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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

STEPAN-MILD® RM1

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
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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

STEPAN-MILD® RM1

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Bronson and Jacobs Pty Ltd (ABN 81 000 063 249)
5 Parkview Dr
Australia Centre
Homebush Bay NSW 2140

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., other names, molecular and structural formulae, molecular weight, analytical methods of detection and determination, spectra, purity, impurities, additives/adjuvants and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: water solubility, dissociation constant, flash point, acute inhalation toxicity, induction of germ cell damage, bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
U K (Notification No. 99-06-1197-00).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
STEPAN-MILD® RM1

3. COMPOSITION

DEGREE OF PURITY
High.

4. INTRODUCTION AND USE INFORMATION

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

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 30	< 30	< 30	< 30	< 30

USE Viscosity adjuster in general household products and cosmetics.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not stated.

IDENTITY OF MANUFACTURER/RECIPIENTS
Notifer.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in 200 L fibre drums, plastic wrapped and palletised.

5.2. Operation Description

The notified chemical will be manually weighed out and added to mixing vessels together with other components. Following mixing, the products (maximum < 5% notified chemical) will be dispensed automatically into containers for household and personal care products for shipment to customers.

5.3. Occupational exposure

Number and Category of Workers in each Workplace

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Drum handlers/ formulators	2	1 hour per day	4 days per year
Raw material testers	2	4 hours per day	4 days per year
Packers	2		4 days per year

Exposure Details

As Australian customers have not been identified as yet, information on formulation in the USA was provided with the exception of the number and category of workers which are estimated for each local workplace. Batch sizes in the USA range from 400 kg to 20000 kg. Local batch sizes can be expected to be somewhat less. To these batches between the notified chemical would need to be added at < 5%. This is accomplished either manually or with solids handling equipment. Inhalation exposure to the powder is possible during weighing out and addition. Typically local exhaust ventilation is employed and a dust mask if required to minimise exposure.

Following mixing, products will be automatically dispensed into typical containers for shipment to customers.

The mixing vessel is cleaned with hot water (about 15% by weight of the total batch). The amount of waste is typically 40 kg for the 400 kg batch and 500 kg for the 20000 kg batch. Some dermal exposure may be possible but the concentration of notified chemical is now a maximum of < 5%.

Exposure to small amounts of notified chemical can occur when testing the raw material and when testing the product for quality.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical will not be manufactured in Australia. The notifier indicates the due to the processes employed by the reformulation industry release of the notified chemical to the environment will be limited. Previous experience with similar products suggests that release to the environment during reformulation and cleaning processes are expected to be small as closed, automated systems are used, and will total approximately 1% or up to 300 kg of the notified chemical. Wastes from these processes will either be incinerated, disposed of to landfill or into the sewer. It is likely that import containers would be rinsed and the rinseate either added into the production of the next batch or released into the sewer. The cleaned import containers will either be recycled or disposed of to landfill.

RELEASE OF CHEMICAL FROM USE
Since the notified chemical will be used as a viscosity adjuster in general household products and cosmetics the majority will eventually be released to sewer. Empty product containers and any residual product they contain will be disposed of to landfill.

5.5. Disposal

The notified chemical will ultimately be disposed of in either the sewer (predominantly) or landfill.

5.6. Public exposure

Typically the public can be extensively and regularly exposed to the notified chemical in sunscreens and moisturisers and to a lesser extent in hair relaxers, car wax and leather conditioner. Sunscreens and moisturisers would be left on the skin for long periods of time until washed off. The worst case would be 10 grams of moisturiser or 0.01 g notified chemical per day. If all of the notified chemical was absorbed the dosage would be 0.16 mg/kg/day for a 60 kg person.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa White powder.

Melting Point 208ºC

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Differential scanning calorimetry used for measurement.
TEST FACILITY Safepharm (1998a).

Boiling Point 360ºC at 101.3 kPa (estimated)
TEST FACILITY Safepharm (1998a).

Density 1090 kg/m^3 at 20ºC

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks Using gas comparison pycnometer.
TEST FACILITY Safepharm (1998a).

