File No: STD/1043

July 2003

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Preparaet 2003

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Heritage.

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Specialty Chemicals Pty Ltd (ABN/ACN 005 061 469) 235 Settlement Rd 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, CAS No., impurities, spectral data, molecular and structural formulae, molecular weight, import volume, identity of manufacturing sites.

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)
None.

NOTIFICATION IN OTHER COUNTRIES
USA.

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Preparaet 2003

MARKETING NAME(S)
The commercial form of the notified chemical to be imported contains another optical brightener. The MSDS for this product was provided by the notifier.

SPECTRAL DATA

ANALYTICAL METHOD	Ultraviolet/visible (UV/Vis), Infrared (IR) and ^{1}H and ^{13}C nuclear magnetic resonance (NMR) spectroscopy
Remarks	The spectra were consistent with the proposed structure.
TEST FACILITY	Ciba Specialty Chemicals.

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	HPLC, GC and elemental analysis
Remarks	The purity of the notified chemical was determined.
TEST FACILITY	Ciba Specialty Chemicals.

3. COMPOSITION

DEGREE OF PURITY
High.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

By-products related to the notified chemical at < 10%.

ADDITIVES/ADJUVANTS

A second optical brightener is used in the commercial form of the notified chemical.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
In a commercial form in 20 kg bags stretch wrapped on to pallets.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 50	< 50	< 50	< 50	< 50

USE
Optical brightener in laundry detergent.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Sydney, Brisbane, Melbourne.

IDENTITY OF MANUFACTURER/RECIPIENTS
Up to 15 manufacturing plants.

TRANSPORTATION AND PACKAGING
The notified chemical is imported in 20 kg bags and the formulated detergents will be packed into typical consumer cardboard and plastic containers to be transported mainly by road.

5.2. Operation Description

The granular form of the notified chemical is manually weighed out and transferred to a mixing vessel of 2000 L or 5000 L capacity for the blending of dry or liquid laundry detergents, respectively. Approximately 20 – 25 kg of the commercial form of the notified chemical will be used daily on the days of production. Following blending and sampling, finished products containing < 1% notified chemical are automatically filled into containers and shipped to customers.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Repacker at notifier's warehouse	2	15 – 20 minutes per day	10 days per year
Storeperson	15	1 hour per day	150 days per year
Weigher/charger	"	2 hours per day	"
Blender/packer/machine operator	"	4 hours per day	"
Laboratory technician	"	0.5 hours per day	"

Exposure Details

The weighing and repackaging operators are potentially exposed to the greatest atmospheric concentration and this is minimised by the use of local exhaust ventilation and a low dusting granular form. Given the relatively small amount of the notified chemical (less than a full 20 kg bag) added to the mixing vessel dermal and secondary ocular exposure will be slight and is likely to be controlled by the use of gloves and chemical goggles or safety glasses.

During transport and storage, workers will handle sealed containers of the imported brightener product. All other workers apart from weighing operators will handle the notified chemical only in the form of finished laundry detergents.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Customers of the notifier will blend the notified chemical into the detergents at their facilities. The waste from the blending process is expected to be limited to traces remaining from the clean-up of spills, residues in empty packaging and discharges to plant effluent systems. At the end of the formulating campaign, the formulating and packing equipment is cleansed and cleansings are included in the next batch. Release during the formulation process is expected to be small as almost exclusively closed and automated systems are used.

Residues of the notified chemical of up to 100 kg per annum are expected to remain in the bags in which the commercial form of the chemical is imported. The notifier expects that due to the high unit value of the material and the high cost of removal from plant effluents most of the residues are reliably shaken off before the bags are recycled or disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

Since the notified chemical will be used in industrial and household laundry detergent formulations, a diffuse release from domestic and commercial washing machines is expected. Under Australian wash conditions, the notified chemical is expected to show high exhaustion rates during the wash cycle, high fixation rates during the rinse cycle and high wash fastness during subsequent washing. Data provided show approximately 80% of the notified chemical is expected to be fixed on the textile after a usual washing procedure. Due to the high level of exhaustion and fixation achieved (at least 80%), a maximum of 10,000 kg of the notified chemical is expected to be released to the sewer per annum.

