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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Chemical in Pergasol Yellow 2801

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Chemical in Pergasol Yellow 2801

1. APPLICANT

Ciba Specialty Chemicals Pty Ltd of 235 Settlement Rd THOMASTOWN VIC 3074 has submitted a standard notification statement in support of their application for an assessment certificate for Chemical in Pergasol Yellow F-6G.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, spectral data, purity, details of exact import volume, exact concentration in formulations and details of customers have been exempted from publication in the Full Public Report and the Summary Report.

Other Names:	Pergasol Yellow 2801 Super Yellow 5GL
Marketing Name:	Pergasol Yellow F-6G (commercial product)
Method of Detection and Determination:	ultraviolet/visible (UV/VIS), infrared (IR) and nuclear magnetic resonance (NMR) spectroscopy
Spectral Data:	UV/VIS, IR and NMR spectra were provided

Comments on Chemical Identity

Reports with ^{1}H NMR and IR spectrometric data were submitted for the identification of the notified substance.

HPLC analysis determined the composition of the notified substance, including the main component and minor impurity by-products.

3. PHYSICAL AND CHEMICAL PROPERTIES

All of the physicochemical properties were measured using the notified chemical itself.

Appearance at 20°C and 101.3 kPa:	reddish-yellow powder, notified chemical; yellow liquid, commercial product, Pergasol Yellow 2801
Melting Point:	220-264°C

Specific Gravity:	1.31 at 25°C
Vapour Pressure:	$< 10^{-23}$ kPa at 25°C
Water Solubility:	1 050 mg/L at 18°C (pH 8.3)
Partition Co-efficient (n-octanol/water):	log P_{ow}< -2.6 at 21°C
Hydrolysis as a Function of pH:	Half-life > 1 year at 25°C at pH 9 and pH 7
Adsorption/Desorption:	not determined (see comments below)
Dissociation Constant:	not determined (see comments below)
Surface tension:	68 mN at 25.6° C and 90% saturated
Particle Size:	< 10 µm ~ 48% 10 – 30 µm ~ 35% 30 – 63 µm ~ 17% > 63 µm 0% mass median diameter: 12.5 µm
Flash Point:	not determined (solid substance)
Flammability Limits:	not flammable
Autoignition Temperature:	> 238°C
Explosive Properties:	not explosive
Reactivity/Stability:	not an oxidising agent

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines (European Commission 1992) at facilities complying with OECD Principles of Good Laboratory Practice.

The maximum water solubility of the notified chemical was 1 050 mg/L at 18°C using the flask method (OECD TG 105).

The notified chemical was found to be hydrolytically stable at 25°C when tested at pH 7.0-pH 9.0 (OECD TG 111). However, the notifier did not perform the hydrolysis test at pH 4.0 due to the low solubility of the notified chemical at that pH.

The partition coefficient log P_{OW} of the chemical between n-octanol and water was estimated to be < -2.6 at 21°C by the flask shaking method (OECD TG 107).
Adsorption/desorption data were not provided. The notifier has indicated that this test was considered unnecessary given the notified chemical's high fixation rate (97%) and

subsequent low environmental release. The chemical has a low partition coefficient (< -2.6), but it would be expected to bind strongly to silicates in soils since it contains quaternary nitrogen (Nabholz et al., 1993) and oxygen atom substituents, however, it is not expected to bind to organic matter (Dragun, 1988).

A dissociation constant was not provided. The notifier has indicated that the notified chemical is soluble in water and is expected to dissociate. It is noted that it would be difficult to estimate an overall dissociation constant, K, for the notified chemical since it contains secondary, tertiary and quaternary amine groups and hydroxyl groups.

