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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Component in TINOCAT® TRS KB1/ TINOCAT® TRS KB2

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Director
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

Component in TINOCAT® TRS KB1/ TINOCAT® TRS KB2

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Specialty Chemicals Pty Ltd (ABN 97 005 061 469)
235 Settlement Road
Thomastown VIC 3074

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

- Chemical Name
- Other Names
- CAS Number
- Molecular Formula
- Structural Formula
- Molecular Weight
- Spectral Data
- Methods of Detection and Determination
- Purity
- Hazardous Impurities & weight %
- Non-hazardous Impurities & weight %
- Additives/Adjuvants
- Import volume
- Use
- Identity of Recipients

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
The chemical was previously notified as CEC/685 (November 2005). This application was rejected on the basis that a CEC cannot be used for chemicals in end-use consumer products such as cosmetics and domestic cleaners.

NOTIFICATION IN OTHER COUNTRIES
Europe
United States
Korea
China
Japan (limited)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Manganese catalyst with an organic tripodal ligand
TINOCAT® TRS
FAT 80240
FAT 80`240

MARKETING NAME(S)
TINOCAT® TRS KB1 (contains <10% of the notified chemical)
TINOCAT® TRS KB2 (contains <10% of the notified chemical)

METHODS OF DETECTION AND DETERMINATION

METHOD	IR-Spectroscopy
Remarks	Reference spectrum provided
TEST FACILITY	Ciba (2002)

METHOD	UV/Vis- Spectroscopy Conducted in accordance with OECD TG No. 101
Remarks	Reference spectrum provided
TEST FACILITY	Ciba (2002)

METHOD	ESI-MS Spectroscopy
Remarks	Reference spectrum provided
TEST FACILITY	Ciba (2002)

METHOD	MALDI Spectroscopy (matrix-assisted laser desorption/ionisation mass spectrometry)
Remarks	No reference spectrum provided
TEST FACILITY	Ciba (2002)

3. COMPOSITION

DEGREE OF PURITY
High

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported in 25 kg fibreboard cartons with polyethylene liners as <10% component of TINOCAT® TRS KB1 or TINOCAT® TRS KB2.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<1	<1	<1	<1	<1

USE
Oxidation catalyst for laundry care products and automatic dishwasher powder/tablets.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne, Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Ciba Specialty Chemicals Pty Ltd
235 Settlement Road
Thomastown VIC 3074

TRANSPORTATION AND PACKAGING
The notified chemical will be imported as a <10% component of TINOCAT® TRS KB1 or

TINOCAT® TRS KB2 in 25 kg plastic liner fibreboard cartons and transported by road to the Ciba Specialty Chemicals sites in Wyong and Thomastown for distribution to formulators. The packaging is intended and designed for international transport. The formulated fabric care product containing <0.2% of the notified chemical will be stored and transported in 1 or 2 kg fibreboard consumer packs. The formulated automatic dishwasher powder/tablets containing <0.01% of the notified chemical will be stored and transported in fibreboard cartons [pack sizes up to 400g (tablets) or 1 kg (powder)]. The mode of transportation is by road.

5.2. Operation description

Transportation and repackaging
Upon arriving at the wharf, TINOCAT® TRS KB1 or TINOCAT® TRS KB2 in granulated form containing <10% of the notified chemical will be transported by road to the Ciba Specialty Chemicals warehouses. It will be unloaded using a forklift from the shipping container at the Ciba Specialty Chemicals warehouse and stored in sturdy racks until required for despatch to customers. No repackaging of the product is expected to take place before reformulation.

Reformulation
Ciba Specialty Chemicals will supply TINOCAT® TRS KB1 or TINOCAT® TRS KB2 directly to its customers for reformulation. Activities at the formulation site include unloading the fibreboard cartons from the transport truck to storage and transfer of the contents of the fibreboard cartons to a closed compounding vessel. Reformulation consists of weighing and addition of the notified chemical by gravity through a pipe system to a closed compounding vessel. It is mixed with other dry ingredients to produce the finished laundry care product or automatic dishwasher powder. It may also be formed into automatic dishwasher tablets in an automatic tableting machine. The process is normally conducted at ambient temperatures. TINOCAT® TRS KB1 or TINOCAT® TRS KB2 will be added to the laundry care product at a level of 0.5 – 2% (equivalent to < 0.2% of the notified chemical) or to the automatic dishwasher powder/tablets at 0.1% (equivalent to < 0.01% of the notified chemical). Testing of the final product will take place at the end of mixing.

The laundry care product is then transferred by means of an automatic dosing system to plastic or fibreboard laundry care containers. The automatic dishwasher powder/tablets are transferred by means of an automatic dosing system to plastic or fibreboard containers. The end products will be packaged in boxes for storage before being transported to supermarkets and/or retail shops for sale.

End use
Workers at supermarkets and/or retail shops will unload the boxes from a truck and stack them in a storage room. When needed, workers will remove the end product containing the notified chemical from the boxes and stack them on shelves for sale to the general public.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport drivers	2 – 6	30 – 60 mins per trip	10 - 20 days per year
Warehouse personnel	3 - 5	20 - 30 mins per load or unload	10 - 20 days per year
Storepersons	3 - 6	20 – 30 mins per unload	12 days per year
Quality Control technicians	5 - 10	3 h per day	24 days per year
Production operators	5 - 10	8 h per day	24 days per year

Exposure Details

Transport drivers, storage and warehouse personnel during importation, formulation and end uses may be potentially exposed to spilled products from damaged containers in the case of accidents.

Dermal and inhalation exposure may potentially occur during reformulation processes involving the notified chemical. The main exposure to the notified chemical is likely to occur during weighing and feeding of the powder into the compounding vessel and testing of the final product. However, the

notifier indicated that the imported products TINOCAT® TRS KB1 and or TINOCAT® TRS KB2 has been formulated as non-dusting granules to minimise inhalation exposure. In addition, all workers involved in the formulation process wear PPE. Local exhaust ventilation is employed during the weighing and transfer of the imported products to the compounding vessel.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The products containing the notified chemical (<10%) will be imported into Sydney and Melbourne by sea and will be transported by road to the Ciba Specialty Chemicals warehouses in Wyong (NSW) and Thomastown (VIC).

