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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in Plantapon LGC

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FULL PUBLIC REPORT

Chemical in Plantapon LGC

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Cognis Australia Pty Ltd (ABN 87 006 374 456)
4 Saligna Drive
Tullamarine, Victoria 3043

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name
Other Names
CAS Number
Molecular Formula
Structural Formula
Molecular Weight
Spectral Data
Hazardous Impurities
Non-hazardous Impurities (>1%)
Import Volume
Additives
Purity

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting Point/Freezing point
Boiling point
Density
Vapour pressure
Water solubility
Hydrolysis as a Function of pH
Partition Co-efficient
Adsorption/Desorption
Dissociation Constant
Particle Size
Flash Point
Flammability Limits
Autoignition Temperature
Explosive Properties
Reactivity
Toxicological studies
Ecotoxicity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
Inventory of Existing Chemical Substances (IECSC) in China (2004)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Plantapon LGC

METHODS OF DETECTION AND DETERMINATION

Remarks The notified chemical is a complex reaction product and there are no specific methods relating to its detection and determination. However, diagnostic Infrared (IR) and ultraviolet/visible (UV/Vis) spectroscopic data were provided.

3. COMPOSITION

DEGREE OF PURITY
> 40%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
Two hazardous impurities present at <10 % which do not render the notified chemical hazardous according to the NOHSC criteria

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The chemical is not manufactured in Australia. It is imported as a component of a complex reaction product for reformulation or in finished personal care products.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 5	< 10	< 15	< 15	< 10

USE
Ingredient in personal care products such as those requiring mild cleansing effects, facial cleansers and baby cleansing products.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Major ports in Australia.

IDENTITY OF MANUFACTURER/RECIPIENTS
The chemical will not be manufactured in Australia. Recipients will be formulators of personal care products or marketers of finished goods of the same type.

TRANSPORTATION AND PACKAGING
The chemical in its commercial form is imported normally by sea as part of Full Container Loads (FCLs). Transportation of containers from the wharf to the notifier's warehouse is expected to be by road. (in sturdy closed head steel drums of capacity designed for international transport).

No repacking will be carried out before reformulation. Stretch-wrapped pallets of 120 kg polyethylene (PE) or 200 L drums, are transported by road or rail to the end-product manufacturers' warehouses. The formulated end products are packed into a wide variety of containers (100 mL – 1 L) for commercial or retail sale. It is expected that end products will be transported by road or rail to

distribution centres, warehouses or retail stores.

5.2. Operation description

The notified chemical is imported as a component of the commercial form, Plantapon LGC Sorb, suitable for reformulation in Australia. No repacking will be carried out before reformulation.

Formulation of end use products

The imported Plantapon LGC Sorb is blended into personal care products at up to 20 (after 5 years) formulation sites. A typical blending procedure may be carried out once or twice per month using a batch process. On average, 0.7% of the notified chemical is present in the blend. Rarely, up to 1.4% may be present in end use products.

During formulation, the drums are expected to be transferred by a forklift from the storage area to the mixing area. The drum is placed on to scales and a dip tube used to pump the required amount from the drum to a lidded blending vessel. Inside the blending vessel, Plantapon LGC Sorb is mixed with other ingredients such as water, emollients, surfactants, stabilisers, colour or fragrance to form the end use product. Blending takes approximately one hour, and does not require the use of heat (at the end of the blending process, a sample is taken for quality control testing using a dipper.)

It is expected that, once formulated, end use products are 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. Cartonning may be automatic or can be carried out manually by packing workers. 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 are cleaned after the end of a campaign for a given range of common base products by flushing the system with water. It is expected that cleaning residues comprise a "heel" for charging into the first batch of the next campaign.

After emptying, the drums that contained Plantapon LGC Sorb are rinsed with water into the blending vessel as part of the batch charge. Rinsed and drained drums are expected to be sent to a drum recycler.

End Use

The final packaged products are sold to consumers through supermarkets, pharmacies and health products stores.

5.3. Occupational exposure

Number and Category of Workers at each site

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport	2	none	none
Stores	1	none	none
Plant operator	1	10 minutes	10-15 times a year
Laboratory technician	1	10 minutes	10-15 times a year

Exposure Details

Transportation and storage

Approximately 1 dockside and 1 warehouse worker are involved in transporting Plantapon LGC in commercial form from the wharf to the Melbourne site of Cognis, and placing the drums into the warehouse.

In the case of import of end use personal care products, workers are involved in transporting the cartons to retail or distribution centres and placing them into the warehouse. Dockside and transport workers do not handle cartons as the imports are in FCLs that are unstuffed at the importers' warehouses.

A further warehouse worker is involved in transferring the drums of Plantapon LGC from the Cognis warehouse to customers' warehouses. These workers may be involved in handling the drums on 1 to 15 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 incident that involves a spill or leak.

Formulation of end products
An operator is responsible for transferring the Plantapon LGC commercial form from the import drum to the blending vessel. It is expected that transfer is by pump using a suction pipe dropped into the drum and a closed system from the pump to the blending vessel. It is likely the drum stands on scales to dose the quantity required into the blending vessel. Blending and packing-off processes may be fully automatic at some facilities so that no exposure is likely.

At the end of blending process, one process operator takes a sample of the formulated product for quality control. This involves opening the blending vessel hatch to take the laboratory sample.

The process operator oversees the blending process and is responsible for cleaning the blending vessel and filling lines once the campaign of blending is complete. The cleaning medium is water. Washings are retained for charging to the first batch of the next campaign of a given product.

Dermal or ocular exposure to the notified chemical at a concentration of 20% may occur if there are drips or splashes during transfer of Plantapon LGC from the drums to the blending vessel. Dermal or ocular exposure to the notified chemical at an average concentration of 0.7% may also occur if there are drips or splashes from the sampling device 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 is less than 0.3%. Exposure to the notified chemical is not expected during blending, as this is carried out in the blending vessel with the hatch closed.

Process workers wear impervious gloves, cotton coveralls and safety eyewear.

The process operator is involved in formulating on up to 15 days a year, for up to approximately 2 hours per day, 10 minutes of which involves charging the imported Plantapon LGC Sorb to the blending vessel.

Quality control
Analysis of the sample of personal care product is done using standard laboratory equipment. Dermal and ocular exposure to the notified chemical at an average concentration of 0.7% is possible if there are splashes or spills during the analysis. Laboratory workers wear laboratory coats when analysing the sample.

Quality control analysis occurs up to 15 times per year, and takes approximately 0.5 hours.

Packaging
If cartonning is not automated, 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 3 hours per day on up to 15 days per year or the containers is automatically cartonned. Exposure to the notified chemical is not expected, except in the case of accidental breaching of a container.

