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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

FAT 75606/A

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

FAT 75606/A

1. APPLICANT

Ciba Specialty Chemicals of 235 Settlement Road THOMASTOWN VIC 3074 has submitted a standard notification statement in support of their application for an assessment certificate for FAT 75606/A.

2. IDENTITY OF THE CHEMICAL

Claims were made and accepted for the identity of FAT 75606/A to be exempt from publication in the Full Public Report. The data items were:

chemical name
CAS number
molecular and structural formulae
molecular weight
purity
identity of toxic and hazardous impurities
percent weight of toxic or hazardous impurities
non-hazardous impurities
identity of additives/adjuvants
percent weight of additives/adjuvants
import volume and formulation

Other Names:	FAT 75606/A
Trade Name:	TINOSORB FD conc. (contains approximately 60% of notified chemical)
Method of Detection and Determination:	ultraviolet/visible (UV/Vis), nuclear magnetic resonance (^{1}H NMR) and infrared (FT-IR) spectroscopy
Spectral Data:	reports with UV/Vis, ^{1}H NMR and FT-IR spectrometric data were submitted for the identification of the notified substance

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	yellowish powder with no odour
Boiling Point:	greater than 400°C (see comments below)
Specific Gravity:	1.50 at 20°
Vapour Pressure:	1.6 X 10^{-29} kPa at 25°C - estimated
Water Solubility:	5 g/L at 20°C
Partition Co-efficient (n-octanol/water):	log P_{ow} = -2.5 at 20°C
Hydrolysis as a Function of pH:	$T_{1/2}$ at pH 4.0 & 7.0 – below detection limit $T_{1/2}$ at pH 9.0 at 50°C – approx. 45 hours (see comments below)
Adsorption/Desorption:	K_{oc} = 0.5 to 0.8 L/kg – QSAR calculation (see comments below)
Dissociation Constant:	not determined (see comments below)
Particle Size:	< 6.6 µm = 6.5% (respirable) 6.6 µm - < 200 µm = 65.7% (inspirable) ≥ 200 µm = 28.2%
Flammability Limits:	not flammable (Schmiedel U, 1997b)
Autoignition Temperature:	not auto-flammable (Schmiedel U, 1997f)
Explosive Properties:	non-explosive
Reactivity/Stability:	not reactive
Surface Activity:	72 mN/m at 10g/L, 20.8°C
Fat Solubility:	not determined (see comments below)
pH:	10.1 – 10.6 (commercial preparation from MSDS)

Comments on Physico-Chemical Properties

Tests were performed according to OECD Test Guidelines/EEC Test Methods at facilities complying with OECD Principles of Good Laboratory Practice.

The notified substance did not melt under the conditions of the test (Schmiedel U, 1997c). An endothermic reaction occurred between 50°C and 200°C. However, this was not due to the substance melting as it was shown to be an irreversible process and may be caused by a change in crystalline structure.

Using thermal analysis, no endothermic peaks indicative of boiling point were detected in the temperature range between 30°C and 400°C from which boiling could be deduced (Schmiedel U, 1997a). The calculation according to Meissner's Method indicates a boiling point at 823°C at 1014 hPa for the H^+-form of the notified chemical. However, the substance will undergo degradation below this temperature under ambient conditions.

The determination of the relative density, using a gas comparison pycnometer, was performed with two independent test samples each measured at least in triplicate (Schmiedel U, 1997e). The densities measured ranged from 1 495-1 500 kg/m^3. The vapour pressure was estimated using the calculated boiling point of 823°C and the Modified Watson Correlation (Schmiedel U, 1997h).

A preliminary test using a simplified flask method with abbreviated equilibration times was conducted to evaluate the magnitude of the water solubility of the notified chemical. In the main test, using the flask shake method, the water solubility was determined to be 5.0 g/L, with concentrations determined after 24 h, 48 h and 72 h differing by less than 15% (Schmiedel U, 1997i). The water solubility was not corrected for the purity of the test substance.

Hydrolysis testing was performed at 50 °C for pH 4.0 and pH 7.0, and at 50°C and 39°C for pH 9.0. (Schmiedel U & Mirbach M, 1997). At pH 4.0 and pH 7.0, the solubility of the notified substance was too low to allow its quantification by HPLC in a saturated solution, therefore hydrolysis rate could not be measured at these pH values. However, the analytical method was sensitive enough to detect < 1% of the nominal concentration. The use of isopropanol or DMSO as solubilising agents did not increase the concentration of the notified substance. At 50°C and pH 9.0, the notified substance hydrolysed slowly (within 54 hours) to approximately 41% of its initial concentration, with no further decrease up to 291 hours. An apparent half-life is also estimated to be approximately 45 hours. It is unclear whether or not the observed effect is true hydrolysis. Further testing indicated that while the notified substance underwent photolysis, the degradation products from this pathway were absent in the hydrolysis solutions. At 39°C, the notified substance hydrolysed to approximately 37% of its original concentration after 84.3 hours. No further decrease occurred up to 190 hours. As such, it is not possible to accurately determine the half - life and the rate constant since the test article did not decrease to 50% of its starting value.

During the preliminary tests, the estimated log P_{OW} was not reproducible and varied around - 2. Three tests were carried out during the main study using the flask shake method, each in duplicate, with volume ratios of both solvents of 1:1, 2:1 and 1:2. After equilibration, the concentration of the notified chemical was determined in every phase by HPLC. The log P_{OW} was calculated for each of the six vessels and was found to be in the range of - 2.50 to - 2.54, with a mean of - 2.5 (Schmiedel U, 1997d)

The adsorption/desorption coefficients were estimated according to the QSAR (Quantitative Structure Activity Relationship) procedure as described in the "Technical Guidance Document[1]" of the European Union (EU). Instead of the adsorption constants for the three types of soil, the normalised value expressed as K_{OC} was estimated. The general equations for "non - hydrophobics" and "triazines and other non-hydrophobics" were calculated and compared. According to the model, the K_{OC} is estimated to be in the range of 0.5-0.8 L/kg, indicating that the notified chemical tends to remain more in the aqueous phase than in soil (Richner P, 1998). However, as the notified chemical has an ionic character, Richner (1998) considered the results as indicative only.

The notifier did not provide dissociation data for the notified substance. The substance is the disodium salt of highly acidic sulfonic acids. The molecule also contains a number of secondary and aromatic ring nitrogen units expected to have typical basicity.