The imported products are mixed with other dry ingredients to produce the finished laundry care product or automatic dishwasher powder. They may also be formed into automatic dishwasher tablets in an automatic tableting machine. The process is normally conducted at ambient temperatures. The products will be added to the laundry care product at a level of 0.5 – 2% (equivalent to < 0.2% of the notified chemical) or to the automatic dishwasher powder/tablets at 0.1% (equivalent to < 0.01% of notified chemical). The laundry care product is then transferred by means of an automatic dosing system to plastic or fibreboard laundry care containers. The automatic dishwasher powder/tablets are transferred by means of an automatic dosing system to plastic or fibreboard containers. The end products will be packaged in boxes for storage before being transported to supermarkets and/or retail shops for sale.

During formulation annual environmental exposure of the products containing the notified chemical will result from the following pathways:

- < 1% generated from cleaning up minor spills and quality control testing
- < 2% from manufacturing process
- < 1% left in empty containers

RELEASE OF CHEMICAL FROM USE

Release of the notified chemical to the environment will be Australia wide as a result of household use in washing machines, hand wash soaking or automatic dishwashing machines. Minor residual amounts in 'empty' consumer packages are likely to go to landfill.

5.5. Disposal

The notified chemical is a prescribed waste and any contaminated or redundant chemical can be disposed by incineration. Waste produced during manufacture will be collected by licensed waste contractors and be incinerated.

5.6. Public exposure

The public may be exposed to the notified chemical in the unlikely event of an accident during transportation, distribution and at retail outlets.

The potential for contact with the skin or eyes of people is possible during use of the fabric care products for the machine cloth washing or for use in automatic dishwashing machines, either directly to the skin or eyes or indirectly via residue materials in laundered clothes and washed dishes. Greater potentials for exposure to the skin or eyes exist if the fabric care product is used for hand-washing.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Dark green to black powder (the notified chemical) Blue granules (TINOCAT® TRS KB1 and or TINOCAT® TRS KB2)
Melting Point	>110°C

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.

Remarks	Determined by differential scanning calorimetry. The melting point could not be determined beyond 110°C due to decomposition.
TEST FACILITY	Solvias AG (2003a)

Boiling Point >110°C at 101.3 kPa

METHOD	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	The boiling point could not be determined beyond 110°C due to decomposition.
TEST FACILITY	Solvias AG (2003b)

Density 1430 kg/m^3 at 22°C

METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Determined with air comparison pycnometer
TEST FACILITY	Solvias AG (2002a)

Vapour Pressure <3 x 10^{-15} kPa at 25°C (estimated highest value)

METHOD	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Estimated using EPA MPBPVP Program based on the lowest value for melting point
TEST FACILITY	Solvias AG (2003c)

Water Solubility Not performed

METHOD	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	From the hydrolysis as a function of pH results, it is known that the test substance is significant sensitive to hydrolysis and has poor solubility.
TEST FACILITY	Solvias AG (2003d)

Hydrolysis as a Function of pH A fast hydrolytic degradation could be observed in the pH range 1 to 7. At pH > 7 the solubility of the notified chemical is too poor for further experiments.

METHOD No standard guideline test used. Due to lack of applicable analytical method to analyse the notified chemical, only preliminary test was performed. No HPLC method could be established without decomposing the test substance. Preliminary experiments were done with an UV/Vis spectrophotometer.

pH	*t½*
1 - 2	Nearly complete degradation of the notified chemical takes place within <10 minutes at room temperature.
4 - 6.9	A very fast degradation is observed.
7 - 13.5	The solubility of the notified chemical is too poor even in the presence of dimethylformamide (co solvent) to study the hydrolytical behaviour.

Remarks	In none of the aqueous solutions the typical absorbance for a Mn (III) complex at the wavelength of about 600 nm could be observed, which is a clear indication for hydrolysis. The absorption spectra after the addition of 0.1 HCl, pH 4 and pH 7 were taken at different times. The results indicated that multi step reaction takes place.
TEST FACILITY	Solvias AG (2003e)

Partition Coefficient (n-octanol/water) Not performed

METHOD OECD 107 Partition Coefficient (n-octanol/water): Shake Flask Method
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Due to the strong sensitivity of the notified chemical to hydrolysis, no partition coefficient measurements could be performed.
TEST FACILITY Solvias AG (2003f)

Adsorption/Desorption Not performed

METHOD OECD 121 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography
EC Directive 2001/59/EC C.19 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography
Remarks The notified chemical is not stable in aqueous solution, hydrolysis occurs immediately by contact with water. Therefore, the adsorption coefficient (K_{oc}) could not be determined using the HPLC method.
TEST FACILITY RCC Ltd (2003a)

Dissociation Constant Not performed

METHOD OECD TG 112 Dissociation Constants in Water.
Remarks Due to the strong sensitivity of the notified chemical to hydrolysis and the very poor solubility in the pH range above 7, no measurements obtaining the dissociation constant could be performed.
TEST FACILITY Solvias AG (2003g)

Particle Size Median of size distribution: 16.70µm

METHOD OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Range (µm)	*Mass (%)*
≤5.00	12.77
≤10.50	24.62
≤18.00	55.30
≤51.00	99.64
≤61.00	100.00

Remarks Measured by a technique based on the principle of light diffraction.
TEST FACILITY Solvias AG (2002b)

Flash Point Not performed

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks The notified chemical is a solid.

Flammability Limits Not considered highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids)
Remarks A preliminary test to determine if propagation by burning with flame or smouldering occurs, followed by a full test on burning rate.
TEST FACILITY Institute of Safety & Security (2002a)

Autoignition Temperature 134ºC

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids
TEST FACILITY Institute of Safety & Security (2002b)

Explosive Properties Not considered an explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks The result is based on test results for thermal sensitivity (effect of a flame) and mechanical sensitivity (shock and friction).
TEST FACILITY Institute of Safety & Security (2002c)

Reactivity

Remarks The notified chemical has been tested for oxidising properties and found not to be an oxidising chemical. There are currently no incompatible chemicals known for the notified chemical although there is strong hydrolytic behaviour in contact with water. Therefore, the notified chemical should be protected from humidity. The notified chemical should also be protected from heat (sensitive to temperatures above 40°C). Thermal decomposition or burning is likely to release carbon and nitrogen oxides.