Vapour Pressure $< 1.2 \times 10^{-7}$ kPa at 25ºC.

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks The vapour pressure of the notified chemical was determined using a vapour pressure balance. Mass difference readings (4 runs) were determined between 180 and 136°C and used to determine the vapour pressure of the notified chemical at these temperatures. A plot of log vapour pressure against the reciprocal of temperature gave a straight line from which the vapour pressure at 25°C was determined by extrapolation. The low value determined indicates that the notified chemical is classified as being slightly volatile (Mensink 1995).
TEST FACILITY Safepharm (1998b).

Water Solubility 2.9×10^{-3} g/L at 20ºC

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks The water solubility was determined using the flask method. The notified chemical (~100 mg) was added to each of three flasks and to each was added double distilled water (500 mL). The flasks were shaken at 30°C for 4 h and then left to stand for 17 h at 20°C. After equilibration, the solutions were filtered and analysed by HPLC. The low water solubility value determined indicates that the notified chemical is classified as being slightly soluble (Mensink 1995).

It should be noted that analysis of filtered solutions used in the aquatic toxicity tests found that the test substance concentrations were below the limits of quantitation (0.10 mg/L). This suggests that the true water solubility of the notified

chemical is likely to be much less that that indicated in the water solubility test conducted above.

TEST FACILITY Safepharm (1998a).

Hydrolysis as a Function of pH Not determined

Remarks The hydrolytic stability was not determined due to the low water solubility of the notified chemical. The notified chemical contains an amide linkage that could be expected to undergo hydrolysis under extreme pH conditions. However, in the environmental pH range of 4 to 9, significant hydrolysis is unlikely to occur.

Partition Coefficient (n-octanol/water) log Pow at 20°C > 6.2

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient HPLC method.

Remarks The partition coefficient of the notified chemical was determined by comparing its retention time against a calibration curve constructed from the retention times of reference standards whose partition coefficients are known. The retention time for the notified chemical was greater than that of the DDT reference standard. The high log Pow value is indicative of partitioning into the octanol phase.

TEST FACILITY Safepharm (1998a).

Adsorption/Desorption log K_{oc} > 5.63

METHOD OECD draft guideline (1997) Estimation of Adsorption Coefficient (Koc) on Soil and on Sewerage Sludge using HPLC

Remarks Koc of the notified chemical was determined by comparing its retention time against a calibration curve constructed from the retention times of reference standards whose adsorption coefficients are known. The retention time for the notified chemical was greater than that of the DDT reference standard. The low water solubility is consistent with the high log Koc, indicating a high affinity for the organic component of soils and sediments.

TEST FACILITY Safepharm (1998a).

Dissociation Constant Not determined

Remarks The notified chemical has low water solubility even in the ionised form.

Surface Tension 61.8 mN/m at 21°C

METHOD EC Directive 92/69/EEC A.5 Surface Tension.

Remarks The surface tension of the notified chemical was determined via the ring method using a 4.03×10^{-4} g/L solution of the notified chemical. The value obtained suggests that the notified chemical is not surface active.

TEST FACILITY Safepharm (1998a).

Particle Size

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

Range (μm)	*Mass (%)*
< 100	43.1%
< 10	33.1%

Remarks Sieve method to measure particles < 100 μm; cascade impactor method to measure particles < 10 μm.

TEST FACILITY Safepharm (1998a).

Flash Point Not determined.

Remarks Not applicable for a solid.

Flammability Limits Not highly flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks Did not propagate combustion over 200 mm in the preliminary test.
TEST FACILITY Safepharm (1998c).

Autoignition Temperature None below the melting temperature of 208°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
TEST FACILITY Safepharm (1998c).

Explosive Properties Not explosive.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
TEST FACILITY Safepharm (1998c).

Oxidizing Properties Not oxidizing.

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
TEST FACILITY Safepharm (1998c).

Reactivity

Remarks The chemical is combustible but not oxidizing and is not known to be unstable.