4. PURITY OF THE CHEMICAL

Degree of Purity: Very high

Hazardous Impurities: none

Non-hazardous Impurities (> 1% by weight): unidentified by-products at < 1%

Additives/Adjuvants: None for the notified chemical;
Commercial, Pergasol Yellow F-6G product, contains:

Chemical name:	formic acid
Synonyms:	methanoic acid
CAS No.:	64-18-6
Weight percentage:	20%
Toxic properties:	Corrosive; Causes Burns (R34)*

Chemical name:	acetic acid
Synonyms:	ethanoic acid; glacial acetic acid
CAS No.:	64-19-7
Weight percentage:	25%
Toxic properties:	Corrosive (C); Causes Burns (R34)*

Chemical name:	water
CAS No.:	7732-18-5
Weight percentage:	20-50%

**NOHSC List of Designated Hazardous Substances* (NOHSC, 1999)

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia, but will be imported as an ingredient of Pergasol Yellow F-6G (10-30%) ready-to-use in 800 kg polyethylene intermediate bulk containers enclosed by an outer, protective structure. Some minor repackaging may be involved.
The notifier indicates that Pergasol Yellow F-6G will be used at one paper mill to colour moulded fibre products (egg carton production) by the continuous dyeing method. The process uses 690-1 840 g notified chemical per tonne of paper. It is also indicated that three mills may be involved in the future of printing and colouring writing paper. Less than 10

tonnes per annum of the notified chemical will be imported in the first five years.

During 1996 and 1999, the notified chemical was in use in Australia under a commercial evaluation permit granted under section 21G of the Act.

6. OCCUPATIONAL EXPOSURE

Transport and Storage
The commercial product containing the notified chemical is transported by road from the dock to the notifier's warehouse, for subsequent delivery to the customer site. Waterside, transport and storage workers would only be exposed to the notified chemical in the event of a spill from a transport or handling incident. The nature of the packaging used for transport minimises the likelihood of release or loss of the chemical in incidents. Three to seven workers could be involved in clean-up tasks.

Product Repackaging: 15-20 min/day; 10 days/year
Occasionally repackaging, for the purpose of supplying samples or material for paper mill trials or where required, is carried out at the notifier's warehouse, where it is stated facilities for safe handling of hazardous substances are used. It is estimated that a maximum of two operators will be involved in repackaging less than 200 L of product each year. Operators may receive dermal and eye contact with Pergasol Yellow F-6G from drips and spills as hoses are connected/disconnected. The notifier indicates these workers are required to wear long PVC coated gloves, PVC aprons, overalls, safety shoes and face shield.

Paper Mill
Specific details on the pulp forming and paper making processes were not provided in the submission. However, the notifier identified the type and duration of exposure expected during various mill operations, and these are summarised in the tables below.

Preparation of Dyeing Solution
Common to both pulp forming and paper making is preparation of the dye solution. Pergasol Yellow F-6G is transferred by metering pump from the bulk import containers to a dilution vessel, using hoses equipped with dry break couplings. The diluted product is then transferred to the paper pulp forming machines or paper making machines using metering pumps. The dilution process is a closed system and does not require the operator to come into contact with the dye solution, other than connection/disconnection of hoses where residual notified chemical may remain. The notified chemical in Pergasol Yellow F-6G in this process is diluted from a 10 to 30% solution to <1% in dye water. Exposure during this process is identified as dermal.

Pulp Forming
The notifier identified machine operators and laboratory technicians as handling the notified chemical in the production of egg cartons. Dermal exposure may occur with the dye solution or where contact with the pulp is required. Exposure to the notified chemical will be at < 1% in dye water. After fixation (at > 97%) any un-fixed chemical will be washed away in backwater and recycled. Pulp forming is described as an automated process with little handling of pulp or contact with dye solution required.

Operation	*Maximum number of workers potentially exposed over all shifts*	*Type of exposure*	*Maximum duration of handling (potential exposure)*	
			hour/day	*days/year*
Dilution of dyestuff	3	Dermal	0.5	24
Pulp colouring and pulp forming	9	Dermal (wet paper)	1	15
		Dermal (dilute dye)	0.5	12
		Inhalation (aerosol)	not significant	

The notifier indicated that potential for aerosol generation during forming or cardboard shaping exists, however, exposure is unlikely as these procedures are automated and occur in enclosed and unmanned systems located in isolated areas.

Paper Making (if carried out)
During paper making, workers may receive dermal exposure to the notified chemical when handling wet paper at paper breaks on paper machines or if contact with the dye solution occurs. Operators may also receive exposure to the notified chemical when handling dry paper during paper conversion finishing processes (reeling, cutting, packaging). Dermal exposure during wet and dry paper operations is expected to be low given the notified chemical is in diluted form (< 1%) and the high fixation rate (> 97%). As described above for pulp forming inhalation exposure is not expected.