The notified substance is not expected to be surface active (Schmiedel U, 1997g). 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, as a concentration in octanol of only 5 mg/L was achieved in the partition coefficient test (Schmiedel U, 1997d), low fat solubility is expected.

4. PURITY

Degree of Purity: high

5. USE, VOLUME AND FORMULATION

The notified chemical, FAT 75606/A will not be manufactured in Australia. It will be imported as a component of the commercial product, Tinosorb FD. Tinosorb FD will be sold to laundry manufacturing plants as granules contained in a ready to use package, for use as a trace ingredient in the manufacture of laundry detergent powders and liquid formulations for industrial and domestic use. The end use concentration of Tinosorb FD will be between 0.1

[1] Technical Guidance Document in Support of the Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and the Commission Regulation (EC) 1488/94 on Risk Assessment for Existing Substances.

to 0.3% weight, while the end use concentration of the notified chemical will be between 0.06 to 0.18%.

Less than ten tonnes of the notified chemical, FAT 75606/A, will be imported in the first year following notification. Import volumes will increase to greater than ten tonnes per year for the following four years.

6. OCCUPATIONAL EXPOSURE

The notified chemical, FAT 75606/A, will be imported as a component of the commercial product, Tinosorb FD. Tinosorb FD will be sold to the laundry manufacturing plants in a ready-to-use form, ready for mixing into laundry detergent powder or liquid. It will be imported in 20 - kg bags, stacked in pallets with each pallet containing 18 bags. Waterside, warehouse and transport workers would not be exposed to the notified chemical under normal circumstances, as they will be handling unopened bags containing the notified chemical. The small mass in each bag will prevent accidental dropping of bags and the packaging, which is designed for international transport would minimise accidental spill of the product containing the notified chemical.

The notifier indicates that 3 major and up to 5 minor laundry detergent manufacturers will be using Tinosorb FD. The nature of work done and the total number of employees estimated to have potential exposure to Tinosorb FD are: formulation equipment operators (40 personnel); plant operators (60 personnel) and laboratory technicians (60 personnel).

Product re-packing

Re-packing of the commercial form of Tinosorb FD before distribution to detergent manufacturers may be required when supplying samples or materials for mill trials. Re-packing will only be carried out in the notifier's warehouse where appropriate facilities are available. The size of the re-packed commercial Tinosorb FD for distribution as samples for mill trial is not provided. The notifier states that re-packing process will be carried under strict supervision. At the warehouse, down flow booth facilities, which are designed to control fine particulates with airflow blowing away from the operator, are used to minimise inhalation exposure to the notified chemical. These facilities are also designed so that the capture velocity for particulates are exceeded to ensure that exposure approaches zero, even in the unlikely event of workers not wearing respiratory protection. A maximum of two personnel will be involved in re-packing and it is estimated that less than 100 kg of the notified chemical will be re-packed each year. This equates to not more than 10 days of re-packing per year, for 12 – 20 minutes on each day. Dermal exposure is likely to occur during re-packing. Workers are to wear personal protective equipment such as gloves (PVC, long impervious), overall, safety glasses or face shield and respiratory device to minimise dermal and inhalation exposure to the product containing the notified chemical.

Detergent manufacturing process

During detergent manufacturing process, the commercial product, Tinosorb FD containing the notified chemical, will be weighed out in a dispensary, dissolved in a detergent preparation vessel and either packed as a liquid product or blended into dry ingredients. The detergent manufacturing process is carried out using enclosed machine systems. Exposure to the machine operators and laboratory technicians is limited to handling the notified chemical in the diluted end use products. Dermal exposure is the commonest route of exposure among these workers. Batch weighers are judged to have the highest potential for inhalation and dermal exposure to the notified chemical. The weighing and addition of the product containing the notified chemical in a blending vessel is carried out under local exhaust ventilation. When handling the product containing the notified chemical, workers are to wear personal protective equipment such as gloves (PVC, long impervious), overalls, safety glasses or face shield and respiratory device, as a minimum requirement.

The notifier used a model case for estimating occupational exposure by batch weighers to the notified chemical by the respiratory route, in eight plants. The model used is that of a non-automated detergent plant producing 7 500 tonnes per year of finished detergent product. This quantity would consume 15 tonnes of the product containing the notified chemical per year. Weighers are estimated to carry out weighing of the product containing the notified chemical for 100 days per year. Approximately 10 kg will be weighed for 15 times per 24 hour/day. On each of the 100 days, 150 kg of the product containing the notified chemical will be used. Thirty weighers over 24 hours will be weighing 10 kg each. This equates to 10 kg of the product being weighed for 5 times per worker per shift. The airborne concentration of the notified chemical is calculated at 5.1 mg/m^3, corresponding to a daily exposure level for each worker of 2.1 mg, or 0.03 mg/kg bodyweight for an average 70 kg worker. This represents inhalation exposure only and does not account for any skin contamination and absorption.

There is no information provided in the submission on the mechanisms involved in packaging of the formulated detergent product for distribution or sale to end-users.

7. PUBLIC EXPOSURE

The notified chemical will be used as a trace ingredient in laundry detergent powder and liquid formulations for industrial and domestic use. The public will make dermal contact with the notified chemical during washing of fabric or clothing, and when wearing clothing washed with products containing the notified chemical. Since the formulated detergents are either liquid or granular “dust free” formulations, the notified chemical is unlikely to be an inhalation hazard. According to the notifier, during application to fabrics in domestic or industrial washing machines, the notified chemical forms a tight bond to the fibre surface of the fabric. There is no evidence of loss of the substance from washing or drying, nor subsequent “bleeding” in the use of the treated clothing or fabric. Hence, exposure to the notified chemical would be low when handling dry or wet fabrics treated with products containing the notified chemical.

8. ENVIRONMENTAL EXPOSURE

Release

Significant quantities of notified substance are not expected to be released to the environment from the detergent product formulation process. Formulating plants do not undertake regular cleaning campaigns, instead the equipment is flushed with the base detergent that is kept for the next run as a 'heel' for blending off. Wastes generated due to maintenance procedures should contain only minimal volumes of the notified chemical.

The bulk of the notified substance will become fixed to cellulose textiles during fabric/textile washing, and in this state is not expected to impact on the environment. The notifier claims that the strong steric bond and tight Van der Waal's forces will bind the substance to the cellulose fibre surface.

