File No: SN/24

May 2012

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Glycine, N-coco acyl derivs., potassium salts (Potassium Cocoyl Glycinate)

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

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
SN/24	Estee Lauder Pty Ltd	Glycine, N-coco acyl derivs., potassium salts (Potassium Cocoyl Glycinate)	Yes	≤ 2 tonnes per annum	A surfactant in a wash-off cosmetic product

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The classification and labelling details are:

Xi; R41 Risk of serious damage to eyes
R38 Irritating to skin

and

The classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2009) is presented below. The environmental classification under this system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	*Hazard statement*
Skin irritation	2	Causes skin irritation
Serious eye damage	1	Causes serious eye damage
Environment	Acute 3	Harmful to aquatic life

Human health risk assessment
Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unacceptable risk to public health.

Environmental risk assessment
On the basis of the PEC/PNEC ratio and assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- Safe Work Australia should consider the following health hazard classification for the notified chemical:
  - Xi; R38 Irritating to skin
  - R41 Risk of serious damage to eyes

- If the notified chemical is imported in future at higher concentrations, it should be further tested to determine the skin and eye irritation potential at these concentrations, or labelled in a precautionary manner as:
  – C; R34 Causes burns

- The following risk phrases are recommended in the workplace on products/mixtures containing the notified chemical:
  – ≥5% Concentration <10%: R36
  – ≥10% Concentration <20%: R41
  – Concentration ≥ 20%: R38, R41

- The notified chemical has previously been referred for scheduling in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) based on the results of skin and eye irritation tests. This assessment report provides further support for this action.

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

- 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 *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Public Health

- Consumer products containing the notified chemical at concentrations ≥ 5% should be labelled with a warning against eye contact, and directions on first aid measures if the product contacts the eye (e.g. avoid contact with eyes, in case of contact with eyes, rinse immediately with plenty of water and seek medical advice). Precautionary warning on possible skin irritation is also recommended.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS 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 notified chemical used in products has increased from 23%;
- if the chemical has begun to be reformulated in Australia;
- the notified chemical is to be used in spray products.

or

(2) Under Section 64(2) of the Act; if

- the function or use of the chemical has changed from a wash-off surfactant in cosmetic products, or is likely to change significantly;
- the amount of chemical being introduced has increased from 2 tonnes, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet

The MSDS of the notified chemical (and product containing the notified chemical) provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Estee Lauder Pty Ltd (ABN 008 444 719)
21 Rosebery Avenue Rosebery NSW 2018

Assessment of the notified chemical was carried out under the *Industrial Chemicals (Notification and Assessment) Act 1989* [the IC(NA) Act], as LTD/1382, with the Summary Report of the assessment published in the *Chemical Gazette* of 2nd December, 2008.

The Director of NICNAS was informed of an increase in the introduction volume of the notified chemical in excess of the permitted volume under the limited category (1 tonne/annum). Under the IC(NA) Act, the Director declared that a secondary notification was required for the chemical known as Glycine, N-coco acyl derivs., potassium salts (Potassium Cocoyl Glycinate).

In accordance with Section 65 of the IC(NA) Act, a notice requiring the secondary notification of Glycine, N-coco acyl derivs., potassium salts (Potassium Cocoyl Glycinate) was published in the *Chemical Gazette*. The notice of 2nd August, 2011 stipulated that the following data were required to undertake further assessment of Glycine, N-coco acyl derivs., potassium salts (Potassium Cocoyl Glycinate):

Any changes in the following data items from that submitted in the original notification:

1. Identity, Properties and Uses

   a) proposed uses of the chemical;
   b) concentration of the chemical in end-use products;
   c) import quantity (and changes to occupational exposure for workers); and
   d) physico-chemical properties.

2. Toxicity

Human health:

   a) the chemical's toxic effects following single dermal and inhalation exposure;
   b) the chemical's toxic effects following repeated exposure;
   c) the chemical's genotoxic effects;

Ecotoxicity:

d) the toxicity of the chemical to fish;
e) the toxicity of the chemical to aquatic invertebrates;
f) the effects of the chemical on algae.

Any additional available data on the toxicological and/or environmental effects of the chemical was also to be provided. The requested data was to be provided through the submission of studies (tests conducted on the notified chemical or suitable analogue) or other sources of information.

This report, SN/24, represents the revised assessment for Glycine, N-coco acyl derivs., potassium salts (Potassium Cocoyl Glycinate). Where additional data has been provided, it has been incorporated into the report and the implications of the data for the health and environmental risks of the notified chemical considered.

NOTIFICATION CATEGORY
Secondary Notification

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Melting Point, Boiling Point, Density, Water Solubility, Hydrolysis as a Function of pH, Partition Coefficient, Adsorption/Desorption, Dissociation Constant, Particle Size, Flash Point, Flammability, Autoignition Temperature, Explosive Properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
LTD/1382