End use
Personal care products are used by consumers in a variety of applications for personal care, but are expected to be predominantly used in hair shampoos.

Dermal or ocular exposure to the notified chemical at an average concentration of 0.7% occurs during dermal application of personal care products.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The imported notified chemical will be blended into personal care products at up to 20 (after 5 years) formulation sites. A typical blending procedure might be carried out once or twice per month using a batch process in which approximately 35 kg of chemical mixture will be used to prepare each 1000 kg batch of personal care product. That is, on average 0.7% (maximum of 1.4%) of the notified chemical would be present in the blend. The drums containing the chemical mixture will be placed on to scales and dip tubes used to pump the required amount from the drum to the lidded blending vessel. Inside the blending vessel, the chemical mixture will be mixed with other ingredients such as water, emollients, surfactants, stabilisers, colour or fragrance to form the end product. It is expected that once formulated, the end product will be transferred from the blending vessel to a range of container types and sizes using an automatic filling line, which places and seals caps on the container automatically. It is expected that blending vessels and filling lines will be cleaned after the end of the process by flushing the system with water. It is expected that cleaning residues will be filled to a heel for charging into the first batch of the next process. During reformulation, 0.45% of the total volume imported of notified chemical is expected to be released to STPs across 20 places around Australia during a period of 10 to 15 days per year. This is based on the EU default release fraction value of 0.003.

After emptying, the drums that contain the chemical mixture will be rinsed with water into the blending vessel as part of batch charge. Rinse and drained drums are expected to be sent to a drum recycler.

It is expected any significant spillages will either be salvaged for use or absorbed in dry absorbent and disposed of to landfill. It is expected that only 5 to 10 kg per year will be sent to landfill as a results of all spills and leaks, including transport.

RELEASE OF CHEMICAL FROM USE

The notified chemical will be imported as a component of the commercial form suitable for reformulation in Australia. The notified chemical will be used as a surfactant in personal care products where mildness of effects on skin is required. Personal care products will be used by consumers in a variety of applications that exist for personal care products, but expected to be predominantly in hair shampoos. The finished product containing the notified chemical will be sold to end-users (hair salons, retail outlets) Australia-wide and thus it is expected that close to 100% of the notified chemical will be released to the sewer nationwide.

5.5. Disposal

Waste incineration or disposal with the approval of the responsible local authority. Empty consumer containers containing residues of the notified chemical will be disposed to landfill through garbage collection.

5.6. Public exposure

The notified chemical will be used in the formulation of personal care products, which will be available to the general public. Public exposure will be widespread and will result through the use of personal care products containing up to 1.4% notified chemical. Members of the public will make dermal contact and possibly accidental ocular contact with products containing the notified chemical.

Typical use profile is estimated as follows

Product	*Grams/Task*	*Use Frequency (tasks per day)*	*Total exposure (grams per day)*
Face cream / Moisturiser	0.8	2	1.6
Body lotion	8	0.71	5.7
Hand moisturiser	0.8	6	4.8

In a worst-case scenario, exposure to the notified chemical could be up to 0.17 g/day, 365 days per year for the above three applications as the effects of exposure from above application can be additive.

Since the personal care product will be stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

Public exposure during transport, storage and retail distribution is unlikely unless the packaging is

breached.

6. PHYSICAL AND CHEMICAL PROPERTIES

Since the notified chemical has never been isolated, physico-chemical properties have not been determined. Data listed below for density and flash point are not regarded as relevant. The respective properties will always be influenced by the mixture and water content. Some of the data were supplied using EPI v3.12 calculation.

Appearance at 20°C and 101.3 kPa The commercial form to be imported is a clear, yellow liquid.

Melting Point/Freezing Point 313-350°C (estimated)

Remarks Estimated with EPI V3.12 (Mean MP)

Boiling Point 716-999°C at 101.3 kPa (estimated)

Method Estimated with EPI V3.12 (Adapted Stain & Brown method)

Density 1002-1004 kg/m^3 at 40°C

METHOD Cognis method
Remarks Source- Cognis Material Safety Data sheet
TEST FACILITY Cognis

Vapour Pressure 6.85×10^{-23} kPa to 5.45×10^{-31} kPa for shortest carbon chain with one or two glucosides.

9.16×10^{-26} kPa to 1.52×10^{-33} kPa for longest carbon chain with one or two glucosides.

Method Estimated with EPI V3.12 (Modified Grain method)

Water Solubility 60.32 g/L at 25°C to 1000 g/L at 25°C for shortest carbon chain with one or two glucosides.

0.057 g/L at 25°C to 5.74 g/L at 25°C for longest carbon chain with one or two glucosides.

Method Estimated with EPI V3.12 (estimated from log K_{ow})

Hydrolysis as a Function of pH Not determined.

METHOD No data – EPIWIN was unable to estimate a hydrolysis rate constants for the structure
Remarks The notifier claimed that product is stable in aqueous solution for up to a year.

Partition Coefficient (n-octanol/water) log P_{ow} = -1.40 to -5.62 for shortest carbon chain with one or two glucosides.

log P_{ow} = -2.68 to 1.54 for longest carbon chain with one or two glucosides.

METHOD Estimated with EPI V3.12

Adsorption/Desorption log P_{oc} = 1.00 to 1.26 for a range of carbon chain and glucosides.

Method Estimated with EPI V3.12

Dissociation Constant	pKa = 3.4 - 4
Method	SPARC calculation
Particle Size	Not relevant
Flash Point	> 100°C at 101 kPa
Remarks	Source US TSCA PMN
Flammability Limits	It is not expected to be flammable based on the structure.
Autoignition Temperature	It is not expected to self ignite based on the structure.
Explosive Properties	It is not expected to have explosive properties based on the structure.
Reactivity	Plantapon LGC Sorb does not react with water, it is dissolved in water (supplied as aqueous formulation), and stable.

