File No: SN/22

October 2011

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Glycine, N-coco acyl derivs., sodium salts (INCI name: 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 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:

Street Address: Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL: + 61 2 8577 8800
FAX: + 61 2 8577 8888
Website: www.nicnas.gov.au

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/22	Clariant (Australia) Pty Ltd	Glycine, N-coco acyl derivs., sodium salts (INCI name: Sodium Cocoyl Glycinate)	Yes	≤ 100 tonnes per annum	Surfactant for rinse-off cosmetic products at ≤ 5%

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] with the following risk phrases:

R38 Irritating to skin
R41 Risk of serious damage to eyes

and

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

	Hazard category	*Hazard statement*
Skin irritation	2	Causes skin irritation
Eye irritant	2A	Causes serious eye irritation
Acute hazards to the aquatic environment	2	Toxic to aquatic life

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

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the 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:
  – R38 Irritating to skin
  – R41 Risk of serious damage to eyes

- 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. A copy of this assessment report will be forwarded to the Advisory Committee on Chemicals Scheduling to support the previous recommendation on scheduling of this chemical.

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 and during formulating the consumer products:
  – Avoid contact with skin and eyes

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced and while formulating the consumer products:
  – Protective eye wear such as goggles
  – Impermeable gloves
  – Coveralls

- Employers should ensure that the following personal protective equipment is used by beauty salon workers to minimise occupational exposure to the notified chemical in the consumer products:
  – Impermeable gloves

- Cosmetic products containing the notified chemical should be carefully formulated to avoid combining it with other ingredients (including colorants and dyes) if transdermal absorption is a health concern.

  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 *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 5% should be labelled with a warning against eye contact, and directions on first aid measures if the product contacts the eyes (e.g. avoid contact with eyes, in case of contact with eyes, rinse immediately with plenty of water and seek medical advice).

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.

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 notified chemical is intended to be used in spray products;
- the function or use of the chemical has changed from a surfactant that is used in rinse-off cosmetic products ≤ 5%.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a surfactant that is used in rinse-off cosmetic products, or is likely to change significantly;
- the amount of chemical being introduced has increased from 100 tonnes per year, 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 product containing the notified chemical provided by the notifier was 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)
Clariant (Australia) Pty Ltd (ABN 30 069 435 552)
Brandon Office Park, Building 5, L2
530-540 Springvale Road
Glen Waverley, Vic 3150

Assessment of the notified chemical was carried out under the *Industrial Chemicals (Notification and Assessment) Act 1989* [the IC(NA) Act], as LTD/1490, with the Summary Report of the assessment published in the *Chemical Gazette* of 7th December, 2010.

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., sodium salts (INCI name: Sodium Cocoyl Glycinate).

In accordance with Section 65 of the IC(NA) Act, a notice requiring the secondary notification of Glycine, N-coco acyl derivs., sodium salts (INCI name: Sodium Cocoyl Glycinate) was published in the *Chemical Gazette*. The notice of 5th April, 2011 stipulated that the following data were required to undertake further assessment of Glycine, N-coco acyl derivs., sodium salts (INCI name: Sodium 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 aquatic invertebrates;
    e) 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/22, represents the revised assessment for Glycine, N-coco acyl derivs., sodium salts (INCI name: Sodium 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)
Data items and details claimed exempt from publication: spectral data, purity, impurties

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, vapour pressure, hydrolysis as a function of pH, partition coefficient, absorption/desorption, dissociation constant, particle size, flash point, flammability limits and autoignition temperature

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
LTD/1490

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Hostapon SG (containing approximately 25% notified chemical)
SCG 3028

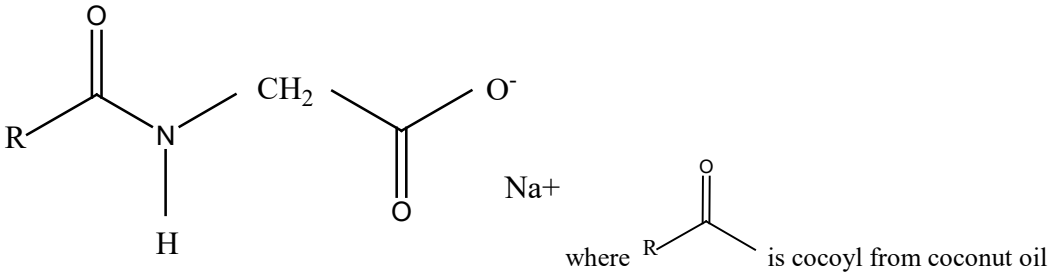
CAS NUMBER
90387-74-9

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

OTHER NAME(S)
INCI name: Sodium Cocoyl Glycinate
N-Cocoyl glycine sodium salt

MOLECULAR FORMULA
Unspecified
The main component, C_{12} derivative: $C_{14}H_{26}NO_3Na$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
Unspecified
The main component, C_{12} derivative: 279.4 Da

ANALYTICAL DATA
Reference ^{1}H NMR, IR and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY 60-80%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: white powder