NOTIFICATION IN OTHER COUNTRIES
Unknown

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Potassium Cocoyl Glycinate

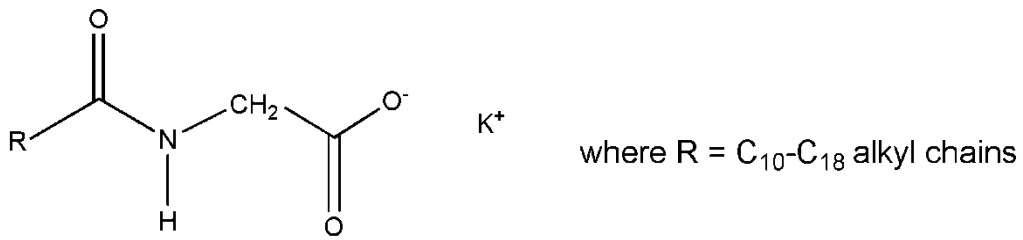
CAS NUMBER
301341-58-2

CHEMICAL NAME
Glycine, N-coco acyl derivs., potassium salts

OTHER NAME(S)
Amilite GCK-11F, Amilite GCK-12

MOLECULAR FORMULA
$C_{14}H_{26}O_3N\ K$ (as lauroyl derivative)
The notified chemical is a mixture of glycine N-acyl derivatives of fatty acids from coconut oil. The main component (47%) represents the derivative of lauric acid.

STRUCTURAL FORMULA



Component derivatives in the Amilite GCK-11F mixture:
47% lauroyl derivatives C12
18% myristoyl derivatives C14
9% palmitoyl derivatives C16
6% capryloyl derivatives C10
6% oleoyl derivatives C18:1
2% linoleoyl derivatives C18:2
3% stearoyl derivatives C15

MOLECULAR WEIGHT
267 – 379Da
295 Da (as lauroyl derivative)

ANALYTICAL DATA
Reference IR spectra were provided. Major peaks observed at 3310, 2920, 2850, 1550 and 1410 cm^{-1}

3. COMPOSITION

DEGREE OF PURITY 85%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

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

Chemical Name	Potassium sulfate		
CAS No.	7778-80-5	*Weight %*	1.2
Chemical Name	Potassium cocoate		
CAS No.	61789-30-8	*Weight %*	13.2
Chemical Name	Potassium Chloride		
CAS No.	7447-40-7	*Weight %*	0.6

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: White to light yellow solid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Imported as a mixture in water.
Boiling Point	Not determined	Imported as a mixture in water.
Density	Not determined	Imported as a mixture in water.
Vapour Pressure	< 10^{-5} kPa	Estimated.
Water Solubility	< 19.2 g/L (approximate) at 25°C	Measured (visual observation).
Hydrolysis as a Function of pH	Not determined	Expected to be very slow in the environmental pH range (4–9). Hydrolytic stability in cosmetic formulations is a functional requirement.
Partition Coefficient (n-octanol/water)	Not determined	The notified chemical is an ionic surfactant. Log P is expected to be low.
Adsorption/Desorption	Not determined	Mobility in soils is not expected to be high. The water solubility suggests some potential for mobility in soil, but the notified chemical can be expected to adsorb to organic carbon, soil and sediment because it is a surfactant.

Dissociation Constant	Not determined	As a potassium salt of a carboxylic acid, the notified chemical is expected to be ionised over the environmental pH range (4–9).
Particle Size	Not determined	Imported as a mixture in water.
Flash Point	Not determined	Imported as a mixture in water.
Flammability	Not determined	Notified chemical is a solid.
Autoignition Temperature	Not determined	Not expected to autoignite.
Explosive Properties	Not determined	Not expected to be explosive based on absence of structural alerts for explosivity.

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, please refer to Appendix A.

Reactivity
Expected to be stable under normal environmental and usage conditions. The CIR compendium and report (CIR 2001, 2004) raised concerns about the possible formation of potentially carcinogenic nitrosated derivatives of the analogue chemicals (acyl sarcosines) for which the precursor amine sarcosine is a secondary amine. Secondary amines are of more concern for nitrosamine formation than primary or tertiary amines. The nitrogen in the notified chemical itself is secondary, however its functional group is an amide rather than amine. Therefore the possibility of nitrosamine formation in the notified chemical is considered to be low.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical is imported as an ingredient (23%) in a finished cosmetic product.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1.5	1.7	2	2	2

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
The cleanser containing the notified chemical is made by Estee Lauder, United States, Inc and imported by Estee Lauder Australia Limited.

TRANSPORTATION AND PACKAGING
The cleanser containing the notified chemical will be imported by ship inside 125ml bottles, which are packed inside cardboard cartons. The cartons will be transported from the wharf to Estee Lauder's central warehouse at Rosebery, NSW. The cartons will be transported to a principal retailer's central distribution centres and retails chains by road**.**

USE
The notified chemical functions as a surfactant in a cosmetic product (facial cleanser) and is used at a level of 23%.

OPERATION DESCRIPTION
Warehouse workers will be involved in transporting the Cleanser from the wharf to Estee Lauder's distribution centre and placing the pallets of product into the warehouse.

A further two warehouse workers in the notifier's warehouse will be involved in transferring pallets from the Estee Lauder's central warehouse to the retailer's central distribution depots. Packers will pick products from the shippers and repack them for further transport directly to stores.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and Storage	12	4	12
Packers	5	4	12
End Users	3×10^5	< 1	365

EXPOSURE DETAILS
The imported finished product is fully packaged inside cartons and workers are not expected to come into contact with the notified chemical except in the case of an accidental breach of packaging.