No estimate is given in the submission for the period of exposure in clean-up procedures. The notifier indicates that in such circumstances workers would be equipped with protective wear and have access to the MSDS.

Operation	*Maximum number of workers potentially exposed over all shifts*	*Type of exposure*	*Maximum duration of handling (potential exposure)*	
			hour/day	*days/year*
Dilution of dyestuff	30	Dermal	0.5	24
Paper making	54	Dermal (wet paper)	1	15
		Dermal (dilute dye)	1	12
		Inhalation (aerosol)	not significant	
Leak/spill clean-up	3-7	Dermal	not estimated	
Finishing	60	Dermal	not significant	
		Inhalation (paper dust)	not significant	

Maintenance
Workers will be exposed to very dilute concentrations of the notified chemical during machine maintenance and clean up.

For the paper mill operations described above the notifier stated that workers are required to wear a face visor, elbow-length PVC coated gloves, PVC apron and overalls.

7. PUBLIC EXPOSURE

There is little potential for exposure of the public to the notified chemical, as it is not directly available to the general public. The public will only come into contact with the notified chemical in finished paper products and egg cartons. The liquid dye containing the notified chemical has good fastness properties with at least 97% fixation.

No public exposure to the notified chemical is expected during transportation except in the event of a spill.

Spillages during transport are to be contained by use of dry absorbent before being transferred to suitable containers, properly labelled, for disposal in accordance with local, state and federal regulations. Prompt attention to spillages is needed to prevent spill and clean-up material from entering waterways.

Release to the environment of the notified chemical is expected to be minimal. At the use site the generation of waste will be limited to traces remaining from the clean-up of any spill, trace residues in empty packaging and discharges to paper mill effluent systems. There is negligible potential for public exposure to the notified chemical arising from its use by dye houses for dyeing paper or paper pulp.

8. ENVIRONMENTAL EXPOSURE

Environmental Exposure

Release
The bulk of the dye will become chemically fixed to the fibres of paper, and in this state is not expected to impact on the environment

The major environmental exposure to dye will come from effluent discharge from paper mills and their wastewater treatment systems. Other releases will be limited to traces remaining from repackaging operations and clean up of spills, and from trace residues in empty packaging.
All clean up of spills and disposal of empty packaging should be carried out according to the Material Safety Data Sheet (MSDS).

Fate
The bulk of the dye will become chemically fixed to the fibres of paper with a fixation performance of 97%, while the remainder would be rinsed into wastewater. The fate of the majority of the notified chemical is linked with the fate of the paper and in this state is not expected to impact on the environment. Eventually the paper will enter the waste disposal stream for either recycling or ultimately for disposal as waste in landfill. Once in the landfill sites

movement of the chemical by leaching is not expected because of the expected high binding affinity to the non-organic component of soil.

The dye released in water as effluent from the paper mill is expected to be the major environmental exposure. The dye may either partition to the non-organic component of sediment, as expected, or stay in the aqueous compartment. Any dye that binds to the sludge during the waste treatment process would be disposed of through incineration or landfill. Incineration is the preferred option because of the high water solubility and potential mobility of the material. Incineration of the dye will produce oxides of carbon and nitrogen, together with ash and a small amount of hydrogen chloride. Disposal by landfill will be at a secured site, so the risk of leaching to the water table is significantly reduced.

The dye was not found to be readily biodegradable. When measured as dissolved organic carbon (DOC) (OECD TG 301A) and expressed as percentage elimination, biodegradation was 0% over the 28-day exposure to microorganisms from a domestic sewage treatment plant. The dye's inherent biodegradability was measured according to OECD TG 302B (Zahn-Wellens/EMPA Test). A test solution of 10 mg/L was used and it was found that after 3 hours there was 98.9% adsorption and the total elimination of the test substance after 28 days was 97.9%. It is noted that it is difficult to estimate the amount of biodegradation of the notified chemical since the notified chemical adsorbs strongly to surfaces, which invalidates the tests carried out above.