Tests indicate that 70% of the notified substance (at 0.2% wt in the laundry detergent) is fixed onto cotton textile fibres after 3 minutes washing, with 75% after 15 minutes (assumed to be the end of the washing cycle). Thus, the major environmental exposure will come from the effluent discharge of commercial and domestic washing facilities to municipal waste-water treatment systems, that may contain up to 25% of the imported volume of notified substance.
Other releases should be limited to traces remaining from re-packing operations, the clean-up of any spills and from trace residues in empty imported packaging (estimated by the notifier at not more than 10 g and more likely to be 5 g). It is also estimated that only a small volume of residues of notified substance remains in empty detergent product packaging.

Fate

The notified substance released in water as effluent from commercial and domestic washing facilities is expected to be the major environmental exposure. The relatively high water solubility of the substance indicates that a significant proportion of the substance passing to effluent may remain in the aqueous compartment. However, the notifier anticipates that the substance will be removed through a combination of chemical and biological degradation, photodegradation and sorption to sludge particulates.

Hydrolysis at pH 9 was found to degrade up to 59% of the notified substance after 54 hours at 50°C (Schmiedel U & Mirbach M, 1997). The substance is also highly photosensitive, with concentrations decreasing to less than 15% in 24 hours during the algal Growth Inhibition test (Memmert U, 1997c). Further, some retention of the substance in sludge in biological effluent treatment works is expected, as evidenced by the 74% elimination in the inherent biodegradability study, with 13% adsorption after 3 hours (Schnalke P, 1997b).

Any substance that binds to the sludge will be disposed of through incineration or more likely landfill. Residues that persist after sewage treatment will enter the aquatic environment in highly diluted solution (from both city and country waste water treatment systems).

Incineration is the preferred option of disposal because of the high water solubility and potential mobility of the material. Incineration of the substance will produce oxides of carbon, nitrogen and sulfur, together with sodium salts in the ash. The notifier also identifies disposal of the substance to a secured landfill site. However, consumers of the laundry detergent products containing the notified substance are likely to dispose of contaminated packaging to municipal landfill. Nonetheless, the empty product packaging should contain minimal residues of the notified substance.

The notified substance was found to be inherently biodegradable over a 28 day exposure period when exposed to micro-organisms from a communal sewage treatment plant under indirect daylight exposure conditions, according to the OECD Test Guideline 302B Zahn-Wellens/ EMPA Test (Schnalke P, 1997b). Expressed as percentage DOC removal, the average biodegradation[2] after 28 days was 70%. The adsorption[3] of the test substance after 3 hours was 13%, and as such the total elimination[4] after 28 days was 74%. There appeared to be no inhibition on the activity of the bacteria in this test, which is consistent with the findings of the Activated Sludge - Respiration Inhibition Test in the Environmental Effects section.

The notified substance was determined (according to EEC Directive 92/69) to have a Chemical Oxygen Demand (COD) of 982 mg O_2/g (Schnalke P, 1997a).
Coupled to the expected biodegradability, the potential for bioaccumulation of the substance is low due to its low calculated partition coefficient (log K_{OW} = - 2.5), very high water solubility (5 g/L) and predicted low fat solubility (5 µg.L^{-1} in octanol) (Connell DW, 1989). The notifier has also supplied calculations on the potential bioaccumulation in fish. The calculation (log BCF_{fish} = 0.85logK_{OW}-0.7) determined the bioconcentration factor (BCF) to be < 0.1, and the result confirms that no bioaccumulation is expected.

[2] Difference between DOC-values of 3 hours and the end of the test.
[3] Difference between DOC-values of the start and after 3 hours.
[4] Difference between DOC-values of the start and the end of the test.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of FAT 75606/A, containing a high proportion of the notified chemical (doses are adjusted accordingly).

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	> 5 000 mg/kg	(Allen DJ, 1997d)
acute dermal toxicity	rat	> 2 000 mg/kg	(Allen DJ, 1997b)
skin irritation	rabbit	slight irritant	(Allen DJ, 1997a)
eye irritation	rabbit	moderate to severe irritant	(Allen DJ, 1997c)
skin sensitisation	guinea pig	non-sensitiser	(Allen DJ, 1997e)

9.1.1 Oral Toxicity (Allen DJ, 1997d)

Species/strain:	rat/Sprague-Dawley CD
Number/sex of animals:	5/sex
Observation period:	14 days
Dose:	5 556 mg/kg (equivalent to 5 000 mg/kg of neat FAT 75606/A)
Method of administration:	10 mL/kg of test substance in arachis oil BP, administered by gavage
Clinical observations:	no signs of systemic toxicity
Mortality:	nil
Morphological findings:	none
Test method:	OECD guideline TG 401(Organisation for Economic Cooperation and Development, 1987c)
LD_{50}:	> 5 000 mg/kg
Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Allen DJ, 1997b)

Species/strain:	rat/Sprague-Dawley CD
Number/sex of animals:	5/sex
Observation period:	14 days
Dose:	2 223 mg/kg (equivalent to 2 000 mg/kg of neat FAT 75606/A)
Method of administration:	test substance administered as a powder moistened with distilled water and held under semi-occlusive dressing; after 24 hours residual test material was wiped with cotton wool moistened with distilled water
Clinical observations:	no signs of systemic toxicity
Mortality:	nil
Morphological findings:	none
Dermal irritation:	no dermal irritation was observed in any animal tested dark green coloured staining was noted on the treatment site of all animals at day 1 and on males at days 2 and 3; the staining prevented accurate evaluation of erythema
Test method:	OECD guideline TG 402 (Organisation for Economic Cooperation and Development, 1987a)
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity

Study not conducted.

