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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Silsoft 034

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Director

NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
GE Toshiba Silicones Australia Pty Ltd (ABN 471 256 1063) of 175 Hammond Road DANDENONG VIC 3175
and
Unilever Australia Pty Ltd (ABN 66 004 050 828) of 219 North Rocks Road, NORTH ROCKS, NSW 1251.

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer, (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical identity
Spectral data
Method of detection and determination
Composition
Degree of purity
Exact volume

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (1955), Europe, China (2204), Korea (2004)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Silsoft 034

3. COMPOSITION

DEGREE OF PURITY
>97%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical is imported as a component of a cosmetic cream or lotion (up to 6%). There is potential for the notified chemical to be imported as neat material.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	0.48	0.48	0.48	0.48	0.48

USE
Component of skin conditioning cosmetic product (the notified chemical is present at up to 6%). It adds lubricity and spreadability to cosmetic creams and lotion products.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
The notified chemical will initially be imported in finished products through Sydney.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported as finished products in small jars and bottles up to 400 mL suitable for retail sale. These bottles will be packed in cardboard cartons and these cartons will be packed 12 cartons to a cardboard shipper. The shippers will be transported in a container from the wharf to warehouse in Sydney NSW. The cartons will be transported to the retail store's central distribution centres by road transport. The neat notified chemical if imported would be transported from the wharf to the warehouse in Sydney NSW.

5.2. Operation description

The notified chemical is not currently reformulated, however there exists potential to reformulate. The operation description provided by the notifier for reformulation below is consistent with the potential customer base.

Reformulation
During the reformulation process, the imported product containing the notified chemical (up to 100%) will be weighed manually and transferred to a mixing tank manually where it is heated. The mixing process is automated and occurs in a closed system. QC sampling may occur during or immediately after mixing. Once the mixing is finished, the resultant product containing the notified polymer (up to 6%) is automatically transferred to a storage tank using dedicated piped lines or filled into plastic bottles (400 ml). Packing of the finished product directly from the blending tank or from storage tanks is automated and involves the manual connection and disconnection of filling lines.

The bottled products will be packed in cardboard cartons and will be sent to retail distribution centres for storage until distribution to retail outlets.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and storage	10	4h	12 days/yr
End Users	3×10^5	8h	365 days/yr
Operations personnel (reformulation)	2	11h	12 days/yr
Personnel (storage and packing for reformulation)	4	12h	12 days/yr

Exposure Details
Transport and Storage
During transport of the product (containing the notified chemical), workers might come into dermal and ocular contact with up to 6% the notified chemical through accidental leaks and spillages of the plastic bottles. During transport of the neat notified chemical workers might come into dermal and ocular contact with up to 100% the notified chemical through accidental leaks and spillages of the drums and containers.

Reformulation
During the automated reformulation process, dermal and ocular exposure to the notified polymer at up to 100% is possible due to splashes and spillages arising during weighing, mixing and packaging processes, equipment cleaning and maintenance. For example, when transferring the notified chemical

into mixing tanks and packaging workers when connecting/disconnecting transfer lines may be potentially exposed to the notified chemical at a concentration up to 100% and 6% respectively. Exposure of cleaning, sampling and testing workers are anticipated to be less frequent and in smaller quantities.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Release of the notified chemical during transport of the chemical prior to formulation is not expected, except in the event of a transport accident. In the event of a transport accident, the type and size of the containers would limit any release of the chemical.

Storage of product containing the notified chemical is also expected to result in limited releases of the notified chemical except during accidental release. Formulation and dispensing of the end use product will take place in a closed system. Releases from the cleaning of formulation equipment is expected to account for 2-3% (<15 kg per year) of the imported notified chemical. This will occur through rinsing the equipment and will be sent to onsite biological treatment plants.

RELEASE OF CHEMICAL FROM USE

All of the notified chemical (except for residues in containers) is expected to enter the sewer during use of the skin conditioning cosmetic product when it is washed from the skin. The notifier estimates a daily release of about 1.3 kg from a maximum yearly import volume of 480 kg of the chemical contained in the cosmetic.

5.5. Disposal

Used containers are expected to be disposed of through domestic garbage disposal from where they will enter landfill or a recycling program.

5.6. Public exposure

The notified chemical will be sold in finished products to the general public for cosmetic use.

Public exposure to the notified chemical (in products) as a result of transportation within Australia is unlikely unless there is an accident. The material safety data sheets (MSDS) supplied for the commercial product have adequate instructions for clean-up and disposal of any accidental spills and therefore public exposure as a result of a transport accident is likely to be negligible.