7. TOXICOLOGICAL INVESTIGATIONS

Some of studies shown below were carried out on the mixture known as Plantpon LGC Sorb or Plantpon LGC. Some are carried out using analogues.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	low toxicity, LD50>2000 mg/kg bw
Rat, acute dermal	low toxicity LD50>2000 mg/kg bw (Analogue 1)
Rat, acute inhalation	Not available
Rabbit, skin irritation	moderately irritating (Analogue 2)
Rabbit, skin irritation	moderately irritating (Analogue 3)
Human volunteers, skin irritation	slightly irritating (Analogue 4)
Rabbit, eye irritation	irritating
RBC test, eye irritation	slightly irritating
LLNA test, skin sensitisation	inadequate evidence of sensitisation – not classified (Analogue 5)
Rat, oral gavage repeat dose toxicity - 90 days.	NOEL = 450 mg/kg/day (Analogue 6)
Genotoxicity - bacterial reverse mutation	not mutagenic (Analogue 7)
Genotoxicity – in vitro	non genotoxic (Analogue 8)

7.1. Acute toxicity – oral

TEST SUBSTANCE	Plantapon LGC (20% of the notified chemical)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/SPF Wistar
Vehicle	Water
Remarks – Method	No deviation from protocol

RESULTS

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

II	3 M	2000	0

LD50 > 2000 mg/kg bw
Remarks – Results The gross necropsy revealed no pathological abnormalities.
Neither male nor female rats died on account of the treatment nor did they show marked signs of toxicosis. The rats had a normal body weight gain during the study period.

Females: 3 animals showed piloerection 1, 3 and 6 hours after the application of the test article. From Day 1 until the end of the observation period on Day 14 no abnormalities were revealed in the three rats.

Males: 3 animals showed piloerection and pinched abdomen 1 hour after the application of the test substance. After 3 and 6 hours piloerection was still observed. From Day 1 until the end of the observation period on Day 14 no abnormalities were revealed at the three rats.

CONCLUSION Plantapon LGC containing notified chemical is of low toxicity via the oral route.

TEST FACILITY Frey-Tox (2002)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Analogue 1

METHOD Federal Insecticide, Fungicide, and Rodenticide Act (40 CFR), the toxic Substance Control Act (40 CFR), and the OECD guidelines.
Species/Strain Rabbits/New Zealand White
Number of animals 5/sex
Type of dressing Occlusive
Remarks – Method The protocol was followed without deviation.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 M	2000	0
II	5 F	2000	0

LD50 > 2000 mg/kg bw
Signs of Toxicity - Local No irritative effects were seen.
Remarks – Results No deaths occurred during the observation period.

CONCLUSION The analogue is of low toxicity via the dermal route.

TEST FACILITY Hill Top Biolabs Inc. (1990)

7.3. Acute toxicity – inhalation

There was no acute inhalation toxicity test submitted.

7.4.1 Irritation – skin

TEST SUBSTANCE Analogue 2

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain Albino Rabbit/NZ white SPF
Number of Animals 3M
Vehicle Moistened with distilled water.
Observation Period 14 days
Type of Dressing Semi-occlusive.

Remarks – Method No significant protocol deviations.

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	2.0	2.0	2.7	3	7 d	0
Oedema	1.7	1.7	1.3	2	7 d	0

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

Remarks – Results

One hour after exposure well defined erythema and very slight oedema were observed in the treated skin-areas of all animals. During the course of the study the degree of erythema and/or oedema slightly increased among the animals. Moderate to severe erythema was observed in one animal and slight oedema was observed in all three animals during the observation period. The skin irritation had resolved within 14 days after exposure in all three animals. Scaliness was observed in the treated skin-area of one animal at 7 and 14 days after exposure.

There was no evidence of a corrosive effect on the skin.

Yellowish staining of the treated skin by the test substance was observed in one animal, which had disappeared within 72 hours after exposure. No staining of the treated skin was observed in the other two animals.

No symptoms of systemic toxicity were observed in the animals during the test period and no mortality occurred.

CONCLUSION The analogue is moderately irritating to rabbit skin.

TEST FACILITY NOTOX (1994)

7.4.2 Irritation – skin

TEST SUBSTANCE Analogue 3

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain Albino Rabbit/NZ white SPF
Number of Animals 6M
Observation Period 14 days
Type of Dressing Semi-occlusive.
Remarks – Method No significant protocol deviations.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	1.7	4	7 d	0
Oedema	0.9	2	3 d	0

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

Remarks – Results	Four hours exposure resulted in well defined erythema and slight oedema in the treated skin-areas of two animals, which had resolved completely within 14 days after exposure. In a third animal severe erythema and slight oedema were observed during the observation period. The skin irritation had also resolved completely within 14 days after exposure in this animal. Scaliness was noted in the treated skin-area of three animals 3 and/or 7 days after exposure. Similar treatment of three additional animals resulted in well defined erythema and very slight or slight oedema, which had resolved completely within 7 days after exposure. Scaliness was noted in the treated skin-area of these three animals at termination. There was no evidence of a corrosive effect on the skin. No staining of the treated skin by the test substance was observed.
CONCLUSION	The analogue is moderately irritating to rabbit skin.
TEST FACILITY	NOTOX (1994a)

7.4.3. Irritation – skin

TEST SUBSTANCE	Plantapon LGC and Analogue 4
METHOD	
Remarks – Method	Single application 24 hr occlusive patch test according to COLIPA is an occlusive epicutaneous test method. The study was performed according to the described protocol.
Numbers of Objects	20 M & F human volunteers
RESULTS	
Remarks – Results	The test substances induced slight erythema and slight scaling reactions. The negative control, aqua demin, produced slight erythema and slight scaling reactions. The reference substance Texapon N28 induced slight and moderate erythema, oedema, and scaling reactions and one slight fissuration.
CONCLUSION	Plantapon LGC and Analogue 4 are slightly irritating using human patch study.
TEST FACILITY	Henkel KGaA (2001)

7.5.1 Irritation – eye

TEST SUBSTANCE	Plantapon LGC
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbits/SPF albino
Number of Animals	3F
Observation Period	14 days
Remarks – Method	No significant protocol deviations.

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	2.0	2.0	2.0	2	7 d	0
Conjunctiva: chemosis	1.3	1.3	1.7	2	3 d	0
Conjunctiva: discharge	1.7	0.3	0.7	2	3 d	
Corneal opacity	1.0	1.0	1.0	1	3 d (degree 1)	0
Iridial inflammation	0.0	1.0	1.0	1	3 d	0

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

Remarks – Results: Well-defined signs of irritation were observed in the treated eyes. All effects were fully reversible within 14 days.

CONCLUSION: Plantapon LGC containing notified chemical is slightly to moderately irritating to the eye.

TEST FACILITY: Frey-Tox (2002a)

7.5.2. Red Blood Cell Test System as surrogate for in-vivo eye irritant test with Plantapon LGC Sorb.

TEST SUBSTANCE: Plantapon LGC Sorb

METHOD: RBC-Test according to SOP 2-02 of Vitro-Tec Development in agreement with INVITTOX protocol 37 & ZEBET Protocol 30.

Remarks – Method: Porcine blood was used instead of calf blood.