Property	Value	Data Source/Justification
Melting Point	6°C	MSDS*
Boiling Point	> 100°C (pressure unknown)	MSDS*
Density	1070 kg/m^3	MSDS*
Vapour Pressure	< 0.001 kPa at 20°C	MSDS (calculated)*
Water Solubility	0.67 ± 0.11 g/L at 20°C	Measured (critical micelle concentration)
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionality, however, hydrolysis is expected to be slow in the environmental pH range (4–9) at ambient temperature.
Partition Coefficient (n-octanol/water)	log K_{ow} = 0.16–1.14 at 20°C	Calculated. The notified chemical is a surfactant and is expected to concentrate at phase boundaries.
Adsorption/Desorption	Not determined	The notified chemical is expected to adsorb to organic carbon, soil and sediment because it is a surfactant
Dissociation Constant	Not determined	As a sodium 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 in liquid particle dispersion.
Flash Point	> 100°C (pressure unknown)	MSDS (closed cup)*
Flammability	Not determined	Imported in liquid particle dispersion.
Autoignition Temperature	Not determined	Imported in liquid particle dispersion.
Explosive Properties	Not determined	The notified chemical does not contain chemical groups expected to be explosive.

*The notified chemical is manufactured in water at approximately 25% (Hostapon SG) and normally is not separated.

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

Reactivity
Thermal decomposition at > 350ºC may produce oxides of carbon. No hazardous reactions are known. The CIR report (CIR 2001) 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 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.

Dangerous Goods classification
Based on the submitted physical-chemical data in the above table the notified chemical is not classified/ according to the Australian Dangerous Goods Code (NTC, 2007). However the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as a component of Hostapon SG (approximately 25% notified chemical).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-30	10-30	30-100	30-100	30-100

PORT OF ENTRY
Sydney or Melbourne

IDENTITY OF RECIPIENTS
Clariant (Australia) Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical as a component of Hostapon SG is to be imported in either 200 L drums or 960 kg IBC (Intermediate Bulk Containers) and will be transported by road from port of entry to Clariant (Australia) Pty Ltd, Lara, Victoria and subsequently to the premises of cosmetic formulators.

USE
Hostapon SG (containing approximately 25% notified chemical) is a surfactant that is used in rinse-off cosmetic products, such as body and hair cleansing products, at up to 5%.

OPERATION DESCRIPTION
As a component of Hostapon SG (approximately 25%), the notified chemical will be reformulated (up to 5%) as a component in wash-off cosmetic products. The reformulation will include transfer of Hostapon SG into blending tanks, mixing with other cosmetic ingredients and packaging. Mixing and dispensing will be carried out in closed systems or under conditions designed not to create aerosols. The final mixed ingredients containing the notified chemical at up to 5% will be packaged into containers (≤ 500 mL) for distribution to retailers for sale to beauty salons or consumers.

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 & distribution personnel	14	4	240
Professional compounder	2	8	240
Quality control chemist	2	3	240
Packers (Dispensing & Capping)	4	8	240
Store personnel	4	4	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 either the product Hostapon SG (approximately 25% notified chemical) or the consumer products containing maximum 5% of the notified chemical. In case of such accident, main routes of exposure would be dermal and ocular. 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 Hostapon SG into the measuring or mixing vessel. However, this exposure is expected to be minimal due to the likely automated process and the personal protective equipment (PPE) used by the workers. Compounders will wear safety glasses with shields, gloves, apron or coverall. Respiratory protection may not be required in the Good manufacturing practice (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 at up to 5% 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 are expected to wear safety glasses and gloves for skin, body and hands protection so no significant exposure is likely for these workers except in the case of an accident.

Dermal and ocular exposure to the notified chemical (at concentrations up to 5%) may occur in professions (e.g. hair dressers, workers in beauty salons) where the services provided involve the application of personal care products. Such professionals may use some personal protective equipment to minimise exposure, and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical.

6.1.2. Public exposure

Public exposure of the notified chemical during transport, storage and retail distribution is unlikely unless the packaging is breached in an accident.

The notified chemical will be used in the manufacture of body and hair cleansing products which will be available to the public through retail outlets.

Public exposure may be widespread due to the use of the cosmetic products containing a maximum of 5% concentration of the notified chemical. The principal route of exposure is dermal, with deliberate application over the skin in a rinse-off formulation. Inhalation exposure is not expected, as the notified chemical will not be used in spray products.

Inadvertent eye exposure is possible during the use of face skin cleansers and/or shampoos. However, any product containing the notified chemical will usually be diluted significantly with water (as per the recommended use on the product label) before application to the skin, reducing ocular exposure. Oral exposure is not a likely route of exposure and it is only possible in case of accidental ingestion of product containing the notified chemical.

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.

In addition, some published information from the Cosmetic Ingredient Review (CIR 2001) on modified fatty acids known as acyl sarcosines and sarcosinates that are structurally related to the notified chemical is included in the health effects assessment, eg. Sodium Lauroyl Sarcosinate.

Endpoint	*Result*
Rat, acute oral toxicity*	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute dermal toxicity**	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation*	moderately irritating
Rabbit, eye irritation*	irritating
Guinea pig, skin sensitisation – adjuvant test *	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation*	non mutagenic
Genotoxicity – in vitro mammalian cell gene mutation test**	non mutagenic

* Tested on Hostapon SG (containing approximately 25% notified chemical)
** Tested on dried Hostapon SG (containing 68.5% notified chemical)

Toxicokinetics, metabolism and distribution

No information was provided on the notified chemical. 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 structurally related chemical, 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. However, 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 to sarcosinates and is not likely to lead to bioaccumulation.