Although the dye does not appear to be biodegradable, the potential for bioaccumulation is low because of the low partition coefficient (log P_{OW} <-2.6) of the substance and the high adsorption to sludge and other surfaces. Also, hydrophilic dyes with log P_{OW}<3 have been shown not to bio-accumulate (Yen *et al*., 1991).

Residues that persist after sewage treatment in city and country wastewater treatment systems will enter marine and freshwater environments in solution. The concentrations are expected to be very low because of the very high fixation rate in the initial process, the expected movement to sediment/sludge and the high dilution rates in the release processes. The notifier claims that residues bound to sediment are expected to undergo reductive degradation.

Trace residues in empty containers are expected by the notifier to amount to only a few milliliters of dilute solution. This is due to the universal practice of thoroughly rinsing out all drums to remove as much of the dyestuff as possible.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Chemical in Pergasol Yellow 2801

Test	*Species*	*Outcome*	*Reference*

acute oral toxicity	rat	LD_{50} > 2 000 mg/kg	(Crouch, 1994a)
acute dermal toxicity	rat	LD_{50} > 2 000 mg/kg	(Crouch, 1994b)
skin irritation	rabbit	slight irritant	(Arcelin, 1994a)
eye irritation	rabbit	slight irritant	(Arcelin, 1994b)
skin sensitisation	guinea pig	non sensitiser	(Arcelin, 1994c)

9.1.1 Oral Toxicity (Crouch, 1994a)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	oral (gavage)
Test method:	OECD TG 401; limit test
Clinical observations:	none
Mortality:	none
Morphological findings:	none
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Crouch, 1994b)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	under semi-occlusive dressing for 24 hours
Clinical observations:	orange discolouration of the skin; slight loss of body weight in 2 females due to the dressing
Test method:	OECD TG 402; limit test
Mortality:	none
Morphological findings:	none
LD_{50}:	> 2 000 mg/kg

Result:	the notified chemical was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity

Data not provided. It was stated that this test was not appropriate on the grounds that the notified substance has a low vapour pressure, low oral toxicity, is a liquid and the manner of use.

9.1.4 Skin Irritation (Arcelin, 1994a)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	1 male, 2 females
Observation period:	14 days
Method of administration:	0.5 g of the test substance under semi-occlusive dressing for 4 hours
Test method:	OECD TG 404
Draize scores(Draize, 1959):	for oedema all scores were zero; for erythema the maximum score was one (slight) observed in one animal at one hour, in all animals at 24 and 48 hours, in two animals at 72 hours and in one animal at 7 days post-treatment; scores were zero in all animals at 14 days
Comment:	orange staining of the skin was observed at the test sites
Result:	the notified chemical was slightly irritating to the skin of rabbits

9.1.5 Eye Irritation (Arcelin, 1994b)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	1 male, 2 female
Observation period:	72 hours
Method of administration:	0.1 g into the conjunctival sac of the left eye of each animal
Draize scores(Draize, 1959):	scores for the cornea and iris were zero at all time points; scores for the conjunctivae were zero at 48 and 72 hours; at one hour, 2 animals exhibited slight conjunctival swelling (score of 1); at 24 hours, 1 animal exhibited slight conjunctival redness (score of 1)
Comment:	no staining of the cornea or conjunctivae was observed
Test method:	OECD TG 405
Result:	the notified chemical was slightly irritating to the eyes of rabbits

9.1.6 Skin Sensitisation-Magnusson and Kligman Maximisation Test (Arcelin, 1994c)

Species/strain: guinea pig/Himalayan spotted

Number of animals: 20 test, 10 controls

Induction procedure: 3 pairs of injections (0.1 mL/site) in the scapular region; pretreatment with sodium lauryl sulphate (SLS) followed by application of aqueous solution of the test substance under occlusive dressing for 48 hours

test group:
day 1 injections as follows:

- 1:1 (v/v) Freund's Complete Adjuvant (FCA) and physiological saline;
- test substance, diluted to 5% with distilled water;
- test substance diluted to 5% by emulsion in a 1:1 (v/v) mixture of FCA and physiological saline

day 7 pretreatment with 10% SLS

day 8 test substance (25% in distilled water) under occlusive dressing for 48 hours

control group: as above, omitting the test substance

Challenge procedure: to the flank under occlusive dressing for 24 hours

day 22 25% test substance applied

Test method: OECD TG 406

Challenge outcome:

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

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

Result: the notified chemical was not sensitising to the skin of guinea pigs

9.2 28-day Oral Repeated Dose Toxicity (Enami and Nishimura, 1990)

Species/strain:	rat/Sprague-Dawley Crj:CD
Number/sex of animals:	6/sex/dose group
Method of administration:	oral gavage of aqueous solution
Dose/Study duration:	0, 40, 200 or 1 000 mg/kg/day for 28 days with 2 extra recovery groups for the control and high dose killed at 14 days following dosing
Test method:	OECD TG 407

Clinical observations
Orange-coloured faeces in the mid and high dose groups; no effects on body weight, food consumption or water intake.

Clinical chemistry/Haematology/Urinalysis
No treatment-related changes; at the end of administration a significant decrease in serum total protein was noted in high dose males; in recovery animals there was a significant increase in triglyceride concentration and a significant decrease in blood urea nitrogen in the high dose males and a significant increase in albumin ratio and A/G ratio for high dose females; these changes were regarded by the authors as of no toxicological significance.

Macroscopic findings
Orange coloured contents of the large intestine of the mid and high dose groups; slight dilatation of the caecum in the high dose group; an increase in absolute and relative full or empty caecum weights in mid dose males and high dose animals was observed; at the end of the recovery period there was an increase in absolute and relative full or empty caecum weights in high dose males; this was also the case for relative weights of caeca in females; for the absolute weights, only the weights of the full caeca were elevated.

Histopathology
Yellow pigmentation of the epithelial cells and yellow or brown pigment-laden macrophages in the submucosa of stomach, caecum and colon in the high dose group; these changes were not observed in the recovery group.

Comment:	the effects of treatment were discolouration of the intestinal contents at the mid and high doses, dilatation of the caecum of high dose animals and cellular colouration in the gastroinstestinal tract of high dose animals
Result:	the NOEL was 40 mg/kg/day and the NOAEL was 200 mg/kg/day for 28 days; systemic effects were minimal; cellular uptake of pigment was not associated with cytological changes

9.3 Genotoxicity

***Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (Takatori, 1989)**

Strains:	TA 98, TA 100, TA 1535, TA 1537 and *E. coli* WP2 *uvrA*

Concentration range:	0, 312.5, 625, 1 250, 2 500 or 5 000 μg/plate
Metabolic activation system:	liver fraction (S9 mix) from rats pretreated with phenobarbital and 5,6-benzoflavone
Test method:	OECD TG 471
Comment:	positive controls demonstrated the sensitivity of the various strains and negative controls were within historical limits; cytotoxicity was observed at 5 000 μg/plate
Result:	the notified chemical was not mutagenic in bacteria in either the absence or the presence of metabolic activation provided by rat liver S9 fraction

9.3.1 Chromosomal Aberration Assay in Chinese Hamster Lung (CHL) Cells (Asakura, 1990)

Cell line:	CHL cells
Doses:	cells were treated for 24 or 48 hours at dose levels of 10 – 80 μg/mL without metabolic activation by rat liver S9 fraction or for 6 hours with metabolic activation at dose levels of 80 – 400 μg/mL
Metabolic activation system:	liver fraction (S9 mix) from rats pretreated with phenobarbital and 5,6-benzoflavone
Test method:	similar to OECD TG 473
Comment:	the positive controls demonstrated the sensitivity of the assay and the negative controls were within historical limits; cytotoxicity was observed at 78 μg/mL without S9 and 310 μg/mL with S9
Result:	the notified chemical was not clastogenic in CHL cells

9.4 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral toxicity and low acute dermal toxicity in rats (LD_{50} > 2 000 mg/kg for both studies). It was a slight skin irritant and a slight eye irritant in rabbits, but not sensitising to guinea pig skin.

Minimal systemic toxicity was observed in a 28-day oral (gavage) repeated dose toxicity study in rats at doses of up to 1 000 mg/kg bw/day.

It was not genotoxic as judged by a lack of mutagenicity in bacteria and clastogenicity in CHL cells.