RESULTS

Remarks – Results: The H50 value of this test substance is 80.79 µg/mL. In comparison to the standard tenside SDS (22.57 µg/mL), this value is 3.6 fold higher. Protein denaturation (DI) levels were 2.08/2.10%. The resulting H50/DI ratio of 38.86/38.55 identifies the substance as slight irritant (> 10 but < 100).

CONCLUSION: Plantapon LGC Sorb containing the notified chemical is slight irritating to eyes.

TEST FACILITY: Vitro-Tec (2004)

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

TEST SUBSTANCE: Analogue 5

METHOD: OECD 406 and OECD 429 Skin Sensitisation: Local Lymph Node Assay

Species/Strain: Mouse/ CBA/CaOlaHsd

Vehicle: Bi-distilled water

Remarks – Method: No significant protocol deviations.

RESULTS

Concentration	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
10.00%	742	2.4
25.00%	692	2.2
50.00%	922	2.9
Positive Control		
1.00%	463	1.0
5.00%	1404	2.9
10.00%	2097	4.4

25.00%	3043	6.4

Remarks – Results
In the preliminary test, the ear of test animal treated with the 100% test substance showed alopecia over the whole application area. As this finding was considered as excessive local skin irritation the concentration chosen for the main study were 10%, 25% and 50% to avoid false positive results.

No deaths occurred during the study period.

All animals of test group treated with 50% test substance showed slight alopecia at application after epicutaneous application. No test substance related clinical signs were observed in animals in other test groups. The body weight gain of all animals was normal.

CONCLUSION There was inadequate evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the analogue.

The SI of the analogue was less than the value of 3 so that the substance is not classified as a skin sensitiser.

TEST FACILITY RCC (2001)

7.7. Repeat dose toxicity

TEST SUBSTANCE Analogue 6

METHOD OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents.

Species/Strain	Rat/Sprague Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 90 days; Dose regimen: 7 days per week; Post-exposure observation period: 4 weeks
Vehicle	Distilled water
Physical Form	Powder
Remarks – Method	No deviations occurred which were considered to have affected the integrity of the study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	10M 10 F	0	0
II (low dose)	10M 10F	50	0
III (mid dose)	10M 10F	150	0
IV (high dose)	10M 10F	450	0
V (control recovery)	5M 5F	0	0
VI (high dose recovery)	5M 5F	450	0

Mortality and Time to Death
No mortalities occurred during the study.

Clinical Observations

Neurotoxicity tests and motor activity measurements performed at the end of the treatment and recovery periods did not show changes which could be ascribed to treatment.

No significant changes were observed in body weight. No toxicological significance was attributed to the slight reduction in body weight gain observed in mid- and high dose males when compared to controls on Day 8 of the study.

No significant variations in food consumption were observed during treatment or recovery periods. No treatment-related findings were seen at the opthalmic examination performed at the end of the study. No macroscopic findings were described that could be correlated with administration of the test substance. Keratinised stomach acanthosis was significantly greater than background degree in 2 animals from the high dose group (450 mg/kg/day). At this incidence this lesion is not considered treatment related. No change was observed in the examined tissues, which could be considered treatment-related.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

A statistically significant increase in alkaline phosphatase was observed in high dose females at the end of the treatment period. This change, within the range of historical control data, was no longer present at the end of the recovery period. No other significant changes were noted.

An increase in urine volume, statistically significant in all treated males and in high dose females, was observed at the end of the treatment. This difference, slight and within historical control values, was no longer evident at the end of the recovery period and is, therefore, considered of no toxicological importance.

No changes of toxicological significance were observed in haematological parameters.

Effects in Organs

No significant changes were observed in the organ weights.

Remarks – Results

Detailed clinical signs with neurotoxicological assessment did not show any signs which could be correlated to treatment with the test substance.

No signs of toxicity were observed during the in-life phase. Slight variations were observed in body weight, clinical chemistry and urine parameters at the end of treatment, all within the range of historical control data. All changes were no longer present at the end of the recovery. No treatment-related changes were seen at histopathological examination.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 450 mg/kg bw/day in this study, based on the absence of any significant effects at the highest dose level.

TEST FACILITY RTC (2003)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Analogue 7
METHOD	OECD TG 471 Bacterial Reverse Mutation Test.
Species/Strain	*Salmonella. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	S9
Concentration Range in Main Test	a) With metabolic activation: 33, 100, 333, 1000, 2500, 5000 µg/plate. b) Without metabolic activation: 33, 100, 333, 1000, 2500, 5000 µg/plate.
Vehicle	Deionised water
Remarks – Method	Updating deviation had no detrimental impact on the outcome of the study.

RESULTS	No substantial increase in revertant colony numbers was observed in any strain at any dose level, either with or without metabolic activation. There was no tendency to higher mutation rates with increasing concentration in the range below the accepted threshold of biological relevance.
Remarks – Results	The test substance did not induce gene mutations by base pair or frameshift in the genome of strains used.
CONCLUSION	The analogue was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	RCC (2002)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Analogue 8
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test. EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.
Cell Type/Cell Line	Chinese hamster V79 lung (fibroblasts) cells
Metabolic Activation System	Liver microsomes (S9 mix) from rats induced with Aroclor 1254.
Vehicle	Water
Remarks - Method	No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	2, 4, 8, 16*	4 hr	7 hr
Test 2	0.5, 1, 2*, 4, 8*, 16*	4 hr	20 hr
Test 3	2, 4, 8, 16*	4 hr	28 hr
Present			
Test 1	20, 40*, 80, 160	4 hr	7 hr
Test 2	5, 10*, 20, 40*, 80*, 160	4 hr	20 hr
Test 3	20, 40, 80*, 160	4 hr	28 hr

*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	> 5			
Test 1		> 16		negative
Test 2		> 16		negative
Test 3		> 16		negative
Present	> 100			
Test 1		> 40		negative
Test 2		> 80		negative
Test 3		> 80		negative

Remarks - Results	No biological effect in respect to the induction of chromosomal aberrations was observed after administration of test substance, neither without nor with S9-mix. There was no significant increase in chromosomal aberrations after treatment compared to concurrent and historical controls. There was no indication of an increase in the frequency of polyploid metaphases after treatment with the test substance compared to the

negative controls.

Positive control experiments were performed using appropriate reference mutagens. They revealed significant increase in cells with chromosomal aberrations.

CONCLUSION The analogue was not clastogenic to fibroblast cells treated in vitro under the conditions of the test.