Release due to residues in consumer product containers is expected to be low. These containers, which will vary in size and construction material, will be disposed of to landfill.

5.5. Disposal

During formulation, the emptied import containers are shaken to remove most of the residues off and may be sent to a recycler, or sent to landfill for disposal. The MSDS advises that spilled notified chemical, imported form containing the notified chemical or contaminated empty import containers must be disposed of as chemical waste.

From end use the notified chemical released from domestic and commercial washing machines will ultimately be disposed of in either the sewer (major) or landfill. The emptied consumer product containers are expected to be disposed of to landfill through domestic and industrial garbage disposal.

5.6. Public exposure

Public exposure during transport of imported products containing the notified chemical should be low and unlikely to occur except in the event of a transport accident. The public are also unlikely to be exposed during reformulation of the notified chemical into detergent products from chemical wastes disposed of in landfill or from recycling of import containers. Exposure of the public to detergent products should be widespread but as the notified chemical is present at a maximum concentration of 0.8%. Exposure of the public following release to the environment should also be low.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Yellowish powder (test article).

Melting Point/Freezing Point No melting point up to 379°C where exothermic degradation occurs.

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
TEST FACILITY Solvias (2002a).

Boiling Point No boiling point up to 379°C where exothermic degradation occurs.

METHOD OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
TEST FACILITY Solvias (2002b).

Density 1600 kg/m^3 at 23°C

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
TEST FACILITY Solvias (2002c).

Vapour Pressure < 10^{-8} kPa at 25°C (estimated).

METHOD OECD TG 104 Vapour Pressure and EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks An estimated boiling point value of 1223.57°C and an estimated melting point value of 349.84°C were used to estimate the vapour pressure using MPBPWIN v1.40. Three vapour pressure estimates were derived using the Antoine Method, Modified Grain Method and the McKay Method and the result of the Modified Grain Method was selected (4 x 10^{-33} kPa).

The Henry's Law constant (H) calculated from the molecular weight, the measured water solubility, and the estimated vapour pressure according to the following equation: H = MW (g/mol) x Vapour Pressure (Pa)/Water Solubility (mg/L) is H = 3.54 x 10^{-31} Pa m^3/mol.

Accordingly, the test substance is essentially non-volatile (Mensink e*t al*. 1995).
TEST FACILITY Solvias AG (2002d).

Water Solubility 8.92 g/L at 20°C

METHOD OECD TG 105 Water Solubility and EC Directive 92/69/EEC A.6 Water Solubility (Flask Method).
Remarks About 2.5 g of the test substance was added to 25 mL double distilled water in each of three flasks and the resulting suspensions were agitated in a water bath at 30°C. After 24, 48 or 72 hours, the suspensions were allowed a further 24 hours at 20°C to equilibrate and then filtered. The filtrate was diluted 250 times and the concentration was measured using UV spectroscopy. The pH of the final solution was about 12.0.

The test substance is readily soluble (Mensink *et al*. 1995).
TEST FACILITY Solvias (2002e).

Hydrolysis as a Function of pH Half-life at 50°C was greater than 1 year at pH 4, 7 and 9.

METHOD OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	$t_{½}$
4	50	No degradation in 5 days
7	50	No degradation in 5 days
9	50	No degradation in 5 days

Remarks About 730 mg of the test substance was added to buffer solution of pH 4.0, 7.0 and 9.0. The test substance was completely dissolved at pH 9 but undissolved particles remained at pH 4 and 7. The solutions were filtered through a 0.22 µm disposable filter unit and the clear filtrate was diluted 1:1 with the corresponding buffer solution. Nitrogen was bubbled through the three test solutions for 5 minutes and 20 mL aliquots of the test solutions were filtered through a 0.22 µm filter before analysis. Portions were then heated to 50°C for 5 days. All test solutions at pH 4 were analysed undiluted while those at pH 7 and 9 were diluted 20 and 100 times, respectively, with double distilled water.