9.1.4 Skin Irritation (Allen DJ, 1997a)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	6/male
Observation period:	3 days
Method of administration:	0.5 g of test substance moistened with 0.5 mL of distilled water was applied to the shaved test site and held under occlusive dressing; after 4 hours residual test substance was removed with cotton wool soaked in distilled water; treated areas were examined for evidence of irritation and graded at 1, 24, 48 and 72 hours after treatment
Skin Irritation:	very slight erythema was noted in five animals one hour after patch removal, in three animals at 24-hour observation period and in one animal at 48-hour observation period; very slight oedema was noted in 2 animals one hour after patch removal; one animal did not demonstrate skin irritation at any time during the study
Test method:	OECD guideline TG 404 (Organisation for Economic Cooperation and Development, 1992a)
Result:	the notified chemical was slightly irritating to the skin of rabbits

9.1.5 Eye Irritation (Allen DJ, 1997c)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	6/male
Observation period:	3 days
Method of administration:	94 mg of test substance was instilled into the conjunctival sac of one eye of each animal; the other eye served as the control; one drop of local anaesthetic (0.5% proxymetacaine hydrochloride) was applied to both eyes 1 to 2 minutes before treatment

Draize scores (Draize, 1959) of unirrigated eyes:

	Time after instillation																			
Animal	***1 hour***			***1 day***			***2 days***			***3 days***			***7 days***			***14 days***			***21 days***	
Cornea [1]	***a***		***o***	***a***		***o***	***a***		***o***	***a***		***o***	***a***		***o***	***a***		***o***	***a***	***o***
1	0		0	0		0	0		0	0		0	*		*	*		*	*	*
2	2		*	3		1	3		1	3		1	1		1	1		1	0	0
3	2		*	3		1	3		1	3		1	2		2	1		1	0	0
4	2		*	4		1	4		2	3		2	1		1	0		0	*	*
5	2		1	3		1	2		1	1		1	0		0	*		*	*	*
6	1		*	3		1	2		2	1		2	0		0	*		*	*	*
Iris [1]																				
1		0			0			0			0			*			*			*	
2		1			1			1			1			1			0			0	
3		1			1			1			1			1			0			0	
4		1			1			1			1			0			0			*	
5		0			1			1			1			0			*			*	
6		1			1			1			0			0			*			*	
Conjunctiva [1]	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	2	2	2	2	1	1	1	0	0	0	0	0	*	*	*	*	*	*	*	*	*
2	2	2	2	2	2	3	2	2	3	2	1	1	2	1	0	0	0	0	0	0	0
3	2	2	3	2	2	3	2	2	2	2	2	2	2	2	2	1	1	0	0	0	0
4	2	2	3	2	2	3	2	2	3	2	2	2	1	1	1	0	0	0	*	*	*
5	2	2	2	2	2	3	2	2	2	1	1	0	0	0	0	*	*	*	*	*	*
6	2	2	2	2	2	3	2	2	3	2	1	1	0	0	0	*	*	*	*	*	*

[1] see Attachment 1 for Draize scales o = opacity a = area of cornea r = redness c = chemosis d = discharge * = score not reported

Unirrigated eyes:	signs of irritation included diffuse or translucent corneal opacity, iris inflammation and mild to moderate conjunctival irritation; eye effects were persistent namely: • corneal opacity persisted to 14 days (2 animals) • iris inflammation persisted to 7 days (2 animals) • conjunctival redness persisted to 7 days (3 animals) and 14 days (one animal) • chemosis persisted to 14 days (one animal) • vascularisation of the cornea persisted through 7 days (2 animals), 14 days (3 animals) and 21 days (one animal)
Test method:	similar to OECD guidelines (Organisation for Economic Cooperation and Development, 1987b)
Result:	the notified chemical was moderate to severe irritant to the eyes of rabbits

9.1.6 Skin Sensitisation (Allen DJ, 1997e)

Species/strain:	guinea pig/Dunkin Hartley
Number of animals:	30/males: 20 tests and 10 controls
Induction procedure:	<u>Test animals:</u> *Intradermal induction* Day 0 : 0.1 mL of the following solutions were injected in rows on the shoulders of 20 animals: a) Freunds Complete Adjuvant (FCA) and distilled water (1:1) b) 5% (w/v) test substance in arachis oil BP; and c) 5% (w/v) test substance in 1:1 FCA in distilled water injection sites were examined at 24 and 48 hours after injection

Topical induction

Day 7: 75% (w/w) test substance in arachis oil BP was applied to the intradermal injection sites of 20 animals; the filter paper containing the test substance was held in place by an occlusive dressing for 48 hours

residual test substance was removed with cotton wool soaked in diethyl ether; test sites were examined at 1 and 24 hours after removal of occlusive dressing

Controls:

Intradermal injection,
Day 0: intradermal injection was performed using similar procedure as for test animals but without the test substance

Topical induction,
Day 7: topical application followed the same procedure as for test animals except that arachis oil BP alone was applied to the intradermal injection sites

Challenge procedure:

Test animals:

doses of 50% w/w and 75% (w/w) of test substance in arachis oil BP were applied on left and right flank of each treated animal, respectively; the filter paper containing the test substance was held in place by an occlusive dressing for 24 hours; residual test substance were removed with cotton wool soaked in diethyl ether; test sites were examined at 24 and 48 hours after test substance application

Challenge outcome:

Challenge concentration	Test animals		Control animals	
	*24 hours**	*48 hours**	*24 hours*	*48 hours*
25%	**0/20	0/20	0/10	0/10
75%	0/20	0/20	0/10	0/10

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

Test method: similar to OECD guidelines TG 406 (Organisation for Economic Cooperation and Development, 1992b)

Result: the notified chemical was not a skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity (Thomas ON et al., 1997)

Species/strain: rat/Sprague-Dawley

Number/sex of animals: test group: 5/sex/group
control group: 5/sex
recovery group: 5/sex/group

Method of administration: gavage

Dose/Study duration:

Test: 2 mL of test substance at 150, 400 and 1 000 mg/kg/day in arachis oil BP for 28 days; doses incorporated a correction factor for 82.5% purity

Low dose: 150 mg/kg/day
Mid dose: 400 mg/kg/day
High dose: 1 000 mg/kg/day

due to technical error, the animals in all groups received higher doses than intended on day 1