TEST FACILITY Henkel KGaA (1995)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE Analogue 5

METHOD OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum Activated sludge from a domestic STP
Exposure Period 29 days
Auxiliary Solvent none
Analytical Monitoring TOC5050A-Carbon Analyser
Remarks - Method The test chemical concentration was 114 mg/L - equates to 20 mg/L of carbon. Ten samples were taking on each sampling day from each replicate in order to determine the emitted CO_2.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
1	0	1	0.8
4	11.5	4	38.3
6	21.5	6	63.1
8	30.7	8	83.9
11	39.6	11	82.6
15	49.4	15	93.2
25	59.4	25	96.4
29	67.9	29	99.9

Remarks - Results The lag-phase ended and degradation began on day one, reaching 10% on day four. The 10 day window began on day four, reaching only 47% degradation after a further 10 days period. After fifteen days, only small changes in degradation were observed, indicating the start of a plateau, with changes remaining below 20% within a time range of two weeks. Biodegradation reached 68% after 29 days.

CONCLUSION The test chemical is not considered readily biodegradable as the 10 days window criteria was not met.

TEST FACILITY LAUS GmbH (2001)

8.1.1.2. Biodegradability in Seawater

TEST SUBSTANCE Analogue 10

METHOD Marine BODIS ISO/TC 147/SC 5/WG 4N 141
Inoculum Micro-organism already present in the seawater
Exposure Period 28 day

Auxiliary Solvent	none
Analytical Monitoring	Polarographic electrode
Remarks - Method	In contrast to the OECD TG 306 closed bottle degradation test the marine BODIS test has both an aqueous and gaseous phase. The gas phase helps maintain the dissolve oxygen levels in the aqueous phase and is not therefore a limiting factor in the degradation process. The extent of degradation is estimated from cumulative BOD relative to the theoretical oxygen consumption if 100% of the material was fully mineralised during the test (calculated from the theoretical oxygen demand and the amount of test material added to the test vessel). The stock solution of test chemical was made in natural seawater. The stock solution of reference/test chemical was made in distilled water to 40 mg of theoretical OD/mL, and 0.5 mL stock used per bottle.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	40	7	81
14	59	14	98
21	75	21	99
28	89	28	99

Remarks - Results	The test chemical is biodegraded by 89% over 28 days. Additionally, it showed an inhibition of 25% to seawater bacteria when the BOD was compared between samples containing the reference substance and the chemical together with samples containing the reference substance and the chemical separated.
CONCLUSION	The notified chemical is considered biodegradable by seawater bacteria.
TEST FACILITY	ERT (2003a)

8.1.2 Bioaccumulation

No bioaccumulation data are available. The potential to bioaccumulate is expected to be low due to the high water solubility and biodegradation potential.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue 9
METHOD	OECD TG 203 Fish, Acute Toxicity Test – semi static conditions.
Species	Zebra barbel (*Brachydanio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	none
Water Hardness	Not determined
Analytical Monitoring	TC Analyser
Remarks – Method	The stock solution of the notified chemical was made by adding 1.18 g/L with reconstituted fish water (made up according to OECD TG 203). How test solutions were prepared is unclear, but as notified chemical is soluble they should have been clear. Following the highest concentration of 10 mg/L notified chemical, the predicted TOC was calculated as only 4.7 mg/L and this was assumed too low for an accompanying analysis. Therefore an additional test vessel with 100 mg/L notified chemical without fish was prepared for the determination of the stability of the chemical.

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

Nominal Test Substance	*Nominal Notified Chemical*		*24 h*	*48 h*	*72 h*	*96 h*
0.6	0.12	7	0	0	0	0
1.25	0.24	7	0	0	0	0
2.5	0.48	7	0	0	0	0
5.0	0.76	7	0	0	0	0
10	1.92	7	7	7	7	7

LC50	1.36 mg/L at 96 hours – nominal concentration of notified chemical.
NOEC	0.96 mg/L at 96 hours – nominal concentration of notified chemical.
Remarks – Results	The non purgeable organic carbon (NPOC) measurement in the test vessel with 100 mg/L of test substance after acid addition and purging with oxygen indicated significant losses by stripping. The recovery rate at 0 hours was about 50 to 60% of the theoretical value. Therefore TOC measurements were performed without preceding elimination of inorganic carbon (IC), therefore, the IC content from $NaHCO_3$ of the reconstituted fish water must be considered (~9.2 mg/L). The recovery rate was then calculated from the difference of the TOC concentrations in the test vessels and the corresponding fish water. Recoveries analysis was performed in two concentrations (10 and 100 mg/L) at 0, 24, 72 and 96 hours by doing NPOC and TOC analysis. The recovery rate for 100 mg/L was between 88.3-105.2 (± 5) %. The recovery rate for 10 mg/L with purging time of 5 min was 85% indicating a loss by stripping. Without purging the recovery was between 97.8-100.4%. There was not an obvious TOC influence through the matter excreted by the fish. At a concentration of 10 mg/L of test substance the mortality was 100%. At 5 mg/L of test substance no fish died. After 48 hours, the fish in the test vessel with 5 mg/L of test substance swam near the surface. However, this behaviour was not observed later. The LC50 estimation was done using the geometric mean values of these two values.
CONCLUSION	The notified chemical is considered to be toxic to Zebra barbel fish under the test conditions.
TEST FACILITY	Hydrotox (2002)

8.2.1. Acute toxicity to seawater fish

TEST SUBSTANCE	Analogue 10
METHOD	OSPARCOM (1995) Acute Toxicity for Fish
Species	Turbot (*Scophthalmus maximus)*
Exposure Period	96 hours
Auxiliary Solvent	none
Water Hardness	Not determined
Analytical Monitoring	TC Analyser
Remarks – Method	
RESULTS	The chemical was characterised to be soluble at 1 g/L, therefore was added to the test system directly via seawater at nominal concentration. The range was obtained from the marine algae test.

Number of Fish			*Mortality*			
Test Substance	*Active Substance*	*Number of Fish*	*24 h*	*48 h*	*72 h*	*96 h*
3.2	0.6	7	0	0	0	0
10	2.0	7	7	7	7	7
32	6.4	7	7	7	7	7
100	20	7	7	7	7	7
320	64	7	7	7	7	7

LC50	1.32 mg/L at 96 hours – nominal concentration of notified chemical analogue.
NOEC	0.64 mg/L at 96 hours – nominal concentration of notified chemical analogue.
Remarks – Results	Nil – limited information in the report.
CONCLUSION	The notified chemical analogue is considered to be toxic to *Scophthalmus maximus* marine fish under the test conditions.
TEST FACILITY	ERT (2003b)

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue 1*
METHOD	EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – semi static conditions.
Species	Zebra barbel (*Brachydanio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	none
Water Hardness	Not determined
Analytical Monitoring	
Remarks – Method	The stock solution of the chemical was made by adding 1 g to drinking water (final volume 100 mL) and stirred for 30 minutes. Test chemical recoveries analysis was performed at two concentrations (2 and 8 mg/L) at 0 and 24 hours.