During 1996 and 1999, the notified chemical was in use in Australia under a commercial evaluation permit granted under section 21G of the Act. The submission indicates no adverse health effects have been noted from its use here or elsewhere.

The notified chemical is not determined to be a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) in terms of the toxicological data supplied.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier has supplied ecotoxicity studies on the notified dye which are summarised in the following table:

Test	***Species***	***Test concentrations (nominal) mg/L***	***Results mg/L***
Acute Toxicity (Static Test) (OECD TG 203)	Rainbow trout (*Oncorhynchus mykiss*)	4.6, 10, 21, 46 & 100	96 h LC_{50} = 1.8
Acute Toxicity -Immobilisation (Static Test) (OECD TG 202 part I)	Water Flea (*Daphnia magna*)	0.010, 0.032, 0.10, 1.0, 3.2 & 10.0	48 h EC_{50} = 0.18
Growth Inhibition - Growth (μ) & Biomass (b) (Static Test)(OECD TG 201)	Green Algae (*Scenedesmus subspicatus*)	0.10, 0.32, 1.0, 3.1 & 10.0	$E\mu C_{50}$ = 1.35 E_bC_{50} = 0.34 LOEC = 0.46
Respiration Inhibition (OECD TG 209)	Activated Sludge-Aerobic Waste Water Bacteria	3.2, 10, 32, 50 & 100	3 h IC_{50} > 100

The tests were performed in compliance with OECD/EEC Test Methods and according to OECD Principles of Good Laboratory Practices.

For all tests, the measured concentrations were significantly lower (sometimes not detected) than nominal concentrations due to strong adsorption of the test substance onto surfaces. All reported biological results are related to the mean measured concentrations.

Fish

The acute toxicity of the notified dye to Rainbow trout was determined in a 96 hours static test. The analytically determined test substance concentrations in the test media samples varied in the range from 11.8% to 80.6% of the nominal values. In the control and lowest test concentration of 1.3mg/L (nominal 4.6 mg/L) no intoxication symptoms were observed and no fish died during the 96 hours test period. In the next higher concentration of 2.6 mg/L (nominal 10.0 mg/L) all fish died after 72 hours test duration. At the highest three nominal concentrations of 21, 46 and 100 mg/L no intoxication symptoms of the test fish could be observed due to the intense test medium colouration and all fish were dead after 24 hours. The 96 hours LC_{50} of the notified dye was determined to be 1.8 mg/L and the highest concentration tested without toxic effects was 1.3 mg/L.

Aquatic Invertebrates

The acute toxicity of the notified dye to daphnia was determined in a 48 hours static test. In

the control and test concentration of 0.006 mg/L (nominal 0.01 mg/L) no immobility or mortality of the test animals was observed during the 48 hours test period. At the test nominal concentrations of 1.0 to 10 mg/L the test animals were coloured by the test substance after 24 hours and immobilised after 48 hours. The 24 and 48 hour LC_{50} of the notified dye were determined to be 1.5 and 0.18 mg/L, respectively, based on mean measured concentrations.

The chronic toxicity of the notified dye to *Daphnia magna* was not determined. Due to the significantly lower 48 hour LC_{50} compared with the 24 hour LC_{50} it is likely that the LC_{50} of the notified dye over the 21 day test period of a reproduction study would be considerably less than the 48 hour LC_{50} determined above.

Algae
The acute toxicity of the notified dye to algae was determined in a 72 hours static test. The 72 hours inhibition rates calculated for algal biomass and growth rate were 0.34 mg/L and 1.35 mg/L, respectively. The lowest concentration of the notified dye tested with significant toxic effects (LOEC) was determined to be 0.46 mg/L.

Microorganisms
The inhibitory effect of the notified substance on aerobic wastewater bacteria, activated sludge from a domestic wastewater treatment plant, was investigated in a respiration test. The notified substance showed no inhibition on the respiration rate at concentrations ranging from 3.2 mg/L to 50 mg/L. At a nominal concentration of 100 mg/L a respiratory inhibition of 38.7% was observed. The final 3 hours IC_{50} was determined to be > 100 mg/L. The measured concentrations did not appear in the test report, thus, the IC_{50} may be below 100 mg/L

Conclusion
The ecotoxicity data for the notified substance indicates that it is moderately toxic to fish, highly toxic to aquatic invertebrates, moderately to highly toxic to algae and slightly toxic to microorganisms.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the dye, when fixed to paper fibres is rated as low.