Control: 2 mL of arachis oil BP

Recovery group (test): 2 mL of test substance at 1 000

		mg/kg/day in arachis oil BP
	Recovery group (control):	2 mL of arachis oil BP recovery group animals were kept for 14 day recovery period following termination of treatment
Mortality:	Test: High dose:	one female died after dosing on day 1; another female died on day 2
Clinical observations:	Test: Low dose:	no treatment related effects in either sex were observed
	Mid dose:	one female developed hunched posture, gasping respiration and red/brown staining of snout on day 10 of treatment; reduced bodyweight was noted in males at weeks 1 and 2; reduced food efficiency was observed in males during the first half of treatment period; however, females showed no adverse effect on bodyweight and food intake during the study
	High dose:	clinical signs including distended abdomen, hunched posture, lethargy, decreased respiratory rate, gasping laboured and noisy respiration, increased salivation, and red or brown staining of the external body surface were observed in animals on day 1 one male developed diarrhoea on day 2; the condition of other animals improved on days 2 and 3; 4 surviving animals showed dehydration, hunched posture, pilo-erection, decreased respiratory rate, laboured respiration and red or brown staining around the eyes on day 4

		similar observations as above were noted sporadically throughout treatment for periods of mostly three to six days duration, after which the animals' physical condition returned to normal; other abnormalities observed included pallor of the extremities, ptosis, increase respiratory rate and tiptoe gait
		one female was killed on day 15, due to severe deterioration in physical condition
		all animals showed bodyweight reduction on week 1 extending to week 2 amongst males
		males showed reduced food intake on weeks 2 and 3, and reduced food efficiency on weeks 1 and 2, while females showed reduced food efficiency only on week 1
	Recovery group:	no signs of toxicity were observed in the test animals during the fourteen day treatment-free period
		bodyweight of test animals was similar to or greater than controls during the fourteen day treatment-free period
		dietary intake and food efficiency of surviving test animals were similar to or greater than controls during the fourteen day treatment free period
Clinical chemistry:	Test:	no treatment related changes in the blood chemistry and in the parameters used for urinalysis were measured in all test groups
	Recovery group:	no significant findings were observed in the test or control group
Haematology:	Test:	no treatment related changes in the haematological parameters were observed

		in any test groups
	Recovery group:	no significant findings were observed in the test or control group
Organ weights:	Test:	
	Low dose:	no treatment-related changes in organ weights were observed
	Mid dose:	in males, the mean liver weight was significantly lower compared to the control group; however no liver weight reduction was observed when liver weight was expressed relative to terminal body weight
	High dose:	in males, mean kidney, liver, and spleen weights were significantly lower in males compared to the control group; however, these reductions were not observed when corresponding organ weights were measured relative to terminal body bodyweight
	Recovery group:	in test females, mean and relative weight of ovaries were significantly higher compared to the control recovery group in test males, liver weights were significantly lower (relative to body weight) compared to control; this effect was not seen at the end of 28 days in any dose group, therefore it is considered to be associated with reduced bodyweight gain
Gross pathology:	Test:	
	Low dose:	one male showed dark foci on the caudal lobe of the lungs; this was attributed to exsanguination of animals at terminal kill
	Mid-dose:	no treatment-related abnormalities were observed
	High dose:	toxicologically significant macroscopic abnormalities were confined to females

and include:

a) gaseous distention of yellow fluid contents in the gastrointestinal tract, reddening of the glandular gastric mucosa in one animal that died early in the study;
b) small spleen, yellow stomach contents, thinning of the non-glandular gastric epithelium and gaseous distention in large intestines in one animal killed on day 15; and
c) gaseous distention of the entire gastro-intestinal tract, and pale and swollen lungs observed in one survivor at termination

Recovery group: no treatment-related abnormalities were observed in either sex

Histopathology: no treatment-related microscopic abnormalities were detected in any group

Test method: OECD guideline TG 407 (Organisation for Economic Cooperation and Development, 1981)

Result: death in 2 animals and signs of adverse health effects were observed in rats treated at the high dose level; at the mid dose level, slight effects on body weight gain, food intake, reduced food efficiency and physical condition were observed; no histopathological abnormalities were observed in association with the gastro-intestinal changes; gastro-intestinal changes were not taken to represent systemic toxicity and in conjunction, respiratory effects were found to be concentration dependent and attributed to sensory irritation; no adverse health effects were detected at a dose level of 150 mg/kg/day; the No Observed Effect Level (NOEL) was judged to be 150 mg/kg/day, based on clinical effects and body weight changes seen at higher doses

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichi coli* Reverse Mutation Assay (Thompson PW, 1997)

Strains:	*S. typhimurium* TA1535, TA1537, TA98, TA100 and *E coli* WP2*uvr*A
Metabolic activation sytem:	liver microsomal fraction (S9) from rats pretreated with Arochlor 1254
Experimental design:	*S. typhimurium* and *E coli* treated with 0, 50, 150, 500, 1 500, 5 000 µg test substance/plate evaluated with or without metabolic activation S9
	vehicle control: dimethyl sulphoxide
	positive control without metabolic activation:
	TA100, TA1535 and WP2*urv*A: N-ethyl-N'-nitro-N-nitrosoguanidine
	TA98: 4-nitroquinoline-1-oxide
	TA1537: 9-aminoacridine
	positive control with metabolic activation: 2-aminoanthracene
Test method:	OECD guideline TG 471 and TG 472 (Organisation for Economic Cooperation and Development, 1983c), (Organisation for Economic Cooperation and Development, 1983a)
Comment:	vehicle control plates produced revertant colonies within the normal range
	positive controls, with or without metabolic activation, produced marked increases in the number of revertant colonies
	the test substance did not exhibit toxicity in any of the strains of bacteria at any dose; no increases in numbers of revertant colonies on plates containing the notified chemical compared to negative control plates were observed for any of the bacterial strains at any dose with or without metabolic activation

Result:	the notified chemical was considered to be non-mutagenic in the bacterial strains tested either with or without metabolic activation

9.3.2 Chromosome Aberration Assay in Chinese Hamster Lung (CHL) cells (Wright NP, 1997)

Cell line:	CHL
Metabolic activation system:	liver microsomal fraction (S9) from rats pretreated with Aroclor 1254
Experimental design:	
Experiment 1:	*without metabolic activation*
12-hour harvest:	12-hour continuous exposure to the test substance prior to cell harvest
dose (µg/mL):	39.06, 78.13, 156.25 and 312.5
vehicle control:	dimethyl sulphoxide
positive control:	mitomycin C (0.075 µg/mL)
	with metabolic activation:
12-hour harvest:	4-hour exposure to the test substance and S9-mix followed by a treatment-free incubation period of 8 hours before harvest
dose (µg/mL):	625, 250 and 2 500
vehicle control:	dimethyl sulphoxide
positive control:	cyclophosphamide (10 µg/mL)
Experiment 2	*without metabolic activation*
12-hour harvest:	12 hours exposure to the test substance prior to cell harvest
dose (µg/mL):	78.13, 156.25, 312.50, 468.75 and 625
24-hour harvest:	a) 24-hour continuous exposure to the test substance prior to cell harvest
dose(µg/mL):	39.06, 78.13, 156.25 and 312.5

