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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Component of Tinogard Q and Tinogard S-FX

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Component of Tinogard Q and Tinogard S-FX

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Specialty Chemicals Pty Ltd (ACN 005 061 469)
235 Settlement Rd
THOMASTOWN VIC 3074

Trimex Pty Ltd (ACN 001 198 787)
5 Crewe Pl
ROSEBERRY NSW 2018

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., molecular and structural formulae, spectral data, purity, impurities, import volume and exact concentration of the notified chemical in products.

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
Italy, USA.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Tinogard Q (contains 10% notified chemical)
Tinogard S-FX (contains 5% notified chemical)

SPECTRAL DATA

METHOD	Infrared (IR), Fast atom bombardment/Mass (FAB/Mass) and nuclear magnetic resonance (NMR) spectroscopy.
Remarks	Reference spectra were provided.

METHODS OF DETECTION AND DETERMINATION

METHOD	IR, FAB/Mass and NMR spectroscopy.

3. COMPOSITION

DEGREE OF PURITY
> 90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
Several impurities at a total of < 10%.

ADDITIVES/ADJUVANTS
None.

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, but will be imported as a component in Tinogard Q at a concentration of 10% in aqueous solution and in Tinogard S-FX at a concentration of 5% in aqueous solution.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 1.1	< 1.1	< 1.1	< 1.1	< 1.1

USE
The notified chemical functions as a new class of stabiliser technology that blocks light-induced degradation of personal care products alone or in combination with conventional UV light absorbers. The stabilizer is used to increase the shelf life of cosmetic and household products. The notified chemical will be used in such products as hand soaps, shampoos, fragrances, conditioners, body washes, lotions, hair gels and in the case of Tinogard S-FX, also in laundry detergents and home and fabric products.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne and Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS
Notifiers.

TRANSPORTATION AND PACKAGING
The commercial forms of the notified chemical will be imported in 5 kg and 20 kg plastic canisters and transported by road from the wharf to the notifier's site. The containers will be unloaded and stretch-wrapped pallets of drums will be transported by road or rail to end product manufacturers' warehouses.

The formulated end products will be packed into a wide variety of containers for commercial, industrial or retail sale.

5.2. Operation description

The notified chemical will predominantly be imported in preformulated personal care or household products.

Tinogard Q may also be blended into personal care products at up to 20 sites. A typical blending procedure may be carried out three to four times per month using a batch process in which approximately 0.5 kg of Tinogard Q will be used to prepare each 1000 kg batch of personal care product.

During formulation, the canisters/drums are expected to be transferred by forklift from the warehouse

area to the mixing area. The drum would be placed onto scales and a dip tube used to pump the required amount from the drum to a lidded blending vessel. Inside the blending vessel, Tinogard Q is mixed with other ingredients such as water, emollients, surfactants, stabilisers, colour or fragrance to form the end use product. Blending will take approximately one hour, and will not require the use of heat. At the end of the blending process, a sample is taken for quality control using a dipper.

It is expected that, once formulated, end use products will be transferred from the blending vessel to a range of container types and sizes using an automated filling line, which places and seals caps on the containers automatically. Packing workers will place containers into cardboard cartons, or cartoning may be automatic. Cartons are expected to be loaded onto a pallet, and transferred to a general warehouse area for storage until they are transported to distribution centre or retailers' warehouses.

It is expected that the blending vessel and filling lines will be cleaned after the end of the campaign for a given range of common-base products by flushing the system with a process liquid. It is expected that cleaning residues will be filled off a "heel" for charging into the first batch of the next campaign.
After emptying, the drums that contained Tinogard Q would be rinsed with process liquid into the blending vessel as part of the batch charge. Rinsed drums are expected to be sent to a drum recycler.

The concentration of the notified chemical in personal care and household products will be in the range 0.01% to 0.1 %.

5.3. Occupational exposure

Number and Category of Workers per site.

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and Warehouse	1	0.5 hours/day	50 days/year
Process operator	1	2 hours/day	50 days/year
Quality control	1	0.5 hours/day	50 days/year
Packaging	1	1 hour/day	50 days/year

Exposure Details

Transportation and storage

Approximately 1 dockside and 1 warehouse worker will be involved in transporting Tingard Q/S-FX from the wharf to the Melbourne site of Ciba Specialty Chemicals, and placing the cartons into the warehouse. When import of end-use personal care products commences, these workers will be involved in transporting the cartons to retail or distribution centre sites and placing them into the warehouse. Dockside and warehouse workers will not handle cartons, as the imports will be in containers that will be unstuffed at the importers warehouses.

A further warehouse worker will be involved in transferring the cartons of Tinogard from the Ciba Specialty Chemicals warehouse to the customers' warehouses. These workers may be involved in handling the cartons on 50 days per year for approximately 0.5 hours per day.

Dockside and warehouse workers routinely wear cotton overalls and steel-capped boots. They are not expected to have any contact with the notified chemical, except in the case of an accident.

Formulation

Process operators will be involved in formulating personal care products incorporating traces of Tinogard Q/S-FX. The operator will be responsible for transferring the Tinogard from the canister or drum to the blending vessel. The process operator will oversee the blending process and be responsible for cleaning the blending vessel and filling lines once the campaign of blending is complete. At the end of the blending process, one of the process operators will also take a sample of the formulated product for quality control, using a dipper.