The notifier has specified that initially only one paper mill will use the notified dye. An estimation of the Predicted Environmental Concentration (PEC) for use in paper pulp forming is provided in the following table:

Calculation Factor	*Medium Shade*	*Dark Shade*
Commercial dyestuff consumed per day	72 kg	192 kg
Notified substance consumed per day	16.56 kg	44.16 kg
Substance not fixed to fibres	0.497 kg	1.325 kg
Volume of water discharged per day	86000 L	86000 L
Dye concentration in effluent	5.8 mg/L	15.4 mg/L
Dilution in STP (Werribee)	100 fold	100 fold
Concentration in Werribee influent	0.057 mg/L	0.1525 mg/L
Degree of removal by elimination in STP*	99%	99%
Predicted Environmental Concentration	0.00057 mg/L	0.0015 mg/L
Safety factor for exposure of most sensitive aquatic organism *Daphnia magna* LC_{50} = 0.18 mg/L	310	120

*The inherent biodegradability of the notified dye was tested (OECD TG 302B Zahn-Wellens/EMPA Test). It was found that after 1 day of exposure to activated sludge the notified substance was almost completely eliminated.

The effluent from the initial dyehouse will make its way to the Werribee STP, where on release the dye will be expected to be adsorbed to soil in the landfarm treatment at the plant with very limited amounts eventually discharged to Port Phillip. Concentrations in natural waters would, therefore, be expected to be very low and final safety factors would, also be expected to be much higher and the environmental hazard acceptable for the particular situation.

The notifier also provided in a model case an estimation of the PEC for use in paper colouration undertaken at a different paper mill. The safety factor for exposure to the most sensitive aquatic organism, *Daphnia magna*, for medium and dark shades was determined to be 3 200 and 1 000, respectively. These safety factors are higher because the dye concentration in the mill effluent was reduced from 3% (97% fixation) to below 1% by the use of a save-all and a clarifier. A primary mill treatment plant also achieves further reductions in dye concentration in the mill effluent.
The PEC calculations for paper pulping (egg carton dyeing) and paper colouration (print and writing paper) assume that a significant amount of the notified chemical will adsorb to soil, sludge and sediment.

The calculations show that the exposure to fish, daphnia, algae and wastewater treatment bacteria, at the particular sites of use, is at levels unlikely to cause any significant effect. Once in the aquatic environment, the chemical is also expected to swiftly dilute to undetectable concentrations, and undergo biotic and abiotic degradation.

The remaining source of environmental contamination is from accidental spills and disposal of packaging. Recommended practices for spillage control given in the MSDS are adequate to control environmental exposure and limit the environmental effects.

In the event of accidental spillage of the dyestuff into waterways, the chemical is expected to disperse into the water due to its high water solubility but also settle out onto sediments. If the dyestuff is spilt on land, either during usage or transport, it is expected that the chemical would become immobilised in the soil layer. Contaminated soil can then be collected and disposed of to landfill.

Solid waste consigned to landfill, either from spillages or residues in packaging, would be expected to be retained at the landfill sites because of its high binding affinity to soil.

Given the above, environmental exposure from the proposed mill use sites the overall environmental hazard is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The submission indicates no adverse health effects have been noted from the chemical's use in Australia under permit or elsewhere.

The notified chemical was of very low acute oral toxicity and low acute dermal toxicity in rats. It was a slight skin irritant and a slight eye irritant in rabbits, and was not a skin sensitiser in guinea pigs. Minimal systemic toxicity was observed in a 28-day oral (gavage) repeated dose toxicity study in rats at doses up to 1 000 mg/kg bw/day. The NOEL was 40 mg/kg bw/day and the NOAEL was 200 mg/kg bw/day for 28 days. It was not genotoxic in the *S. typhimurium* and *E. coli* studies, or in CHL cells *in vitro*.

The notified chemical in Pergasol Yellow F-6G is not determined to be a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) in terms of the toxicological data supplied.

