] discharge

Unirrigated eyes:	conjunctival irritation (scores 1 to 2) was observed in all animals at one hour post-treatment, which persisted in 2 animals (score 1) up to 48 hours; all eyes appeared normal after 72 hours
Test method:	similar to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	the notified chemical was a slight eye irritant in rabbits

9.1.6 Skin Sensitisation (Acrelin G, 1996))

Species/strain:	guinea pig/Himalayan spotted
Number of animals:	20 females (test group) 10 females (control group)

Induction procedure:

Day 1:
test group
3 pairs of intradermal injections:
0.1 mL of 1:1 (v/v) mixture of Freund's Complete Adjuvant (FCA) and physiological saline
0.1 mL of 5% concentration of test substance in bi-distilled water

0.1 mL of 5% concentration of test material in FCA:: physiological saline (1:1 (v/v))

control group
0.1 mL of 1:1(v/v) mixture of FCA and physiological saline

0.1 mL of bi-distilled water

0.1 mL 1:1 (w/w) mixture of bi-distilled water and a 1:1 (v/v) mixture of FCA and physiological saline

Day 7
the scapular area of the control and test groups were prepared with 10% sodium-lauryl-sulphate (SLS) in paraffin perliquidum (10% concentration of SLS enhances sensitisation by provoking a mild inflammatory reaction)

Day 8
occluded application of filter paper soaked in test substance (50% in *vaselinum album*) for 48 hours

Challenge procedure:

Day 22:
occluded application of filter paper soaked in test material (50% in *vaselinum album*) for 24 hours

Challenge outcome:

Challenge concentration	***Test animals***		***Control animals***	
	24 hours*	***48 hours****	***24 hours***	***48 hours***
50%	0/20	0/20	0/10	0/10

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

Test method:	similar to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	the notified chemical was not a skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity (Allard G, 1996)

Species/strain:	rat/Han Ibm: Wist
Number/sex of animals:	30/sex; control and high dose groups: 10/sex low and mid dose groups: 5/sex
Method of administration:	gavage; vehicle bi-distilled water
Dose/Study duration::	dose levels were based on the results of 5-day range finding study in rats (Allard G, 1996) test substance administered daily for a total of 28 days: control: 0 mg/kg/day low dose: 50 mg/kg/day mid dose 200 mg/kg/day high dose 1 000 mg/kg/day all animals were sacrificed at the end of the treatment period, with the exception of 10 animals from control and high dose groups, which were maintained for an additional 2 week recovery period before sacrifice
Clinical observations:	no clinical signs noted in any dose group
Clinical chemistry/Haematology:	treatment-related effects: the only change noted was a slight decrease in glucose level in males ($p < 0.05$) an slight increase in uric acid level in both sexes ($p < 0.01$) of the high dose group at termination of treatment this was considered related to treatment but adaptive in nature; the changes were reversible
Urinalysis:	no treatment related effects

Histopathology:	no treatment related changes
Organ weights:	higher (by 17%) but statistically significant ($p < 0.05$) kidney to brain weight ratios were observed in females at 50 and 1 000 mg/kg/day dose groups; lack of dose-relationship and histopathological correlates suggest these findings were unrelated to treatment
Test method:	similar to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	the notified chemical did not exhibit any significant organ toxicity in males or females the no-observed effect level (NOEL) for this 28-day rat study of the notified chemical is 200 mg/kg/day, based on treatment related biochemical changes at the highest dose.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Wollny H, 1996)

Strains:	*Salmonella typhimurium* TA 1537, TA 1535, TA 100, TA 98 and *Escherichia coli* strains WP2 *and* WP2*uvrA*
Metabolic activation system:	liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Concentration range:	the assay was performed in two independent experiments with or without metabolic activation; the test substance and the controls were tested in triplicate at concentrations of 33.3, 100.0, 333.3, 1 000.0, 2 500.0 and 5 000.0 µg/plate
Test method:	similar to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Comment:	no relevant toxic effects, evident as a reduction in the number of revertants, occurred in the test groups with or without metabolic activation in all

	strains used; there were no significant increases in revertant colony numbers at any dose level, with or without metabolic activation
Result:	the notified chemical is not considered to be mutagenic in bacteria