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	severely irritating
Guinea pig, skin sensitisation - adjuvant test.	no evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days.	NOEL = 15 mg/kg/day bw
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 420 Acute Oral Toxicity – Fixed Dose Method.
EC Directive 92/69/EEC B.1bis Acute Oral Toxicity.

Species/Strain	Rat/Sprague Dawley.
Vehicle	Distilled water.
Remarks - Method	A preliminary study was performed with 1 animal per sex at 500 and 2000 mg/kg bw. No deaths occurred.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	1/10

LD50	> 2000 mg/kg bw
Signs of Toxicity	One male animal was found dead 5 days after dosing. Hunched posture with isolated incidents of ataxia.
Effects in Organs	No findings.
Remarks - Results	No necropsy was performed on the animal which was found dead.

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

TEST FACILITY — Safepharm (1998d).

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	Distilled water.
Type of dressing	Semi-occlusive.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	0/10

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Desquamation at the treatment site in one female 3 to 5 days after dosing.
Signs of Toxicity - Systemic	None.

Effects in Organs	None.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Safepharm (1983e).

7.3. 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	Distilled water.
Observation Period	7 days.
Type of Dressing	Semi-occlusive.

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	1.33	0.67	1.33	2	3 days	0
Oedema	0.67	0	0.67	2	2 days	0

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

Remarks - Results	Slight erythema observed in 2 animals at 72 hours cleared by the 7 day observation. One of these animal showed very slight desquamation at 7 days.
CONCLUSION	The notified chemical is slightly irritating to skin.
TEST FACILITY	Safepharm (1998f).

7.4. 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	1
Observation Period	48 hours.
Remarks - Method	The single animal was killed at 48 hours due to severe irritation.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	2.5	3	48 hours	2
Conjunctiva: chemosis	3	3	"	3
Conjunctiva: discharge	3	3	"	3
Corneal opacity	2	2	"	2

Iridial inflammation	1	1	"	1

*Mean of 24 and 48 hour observations

Remarks – Results: A blood stained discharge was present at the 48 hour observation.
CONCLUSION: The notified chemical is severely irritating to the eye.

TEST FACILITY: Safepharm (1998g).

7.5. Skin sensitisation

TEST SUBSTANCE: Notified chemical.

METHOD: OECD TG 406 Skin Sensitisation – Maximisation test.
EC Directive 96/54/EC B.6 Skin Sensitisation - Maximisation test.
Species/Strain: Guinea pig/Dunkin Hartley.
PRELIMINARY STUDY: Maximum Non-irritating Concentration
intradermal: None
topical: 2% (w/v)
MAIN STUDY
Number of Animals: Test Group: 9 Control Group: 5
INDUCTION PHASE: Induction Concentration:
intradermal injection, 0.5% (w/v)
topical application, 25% (w/v)
Signs of Irritation: Very slight or well defined erythema was noted at the intradermal induction sites of all test group animals at the 24 and 48-hour observations. Well defined erythema and very slight or slight oedema were noted at the topical induction sites of all test group animals at the 1 hour observation with very slight or well defined erythema and very slight or slight oedema at the induction sites of nine test group animals at the 24-hour observation
CHALLENGE PHASE
topical application: 1% (w/v) and 2% (w/v)

RESULTS
Remarks - Results: No erythema or oedema was observed in any of the test or control group animals at 24 or 48 hours after challenge patch removal.

CONCLUSION: There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY: Safepharm (1998h).

7.6. 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: Distilled water.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*

I (control)	5/sex	0	None
II (low dose)	"	15	"
III (mid dose)	"	150	"
IV (high dose)	"	300	"

Clinical Observations
No toxicologically significant observations. No clinical signs, changes in bodyweight or bodyweight gain, behavioural changes, functional performance or sensory reactivity changes.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Clinical chemistry High dose animals exhibited elevated alanine aminotransferase and aspartate aminotransferase and high dose females had an increased in albumin/globulin ration although no concomitant shifts in albumin or total protein levels occurred in these animals.