Acute toxicity

The oral LD50 of the test substance containing 25% of the notified chemical was determined to be > 2000 mg/kg

bw in rats. Based on the data, the toxicity of the notified chemical at 100% can not be determined.

The dermal LD50 of the test substance containing 68.5% of the notified chemical was determined to be > 2000 mg/kg bw in rats. A study involving dermal application of Sodium Lauroyl Sarcosinate on the skin of rabbits for 14 days was reported to result in no signs of dermal toxicity. These results suggest that the notified chemical is of low acute dermal toxicity.

No data is available on the acute inhalation toxicity of the notified chemical or of acyl sarcosines or sarcosinates.

Irritation
The test substance (containing approximately 25% notified chemical) was irritating to skin and eyes in tests conducted in rabbits. Irritation effects were also seen in dermal toxicity study at 68.5%. The notified chemical at 100% is expected to have severe eye irritation effects.

Sensitisation
The test substance (containing approximately 25% notified chemical) was not a skin sensitiser in a Magnusson and Kligman Maximisation Test. Therefore, the notified chemical is not expected to be a skin sensitiser.

Subchronic and chronic toxicity
No information on repeat dose toxicity was available for the notified chemical. Weanling rats given a diet containing 2% Sodium Lauroyl Sarcosinate for 6 months had no effect on weight gain, feeding, general health or behaviour (CIR 2001). 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). It is expected that the notified chemical may have similar repeat dose toxicity to that described above for Sodium Lauroyl Sarcosinate.

Reproductive Effects
Information on Sodium Lauroyl Sarcosinate indicated 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).

Mutagenicity
The test substance was not mutagenic to bacteria in the Ames test in the presence or absence of metabolic activation. In an *in vitro* mammalian cell gene mutation test, the notified chemical was not mutagenic to L5178Y cells in the absence and presence of metabolic activation.

Health hazard classification
Based on the results of the eye irritation and skin irritation tests conducted on the notified chemical at concentration of approximately 25%, the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrases:
R38 Irritating to skin
R41 Risk of serious damage to eyes

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Based on the available data, adverse effects associated with exposure to the notified chemical may include eye and skin irritation. Exposure of workers to the notified chemical at ~25% may occur during reformulation processes (dermal, ocular, or aerosols inhalation).

Upon dermal contact with the notified chemical, irritation may occur and the severity of this is likely to be dependent on the concentration. Ocular contact with the notified chemical at concentrations above 5% may cause significant eye irritation. Appropriate use of exhaust hoods, automated systems and personal protective equipment, particularly safety glasses or face masks, coveralls, impervious gloves, and safety shoes during reformulation operations is expected to reduce exposure levels to the notified chemical and hence lower the incidence of irritation effects.

Overall, the notified chemical is not considered to pose an unacceptable risk to cosmetic production workers, given the use of automated systems and personal protective equipment. Appropriate control measures to minimise dermal and ocular exposure are required to protect workers from irritation effects at higher concentrations.

Irritation effects are not expected when using end use products (up to 5% notified chemical). The risk for beauty care professionals who regularly use products containing the notified chemical (up to 5%) is expected to be of a similar or perhaps higher level than that experienced by members of the public who use such products on a regular basis, in light of the duration and frequency of exposure. Skin irritation effects from formulated products containing up to 5% of the notified chemical are not expected. Accidental eye contact of beauty care professionals using such products is expected to occur less frequently than that of members of the public.

6.3.2. Public health

The public will have widespread dermal exposure to the notified chemical, which is proposed to be used at a concentration up to 5% in rinse-off cosmetic products. Eye exposure is also a possibility due to accidental contact.

Eye contact with the notified chemical at 5% in rinse-off products may lead to eye irritation. The dilution and reduced contact time generally associated with use of rinse-off products is expected to reduce effects.

In the absence of repeat dose toxicity data (NOAEL) for the notified chemical a quantitative risk assessment was not conducted. Though information was not available on the effects of long term repeated exposure to the notified chemical, information on sodium lauroyl sarcosinate suggests that the notified chemical is likely to be of low repeated dose toxicity.

Use of products containing the notified chemical at 5% may lead to eye irritation. The risk is not expected to be significant when the notified chemical is present in rinse-off products (up to 5%) due to the dilution and reduced skin/eye contact time. The eye and any possible skin irritation risk associated with use of the notified chemical in cosmetic products may be further minimised by the inclusion of appropriate labelling and directions for use to warn against eye contact and of the possibility of skin irritation reactions. Packaging directions, should recommend that use be discontinued if irritation occurs. When used in the proposed manner, with appropriate safety information on the packaging, the risk to the public associated with eye and skin contact with the notified chemical at the proposed concentrations is not considered to be unacceptable.

