File No: EX/130 (LTD/1306)

August 2010

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Glycine, N-coco acyl derivs., sodium salts (Sodium 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 the Environment and Water Resources.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full 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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FULL PUBLIC REPORT

This assessment report is for an extension of original assessment certificate for Glycine, N-coco acyl derivs., sodium salts (Sodium Cocoyl Glycinate). Based on the submission of new information by the extension notifier, some sections of the original assessment report have been modified. These modifications have been made under the heading 'Extension Application' in the respective sections.

Glycine, N-coco acyl derivs., sodium salts (Sodium Cocoyl Glycinate)

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Unilever Australia Limited (ABN 66 004 050 828)
219 North Rocks Road
North Rocks NSW 2151

Applicant for an Extension of the Original Assessment Certificate:
Amtrade International Pty Ltd (ABN 49 006 409 936)
574 St Kilda Rd
MELBOURNE VIC 3004

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

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
Vapour Pressure
Water Solubility
Hydrolysis as a Function of pH
Dissociation Constant
Flammability Limits
Auto ignition Temperature
Explosive Properties
Reactivity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

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

OTHER NAME(S)
Sodium Cocoyl Glycinate

MARKETING NAME(S)
Amilite GCS-11
Amilite GCS-12
Extension Application:

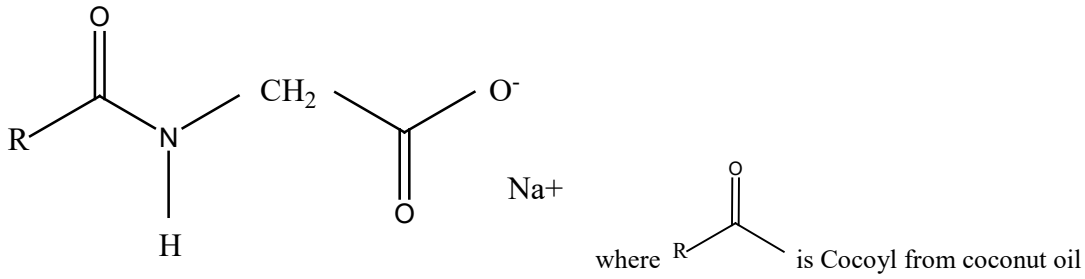
Amilite GCS-11 (product containing the notified chemical at ≥87% concentration)

CAS NUMBER
90387-74-9

MOLECULAR FORMULA
The notified chemical is a mixture of glycine N-acyl derivatives of fatty acids from coconut oil. Main component (47%) represents the derivative of the lauric acid.

$C_{14}\ H_{26}O_3N\ Na$ (as lauroyl derivative)

STRUCTURAL FORMULA



MOLECULAR WEIGHT
279 as lauroyl derivative

ANALYTICAL DATA
Reference IR, spectra was provided
Summary HPLC study was provided
Component derivatives in the Amilite GCS-11 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

3. COMPOSITION

DEGREE OF PURITY
>87 % for Amilite GCS-11 (powder)
Amilite GCS-12 is a 31.5% water solution of Amilite GCS-11 containing 27.4% of notified chemical

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

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

Chemical Name	Cocoyl Fatty Acid		
CAS No.	61788-47-4	*Weight %*	9 % maximum
Chemical Name	Sodium Sulfate		
CAS No.	7757-82-6	*Weight %*	2.5 % maximum

Chemical Name	Sodium Chloride		
CAS No.	7647-14-5	*Weight %*	1.5 % maximum
Chemical Name	Water		
CAS No.	7732-18-5	*Weight %*	1 % maximum

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa White to light yellow powder

Property	Value	Data Source/Justification
Melting Point	32-34 ºC	MSDS
Boiling Point	Not provided	Decomposition occurs at temperatures above 150ºC
Density	Not provided	
Vapour Pressure	$<10^{-5}$ kPa	Estimated
Water Solubility	<0.5% w/w at 25°C	Measured
Hydrolysis as a Function of pH	Not provided	The notified chemical contains hydrolysable functionality. However, based on the biodegradability test report (provided in Japanese only), it would appear that hydrolysis was not observed in the 28 d test period.
Partition Coefficient (n-octanol/water)	Not provided	The notified chemical is an anionic surfactant, and therefore a partition coefficient cannot be accurately determined.
Adsorption/Desorption	Not provided	Based on the structure, appreciable adsorption to organic carbon, soil and sediments could be expected.
Dissociation Constant	pKa = 4.64-5.86	Estimated based on main components of the notified chemical, namely Sodium Lauroyl Glycinate and Sodium Myristoyl Glycinate
Particle Size	Inhalable fraction (<100 μm): <23 % Respirable fraction (<10 μm): <9.6 % D50 average 126 μm	Measured
Flash Point	Not provided for solid	
Flammability	Not provided	
Autoignition Temperature	Not provided	
Explosive Properties		The notified chemical does not contain chemical groups expected to be explosive