9.3.2 Chromosome Aberration Assay in Chinese Hamster V79 Cells (Czich A, 1996)

Cells:	Chinese Hamster V79 Cells
Metabolic activation system:	liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Doses:	*without metabolic activation* Experiment 1 30, 50 and 1 000 µg/mL treatment time = 18 hours, 100 µg/mL treatment time = 28 hours Experiment 2 10, 50, and 250 µg/mL treatment time = 18 hours, 150 µg/mL treatment time = 28 hours *with metabolic activation* Experiment 1 50, 300, 500 and 5000 µg/mL treatment time = 18 hours 500 and 5 000 µg/mL treatment time = 28 hours Experiment 2 30, 300, 500 and 5 000 µg/mL treatment time = 18 hours 500 and 5 000 µg/mL treatment time = 28 hours
Test method:	similar to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996ref)
Test method:	similar to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Comments:	Toxicity in the pre-test toxicity evaluation without S9, substantial toxicity was evident at ≥ 300 µg/mL; in the presence of S9, no toxicity was observed up to

1 000 µg/mL

in experiment 2 without metabolic activation at the 28 hour harvest time and at an evaluation concentration of 150 µg/mL, toxic effects were evident by a reduction of the mitotic index (50.8% compared with solvent control); in experiment 1, at both harvest times in the presence of metabolic activation, distinct reductions in mitotic indices (55.6% and 37.3%) were observed, but were not reproduced in experiment 2

Aberrations
summary of the findings is presented in Table 1

in experiment 1, at 5 000 µg/mL in the presence of metabolic activation at a harvest time of 28 hours, a statistically significant increase in cells with structural chromosomal aberrations was observed, but this was not reproduced in experiment 2

in experiment 2, at concentrations of 150 µg/mL without metabolic activation (28 hour harvest time) and 5 000 µg/mL with metabolic activation (18 hour harvest time) statistically significant increase in cells with structural chromosomal aberrations were observed; the study authors pointed out that frequencies of 2% aberrant cells exclusive of gaps were within the laboratory's historical negative control range (0 – 4%); therefore they considered the results to be of no biological relevance; it is also to be noted that the test substance at 5 000 µg/mL precipitated in the culture medium.

In both experiments, no biologically relevant increase in the frequencies of polyploid metaphases were observed after treatment with the test substance compared to the frequencies of the controls

Result:

*the study authors concluded notified chemical was non mutagenic under the conditions of this chromosomal aberration test

*NICNAS concluded that although the current data did not support classification of the notified

chemical as clastogenic, the variability of the results raised doubts about the validity of the study. The data with metabolic activation was variable. The reasons for this variability needed to be addressed by changing the experimental design or delivery of the test compound in the test system. Alternatively NICNAS recommended another mammalian genotoxicity could be conducted. The notifier agreed to conduct a test according to a new protocol devised with input from NICNAS, to clarify the above test data.

Table 1
Summary of Results of the Chromosome Aberration Study (Czich A, 1996)

Exp	*Fixation Interval*	*S9 Mix*	*Concentration µg/mL*	*Polyploid Cells %*	*Mitotic Index in % of Control*	*Aberrant Cells %*		
						incl gaps	*excl gaps*	**exch*
1	18 h	-	30	4.0	92.3	0.0	0.0	0.0
1	18 h	-	50	3.0	90.6	0.5	0.5	0.0
1	18 h	-	100	3.5	92.0	5.5	2.0	0.5
11	18 h	-	10	4.0	100.3	3.0	2.0	0.5
11	18 h	-	50	4.0	87.7	1.0	0.0	0.0
11	18 h	-	100	4.5	86.5	4.5	3.0	0.0
1	28 h	-	100	2.5	93.0	2.0	1.5	0.5
11	28 h	-	150	5.0	50.8	3.0	2.0**	0.5
1	18 h	+	50	2.0	71.8	3.5	1.5	0.0
1	18 h	+	300	3.0	80.1	2.5	0.5	0.0
1	18 h	+	500	2.0	55.6	2.0	0.0	0.0
1	18 h	+	5000#	2.5	62.7	4.0	1.5	1.0
11	18 h	+	50	5.0	93.2	2.0	1.5	0.5
11	18 h	+	300	3.5	87.3	1.5	1.0	0.0
11	18 h	+	500	4.0	84.4	1.0	0.5	0.5
11	18 h	+	5000#	4.5	83.4	3.5	2.0**	0.5
1	28 h	+	500	3.0	98.8	0.5	0.5	0.0
1	28 h	+	5000#	3.5	37.3	8.5	7.5**	2.0
11	28 h	+	500	4.5	108.8	0.5	0.0	0.0
11	28 h	+	5000#	3.0	93.5	1.0	0.0	0.0