In addition, the risk associated with repeated exposure to the notified chemical in rise-off products 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

The notified chemical is likely to be released in limited quantities as a result of local reformulation of the water based imported product into formulated end-use cosmetic products. Reformulation will be executed in closed automated systems and residues of notified chemical remaining in blending equipment are released to waste water while cleaning the equipment. It is estimated that 2–3% of the notified chemical used in local blending will be rinsed into the waste water collection system which then goes to a biological treatment plant, with subsequent release to sewer. Accidental spills during transport or reformulation are expected to be collected with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

As the notified chemical will be used in cosmetic cleansing products for body and hair, 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 of the notified chemical in empty containers (1%) are likely to share the fate of the container and be disposed of to landfill, or to be washed to sewer when containers are rinsed before recycling.

7.1.2 Environmental fate

The notified chemical is readily biodegradable and is expected to be largely degraded by sewage treatment processes. Approximately 32% of the total annual import of the notified chemical (calculated by SimpleTreat; European Commission, 2003) may be discharged to receiving waters in treated effluent as the notified chemical is water soluble, yet the notified chemical is expected to disperse and degrade. Bioaccumulation is not likely as the notified chemical is water soluble and readily biodegradable. In landfill, the notified chemical is expected to biodegrade to form water and oxides of carbon and nitrogen, and inorganic salts. For details of the environmental fate study refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

The notified chemical was found to be readily biodegradable, thus, its removal from influent by sewage treatment plant (STP) processes is expected. A mitigated PEC is presented below, based on the assumption that all of notified chemical will be discharged to the aquatic compartment via STPs and taking into account degradation of up to 68% in STPs, as calculated by the SimpleTreat Model (European Commission, 2003).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	100,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	100,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	273.97	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	68%	Mitigation
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	20.72	µg/L
PEC - Ocean:	2.07	µg/L

The SimpleTreat Model estimates that 32% of the notified chemical may remain in the effluent after STP processes, however the SimpleTreat Model may overestimate environmental concentrations for water soluble and highly adsorptive substances (European Commission, 2003). Thus, it is possible that the environmental concentration of the notified chemical may be even lower than calculated.

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 20.72 µg/L may potentially result in a soil concentration of approximately 0.138 mg/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 0.69 mg/kg and 1.38 mg/kg, respectively. However, due to the ready biodegradability and adsorptive nature of the notified chemical, these calculated values represent maximum concentrations only.

7.2. Environmental effects assessment

The results from an ecotoxicological studies of the acute effects of the notified chemical on fish, aquatic invertebrate (*Daphnia magna*) and algae are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (96 h)	LC_{50} > 25 mg/L	Potentially harmful to fish
Aquatic Invertebrate Toxicity (48 h)	EC_{50} = 6.53 mg/L	Toxic to aquatic invertebrate
Algal Growth Toxicity (72 h)	E_rC_{50} = 89.9 mg/L	Harmful to algae

The notified chemical is classified as toxic to aquatic life under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009). On the basis of its ready biodegradability and low potential to bioaccumulate the notified chemical is not classified for chronic hazards to the aquatic environment.

7.2.1 Predicted No-Effect Concentration

The predicted no-effect concentration for the notified chemical was calculated based on the aquatic invertebrate acute toxicity and an assessment factor of 100. The assessment factor of 100 has been applied as acute ecotoxicity data for the notified chemical are available for three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
48 h EC_{50} (*Daphnia magna*)	6.53	mg/L
Assessment Factor	100	
PNEC:	65.3	µg/L

7.3. Environmental risk assessment

The Risk Quotient (Q = PEC/PNEC) values have been calculated as follows:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	20.72	65.3	**0.317**
Q - Ocean	2.07	65.3	**0.032**

The risk quotient for aquatic exposure is calculated to be <1 based on the above calculated PECs and PNEC. The Q value of < 1 indicates that the notified chemical is not considered to pose an unreasonable risk to the aquatic environment from its proposed use pattern as a component in cosmetics and at the maximum annual import volume.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility 0.67 ± 0.11 g/L at 20°C

Method The test substance was a dried sample of Hostapon SG containing 60-80% w/w notified chemical. Water solubility was determined as the critical micelle concentration of the test substance at 20°C. The critical micelle concentration was calculated by plotting surface tension against concentration. The surface tension of liquid particle dispersion of the test substance was determined by the plate method in accordance with ISO 4311.

Remarks The notified chemical is a surfactant with complex solubility behaviour due to aggregation. The critical micelle concentration was considered as the limiting solubility of the dispersed notified chemical.

Test Facility Clariant Analytical Services (2010a)

Partition Coefficient (n-octanol/water) log K_{ow} = 0.16–1.14 at 20°C

Method The partition coefficient of the ionised forms of the N-dodecanoyl and N-tetradecanoyl glycine components of the notified chemical (log K_{ow} = 0.16 and 1.14, respectively) were calculated using the group additivity method of KOWWIN v 1.67.

Remarks The notified chemical is a surfactant and is expected to concentrate at phase boundaries.

Test Facility Clariant Analytical Services (2010b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Hostapon SG

METHOD: OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 440/2008 B.1tris Acute Oral Toxicity – Acute Toxic Class Method.

Species/Strain	Rat/HanRcc: WIST(SPF)
Vehicle	Purified water
Remarks - Method	No deviations from the protocol.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 F	2000	0
2	3 F	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	No clinical signs were observed during the course of the study.
Effects in Organs	No macroscopic findings were recorded at necropsy.
Remarks - Results	The body weight of the animals was within the range commonly recorded for this strain and age.