Haematology Mid and high dose males showed a large increase in prothrombin time which at the high dose, was accompanied by an increase in activated partial thromboplastin time. Females in the mid and high dose group also showed slightly increased prothrombin time.

Effects in Organs
Organ weights No differences in treated groups compared to controls.

Macroscopic findings Incidental findings probably unrelated to treatment.

Histopathology No treatment-related changes.

Remarks – Results
Slightly elevated clotting time was seen at mid and high dose, particularly in males. This suggests possible hepatotoxicity which was indicated by elevated alanine aminotransferase in high dose animals but not supported by histopathological changes.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 15 mg/kg bw/day in this study, based on minor haematological effects related to clotting time.

TEST FACILITY Safepharm (1998i).

7.7. 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: 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 Distilled water.

RESULTS

Remarks - Results The notified chemical caused no visible reduction in growth of the background lawn at any dose level. There were consistent reductions in the number of revertants found with TA100 at high concentrations which indicates toxicity at a lower concentrations as the number of spontaneous revertants observed in this system is constant regardless of viable cell

number over a wide range. Toxicity as indicated by reduction in revertant colony numbers was observed in several cases, particularly for TA100 in the absence of metabolic activation where reduction in colony numbers was seen at and above 500 µg/plate. No increases in the number of revertant colonies were seen with any strain treated with the notified chemical in the presence or absence of metabolic activation.

Negative and positive controls gave the expected responses.

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

TEST FACILITY Safepharm (1998j).

7.8. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
EC Directive 92/69/EEC B.10.

Cell Type/Cell Line Human lymphocytes.

Metabolic Activation System Aroclor 1254 induced rat liver S9 fraction.

Vehicle Minimal Essential Medium.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 17.15, 34.30, 68.59*, 137.19*, 274.38*, 548.75*, 1097.5, 2195	4 hours	20 hours
Test 2	0*, 2.14, 4.29, 8.57, 17.15*, 34.30*, 68.59*, 137.19, 274.38,	20 hours	20 hours
Present			
Test 1	0*, 17.15, 34.30, 68.59*, 137.19*, 274.38*, 548.75*, 1097.5, 2195	4 hours	20 hours
Test 2	0*, 2.14, 4.29, 8.57, 17.15, 34.30, 68.59*, 137.19*, 274.38*,	4 hours	20 hours

*Cultures selected for metaphase analysis.

RESULTS

Remarks - Results No statistically significant increase in the frequency of cells with chromosomal aberrations was induced in either test.

In test 1 there were no scorable metaphases at and above 1097.5 µg/mL and few scorable metaphases in the + S9 group at 548.75 µg/mL. Precipitate was observed at the end of the exposure period at and above 548.75 µg/mL in both the presence and absence of S9. In test 2 there were scorable metaphases up to the maximum dose in both treatment groups. A precipitate was observed at the end of the treatment period at 274.38 µg/mL in the – S9 group and at 548.75 µg/mL in the + S9 group.

All of the vehicle control cultures had frequencies of cells with chromosomal aberrations within the expected range. The positive control treatments gave statistically significant increases in the frequency of cells with chromosomal aberrations.

CONCLUSION The notified chemical was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY	Safepharm (1998k).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical.

METHOD
- Inoculum: Activated sludge from sewage treatment plant (Severn Trent Water Plc Sewage Treatment Plant) which treats predominantly domestic sewage.
- Exposure Period: 28 days.
- Auxiliary Solvent: None.
- Remarks - Method: The notified chemical was incubated for 28 days at a test substance concentration of 14.4 mg/L, equivalent to 10 mg C/L.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% degradation*	*Day*	*% degradation*
14	94	14	86
28	95	28	95

- Remarks - Results: The biodegradation of the reference substance, sodium benzoate, was 95% degraded after 28 days, indicating the test conditions were valid. After 28 days at 21°C, the test substance underwent 95% biodegradation within the 10-day window validation criterion which indicates the notified chemical is readily biodegradable in aerobic environments. The test substance was also found to be non-inhibitory to micro-organisms.