However, Pergasol Yellow F-6G is classified as a hazardous mixture as it contains two adjuvants, namely formic acid (20%) and acetic acid (25%) which are classified as hazardous substances, Corrosive (C), R34 - Causes Burns when present at these levels (NOHSC, 1999). The NOHSC exposure standards for formic acid 5 ppm (9.4 mg/m^3) Time-Weighted Average (TWA) and for acetic acid 10 ppm (25 mg/m^3) TWA should not be exceeded in the workplace (NOHSC, 1995).
Pergasol Yellow F-6G is classified for transport as a Dangerous Good (Class 8).

Occupational Health and Safety

Transport and Storage
The risk of adverse health effects to waterside, transport and storage workers is expected to be negligible, 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.

Paper Mill
Occupational exposure is expected to occur during repackaging of Pergasol Yellow F-6G, preparation of dye solutions, and pulp forming and paper making operations. Inhalation exposure is expected to be insignificant as the chemical has low vapour pressure and aerosol formation can only occur within enclosed automated operation systems.

Skin contact will be the main route of exposure. Exposure to neat Pergasol Yellow F-6G may occur during connection/disconnection of transfer hoses. Given the low hazard of the notified chemical and its physicochemical properties (molecular weight > 500 and low fat solubility) adverse skin effects or significant dermal absorption through intact skin are not expected.

Pergasol Yellow F-6G also contains corrosive organic acids as adjuvants. Prolonged exposure may cause skin irritation and lead to a compromised skin barrier function. Workers will need to wear safety goggles or face shields, elbow length PVC coated gloves and PVC aprons and overalls when handling the undiluted product. The notifier states that workers will be trained in the safe handling of hazardous substances.

Dermal exposure is also expected if contact with wet paper/pulp occurs, or during maintenance and clean-up procedures. Exposure to the notified chemical during the dyeing process is expected to be minimal because it is an enclosed process. Should exposure occur, the notified chemical will now be present at < 1%. The pH of the dilute dye solution is approximately 7, mitigating the hazard associated with the organic acid adjuvants. The notifier states that workers will be wearing the same personal protective equipment described above. Given the control measures in place, and the diluted form of the notified chemical and overall neutral pH, the risk of adverse health effects is expected to be negligible.

Workers involved in dry paper finishing processes will have negligible exposure to the notified chemical since it has been fixed to the paper, and the notifier states that there is no evidence of loss of the fixed dye. Therefore, the health risk to these workers is also negligible.

Public Health
There is negligible potential for public exposure to the notified chemical arising from its use for dyeing paper or paper pulp. There will be public contact with the notified chemical when incorporated into products, but low exposure indicates a negligible risk to public health. Based on the information provided by the notifier, it is considered that the notified chemical in Pergasol Yellow F-6G will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to Pergasol Yellow F-6G the following guidelines and precautions should be observed:

- Safety goggles 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);

- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia 1987) and AS 3765.1 (Standards Australia 1990);

- Impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/Standards New Zealand 1998). The notifier recommends elbow length PVC gloves;

- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand 1994);

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should 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;

- The commercial product, Pergasol Yellow F-6G, contains formic acid (20%) and acetic acid (25%), workers should be advised of the potential for occupational dermatoses following repeated or prolonged exposure and to report any skin changes to the occupational health and safety officer at the workplace. When an occupational skin disease occurs, employers should review work practices and opportunities for contact with the substance and instigate preventive measures to ensure other workers do not develop the same condition. Further guidance on preventing the occurrence of occupational skin diseases can be found in the NOHSC guide Occupational Diseases of the Skin (NOHSC, 1990); and

- The employer is responsible for maintaining exposure to formic acid and acetic acid below the NOHSC exposure standards of 5 ppm (9.4 mg/m^3) Time-Weighted Average (TWA) and 10 ppm (25 mg/m^3) TWA, respectively (NOHSC, 1995).

If the conditions of use are varied from the notified use, greater exposure of the public to the product may occur. In such circumstances, further information may be required to assess the hazards to public health.

14. MATERIAL SAFETY DATA SHEET

The MSDS for Pergasol Yellow F-6G was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

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. This should include use of other mill sites where higher aquatic exposures may result, in which case results for chronic toxicity to Daphnia should be provided.

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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.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	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