Dermal or ocular exposure to the notified chemical at a concentration of 5% or 10% may occur if there are drips or splashes during transfer of Tinogard from the drums or canisters to the blending vessel. Dermal or ocular exposure to the notified chemical at a concentration of 0.01% to 0.1% may also occur if there are drips or splashes from the dipper used to take the sample for quality control. Dermal or ocular exposure to the notified chemical is possible if there are splashes or spills of the watery residues

during cleaning of the blending vessel or transfer lines. The concentration of the notified chemical in the residues will be less than 0.1%. Exposure to the notified chemical is not expected during blending, as this is carried out in a closed vessel.

Process operators will wear impervious gloves, cotton coveralls, safety eyewear.

The process operator will be involved in formulating on up to 50 days per year, for up to approximately 2 hours per day.

Quality control

Analysis of the sample of personal care products will be done using standard laboratory equipment. Dermal and ocular exposure to the notified chemical at a concentration of up to 0.1% is possible if there are splashes or spills during the analysis. Laboratory workers will wear laboratory coats when analysing the sample.

Quality control analysis will occur up to 50 times per year, and takes approximately 0.5 hours.

Packaging

A packaging worker is expected to be involved in taking the containers of personal care product from the automated filling line and placing them into cardboard cartons for approximately three hours per day on up to 50 days per year or the containers will be automatically cartoned. Exposure to the notified chemical is not expected, except in the case of accidental breaching of a container.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Since the notified chemical will not be manufactured locally, there will be no environmental exposure associated with this process in Australia. Environmental release of the notified chemical is unlikely during importation, storage and transportation, and an accidental spill or leak is the most likely reason for environmental release. The size of the containers (5 and 20 kg plastic canisters) together with the predicted maximum concentration of 10% will limit the impact on the environment of such incidents. Any significant spillage either will be salvaged for use or collected using dry absorbent material and disposed of to landfill.

Release of the notified chemical to the environment during blending of cosmetic and household products is expected to be minimal due to the use of mostly automated and closed systems. Water used for cleaning the blending equipment will be reused in the first batch of the next campaign or sent to the on-site wastewater effluent treatment plant if not permitted for quality control reasons. Some of the notified chemical is expected to be adsorbed to sludge during the on-site treatment, which would be disposed of in landfill. The notifier expects a total of 0.3% (up to 3 kg per annum) of the notified chemical to be released to water from the formulation process. The amounts expected to be disposed of to landfill are not specified.

It can be reasonably assumed that up to 1% or 10 kg per annum of the imported chemical remains in the empty containers. These will be rinsed and the rinsate containing the notified chemical is either reused or disposed of to the on-site treatment plant.

RELEASE OF CHEMICAL FROM USE

Since the notified chemical will be used in cosmetics, toiletries, laundry and household products, almost all of the imported volume will enter the sewer when the products are washed off the hair and skin and disposed of following household washing and cleaning activities.

The percentage of notified chemical remaining in emptied consumer product containers is not specified but will vary depending on the size and type of the containers and the type of consumer product. Generally this amount is less than 5% of the container content, containing end product at up to 0.1% notified chemical. The end product containers primarily will be sent to landfill.

5.5. Disposal

Spilled or leaked material should be collected using absorbent material into properly labelled containers and disposed of by a licensed waste disposal company. Rinsed empty import containers are sent to a recycler. Drum rinsate may be discharged to an on-site wastewater treatment plant if not reused. Following use, emptied consumer product containers are expected to be collected through domestic garbage disposal and then disposed of to landfill.

5.6. Public exposure

Dermal or ocular exposure to the notified chemical at a concentration of up to 0.1% would occur during dermal application of personal care products or if there are splashes or spills during use of home/fabric care products.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Orange flakes.

Melting Point 59 - 64°C

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Method: Differential Scanning Calorimetry.
TEST FACILITY	Ciba Specialty Chemicals (1999a).

Boiling Point Not determined.

METHOD	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Method: Differential Scanning Calorimetry. Decomposes above 90°C under nitrogen.
TEST FACILITY	Ciba Specialty Chemicals (1999b).

Density 1190 kg/m^3 at 24°C

METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Method: Gas comparison pycnometer.
TEST FACILITY	Ciba Specialty Chemicals (1999c).

Vapour Pressure < 6 x 10^{-4} kPa at 20°C

METHOD	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Estimated from the decomposition temperature as the minimum boiling point.
TEST FACILITY	Ciba Specialty Chemicals (1999d).

Water Solubility > 500 g/L at 20°C

METHOD	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Flask Method. The test substance is readily soluble in water (Mensink e*t al*. 1995).
TEST FACILITY	Ciba Specialty Chemicals (1999e).

Fat Solubility 7 x 10^{-3} g/kg to 1 x 10^{-2} g/kg HB307 synthetic fat (24 hours at 37°C).

METHOD	OECD TG 116 Fat Solubility of Solid and Liquid Substances.
Remarks	Analytical Method: HPLC.
TEST FACILITY	Ciba Specialty Chemicals (2000a).

Hydrolysis as a Function of pH Hydrolytically stable at pH 4, 7 and 9.

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

Remarks After 5 days at 50°C less than 10% of the notified chemical degraded. While there was about 13% loss at pH 4, the degradation pathway is said to be oxidation rather than hydrolysis.

TEST FACILITY Ciba Specialty Chemicals (1999f).