CONCLUSION: The test substance is of low toxicity via the oral route.

TEST FACILITY: Harlan Laboratories Ltd (2008a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE: Hostapon SG dried (68.5% notified chemical)

METHOD: OECD TG 402 Acute Dermal Toxicity.
EC Directive 440/2008 B.3 Acute Toxicity (Dermal).

Species/Strain	Rat/HanRcc: WIST(SPF)
Vehicle	Polyethylene glycol 300
Type of dressing	Semi-occlusive.
Remarks - Method	No deviations from the protocol.

RESULTS

Number and Sex of Animals	*Dose (mg/kg bw)*	*Mortality*
5 per sex	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Very slight to slight erythema was observed on test day 2 (1 male) of from test day 2 to test day 4 (1 female) or test day 6 (1 male). Very slight to slight oedema and slightly maculated crusts were observed in one female from test day 2 to 3 or from test day 7 to 15, the end of the observation period. Slight desquamation was noted in one male and three females during test day 3 to test day 7 or 11 and in one male from test day 8 to test day 12. Slight to moderate desquamation was noted in one female from test day 3 to test day 14. The test substance caused white to yellow discolouration of the treated skin in two males and one female on test day 2.
Signs of Toxicity - Systemic	No clinical signs were recorded throughout the entire observation period. One animal lost body weight (-1.0%) during the first week after the test

substance administration. However, the animal regained weight until the end of the observation period. Otherwise, the body weight of the animals was within the range commonly recorded for animals of this strain and age.

Effects in Organs: No macroscopic findings were recorded at necropsy.

Remarks - Results: Irritation effects were seen in this study.

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

TEST FACILITY: Harlan Laboratories Ltd (2010)

B.3. Irritation – skin

TEST SUBSTANCE: Hostapon SG

METHOD: OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 440/2008 B.4 Acute Toxicity (Skin Irritation).

Species/Strain: Rabbit/New Zealand White

Number of Animals: 1 M, 2 F

Vehicle: None

Observation Period: 14 days

Type of Dressing: Semi-occlusive.

Remarks - Method: No deviations from the protocol.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1.3	1.7	2	2	< 10 days	0
Oedema	1	1.3	1	2	< 7 days	0

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

Remarks - Results: No mortality occurred. No clinical signs were observed during the course of the study. The body weights of all animals were considered to be within the normal range of variability. No necropsy was performed at the end of the study.
A well-defined erythema was observed in all animals 1 hour after test substance exposure and persisted up to the 72-hour reading in one female and as very slight erythema up to the same observation time point or day 7 in the male and one female. A very slight to slight swelling was recorded in the three animals at the 1-hour observation and persisted as very slight up to the 72-hour observation. Dry/inelastic skin was recorded 24 hours after removal of the dressing in all animals and persisted up to the 72-hour reading or day 7 post treatment in the females. Scaling of the skin was noted in all animals 48 or 72 hours after test substance exposure or on day 7 and persisted up to days 10 and 14, respectively. The significance of the scaling is not clear, noting that all other effects had reversed by day 10.
No abnormal findings were observed on the treated skin of the male 14 days after treatment. Both females were observed with scaling of the skin up to day 14 post treatment, the end of observation period.
No staining produced by the test substance of the treated skin was observed.
Neither alterations of the treated skin were observed nor were corrosive effects evident on the skin.

CONCLUSION: The test substance is irritating to the skin.

TEST FACILITY: Harlan Laboratories Ltd (2008b)

B.4. Irritation – eye

TEST SUBSTANCE Hostapon SG

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 440/2008 B.5 Acute Toxicity (Eye Irritation).

Species/Strain Rabbit/New Zealand White
Number of Animals 1 M, 2 F
Observation Period 7 days
Remarks - Method No deviations from the protocol.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1.7	2	1.7	2	< 7 days	0
Conjunctiva: chemosis	2	1.3	2	3	< 7 days	0
Conjunctiva: discharge	1	1	1	2	< 7 days	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results No mortality occurred. No clinical signs were observed during the course of the study. One female slightly lost body weight (-1.5%) from the day of application to the termination of the test. Otherwise, the body weights of all animals were considered to be within the normal range of variability. No necropsy was performed at the end of the study.
No abnormal findings were observed in the cornea or iris of any animal at any of the measurement intervals.
Slight to moderate reddening of the conjunctivae was noted in all animals 1 to 72 hours after treatment. Slight to marked swelling of the conjunctivae (chemosis with half-closed lids) was observed in all animals 1 to 72 hours after treatment. Moderate reddening of the sclera was present in one animal 1 to 72 hours after treatment. Due to the marked swelling (with half closed lids) of the conjunctivae, the assessment of the sclera was first prevented in two animals. When assessable at the 24-hour reading, a moderate reddening of the sclera was noted. Slight to moderate ocular discharge was recorded in all animals 1 to 72 hours after treatment.
No abnormal findings were observed in the treated eye of any animal 7 days after treatment, the end of the observation period for all animals.
No staining produced by the test substance of the treated eye was observed.
No corrosion of the cornea was observed at any of the reading times.