ADDITIONAL TESTS

Surface Tension 72.6 mN/m at 20ºC

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Digital Tensiometer method. A correction factor of 0.9905 was found. All instruments reading were multiplied by this value to obtain the surface tension.
TEST FACILITY Solvias AG (2003h)

Oxidising Properties Not an oxidising chemical

METHOD EC Directive 92/69/EEC A.17 Oxidising Properties (Solids).
Remarks Measured as an effect on burning of Barium nitrate.
TEST FACILITY Institute of Safety & Security (2002d)

Pyrophoric Properties Not considered a pyrophoric chemical

METHOD EC Directive 92/69/EEC A.13 Pyrophoric Properties (Solids).
Remarks Six trials were conducted. The principle is to observe if the notified chemical ignites when it is in contact with air at ambient temperature for five minutes.
TEST FACILITY Institute of Safety & Security (2002e)

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	Low toxicity (LD50 >2000 mg/kg bw)
Rat, acute dermal	Low toxicity (LD50 >2000 mg/kg bw)
Rat, acute inhalation	Not performed
Rabbit, skin irritation	Non-irritating
Rabbit, eye irritation	Non-irritating
Guinea pig, skin sensitisation - adjuvant test	Evidence of sensitisation
Skin sensitisation – LLNA	Non-sensitiser
Skin sensitisation – LLNA (TINOCAT® TRS KB1)	Non-sensitiser
Rat, oral gavage, repeat dose toxicity - 28 days	NOAEL = 50 mg/kg bw/day
Genotoxicity - bacterial reverse mutation	Non mutagenic
Genotoxicity – in vitro chromosome aberration test (Chinese hamster)	Clastogenic without activation
Genotoxicity – in vivo chromosome aberration test (bone marrow)	Non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.

Species/Strain: Rat/HanBrl: WIST (SPF)
Vehicle: PEG 300
Remarks - Method: The test substance was diluted in vehicle at a concentration of 0.2 g/mL and administered to the rat via oral gavage at a volume of 10 mL/kg.

All animals were examined for clinical signs at approximately 1, 2, 3, and 5 hours after treatment on day 1 and once daily during test days 2-15.

Mortality/viability was recorded daily during test days 1-15. Body weights were recorded on day 1, 8 and 15. All animals were necropsied and examined macroscopically.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3/sex	2000 mg/kg bw	0

LD50: > 2000 mg/kg bw
Signs of Toxicity: None
Effects in Organs: None
Remarks – Results: The body weight of the animals was within the range commonly recorded for this strain and age.

CONCLUSION: The notified chemical is of low toxicity via the oral route.

TEST FACILITY: RCC Ltd. (2002a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain	Rat/ HanBrl: WIST (SPF)
Vehicle	PEG 300
Type of dressing	Semi-occlusive
Remarks - Method	The test substance was diluted in vehicle at a concentration of 0.5 g/mL and applied onto the rat skin at a volume of 4 mL/kg for 24 hours. All animals were examined for clinical signs at approximately 1, 2, 3, and 5 hours after treatment on day 1 and once daily during test days 2-15. Mortality/viability was recorded twice daily during test days 1-15. Body weights were recorded on day 1, 8 and 15. All animals were necropsied and examined macroscopically.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000 mg/kg bw	0

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	A slight green-yellow staining was present at the test site of all animals from day 2 to 7.
Signs of Toxicity - Systemic	None
Effects in Organs	None
Remarks – Results	The body weight of the animals was within the range commonly recorded for this strain and age.
CONCLUSION	The notified chemical of low toxicity via the dermal route.
TEST FACILITY	RCC Ltd. (2002b)

7.3. Acute toxicity – inhalation

TEST SUBSTANCE	Not performed

7.4. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (1 male and 2 females)
Vehicle	Purified water
Observation Period	72 h
Type of Dressing	Semi-occlusive
Remarks - Method	0.5 g test substance was administered by topical semi-occluisive application for 4 hours before being removed for observations. All animals were examined for clinical signs, mortality/viability, and body weights on the daily basis. Skin irritation score was assessed according to the scoring system listed

in the EC Directive 92/69/EEC.

There is no significant study variation.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	0	NA	0
Oedema	0	0	0	0	NA	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal. NA, not applicable.

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY RCC Ltd. (2002c)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain Rabbit/New Zealand White
Number of Animals 3 (1 male and 2 females)
Observation Period 17 d
Remarks - Method 0.1 g undiluted test substance was placed in the conjunctival sac of the left eye of each animal. The treated eyes were not rinsed after instillation.

All animals were examined for clinical signs, mortality/viability, and body weights on the daily basis.

Ocular irritation score was assessed according to the scoring system listed in the EC Directive 92/69/EEC.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.67	1	1	1	7 d	0
Conjunctiva: chemosis	0	0	0	0	NA	0
Corneal opacity	0	0	0	0	NA	0
Iridial inflammation	0	0	0	0	NA	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal. NA, not applicable.

Remarks - Results The Primary Eye Irritation score is 0.89.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY RCC Ltd. (2002d)

7.6.1 Skin sensitisation – Guinea Pig Maximisation Test

TEST SUBSTANCE Notified chemical

METHOD: OECD TG 406 Skin Sensitisation – Guinea Pig Maximization Test (GPMT).
EC Directive 96/54/EC B.6 Skin Sensitisation – GPMT.

Species/Strain: Guinea pig/albino

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
intradermal: 1%
topical: 50%

MAIN STUDY

Number of Animals: Test Group: 10 females Control Group: 5 females

INDUCTION PHASE: Induction Concentration:
intradermal: 1%
topical: 50%

Signs of Irritation: After intradermal induction:
Expected findings (erythema, odedema, necrotizing dermatitis, encrustation and exfoliation of encrustation) were observed.

After topical induction:
Control group – discrete/patchy erythema were observed in 3 (at 24 hour) and 2 (at 48 hours) out of 5 animals.
Test group – no oedema was observed. It is not possible to determine erythema due to skin stain.

CHALLENGE PHASE

1st challenge: topical: 50%

Remarks - Method: The maximum possible concentration of test substance in PEG 400, under the conditions of the procedure, was found to be 50%.

The intradermal induction of sensitisation in the test group was performed with a 1% dilution of the test substance in PEG 400 and in an emulsion of Freud's Complete Adjuvant (FCA)/physiological saline. The epidermal induction of sensitisation was conducted for 48 hours under occlusion with the test substance at 50% in PEG 4000 one week after the intradermal induction and following pre-treatment of the test areas with 10% sodium lauryl sulfate (SLS) approximately 23.5 hours prior to application of the test substance. The control group were intradermally induced with PEG 400 under occlusion following pre-treatment with 10% SLS.

Two weeks after epidermal induction the control and test animals were challenged by epidermal applicator of the test substances at 50% in PEG 400 and PEG 400 alone under occlusive dressing.

Skin reactions were evaluated at 24 and 48 hours after removal of the dressing. Observations at 72 hours were also made for the test group only.