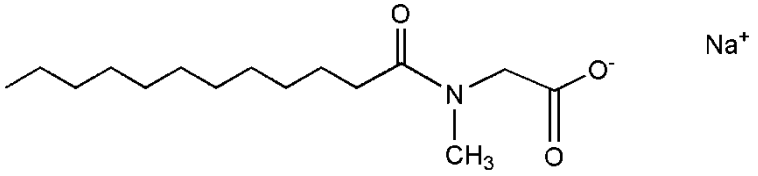
6.1.2. Public exposure
Since the finished product will be sold to the general public there will be widespread dermal exposure to the product containing 23% of the notified chemical. Due to its use as a wash-off facial cleanser, accidental ocular exposure is also expected.

The following exposure estimate was derived using published consumer exposure data in the Food and Chemical Toxicology journal (Loretz et al 2008) and exposure calculations from the *SCCP's Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation* (2006).

The maximum dermal exposure is estimated using a retention factor of 0.01 with the concentration of the notified chemical calculated as being 23% of the final product. Assuming a worst-case scenario, a 60 kg person may apply the facial cleanser 1- 2 times daily using an average of 4.06 g per day. The dermal absorption level is assumed to be 100% (in the absence of measured data and given the low molecular weight). This results in a dermal exposure estimate of 0.16 mg/kg bw/day.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified chemical and analogue chemical (Glycine, N-coco acyl derivs., sodium salts or Sodium Cocoyl Glycinate) are summarised in the table below. Details of these studies can be found in Appendix B. Published information from the Cosmetic Ingredient Review (CIR) on similar modified fatty acids known as acyl sarcosines and sarcosinates is included in the health effects assessment. An example is Sodium Lauroyl Sarcosinate (structural formula shown).



Endpoint	*Test substance*	*Result and Assessment Conclusion*
Rat, acute oral toxicity	Notified chemical	Oral LD50 > 2000 mg/kg bw low toxicity
Rabbit, skin irritation	Notified chemical	Irritating at 5% concentration
Rabbit, eye irritation	Notified chemical	Irritating at 5% concentration

Guinea pig, skin sensitisation – adjuvant test	Notified chemical	No evidence of sensitisation up to 2.5% concentration
Mutagenicity – bacterial reverse mutation	Notified chemical	Non mutagenic
Genotoxicity – bacterial reverse mutation	Analogue chemical	Non mutagenic
Genotoxicity – in vitro Chromosome Aberration Test in hamster lung fibroblasts (CHL/IU)	Analogue chemical	Genotoxic in the presence of metabolic activation
Genotoxicity – in vivo Mammalian Erythrocyte Micronucleus Test	Analogue chemical	Non genotoxic

Toxicokinetics, metabolism and distribution

No information was provided. N-acyl derivatives of sarcosine (acyl sarcosines) and their salts (sarcosinates) are structurally similar to the notified chemical and are also used as surfactant-cleansing agents in cosmetic products. A skin permeability test on rats revealed that acyl sarcosines and sarcosinates enhanced the skin absorption of other ingredients when applied together in the same formulation (CIR 2001). Due to this finding, cosmetic products containing the notified chemical should be carefully formulated to avoid combining with other ingredients (including colourants and dyes) if transdermal absorption is a health concern. The analogue, Sodium Lauroyl Sarcosinate is reported as not being hydrolysable by either gastric or intestinal enzymes *in vitro*. In a metabolism study in rats, 82%-89% of a 50 mg/kg oral dose of Sodium Lauroyl Sarcosinate was excreted in the urine and faeces within 24 hours, and 1%-2% was excreted over the next 24 hours (CIR 2001), suggesting that it is not readily absorbed through the gastrointestinal wall. In an oral dosing study in rats, radiolabelled Sodium Lauroyl Sarcosinate was administered and tissue samples (including urine and faeces) were analysed. At 24 hours after administration, 42% was present in the urine and less than 2% were found in organs such as the liver, kidneys, teeth and oral mucosa. Around 1% of the compound remained adhered to the teeth, oral mucosa and tongue and the radioactivity could not be washed out by physiological saline, indicating that Sodium Lauroyl Sarcosinate was absorbed into the blood. But the uptake is not permanent according to a different study, which found that frequent application did not cause an accumulation of radiolabelled sarcosinate in bone or muscle (CIR 2001). The notified chemical is likely to have similar absorption, metabolism and elimination kinetics as sarcosinates and is not likely to lead to bioaccumulation.

Acute toxicity

The oral LD_{50} of the notified chemical was determined to be over 2000 mg/kg bw in a test conducted in rats (Bozo Research Center Inc 1997). Based on this data, the notified chemical is considered to be of low toxicity via the oral route. Information is not available on the acute dermal or inhalation toxicity of the chemical.

Skin irritation

The notified chemical caused moderate to severe erythema in the skin of rabbits when tested at 5%, and although the symptoms had resolved after one week, all animals showed obvious scaling by the end of the study period (Ajinomoto Co Inc 1998a). Based on the persistence of skin scaling in all animals tested, the notified chemical is classified as irritating to the skin.

Eye irritation

In an eye irritation test in rabbits, 5% notified chemical caused iridial inflammation, corneal opacity and signs of conjunctival irritation in all animals tested. Four out of 6 animals continued to show conjunctival redness at the end of the observation period (Ajinomoto Co Inc 1998b). Based on the persistence of conjunctival redness, the notified chemical is classified as a severe eye irritant.