CONCLUSION The test substance is irritating to the eye.

TEST FACILITY Harlan Laboratories Ltd (2008c)

B.5. Skin sensitisation

TEST SUBSTANCE Hostapon SG

METHOD OECD TG 406 Skin Sensitisation - <Magnusson and Kligman Maximisation-Test>.
EC Directive 440/2008 B.6 Skin Sensitisation - <Magnusson and Kligman Maximisation-Test>.

Species/Strain	Guinea pig/Dunkin Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: 5% intradermal: 5, 10, 15, 25, 50, 75% topical: 3, 5, 10, 15, 25, 50, 75, 100%
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal: 5% topical: 50%
Signs of Irritation	The expected and common findings were observed in the control and test group after the different intradermal induction applications using FCA intradermally. These findings consisted of erythema, oedema, necrotising dermatitis, encrustation and exfoliation of encrustation. No erythematous or oedematous reaction was observed in the control animals treated with purified water only during epidermal induction. Discrete/patchy to moderate/confluent erythema was observed in all test animals at the 24-hour reading and in eight animals at the 48-hour reading after treatment with the test substance at 50% in purified water.
CHALLENGE PHASE	
challenge	topical: 5%
Remarks - Method	No deviations from the protocol. The positive control study was not done concurrently with the test of the notified chemical.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: challenge*	
		24 h	*48 h*
Test Group	5%	0/10	0/10
Control Group	5%	0/5	0/5

Remarks - Results	No death and no clinical signs of systemic toxicity were observed in the animals during the study. No skin reactions were observed in the test and control animals when treated with either purified water only or the test substance at 5 % in purified water. The positive control, alpha-hexylcinnamaldehyde was tested to produce evidence of skin sensitisation thus confirming the sensitivity and reliability of the experimental technique.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.
TEST FACILITY	Harlan Laboratories Ltd (2008d)

B.6. Genotoxicity – bacteria

TEST SUBSTANCE	Hostapon SG
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 440/2008 B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure (test 1)/Pre incubation procedure (test 2)
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Phenobarbital/β-Naphthoflavone induced rat liver S9.
Concentration Range in Main Test	Test 1: 0, 3, 10, 33, 100, 333, 1000, 2500 and 5000 µg/plate Test 2: 0, 3, 10, 33, 100, 333, 1000, 2500 and 5000 µg/plate
Vehicle	Deionised water

Remarks - Method No deviations from the protocol. The preliminary test was repeated as test 1.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	≥ 2500			
Test 1		≥ 2500	> 5000	≥ 2500
Test 2		≥ 1000	> 5000	≥ 1000
Present	≥ 2500			
Test 1		≥ 2500	> 5000	≥ 2500
Test 2		≥ 1000	> 5000	≥ 1000

Remarks - Results The plates incubated with the test substance showed reduced background growth in nearly all strains with and without metabolic activation in both independent experiments.
Toxic effects, evident as a reduction in the number of revertants (below the indication factor of 0.5), occurred in nearly all strains in both experiments.
No substantial increase in revertant colony numbers of any of the five tester strains was observed following treatment with Hostapon SG at any dose level, neither in the presence nor absence of metabolic activation (S9 mix). There was also no tendency of higher mutation rates with increasing concentrations in the range below the generally acknowledged border of biological relevance.
Appropriate reference mutagens were used as positive controls. They showed a distinct increase of induced revertant colonies, thus confirming the efficiency of the test system.

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

TEST FACILITY Harlan Laboratories Ltd (2008e)

B.7. Genotoxicity – in vitro

TEST SUBSTANCE Hostapon SG dried (68.5% notified chemical)

METHOD OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.
EC Directive 440/2008 B.17 Mutagenicity - In vitro Mammalian Cell Gene Mutation Test.

Cell Type/Cell Line L5178Y Thymidine Kinase Locus ($TK^{+/-}$) mouse lymphoma cell line
Metabolic Activation System Phenobarbital/β-Naphthoflavone induced rat liver S9.
Vehicle Deionised water
Remarks - Method The concentration range of the main experiments was limited by cytotoxicity of the test substance. The cultures at the maximum concentration in both main experiments were discontinued due to exceedingly strong toxic effects.

The study authors considered a test substance to be mutagenic if the induced mutation frequency reproducibly exceeds a threshold of 126 colonies per 10^6 cells above the corresponding solvent control.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	0, 5.9, 11.8, 23.5. 47.0. 94.0, 141.0	4 hours	48 hours	10-15 days

Test 2	0, 11.8, 23.5. 47.0. 94.0, 188.0, 282.0	24 hours	48 hours	10-15 days
Present				
Test 1	0, 11.8, 23.5. 47.0. 94.0, 188.0, 282.0	4 hours	48 hours	10-15 days
Test 2	0, 8.8, 17.5, 35.0, 70.0, 105.0, 140.0	4 hours	48 hours	10-15 days

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	> 187.5			
Test 1		> 94.0	> 94.0	negative
Test 2		> 94.0	> 188.0	negative
Present	> 187.5			
Test 1		> 188.0	> 188.0	negative
Test 2		> 8.8	> 105.0	negative

Remarks - Results

No substantial and reproducible dose dependent increase in mutant colony numbers was observed in both main experiments. No relevant shift of the ratio of small versus large colonies was observed up to the maximum concentration of the test substance.