b) 6-hour exposure to the test substance prior to cell harvest

dose (µg/mL): 625, 1 250 and 2 500

48-hour harvest: 48-hour continuous exposure to the test substance prior to cell harvest

dose (µg/mL): 39.06, 78.12, 156.25 and 312.5

vehicle control: dimethyl sulphoxide

positive control: mitomycin C (0.075 µg/mL)

with metabolic activation

12-hour harvest: 4-hour exposure to the test substance and S9-mix followed by a treatment-free incubation period of 8 hours prior to cell harvest

dose (µg/mL): 625, 1 250 and 2 500

24-hour harvest: 6-hour exposure to the test substance and S9-mix followed by a treatment-free incubation period of 18 hours prior to cell harvest

dose (µg/mL): 625, 1 250 and 2 500

Comment:

Experiment 1:

without metabolic activation

12-hour harvest: the toxicity observed in CHL cells in all doses was similar to that of the preliminary test; there were no cells in metaphase scored at and above 625 µg/mL

with metabolic activation

12-hour harvest: the toxicity observed in CHL cells in all doses was similar to that of the preliminary test

no dose-related increases in the frequency of chromosomal aberrations were observed at any dose tested with or without metabolic activation S9

Experiment 2:

without metabolic activation

12, 24 and 48-hour harvests: the toxicity observed in CHL cells in any treatment group at all doses was similar to that of the preliminary test and experiment 1; no dose-related

	increases in the frequency of chromosomal aberrations were observed in any treatment group at any dose tested
	with metabolic activation
12-hour harvest:	the toxicity observed in CHL cells in all doses was similar to that of experiment 1; there was an increase in the frequency of chromosomal aberrations at 625 µg/mL; however the increase in CHL chromosomal aberrations is not considered significant since it was observed at the same dose in the 24-hour harvest and only occurred at this (the lowest) dose
24-hour harvest:	the toxicity observed in CHL cells in all doses was similar to that of experiment 1; there was an increase in the frequency of chromosomal aberrations at 625 µg/mL; however, this increase was only observed at the lowest dose
vehicle control:	cultures produced chromosomal aberrations within the expected range
positive control:	cultures produced significant increases in the frequency of chromosomal aberrations
Test method:	OECD guideline (Organisation for Economic Cooperation and Development, 1983b)
Result:	the test substance did not induce reproducible and dose-related increases in the frequency of chromosomal aberrations in CHL cells with or without metabolic activation provided by rat liver S9 fraction; the test substance was non-clastogenic to CHL cells *in vitro*

9.4 Overall Assessment of Toxicological Data

No inhalation studies have been performed on the notified chemical. The notifier made a claim for variation on the schedule data requirements for an acute inhalation study for reasons including the low percentage of respirable size particles, low vapour pressure and low oral toxicity. The claim for variation was accepted on the basis of the above reasons.

FAT 75606/A exhibited very low acute oral and low dermal toxicity in rats with LD_{50} values of > 5 000 mg/kg and > 2 000 mg/kg, respectively. FAT 75606/A is moderate to severe irritant to the eyes of rabbits. The eye irritant study showed that iris inflammation persisted for 7 days, while the redness of the conjunctiva, chemosis and corneal opacity persisted for 14 days. Vascularisation of the cornea was also observed at day 7 and persisted to day 21 in one animal. FAT 75606/A is a slight skin irritant because of the presence of slight erythema

and oedema at the 24-hour and 48- hour observation period. The notified chemical was not a skin sensitiser in guinea pigs.

In a 28-day oral repeat-dose toxicity, two animals died and there were signs of adverse health effects in rats treated at the highest dose. At mid dose, there were slight effects on body weight gain, food intake, reduced food efficiency and physical condition. There were no histopathological abnormalities observed in association with the gastro-intestinal changes, which were suggestive of disturbance of the digestive system. However, these changes together with respiratory effects were found to be concentration dependent and attributed to sensory irritation. No adverse health effects were detected at 150 mg/kg/day, therefore the No Observed Effect Level (NOEL) is 150 mg/kg/day.

The notified chemical was non-mutagenic in a bacterial mutation assay. It did not induce reproducible and dose-related increases in the frequency of chromosomal aberrations in CHL cells with or without metabolic activation. The notified chemical was found to be non-clastogenic to CHL cells *in vitro.*

Based on the persistent eye irritant effects, the notified chemical, FAT 75606/A, would be classified for health effects as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a). The appropriate risk phrase for FAT 75606/A is R41 - risk of serious eye damage.

The notifier provided a summary of the toxicokinetic data for FAT 75606/A (Mentzel U, 1997). The summary states that dermal absorption of FAT 75606/A would be negligible under normal conditions based on its physico-chemical properties, namely that partition coefficient of – 2.5 is below the partition coefficient of – 1, suggested as the value below which penetration of the stratum corneum would not occur. The summary further suggests that exposure to FAT 75606/A via inhalation is also low because of the small proportion (6.5%) of particle size less than 6.6 µm (respirable) present in FAT 75606/A. The systemic effects observed in a 28-day study indicate that FAT 75606/A is absorbed in the gastro-intestinal tract, especially in the high dosed animals. However, there is insufficient data to determine if FAT 75606/A is eliminated via the faeces or urine following absorption by oral route.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Test	*Species*	*Results*	*Reference*
Acute Toxicity 96 hour Semi-Static OECD TG 203	Rainbow trout (*Oncorhynchus mykiss*)	LC_{50} >120 mg/L NOEC = 120 mg/L	(Memmert U, 1997b)
Acute Immobilisation 48 hour Static OECD TG 202 - Part I	Water Flea (*Daphnia magna*)	EC_{50} >120 mg/L NOEC = 120 mg/L	(Memmert U, 1997a)
Reproduction 14 days OECD TG 202 - Part II	Water Flea (*Daphnia magna*)		
Growth Inhibition 72 hour Static OECD TG 201	Green Algae (*Scenedesmus subspicatus*)	EbC_{50} > 120 mg/L $E_{\mu}C_{50}$ > 120 mg/L NOEC = 120 mg/L	(Memmert U, 1997c)
Respiration Inhibition 3 hour OECD TG 209	Aerobic Waste Water Microorganisms	EC_{50} > 1 000 mg/L	(Memmert U, 1997d)

- NOEC - no observable effect concentration
- LC_{50} – median lethal concentration
- E_bC_{50} – calculated concentration of test substance which results in a 50% reduction of biomass b relative to control
- $E_{\mu}C_{50}$ - calculated concentration of test substance which results in a 50% reduction of growth rate μ relative to control

Fish

A limit test was performed to demonstrate that the test substance had no toxic effects on the test fish up to the concentration of nominal 120 mg/L. Thus in the definitive study the only concentration tested was nominal 120 mg/L and a control. Due to the photosensitivity of the test substance, the aquaria were shaded as far as possible to avoid photolytic degradation of the test substance. Light intensity was limited to approximately 30 Lux.