The test substance can be considered to be hydrolytically stable at pH 4, 7 and 9.

TEST FACILITY Solvias (2002f).

Partition Coefficient (n-octanol/water) log Pow at 20°C = -3.37

METHOD OECD TG 107 Partition Coefficient (n-octanol/water) and EC Directive 92/69/EEC A.8 Partition Coefficient (Shake Flask Method).

Remarks First estimates of the partition coefficient and the dissociation constant (pKa) values were obtained using the ACD/logP (Vers 4.06) and ACD/pKa (Vers 4.06), respectively. Based on the results on the pKa values the pH value of 8 was selected for the partitioning experiment.

The stock solution was prepared by dissolving 99 mg of the test item in 50 mL of phosphate buffer solution of pH 8. This solution was centrifuged for 10 minutes due to undissolved test substance (attributed to its impurities). Test tubes with defined volumes of each of the supernatant of the stock solution and the octanol phase were shaken by rotating them through 180° about their transverse axis for hundred times at a temperature of 23°C and then allowed to sit for 30 minutes. After separation, each phase was centrifuged for 10 minutes before analysis using UV/Vis spectroscopy.

A reference solution for the octanol phase could not be obtained due to the very low solubility of the test substance in octanol. As the spectra in the buffer and octanol were similar, the extinction coefficient from the buffer reference solution was used for the calculation of the concentration in the octanol phase.

The low log P_{ow} is consistent with the high water solubility and the low K_{oc} value, indicating a low affinity for the organic phase and component of soils and sediments.

TEST FACILITY Solvias (2002g).

Adsorption/Desorption log $K_{oc} \leq 1.25$ and $K_{oc} < 18$ at 20°C.

METHOD OECD TG 121 Estimation of the Adsorption Coefficient (Koc) on Soil and Sewage Sludge using High Performance Liquid Chromatography (HPLC)
EC Directive 2001/59/EC, C. 19.

REMARKS The test substance was dissolved in a mixture of acetonitrile and water to prepare the stock solution of 1100 µg/mL which was diluted with a solvent mixture of 0.1% ammonium acetate and acetonitrile to obtain a standard solution of 11 µg/mL.

The test solution was injected onto a HPLC column three times and the retention time was compared against retention times of 6 reference substances to determine the soil adsorption coefficient. The retention time of the test substance was shorter than the lowest retention time of reference substances (acetanilide with K_{oc}=18 and

log K_{oc}.=1.25).

The low K_{oc} value indicates that the mobility of the notified chemical in soil as being very high.

TEST FACILITY RCC Ltd (2002)

Dissociation Constant pKa = 4.8 (in 0.001M phosphate buffer solution with 5% ethanol)

METHOD OECD TG 112 Dissociation Constants in Water.

REMARKS A first estimate of the pKa was obtained by using ACD/pKa (Vers 4.06). Preliminary experiments were carried out to obtain a suitable test solution and to determine the useful pH range for the main experiments.

The test solution was prepared by adding 0.098 mg of the test substance into a 100 mL flask that was then filled up to the mark with 0.001M phosphate buffer solution with 5% ethanol (as a cosolvent, due to the very poor solubility in the acidic pH range). Spectrophotometric titrations were performed with 0.1M HCl solution as titrant. The series of spectra recorded at various pH levels were analysed using the software SPECFIT (Vers 2.12 Rev.A).

Due to the poor solubility of the test substance in the pH range below pH 4, no pKa between pH 0 and pH 4 could be determined.

TEST FACILITY Solvias (2002h).

Particle Size Median size: 7.09 µm

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

Range (µm)	*Mass (%)*
< 1.8	7.9
< 7.4	51.9
< 102	99.5

TEST FACILITY Solvias (2002i).

Flash Point Not determined.

Flammability Limits Not highly flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).

TEST FACILITY Institute of Safety and Security (2002a).

Autoignition Temperature Exotherm started at ~280°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.

TEST FACILITY Institute of Safety and Security (2002b).

Explosive Properties Not explosive.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.