Discussion of Observed Effects

For full details of the physical-chemical properties tests please refer to Appendix A.

Reactivity

The notified chemical is expected to be stable under normal environmental conditions. No test of oxidising properties was performed. The notified chemical does not have any structural indications of oxidising properties or other unusual activity.

The CIR compendium and report (CIR 2001, 2004) on the analogue chemicals acyl sarcosines raised concern about the possible formation of potentially carcinogenic nitrosated derivatives. For the analogue, the reactive material is likely to be the precursor sarcosine. The situation for the notified

chemical varies in that the precursor amine glycine is a primary amine, whereas the precursor amine sarcosine in the analogue material is a secondary amine. Secondary amines are of more concern for nitrosamine formation than primary or tertiary amines. Whereas the nitrogen in the notified chemical itself (coco acyl glycinate) is secondary, its functional group is an amide rather than an amine and has different chemical properties. Free amine is not present in the notified chemical, based on the information supplied for the assessment. Therefore the possibility of nitrosamine formation in the notified chemical is considered to be low.

Dangerous Goods classification
Based on the available physico-chemical properties the notified chemical is not classified as a Dangerous Good according to the Australian Dangerous Goods Code (FORS, 1998).

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported as a component (2-5%) of finished cosmetic facial cleansers.

In the future the notified chemical may be introduced into Australia as a raw material Amilite GCS-11 (87% notified chemical) or Amilite GCS-12 (27% notified chemical) for local formulation in cosmetic facial cleansers.

Extension Application:
The product, Amilite GCS-11 containing the notified chemical at 87% concentration, will be imported into Australia as a raw material for local formulation in cosmetic facial cleansers.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonne	<1	<1	<1	<1	<1
Extension Application					
Year	1	2	3	4	5
Tonne	<1	<1	<1	<1	<1
The total amount of the notified chemical that will be imported by the original applicant and the extension applicant will be up to 1 tonne/year.					

PORT OF ENTRY
Sydney by wharf

IDENTITY OF MANUFACTURER/RECIPIENTS
The formulated products containing the notified chemical will be imported by Unilever Australia Limited and distributed to retail stores.

TRANSPORTATION AND PACKAGING
The product containing the notified chemical will be packaged in 200ml bottles suitable for retail sale. These bottles will be packaged in cardboard cartons packed 12 per cardboard shipper.
The shippers with finished products containing the notified chemical will be transported in a container from the wharf to the Unilever Australia Limited's central warehouse at Ingleburn NSW. The cartons will be transported to retail stores' distribution centres by road.
The raw material, if imported, will be packaged in 15kg containers packaged in cardboard cartons and transported from wharf to Unilever warehouse and onwards to formulators by road.

Extension Application:
Amilite GCS-11 product will be imported into Australia in 15 kg carboy pack with inner lining.

USE
The notified chemical will be used as a surfactant component of skin cleansers at concentrations from 2-5% and typically at 2.6%.

OPERATION DESCRIPTION

The notified chemical will be introduced into Australia as a component of finished cosmetic products for personal care in 200 mL plastic containers. These will be warehoused and transported to retail outlets, where they will be sold to consumers.

If in the future the notified chemical is introduced into Australia as a raw material, reformulation will occur at various sites. The reformulation will include transfer of the notified chemical from the 15 kg containers and mixing with other cosmetic ingredients followed by packaging into the small 200mL containers that will be distributed to consumers. Mixing and dispensing will be carried out in a closed system or under conditions designed not to create aerosols or to generate airborne dust.