The analytically determined mean test substance concentration in the test medium varied in the range from 85% to 92% of nominal during the test period. The test substance was found to be sufficiently stable during the renewal period of 48 hours. Despite precipitation and settling of a small part of the test substance, the mean overall measurements of 88% of the nominal concentration were found.

Symptoms of intoxication could not be determined during the test period due to the intense turbidity at 120 mg/L. At the conclusion of the test, fish were placed in a control medium for observation. No signs of intoxication were observed and all fish survived until the end of the test.

The 96 h NOEC and the 96 h LC_0 of the notified substance to Rainbow Trout were determined to be at least 120 mg/L. The 96 h LC_{50} was determined to be greater than

120 mg/L, and could not be quantified due to the absence of toxicity up to the tested concentration.

Aquatic Invertebrates

A limit test demonstrated that the test substance had no toxic effects on the daphnids up to the concentration of nominal 120 mg/L. Thus in the definitive study the only concentration tested was nominal 120 mg/L and a control. Due to the photosensitivity of the test substance, the test was performed as much as possible in the dark to avoid photolytic degradation of the test substance.

Despite precipitation and settling of a small part of the test substance during the test, the analytically determined mean test substance concentrations in the test medium were consistently 98% of the nominal value during the test period. The test substance was found to be sufficiently stable under the conditions of the test during the test period of 48 hours. All reported biological results were related to the nominal concentration.

There is no mention in this test report of the intense turbidity experienced in the Rainbow trout study that inhibited visual observations. Immobility or mortality of the daphnids was determined by visual controls after 24 and 48 hours. No immobilised or dead daphnids were observed during the test period.

The 48 h NOEC and the 48 h EC_0 of the notified substance to *Daphnia magna* were determined to be at least 120 mg/L. The 48 h EC_{50} was determined to be greater than 120 mg/L, and could not be quantified due to the absence of toxicity up to the tested concentration.

A *Daphnia* species reproduction test was not supplied. However, based on the low acute toxicity to both fish and daphnids, reproduction effects on daphnids are not expected to occur.

Algae

Due to the photosensitivity of the test substance, the test included two parallel experimental parts. Two limit tests, one with a freshly prepared test medium and the other with 24 hours aged test medium, were performed to determine the toxicity of both the notified substance and its photodegradation products, up to the concentration of nominal 120 mg/L during the test period of 72 hours. All biological results (for both experimental parts) are related to the nominal test substance concentration of 120 mg/L.

The analytically determined mean test substance concentrations in the test media of both experimental parts just after the test media preparations corresponded to 99% of the nominal value. After 24 hours incubation under the test conditions, the concentration had strongly decreased to 12-14% of the nominal value, due to photolytic degradation as a consequence of the intense irradiation of the test media. This concentration was constantly determined until the end of the test.

The mean algal cell densities in the test media of both treatments were at all counting dates nearly identical to those in the parallel control cultures. The mean biomass (b) and growth rates (μ) were not statistically significantly different. There was no observed difference in the shape of the algal cells between the algae growing in the 120 mg/L test concentration and the control.

The 72 h NOEC of the notified substance to algae was determined to be at least 120 mg/L. The 72 h LOEC and 72 h EC_{50} for the algal biomass (b) and the growth rate (μ) were determined to be greater than 120 mg/L and could not be quantified due to the absence of toxicity up to the tested concentration.

Aerobic Waste Water Microorganisms

Nominal concentrations of 10, 32, 100, 320 and 1 000 mg test substance/L were tested. Three controls and four different concentrations of the reference substance were tested in parallel. The notified substance had no inhibitory effect on the respiration rate of aerobic activated sludge from a wastewater treatment plant (treating predominantly domestic sewage) after the incubation period of 3 hours, up to and including the highest test substance concentration tested. Thus the 3 h EC_{20} and 3 h EC_{50} could not be quantified but are higher than 1 000 mg/L.

The ecotoxicity data for the notified chemical indicate that it is practically non - toxic to fish, aquatic invertebrates, algae (both growth and biomass) and aerobic bacteria under acute exposure conditions. Reproduction effects on aquatic invertebrates are not expected.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

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

The notifier has specified that eight laundry detergent manufacturing sites will use the product containing the notified substance. Wastes generated at these sites should be limited to the residues of empty product packaging disposed of to a secure landfill site or by incineration. The notifier estimates the volume of these residues at 5 to 10 g per bag, or 7.4 to 14.8 kg notified substance per year at maximum import volumes.

The major environmental exposure will result from the discharge of commercial and domestic wastewaters to municipal sewage treatment systems. The notifier has calculated the Predicted Environmental Concentrations (PEC) at 0.42 μg/L (city) and 2.35 μg/L (country), based on a single use application scenario. This scenario is based on the following assumptions: 20% of households use detergent containing 0.2% Tinosorb FD, 75% fixation, 9 washes per week (1.3 per day) per household with each wash using 108 L.

As use of the detergent products is expected to be widespread across Australia. A worst case

scenario was calculated where a concentration of 7.5 µg/L is predicted if all of the imported chemical remains dissolved in sewage waters (assuming: 29.7 tonnes maximum annual use, 75% fixation rate, an Australian population of 18 million and a daily per capita waste water discharge of 150 L). This is well below levels that have been shown to be non-toxic to aquatic species.

Both calculations show that the exposure to fish, aquatic invertebrates, algae and wastewater treatment microorganisms will be at levels unlikely to cause any deleterious effects. Once in the aquatic environment, the substance is expected to be swiftly diluted to undetectable concentrations and be removed through a combination of chemical and biological degradation, photodegradation and sorption to particulates.