TEST FACILITY Institute of Safety and Security (2002c).

Reactivity

REMARKS Not expected to be oxidising from consideration of structure. Expected to be stable under normal environmental conditions.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test.	no evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days.	NOEL = 1000 mg/kg/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberrations	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/Sprague-Dawley.
Vehicle — Purified water.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 males	200	None
2	3 males	2000	None
3	3 females	2000	None

LD50 — > 2000 mg/kg bw.
Signs of Toxicity — Dyspnea and piloerection in high dose males.
Effects in Organs — None.

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

TEST FACILITY — CIT (2002a)

7.2. Acute toxicity - dermal

TEST SUBSTANCE — Notified chemical.

METHOD — OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain — Rat/Sprague-Dawley.
Vehicle — Purified water.
Type of dressing — Semi-occlusive.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	None

LD50 — > 2000 mg/kg bw
Signs of Toxicity - Local — None.
Signs of Toxicity - Systemic — None.

Effects in Organs	None.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	CIT (2002b).

7.3. Acute toxicity - inhalation

Data not provided.

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
Vehicle	Purified water.
Observation Period	72 hours.
Type of Dressing	Semi-occlusive.
Remarks - Method	A pretest with 3 minute exposure was performed using one animal

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	0.33	0	1	24 hours	0
Oedema	0	0	0	0		0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

CONCLUSION	The notified chemical is slightly irritating to skin.
TEST FACILITY	CIT (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
Observation Period	9 days.

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	1.7	0.7	3	3	7 days	0
Conjunctiva: chemosis	0.7	0	2	2	6 days	0
Conjunctiva: discharge	0	0	2	2	4 days	2

Corneal opacity	0.3	0	1	1	3 days	1
Iridial inflammation	0	0	0	0		0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY CIT (2002d).

7.6. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 406 Skin Sensitisation.
OECD Draft New Guideline 429 Skin Sensitisation: Local Lymph Node Assay.
EC Directive 96/54/EC B.6 Skin Sensitization.
Species/Strain Mouse/CBA/J
Vehicle Ethanol:Water::1:1

RESULTS

Concentration	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0	125.14	
0.5%	92.35	0.74
1%	127.13	1.02
2.5%	136.71	1.09
5%	134.42	1.07
10%	103.70	0.83
Positive Control		
HCA at 25%	799.09	6.39

CONCLUSION There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY CIT (2002e).

7.7. Repeat dose toxicity

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/Sprague-Dawley.
Route of Administration Oral – gavage.
Exposure Information Total exposure days: 28 days;
Dose regimen: 7 days per week.
Vehicle Purified water.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	None
II (low dose)	"	150	"
III (mid dose)	"	450	1/10

IV (high dose)	"	1000	None
V (control recovery)	"	0	"
VI (high dose recovery)	"	1000	"

Mortality and time to death
One death at the mid dose was probably not treatment related as no deaths occurred at the high dose.

Clinical Observations
No relevant signs.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No treatment-related changes. A reduction on white blood cell count in high dose and high dose recovery females was slight, and was within the range of historical controls, it was considered not to be treatment related.

Effects in Organs
No effect of the test substance was noted on organ weights and there were no macroscopic or microscopic findings.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day in this study.

TEST FACILITY CIT (2002f).

7.8. Genotoxicity - bacteria

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102. *E. coli*: WP2 uvrA.
Metabolic Activation System	Aroclor 1254 induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 0 - 5000 µg/plate. b) Without metabolic activation: 0 - 5000 µg/plate.
Vehicle	DMSO

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	None	None	1250	None
Test 2		"		"
Present				
Test 1	None	"	1250	"
Test 2		"		"

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

TEST FACILITY CIT (2002g).