All animals were examined for clinical signs and mortality/viability on the daily basis. Body weights were measured at pre-test, day 1 and termination of the test.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	50% in PEG 400	0/10	5/10	NA	NA

	PEG 400 alone	0/10	0/10	NA	NA
Control Group	50% in PEG 400	0/5	0/5	NA	NA
	PEG 400 alone	0/5	0/5	NA	NA

Remarks – Results

Discrete/patchy erythema was observed in 5 test animals at 48 hours during the challenge procedure. As they did not fade but were reproducible in all 5 animals 72 hours later, the skin reactions should be regarded as a response to an allergic potential of the test article. No skin reactions were observed in the control group.

No deaths, signs of systemic toxicity, and body weight changes were observed.

CONCLUSION

There was evidence of reactions indicative of skin sensitisation to the notified chemical at a 50% challenge concentration under the conditions of the test.

TEST FACILITY

RCC Ltd (2000a)

7.6.2 Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 406 Skin Sensitisation
OECD 429 Skin Sensitisation: Local Lymph Node Assay

Species/Strain: Mouse/CBA/CaOlaHsd, females

Vehicle: Acetone:olive oil (4:1)

Remarks – Method

In a non-GLP pre-test the highest non-irritant and technically applicable test item concentration was found to be 25%.

In the main study five groups of 4 animals were treated with the test substance at concentrations of 1, 2.5, 5, 10 and 25% (w/v) by topical application to the ear lobe for 3 consecutive days.

Viability/mortality, clinical signs and body weight were observed during the study period.

No significant protocol deviations noted.

RESULTS

Concentration	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Control group	689	-
Test substance		
1%	1189	1.7
2.5%	995	1.4
5%	897	1.3
10%	885	1.3
25%	685	1.0
Positive control (HCA)		
5%	1521	2.9
10%	1372	2.6
25%	3732	7.1

HCA = α-hexylcinnamaldehyde

Remarks – Results

All treated animals survived the scheduled study period and no treatment related clinical signs and body weight changes were observed. A

stimulation index of 7.1 was observed for the positive control group at 25%, indicating that the test was valid.

CONCLUSION There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical at concentrations up to 25%.

TEST FACILITY RCC Ltd (2002f)

7.6.3 Skin sensitisation – mouse local lymph node assay (LLNA) on imported product

TEST SUBSTANCE TINOCAT® TRS KB1 (contains <10% the notified chemical)

METHOD OECD 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain Mouse/CBA/J, females
Vehicle Dimethylformamide (DMF)
Remarks – Method The maximum practicable concentration of test substance in DMF, under the conditions of the procedure, was found to be 25%.

Five groups of 4 animals were treated with the test substance at concentrations of 1, 2.5, 5, 10 and 25% (w/v) by topical application to the ear lobe for 3 consecutive days.

Viability/mortality, clinical signs and body weight were observed during the study period.

No significant protocol deviations noted.

RESULTS

Concentration	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Control group	84	-
Test substance		
1%	59	0.71
2.5%	68	0.81
5%	101	1.21
10%	66	0.79
25%	56	0.67
Positive control (HCA)		
25%	497	5.95

HCA = α-hexylcinnamaldehyde

Remarks – Results All treated animals survived the scheduled study period and no treatment related clinical signs or body weight changes were observed. A stimulation index of 5.95 was observed for the positive control group, indicating that the test was valid.

CONCLUSION There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the mixture TINOCAT® TRS KB1 at concentrations up to 25%.

TEST FACILITY CIT (2006)

7.7.1 Repeat dose toxicity – 5 day range-finding oral study

TEST SUBSTANCE Notified chemical

METHOD A summary of findings was submitted. No full study report was provided.
Species/Strain Rats/SPF-bred Wistar
Route of Administration Oral – gavage
Exposure Information Total exposure days: 5 days
Dose regimen: daily
Post-exposure observation period: none
Vehicle PEG 300

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	2/sex	0	0
II (low dose)	2/sex	200	0
III (mid dose)	2/sex	600	0
IV (high dose)	2/sex	1000	3/4

Mortality and Time to Death
One male and one female at high dose were dead on day 4 and one female of the same dose group died on treatment day 5.

Clinical Observations
Slight to moderate emaciation was observed in one male and all females at high dose from day 4 until the end of the study or until animal died. Hunched posture and abnormal gait were seen in both females, slight sedation, slightly ruffled fur and bradypnea were seen in one female at high dose in day 4. Dyspnea, hunched posture and slightly ruffled fur were seen in one male at high dose on day 4. Additionally to these signs abnormal gait and slight sedation were seen in this male rat on day 5.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Not reported.

Effects in Organs
The mean thymus weight, thymus to body weight ratio, spleen weight and spleen to body weight ratio were reduced in the one surviving male at the high dose when compared with control group.

The mean body weights were reduced by approximately 20% in males and 30% in females of the control values at high dose.

Remarks – Results
Macroscopical findings:
Reduced thymus size was noted in one male at high dose. One dark red isolated focus was seen on the adrenal glands in one female at high dose. Several reddish foci were noted on the thymus in one female at mid dose. Pelvic dilation in both sides was observed in one male at low dose.

CONCLUSION
The dose levels of 50, 150, and 500 mg/kg bw/d are proposed for the 28-day study.

TEST FACILITY RCC Ltd (2002e)

7.7.2 Repeat dose toxicity – 28 day oral study

TEST SUBSTANCE Notified chemical

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain Rat, HanBrl:WIST (SPF)-fed Wistar
Route of Administration Oral – gavage.
Exposure Information Total exposure days: 28 days

	Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	PEG 300
Remarks – Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	50	0
III (mid dose)	5/sex	150	0
IV (high dose)	5/sex	500	0
V (control recovery)	5/sex	0	0
VI (high dose recovery)	5/sex	500	0

Mortality and Time to Death

No mortality was observed during either the treatment or recovery phase.

Clinical Observations

No treatment related clinical signs and functional observational battery (including grip strength and locomotor activity) were observed.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No treatment related differences in parameters of clinical biochemistry, haematology, and urinalysis were noted when compared with controls.

Effects in Organs

Organ Weight

The mean kidney to body weight ratio was increased in females of high dose group and the mean kidney to body weight and kidney to brain weight ratios were increased in females of mid dose group when compared with controls after 4 weeks of treatment. These findings were considered to be treatment related because a dose response relationship was observed and these findings match well with the microscopic findings described below. However, they were fully reversible after a 2 week recovery period. After 4 weeks of treatment followed by a 2 week recovery period the mean kidney weight and kidney to brain weight ratio were increased in males when compared with controls. However, no effects on absolute or relative kidney weights were observed in males treated at high dose for 4 weeks.