The finished products will be sold to the general public hence widespread public exposure is expected. Members of the public are likely to make dermal and possibly ocular contact with the notified chemical as a result of use of the product at a concentration of up to 6%. The product is recommended for use every day and is designed to be left on the skin after application, therefore dermal exposure is the most likely route. Ocular contact with products containing the notified chemical are not recommended but are possible by accidental means. Inhalation exposure is not likely given the low vapour pressure of the notified chemical.

As the finished products will be stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Clear colourless liquid

Melting Point <20°C

Remarks No study report submitted.
TEST FACILITY GE Silicones Analytical Lab, Sisterville WV USA

Boiling Point 285°C at 101.3 kPa

Remarks No study report submitted. Result from a Physical Properties Index from Tanawanda Research.

Density 835 kg/m^3 at 25°C

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks
TEST FACILITY GE Silicones Analytical Lab, Sisterville WV USA

Vapour Pressure <1.33 hPa at 20°C

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Not expected to be volatile.
TEST FACILITY GE Silicones Analytical Lab, Sisterville WV USA

Water Solubility 0.033 mg/L at 25°C

METHOD In-house method.
Remarks Samples were prepared in distilled, deionised water at 1% concentration and mixed for 16 h at 25°C. The insoluble test material was removed from the water phase by filtration through 0.2 micron nitrocellulose syringe filters. The samples were analysed by reverse phase HPLC in triplicate.
TEST FACILITY GE Advanced Materials (2005a)

Hydrolysis as a Function of pH Not determined, chemical is insoluble in water

Remarks The notified chemical does contain functional groups which are expected to hydrolyse under the environmental pH range (4-9).

Partition Coefficient (n-octanol/water) log Pow = 8.63 at 20°C

METHOD ASTM E1147-92 Partition co-efficient
Remarks HPLC Method
The Log Pow of the standards used to calibrate the column was 5.00-8.43. The test material eluted just after the last standard. The partition coefficient indicates that the notified chemical would partition to the organic phase.
TEST FACILITY GE Advance Materials (2005b)

Adsorption/Desorption Not determined

Remarks Based on the low water solubility and high partition coefficient the notified chemical is expected to bind strongly to soil and sediment.

Dissociation Constant Not determined

Remarks The notified chemical does not contain functional groups which are capable of undergoing associative dissociative processes.

Flash Point 110°C at 101 kPa

METHOD Pensky Martens closed cup
Remarks
TEST FACILITY GE Silicones Analytical Lab, Sisterville WV, USA

Explosive Properties Not determined

Remarks Not expected to be explosive

Reactivity Stable under normal temperature and environmental conditions. Not expected to undergo decomposition or

degradation at normal temperatures. Not susceptible to change by acids, alkalis or oxidising agents.
The notified chemical emulsifies in water and is comparatively stable to heat. Carbon oxides and nitrogen oxides are probable decomposition products. The product is not flammable or explosive and has no oxidising potential.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	Assessment Conclusion
Rat, acute peroral LD50 >5000 mg/kg bw	low toxicity
Rabbit, acute dermal LD50 >2000 mg/kg bw	low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test/non-adjuvant test.	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days	NOEL 500 mg/kg bw, NOAEL 1000 mg/kg bw
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vivo mammalian erythrocyte micronucleus	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical (purity >97%)
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/Sprague Dawley
Vehicle	None – administered as neat substance
Remarks - Method	Statement of GLP Dosed by stomach intubation.

Results

Group	Number and Sex of Animals	Dose mg/kg bw	Mortality
1	5 males	5000	0/5
2	5 females	5000	0/5

LD50	5000mg/kg bw
Signs of Toxicity	None. An unkempt appearance for male rats was noted at day 1 followed by recovery at 3 days.
Effects in Organs	No adverse macroscopic observations at necropsy.
Remarks - Results	There were no deaths or notified chemical related clinical signs or remarkable body weight changes during the study period.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	BRRC (1995a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical (purity >97%)
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rabbit/New Zealand White
Vehicle	None – administered as neat substance
Type of dressing	Occlusive
Remarks - Method	Statement of GLP

Results

Group	Number and Sex of Animals	Dose mg/kg bw	Mortality
1	5 males	2000	0/5
2	5 females	2000	0/5