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test. EC Directive 2000/32/EC B.10.
Cell Type/Cell Line	Cultured Human Lymphocytes
Metabolic Activation System	Aroclor 1254 induced rat liver S9 fraction.
Vehicle	DMSO

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	15.6, 31.3, 62.5, 125, 250, 500*, 1000*, 2000*	3 hours	20 hours
Test 2	62.5, 125, 250, 500*, 1000*, 2000*	20 hours	20 hours
Test 3	62.5, 125, 250, 500, 1000, 2000*	44 hours	44 hours
Present			
Test 1	15.6, 31.3, 62.5, 125, 250, 500*, 1000*, 2000*	3 hours	20 hours
Test 2	62.5, 125, 250, 500*, 1000*, 2000*	3 hours	20 hours
Test 3	62.5, 125, 250, 500, 1000, 2000*	3 hours	44 hours

*Cultures selected for metaphase analysis.

RESULTS	No precipitation or cytotoxicity was observed and no increase in the frequency of chromosomal aberrations occurred in cultures treated with the test substance.
CONCLUSION	The notified chemical was not clastogenic to cultured human lymphocytes treated in vitro under the conditions of the test.
TEST FACILITY	CIT (2002h).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1 Inherent biodegradability

TEST SUBSTANCE Preparaet 2003

METHOD OECD TG 302B (Zahn-Wellens Test/EMPA Test)
Inoculum Activated sludge from a communal wastewater treatment plant
Exposure Period 28 days
Auxiliary Solvent None
Analytical Monitoring Dissolved Organic Carbon (DOC)
Remarks - Method The use of liquid chromatography for analysis and a nominal test concentration of 1 mg/L were deviations from the Guideline and method. In addition to the test substance, blank and reference (diethylene glycol) controls in duplicate were tested under the same test conditions.

RESULTS

	% Degradation	
Incubation time	*Preparaet 2003*	*Diethylene glycol*
Days	*Mean*	*Mean*
1	3	4
7	23	42
14	20	98
21	28	98
27	32	99
28	38	100

Remarks - Results After 3 hours, 3% of the test substance was found to be adsorbed and attained 38% degradation after 28 days. As approximately 40% of test substance was eliminated after 28 days (greater than 20%) it can be regarded as inherently biodegradable.

Degradation of the reference substance (more than 70% after 14 days) indicates the viability of the culture and test conditions.

CONCLUSION The test substance is inherently biodegradable as approximately 40% was eliminated after 28 days.

TEST FACILITY Solvias (2002j)

8.1.2. Bioaccumulation

No bioaccumulation data were provided in the notification dossier. The high molecular weight, water solubility and the low log P_{ow} suggest that the notified chemical has a poor affinity for lipids and hence is not likely to diffuse across biological membranes and bioaccumulate (Connell 1990).

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE Preparaet 2003

METHOD OECD TG 203 Fish, Acute Toxicity Test and EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – Semi static conditions (24 hour renewal)
Species Zebra Fish (*Danio rerio*)

Exposure Period	96 hours
Concentration Range	
Nominal	Five test concentrations between 43 and 1000 mg/L
Auxiliary Solvent	None
Water Hardness	142 mg $CaCO_3$/L
Analytical Monitoring	Liquid Chromatography
Remarks – Method	Due to the light sensitivity of the test substance, the test solutions were changed every 24 hours. Since no mortality was observed, only samples from the highest test concentration and control were analysed for concentration. Oxygen content, pH and temperature were all satisfactorily maintained. Seven fish were tested per concentration.

RESULTS

LC50	> 1000 mg/L (nominal) at 96 hours.
NOEC	1000 mg/L (nominal) at 96 hours.
Remarks – Results	No sublethal effects were observed in the control or any of the treatments. The actual concentrations of test media varied from 93% to 104% of the nominal values between the beginning and end of exposure.

CONCLUSION The test substance is practically non-toxic to fish.

TEST FACILITY Solvias (2002k)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Preparaet 2003

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test and EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Static

Species	*Daphnia magna*
Exposure Period	48 hours
Concentration Range	
Nominal	Five test concentrations between 43 and 1000 mg/L
Actual	44.7 to 1075 mg/L
Auxiliary Solvent	None
Water Hardness	231 mg $CaCO_3$/L
Analytical Monitoring	Liquid Chromatography
Remarks - Method	Oxygen content and temperature were satisfactorily maintained. Only the pH in the highest test concentration and the oxygen content and temperature in the control were measured. At the start of the test, the pH in the highest test concentration was 8.9 which was beyond the pH range of the test medium of 7.8 – 8.1 indicated in the study plan. Ten Daphnia were tested per concentration, in duplicate.