The only other source of environmental contamination is from accidental spills and disposal of end-use product packaging. The MSDS provides adequate information to enable workers to limit the environmental exposure and therefore the environmental effects due to spillage. The volume of notified substance remaining in empty detergent product packaging would be minimal, with disposal expected to both landfill and recycling facilities. The notified substance is expected

Overall, the environmental hazard due to the importation and use of the product containing the notified substance is expected to be very low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical exhibited very low acute oral and low dermal toxicity in rats with LD_{50} values of > 5 000 mg/kg and > 2 000 mg/kg, respectively. However, it is moderate to severe irritant to the eyes of rabbits. The eye irritant study showed iris inflammation, redness of the conjunctiva, chemosis and corneal opacity. Vascularisation of the cornea was also observed. Eye effects were persistent. The notified chemical is a slight skin irritant, but not a skin sensitiser in guinea pigs. Inhalation toxicity data was not provided. The notified chemical contains approximately 66% of particles in the inspirable range and 6.5% in the respirable range. It is possible that secondary ingestion of inspired particles could occur; however, direct toxicity resulting from respirable particles is not anticipated.

In a 28-day oral repeat-dose toxicity, there was no health effects detected at 150 mg/kg/day and therefore No Health Effect Level (NOEL) was determined to be 150 mg/kg/day. The notified chemical was non-mutagenic in a bacterial mutation assay and was found to be non-clastogenic to CHL cells *in vitro*.

The notifier provided a summary of the toxicokinetic data for the notified chemical (Mentzel U, 1997). The summary states that dermal absorption of FAT 75606/A would be negligible under normal conditions based on its physico-chemical properties, namely that partition coefficient of – 2.5 is below the partition coefficient of – 1, suggested as the value below which penetration of the stratum corneum would not occur. The summary further suggests

that exposure to FAT 75606/A via inhalation is also low because of the small proportion (6.5%) of particle size less than 6.6 µm (respirable) present in FAT 75606/A. The systemic effects observed in a 28-day study indicate that FAT 75606/A is absorbed in the gastro-intestinal tract, especially in the high dosed animals. However, there is insufficient data to determine if FAT 75606/A is eliminated via the faeces or urine following absorption by oral route.

Based on the persistent eye irritant effects, the notified chemical, FAT 75606/A, would be classified for health effects as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a). It will warrant the Risk phrase R41, risk of serious damage to eyes. The commercial product Tinosorb FD will also require this risk phrase and a reference to the Material Safety Data Sheet (MSDS) on the label. End use products will contain the commercial Tinosorb FD at 0.1 to 0.3% by weight . Given that the notified chemical will be present in the formulated detergent product at very low levels (0.06 to 0.18%), the end use product would not be classified as a hazardous substance and would not require risk phrases solely on consideration of the notified chemical.

Waterside, warehouse and transport workers will only be exposed to the notified chemical, FAT 75606/A, in the event of accident or damage to packaging. The occupational health risk to these workers is negligible, particularly considering the small packaging and the sturdy receptacles designed for international transport of the product containing the notified chemical.

Re-packing operators would handle the product containing the notified chemical, in the commercial form of the product Tinosorb FD, when weighing out the requisite amounts to supply samples and materials for mill trials. Dermal and inhalation exposure to the notified chemical can occur while carrying this task. Given the skin irritation and persistent eye irritation of the notified chemical, it is important that topical exposure to the notified chemical and dust is controlled. The exposure control mechanisms identified as operating at the notifier's warehouse, namely down flow ventilation and the wearing of skin, eye and additional respiratory protection will be required.

During detergent manufacturing process, dermal and inhalation exposure to batch weighing operators can occur when weighing the commercial product, Tinosorb FD, in preparation for manufacturing process. The notified chemical contains a small proportion (6.5%) of the respirable fraction (<6.6µm). Furthermore, the notified chemical will not be sold neat (100% concentration) but will only be available in the commercial form, which is presented as granules and contains adjuvants and other ingredients. However, as exposure to the commercial product containing the notified chemical may occur during the weighing process, the exposure controls identified in the submission, namely local exhaust as well as the use of enclosed mixing systems, will reduce airborne exposure. Submitted data also indicates these workers will use respiratory protection. There is the potential for weighers to become contaminated with the notified chemical during this activity. Once exposed, dermal absorption is not expected to be high, given the dry formulation, the high molecular weight and the low partition coefficient. Personal protective equipment is needed to reduce exposure

and the risk of topical skin effects. The detergent manufacturing process is carried out using an enclosed system, therefore occupational exposure for detergent manufacturing machine operators and laboratory technicians, who may handle the diluted solutions containing 0.1 to 0.3% of Tinosorb FD, should be low and would not result in adverse health effects.

The notifier provided some theoretical inhalation exposure data for workers involved in weighing the notified chemical. The estimate covers workers handling 50 kg of the commercial product Tinososorb FD per shift, for a duration of 0.5 hours. The estimate covers the weighing of 15 tonnes of Tinosorb FD per year in the one plant. This is the maximum tonnage handled per plant, as provided in the submission. Daily airborne exposure per worker is 2.1 mg. The rationale for this exposure estimate is not provided. However, it corresponds to a daily exposure of 0.03 mg/kg bodyweight, for an average 70 kg worker. When compared to the NOEL of 150 mg/kg bodyweight per day, and assuming 100% inhalation absorption, the margin of exposure is 5 000. This assumes that no other airborne exposure occurs to the chemical except during the weighing process. It also does not account for any dermal exposure and absorption. Nevertheless, it suggests that the risk of systemic toxicity is low, particularly considering that additional exposure controls would also be operating.

The potential for public exposure to the notified chemical during transport, product formulation and use or from disposal is assessed as negligible. Although the public will make dermal contact with fabrics treated with products containing the notified chemical, exposure is assessed to be negligible because of the low concentration of the notified chemical in the products. In addition, in the "fixed state" of the notified chemical in fabrics from which the notified chemical is not expected to leach out, the notified chemical is not expected to be dermally absorbed.

13. RECOMMENDATIONS

To minimise occupational exposure to FAT 75606/A 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, 1998);
- 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 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.

14. MATERIAL SAFETY DATA SHEET

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

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.

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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