Partition Coefficient (n-octanol/water) log Pow = – 0.29 at 20°C and pH 4.

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks Flask Method. The partition coefficient was determined using 3 different ratios of pre-saturated n-octanol and a buffer of pH 4 to ensure the non-ionised form (1:1, 1:2 and 2:1) was measured.

TEST FACILITY Ciba Specialty Chemicals (1999g).

Adsorption/Desorption – screening test

K_{oc} = 351 (acidic soil)
K_{oc} = 395 (loamy sand)
K_{oc} = 183 (alkaline soil)

Soil Type	*Organic Carbon Content (%)*	*pH*	*Koc*
SC-1 (Sand)	0.471	4.4	351
Roger Myron-North (Loamy sand)	1.29	6.3	395
Mutchler Sandy Loam (Sandy loam)	1.47	8.0	183

METHOD OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.

Remarks Based on the results of a preliminary test the screening test was performed with ~ 5:1 solution to soil ratio. Soil samples and 40 mL of the test solution (5.0 mg/L 0.01 M $CaCl_2$) were added to each test tube. Additional tubes were prepared with 40 mL of test solution only (soil-less controls) and 40 mL of undosed 0.01 M $CaCl_2$ solution (soil blanks). All samples were shaken for 16 hours at ~125 rpm and centrifuged. The volumes of decanted supernatants were recorded and analysed by gas chromatography with nitrogen phosphorous detection.

The desorption phase of the test was performed by adding a volume of unfortified 0.01 M $CaCl_2$ solution equal to that recovered from each soil control blank. The test substance retained in the solid phase was allowed to desorb while shaking for 16 hours at 125 rpm. The samples were then centrifuged at 1000 rpm for 10 minutes to separate the sorbent and aqueous phases. The aqueous phase was sampled and processed as in the adsorption phase. A second desorption phase was performed by adding new aliquots of 0.01 M $CaCl_2$ in soil and repeating the above process.

The test substance did not desorb readily from any of the soils. Accordingly, the test substance can be expected to have medium mobility in soil (McCall e*t al*. 1980).

Minor deviations from the test protocol were reported but these were considered not to have affected the test negatively.

TEST FACILITY Springborn Laboratories (2000a)

Dissociation Constant pKa = 6.32

METHOD OECD TG 112 Dissociation Constants in Water.

Remarks Determined by titration at 20°C.

TEST FACILITY Ciba Specialty Chemicals (1999h).

Particle Size Average size = 4.06 mm.

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

Range (μm)	*Mass (%)*
75 - 125	1
125 – 500	3
500 – 1000	3
1000 – 2000	14
> 2000	79

TEST FACILITY Springborn Laboratories (1999a).

Flash Point Not determined.

Remarks Test substance was not flammable.

Flammability Limits Not highly flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks Began to burn but the flame did not propagate.
TEST FACILITY Springborn Laboratories (1999b).

Autoignition Temperature > 400°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks Decomposition to ash occurred during the experiment.
TEST FACILITY Ciba Specialty Chemicals (1999i).

Explosive Properties Not explosive.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks A negative result was obtained for sensitivity to shock, friction and to heat.
TEST FACILITY Springborn Laboratories (1999c).

Oxidising Properties Not oxidising.

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks No signs of a vigorous oxidation reaction or combustion during the preliminary experiment.
TEST FACILITY Springborn Laboratories (1999d).

Reactivity

Remarks Expected to be stable under normal environmental conditions.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 = 1758 mg/kg bw	harmful
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rat, acute inhalation LC50 > 5.08 mg/L/4 hours.	very low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test.	no evidence evidence of sensitisation.
Rat, repeat dose oral toxicity – 28 days.	NOEL = 100 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration test	genotoxic
Genotoxicity – in vivo mouse bone marrow micronucleus test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified chemical.

METHOD
- Species/Strain: Rat/Wistar.
- Vehicle: None.
- Remarks - Method: Minor protocol deviations were judged not to have affected the results. The dose levels were chosen as dose of the active ingredient where the purity was taken into account.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*	
			Male	*Female*
I	5 females	500		0/5
II	5 per sex	1000	0/5	0/5
III	5 females	1500		5/5
IV	5 per sex	2000	1/5	5/5
V	5 males	2500	4/5	
VI	5 males	3000	3/5	

- LD50: 1758 mg/kg bw average (1646 mg/kg bw active) (2495 mg/kg bw in males and 1068 mg/kg bw in females).
- Signs of Toxicity: All mortality occurred by study day 1. The most notable clinical abnormalities observed during the study included decreased activity, convulsions, wobbly gait, breathing abnormalities, prostration, decreased defecation, soft stools, piloerection, apparent hypothermia, skin blue in colour, hunched posture, urine/faecal staining, partially closed eyelids, salivation, dilated pupil(s), ocular discharge and dark material around the facial area. A slight body weight loss was noted for two 500 mg/kg female rats and one 1000 mg/kg female rat during the study days 7 - 14. Body weight gain was noted for all other surviving animals during the test period. Food consumption was consistent throughout the test period.
- Effects in Organs: The most notable gross internal findings were observed in the animals that died and included abnormal content in the digestive tract, stained mucosa in the stomach and dark red lungs.
- Remarks - Results: None.

CONCLUSION — The notified chemical is harmful via the oral route.