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	There were no observed dermal reactions except for erythema and odema

	at day 1.
Signs of Toxicity - Systemic Effects in Organs	There were no observed dermal reactions. No abnormalities were observed upon macroscopic examination at the end of the study.
Remarks - Results	There were no deaths or clinical signs or remarkable body weight changes observed during the study period. A slight decrease in body weight was observed in 3 males after 7 days but full recovery was observed at 14 days, this result was not statistically significant. The skin of the animals showed erythema and oedema only at day 1.
CONCLUSION	The notified chemical displayed transient skin reactions and is of low toxicity via the dermal route.
TEST FACILITY	BRRC (1995a)

7.3. Irritation – skin

TEST SUBSTANCE	Notified chemical (purity >97%)
Method	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males/ 3 females
Vehicle	Neat.
Observation Period	72 hours
Type of Dressing	Occlusive
Remarks - Method	Statement of GLP

Results

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0.06	1	1 day	0
Oedema	0	-	-	0

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

Remarks - Results	There were no deaths or clinical signs or noted during the study period. Minor erythema was observed in 4/6 rabbits within 1 hour following the contact period, but had subsided within 24 hours in 3/4 animals and within 48 hours for the remaining animal. Minor oedema was apparent on 1 animal within 1 hour, but subsided by 24 hours. At 7 days, desquamation developed on 1 rabbit. No other irritation was observed at this time.
CONCLUSION	The notified chemical is slightly irritating to the skin.
TEST FACILITY	BRRC (1995a)

7.4. Irritation – eye

TEST SUBSTANCE	Notified chemical (purity >97%)
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males/ 3 females
Observation Period	72 hours
Remarks - Method	Statement of GLP

Results

Lesion	Mean Score*	Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
Conjunctiva: redness	0.06	1	1 day	0
Conjunctiva: chemosis	0	0	-	0
Conjunctiva: discharge	0	0	-	0
Corneal opacity	0	0	-	0
Iridial inflammation	0	0	-	0

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

Remarks - Results: No corneal injury or iritis was observed in any of the six rabbits. Minor conjunctival redness with a minor (in fiver rabbits) to a moderate (in 1 rabbit) ocular discharge was produced in 6/6 rabbit eyes. Ocular irritation subsided in 5/6 rabbits within 24 hours and in the remaining eye by 48 hours.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: BRRC (1995a)

7.5. Skin sensitisation

TEST SUBSTANCE

METHOD

and in Freund's Complete Adjuvant
and in 1:1 Freund's Complete Adjuvant:Saline
Intradermal injection: The intradermal injections using Freund's Complete Adjuvant/saline (1:1) (with and without notified chemical 5%) did not cause ulceration of the injection sites and were systemically well-tolerated.
Topical Induction: The administration sites treated with only the notified chemical at 5% induced minor dermal irritation however administration sites treated with 5% notified chemical in mineral oil showed no signs of irritation. Therefore the notified chemical was used neat in the induction phase and diluted in mineral oil in the challenge phase.

challenge phase

1st challenge: topical: 5% in mineral oil

Remarks - Method: Statement of GLP.

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	5%	0	0
Control Group	5%	0	0

Results: Two slight dermal reactions were observed for the negative control group (5% test item in mineral oil) at the 24 hour evaluation. No dermal reactions were seen in either the control or the test groups at 48 hours after patch removal.

Remarks - Results: There were no deaths during the course of the study. There were no signs of systemic toxicity observed in the animals. No toxicologically significant changes in body weights were observed in the test animals.

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

TEST FACILITY: Witco Corporation (1999)

7.6. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rats/Sprague-Dawley Crl:CD®BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7/7 days per week Post-exposure observation period:
Vehicle	Neat
Remarks - Method	Statement of GLP. No protocol deviations.

Results

Group	Number and Sex of Animals	Dose mg/kg bw/day	Mortality
I (control)	10/sex	0	0/20
II (low dose)	10/sex	500	2/20
III (mid dose)	10/sex	1000	3/20
IV (high dose)	10/sex	5000	4/20

Mortality and Time to Death
Two females treated with 500 mg/kg bw, one male and two females treated with 1000 mg/kg bw and three males and one female treated with 5000 mg/kg bw died prior to terminal sacrifice.

Clinical Observations
Treatment-related clinical signs were generally limited to the 5000 mg/kg bw and consisted mostly of skin and fur observations (sores, alopecia, rough haircoat, and urine stains) of the posterior region (ventral abdominal, hindlegs, and lumbar regions) of the body.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
There were no statistically significant differences observed for the measured haematology parameters, and the differential leukocyte counts and cellular morphology findings between groups. All clinical chemistry observations were within the normal physiological range. No treatment-related urinalysis changes were noted.