Extension Application:
Raw material containing the notified chemical at 87% concentration will be imported and reformulated by Unilever Australia Limited into different products of skin cleansers. The reformulation procedure will be as detailed above.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure assessment

6.1.1. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration h/day*	*Exposure Frequency Days/year*
Transport and Storage	10	4	240
Professional compounder	1	8	240
Quality control Chemist	1	3	240
Packers (Dispensing and Capping)	2	8	240
Store Persons	2	4	240
Point of Sale	1000	6	240

Exposure Details

Transport and distribution workers are not expected to be exposed to the notified chemical except in the unlikely event of an accident and breakage of the packaging of the consumer products containing maximum 5% of the notified chemical. Accidental exposure of transport and distribution workers is also possible in the case of import and distribution of the notified chemical as raw material. In case of such accident, main routes of exposure would be dermal and ocular. Inhalation exposure to dust particles of the raw material is also possible. However, the likelihood of such an accidental exposure is low.

In case of import of the notified chemical as raw material for reformulation into consumer products, dermal, ocular and inhalation exposure of compounder workers involved in reformulation may occur during transfer of the notified chemical (>87 % purity) from the 15 kg containers in to the measuring or mixing vessel. However, this exposure is expected to be minimal due to the likely automated process and the PPE used by the workers. The compounder will wear safety glasses with shields, gloves, apron or coverall. Respiratory protection may not be required in the GMP certified sites with adequate local ventilation. However respiratory protection in form of mask should be available if required.

Dermal and ocular exposure to the notified chemical is also possible for workers involved in quality control during sampling and testing of finished products. This exposure is also likely to be minimal as these workers are expected to wear laboratory coats, safety glasses and rubber gloves.

Packers would monitor the line filler and the capper where the finished product is filled into retail bottles. They would wear safety glasses and gloves for skin, body and hands protection so no significant exposure is likely for these workers except in the cease of accident.

Sales workers can have frequent dermal and ocular exposure to the notified chemical if involved in

demonstration of cosmetic products containing the notified chemical to the consumers. Hovewer, this is less likely for cleansers, which is the intended use of the notified chemical.

Overall, the exposure of workers to the notified chemical is expected to be low.

6.1.2. Public exposure

Public exposure is expected to be widespread and frequent through a daily use of skin cleansers containing the notified chemical as a surfactant at concentrations from 2-5% and typically at 2.6%.

The principal route of exposure is dermal, with deliberate application over the skin in a rinse-off formulation. It would be expected that only a small amount of the notified chemical would be left on the skin after washing. However, some adsorption is possible similar to that demonstrated for the salts of analogous Acyl sarcosines that were found to strongly adsorb to various protein like substrates such as hair and skin (CIR, 2001).

Inadvertent eye exposure is also likely during the use and application of the face skin cleansers. However, the notified chemical will usually be diluted significantly with water (as per the recommended use on the product label) even before application to the skin, reducing ocular exposure to the notified chemical.

Oral exposure is only possible in case of accidental ingestion of product containing the notified substance.

6.2. Human health effects assessment

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

Endpoint	*Result and Assessment Conclusion*
Mice, acute oral toxicity LD50 >2000 mg/kg bw	low toxicity
Rabbit, skin irritation	slightly irritating to the skin at concentrations of 5%
Rabbit, eye irritation	irritating to the eyes at 5%
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Chromosome Aberration Test in hamster lung fibroblasts (CHL/IU)	genotoxic in the presence of metabolic activation
Genotoxicity – in vivo Mammalian Erythrocyte Micronucleus Test	non genotoxic

Information on the absorption, metabolism and excretion of the notified chemical was not provided.

The notified chemical represents a Sodium salt of an N-acyl glycine acyl derivative of the mixture of fatty acids from coconut oil with surfactant properties and low water solubility (<5% w/w).
It was of low acute oral toxicity with LD50 >2000 mg.kg bw as determined in a limit test in mice.
No repeated dose toxicity studies were available on the notified chemical.

The notified chemical was tested for skin and eye irritation potential at concentration of 5%. This concentration was chosen for the tests based on the concentration of notified chemical that will be used in consumer products.

In a Draize test-based study for skin irritation with rabbits, the notified chemical was slightly irritating at 5%. At the same concentration of the notified chemical there were no detectable skin sensitisation reaction after 24 or 48 hours after topical challenge in a maximization test.