In the second test the threshold of 126 plus the solvent control count was exceeded in the first culture at 188 µg/mL without metabolic activation. However, no comparable increase was noted in parallel culture under identical conditions and the range of historical control data was not exceeded. Therefore, this effect was judged as biologically irrelevant.

A linear regression analysis was performed to assess a possible dose dependent increase of mutant frequencies. A significant dose dependent trend of the mutation frequency indicated by a probability value of < 0.05 was determined in the first culture of the first test with metabolic activation, but was not seen in the parallel culture. Since the mutation frequency neither exceeded the historical range of solvent controls nor the threshold of 126 plus the solvent control count, the statistical result was considered to be biologically irrelevant.

Appropriate reference mutagens were used as positive controls and showed a district increase in induced mutant colonies, indicating that the tests were sensitive and valid.

CONCLUSION

The notified chemical was not clastogenic to the call line L5178Y treated in vitro under the conditions of the test.

TEST FACILITY

Harlan Cytotest Cell Research GmbH (2010)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATION

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical (~25% liquid particle dispersion)
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test (Modified Sturm Test)
Inoculum	Activated sludge suspension derived from a municipal sewage treatment plant treating domestic sewage
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	pH, CO_2, Temperature, Aeration
Remarks - Method	Minor changes from the guideline: The mineral nutrient solution was directly prepared in the test vessels. The pH of the mineral nutrient solution was checked and adjusted to pH 7.4 ± 0.2 if necessary. The titration of barium hydroxide solution was performed potentiometrically instead of by visual titration against phenolphthalein indicator.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% degradation*	*Day*	*% degradation*
9	67	9	Not evaluated
28	84.5	28	Not evaluated

Remarks – Results	The test substance is classified as ready biodegradable as the pass level (60% $ThCO_2$) was reached in a 10-day window within the 28-day period of the test. The complete evolved CO_2 for the reference substance (sodium benzoate) could not be determined due to leakage between day 1 and 2. The characteristics of the resulting biodegradation curve correspond to a typical biodegradation curve of sodium benzoate with a less steep slope in the beginning. The overall biodegradation determined in the procedural control was 69% after 28 days. The test is therefore considered to be valid. Moreover, the test substance can be assumed to be not inhibitory as the toxicity control reached a degree of degradation of > 25% within 14 days.
CONCLUSION	The notified chemical is readily biodegradable
TEST FACILITY	Clariant Analytical Services (2009)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical (~25% liquid particle dispersion)
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static
Species	Zebra Fish (*Danio rerio)*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	59 mg $CaCO_3$/L
Analytical Monitoring	DOC according to guideline DIN EN 1484
Remarks – Method	A static limit test was performed with one application of the test substance at test initiation. DOC analysis was carried out only at the beginning of the test (16.6 mg/L). Therefore, no information on stability and recovery of the test substance under test conditions was given.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	-	7	0	0	0	0	0
100	-	7	0	0	0	0	0

LC_{50}	> 25 mg/L at 96 hours (adjusted for notified chemical in test substance)
NOEC	25 mg/L at 96 hours
Remarks – Results	LC_{50} values for the notified chemical were > 25 mg/L at each observation time. After 96 hours of exposure, there were no fish mortalities or sub-lethal effects in the test vessels or controls, thereby validating the test. The results of this limit test do not exclude the possibility that the notified chemical has an LC_{50} of ≤ 100 mg/L, which is the upper limit for chemicals to be classified as harmful to aquatic life under the Globally Harmonised System of Classification and Labelling of chemicals (United Nations, 2009). A conservative assumption is therefore made that the notified chemical is potentially harmful to fish.
CONCLUSION	The notified chemical is potentially harmful to fish
TEST FACILITY	Dr. U. Noack-Laboratorien (2008)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical (19.8% w/w active content)
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilization Test – Static
Species	*Daphnia magna (straus)*
Exposure Period	48 hours
Auxiliary Solvent	Water containing 800 mg/L Na_2EDTA
Water Hardness	21.4 mg $CaCO_3$/L
Analytical Monitoring	pH, dissolved oxygen concentration, conductivity, total hardness, temperature, LC-MS/MS
Remarks – Method	The test was conducted according to the guideline above at test substance concentrations of 1.64, 4.10, 10.2, 25.6, 64 and 160 mg/L. The notified chemical formed calcium salts with very low solubility removing most of the test substance from the aqueous solution. To overcome this test issue, Ca^{2+} ions were complexed by Na_2EDTA. No effects on *Daphnia magna* toxicity were noted due to Na_2EDTA in a preliminary range finding test. Hence, no additional control without Na_2EDTA was necessary. Test conditions were: 19-20°C, pH 7.08, 9.10 mg O_2/L.