*inclusive cells carrying exchanges
**aberration frequency statistically significant higher than corresponding solvent control values
aberrant cells in the negative (solvent) control groups: 0.0% - 1.0%
aberrant cells in the positive control groups: 10.5% - 19.0%
#precipitation occured

9.3.3 Chromosomal Aberration Assay in Chinese Hamster V79 Cells (Additional Study Requested by NICNAS) (Czich A, 1998)

The variability of the data with metabolic activation in the previous study raised doubts about the validity of the experimental design. In order to address the reasons for this variability a further study was undertaken solely with metabolic activation at dose levels less than 5 000 µg/mL.

Cells:	Chinese Hamster V79 Cells
Metabolic activation system:	liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Doses:	*with metabolic activtion* Experiment 1 100, 300 500 and 1 000 µg/mL, treatment time = 18 hours 500 and 1 000 µg/mL, treatment time = 28 hours Experiment 2 100, 300, 500 and 1 000 µg/mL, treatment time = 18 hours 500 and 1 000 µg/mL, treatment time = 28 hours
Comments:	in both experiments precipitation of the test material in culture medium was observed at 1 000 µg/mL; this means that the aberration frequencies observed in study 9.3.2 at a concentration of 5 000 µg/mL at both 18 and 28 hours could not be confirmed due to precipitation of the test substance in the culture medium in experiment 1 at a concentration of 500 µg/mL there was a significant increase in aberrant cells excluding gaps (4%) at 18 hour treatment time; the same experiment also showed a dose response relationship (although only the result at 500 µg/mL was statistically significant); however, the above result was not reproducible in experiment 2 under the same conditions
Result:	under the conditions of this chromosomal aberration test, notified chemical is not clastogenic; however the potential for weak clastogenicity cannot be excluded

Table 2
*Summary of Results of the Chromosome Aberration Study (***Czich A, 1998***)*

Exp	*Fixation Interval*	*S9 Mix*	*Concentration μg/mL*	*Polyploid Cells %*	*Mitotic Index in % of Control**	*Aberrant Cells %*		
						incl gaps	*excl gap**	*exch*
1	18 h	+	solvent control	3.1	100.0	1.0	1.0	0.0
1	18 h	+	positive control	3.3	51.4	22.0	21.5	10.0
1	18 h	+	100	3.8	93.8	4.5	2.0	0.0
1	18 h	+	300	2.8	71.7	5.0	3.5	2.0
1	18 h	+	500	3.6	77.6	7.0	4.0[s]	1.0
1	18 h	+	1000[p]	4.1	71.7	3.5	2.5	1.0
11	18 h	+	solvent control	5.3	100.0	3.0	1.0	0.5
11	18 h	-	positive control	3.2	98.5	30.5	30.0	10.0
11	18 h	+	100	3.2	108.0	3.5	3.0	0.0
11	18 h	+	300	4.5	93.1	2.5	1.5	0.0
11	18 h	+	500	5.2	96.7	2.0	1.0	0.0
11	18 h	+	1000[p]	2.8	102.5	1.0	1.0	0.5
1	28 h	+	solvent control	3.7	100.0	3.5	1.5	0.5
1	28 h	+	500	2.6	76.9	2.0	1.5	0.5
1	28 h	+	1000[p]	4.4	97.8	2.0	1.0	0.0
11	28 h	+	solvent control	4.5	100.0	3.0	3.0	1.0
11	28 h	+	500	4.1	107.9	4.0	3.5	0.5
11	28 h	+	1000[p]	3.6	109.2	1.5	1.0	0.0