CONCLUSION: The notified chemical is readily biodegradable.

TEST FACILITY: Safepharm (1998l)

8.1.2. Bioaccumulation

Data on the bioaccumulation potential of the notified chemical were not provided for this notification. The chemical structure, molecular weight (~400), water solubility, and Pow suggest a potential for the notified chemical to cross biological membranes and bioaccumulate (Connell 1990). However, the notified chemical's ready biodegradability suggest the potential for bioaccumulation will be low.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified chemical

METHOD
- Species: Rainbow trout (*Oncorhynchus mykiss*)
- Exposure Period: 96 h
- Auxiliary Solvent: Ethanol
- Water Hardness: 100 mg $CaCO_3$/L
- Analytical Monitoring: Water temperature, pH and dissolved oxygen were monitored and found to be within acceptable limits. Test substance concentrations were determined using HPLC. The test substance concentration of 0.8 mg/L was the highest attainable due to the limited solubility of the notified chemical in the water and auxiliary solvent, and having due regard to the amount of auxiliary solvent permitted in the test under the OECD

Guidelines.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	-	10	0	0	0	0	0
Solvent Control	-	10	0	0	0	0	0
0.8	0.73	20	0	0	0	0	0

LC50 > 0.73 mg/L at 96 hours
NOEC (or LOEC) 0.73 mg/L at 96 hours
Remarks – Results The results of the definitive study showed that no mortalities were observed in the test vessels with 0.8 mg/L of test substance. There were no sub-lethal effects experienced during the test. The 96-hour EC50 for the notified chemical to *Oncorhynchus mykiss* is greater than 0.73 mg/L based on mean measured concentrations. Filtration of the test solution resulted in significant loss of the test material.

CONCLUSION The ecotoxicity data indicates the test substance is non-toxic to fish up to the limit of its solubility.

TEST FACILITY Safepharm (1998m).

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test – 48 h.
Species *Daphnia magna*
Exposure Period 48 hours.
Auxiliary Solvent Ethanol.
Water Hardness 250 mg $CaCO_3$/L.
Analytical Monitoring Water temperature, pH and dissolved oxygen were monitored and found to be within acceptable limits. Test substance concentrations were determined using HPLC. The test substance concentration of 0.8 mg/L was the highest attainable due to the limited solubility of the notified chemical in the water and auxiliary solvent, and having due regard to the amount of auxiliary solvent permitted in the test under the OECD Guidelines.
Remarks - Method

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	-	20	0	0
Solvent control	-	20	0	0
0.8	0.65	40	0	0

LC50 >0.65 mg/L at 24 hours
NOEC (or LOEC) 0.65 mg/L at 48 hours
Remarks - Results The immobilisation tests with *Daphnia* were performed in quadruplicate using 10 daphnids per flask with observations performed at 24 and 48 hours. The tests were conducted using a nominal test substance concentration of 0.8 mg/L. After 48 h, no immobilised daphnids were observed in the any test vessels. The 48-hour EC50 for the notified chemical to *Daphnia magna* is greater than 0.65 mg/L based on measured concentrations. Filtration of the test solution resulted in significant loss of

	the test material.
CONCLUSION	The ecotoxicity data indicates the test substance is non-toxic to daphnia up to the limit of its solubility.
TEST FACILITY	Safepharm (1998n)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration:	
Nominal	0.8 mg/L
Actual	0.4 mg/L
Auxiliary Solvent	Ethanol.
Analytical Monitoring	Test substance concentrations were determined using HPLC. The test substance concentration of 0.8 mg/L was the highest attainable due to the limited solubility of the notified chemical in the water and auxiliary solvent, and having due regard to the amount of auxiliary solvent permitted in the test under the OECD Guidelines.
Remarks - Method	

RESULTS

Biomass E_bC50 *mg/L at 72 h*	*Growth* E_rC50 *mg/L at 72 h*	*NOEC mg/L at 72 h*
> 0.4	>0.4	≥0.4