The mean liver weights, liver to body weight and liver to brain weight ratios were increased in females of high dose group when compared with controls after 4 weeks of treatment.

No other treatment related changes in organ weights, organ to body- or organ to brain weight ratios were noted.

Macroscopic/Microscopic Findings

In the cortex of the kidneys, a dose-related increased incidence and grade of basophilic tubuli in males was found (1/5, 4/5, 5/5 in low, mid, and high dose group, respectively). This finding may be a sign of an increased tubular regeneration after a preceding tubular damage. The change was still recorded in the high dose recovery group (5/5) and was regarded as an adverse effect. As the incidence of this change in low dose group was the same as the control group (1/5), plus the change in mean kidney to body weight ratio in females was observed at the mid dose (150 mg/kg bw/day) and above, the NOAEL based on the adverse effects seen in the kidneys is determined as 50 mg/kg bw/day.

In the stomach a minimal to slight glandular ectasia was recorded at the high dose only. The slightly dilated crypts often were filled with mucus. Additionally a dose-related minimal to slight hyperkeratosis was recorded at the limiting ridge and/or the forestomach in both males and females. However, the grades and incidences of both changes decreased to normal after the recovery period. These findings were regarded as adaptive effects.

A dose-related increased incidence of minimal to slight liver cell hypertrophy was recorded but decreased to normal incidences after the recovery period. This finding was not considered to be of adverse character, but

was deemed to be an adaptive effect.

CONCLUSION
Based on the results of this study, the no-observed-adverse-effect-level (NOAEL) is determined to be 50 mg/kg bw/day based on changes in the kidneys at the next higher dose.

TEST FACILITY RCC Ltd (2003b)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC L1362000, Annex 4D
Japanese guidelines (a few)
Plate incorporation procedure and Pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, *E. coli*: WP2 uvrA
Metabolic Activation System	Rat liver S9
Concentration Range in Main Test	a) With metabolic activation: 33-5000 µg/plate. b) Without metabolic activation: 33-5000 µg/plate.
Vehicle	None
Physical Form	Solid
Remarks – Method	No significant protocol deviations.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	NA	Negative	333-5000	Negative
Test 2	NA	1000-5000	333-5000	Negative
Absent				
Test 1	NA	Negative	333-5000	Negative
Test 2	NA	2500, 5000	333-5000	Negative

Remarks – Results The notified chemical did not induce gene mutations by base pair changes or frameshifts in the genome of the strains used.

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY RCC Ltd (2003c)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
EC Directive 2000/32/EC L1362000, Annex 4A: Mutagenicity - *In vitro* Mammalian Chromosome Aberration Test
Japanese Guidelines

Species/Strain	Chinese Hamster
Cell Type/Cell Line	V79

Metabolic Activation System	Rat liver S9 mix
Vehicle	DMSO
Physical Form	Solid
Remarks – Method	A range finding preliminary test on toxicity was conducted using scores for the cell numbers 24 hours after start of treatment as an indicator for cytotoxicity. Concentrations between 5.1 and 650 µg/mL were applied. Dose selection of the cytogenetic experiments (shown in the table below) was performed considering the toxicity data and the occurrence of precipitation. No significant protocol deviations noted.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Present			
Test 1	5, 10*, 20*, 162.5*, 3.25, 650	4 h	18 h
Test 2	5, 10*, 20, 80, 160*, 320	4 h	28 h
Test 3	2.5, 5*, 7.5, 10*, 15*, 20*	4 h	28 h
Absent			
Test 1	5, 10*, 20*, 162.5*, 3.25, 650	4 h	18 h
Test 2	0.6, 1.3, 2.5*, 5*, 10*, 20	18 h	18 h
	2.5, 5*, 10*, 20	28 h	28 h
Test 3	5*, 7.5, 10*, 20*	18 h	18 h
	2.5, 5*, 7.5, 10*, 15*, 20*	28 h	28 h

*Cultures selected for metaphase analysis.

RESULTS

In the range finding preliminary test, clear toxic effects (reduced number of cells) were observed after 4 hours treatment with ≥ 81.3 µg/mL in the absence of S9 mix and with ≥ 162.5 µg/mL in the presence of S9 mix. In addition, 24 hours continuous treatment with ≥ 10.2 µg/mL in the absence of S9 mix induced strong toxic effects.

In all experiments toxic effects indicated by reduced cell numbers or reduced mitotic indices of about or below 50% of control were observed.

In test 2 and 3, after 28 hours continuos treatment in the absence of S9 mix, statistically significant increases in the number of cells carrying structural chromosomal aberrations were observed. Due to the confirmation of the genotoxic effect at partly different concentrations in test 3, these findings have to be regarded as biologically relevant, although these effects were seen only at cytotoxic concentrations.

The statistically significant increase in the number of carrying structural chromosomal aberrations observed in test 2 after 4 hours treatment at 28 hour harvest time in the presence of S9 mix was not confirmed in test 3, therefore, this observation may not be biological relevant.

No increase in the frequencies of polyploid metaphases was found after treatment with the test substance as compared to the controls.

Under the experimental conditions reported, the notified chemical induced structural chromosome aberrations as determined by the chromosome aberration test in V79 cells (Chinese hamster cell line) *in vitro*.

CONCLUSION

The notified chemical was clastogenic to V79 treated in vitro under the conditions of the test in the absence of S9 mix after 28 hours continuous treatment only.

TEST FACILITY RCC Ltd (2003d)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE Notified chemical

METHOD OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 2000/32/EC B.11 Mutagenicity - In vivo Mammalian Bone-Marrow Chromosome Aberration Test.

Species/Strain Mouse/NMRI
Route of Administration Oral
Vehicle Corn oil
Remarks – Method A preliminary study on acute toxicity was performed with 2 animals per sex received a single dose of 2000 mg/kg bw under identical conditions as the main study. Acute toxic symptoms were observed at interval of around 1, 2-4, 6, 24, 30 and 48 hours.

At least 2000 polychromatic erythrocytes (PCEs) per animal were scored for micronuclei. The ratio between polychromatic and total erythrocytes was determined and reported as the number of PCEs per 2000 erythrocytes.

No significant protocol deviations

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time Hours*
Low dose	6/sex	500	24 h
Medium dose	6/sex	1000	24 h
High dose	6/sex	2000	24, 48 h

RESULTS

Doses Producing Toxicity In the preliminary test, the animal did not express any toxic reactions. Therefore, 2000 mg/kg bw was used as the highest dose for the main study.