Sensitisation

The notified chemical did not produce a reaction in a guinea pig maximisation test (Ajinomoto Co Inc 2004) when tested up to the maximum non-irritating concentration of 2.5%, and is therefore not considered to be a skin sensitiser.

Subchronic and chronic toxicity

No information on repeat dose toxicity was available for the notified chemical. The Cosmetic Ingredient Review reports that weanling rats given a diet containing 2% Sodium Lauroyl Sarcosinate for 6 months had no effect on weight gain, feeding, general health or behaviour. There were no abnormalities of the internal organs. Rats fed 0.5% Sodium Lauroyl Sarcosinate for 100 days also showed no signs of toxicity. In a chronic toxicity study, 200

albino Wistar rats were fed Sodium Lauroyl Sarcosinate ranging from 0.05% to 2.0% for a period of 2 years. There were no significant differences in lesions, fertility, mortality, haematology or body weight gain between the control and treated groups. The only significant change after 24 months was minor hyperplasia of the stratified squamous epithelium and excess keratin formation in the stomach mucosa of rats treated at the highest doses (1% and 2%) (CIR 2001).

Mutagenicity
The notified chemical was not mutagenic to bacteria in the presence or absence of metabolic activation in an Ames test (BML Inc 1994). The analogue chemical was also not mutagenic to bacteria in the Ames test in the presence or absence of metabolic activation, using the pre-incubation method (BML 1997).

The analogue chemical was not clastogenic in a Chromosomal Aberration test using Mammalian lung fibroblasts in the absence of metabolic activation but it increased the percentage of cells with aberrations in the presence of metabolic activation at the highest concentration tested (BML 1998). Based on this result the analogue chemical is considered to be clastogenic to mammalian cells *in vitro* in the presence of metabolic activation. However, the significance of the positive result is unclear as the increase of aberrations was only observed at the highest concentration and there was no repeat of the experiment at the selected or other concentrations of the analogue chemical. The analogue chemical was not clastogenic in an *in vivo* micronucleus test in mice (JBC 1998). Some cytotoxic effects were observed as determined by the decrease of the number of immature erythroblasts, indicating that the analogue chemical has reached the bone marrow. Due to cytotoxicity of the analogue chemical the test concentrations for all genotoxicity studies were low. The cytotoxicity of the analogue chemical is most likely due to the surfactant characteristics and interference with the cell membrane. Based on the available data, the notified chemical is not considered mutagenic.

Reproductive and developmental toxicity
There is insufficient information to classify the notified chemical regarding reproductive toxicity but published information on sodium lauroyl sarcosinate describes that rats fed up to 1000 mg/kg/day did not experience adverse effects on fertility in a 2-year oral toxicity study (CIR 2001).

Carcinogenicity
No carcinogenicity data was available for the notified chemical. The CIR compendium and report (CIR 2001 and CIR 2004) on acyl sarcosines addresses health concerns arising from the reaction of a secondary amine group in the starting material sarcosine that can lead to the formation of nitrosated derivates (N-nitrososarcosine) that are known to be carcinogenic. Because of this reaction, the report recommends that sarcosine should not be used in cosmetic products in which nitrosamine compounds may be formed. However the possibility of nitrosamine formation in the notified chemical is less likely as the functional group is an amide rather than an amine, and therefore the potential for carcinogenicity due to nitrosamine formation is low.

Health hazard classification
Based on the eye irritation and skin irritation tests, the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Xi; R41 Risk of serious damage to eyes
R38 Irritating to skin

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Workers are not likely to be exposed to the product containing the notified chemical, unless there was a packaging breakage in which minor dermal contact is possible. The notified chemical causes skin irritation and there is a risk of workers experiencing symptoms of skin irritation after a single exposure. However the likelihood of exposure is very low and the risk to workers is not considered to be unacceptable.

6.3.2. Public health

The public will have widespread dermal exposure to the notified chemical, which is proposed to be used at a level of 23% in facial cleansers. Eye exposure is also a possibility due to accidental contact. The notified chemical caused persistent eye irritation at 5% in animal tests, and eye contact with the cleanser containing 23% could lead to serious eye damage. Even below the concentration cut-off of 5%, eye irritation cannot be ruled out. If the product were diluted with water when eye contact occurs, significant eye irritation may still occur and in a worst-case scenario may lead to eye damage. Skin scaling was evident in animals when tested at 5% and there is potential for significant skin irritation when used as a facial cleanser at the proposed concentration, particularly in individuals with sensitive or damaged skin. However the animal test was conducted using a 24-hour patch application simulating a 'leave-on' application, whereas cleansers are typically used as a 'wash-off' product where the exposure time is relatively brief. In this case, skin irritation may not necessarily occur with normal use.

The product containing the notified chemical may lead to significant eye damage and irritation, but the risk may be minimised by the use of clear and appropriate directions for use and safety precautions to avoid eye contact. First aid information should also be included to minimise adverse effects if eye contact occurs. Although the notified chemical may cause serious damage to eyes and is classified as a skin irritant, under the proposed usage in a wash-off product, the risk for public health is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

No releases are expected as the notified chemical will be imported as part of a finished cosmetic facial cleanser and no reformulation will occur in Australia.