TEST FACILITY — Ciba Specialty Chemicals (1999j).

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rabbit/New Zealand White.
Vehicle	None.
Type of dressing	Semi-occlusive.
Remarks - Method	Minor protocol deviations were judged not to have affected the outcome.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5/sex	2000	0
II	"	2136 (2000 active)	0

LD50	> 2000 mg/kg bw (active).
Signs of Toxicity - Local	Irritation observed at application site.
Signs of Toxicity - Systemic	Body weight loss noted in one male and one female of 2000 mk/kg group and one male of 2136 mg/kg group. No other clinical signs of systemic toxicity were observed.
Effects in Organs	No gross pathological changes were observed at necropsy.
Remarks - Results	None.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Ciba Specialty Chemicals (1999k).

7.3. Acute toxicity – inhalation

TEST SUBSTANCE	FAT 76'042/C.
METHOD	OECD TG 403 Acute Inhalation Toxicity – Limit Test.
Species/Strain	Rat/Sprague-Dawley.
Method of Exposure	Oro-nasal exposure.
Exposure Period	4 hours.
Physical Form	Solid aerosol (particulate).
Particle Size	3.8 μm M.A.D.
Remarks - Method	No deviations from final protocol. FAT 76'042/C was a fine white powder and was stated to be the notified chemical with a purity of 94.8%.

RESULTS

Group	*Number and Sex of Animals*	*Concentration mg/L*		*Mortality*
		Nominal	*Actual*	
1	5/sex		5.08	None.

LC50	> 5.08 mg/L/4 hours.
Signs of Toxicity	None.
Effects in Organs	None.
Remarks - Results	None.
CONCLUSION	The notified chemical is of very low toxicity via inhalation.
TEST FACILITY	Product Safety Laboratories (2003).

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	6
Vehicle	None.
Observation Period	14 days.
Type of Dressing	Semi-occlusive.
Remarks - Method	Minor protocol deviations were judged not to have affected the outcome.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	1	2	72 hours	0
Oedema	0	0		0

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

Remarks - Results	None.
CONCLUSION	The notified chemical is slightly irritating to the skin.
TEST FACILITY	Springborn Laboratories (2000b).

7.5. Irritation – eye

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	10 days.
Remarks - Method	Minor protocol deviations were judged not to have affected the outcome.

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	0.7	0.7	1	7 days	0
Conjunctiva: chemosis	0	0	0	1	1 hour	
Conjunctiva: discharge	0	0	0	1	1 hour	
Corneal opacity	0	0	0	0		
Iridial inflammation	0	0	0	0		

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

Remarks - Results	None.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	Springborn Laboratories (2000c).

7.6. Skin sensitisation

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 406 Skin Sensitisation – maximisation test.
Species/Strain	Guinea pig/Dunkin-Hartley.

PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: < 0.1% topical: 100%
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 10
INDUCTION PHASE	Induction Concentration: intradermal: 5% topical: 100%
Signs of Irritation	Not stated.
CHALLENGE PHASE	
1st challenge	topical: 100%
2nd challenge	topical: 100%
Remarks - Method	Minor protocol deviations were judged not to have affected the outcome.

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	100%	0	0	0	0
Control Group	100%	0	0	0	0

Remarks - Results	None.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Springborn Laboratories (2000d).

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Sprague-Dawley.
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	Distilled water.
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)	"	100	0
III (mid dose)	"	500	0
IV (high dose)	"	1000	0
V (control recovery)	"	0	0
VI (high dose recovery)	"	1000	0

Clinical Observations

A dose dependent increase in clinical abnormalities was primarily observed in the mid and high dose animals, mainly in the latter part of the treatment. There were indications of salivation, dark material around the nose and/or mouth, reddish staining around the nose and/or mouth, reddish staining on neck and forelimbs, wet reddish matting around nose, mouth, neck and/or forelimbs, wet colourless matting around the nose, mouth

and/or neck and dry matting round the mouth. No remarkable signs were noted in low dose and high dose recovery animals.

A slight dose-dependent decrease in mean body weights (maximum of 6% at the high dose) accompanied reduced body weight gain primarily during the fourth week of dosing.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical Chemistry: Slightly increased serum bilirubin in high dose males. Slightly elevated alanine aminotransferase in high dose females was primarily from one animal.

Haematology: Slight nonregenerative anaemia was indicated in mid and high dose animals by a slight dose-dependent decrease in red blood cell (RBC) counts, haemoglobin and haematocrit (statistically significant in females except for RBC at the mid dose). These effects resolved during the recovery period.

Urinalysis: No significant differences from control urinalyses were found.

Effects in Organs

Slightly increased relative spleen weights in high dose males and minimal to mild congestion of the red pulp of the spleen in some high dose animals may be correlated with the slight nonregenerative anaemia indicated by the haematology parameters.

Remarks – Results

All adverse effects resolved during the recovery period. All other observations were considered to be scattered and/or spontaneous in origin.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 100 mg/kg bw/day in this study, based on slight nonregenerative anaemia.

TEST FACILITY	Ciba Specialty Chemicals (1999l).

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. *E. coli*: WP2uvrA.
Metabolic Activation System	Phenobarbital/5,6-benzoflavone-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	Distilled water.
Remarks - Method	None.

RESULTS

Remarks - Results	No cytotoxicity was detected. The positive and negative controls gave the expected responses. The test substance did not result in an increase in the number of revertant colonies at any dose level.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Covance (1999a).