*inclusive cells carrying exchanges
[s] aberration frequency statistically significant higher than corresponding solvent control values
[p] precipitation occurred

9.4 Overall Assessment of Toxicological Data

The notified chemical had very low acute oral toxicity and low acute dermal toxicity (LD_{50} > 2 000 mg/kg for both studies) in rats. The notified chemical was a slight eye irritant in rabbits, a non-irritant and non-sensitiser to the skin of rabbits and guinea pigs, respectively.

In a 28-day repeat oral dose study, the notified chemical exhibited no signs of oral toxicity in either males or females. A NOEL of 200 mg/kg/day for rats was determined.

The notified chemical was not mutagenic *in vitro* in studies using bacteria. While the majority of the data at high doses was negative in *in vitro* Chromosomal Aberration Assays in Chinese Hamster V79 cells, the possibility of weak clastogenic activity cannot be excluded.

The notified chemical could not be determined to be a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a), based on the data submitted. The genotoxic studies are insufficient to enable a health effects classification for genotoxicity.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out in accordance with OECD Test Methods.

Test	Species	Results (Nominal)
Acute Toxicity 96 hours Semi-static[1] OECD TG 203	Rainbow trout (*Oncorhynchus mykiss*)	LC_{50} > 200 mg/L NOEC = 91 mg/L
Acute Immobilisation 48 hours Static[2] OECD TG 202	Water Flea (*Daphnia magna*)	EC_{50} > 220 mg/L NOEC = 100 mg/L
Growth Inhibition 72 hours Static[3] OECD TG 201	Algae (*Scenedesmus subspicatus*)	$E_{(b\ \&\ \mu)}C_{50}$ > 200 mg/L NOEC > 200 mg/L
Respiration Inhibition 30 minutes Static[4] OECD TG 209	Aerobic Waste Water Bacteria	EC_{50} > 100 mg/L NOEC = 32 mg/L

1. Daily test medium renewal, nominal concentrations of 9, 19, 41, 91 & 200 mg/L.
2. Nominal test concentrations of 4.3, 9.4, 21, 45, 100 & 220 mg/L.
3. Nominal test concentrations of 9, 19, 41, 91 & 200 mg/L.
4. Nominal test concentrations of 3.2, 10, 32, 50 & 100 mg/L.

Testing to determine the actual concentration of the notified chemical in the test media detected that the main component degraded significantly into a defined reaction product. It is assumed that the reaction product is the hydrolysis product of the notified chemical. However, if the quantification is based on the sum of the main component and the degradation product, the mean measured test substance concentration varied from 100 to 101% of nominal values for the fish test, 101 to 103% of nominal values for the water flea test and 84 to 100% of nominal values for the algal test.

The ecotoxicity data for the notified chemical suggest that it is practically non-toxic to fish, water invertebrates and algae (both growth and biomass).

The respiration rate of aerobic waste water bacteria was not inhibited (-8.1 to -0.8%) up to a test concentration of 32 mg/L. However, slight inhibition of the respiration rate was determined when bacteria were exposed to the next highest test concentrations of 50 and 100 mg/L (5.1% and 6.8%, respectively). The results indicate that the notified chemical is

practically non-toxic to aerobic bacteria from a domestic waste water treatment plant after a thirty minute treatment time.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical, when fixed to the cellulose fibre, is rated as negligible.

The notifier has specified that a limited number of dyehouses (approximately 12) in city and country areas will be using the product containing the notified chemical. The environmental hazard has been determined for two dyehouses located in two general locations, metropolitan and country. The Predicted Environmental Concentration (PEC) is estimated in Table 3.

These calculations assume that none of the substance is removed during treatment of the different waste effluents and represent the worst case scenario for dyehouses. The "typical use of product expected per day" amount was supplied by the notifier.