Effects in Organs
Statistically significant mean organ to body weight change values were only observed at 5000 mg/kg bw in males and females, and were a result of lower body weights in this group relative to controls. Organ to brain weight ratios of the treated groups were not significantly different from controls. Gross findings of sores and alopecia involving skin from the lumbar and perineal regions and hindlegs were noted in animals treated at 5000 mg/kg bw terminally sacrificed rats generally correlated with microscopic finding of acanthosis, sometimes associated with inflammation and necrosis. Lung findings of mottled and dark were associated with microscopic findings of dark and enlarged livers correlated with microscopic finding of congestion. Gross findings in the lung and liver were only note among unscheduled deaths.

Remarks – Results
Several animals from groups 2,3 and 4 died prior to terminal sacrifice. Based on the histopathological findings, it appears that the unscheduled deaths occurred as a result of respiratory insufficiency following aspiration of the test material and characterized by some combinations of granulomatous and suppurative inflammation, congestion, and oedema of the lung. Gross necropsy findings of these animals included mottled and dark lungs, which were associated with microscopic findings of inflammation, oedema, and congestion, and dark and enlarged livers, which correlated with the microscopic findings of congestion. Granulomatous inflammation was also noted in the lungs of three females and three males sacrificed at study termination. The unscheduled deaths were not test-item related.

CONCLUSION

In conclusion, the notified chemical caused no adverse effects when administered 28 times during 30 days at the dose level of 1000 mg/kg body weight per day. The unscheduled death of two females treated with 500 mg/kg bw, one male and two females treated with 1000 mg/kg bw and three males and one female treated with 5000 mg/kg bw died prior to terminal sacrifice were attributed to aspiration of the test item.

The No Observed (Adverse) Effect Level (NO(A)EL) was established as 1000 mg/kg bw/day in this study, and the NOEL is 500 mg/kg bw/day based on treatment, clinical signs and/or effects seen at the higher dose level.

TEST FACILITY	Corning Hazelton Incorporated (1995a)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical (purity >97%)
METHOD	Analogous to OECD TG 471 Bacterial Reverse Mutation Test Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100.
Metabolic Activation System	Aroclor1254
Concentration Range in Main Test	a) With metabolic activation: 100–5000 µg/plate b) Without metabolic activation: 100–5000 µg/plate
Vehicle	Ethanol
Remarks - Method	No historical control data were provided. Statement of GLP.

Results

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in: Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
Absent				
Test 1	> 5000 µg/plate	> 5000 µg/plate	> 5000 µg/plate	None
Test 2	> 5000 µg/plate	> 5000 µg/plate	> 5000 µg/plate	None
Present				
Test 1	> 5000 µg/plate	> 5000 µg/plate	> 5000 µg/plate	None
Test 2	> 5000 µg/plate	> 5000 µg/plate	> 5000 µg/plate	None

Remarks - Results	No precipitation was observed. Concurrent positive controls demonstrated the sensitivity of the assay and metabolising activity of the liver preparations. No comment in the study report if negative controls were within historical limits.
CONCLUSION	The notified chemical was not mutagenic to *S. typhimurium* under the conditions of the test.
TEST FACILITY	

7.9. Genotoxicity – in vivo

TEST SUBSTANCE	
METHOD	Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mice/ Crl:CD-1®(ICR) BR
Route of Administration	Intraperitoneal injections
Vehicle	Neat
Remarks - Method	In-house protocol. Study conducted using modifications of Heddle *et. al.* (1983).

[Use this table for reporting administration by oral gavage, intraperitoneal injection or dermal application. Assessor delete this instruction and or table if not applicable]

Group	Number and Sex of Animals	Dose mg/kg bw	Sacrifice Time hours
I (vehicle control)	5 males/5 females	0	24,48,72
II (low dose)	5 males/5 females	1253	24,48,72
III (mid dose)	5 males/5 females	2505	24,48,72
IV (high dose)	5 males/5 females	5010	24,48,72
V (positive control, CP)	5 males/5 females	80	24