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Cell Type/Cell Line	Chinese hamster ovary (CHO) cells.
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with phenobarbitoal and 5,6-benzoflavone.
Vehicle	Water.
Remarks - Method	The concentrations were corrected for the purity of the notified chemical.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	33.9, 48.4, 69.1, 98.7, 141, 202, 288, 412, 588, 840, 1200, 1720*, 2450*, 3500*, 5000*	3 hours	20 hours
Test 2	198, 395*, 790*, 1580*, 2110*, 2810*, 3750, 5000	17.8 hours	20 hours
Present			
Test 1	33.9, 48.4, 69.1, 98.7, 141, 202, 288, 412, 588, 840, 1200, 1720*, 2450*, 3500*, 5000*	3 hours	20 hours
Test 2	1580, 2110*, 2810*, 3750*, 5000*	3 hours	20 hours

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1		3500	-	+ (at 5000 µg/mL)
Test 2		1580	-	+ (at 2110 µg/mL)
Present				
Test 1		-	-	-
Test 2		-	-	-

Remarks - Results	In the absence of metabolic activation in test 1 at 5000 µg/mL 12.6% of cells had chromosomal aberrations (- gaps); in test 2 at 2110 µg/mL 7.5% of cells had chromosomal aberrations (- gaps). Positive and negative controls gave the expected results.
CONCLUSION	The notified chemical was clastogenic to CHO cells treated in vitro under the conditions of the test in the absence of metabolic activation.
TEST FACILITY	Covance (1999b).

7.10. Genotoxicity – in vivo

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mouse Crl:CD-1(ICR) BR.
Route of Administration	Intraperitoneal.
Vehicle	Water.
Remarks - Method	The concentrations were corrected for the purity of the notified chemical.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*

I – vehicle control	6 males	0	24, 48
II	6 males	50	24, 48
III	6 males	100	24, 48
IV	14 males (6 + 8)	200	24, 48
V – positive control (CP)	6 males	80 (PO)	24, 48

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity	200 mg/kg bw.
Genotoxic Effects	Negative.
Remarks - Results	The notified chemical did not exert cytotoxic effects on the bone marrow as indicated by unchanged polychromatic to normochromatic erythrocyte (PCE:NCE) ratios in treated animals compared to controls. The positive control demonstrated the sensitivity of the test and the negative control was within historical limits.

CONCLUSION — The notified chemical was not clastogenic under the conditions of this in vivo mouse bone marrow micronucleus test.

TEST FACILITY — Covance (1999c).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical.
METHOD	In house test protocol entitled "Determination of the Biodegradability of a Test Substance Based on OECD Method 301B (CO_2 Evolution Test – Modified Sturm Test).
Inoculum	Activated sludge collected from a wastewater treatment plant that treats predominantly domestic waste.
Exposure Period	28 Days.
Auxiliary Solvent	None.
Analytical Monitoring	CO_2 evolution.
Remarks – Method	Sodium benzoate was used as the reference substance, and both the notified chemical and the reference substance were at a concentration of 20 mg C/L. In addition to the test sample, blank, procedural (20 mg C/L sodium benzoate), toxicity (20 mg C/L of test substance and 20 mg C/L sodium benzoate) and metabolically inhibited (20 mg C/L of test substance and 30 mg/mL $HgCl_2$) control samples were measured. The activated sludge was centrifuged for only 10 minutes. This deviation was not considered to have affected the integrity of the study.

RESULTS

Test substance			*Sodium benzoate*	
Day	*% degradation*		*Day*	*% degradation*
	Replicate 1	*Replicate 2*		
2	4.28	7.39	2	17.32
4	8.60	11.32	4	52.64
6	11.35	12.37	6	62.32
18	16.35	18.68	18	81.49
24	17.34	20.14	24	85.08
28	16.72	22.13	28	86.35

Remarks – Results	The average degradation of the test substance was 19.42%. The variation between the test substance replicates (24.4%) exceeded the 20% variation recommended in the protocol. This difference, which is stated to be not unusual for poorly degradable chemicals and was considered not to have impacted the quality of the study. The toxicity control attained 52% degradation after 28 days confirming that the test substance was not inhibitory to activated sludge bacteria under the test conditions and that the degradation of sodium benzoate was not inhibited by the presence of the test substance. Degradation of the reference substance confirmed the suitability of the innoculum and validity of test conditions. Based on the CO_2 analysis results, TA 45021 cannot be classified as readily biodegradable under the OECD guideline since the test substance degradation during the study (19.4%) was less than the guideline criteria of 60% degradation within 28 days.
CONCLUSION	The test substance cannot be considered to be readily biodegradable according to the OECD criteria.
TEST FACILITY	Springborn Laboratories (1999e)

8.1.2. Inherent biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 302B (Zahn-Wellens Test/ EMPA Test) and 87/302/EEC, Part C
Inoculum	Activated sludge containing a mixture of Polyvalent bacteria from a communal wastewater treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Liquid chromatography and DOC
Remarks – Method	In addition to the test substance (20 mg/L), blank samples and samples containing a reference substance (diethylene glycol at 152.5 and 152.4 mg/L) were measured.