In a Draize test-based study for eye irritation with rabbits, the notified chemical was slightly irritating to the rabbit eye at 5% based on the irritation scores. However, mild redness of the conjunctivae was persistent and was not reversible even after 7 days in 3/6 animals. Based on these results at 5%, the notified chemical would be classified as R41 - Risk of serious damage to eyes. In addition, in the absence of data on the neat notified chemical a precautionary classification R34 –Causes burns, is recommended for the concentrated material if it is imported

in the future.

The notified chemical was not mutagenic to bacteria in the Ames test in the presence or absence of metabolic activation. It also 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. Based on this result the notified chemical is considered to be clastogenic to mammalian cells in vitro 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 notified chemical. The notified chemical was not clastogenic in an in vivo micronucleus test in mice. Some cytotoxic effect was observed as determined by the decrease of the number of immature erythroblasts, indicating that the notified chemical has reached the bone marrow. Due to cytotoxicity of the notified chemical the test concentrations for all genotoxiciyt studies were low. The cytotoxicity of the notified 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.

Based on the observed eye irritation effects at concentration of 5% the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Xi – irritant at 5%
R41 Risk of serious damage to the eyes

The toxicological effects of the concentrated imported material (30% and 100%) are likely to be more severe.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Based on the available data, adverse effects expected in case of exposure to the notified chemical at 5% include eye irritation and possibly skin irritation. It is expected that the effects would increase in severity at higher concentrations and the raw material may be classified as corrosive at 100% concentration. These more severe effects would be relevant if in future the notified chemical is imported at > 5% ie if formulation of products occurs in Australia.

Overall, the exposure of workers to the notified chemical is expected to be low in the current scenario, where finished products containing up to 5% of the notified chemical are imported.

The worst case scenarios include dermal, ocular and inhalation exposure of transport workers in case of accidental spillage if raw material containing the notified chemical (>87 % purity) is imported in Australia. In such case there will be a risk of skin and eye irritation. However, this situation is very unlikely.

In case of import of the notified chemical as raw material dermal, ocular and inhalation exposure and therefore a risk of skin and eye irritation is possible for formulators and workers involved in quality control testing. However, exposure is expected to be controlled by the likely automated process and the PPE used by the workers (described in detail in section 6.1.1.).

The risk of skin and eye irritation for the workers involved in packaging of the finished consumer products that may have dermal and ocular exposure to the notified chemical at concentrations up to 5% is also low as these workers are expected to wear safety glasses and gloves for skin protection.

Sales workers can have frequent dermal and ocular exposure to the notified chemical if involved in demonstration of the products containing the notified chemical to the consumers, but this is unlikely for cleansers.

6.3.2. Public health

The potential adverse effects of the notified chemical at 5% (expected level of use) are significant eye irritation and slight skin irritation. Genotoxicity studies were negative, except for a positive result in the presence of metabolic activation at the highest level tested in an in vitro

chromosome aberration study. The significance of this result is not clear. However, based on the other suite of genotoxicological studies the notified chemical is not considered genotoxic.

The public will be exposed to a maximum of 5% of the notified chemical in wash-off consumer products such as skin cleansers. The principal route of exposure is dermal, with deliberate application over the skin. Inadvertent ocular exposure may also occur. The concentration of the notified chemical at eye or skin contact is likely to be lower than the concentration in the product, because the product is usually diluted with water before application. Although it may adhere to the skin but it is expected to be rinsed off with water and thus will not be bioavailable.

It should be noted that the notified chemical is similar to the N-methyl derivatives of fatty acids (acyl sarcosinates) that can enhance the penetration of other ingredients through the skin (CIR 2001 and 2004). Thus, although enhanced percutaneous absorption of ingredients in the formulated cosmetic products containing the notified chemical cannot be excluded, it is not expected to be significant for the wash-off products.

Based on the structural similarity of the notified chemical with the acyl sarcosines the possibility of formation of nitrosamines in formulations containing the notified chemical was considered. However the risk is considered to be low as the functional group including the nitrogen in the notified chemical is an amide rather than an amine and has different chemical properties than the secondary amine in the analogous acyl sarcosines. In addition, free amine is not known to be present in the raw notified chemical material.