Table 3: Predicted Environmental Concentration (PEC)

Calculation Factor	City Dyehouse	Country Dyehouse
Typical use of product expected per day	20.0 kg	20.0 kg
Amount of Notified Chemical (at 20%)	4.0 kg	4.0 kg
Conc. in wastewater (fixation rate 85%)	0.6 kg	0.6 kg
Quantity of water used incl. wash-off water (100 L/k)	250 000 L	200 000 L
Effluent conc. in product-specific wash-water	2.4 mg/L	3.0 mg/L
Dilution factor in dyehouse by other wash-waters	1:10 (2.5 ML/day effluent)	1:10 (2 ML/day effluent)
Influent concentration	0.24 mg/L	0.3 mg/L
Dilution factor in sewage treatment plant[1]	1:100 (250 ML/day)	1:3 (5-6 ML/day)
Conc. balance in effluent from sewage treatment plant	2.4 µg/L	0.1 mg/L
Dilution factor in receiving waters	1:0 (ocean)	1:2 (river)
PEC in receiving waters	0.24 µg/L (0.24 ppb)	50 µg/L (50 ppb)
Safety factor for exposure to most sensitive aquatic organism, bacteria[2] (NOEC of 32 mg/L)	> 130 000	640

1. The dilution at a rural town could reasonably be expected to be about 5-6 ML/day, while for a major city, say Sydney, it would be between 150-500 ML/day.
2. The respiration rate of aerobic waste water bacteria was not inhibited up to a test concentration of 32 mg/L. Slight inhibition was noted at the next highest test concentration tested of 50 mg/L

These calculations show that the exposure to fish, daphnia, algae and waste water treatment bacteria is at levels unlikely to cause any significant effect. At higher release rates, there is still unlikely to be any significant effect on these species. Once in the aquatic environment, the chemical is expected to swiftly dilute to undetectable concentrations, and undergo biotic and abiotic degradation.

The only other source of environmental contamination is from accidental spills and disposal of packaging. The information contained in the MSDS is adequate to enable those disposing of the chemical to limit the environmental exposure and therefore limit the environmental effects.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical had very low acute oral toxicity and low acute dermal toxicity (LD_{50} > 2 000 mg/kg) for both studies in rats. The notified chemical was a slight eye irritant in rabbits and a non-irritant and non-sensitiser to skin of rabbit and guinea pigs, respectively. In a 28-day repeat oral dose study, the notified chemical exhibited no signs of oral toxicity in either male or female rats. A NOEL of 200 mg/kg/day was determined. The notified chemical was not mutagenic in bacteria, while the majority of the data at high doses was negative in *in vitro* Chromosomal Aberration Assays in Chinese Hamster V79 cells, the possibility of weak clastogenic activity cannot be excluded. Based on the data submitted the notified chemical could not be determined to be a hazardous substance under the NOHSC *Approved Criteria for Classifying Hazardous Substances.*

Occupational Health and Safety
During the importation and transportation of the notified chemical, there is unlikely to be any worker exposure, except in the event of a spill. Exposure after a spill would be controlled by use of the recommended practices for spillage clean up given in the MSDS supplied by the notifier.

Some repackaging of the powdered form of the product containing the notified chemical may occur. Since the product contains an antidusting agent and the process is conducted in an air flow booth dermal, inhalational and ocular exposure to the notified chemical is considered to be minimal. However, the notifier must ensure that these protective engineering controls are in place, especially the maintenance of air flow within the booth to capture particulates.

Exposure may occur to the notified chemical during batching operations especially during preparation of the "application solution", high speed stirring, (which may generate aerosols) and when connecting and disconnecting hoses. There is potential for dermal, ocular contact and inhalational exposure to the dust form of the notified chemical, during manual transfer from fibre board cartons into weighing containers and thereafter to open vats. Should dermal, ocular contact or inhalation exposure occur, the notified chemical is unlikely to cause short term systemic toxicity. However, it may cause slight eye irritation. Of particular concern would be upper respiratory tract irritation, given that approximately 80% of the particle size of the notified chemical is within the inspirable range, that is less than 180 µm. Therefore respiratory and ocular exposure should be controlled and workers must be attired with safety glasses, gloves, respiratory protection and overalls as stipulated under Recommendations (see section 13).