RELEASE OF CHEMICAL FROM USE

As the notified chemical will be used in water-based cosmetic facial cleansers, most release of the chemical will be from bathrooms or similar 'wet' areas, which normally drain to sewer. Consequently, the major proportion of the introduced quantity of the notified chemical is expected to be released into the domestic sewer system.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues in empty containers are expected to be disposed of to landfill, together with the empty containers. Waste and expired material is similarly expected to be disposed of to landfill.

7.1.2 Environmental fate

The notified chemical is readily biodegradable, and can therefore be expected to degrade during sewage treatment and if discharged to aquatic environments. Degradation in landfill can also be expected, based on the ready biodegradability and chemical structure of the notified chemical. For the details of the environmental fate studies please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

The following PECs are estimated based on the worst-case assumption that there is no elimination during sewage treatment. Environmental exposure is expected to remain below these estimates under actual conditions of use, as the notified chemical is readily biodegradable.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	2,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	2,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	5.48	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	1.29	µg/L
PEC - □cean:	0.13	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 1.295 µg/L may potentially result in a soil concentration of approximately 8.631 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 43.16 µg/kg and 86.31 µg/kg, respectively.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (96 h)*	LC50 > 100 mg/L	Not harmful
Aquatic Invertebrate Toxicity (48 h)	EC50 > 80 mg/L	Not toxic
Algal Toxicity (72 h)	E_rC50 = 16.3 mg/L	Harmful

*Calculated by QSAR

Under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009) the notified chemical is classified as not harmful to fish, not toxic to aquatic invertebrates and harmful to algae. Based on the toxicity to algae the notified chemical is formally classified under the GHS as “Acute category 3: Harmful to aquatic life”. As the notified chemical is readily biodegradable, and it is not expected to bioaccumulate due to its water solubility, the notified chemical has not been classified for long-term hazard under the GHS.

7.2.1 Predicted No-Effect Concentration

The lowest endpoint from ecotoxicological studies on notified chemical was used to calculate the PNEC. Acute toxicity endpoints are available for the effects of the notified chemical on aquatic species from three trophic levels (two experimental results and one based on QSAR). An assessment factor of 500 was used since the QSAR result was not a conservative estimate.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E_rC50 (algae)	16.3	mg/L
Assessment Factor	500	
PNEC:	32.6	µg/L

7.3. Environmental risk assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q – River	1.29	32.6	0.040
Q – Ocean	0.13	32.6	0.004

The Risk Quotients (Q = PEC/PNEC) for the worst case discharge scenario have been calculated to be < 1 for the river and ocean compartments. This indicates the notified chemical is not expected to pose an unacceptable risk to the aquatic environment based on its reported use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility < 19.2 g/L at 25ºC

Method	Not stated. There is no test report, just a brief description of the method and graphical presentation of results.
Remarks	The water solubility was determined by visual observation of the clarity of solutions that had been prepared at 80ºC and set aside for a week at lower temperatures. The notifier claims a solubility of 1.92 g/L, but appears to have misinterpreted the units for one of the axes in the graphical presentation of results.
Test Facility	Ajinomoto (2008).

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	In-house test similar to OECD TG 401 – Limit Test.
Species/Strain	Mice/ICR
Vehicle	30% test solution was diluted with water to 20% solution at time of use.
Remarks - Method	10 animals (5 female, 5 male) were given 2000 mg/kg of the notified chemical as a 20% test substance solution by oral gavage after being deprived of food for approximately 16 hours. 10 mice (5 female, 5 male) were given water only and served as the control. The animals were observed for 14 days after administration.
RESULTS	
LD50	> 2000 mg/kg bw
Signs of Toxicity	None were observed.
Effects in Organs	No changes in organs at necropsy.
Remarks - Results	No deaths occurred and there were no abnormal clinical signs. There was no significant difference in body weights of the animals in the treatment group compared with that of the control group.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Bozo Research Center Inc (1997)

B.2. Irritation – skin

TEST SUBSTANCE	The notified chemical at 5% in aqueous solution
METHOD	In-house modified Draize test
Species/Strain	Rabbit/New Zealand White
Number of Animals	4 Males
Vehicle	Distilled water
Observation Period	7 days
Type of Dressing	Occlusive
Remarks - Method	0.3 ml of the test substance solution was placed on a patch with adhesive plaster and applied to previously clipped area of skin. The area was covered with a torso cover and left for 24 hours. Skin irritation was assessed according to the Draize scale at 24, 48 and 72 hours and 1 week after the application.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	1.08	2	< 7 days	0
Oedema	0	0	0	0

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

Remarks - Results	At the end of the observation period, all animals showed scaling of the skin.
CONCLUSION	The notified chemical is irritating to the skin based on the persistence of scaling at the end of the observation period.

TEST FACILITY Ajinomoto Co Inc (1998a)

B.3. Irritation – eye

TEST SUBSTANCE The notified chemical at 1% and 5%, in aqueous solution.

METHOD In-house modified Draize test
Species/Strain Rabbit/New Zealand White
Number of Animals 6 Males
Observation Period 7 days
Remarks - Method The observation period is 7 days, which is a shorter period than the 21 days recommended in the OECD test method. The report using 5% test substance did not provide individual scores for conjunctival symptoms at the 48 and 72 hour observation points, therefore the mean overall scores could not be calculated for conjunctival redness, chemosis and discharge. SLS (5%) was used as a positive control.