Considering the expected low exposure to the notified chemical, the risk from the use of rinse off products for skin care containing 5% of the notified chemical is considered to be acceptable. Eye irritation may occur under the conditions of use and may be minimised by suitable directions for use.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

Release to the environment may be considered at several stages:

Transport of the chemical prior to formulation.

This is not likely to constitute a major hazard, as the material is likely to be containerised, or in packaging designed to withstand impact. Accidental spills during transportation should be relatively easily recovered and disposed of, as described under Environmental Emergency Procedures.

Storage and product formulation

With the relatively low level use proposed for this product and with its formulation and dispensing in closed systems, it is unlikely that there will be any significant release to the environment. Accidental releases during product formulation are unlikely to present a major hazard, and should be dealt with as described under Occupational Emergency Procedures.

Formulation is a batch process, with a typical batch being 6 tonne of which 180kg will be notified chemical. The formulation process is expected to take approximately 4 hours, and it is likely that there will be 5 batches produced per year. Emissions to waste water are possible while cleaning the equipment. It is estimated that 2-3% final product are rinsed into the waste water collection system which then goes to a biological treatment plant, with subsequent release to sewer.

It is anticipated that the Amilite GCS-11 will be incorporated at 2 to 5% (1.74% to 4.0% notified chemical) but typically at 3% (2.6% notified chemical) in a finished product with pack sizes up to 500 mL but most likely to be in the range 50-200 mL.

RELEASE OF CHEMICAL FROM USE

Most use will take place in bathrooms or similar ‘wet’ areas which normally drain to sewer. While direct release is likely to be to the aquatic compartment, the environmental medium the chemical will finally reside in is likely to be the aqueous phase. Consequently, once in the sewage treatment plant,

the chemical may end up in receiving waters.

A small proportion of notified chemical may remain as residual within consumer containers, which is expected to be disposed of to domestic landfill.

RELEASE OF CHEMICAL FROM DISPOSAL
Waste and expired material will be disposed of according to Federal, State and Local regulations. If a spill occurs the spill is to be absorbed with sand or other absorbent and the area washed with water. Solutions are neutral pH. The chemical is biodegradable in solution. It is to be disposed of to approved landfills, where the notified chemical is expected to degrade via abiotic and biotic means to form simple carbon and nitrogen based compounds. If the product is burnt the combustion products will be carbon oxides and nitrogen oxides.

The majority of notified chemical will be disposed of to sewer after use. It is expected that this will remain within the aquatic compartment, degrading abiotically and biotically to form simple carbon and nitrogen based compounds.

7.1.2 Environmental fate

A biodegradability test was provided for the notified chemical which appears to indicate that the notified chemical may be classed as ready biodegradable. However, as the test report was only provided in Japanese, the adequacy of the test and its conditions cannot be stated.

7.1.3 Predicted Environmental Concentration (PEC)

Since most of the polymer will be washed into the sewer, under a worst case scenario, with no removal of the notified polymer in the sewage treatment plant, the resultant Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Removal within STP	0%	
Daily effluent production:	4,099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.67	µg/L
PEC - Ocean:	0.07	µg/L

7.2. Environmental effects assessment

No ecotoxicity data were submitted.

7.2.1 Predicted No-Effect Concentration

As ecotoxicity data for the notified chemical was not provided, it is not possible to calculate a Predicted No-Effect Concentration (PNEC) value.

7.3. Environmental risk assessment

Without a PNEC, it is not possible to calculate a risk quotient. Based on the proposed use, low volume and diffuse release pattern, the risk to the aquatic environment is expected to be acceptable.

8. CONCLUSIONS – SUMMARY OF RISK ASSESSMENT FOR THE ENVIRONMENT AND HUMAN HEALTH

8.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:
Xi – irritant at 5%
R41 Risk of serious damage to eyes

The toxicological effects of the concentrated imported material (30% and 100%) are likely to be more severe.

As a comparison only, the classification of notified chemical/polymer 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*
Eye irritation at 5%	1	Causes severe eye damage

8.2. Human health risk assessment

8.2.1. Occupational health and safety

Under the conditions of the occupational settings described, the risk to workers is considered to be acceptable.

8.2.2. Public health

When used in the proposed manner the risk to the public is considered to be acceptable.