RESULTS

Test substance		*Diethylene glycol*	
Day	*% degradation*	*Day*	*% degradation*
1	27	1	3
7	48	7	100
14	42	14	100
28	77	28	100

Remarks – Results	The test substance attained 77% degradation by 28 days. Degradation of the reference substance (more than 70% after 14 days) indicates the viability of the culture and test conditions.
CONCLUSION	As the biodegradation level exceeded 20%, the test substance can be considered to be inherently biodegradable. As it exceeded 70% the test substance also may be regarded as ultimately biodegradable.
TEST FACILITY	Solvias AG (2003)

8.1.2. Bioaccumulation

No bioaccumulation data were provided. However, if there is any release to the aquatic compartment bioaccumulation is not expected due to the high water solubility and the low log P_{ow} of the notified chemical.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test and Springborn Laboratories Protocol # 092498/OECD/103 - Static.
Species	Rainbow trout (*Oncorhynchus mykiss*).
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	40 mg $CaCO_3$/L
Analytical Monitoring	One water sample was removed from each replicate solution (3 replicates each of test solutions and control) at 0 and 96 hours to verify the test substance concentration in test solutions. These were analysed by gas chromatography (GC) based on methodology validated at Springborn.
Remarks – Method	A single concentration of 100 mg/L was selected for the definitive test

following a preliminary range-finding study. Three replicates of the test solution were prepared by mixing appropriate amounts of stock solution with dilution water.

Oxygen content (6.1 to 9.4 mgO_2/L in control and 6.2 to 9.4 mgO_2/L in the test substance solutions), pH (7.0 to 7.4 in control and 6.1 to 6.9 in test solutions) and temperature (14 to 16°C in control and test solutions) were all satisfactorily maintained.

RESULTS

Concentration mg/L Nominal	*Number of Fish*	*Mortality*					
		3 h	*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	10	0	0	0	0	0	0
100	10	0	0	0	0	0	0

LC50	>100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	No abnormalities or sub-lethal effects were observed in the control or test media. Analysis of the test media showed the measured test concentrations to be in the range of 80.6 to 108% of the nominal level throughout the exposure period.

CONCLUSION The notified chemical is practically non-toxic to fish.

TEST FACILITY Springborn Laboratories (1999f)

8.2.2 Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test and Springborn Laboratories Protocol #: 092498/OECD/110 - Static

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	170 mg $CaCO_3/L$
Analytical Monitoring	One sample from each exposure solution (before division into the replicate vessels) and control at test initiation and from composited replicate test solutions and control at 48 hours were removed to verify the test substance concentration in test solutions. These were analysed by gas chromatography (GC) based on methodology validated at Springborn.
Remarks – Method	Test concentrations were chosen based on a preliminary range-finding study. Oxygen content (8.7 to 9.3 mgO_2/L in control and 8.3 to 9.3 mgO_2/L in the test substance solutions) and temperature (19 to 20°C in control and test solutions) were satisfactorily maintained. The pH was 8.0 in control and 5.7 to 7.9 in the test solutions. The low pH value of 5.7 was observed only in the 1000 mg/L level (at 24 hours). The increase in pH of some of the test solutions exceeded the 0.3 units limit recommended by the guideline.

RESULTS

Concentration mg/L		*Number of D. magna*	*% Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	0	20	0	0
63	61	20	0	0
130	140	20	0	0
250	260	20	0	0
500	500	20	0	35
1000	990	20	25	95

LC50	570 mg/L at 48 hours (95% confidence limits of 490 and 680 mg/L)
NOEC	260 mg/L at 48 hours
Remarks – Results	The 48 hour EC50 was calculated by probit analysis. Solutions of concentrations above 130 mg/L (nominal) were observed to have a slight yellow tint throughout the exposure period. Adverse effects (i.e. lethargy) were observed in all of the surviving organisms in the 500 mg/L (nominal) level and one of the exposed organisms in the 250 mg/L (nominal) level. Analysis of the test media showed the measured test concentrations to be in the range of 91.5 to 116% of the nominal level throughout the exposure period.
CONCLUSION	The notified chemical is practically non-toxic to aquatic invertebrates.
TEST FACILITY	Springborn Laboratories (1999g)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test, TSCA Guideline 797.1050, EC Guideline L383A - C.3 and Springborn Laboratories Protocol # 101998/TSCA/OECD/EC/43.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	96 hours
Concentration Range Nominal	10, 26, 64, 160, 400 and 1000 mg/L
Concentration Range Actual	11, 31, 74, 150, 390 and 1000 mg/L
Auxiliary Solvent	None
Water Hardness	Algal Assay Procedure (AAP) medium was used.
Analytical Monitoring	One sample from each exposure solution (before division into the replicate vessels) and control at test initiation and from individually composited replicate test solutions of each treatment level and control at 96 hours were removed to verify the test substance concentration in test solutions. At test termination, a sample was removed from one replicate of the 160 mg/L (nominal) concentration (containing algae) to assess the impact of the algae on test substance concentration. These samples were analysed by gas chromatography (GC) based on methodology validated at Springborn. In addition three quality controls were also prepared at test initiation and termination at concentrations ranging from 10 to 1000 mg/L.
Remarks – Method	Test concentrations were chosen based on a preliminary range-finding study. At test termination, a sample was removed from the composite of the three replicate solutions of the 1000 mg/L level and tested for growth

recovery in fresh medium.