Concentration mg/L			*Number of Fish*		*Mortality*			
Test Substance	*Actual*	*Precursor Chemical*	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
0	-	0	-	10	0	0	0	0
2	2.45	1	1.25	10	0	0	0	0
4	-	2	-	10	0	0	0	0
8	-	4	-	10	60	90	90	90
16	7.33	8	3.67	10	100	100	100	100

LC50	2.95 mg/L at 96 hours – measured precursor chemical.
LC100	8.0 mg/L at 96 hours – measured precursor chemical.
NOEC	2.0 mg/L at 96 hours– measured precursor chemical.
Remarks – Results	*This analogue was not considered acceptable for the environment assessment. The LC50 was estimated by interpolation in a semi-logarithmic coordinate system by using LC0. At 8 mg/L, sublethal effects (impaired balance) were observed after 24 hours.
CONCLUSION	The test chemical (precursor chemical) is considered to be toxic to Zebra barbel fish under the test conditions.
TEST FACILITY	Henkel KGaA (1995a)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Analogue 1*
METHOD	EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – Static conditions.
Species	*Daphnia magna*
Exposure Period	48 hours

Auxiliary Solvent	none
Water Hardness	Not specified
Analytical Monitoring	Not specified
Remarks - Method	The stock solution of the chemical was made by adding 1 g to deionized water (final volume 100 mL) and stirred for 30 minutes. Notified chemical recoveries analysis was performed at 3 concentrations (1, 8 and 32 mg/L) at 0, 24 and 48 hours.

RESULTS

Concentration mg/L					*Mortality (%)*				
Test Substance	*0 h*	*24 h*	*48 h*	*Precursor Chemical*	*0 h*	*24 h*	*48 h*	*24 h*	*48 h*
0	-	-	-	0	-	-	-	0	0
1	1.10	0.2	0.10	0.5	0.55	0.1	0.05	0	0
2	-	-	-	1	-	-	-	10	10
4	-	-	-	2	-	-	-	10	10
4	-	-	-	2	-	-	-	0	0
8	-	-	-	4	-	-	-	0	0
8	8.70	5.40	4.50	4	4.35	2.7	2.25	20	20
16	-	-	-	8	-	-	-	20	20
32	28.6	23.4	20.60	16	14.3	11.7	10.3	40	100

LC50	7 mg/L at 48 hours – measured precursor chemical.
NOEC	0.54 mg/L at 24 hours – measured precursor chemical. 0.44 mg/L at 48 hours – measured precursor chemical.
Remarks - Results	*This analogue was not considered acceptable for the environment assessment. Neither foam, turbidity nor precipitations were observed in the solutions. Because the greater reduction in concentration of the notified chemical during the 48 hours incubation period, the arithmetic mean of the analytically determined recovery rates (66%) was used to calculate the effective concentration. The LC50 was estimated by interpolation in a semi-logarithmic coordinate system by using LC100.

CONCLUSION The test chemical (precursor chemical) is considered to be toxic to *Daphnia magna* under the test conditions.

TEST FACILITY Henkel KGaA (1995b)

8.2.2. Acute toxicity to aquatic marine invertebrates

TEST SUBSTANCE Analogue 10

METHOD ISO 14669 (1999) Acute Lethal Toxicity to Marine Copepods

Species	Copepod (*Acartia tonsa*)
Exposure Period	48 hours
Auxiliary Solvent	none
Water Hardness	Not specified
Analytical Monitoring	Not specified
Remarks - Method	The chemical was characterised as soluble in filtered seawater (1 g/L) after 20 hours stirring, therefore, a dilution series was used to prepare working solutions. A range finding test was conducted at concentrations of 1 to 1000 mg/L plus four control vessels.

Range Finding Test

Concentration mg/L		*Number of Acartia tonsa*	*Number Immobilised*
Test Substance	*Notified Analogue*		*48 h*

1	0.2	5	0
10	2	5	1
100	20	5	5
1000	200	5	5

Definitive Test

Concentration mg/L		*Number of Acartia tonsa*	*Number Immobilised*			
Test Substance	*Notified Analogue*		*24 h*		*48 h*	
3.2	0.64	10	0	0	0	0
10	2.00	10	0	0	0	0
18	3.60	10	2	3	2	3
32	6.40	10	10	10	10	10
100	20.0	10	10	10	10	10

LC50 4.55 mg/L at 48 hours – nominal concentration of notified chemical analogue.

NOEC 2 mg/L at 48 hours – nominal concentration of notified chemical analogue.

Remarks - Results Nil – limited information in the report.

CONCLUSION The chemical is considered to be harmful to *Acartia tonsa* under the test conditions.

TEST FACILITY ERT (2003c)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Analogue 1*

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

Species *Scenedesmus subspicatus*
Exposure Period 72 hours
Concentration Range Nominal: 1, 2, 4, 8, 16, 32, 64, 128 mg/L of test substance
Auxiliary Solvent none
Water Hardness Not specified
Analytical Monitoring Not specified
Remarks - Method The stock solution of the chemical was made by adding 1 g to dissolve to 1000 mL following by serial dilution to obtain working solutions.

	Biomass		*Growth*	
	E_bC_{50} (95% CL) mg/L (0-72 h)	*NOEC* mg/L	*E_rC_{50} (95% CL)* mg/L (0-72 h)	*NOEC* mg/L
Test substance	12	4	38	4
Analogue chemical	6	2	19	2

Remarks - Results *This analogue was not considered acceptable for the environment assessment.
In the 32 mg/L concentration a slight foam formation was observed. Since the growth rate is expressed by the logarithm of the cell count change (small changes in the growth rate can cause large changes in the biomass), the E_bC_{50} and the E_rC_{50} values cannot be compared with each other numerically. The former are generally lower and should be preferred over the latter for risk assessment purposes.

CONCLUSION The test chemical (precursor chemical) is considered to be harmful to *Scenedesmus subspicatus* under the test conditions.

TEST FACILITY Henkel KGaA (1994)

8.2.3. Marine algal growth inhibition test

TEST SUBSTANCE	Analogue 10
METHOD	ISO 10253 Water quality, Marine Algal Inhibition Test.
Species	*Skeletonema costatum*
Exposure Period	72 hours
Concentration Range	Nominal: 1, 1.8, 3.2, 5.6, 10 mg/L of test substance
Auxiliary Solvent	none
Water Hardness	Not specified
Analytical Monitoring	Not specified
Remarks - Method	The chemical was characterised as soluble in filtered seawater (1 g/L), therefore a dilution series was used to prepare working solutions.