8.3. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

9. RISK ASSESSMENT RELATING TO EXTENSION APPLICATION

The use and the fate of the notified chemical will not change under the proposed extension. The increase in proposed introduction volume is not expected to significantly change the environment and health impacts. Therefore, there are no changes required in the risk assessment

10. MATERIAL SAFETY DATA SHEET

The MSDS of the notified chemical and products containing the notified chemical provided by the notifier were reviewed by NICNAS and are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant. The MSDS were found to be in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003).

Extension Application:
The applicant for extension application has provided MSDS of a product containing the notified chemical. The accuracy of the information on the MSDS remains the responsibility of the extension applicant.

11. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health, hazard classification for the notified chemical:
  - R41 Risk of serious damage to the eyes

  - 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
  - S37 Wear suitable gloves
  - S39 Wear eye/face protection

- 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:
  - Corrosive R34 – Causes burns

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced and as diluted for use in formulating the consumer product:
  - Use in well ventilated areas

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical introduced and as diluted for use in formulating the consumer product:
  - 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 diluted for use in formulating the consumer product:
  - Protective eye wear such as goggles
  - Impermeable gloves

  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.

Public Health

  - Consumer products containing the notified chemical should be labelled with a warning against eye contact, and directions on first aid measures if the product contacts the eyes.

Environment

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

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

12. 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 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 importation volume exceeds one tonne per annum notified chemical

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from use in wash-off products at maximum 5%, or is likely to change significantly. In this case additional toxicological data will be required including percutaneous absorption and further relevant genotoxicity testing.
- if 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;
- if any regulatory action concerning the notified chemical occurs in other jurisdictions..

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

AICS Annotation

- When the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS) the entry should be annotated with the following statement(s):
  - For use in wash-off products at concentrations of $\leq$ 5%

Under Section 11(4) of the *Industrial Chemicals (Notification and Assessment) Act (1989*), once the chemical has been entered on the inventory with the condition described above, the notified chemical may only be imported or manufactured without obtaining an assessment certificate or permit if the importation or manufacture is in accordance with this condition.

APPENDIX A: PHYSICO-CHEMICAL PROPERTIES

Vapour Pressure Estimated $<10^{-5}$ kPa

Remarks The notified chemical is a solid with molecular weight of 279 Daltons and is estimated by the notifier to have a low vapour pressure at $<10^{-5}$ kPa.

Water Solubility <0.5% w/w at 25°C

Remarks A number of concentrations (0.5, 1, 2, 3, 5, 8, 10, 12, 15 and 18 wt.%) were prepared and dissolved in deionised water by heating at 80°C, and then cooled by air-cooling until their temperature reached 25°C. After 24 h, at 25°C, the state of each preparation was assessed visually. All samples were visually transparent in water at 80°C. Precipitation was observed after 24 h at 25°C in all samples. However, in promotional literature and some toxicological test reports it is stated that the 30% solution of the notified chemical was clear at 25°C. It is possible that this discrepancy is a result of the different solubility of the notified chemical and that of some impurities that could be present in the preparation tested for water solubility.

TEST FACILITY Not identified.

Dissociation Constant pKa = 4.64-5.86 (estimated)

Remarks The notified chemical is an anionic surfactant and would be expected to dissociate within the environmental pH range of 4-9. This is supported by the range of pKa values for some of the main chemical components of the notified chemical, namely Sodium Lauroyl Glycinate and Sodium Myristoyl Glycinate.

Particle Size

METHOD In house sieve method

Range (μm)	*Mass (%)*
<63	9.26
63-90	16.9
90-125	23.1
125-180	27.7
180-250	14.5
250-355	4.8
>355	0.33

Remarks D50 average 126 μm

TEST FACILITY Ajinomoto (2006)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD
- Species/Strain: Mice – ICR from Charles River Japan
- Vehicle: Water
- Remarks - Method: Ten 4-week old animals, 5/sex in each dose group, were used in each treatment dose group. They were dosed after 7 days of acclimatization period.
  Clinical symptoms were observed two and six hours following administration and once a day for the following 14days.
  Body weight was recorded at the time of dosing, and on the following days 1,7 and 14.
  All animals were sacrificed on day 14 and the organs were examined macroscopically.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	0	none
2	5/sex	1000	none
3	5/sex	2000	none

- LD50: >2000 mg/kg bw
- Signs of Toxicity: There were no deaths or significant test substance-related clinical signs and remarkable body weight changes during the study period.
- Effects in Organs: In autopsy a cyst in the left kidney in one case and an oedema in the uterus in one case was found in the female 1000 mg/kg group. Oedema in the left ovary was observed in one case in the female 2000mg/kg group. These conditions develop spontaneously in this type of mouse and they are not considered to be related to the administration of the test substance.
- Remarks - Results: Loss of vigour was observed in 1 male mouse in the 2000mg/kg group.
  Wet hair around the anus was observed during the observation period for one 1000mg/kg male, one 2000 mg/kg male and one 2000mg/kg female. No abnormality was observed and six hours and onwards and are probably related to the administration rather than the test article itself.