The pH of the exposure and control solutions ranged from 5.6 to 7.3 (at test initiation) and increased to a range of 7.6 to 10.1 at test termination. The pH decreased with increasing test substance concentration. The pH of one replicate of control solutions was 9.6 at 72 hours. This increase in pH was attributed to the rapid growth of algal cells and was considered not to have affected the integrity of the study results. The test temperature was maintained between 23 and 24°C.

RESULTS

Cell density[#]		*Biomass*[#]		*Growth*	
EC50 (95% CL) mg/L at 96 h*	*NOEC* mg/L*	*EbC50* (95% CL) mg/L at 72h*	*NOEC* mg/L*	*ErC50* (95% CL) mg/L at 72h*[##]	*NOEC* mg/L*[###]
110 (42-290)	11	120 (39-400)	11	380 (110-1400)	74

* Based on the measured test concentrations.

[#] Based on statistical analysis using the William's Test

[##] Based on statistical analysis using the Kruskal-Wallis Test

[###] Empirically estimated.

Remarks – Results

Analysis of the test media showed the mean measured test concentrations to be in the range of 95 to 120% of the nominal level throughout the exposure period. The analysis of the 96 hour sample from the 160 mg/L nominal level with no algae present (120% of nominal) and the equivalent 96 hour sample with algae present (92% of the nominal) showed that the presence of the algae had little impact on the test substance concentration in the test solution.

Algal cells in treatment levels ≤150 mg/L and control appeared normal at test termination. Bloated cells and cell fragments were observed in the 400 (nominal) and 1000 mg/L treatments. After 4 days in fresh medium the growth of the algae indicated that the test substance has an algistatic rather than an algicidal effect at a nominal concentration of 1000 mg/L.

CONCLUSION

The notified chemical is practically non-toxic to algae.

TEST FACILITY

Springborn Laboratories (1999h)

8.2.4. Inhibition of microbial activity

No test report was provided, however the MSDS indicates that the IC50 for bacterial toxicity is greater than 100 mg/L. This is supported by the results observed in the biodegradation test (summarised in 8.1.1).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Up to 13 kg per annum of the notified chemical is expected to be released to the environment during the formulation process (to wastewater and as residue in empty import containers). Nearly all of the imported notified chemical will eventually be released into the aquatic environment via the sewerage systems through formulation and use (washing off the skin, hair etc or cleaning activities) of the cosmetic and household products. A small amount of the chemical is also expected to be disposed of to landfill as residue in empty consumer containers via domestic garbage.

The notified chemical is not volatile, therefore, is not expected to dissipate into air from the surfaces to which the products containing it is applied. It is readily soluble in water but not expected to readily hydrolyse in natural waters at environmental pH values.

The low $logP_{ow}$ indicates a poor affinity for the organic component of the soils and sediments. The experimental log K_{oc} indicates that the notified chemical will have medium mobility in soils. It is not readily biodegradable, however the test results for the inherent biodegradability study indicates that the notified chemical is inherently degradable. Therefore, when disposed in landfill the chemical can be expected to eventually become associated with soil and sediment and will slowly degrade through biological and abiotic processes.

Based on maximum annual imports of 1000 kg per annum, and assuming a worst-case scenario that all of this is eventually released to sewer and not removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 2.74 kg/day. Assuming a national population of 20 million and that each person contributes an average 200 L/day to overall sewage flows, the worst-case predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated as 0.6849 µg/L (Environment Australia 2003). Based on the respective dilution factors of 0 and 10 for inland and ocean discharges of effluents, the PECs of the notified chemical in freshwater and marine water may approximate 0.6849 µg/L and 0.0685 µg/L, respectively.

The notified chemical is not readily biodegradable, however, based on the results of the inherent biodegradability test it was considered to be inherently biodegradable (may also be ultimately biodegradable). The SIMPLETREAT model (European Commission 2003) was used to model the partitioning and losses in sewage treatment plants (STP) throughout Australia. The vapour pressure value (<0.6 Pa) and the water solubility (>5 x 10^5 mg/L) are both limit values resulting in a Henry's Law Constant calculated using these to also be a limit value of less than 8.54 x 10^{-4} Pa m^3/mol (log H < -3.07). Therefore, a worst-case scenario of log H ≤ -4 was assumed in using the SIMPLETREAT table for chemicals that are inherently biodegradable to approximate the partitioning behaviour of the notified chemical.

The results obtained indicate that when the chemical is released into the aqueous phase of a STP, 0% (approximately) is released to air through volatilisation, 59% (590 kg) partitions to water, 0% partitions to biosolids and 41% (410 kg) degrades. The worst-case PEC for the aquatic environment resulting from the nationwide release of the notified chemical into the sewage systems is therefore, reduced to 0.4041 µg/L prior to any dilution and the respective concentrations in freshwater and marine water may approximate 0.4041 and 0.0404 µg/L. These PEC values are used in the following risk assessment.

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 0.4041 µg/L may potentially result in a soil concentration of approximately 0.0040 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 0.02 mg/kg and 0.04 mg/kg, respectively.

The potential for the notified chemical to bioaccumulate is low due to the high water solubility and the low log P_{ow} and also will be limited due to the relatively low volume imported and diffuse release to the sewer Australia wide.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests are listed below. The most sensitive species was algae with 96 hour EC50 value for cell density of 110 mg/L.