CP=cyclophosphamide administered by oral gavage

Results

Doses Producing Toxicity	No toxic effects were observed at any dose levels.
Genotoxic Effects	The test substance did not induce a statistically significant increase in the frequency of micronucleated polychromatic erythrocytes PCE over the levels observed in the vehicle control. There was no statistically significant decrease in the PCE/NCE (normochromatic erythrocytes) ratio, demonstrating that the test substance was not cytotoxic to the bone marrow. Negative controls were within historical limits. Positive controls confirmed the sensitivity of the test system
Remarks - Results	Although no decrease in the PCE/NCE ratio was observed, the dosages were sufficiently high (5000 mg/kg bw).
CONCLUSION	The notified chemical was not clastogenic under the conditions of this in vivo mouse micronucleus assay.
TEST FACILITY	Corning Hazelton Incorporated (1995b)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Biochemical oxygen demand (BOD_5)

TEST SUBSTANCE	Notified chemical
METHOD	Springborn laboratories Protocol #: 081094/5-DAY BOD
Inoculum	Secondary effluent from Wareham, Massachusetts.
Exposure Period	5 days
Auxiliary Solvent	None
Analytical Monitoring	DOC
Remarks – Method	The test substance was incubated in dark in completely filled and stoppered bottles at 20±1°C for 5 days. The test substance was investigated at a nominal concentration of 5.0 mg/L. Sodium benzoate was used as the reference substance.

RESULTS

Remarks – Results	The test was considered valid since the reference substance was found to have degraded 57% by day 5.
CONCLUSION	The BOD_5 of the test substance was 0 mg O_2/g. This result indicates a lack of rapid biodegradability.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	TSCA Guideline797.1400 flow through conditions
Species	Fathead minnow (*Pimephales promelas*)
Exposure Period	96 h
Auxiliary Solvent	none
Water Hardness	40 mg $CaCO_3$/L
Analytical Monitoring	
Remarks – Method	Test material was delivered by a calibrated to deliver a set rate of the neat test material directly into the diluter's chemical mixing chamber to which dilution water was added at a given rate over a water driven magnetic stirrer. The chamber was partially submerged in an ultrasonic bath. The water in this chamber corresponded to the highest nominal test concentration and was subsequently diluted to give lower test concentrations in diluter cells prior to addition to the exposure vessels. Undissolved test material (in the form of cloudy solutions and a thin surface film) was observed in the mixing chamber, diluter cells and exposure vessels. Control solutions were clear and colourless with no surface film. The temperature, dissolved oxygen and pH were measured daily. The temperature ranged from 22 to 23°C, dissolved oxygen ranged from 6.9 to 8.9 and the pH ranged from 7.1 to 7.4. All these parameters were within acceptable variation ranges.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality*

Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	-	20	0	0	0	0	0
15	-	20	0	0	0	0	0
25	-	20	0	0	0	0	0
41	-	20	0	0	0	0	0
69	-	20	0	0	0	0	0
110	-	20	0	0	0	0	0

LC50	>110 mg/L at 96 hours (nominal concentration).
NOEC	110 mg/L at 96 hours.
Remarks – Results	No mortality or sublethal effects were observed throughout the study.

CONCLUSION	Thr test material is not toxic to fish up to the limit of its water solubility
TEST FACILITY	Springborn Laboratories 1995

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Most of the notified chemical will be released into the aquatic environment via sewage treatment facilities when the cosmetic products are washed from the skin during bathing. However, release is expected to occur in a diffuse manner owing to the low import volumes and the nationwide use of the products.

The notified chemical is not soluble in water and not expected to readily hydrolyse in natural waters at environmental pH values.

The estimated log Pow indicate a strong affinity for the organic component of the soils and sediments. The notified chemical is not expected to be readily biodegradable. However, 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 480 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 1.32 kg/day. Assuming a national population of 20.1 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 0.3 µg/L (Environment Australia 2003). Based on the respective dilution factors of 1 and 10 for inland and ocean discharges of effluents, the PECs of the notified chemical in freshwater and marine water may approximate 0.3 µg/L and 0.03 µg/L, respectively.

9.1.2. Environment – effects assessment

The only ecotoxicity data provided is for fish (LC50 > 110 mg/L nominal concentration) and the notified chemical is very slightly toxic to fish. On the basis of a single endpoint a predicted no effect concentration (PNEC) of >110 µg/L has been determined based on an assessment factor of 1000.

9.1.3. Environment – risk characterisation

The risk quotient (RQ) values (PEC/PNEC) for the aquatic environment were determined as follows assuming nationwide use and that the chemical is not removed in STP.