Remarks - Results	Algae were exposed to the test substance at a nominal concentration of 0.8 mg/L for 72 h at 24˚C under constant illumination and shaking. Analysis of the test substance concentrations after 72 h showed measured concentrations to range from 0.4 mg/L. No abnormalities were detected in any of the replicate test samples. Neither the biomass nor growth rate of *Scenedesmus subspicatus* were adversely affected by the test substance. Filtration of the test solution resulted in significant loss of the test material.
CONCLUSION	The ecotoxicity data indicates the test substance is non-toxic to algae up to the limit of its solubility.
TEST FACILITY	Safepharm (1998o)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Exposure

The notified chemical will be used as a viscosity adjuster in general household products and cosmetics and this will result in most of the import volume being released to the environment. Wastes from formulation processes will be incinerated, disposed of to landfill or released into the sewer. It is likely that import containers would be rinsed and the rinseate either added into the production of the next batch or released into the sewer. The cleaned import containers will either be recycled or disposed of in landfill. Empty product containers and any residual product containing the notified chemical will be disposed of to landfill.

Fate

The notified chemical is not soluble in water and as such is unlikely to be mobile in either aquatic or terrestrial compartments. When released to sewer and in landfill, as a consequence of its low water solubility, the notified chemical is expected to associate to soil and sediment and degrade through the abiotic and biotic processes. Incineration of the notifier chemical will produce water vapour and oxides of carbon and nitrogen and sodium salts.

For that proportion of the chemical which reaches sewage treatment plants (ie is not volatilised or otherwise destroyed during passage to the plant), the proportions of the chemical which partition into the different environmental compartments may be estimated using the Simpletreat Model (EEC Technical Guidance Document, 1996). These estimates, based on the chemical having a calculated Henry's constant of 1.82×10^{-2} Pa/m^3/mole from measured vapour pressure and water solubility, a log Pow of greater than 6.2 and being biodegradable, indicate that the chemical would be expected to partition into the air, water and sewer sludge compartments and degrade as follows:

Air	Water	Sludge	Degradation
0%	7%	72%	21%

Based on annual releases of 30000 kg per annum to sewer and no removal during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 82.2 kg/day. Assuming a national population of 19.5 million and that each person contributes an average 200 L/day to overall sewage flows, the predicted concentration in sewage effluent on a nationwide basis to ocean and inland rivers are estimated to be 0.15 and 1.48 µg/L.

Amount entering sewer annually	30000 kg
Population of Australia	19.5 million
Amount of water used per person per day	200 L
Number of days in a year	365
Estimated PEC_{ocean}	2.11 µg/L (2.11 ppb)
Estimated PEC_{river}	21.1 µg/L (21.1 ppb)

However, assuming that 93% of the notified chemical is removed during treatment in the STP (see above), the revised PECs for release to ocean, inland river and soil (after one year) are:

Revised PEC_{ocean}	0.15 µg/L (0.15 ppb)
Revised PEC_{river}	1.48 µg/L (1.48 ppb)
Revised PEC_{soil}	0.01 mg/kg

Due to its ready biodegradability, the notified chemical is not expected to bioaccumulate.

9.1.2. Environment – effects assessment

The ecotoxicity data and biodegradation study submitted suggest that the notified chemical is non-toxic to fish, Daphnia, algae and microorganisms and is readily biodegradable. The lowest reported EC50 is for algae, where the 72 hour EC50 is greater than 0.4 mg/L and the NOEC is greater than or equal to 0.4 mg/L.

A predicted no effects concentration (PNEC) can be determined when at least one acute EC50 for each of the three trophic levels is available (ie. fish, *Daphnia*, algae). The PNEC is calculated

by taking the EC50 value of the most sensitive species, and dividing this value by an assessment safety factor of either 100 (OECD) or 1000 (EU). Using a worst case scenario safety factor of 100, the PNEC is greater than 4.0 μg/L.