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

TEST FACILITY: Ajinomoto (1997a)

B.2. Irritation – skin

TEST SUBSTANCE: Notified chemical at 5%

METHOD: In house method scored by Draize scale analogous to OECD TG 404 Acute Dermal Irritation
- Species/Strain: Rabbit/New Zealand White Male
- Number of Animals: 6 treated and 12 controls (6 vehicle and 6 5% sodium lauryl sulphate as positive control)
- Vehicle: Water
- Observation Period: 7 days
- Type of Dressing: Occlusive for 24 hours
- Remarks - Method: Approximately 5% solution of the notified chemical was tested. The test concentration was chosen on the basis of the likely concentration of the

notified chemical in final products. It was not stated whether the test material was removed from the skin after the 24h test period.
The levels of erythema and oedema using Draize scale were evaluated after 30 min after patch removal (24 h post treatment) and 48h, 72h and seven days post treatment.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	1.83	3	≥72h to <1 week	0
Oedema	0	-	-	0

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

Remarks - Results

CONCLUSION The notified chemical is slightly irritating to the skin at concentrations of approximately 5% .

TEST FACILITY Ajinomoto (1998a)

B.3. Irritation – eye

TEST SUBSTANCE Notified chemical at 5%

METHOD In house method scored by Draize scale analogous to OECD TG 405 Acute Eye Irritation

Species/Strain Rabbit/New Zealand White Male

Number of Animals 6 treated and 12 controls (6 vehicle and 6 5% sodium lauryl sulphate as positive control)

Observation Period 7 days

Remarks - Method Approximately 5% solution of the notified chemical was tested. The test concentration was chosen on the basis of the likely concentration of the notified chemical in final products.
The cornea, iris, conjunctivae and discharge were evaluated using Draize scale at 24 h 48h, 72h, 96h and seven days post treatment.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	1.22	2	Present at 1 week	1
Conjunctiva: chemosis	0.78	2	48h	0
Conjunctiva: discharge	0.94	3	48h	0
Corneal opacity	1.17	2	96h	0
Iridial inflammation	0.06	1	24h	0

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

Remarks - Results Effects on the conjunctivae had not resolved by the end of the observation period (7 days), which is a shorter period than the 21 days recommended in the OECD test method.

CONCLUSION The notified chemical is irritating to the eye and causes persistent effects on the conjunctivae at concentrations of approximately 5%.

TEST FACILITY Ajinomoto (1997b)

B.4. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD Skin Sensitisation – Maximisation test
Species/Strain Guinea pig/Hartley female
PRELIMINARY STUDY Not performed

MAIN STUDY
Number of Animals Test Group: 10 Control Group: 5
Each testing material (notified chemical, vehicle and positive control were tested using 10 test and 5 control, saline-treated animals).
INDUCTION PHASE Induction Concentration:
intradermal: ~5%
topical: ~5%
Signs of Irritation Not recorded
CHALLENGE PHASE 16 days following intradermal and 10 days following topical induction
1st challenge topical: ~5%
2nd challenge Not performed
Remarks - Method 0.1% of 2,4-dinitrochlorobenzrne (DNCB) was used as a positive control. The skean was treated with sodium lauryl sulphate prior to dermal induction.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	~5%	0	0	-	-
Negative Control Group	~5%	0	0	-	-

Remarks - Results Oedema and severe erythema were observed at 24 hours and 48 hours post challenge in all the animals in the Positive Control Test Group treated with DNCB.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test with approximately 5% of the notified chemical.

TEST FACILITY Ajinomoto (1998b)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

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.6. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

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.7. Genotoxicity – in vivo

TEST SUBSTANCE

Notified chemical

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)

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