RESULTS

1% test substance

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.33	1	< 72 hours	0
Conjunctiva: chemosis	0	0	0	0
Conjunctiva: discharge	0	0	0	0
Corneal opacity	0	0	0	0
Iridial inflammation	0	0	0	0

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

5% test substance

Lesion	*Mean Score at 24 hours**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	2.83	3.0	Present after 7 days	1
Conjunctiva: chemosis	1.83	3.0	< 7 days	0
Conjunctiva: discharge	1.67	3.0	< 7 days	0
	*Mean Score^*			
Corneal opacity	0.08	1.0	< 48 hours	0
Iridial inflammation	0.33	1.0	< 48 hours	0

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

Remarks - Results *1% test substance*: Only slight irritation effects observed at this concentration, which cleared within 72 hours.
5% test substance: Corneal opacity and iridial inflammation were only observed in one animal at the 24 hour observation. Conjunctival irritation was maximal at 24 hours and slowly improved over time. However redness of the conjunctiva was still present after 7 days.

CONCLUSION The notified chemical is severely irritating to the eye based on the persistence of irritation effects at the end of the observation period.

TEST FACILITY Ajinomoto Co Inc (1998b)

B.4. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation – Guinea Pig Maximisation Test
EC Directive 96/54/EC B.6 Skin Sensitisation.
Species/Strain Guinea pig/Hartley
VEHICLE Physiological saline for intradermal and water for topical application.

PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 0.1% topical: 2.5% Maximum concentration to cause mild-moderate irritation: intradermal: 0.1% (no irritation, but necrosis observed at 0.25% and 0.5%) topical: 5%
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal: 0.1% topical: 5%
CHALLENGE PHASE	
1st challenge	topical: 2.5, 1%
Remarks - Method	No observations of irritation during the induction phase were included in the study.

RESULTS

Remarks - Results	No skin reactions (score 0) were observed at any site of application on any animal when challenged with 2.5% or 1% test substance solution. No skin reactions were observed at any site of application on any animal in the control group. There were no deaths and no signs of systemic toxicity in any group during the observation period. Six animals in the test group and 4 animals in the control group at the challenge observation period (day 24) showed body weight loss but all of these animals were recovered at the end of the study on day 25. The reason for the temporary weight loss was unclear.

CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Ajinomoto Co Inc (2004)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical (30% aqueous solution)
METHOD	Study in compliance with Japanese regulatory standards - Standards for Mutagenicity Tests using Microorganism (Ministry of Labour, Japan) and GLP standards.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 fraction from Phenobarbital and 5,6-benzoflavone activated rat liver
Concentration Range in Main Test	a) With metabolic activation: Salmonella typhimurium: 10-313 µg/plate; *E. coli*: 156-5000 µg/plate b) Without metabolic activation: *Salmonella typhimurium*: 1.2-78 µg/plate (TA100, TA1535, TA1537); 1.2-313 µg/plate (TA98) *E. coli*: 156-5000 µg/plate
Vehicle	Water
Remarks - Method	Concentration of the tested material was 30% and the measured weights of test substance were corrected accordingly. The positive controls used were (2-(2-furyl)-3-(5-nitro-2-furyl)acrylamide, sodium azide, 2-methoxy-6-chloro-9-[3-(2-chloroethyl) aminopropylamino] acridine.2HCl, 2-aminoanthracene, Benzo(a)pyrene. The preincubation method was used. A second test (Test 2) was run for the strains TA100, TA1535 and TA 1537 due to the low number of doses without growth inhibition in the preliminary toxicity test.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:* *Cytotoxicity in Preliminary Test*	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 78 for *S. typhimurium**	≥ 39 for *S. typhimurium*	> 313	Negative
	5000 for *E.coli*	≥ 2500 for *E.coli*	> 5000	Negative
Test 2	-	≥ 39 for *S. typhimurium*	> 313	Negative
Present				
Test 1	≥ 313 for *S. typhimurium*	≥ 156 for *S. typhimurium*	> 313	Negative
	5000 for *E.coli*	≥ 2500 for *E.coli*	> 5000	Negative

* Except for TA98, where cytotoxicity was observed at ≥ 313 µg/plate.

Remarks - Results

There was no significant increase in the number of revertant colonies with or without metabolic activation compared to the negative control, and there was no dose-related effect observed in any strain. The revertant colonies of the positive control showed an increase of more than twice that of the negative controls indicating that the study was performed correctly.

CONCLUSION

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

TEST FACILITY

General Laboratory, BML Inc 1994

B.6. Genotoxicity – bacteria

TEST SUBSTANCE

Analogue chemical 28% (Glycine, N-coco acyl derivs., sodium salts)

METHOD

Study in compliance with Japanese regulatory standards for Microbial Mutagenicity and GLP standards.
Pre incubation procedure

Species/Strain

S. typhimurium: TA1535, TA1537, TA98, TA100
E. coli: WP2uvrA

Metabolic Activation System

S9 fraction from Phenobarbital and 5,6-benzoflavone activated Sprague-Dawleyr Rat liver at 10%

Concentration Range in Main Test

Without metabolic activation for *S. typhimurium* strains: 2.4 to 78 µg/plate
With metabolic activation for *S. typhimurium* strains: 10 to 313 µg/plate
Without metabolic activation for *E. coli* strain 156 to 5000 µg/plate
With metabolic activation for *E. coli* strain: 156 to 5000 µg/plate

Vehicle

Water (for the notified chemical)