9.1.3. Environment – risk characterisation

The majority of the new chemical will be used in general household products and cosmetics. As such, most will eventually be released into domestic sewage systems as a consequence of product use. The compound is readily biodegradable (95% over 28 days), and has a high partition coefficient and a low water solubility, all indicating that the material would not be mobile in either aquatic or terrestrial compartments. As a consequence, the notified chemical is expected to associate with soil and sediment and slowly degrade to water and oxides of carbon and nitrogen and salts of sodium through the processes described above.

Using the revised figures following consideration of the sewerage processes, the PEC/PNEC ratios for the aquatic environment after release to ocean and inland river, assuming nationwide use, are less than 0.04 and less than 0.37, respectively. These values are significantly less than 1, indicating no immediate concern to the aquatic compartment.

Due to its ready biodegradability, the notified chemical is not expected to bioaccumulate.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The most likely point at which exposure to the notified chemical may occur is during weighing out and addition to the mixing vessel. Typically, local exhaust ventilation employed at weighing stations and over the mixing vessel should limit the atmospheric concentration to low levels. Once the notified chemical is in the mixing vessel, subsequent exposure should be low. This includes exposure during cleaning, maintenance, QC testing and packing operations.

Exposure during transport and storage is unlikely except in the event of accidental rupture of the containers.

9.2.2. Public health – exposure assessment

The public mainly will be exposed to the notified chemical in moisturisers and sunscreens at a concentration of < 5% applied on a daily basis and left on the skin. Exposure to the notified chemical in hair relaxers, car wax and leather conditioners is likely to occur 3 to 4 times per year. Exposure should be dermal with little eye exposure except through transfer from the hands.

9.2.3. Human health - effects assessment

The notified chemical was shown to be of low acute toxicity via the oral and dermal routes in rats, was a slight skin irritant and a severe eye irritant in rabbits, was not a skin sensitiser in guinea pigs and was neither mutagenic in bacteria nor clastogenic in human lymphocytes in vitro. In a 28-day oral repeat dose study the NOEL was 15 mg/kg/day bw but severe effects were not seen up to a dose of 300 mg/kg/day bw.

The notified chemical is classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) and is assigned the risk phrase R41: Risk of Serious Damage to Eyes.

9.2.4. Occupational health and safety – risk characterisation

From the toxicological data the risk of acute or chronic toxic effects, skin irritation, skin sensitisation or mutagenic effects is likely to be low. The notified chemical is imported as a fine powder which potentially can enter and remain suspended in the atmosphere with the possibility of causing eye irritation. Workplaces involved in formulation of products containing the notified chemical are expected to have local exhaust ventilation at weighing stations and over the mixing vessel. This should ameliorate the risk of eye irritation from atmospheric sources. There is also a risk of eye irritation via transfer of the chemical from gloves to eyes.

There is a low risk to workers of eye irritation resulting from a transport or storage accident and

a similar low risk from exposure to final products containing < 5% notified chemical.

9.2.5. Public health – risk characterisation

As the public is exposed to the notified chemical at a concentration of < 5%, the health risk is considered to be low.

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* (NOHSC, 1999). The classification and labelling details are:

R41: Risk of serious eye damage

According to the OECD (2003) Globally Harmonised System for the Classification and Labelling of Chemicals, the notified chemical is categorised as:

	Hazard category	***Hazard statement***
Serious eye damage/ eye irritation	1 Irreversible effects	Causes serious eye damage

10.2. Environmental risk assessment

The 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 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 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

REGULATORY CONTROLS
Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R41: Risk of serious eye damage

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - $\geq$ 10%: R41 Risk of serious eye damage
  - 5% $\leq$ conc $\leq$ 10%: R36 Irritating to eyes

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - Local exhaust ventilation should be used in weighing and mixing areas where aerosol generation is possible

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Eye protection

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

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

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

Environment

Disposal

- Wastes containing the notified chemical should be disposed of to landfill.

Emergency procedures

- Spills/release of the notified chemical should be contained as described in the MSDS (ie. collect spilled material with an inert absorbent) and the resulting waste disposed of to an authorised landfill.

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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