RESULTS

EC50	>1000 mg/L at 48 hours based on nominal concentrations
NOEC	1000 mg/L at 48 hours based on nominal concentrations
Remarks – Results	No immobilisation of daphnia was observed in the control and at any test concentration after 24 and 48 hours.

CONCLUSION The test substance is practically non-toxic to *Daphnia magna*.

TEST FACILITY Solvias (2002l)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Preparaet 2003

METHOD	OECD TG 201 Alga, Growth Inhibition Test and EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Selenastrum capricornutum (Pseudokirchneriella subcapitata)*
Exposure Period	72 hours
Concentration Range	
Nominal	Five test concentrations between 198 and 1000 mg/L
Actual	207 to 1041 mg/L
Auxiliary Solvent	None
Analytical Monitoring	HPLC
Remarks – Method	Algae were exposed to continuous light and the flasks were continuously shaken at 150 rpm.

RESULTS

Biomass	*Growth*	*NOEC*
E_bC50 mg/L at 72 h	*E_rC50 mg/L at 72 h*	*mg/L at 72 h*
661	> 1000	198

Remarks – Results	The measured test concentrations varied from 104% to 107% or the nominal concentrations at the beginning and from 104% to 106% at the end of the exposure. Test results are based on nominal concentrations. No comments were reported on cell abnormalities in any of the samples.
CONCLUSION	The test substance is practically non-toxic to algae.
TEST FACILITY	Solvias (2002m)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Preparaet 2003
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test and EC Directive 67/548/EEC L.133 Part C
Inoculum	Activated sludge obtained from a communal wastewater treatment plant
Exposure Period	3 hours
Concentration Range	Five test concentrations between 26 and 1000 mg/L
Nominal	
Remarks – Method	Test concentrations of the reference substance (3,5-dichlorophenol) were 3.2, 10 and 30 mg/L.
RESULTS	
IC50	> 1000 mg/L
NOEC	1000 mg/L (highest concentration tested)
Remarks – Results	No significant effect on respiration was observed at any of the test concentrations used (% inhibition of the respiration rate < 15%). The IC50 of the reference substance was 8.1 mg/L, thus validating the test.
CONCLUSION	No microbial inhibition was observed at any of the test concentrations.
TEST FACILITY	Solvias (2002n)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is essentially non-volatile (based on the Henry's Law constant) and will not readily hydrolyse in natural waters at environmental pH values. It is considered to be inherently biodegradable with 40% elimination after 28 days. The notified chemical is readily soluble in water and has a low affinity to adsorb to particulate organic material due to its low log P_{ow} value. Its low K_{oc} indicates high mobility, and the notified chemical is expected to be highly mobile in soils and groundwater.

The waste from the formulation process is expected to be limited to traces remaining from the clean-up of spills, residues in empty packaging and discharges to plant effluent systems. Residues of the notified chemical of up to 100 kg per annum are expected to remain in the bags in which the commercial form of the product is imported which are either recycled or disposed of to landfill. Incineration of the notified chemical will generate water vapour and oxides of carbon, nitrogen and sulphur. Some acidic sulphur combustion products may result in the absence of acid receptors.

As the majority of the notified chemical in household and industrial laundry detergent products will eventually be released into the aquatic environment via the sewerage systems the predicted environmental concentration (PEC) in the aquatic environment is estimated using a worst-case scenario (Environment Australia, 2003). The majority of the wastes generated are expected to be discharged to sewer from domestic and commercial washing machines. Due to the exhaustion rates during the wash cycle, fixation rates during the rinse cycle and wash fastness during subsequent washing, at least 80% of the notified chemical is expected to be fixed on the textile after a usual washing procedure.