Remarks - Method

Concentration of the tested material was 30%
Appropriate vehicle and positive controls were used. The negative controls were within normal limits and the positive controls (2-(2-furyl)-3-(5-nitro-2-furyl)acrylamide, sodium azide, 2-methoxy-6-chloro-9-[3-(2-chloroethyl) aminopropylamino] acridine.2HCl, 2-aminoanthracene, Benzo(a)pyrene demonstrated the sensitivity of the test system.
The mutagenicity study on S. Typhimurium strains was repeated without metabolic activation because of growth inhibition in the initial test.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:* *Cytotoxicity in Preliminary Test*	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 78 for *S. typhimurium* 5000 for *E. coli*	78 for *S. typhimurium* 2500 for *E. coli*	Not observed	no
Test 2	-	78 for *S. typhimurium*	Not observed	no

Present				
Test 1	≥313 for *S. typhimurium* 5000 for *E. coli*	156 for *S. typhimurium* 2500 for *E. coli*	Not observed	no
Test 2	-	not performed	-	no

Remarks - Results: The observed cytotoxicity of the notified chemical at relatively low concentrations of the notified chemical is most likely due to the surfactant properties.

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

TEST FACILITY: BML (1997)

B.7. Genotoxicity – in vitro

TEST SUBSTANCE: Analogue chemical (Glycine, N-coco acyl derivs., sodium salts)

METHOD: Study in compliance with Japanese regulatory standards for Toxicity testing of Pharmaceutical products and GLP standards.

Species/Strain: Chinese hamster

Cell Type/Cell Line: Lung fibroblasts (CHL/IU) cells

Metabolic Activation System: S9 fraction from Phenobarbital and 5,6-benzoflavone activated Sprague-Dawleyr Rat liver at 5%

Vehicle: Saline

Remarks - Method: Concentration of the notified chemical in the test is stated to be ten times higher than in the table below. However, the dilution in the cell medium was not taken into account.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	4*; 8*; 12*; 16*	24h	24h
Test 2	4*; 8*; 12*; 16*	48h	48h
Test 3	7.8*; 15.6*; 31.3*; 62.5*	6h	24h
Present			
Test 3	7,8*; 15,6*; 31,3*; 62,5*	6h	24h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	10.5	Not determined	Not observed	no
Test 2	-	16	Not observed	no[a]
Test 3				no
Present				
Test 1	42	-	-	-
Test 3	-	Not determined	Not observed	yes[b]

Remarks - Results

a There was a small increase of the percentage of cells with aberrations including gaps in cultures treated with 8 and 12 μg/mL of notified chemical (2% and 1.5%, respectively) compared with the solvent control (0%) . However, this is not considered to be significant as there were also

some aberrant cells (0.5%) in the non-treated control while the positive control using treatment with MMC generated significantly higher increase. At the highest concentration tested in the Main test 1, the cytotoxicity was very high and did not allow for examination of sufficient number of cells to determine genotoxicity.

b The percentage of cells with aberrations including and excluding gaps was increased to 23% in the cultures treated with 62,5 µg/mL of notified chemical in the presence of metabolic activation. This increase was assessed as a positive genotoxic effect even though concentration dependent trend was not observed at the lower concentrations. In Tests 1 and 2, the incidence of structural aberrations was increased with the positive control Mitomycin C (MMC). In Test 3 the percentage of cells with structural aberrations tested with the positive control N-nitrosodimethylamine (DMN) i was increased in the presence of metabolic activation, but was not increased in the absence of metabolic .activation. A possible reason for the result is that this control requires metabolic activation.

CONCLUSION The notified chemical was clastogenic to hamster lung fibroblasts (CHL/IU) treated in vitro in the presence of metabolic activation.

TEST FACILITY BML (1998)

B.8. Genotoxicity – in vivo

TEST SUBSTANCE Analogue chemical (Glycine, N-coco acyl derivs., sodium salts)

METHOD In house method similar to OECD TG 474 Mammalian Erythrocyte Micronucleus Test.

Species/Strain Mouse/ICR (Crj:CD-1) SPF

Route of Administration Intraperitoneal twice within 24h

Vehicle Saline

Remarks - Method In a preliminary, range finding study, the LD50 for intraperitoneal administration was determined to be between 250 and 500 mg/kg bw.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	6 male	0	24h
II (low dose)	6 male	50	24h
III (mid dose 1)	6 male	100	24h
IV (mid dose 2)	6 male	200	24h
V (high dose)	6 male	400	24h
VI (positive control - M)	6 male	2	24h

M=mitomycin C

RESULTS

Doses Producing Toxicity In the main test four deaths were observed in the 400 mg/kg bw group (4/6) and one death was observed in the 200 mg/kg bw group (1/6). A decrease in locomotor activity and bradypnea were observed in the 50mg/kg bw or higher concentration groups, piloerection was observed in the 100 mg/kg bw or higher concentration groups, hypothermia, lacrimation and prone position were observed in the 200 mg/kg bw or higher concentration groups.

Genotoxic Effects None observed in the animals treated with the solvent control.

No increase in the frequency of micronucleated polychromatic erythrocytes at any dose level or exposure time was observed in the dose range finding study or the main.