Location	PEC µg/L	PNEC µg/L	RQ
Worst Case			
Ocean outfall	0.03	>110	>> 0.1
Inland River	0.3	>110	>> 0.1
Mitigated Sewage Discharge (90% removal)			

Ocean outfall	0.03	>110	>> 0.1
Inland River	0.3	>110	>> 0.1

The resulting RQ values for the mitigated discharge to the aquatic environment are both below 1 for both fresh and marine water, indicating no immediate concern to the aquatic compartment. Further, a part of the notified chemical can 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.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport & Storage

Occupational exposure to the notified chemical during its transport and storage of finished products containing up to 6% notified chemical or up to 100% notified chemical when imported neat, is only likely in the event of accidental container spillage involving breach of packaging. Exposure in these circumstances is expected to be infrequent and limited by use of appropriate personal protective equipment (PPE) during clean-up operations.

Reformulation

The main operations during reformulation which dermal or ocular exposure could occur will be weighing and adding the notified chemical (up to 100%) to the mixing vessel. This exposure is controlled by the use of LEV and PPE (such as impervious gloves and safety goggles). Once the notified chemical has been added to the mixing vessel, it is in a closed system and exposure should be precluded.

9.2.2. Public health – exposure assessment

Public exposure to cosmetic creams containing up to 6% of the notified chemical is expected, through use of cosmetic creams and lotions for personal use. The main potential route of exposure would be dermal, through application to the skin. Some accidental ocular exposure is also possible. The frequency of application depends on individuals. An estimate of exposure as determined by the recommended usage is as follows:

Product	*Application Quantity (mg/application)**	*Application Frequency per Day*	*Retention Factor (%)**	*% Notified Chemical in Product*	*Exposure to Notified Chemical (mg/kg bw/day)***
General Purpose Cream	2000	1	10	5	0.14
	2000	1	100	5	1.4

* Application quantity estimated by the notifier (1200 mg/application from the data from EU SCCNFP (Scientific Committee on Cosmetic Products and Non-food products intended for Consumers) (SNCNFP, 2003))

* *Assuming body weight of 70 kg

Dermal Exposure=

$$\frac{\text{(amount of product applied)}\times\text{(\%notified chemical in product)}\times\text{(\%retention factor)}\times\text{(frequency)}}{100\times100\times\text{bw}}$$

Due to the high molecular weight the notified chemical is unlikely to absorb completely through the skin. A 100% retention factor is therefore an overestimate of dermal exposure and provides a worst-case scenario.

9.2.3. Human health – effects assessment

No specific information was provided on the toxicokinetics, metabolism or distribution of the notified chemical. The notified chemical has low acute oral toxicity (LD50>2000 mg/kg bw) and low acute dermal toxicity (LD50>5000 mg/kg bw). The notified chemical is not skin or eye irritant. The notified chemical was not a skin sensitiser in the guinea pig maximization test. An NO(A)EL of 1000 mg/kg bw/day and an NOEL of 500 mg/kg bw/day in a rat 28-day oral study

was established for the notified chemical. The notified chemical is not mutagenic and not clastogenic.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

Considering the notified chemical is imported in final products a low concentrations and that the chemical is not classified as hazardous, the risk to occupational health and safety is considered low. During reformulation the process is fully automated and considering the non-hazardous nature of the notified chemical the risk to occupational health and safety is considered low.

9.2.5. Public health – risk characterisation

The primary source of exposure to the notified chemical will by dermal exposure. Other routes of accidental or incidental exposure will be ocular or oral exposure.

The notified chemical is of low acute oral and dermal toxicity, does not cause skin irritation or eye irritation, and is not a skin sensitiser.

Using a NOAEL of the 1000 mg/kg bw/day, the expected daily dose of 0.14 mg/kg bw/day (based on 10% dermal absorption) calculated in Section 9.2.2, the Margin of Exposure (MOE) is greater than 1000. The MOE greater than 100 (A worst-case scenario with 100% dermal absorption would give an MOE of 714 but exceeds the value of 100). An MOE greater than 100 (for inter and intra species variation) and combined with low toxicity suggests the notified chemical poses a low public health regulatory concern.

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

10.1. Hazard classification

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

and

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

The notified chemical is not classified under the GHS.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio 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 No Significant Concern to public health when the notified chemical is used as a component of skin creams.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical and product containing 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 2003). 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 product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

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

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

Disposal

The notified chemical should be disposed of to landfill in accordance with State/Territory waste disposal regulations.

Emergency procedures

- Spills/accidental release of the notified chemical should be contained with an absorbent, inert material (soil, sand, sawdust, vermiculite) and collected in sealable, labelled containers for disposal.

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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