It is assumed that the total quantity of the notified chemical imported (up to 100 tonnes per annum) is used and with 80% fixed on the fabric, 10,000 kg are discharged into sewerage systems throughout Australia and none is attenuated within these systems. Australia has a population of ~19.5 million people, and an average value for water consumption of 200 L/person/day has been adopted for this national-level assessment (3900 ML/day for total population). Therefore, the concentration of notified chemical in the Australian sewerage network may approximate 7 μg/L (ie. 10,000 x 10^6 mg ÷ 365 days/year ÷ 3900 x 10^6 L). Based on dilution factors of 1 and 10 for inland and ocean discharges of STP-treated effluents, outfall PECs of the notified chemical in freshwater and marine surface waters may approximate 14 μg/L (i.e. 0.7 x 10^{-2} mg/L) and 0.7 μg/L (0.7 x 10^{-3} mg/L), respectively.

The biodegradability test results showed that 40 % of the notified chemical was eliminated after 28 days and therefore the notified chemical was considered to be inherently biodegradable. The SIMPLETREAT model (European Commission, 1996) for modelling partitioning and losses in sewage treatment plants (STP) was used to estimate the proportions of the chemical partitioning into the different environmental compartments. The results indicate that when the chemical (10,000 kg) is released into the aqueous phase of a STP, about 49% (4,900 kg) partitions to water and 51% (5,100 kg) degrades while there is no release to air through volatilisation or partitioning to biosolids. These results are consistent with the non-volatility, high solubility, low log P_{ow} and low K_{oc} values of the notified chemical.

Assuming 49% of the notified chemical (up to 4,900 kg) may potentially remain in solution, the following PECwater and PECsoil values were obtained (Environment Australia, 2003). The worst-case scenario daily predicted environmental concentration (PEC) for the aquatic environment resulting from the nationwide release of the notified chemical into the sewage systems is reduced to 3.44 μg/L (3.44 x 10^{-3} mg/L) prior to any dilution. Based on dilution factors of 1 and 10 for inland and ocean discharges of STP-treated effluents, outfalls PECs of the notified chemical in freshwater and marine surface waters may approximate 3.44 μg/L (i.e. 3.4 x 10^{-3} mg/L) and 0.34 μg/L (3.44 x 10^{-4} mg/L), respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 0.1 m of soil (density 1000 kg/m^3). Using these assumptions, irrigation with a concentration of 3.44 x 10^{-3} mg/L may potentially result in a soil concentration of approximately 3.44 x 10^{-2} mg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 1.72 x 10^{-3} mg/kg and 3.44 x 10^{-3} mg/kg, respectively.

Concentration in effluent	3.44 µg/L	
PECsoil (mg/kg) (assumes no degradation)		
		Recycled water
Soil concentration	1 year	3.44 x 10^{-3}
	5 years	1.72 x 10^{-3}
	10 years	3.44 x 10^{-3}

Bioaccumulation is not expected due to the high molecular weight and water solubility of the notified chemical and its low log P_{ow} which indicates a poor affinity to lipids. The inherent biodegradability of the notified chemical would also limit its bioaccumulation potential

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests are listed below. The most sensitive species was algae with a 72 hour E_bC50 of 661 mg/L.

Organism	*Duration*	*End Point*	*mg/L*
Fish	96-hr	LC50	> 1000
Daphnia	48-hr	EC50	>1000
Algae	72-hr	E_bC50	661
		E_rC50	>1000

A predicted no effect concentration (PNEC - aquatic ecosystems) of 6.61 mg/L (6610 µg/L) has been derived by dividing the EC50 value by a worst-case scenario uncertainty (safety) factor of 100.

9.1.3. Environment – risk characterisation

The risk quotient values estimated based on the scenario of discharging 20% of the notified chemical imported into sewage systems in Australia are less than 1. Treatment in STPs further reduces the risk as shown below. Therefore, the proposed use of the notified chemical is unlikely to pose an unacceptable risk to the aquatic life.