The positive control showed a marked increase in the frequency of micronucleated polychromatic erythrocytes, indicating that the test

	system responded appropriately
Remarks - Results	The ratio of polychromatic erythrocytes to total erythrocytes was significantly decreased in the mid dose I (group III) and above. This finding suggests that the notified chemical has reached the bone marrow after intraperitoneal administration and it is toxic to erythroblasts.
CONCLUSION	The notified chemical was not clastogenic under the conditions of this in vivo Mammalian Erythrocyte Micronucleus Test.
TEST FACILITY	JBC (1998)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Liquid formulation containing 30 % notified chemical
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).
Inoculum	Standard activated sludge (30 mg/L).
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	BOD and DOC
Remarks - Method	The test substance (340 mg/L) contained 30% of the notified chemical.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	65.8	7	56.7
14	73.2	14	63.6
21	75.2	21	66.2
28	79.8	28	69.5

Remarks - Results	Biodegradability of the test substance based on DOC was > 90%. Degradation also occurred in deionised water without activated sludge, reaching 43% after 28 days based on BOD.
CONCLUSION	The notified chemical is readily biodegradable.
TEST FACILITY	Ajinomoto (1995).

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified chemical

METHOD QSAR estimation methods

RESULTS

ECOSAR (v1.00) *Anionic surfactant class* *LC50 (96 h) mg/L*
> 100

REMARKS - RESULTS

Surfactant toxicity has been found to depend on carbon chain length (Nabholz et al., 1993) and consequently, QSARs based on chain length have been derived and validated for fish (US EPA, 2009). If the toxicity of a mixture is to be estimated, usually the weighted average carbon chain length (WACCL) is used for the calculation. In the notified chemical the cocoyl acid profile depends on the source coconuts and, as a result, the WACCL is variable. The chain length of the most abundant component is C12 (i.e. the lauroyl derivatives). However, since the hydrophobic side chain of the notified chemical is complex (i.e. not a straight chain alkyl group) the Kow of the side chain was calculated and the alkyl side chain with the closest Kow (C8) was used for the estimation of fish toxicity (method suggested by Clements et al., 1996). This gave an endpoint of LC50 (96 h) > 100 mg/L (US EPA 2009, ECOSAR (v1.00), anionic surfactant class).

CONCLUSION The notified chemical is not harmful to fish

TEST FACILITY US EPA (2009)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – Static.

Species	*Ceriodaphnia dubia*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	91 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks - Method	The test was conducted according to the guidelines above at test substance concentrations of 80.0, 40.0, 19.7, 10.0 and 5.1 mg/L. The test substance did not completely dissolve upon addition of dilution water. The solutions were stirred for 24 h, and allowed to settle for 5.5 h. All solutions were observed to contain suspended material, and the 80 mg/L solution contained precipitate on the bottom of the vessel. The solutions were siphoned off into clean vessels to remove the suspended matter. A control and toxicant reference control were run in parallel. Test conditions: 25 ± 1°C, 16 h/8 h light dark cycle, pH 7.9–8.2, 97.4–100.4 mg O_2/L.

RESULTS

Concentration mg/L	*Number of C. dubia*	*Number Immobilised*

Nominal	*Actual*		*24 h*	*48 h*
0	Not tested	20	0	0
5.1	Not tested	20	0	0
10.0	Not tested	20	0	0
19.7	Not tested	20	0	0
40.0	Not tested	20	0	2
80.0	Not tested	20	0	6

EC50 > 80 mg/L at 48 hours
NOEC 40 mg/L at 48 hours
Remarks - Results After siphoning, all the solutions still contained suspended material. The 80.0 mg/L solution was also cloudy in appearance. There were no immobilised daphnia in the control after 48 h, and the reference toxicant endpoint was between the acceptable limits 179.1–268.7 mg KCl/L (260.8 mg KCl/L), thus validating the test.

CONCLUSION The notified chemical is not toxic to aquatic invertebrates

TEST FACILITY Ecotox (2009)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
Species *Pseudokirchneriella subcaptiata*
Exposure Period 72 hours
Concentration Range Nominal: 0–32.0 mg/L
Actual: Not reported
Auxiliary Solvent None
Water Hardness Not reported
Analytical Monitoring A spectrophotometer was used to measure algal density
Remarks - Method The test was conducted according to the guidelines above at test substance concentrations of 32.0, 15.9, 8.0, 4.4, 2.4, 1.2, and 0.6 mg/L in triplicate. A blank and reference toxicant control (potassium chloride) were run in parallel. Test conditions: 25 ± 2°C, pH 7.7–8.9, continuous illumination. The endpoints and confidence limits were determined by linear interpolation, and Dunnett's Test (Toxcalc v5.0.31).

RESULTS

Biomass		*Growth*	
E_bC_{50} mg/L at 72 h	*NOEC mg/L*	*E_rC_{50} mg/L at 72 h*	*NOEC mg/L*
5.7 (4.3–6.4)	1.2	16.3 (14.5–18.3)	1.2

Remarks - Results After mixing, all solutions contained a small amount of suspended matter, and the 32.0 mg/L solution appeared cloudy. Negative inhibition (i.e. stimulation) was observed for the test substance at concentration 1.2 mg/L at 72 hours. Cell density of the control increased 195-fold, and the reference toxicant endpoint was between the acceptable limits 0.9–4.2 g KCl/L (2.6 g KCl/L), thus validating the test.

CONCLUSION The notified chemical is harmful to algae

TEST FACILITY Ecotox (2009)

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