	Biomass EC_{50} *(95% CL)* mg/L (0-72 h)	*Growth* *NOEC* mg/L
Test substance	7.32	3.2
Analogue chemical	1.46	0.64

Remarks - Results	No cell growth was observed at concentration of 10 mg/L at 72 hours, which indicates a very steep curve.
CONCLUSION	The analogue chemical is considered to be toxic to *Skeletonema costatum* under the test conditions.
TEST FACILITY	ERT (2003c)

8.3. Terrestrial Organism

TEST SUBSTANCE	Analogue 5
Species	Earthworm Toxicity Test with *Eisenia foetida,* 14 days, German UBA method (1984), similar to OECD 207. LC50 > 654 mg/kg[3]
Species	Higher Plants Test with *Avena sativa* (turnip)*, Brassica rapa* (oat) and *Lycopersicum esculentum* (tomato), 21 days. EEC ring test protocol C(21)3, similar to OECD 208 LC50 > 654 mg/kg[3]

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be imported as a component of the commercial form suitable for reformulation in Australia. The notified chemical will be used as a surfactant in personal care products, which will be used by consumers in a variety of applications, but expected to be predominantly in hair shampoos. The finished product containing the notified chemical will be sold to end-users Australia-wide.

Nearly all of the notified chemical may potentially be disposed of to sewer after use, with only small quantities (10 to 15 kg per year), including that proportion remaining as residual in containers and major spills, being disposed of to landfill.

Case Study 1: Australia-Wide Release

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

Case Study 2: Formulation Release
During reformulation, 0.3% of the total volume imported of notified chemical is expected to be released to STP across 20 sites (after 5 years) around Australia during a period of 10 to 15 days per year. The notified chemical will be released to communal sewer via industrial effluent discharge. Based on the typical use per day, worst-case predicted environmental concentration (PEC) values are estimated for discharging into a large sewage treatment works and the other into a small sewage treatment works assuming no partitioning to sludge within the sewage treatment works.

Process or Dilution Factor	Australia-Wide Release	Formulation Release to Large STP	Formulation Release to Small STP
Concentration of notified chemical per year	14955	45	45
Typical notified chemical use expected per day	41.0 kg	4.5 kg	4.5 kg
Number of day used	365 days	10 days	10 days
Australian population	20 million people	Large City	Small City
Water consumed average	200/L/person		
STP daily Volume	4000 ML	100 ML	4 ML
Concentration in effluent from sewage treatment plant	10.24 µg/L	45.0 µg/L	1,125 µg/L
Predicted environmental concentrations (PECs) in receiving waters			
Ocean (Dilution Factor 1:10)			
PEC	1.02 µg/L	4.5 µg/L	112.5 µg/L
River (Dilution Factor 1:1)			
PEC	10.24 µg/L	45.0 µg/L	1,125 µg/L

The water solubility test results indicate that large proportion of the notified chemical would partition into the water column. However, as it is designed to be a surface active chemical, therefore, it may to bind readily to or be associated with soil and sediments.

The potential for bioaccumulation is also low due to the high water solubility.

A SIMPLETREAT cannot be used for mitigation studies due to the range of water solubility, Kow and vapour pressure values. However, assuming the lowest log H (-4) and log Kow values (0) and ready biodegradation 10 days criterion not met, it may be predicted 33% will remain in the water and 67% will be degraded. While some may bind to sludge, the extent of this cannot be estimated.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests are listed below.

Organism	*Chemical*	*Duration*	*End Point*	*mg/L**
Freshwater Fish	Notified chemical	96 h	LC50	1.36
Freshwater Fish	Analogue 1*	96 h	LC50	2.95
Marine water Fish	Analogue 10	96 h	LC50	1.32

Freshwater Daphnia	Analogue 1*	48 h	LC50	7.00
Marine water Copepod	Analogue 10	48 h	LC50	4.55
Freshwater Algae	Analogue 1*	0-72 h	E_bC50	6.00
			E_rC50	19.0
Marine water Algae	Analogue 10	0-72 h	E_bC50	1.46

*This analogue was not considered acceptable for the environment assessment.

Using the lowest value of 1.32 mg/L (based on analogue 10) and a safety factor of 100 (based on 3 experimental results) for fish/*Daphnia*/algal acute toxicity endpoints, a Predicted No Effect Concentration (PNEC) for aquatic ecosystems of 13.2 µg/L is estimated.

9.1.3. Environment – risk characterisation

Case Study 1: Australia-Wide Release

	Location	PEC* µg/L	PNEC µg/L	Risk Quotient (RQ)*
Notified Chemical	Ocean outfall	1.02	13.2	0.08
	Inland River	10.24	13.2	0.78

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

Assuming that the chemical is not removed in the communal STP, the resulting risk quotient (RQ = PEC/PNEC) values for Australia-wide release to the aquatic environment are < 1 for freshwater and marine environment indicating an acceptable risk, which will improve further taking degradation into account.

Case Study 2: Formulation Release

	Location	PEC* µg/L	PNEC µg/L	Risk Quotient (RQ)*
Large STP	Ocean outfall	4.50	13.2	0.34
	Inland River	45.0	13.2	3.41
Small STP	Ocean outfall	112.5	13.2	8.52
	Inland River	1,125	13.2	85.23

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

Assuming that the chemical is not removed by a large STP, the resulting RQ values for the aquatic environment are < 1 for the marine environment indicating no concern. However, RQ is > 1 for a large STP discharging into freshwater indicating a risk for this aquatic compartment.

Assuming that the chemical is not removed by a small STP, the resulting RQ values for the aquatic environment, are >> 1 indicating a high risk for both, freshwater and marine environment.

While this has been assumed to be all discharged from one site (as may occur initially), even if the release value is divided by 20, the RQ for release to an inland river remains > 1. Therefore, it is recommended there should be no release to the aquatic environment during formulation.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Formulation

Dermal and possibly ocular exposure to the notified chemical could occur during the transfer of the Plantapon LGC commercial form to the blending vessel. The level of exposure would vary

from site to site depending on the level of automation of the formulation process. The estimated dermal exposure is 84 mg/day, based on the EASE model using reasonable worst case defaults for the exposure scenario 'manual addition of liquids' (European Commission, 2003) and assuming the notified chemical is present at concentration of 20%. Therefore, for a 70 kg worker and a 100% dermal absorption factor, systemic exposure is estimated to be 1.2 mg/kg bw/day.

Exposure would be limited by the use of PPE.

Following formulation of the end use products, exposure to the notified chemical is expected to be very low due to the low concentration of the notified chemical (up to 1.4%) and the expected use of PPE.