Location	PEC	PNEC	Risk Quotient (RQ)
Australia-wide STPs			
Ocean outfall	0.7 x 10^{-3} mg/L (3.44 x 10^{-4} mg/L) #	6.61 mg/L	1.06 x 10^{-4} (0.52 x 10^{-4}) #
Inland River	0.7 x 10^{-2} mg/L (3.44 x 10^{-3} mg/L) #	6.61 mg/L	1.06 x 10^{-3} (0.52 x 10^{-3}) #

PEC and RQ values calculated assuming 49% of the notified chemical partitioned into water and 51% degrades during the STP process based on SIMPLETREAT model.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Exposure of transport and storage workers should only occur in the event of an accident where the import containers are ruptured.

The only point of potential high exposure to the notified chemical is at the time of repackaging or weighing out the commercial form and its addition to the blending vessel. This form is granular and should be relatively free of fines. As local exhaust ventilation is used, inhalation exposure should be low. Some exposure may occur due to spillage but this should be low given

the low amount of chemical used on a daily basis. Workers involved in weighing out and addition to the blending vessel would normally be wearing impervious gloves and eye protection further reducing the likelihood of exposure.

Once the chemical is in the laundry detergent it is at a low level and the use of automated mixing and packaging equipment should preclude exposure.

9.2.2. Public health – exposure assessment

The public would normally be exposed to the notified chemical in the final detergent and this exposure can be via inhalation, skin or eye. There will also be exposure on washed clothes.

9.2.3. Human health - effects assessment

The notified chemical exhibited low acute oral and dermal toxicity in rats, was a slight skin irritant in rabbits and a slight eye irritant in this species with conjunctival effects persisting for up to 7 days. Eye irritant effects were below the threshold for classification of the notified chemical as an eye irritant. The notified chemical was not a skin sensitiser as determined by the mouse local lymph node assay and was neither mutagenic in bacteria nor clastogenic in cultured human lymphocytes. The NOEL for a 28-day oral repeated dose toxicity study was 1000 mg/kg/day.

Based on the submitted data, the notified chemical would not be classified as hazardous according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

9.2.4. Occupational health and safety – risk characterisation

From the toxicological data, the main potential adverse health effect arising from use of the notified chemical itself is slight eye irritation to workers who may be susceptible. However, the risk of this occurring is considered to be low given the use of local exhaust ventilation during weighing out. Some potential exists for transmission from gloves to eyes and workers need to be made aware of this possibility.

However, the commercial form of which the notified chemical is a component is classified as hazardous according to NOHSC criteria and assigned the risk phrase R41: Risk of serious eye damage according to the MSDS. Therefore, there may be a risk of serious eye damage during weighing out and cleaning up of spills. Precautions used to prevent ocular exposure to the product will prevent significant exposure to the notified chemical itself.

9.2.5. Public health – risk characterisation

The public will be mainly exposed to the notified chemical in retail products at less than 0.8%. Due to the low toxicity of the notified chemical, the public health risk from exposure to the notified chemical is negligible.

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

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

According to the criteria of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), the notified chemical is not toxic to aquatic organisms (OECD, 2001).

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratios, the notified chemical is not considered to pose a risk to the aquatic environment based on its reported use patterns.

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 Negligible Concern to public health when used as described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is 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 label for a product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- 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. In particular, the commercial form of the notified chemical is classified as hazardous according to the NOHSC criteria and assigned the risk phrase R41: Risk of serious eye damage. Therefore, the chemical identity of the component responsible for this classification must be revealed on MSDS and labels, appropriate engineering and isolation controls should be implemented and chemical safety glasses with side shields or chemical safety goggles used. Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Environment

Disposal

- The notified chemical and empty containers should be disposed of by incineration or landfill according to local regulations although the MSDS for the notified chemical recommends that waste product must be disposed of by incineration and to secure landfill and contaminated packaging must be disposed of as chemical waste. The notified chemical is inherently biodegradable, not toxic to aquatic organisms and only minor amounts are expected to be released during formulation and via empty containers.
- Avoid disposing into drains and waterways.

Emergency procedures

- When spilled damp down and scoop into marked containers for disposal as chemical waste.
- Prevent runoff into drains and waterways.

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(2) of the Act:

– if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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