In the main study, a number of symptoms (reduction of spontaneous activity, abdominal position, eyelid closure and ruffled fur) were observed in a few (less than 4) females at 2000 mg/kg bw dose group. reduction of spontaneous activity and ruffled fur were also seen in a couple of male mice at dose level of 500mg/kg bw, but all these symptoms were recovered by 24 hours.

Genotoxic Effects The number of PCEs was not substantially decreased in the treated groups compared to the controls.

Remarks – Results During the study and under the experimental conditions reported, the notified chemical did not induce micronuclei as determined by the micronucleus test with bone marrow cells of the mouse.

CONCLUSION The notified chemical was not clastogenic in this in vivo micronucleus assay under the conditions of the test.

TEST FACILITY RCC Ltd (2003e)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301F: Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Remarks - Method	The concentration of the notified chemical used was 100 mg/L. As the notified chemical was not completely soluble in the test medium (< 50 mg/L) it was added directly into the test system without preparation of stock solution.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	14	2	38
4	36	4	56
6	42	6	66
12	49	12	79
18	52	18	86
22	54	22	86
24	54	24	86
28	55	28	87

Remarks - Results	The biodegradation of the notified chemical was determined as 55% after 28 days of incubation. The test substance did not reach the pass level of 60% for ready biodegradation. In the toxicity control no inhibition effect was observed (pass level of 25% after 28 days was reached).
CONCLUSION	The notified chemical is not ready biodegradable under the test conditions.
TEST FACILITY	Solvias (2002c)

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – semi static conditions EC Directive 92/69/EEC C.1
Species	Zebrafish (*Danio rerio*)
Exposure Period	96 h
Auxiliary Solvent	none
Water Hardness	142 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	As the notified chemical is prone to hydrolysis, the first stock solution was prepared as close as practically possible to the start of the test. 400 mg of notified chemical was dissolved in 4000 mL tap water. The stock solution was homogenised by 10 minutes ultrasonication and then stirred for another 5 minutes. Due to the poor solubility, samples were filtered to

remove undissolved parts. Additionally, due to the light sensitivity of the notified chemical, the glass vessel was covered with aluminium. Sample from each concentration (blank and 100 mg/L) were drawn from the approximate centre of the test vessels. They were taken at the beginning and the end of each renewal period. Two methods were used to determine the actual concentration of notified chemical in solution. An indirect method based on a metabolite and DOC. The indirect method was based on measured concentration of salicylaldehyde as it is more water soluble than the notified chemical. To ensure the complete transformation of the notified chemical to salicylaldehyde, HCl was added to the samples. The second method was developed to measure the DOC in the notified chemical media. The reported results are related to the DOC test.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Blank	-	7	0	0	0	0	0
100	2.9	7	0	0	0	0	0

LC50	> 2.9 mg/L at 96 hours
NOEC	2.9 mg/L at 96 hours
Remarks – Results	At concentration of 100 mg/L, a slightly precipitation appeared at 72 hours. The salicylaldehyde method, the concentration of the notified chemical varied from 5.6 mg/L to 1.4 mg/L at the start and from 3.6 mg/L to 1.2 mg/L at the end of each renewal period. Using the DOC method, the notified chemical concentration varied from 3.8 mg/L to 1.4 mg/L at the start and from 3.3 mg/L to 1.7 mg/L at the end of each renewal period.

CONCLUSION The dissolve fraction of the notified chemical is considered not toxic to zebrafish under the test conditions.

TEST FACILITY Solvias (2003i)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – semi static conditions

Species	*Daphnia magna*
Exposure Period	48 h
Auxiliary Solvent	None
Water Hardness	Not determined
Analytical Monitoring	HPLC
Remarks - Method	The preparation of the notified chemical stock solutions and actual concentration analytical determination were done as described in test of acute toxicity to fish. Sample for analytical determination were taken from all concentrations at the start, at 24 and 48 hours and analysed for salicylaldehyde. For DOC, only the blank, 45 mg/L and 100 mg/L were analysed. 20 Daphnia per concentration, two beakers per concentration with 10 animals each were used for the test. The reported results are related to the average DOC test.

Concentration mg/L	*Number of D. magna*	*Number Immobilised*

Nominal	*Actual*		*24 h*	*48 h*
Blank	-	20	0	0
4.3	-	20	0	0
9.4	-	20	0	0
21	0.68	20	2	2
45	-	20	2	4
100	3.25	20	4	7

LC50	>3.25 mg/L at 48 hours
NOEC	0.68 mg/L at 48 hours
Remarks - Results	Using the DOC method, the notified chemical concentration of the freshly prepared solution were 2.1 mg/L and 4.6 mg/L at the start of renewal period of 24 hours. At the end of the renewal period, chemical concentrations in the solution were 1.7 mg/L and 0.8 mg/L. No immobilisation of daphnia was observed in the control and at nominal concentration of 4.3 and 9.4 mg/L after 24 hours and at the end of the exposure period. At a nominal concentration of 21 mg/L, 10% immobilisation was recorded at 24 and 48 hours. At a nominal concentration of 45 mg/L, 10% immobilisation was recorded at 24 hours and increases to 20% at 48 hours. At a nominal concentration of 100 mg/L, 20% immobilisation was recorded at 24 hours and increases to 35% at 48 hours.

CONCLUSION The dissolve fraction of the notified chemical is considered to be toxic to *Daphnia magna* under the test conditions.

TEST FACILITY Solvia (2003j)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	Green algae (*Selenastrum capricornutum*)
Exposure Period	72 hours
Concentration Range	Nominal: 4.3, 9.4, 21, 45, and 100 mg/L Actual: only for the highest concentration (8.7 to 8.1) mg/L
Auxiliary Solvent	None
Water Hardness	Not determined
Analytical Monitoring	HPLC
Remarks - Method	The preparation of notified chemical stock solutions and actual concentration analytical determination were done as described in test of acute toxicity to fish. Samples for analytical determination were taken from all concentrations at the start, and end of the period and analysed for salicylaldehyde. For DOC, only the samples with the highest concentration were analysed. Three replicates were carried out for each notified chemical concentration and six for the control. Additionally, the highest concentration was tested without algae and served for the determination of the particle background. The reported results are related to the DOC test. The reported values were calculated from the determined solubility of the 100 mg/L sample (an average solubility of 8.4%).