End use
Workers may be exposed to the notified chemical during final application of the formulated cosmetic products or during their addition to water if dilution is required. Although the level and route of exposure will vary depending on the method of application and work practices employed, exposure is considered to be low due to the low concentration of the notified chemical (up to 1.4%).

9.2.2. Public health – exposure assessment

Since the notified chemical will be in products sold to the general public, widespread public exposure to the notified chemical at a concentration up to 1.4% is expected. Based on exposure to a range of household, personal care and cosmetic products in Europe (SDA, 2005), public exposure (dermal and inhalation) to the notified chemical through use of a wide range of products containing the notified chemical, is estimated to be 3.7 mg/kg bw/day, assuming a bodyweight of 60 kg, a 100% dermal absorption factor, a concentration of 1.4% and that product usage (amount used per use and frequency of use) is similar in Australia to Europe. This estimate is considered to be an overestimate as it assumes all products (household, personal care and cosmetic) used by one person contain the notified chemical and uses the maximum 'product amount used' from the range in the dataset.

Based on exposure to a range of household, personal care and cosmetic products in Europe (SDA, 2005), maximum single product use exposure is expected for the products; fragrance cream, facial moisturiser, body lotions and hand moisturiser. Assuming a bodyweight of 60 kg, a 100% dermal absorption factor, a concentration of 1.4% and that product usage (amount used per use and frequency of use) is similar in Australia to Europe, exposure to the notified chemical in these products is as follows:

Fragrance cream: 0.3 mg/kg bw/day
Facial moisturiser: 0.4 mg/kg bw/day
Body lotion: 1.3 mg/kg bw/day
Hand moisturiser: 1.3 mg/kg bw/day

If the notified chemical is used in baby care products, a child's exposure is estimated to be 4.5 mg/kg bw/day assuming a bodyweight of 15 kg, a 100% dermal absorption factor, a concentration of 1.4% and that product usage (amount used per use and frequency of use) is similar in Australia to Europe. Since products containing the notified chemical are stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

9.2.3. Human health – effects assessment

Acute toxicity
Plantapon LGC containing 20% notified chemical is of low acute toxicity via the oral route and the analogue is of low acute toxicity via the dermal route.

Irritation
Based on the studies provided the analogues are considered to be moderately irritating in the rabbit skin irritation test. Plantapon LGC and an analogue are considered to be slightly irritating in the human patch study. Plantapon LGC containing 20% the notified chemical is considered to be irritating in rabbit eye irritation test and slightly irritating in the RBC test.

Sensitisation
There was inadequate evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to an analogue in a mouse LLNA.

Overall, the notified chemical is considered not to be a potential skin sensitiser.

Repeated Dose Toxicity
In a 90-day oral repeat dose study in rats, a No Observed Adverse Effect Level (NOAEL) was established for an analogue as 450 mg/kg bw/day, based on the absence of treatment related effects.

Genotoxicity
The analogues were not mutagenic to bacteria and not clastogenic to fibroblast cells treated in vitro.

Hazard classification for health effects
Based on the limited toxicological data for the notified chemical, it is not possible to classify the notified chemical as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004). However, based on the skin and eye irritation study, the analogue data provided and classification of similar chemicals, the notified chemical is likely to be classified as a skin and eye irritant.

9.2.4. Occupational health and safety – risk characterisation

Reasonable worst-case exposure to the notified chemical during formulation was estimated to be 1.2 mg/kg bw/day. Based on a NOAEL of 450 mg/kg bw/day, derived from a 90-day rat oral study, the margin of exposure (MOE) is calculated as 380. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects using modelled worker data is acceptable for formulation workers.

Following formulation of the end products, exposure is expected to be very low and as such the risk to workers is also considered to be low.

9.2.5. Public health – risk characterisation

Based on a NOAEL of 450 mg/kg bw/day, derived from a 90-day rat oral study the margin of exposure (MOE) from a number of exposure scenarios is calculated as follows:

Product(s) used	*Adult/Child*	*Estimated Exposure <mg/kg bw/day>*	*MOE*
Wide range of household, personal care and cosmetic products.	Adult	3.7*	120
Fragrance cream	Adult	0.3	1500
Facial moisturiser	Adult	0.4	1100
Body lotion	Adult	1.3	350
Hand moisturiser	Adult	1.3	350
Baby care products	Child	4.5	100

*SDA (2005)

MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. As the all the calculated MOEs are ≥ 100, the risk to public health is considered to be low.

Since products formulated with the notified chemical will be stored and used in a domestic environment, there is also the possibility for children to be exposed to the notified chemical by

accidental ingestion. However, as the notified chemical is considered to be of low acute toxicity and given the low concentration of the notified chemical in the formulated products, the risk of lethal effects as a result of accidental ingestion 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 cannot be classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004). However, as precaution measurement, the notifier has classified the notified chemical as a skin and eye irritant.

and

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

	Hazard category	***Hazard statement***
Chronic hazards to the aquatic environment	2	Toxic to aquatic life with long-lasting effects.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:
The chemical may pose a risk to the environment based on the 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 Low Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of products 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 products 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

REGULATORY CONTROLS
Hazard Classification and Labelling

- The notifier should apply the following health hazard classification to the notified chemical:

– R36/38 Irritating to eyes and skin.

Use the following safety phrases for products/mixtures containing the notified chemical:

- S24/25 Avoid contact with skin and eyes
- S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- S28 After contact with skin, wash immediately with plenty of water.
- S37/39 Wear suitable gloves and eye/face protection.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  – Avoid contact with skin and eyes

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  – Workers are required to wear protective goggles and hand protection when handling the commercial form, for example, when connecting/disconnection transfer hoses between imported container and end-product blending vessel. The handling of the imported form is facilitated by its dilute (20%) liquid form and no hazardous vapours would be emitted that would require local exhaust ventilation, although such a system is usually present at the loading hatch of blending vessels.

  o 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

- The following control measures should be implemented to minimise environmental exposure during reformulation of the products containing the notified chemical:
  – Do not release formulation washing to the sewer.

Disposal

- The notified chemical should be disposed of by waste incineration or disposal with the approval of responsible local authority.

Storage

- The following precautions should be taken regarding storage of the notified chemical:
  – Keep container tightly sealed.
  – < + 30 °C

Emergency procedures

- Spills/release of the notified chemical should be handled by removing with liquid absorbing material such as sand, peat, sawdust. Do not empty into drains, surface water or ground 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(1) of the Act; if
- the concentration of the chemical in personal care consumer products exceeds 2%.
- further information becomes available on the irritating potential of the notified chemical.

or

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

The Director will then decide whether secondary notification is required.

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