Organism	Duration	End Point	mg/L
Fish	96 h	LC_{50}	>100
Daphnia	48 h	EC_{50}	570
Algae	96 h	EC_{50} (Cell density)	110
	72 h	E_bC_{50} (Biomass)	120
	72 h	E_rC_{50} (Growth)	380

A predicted no effect concentration (PNEC - aquatic ecosystems) of 1.1 mg/L (1100 µg/L) has been derived by dividing the end point of 110 mg/L by a worst-case scenario uncertainty (safety) factor of 100 (as toxicity data are available for three trophic levels).

9.1.3. Environment – risk characterisation

The risk quotient (RQ) values (PEC/PNEC) for the aquatic environment were determined as follows.

Location	PEC µg/L	PNEC µg/L	RQ
Australia-wide STPs			
Ocean outfall	0.0685	1100	6.23×10^{-5}
	0.0404#		3.67×10^{-5}#
Inland River	0.6849	1100	6.23×10^{-4}
	0.4041#		3.67×10^{-4}#

PEC and the RQ values calculated assuming 59% of the notified chemical partitioned into water and 41% degraded during the STP process (based on the results from applying the SIMPLETREAT model).

The resulting RQ values for the aquatic environment are significantly below 1 for both fresh and marine water, indicating no immediate concern to the aquatic compartment. A part of the notified chemical can also be expected to be removed due to adsorption to sediments in aquatic environment further reducing the PEC and the risk quotients.

Based on the proposed use pattern the notified chemical is not expected to pose an unacceptable risk to the health of aquatic life. Bioaccumulation is not expected from the diffuse use pattern and low import volume.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The maximum concentration of the notified chemical in any imported formulation of 10% will limit exposure to this level.

Occupational exposure to the notified chemical may occur during transport and storage of preparations and products containing the notified chemical at up to 10% mainly in the event of accidental spillage if rupture of containers occurs.

During reformulation of preparations containing the notified chemical into personal care products and household products, dermal exposure is the most likely route. Ocular exposure may occur due to accidental splashes or transfer from hand to eye but inhalation exposure is unlikely due to the low vapour pressure. Exposure may occur when workers open the drums containing

imported notified chemical at up to 10%, when weighing and transferring the imported preparations into mixing vessels, during blending operations and when cleaning up spills and equipment. Blending operations can be in open or closed systems, however, the process is often automated and local exhaust ventilation is usually employed. All workers handling preparations containing the notified chemical, taking samples for quality control or cleaning equipment wear impervious gloves, eye protection and protective clothing to minimise exposure. Once the notified chemical is formulated into a personal care or household product it is at < 0.1% and exposure is low.

9.2.2. Public health – exposure assessment

Although public exposure to the notified chemical will be widespread, exposure is mainly expected to be to the final products in which it is contained at less than 0.1%.

9.2.3. Human health – effects assessment

The notified chemical was harmful in rats via the oral route (acute oral LD50 = 1758 mg/kg bw) and of low acute toxicity via the dermal route (LD50 > 2000 mg/kg bw) and inhalation route (LC50 > 5.08 mg/L/4 hours). The NOEL for the notified chemical in a 28-day oral repeated dose toxicity test was 100 mg/kg/day bw based on slight nonregenerative anaemia. The notified chemical was non-irritating to skin and eyes in rabbits and was not a skin sensitiser in guinea pigs. It was neither mutagenic in bacteria nor clastogenic in vivo in a mouse bone marrow micronucleus test but was clastogenic at high doses in a chromosomal aberration test in CHO cells in vitro in the absence of metabolic activation.

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2002) in terms of acute oral toxicity and assigned the risk phrase R22: Harmful if swallowed.

9.2.4. Occupational health and safety – risk characterisation

Exposure to the notified chemical at the maximum concentration to be imported (10%) is most likely to occur during transfer of the imported product. Although the notified chemical is classified as harmful via the oral route, the product to be imported would not be so classified solely on the basis of the notified chemical content. Although the notified chemical may be clastogenic in vitro, there is a low probability of mutagenic effects on the basis of the other short term genotoxicity tests. Therefore, the probability of adverse health effects in workers involved in transport, storage or reformulation of the notified chemical from exposure by the most likely route of exposure, the dermal route, is considered to be low. Once the notified chemical is formulated into final products the risk of adverse health effects is considerably reduced.

9.2.5. Public health – risk characterisation

Given the low concentration of the notified chemical in products to which the public would normally be exposed together with the low order of toxicity, there is a low risk of adverse public health effects.

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:

R22: Harmful if swallowed

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.

The acute oral toxicity category is category 4.

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 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 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 and a product containing the notified chemical 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 label for the notified chemical and products containing the notified chemical 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 NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R22: Harmful if swallowed.

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥ 25%: R22

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.

Environment

Disposal

- The notified chemical should be disposed of by incineration in accordance with local regulations or to landfill if unavailable.

- Contaminated empty containers must be disposed of as chemical waste.

Emergency procedures

- Spills/release of the notified chemical should be cleaned up promptly.
- Spilled material should be contained with suitable absorbent material. Scoop into marked containers for disposal as chemical waste.
- In a large spill, create a dyke to prevent liquid entering drains, waterways or soil. Flush small residues away with water and adsorb the watery residues in dry inert material. Place the used adsorbent material in properly labelled containers to be disposed of to landfill by a licensed disposal company. .
- Prevent entry into surface water.

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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