RESULTS

Biomass Experiment A *Growth Experiment A*

E_bC50 (95% CL) mg/L (0-72 h)	*NOEC* mg/L	*E_uC50 (95% CL)* mg/L (0-72 h)	*NOEC* mg/L
2.10	0.36	3.28	0.79

Remarks - Results: At nominal concentration of 9.4, 21, 45 and 100 mg/L, statistical analysis showed that the calculated areas under the growth curve (AUC) were significant reduced relative to control. After 72 hours of exposure no misshaped cells or cell-debris were observed microscopically at the nominal concentration of 4.3 mg/L. The LOEC and NOEC were determined at nominal concentration of 9.4 and 4.3 mg/L, respectively. At the 3 highest concentrations (nominal concentration of 21, 45 and 100 mg/L) the growth rates were statistically lower than controls. After 72 hours of exposure no misshaped cells or cell-debris were observed microscopically at the nominal concentration of 9.4 mg/L. The LOEC and NOEC were determined at nominal concentration of 21 and 9.4 mg/L, respectively. Referring to the highest concentration (nominal 100 mg/L), AUC and growth rate were grater than control after 24 hours and at 48 hours an inhibition of about 76% and 105% were observed, respectively. At the end of the exposure period, the inhibition values corresponding to the endpoints biomass and growth rate were about 98% and 106%.

CONCLUSION: The dissolve fraction of the notified chemical is considered to be toxic to algae under the test conditions.

TEST FACILITY: Solvia (2003k)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 209 Activated Sludge
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test

Inoculum: Activated sludge from domestic STP
Exposure Period: 3 h
Concentration Range: Nominal: 11, 19, 33, 57 and 100 mg/L
Actual: not determined
Remarks – Method: Due to the poor water solubility of the notified chemical, the test was performed by direct addition of the notified chemical to the vessels. The vessels were filled with 100 mL tap water, 3.2 mL synthetic sewer and 40 mL sludge.

RESULTS
IC50: > 100 mg/L – nominal concentration
NOEC: < 11 mg/L– nominal concentration
Remarks – Results: At all applied concentrations, the notified chemical showed no significant toxicity effect (% inhibition of respiration rate < 15%) to the activated sludge. Inhibition of the reference item varied from 16 to 87.7 %, and the IC50 (3 h) was estimated to be 9 mg/L.

CONCLUSION: The notified chemical is not considered to be toxic to activated sludge bacterias under the test conditions.

TEST FACILITY: Solvias (2003l)

8.3. Terrestrial Organism

TEST SUBSTANCE: Notified chemical

METHOD	German UBA method (1984), similar to OECD TG 207.
Species	Earthworm (*Eisenia foetida)*
Exposure Period	14 days
RESULTS	LC_{50} 437 mg/kg[3]
TEST FACILITY	Solvias (2003m)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The products containing the notified chemical (<10%) will be imported into Sydney and Melbourne by sea and will be transported by road to the Ciba Specialty Chemicals warehouses in Wyong (NSW) and Thomastown (VIC).

During formulation annual environmental exposure of the products containing the notified chemical will result from the following pathways:

- < 1% generated from cleaning up minor spills and quality control testing
- < 2% from manufacturing process
- < 1% left in empty containers

Nearly all of the notified chemical may potentially be disposed of to sewer after use, with only small quantities (10 kg per year), including that proportion remaining as residual in containers and major spills, being disposed of to landfill.

Case Study 1: Australia-Wide Release

Based on the worst-case scenario of 100% notified chemical being released to the aquatic environment via the sewer, with nil removal, a predicted environmental concentration (PEC) of the notified chemical has been calculated:

Case Study 2: Formulation Release

Assuming that the total volume of waste produced (3%) during reformulation is released to STP during 265 days per year. Based on the typical use per day, worst-case predicted environmental concentration (PEC) values are estimated for discharging into a large sewage treatment works and the other into a small sewage treatment works assuming no partitioning to sludge within the sewage treatment works.

Process or Dilution Factor	Australia-Wide Release	Formulation Release to Large STP	Formulation Release to Small STP
Concentration of notified chemical per year	970 kg	30 kg	30 kg
Typical notified chemical use expected per day	2.66 kg	0.082 kg	0.082 kg
Number of day used	365 days	265 days	265 days
Australian population	20 million	Large City	Small City
Water consumed average	200/L/person	200/L/person	200/L/person
STP daily Volume	4000 ML	100 ML	4 ML
Concentration in effluent from sewage treatment plant	0.66 µg/L	0.28 µg/L	28.3 µg/L
Predicted environmental concentrations (PECs) in receiving waters			
Ocean (Dilution Factor 1:10)			

PEC	0.07 µg/L	0.03 µg/L	2.83 µg/L
River (Dilution Factor 1:1)			
PEC	0.66 µg/L	0.28 µg/L	28.3 µg/L

The notified chemical is not stable in aqueous solution as hydrolysis occurs in contact with water. The limited water solubility seen in the toxicity results of the by-product and notified chemical (~ 2 mg/L) indicates that large proportion of the notified chemical would partition into solid phases.

There is a potential for bioaccumulation due to the limited water solubility, expected values of partitioning coefficients (~ 4 to 6) and small molecular weight of the compounds. However, it will be expected to be limited by the hydrolytic instability.

A SIMPLETREAT cannot be used for mitigation studies due to the hydrolysis of the notified chemical in water. However, assuming the lowest log H (-4) and log Kow values (6) and ready biodegradation not met. It may be predicted that 15% will remain in the water, and 85% will remain in the sludge. A total of 85% could be removed by a STP depending on the treatment type.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests are listed below.

Organism	*Duration*	*End Point*	*mg/L*
Freshwater Fish	96 h	LC_{50}	> 2.90
Freshwater Daphnia	48 h	LC_{50}	3.25
Freshwater Algae	0-72 h	E_bC_{50}	2.10
		E_rC_{50}	3.28

Using the lowest value of 2.1 mg/L and a safety factor of 100 (based on 3 experimental results) for fish/*Daphnia*/algal acute toxicity endpoints, a Predicted No Effect Concentration (PNEC) for aquatic ecosystems of 21 µg/L is estimated.

9.1.3. Environment – risk characterisation

Case Study 1: Australia-Wide Release

	Location	PEC* µg/L	PNEC µg/L	Risk Quotient (RQ)*
Notified Chemical	Ocean outfall	0.07	21	0.003
	Inland River	0.66	21	0.031

* The worst-case PEC and the RQ values calculated assuming the notified chemical is not removed during the wastewater treatment process.

The resulting risk quotient (RQ = PEC/PNEC) values for Australia-wide release to the aquatic environment, assuming that the notified chemical is not removed in the communal STP, is < 1 for freshwater and marine environment indicating an acceptable risk.