General ventilation in the batching area, local exhaust ventilation over the weighing area and the anti-dusting nature of the product should be sufficient to control exposure to the notified chemical.

The notifier states that the notifier has no control over the education and training of workers on safe use of dust products and preventive controls in dye houses. Some safe handling

instructions for the notified chemical are provided on the MSDS and dissemination of this information will be facilitated by the supply of a comprehensive MSDS. This, in combination with engineering controls, a predominantly closed system and use of personal protective equipment will control exposure to the notified chemical and consequently any adverse health effects

An air borne exposure study was provided based on the ETAD/USEPA/ATMI model. The study covered workers attached to a major dye house using 300 kg/year or a minor dye house using 50 kg/year of the notified chemical. Based on an application rate of 1% of the weight of cellulose and consumption of 4 kg of the notified chemical, five times per day, approximately 5 batches of 400 kg of cellulose would be processed in a major dye house. This would result in approximately 0.0063 mg/kg/bw/day for daily exposure for a batch worker of average weight 70 kg. When compared with the oral subacute NOEL of 200 mg/kg/day and assuming 100 % inhalation absorption, this results in a very high margin of exposure. It should be noted however that the exposure is inhalation only, and assumes no other inhalation exposure occurs outside the weighing process. In addition, the model does not account for any dermal exposure or absorption. Finally, the NOEL is derived from a subacute study, which is not designed to test any long term effects of the chemical. This is of relevance because the possibility of genotoxic effects has not been excluded.

The notified chemical has an average particle size in the inspirable range. To avoid adverse health effects of high concentration of dust in the workplace, good hygiene practices should be adopted to minimise airborne dust levels. Exposure to the dust in the workplace should be controlled below the NOHSC exposure standard for dusts, not otherwise classified, 10 mg/m^3 TWA (measures as inspirable fraction) (National Occupational Health and Safety Commission, 1995). Employers are responsible for ensuring the NOHSC exposure standard is not exceeded. It is recommended that MSDS and labels for the notified chemical carry safety phrases – avoid breathing dust.

It should be noted that the potential for dust explosion exists when handling the notified chemical in the powdered form. The notifiers MSDS provides advice on safe storage and handling.

Minimal exposure to the notified chemical may occur during continuous fixation and cleaning processes and workers must be attired with gloves and overalls.

The notified chemical is a reactive dye which binds covalently to the cellulose fibres of treated fabrics. Although contact with the notified chemical over substantial areas of the body will occur in people wearing clothes made from fabric treated with the notified chemical, exposure will occur only to any residual unbound material. Evidence of a high fixation rate has been provided and as the notified chemical is water soluble (22 g/L), the level of unbound residual material in the finished fabric is likely to be negligible and will be reduced during normal washing of the clothes. The notified chemical has low fat solubility (3.3 mg/L octanol), has high molecular weight (816) and calculated log P_{ow} of less than –2 at 20°C. As these characteristics are not consistent with ready dermal penetrability, systemic exposure following topical contact with the notified chemical is likely to be negligible. As the

anticipated exposure is low and the notified chemical does not pose a significant acute toxicological hazard, the risk to the public from the use of the notified chemical in the proposed manner is negligible.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical the following guidelines and precautions should be observed:

- Safety glasses should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992));
- Respiratory protection should be selected and fitted in accordance with AS/NZS 1715 (Standards Australia/Standards New Zealand 1994a) to comply with AS/NZS 1716 (Standard Australia/Standards New Zealand 1994b);
- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990);
- Impermeable gloves or mittens should conform to AS 2161 (Standards Australia, 1998);
- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand 1994c);
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

Since the notified chemical is of respirable particle size, the MSDS and labels should carry the safety phrase – avoid breathing dust.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical and product were provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994b).

These MSDS were 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.

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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