Case Study 2: Formulation Release

	Location	PEC* µg/L	PNEC µg/L	Risk Quotient (RQ)*
Large STP	Ocean outfall	0.03	21	0.001

	Inland River	0.28	21	0.013
Small STP	Ocean outfall	2.83	21	0.14
	Inland River	28.3	21	1.35

* The worst-case PEC and the RQ values calculated assuming the notified chemical is not removed during the wastewater treatment process.

The RQ values indicate concern for a small STP releasing into freshwater environment.

While this has been assumed to be all discharged from one site, the release should be divided by 3 placed, and then the RQ for release to an inland river remains < 1and acceptable.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Exposure of workers involved in transport or storage of the products containing the notified chemical during importation, reformulation and at retail outlets should only occur in the event of accidental spillage or if the packaging is accidentally breached.

During reformulation, the main workers' exposure to the notified chemical is likely to occur during weighing and feeding of the powder into the compounding vessel and testing of the final product. The most likely exposure route is dermal. Ocular exposure may also occur as a result of accidental spills. Dermal exposure is expected to be low due to the enclosed mixing system and use of PPE such as impervious gloves, coveralls and safety boots. Inhalation exposure will be limited by the low vapour pressure (< 3 x 10^{-12} Pa at 25°C), the particle size (median 16.70 µm) and ventilation including local exhaust ventilation fitted to compounding and mixing vessels. In addition, the imported products containing <10% of the notified chemical have been formulated as non-dusting granules to minimise inhalation exposure.

9.2.2. Public health – exposure assessment

Public exposure to the notified chemical during transport and distribution and at retail outlets is predicted to be minimal. The potential for contact with the skin and eyes during use of the automatic dishwasher products or fabric care products for the machine washing of clothes, either directly to the skin or indirectly via residue material in laundered clothes, is low. Exposure to the skin or eyes may occur if the fabric care product is used for hand-washing but is expected to be low given the low concentration of the notified chemical in the fabric care product (<0.2%).

9.2.3. Human health – effects assessment

The notified chemical was of very low acute oral toxicity in rats (LD_{50} > 2000 mg/kg) and very low acute dermal toxicity in rats (LD_{50} > 2000 mg/kg).

The notified chemical was not irritating to rabbits by skin contact and is slightly irritating to the eyes. The notified chemical showed skin sensitising potential in guinea pigs but not in a LLNA test in mice. Although the LLNA test is the preferred test method in determining the skin sensitisation potential of a chemical, the LLNA test was conducted at up to 25% of the notified chemical whereas the GPMT was conducted at 50%. In addition, the skin reactions observed in 5/10 test animals at 48 hours during the challenge stage of the GPMT were reproducible in all 5 animals at 72 hours. Therefore, hazard classification of skin sensitisation (R43) for the notified chemical is warranted. However, TINOCAT® TRS KB1 (which contains <10% the notified chemical) was negative in a LLNA test in mice, and therefore the notified chemical as introduced is unlikely to induce a skin sensitisation reaction.

Adverse effects on the kidneys (a dose-related increased incidence and grade of basophilic tubuli in the cortex) was observed in a 28 days repeated dose study at dose of 150 mg/kg/day and above in male rats. A NOAEL of 50 mg/kg/day was determined.

The notified chemical was not mutagenic in the Salmonella typhimurium and Escherichia coli reverse mutation assay and not mutagenic in bone marrow cells of mice as measured by

micronucleus assay. However, it was clastogenic as measured by induction of chromosomal aberrations in V79 cells.

Hazard classification for health effects.
Based on the results of the GPMT sensitisation assay, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

The notified chemical is only introduced into Australia in the closely related products TINOCAT® TRS KB1 and TINOCAT® TRS KB2. Based on the results of a LLNA test in mice, TINOCAT® TRS KB1 is not classified as hazardous in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). In addition, based on the results of the LLNA test in mice using TINOCAT® TRS KB1, the closely related product TINOCAT® TRS KB2 is also not classified as hazardous. This is due to the fact that the concentration of the notified chemical is not significantly different in the two TINOCAT TRS products; and the differences between the two products with respect to the additional ingredients are minor and are not considered to affect the sensitisation potential of the products.

9.2.4. Occupational health and safety – risk characterisation

The imported products containing <10% of the notified chemical are to be formulated to very low concentrations in finished products (< 0.2%). As the notified chemical is a skin sensitiser, it may be expected that repeated or prolonged contact with skin may lead to irritant effects. However the imported products containing <10% of the notified chemical are not classified as skin sensitisers based on an LLNA study on one of the products. The risk of sensitisation effects in workers when handling the notified chemical as introduced is therefore expected to be low. In addition, the risk of local and systemic effects will be mitigated by the mainly enclosed formulation process, local exhaust ventilation, and use of PPE.

9.2.5. Public health – risk characterisation

Users of the finished products containing the notified chemical are likely to be exposed frequently to the formulation. Thus, the general public is expected to have intermittent dermal exposure and possibly accidental ocular and oral exposure to the notified chemical. However, the risk of skin sensitisation will be limited by the low concentration of the notified chemical within the finished product (maximum 0.2%) and short duration of product handling. At 0.2% the product is not expected to be sensitising. However, if the concentration is proposed to increase above the concentration cut-off for classification as a sensitiser (1%), the risk of skin sensitisation will need to be reconsidered.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

- R43: May cause sensitisation by skin contact

and

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard Category	Hazard Statement
Skin Sensitisation	1	May cause an allergic skin reaction

10.2. Environmental risk assessment

The notified chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is low concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is insignificant concern to public health when used in laundry care products and dishwasher powders/tablets.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of TINOCAT® TRS KB1 and TINOCAT® TRS KB2 provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The labels for TINOCAT® TRS KB1 and TINOCAT® TRS KB2 provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:
  - R43: May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified chemical (unless the product/mixture has been tested for its sensitisation potential as a whole):
  - Conc ≥1%: R43 May cause sensitisation by skin contact

CONTROL MEASURES
Occupational Health and Safety

- As the notified chemical is a skin sensitiser, employers should determine whether it is necessary to carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of the health effect.

- Sensitised workers should be advised not to further handle the notified chemical.

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - a downdraft weighing booth or efficient local exhaust ventilation should be used during operations involving handling the notified chemical.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - face shield or safety goggles
  - respiratory protection where inhalation of dust may occur
  - protective gloves
  - industrial clothing

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed by incineration.

Emergency procedures

- Spills or accidental release of the notified chemical should be collected by licensed waste contractors and be incinerated.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
  - the consumer product contains ≥1% of the notified chemical.

or

(2) Under Section 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

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