RESULTS

Concentration mg/L		*Number of Daphnia magna*	*Number Immobilised* (%)	
Nominal	*Actual** (C12 fraction in mg a.i./L)		*24 h*	*48 h*
1.64	0.179	20	0	0
4.10	0.403	20	0	0
10.2	1.32	20	0	0
25.6	2.86	20	0	6 (30)
64.0	7.65	20	6 (30)	18 (90)
160	18.8	20	17 (85)	20 (100)
Na_2EDTA control	<LOQ	20	0	0

* Measured concentration of C12 fraction in old media at 48 h

EC_{50}	6.53 mg/L at 48 hours (adjusted for active content in test substance)
NOEC	2.02 mg/L at 48 hours
Remarks – Results	The EC50 and NOEC values after 48 h for the notified chemical were 6.53 mg/L and 2.02 mg/L. After 48 hours of exposure, there were no immobilised Daphnia in the Na_2EDTA control. The validity criteria of the test guideline were fulfilled.
CONCLUSION	The notified chemical is toxic to *Daphnia magna*
TEST FACILITY	Dr. U. Noack-Laboratorien (2011a)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical (Dried, 68.5% w/w active content)
METHOD	OECD TG 201 Algal Growth Inhibition Test
Species	*Desmodesmus subspicatus* CHODAT SAG 86.81
Exposure Period	72 hours
Concentration Range	Nominal: 0.32 – 320 mg/L Actual: Not reported
Auxiliary Solvent	None
Water Hardness	0.24 mmol Ca + Mg/L
Analytical Monitoring	LC-MS/MS
Remarks – Method	The test was conducted according to the guidelines above at test substance concentrations of 0.32, 1.00, 3.20, 10.0, 32.0, 100 and 320 mg/L in three replicates and six replicates for the control. All validity criteria for the test were satisfied. Test conditions were: 21-24°C, pH 8.07–8.33.

RESULTS

Growth		*Biomass*	
E_rC_{50} (95% CI) mg/L at 72 h	*NOEC* mg/L	E_bC_{50} mg/L at 72 h	*NOEC* mg/L
89.9 (84.3 – 96.2)	32.0	30.5 (21.5 – 43.4)	1.0

Remarks – Results	All validity criteria were satisfied. The recoveries of the active constituents were outside the range of 70 – 110%. However, all effect values are given based on nominal concentrations of the test item as it contains different C-chains of the N-Cocoyl glycerine sodium salt, and toxicity cannot be attributed to any single component.
CONCLUSION	The notified chemical is harmful to algae.
TEST FACILITY	Dr. U. Noack-Laboratorien (2011b)

BIBLIOGRAPHY

CIR (2001) Final Report on the Safety Assessment of Cocoyl Sarcosine, Lauroyl Sarcosine, Myristoyl Sarcosine, Oleoyl Sarcosine, Stearoyl Sarcosine, Sodium Cocoyl Sarcosinate, Sodium Lauroyl Sarcosinate, Sodium Myristoyl Sarcosinate, Ammonium Cocoyl Sarcosinate, and Ammonium Lauroyl Sarcosinate. IJT 20: Suppl 1 (Reprinted in Cosmetic Ingredient Review 2006).

Clariant Analytical Services (2009) Biodegradability of Hostapon SG in the OECD 301 B "CO_2 Evolution Test" Modified Sturm Test (Study code No. 08-47310, 13 February 2009). Frankfurt, Germany, Clariant Analytical Services Rhein-Main, R & D Analytics Lab D562 (Unpublished report submitted by the notifier).

Clariant Analytical Services (2010a) Critical micelle concentration/solubility (Study No. 10-81030, 9 June 2010). Frankfurt, Germany, Clariant Analytical Services Rhein-Main, R & D Analytics Lab D561 (Unpublished report submitted by the notifier).

Clariant Analytical Services (2010b) Physical Properties Calculation of Hostapon SG (Study Order No. 10-86119.1, 30 August 2010). Frankfurt, Germany, Clariant Analytical Services Rhein-Main, Clariant Produkte (Deutschland) GmbH (Unpublished report submitted by the notifier).

Dr. U. Noack-Laboratorien (2008) Hostapon SG Fish (Zebra Fish), Acute Toxicity Test, Static, 96 h (Study No. FAZ12615, 05 September 2008). Sarstedt, Germany, Dr. U. Noack-Laboratorien (Unpublished report submitted by the notifier).

Dr. U. Noack-Laboratorien (2011a) Hostapon SG Acute Immobilization Test to *Daphnia magna*, Static, 48 h (Study No. DA114343, 06 July 2011). Sarstedt, Germany, Dr. U. Noack-Laboratorien (Unpublished report submitted by the notifier).

Dr. U. Noack-Laboratorien (2011b) Hostapon SG dried Algal Growth Inhibition Test with *Desmodesmus subspicatus*, 72 h (Study No. SSO13886, 21 January 2011). Sarstedt, Germany, Dr. U. Noack-Laboratorien (Unpublished report submitted by the notifier).

European Commission (2003). Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and of the Council Concerning the Placing of Biocidal Products on the Market – Part II. Institute for Health and Consumer protection, European Chemicals Bureau, European Communities.

Harlan Laboratories Ltd (2008a) Hostapon SG: Acute Oral Toxicity Study in Rats – Acute Toxic Class Method (Study No. C14270) for Clariant Produkte (Deutschland) GmbH 65926 Frankfurt am Main, Germany. Harlan Laboratories Ltd (former RCC Ltd) 4414 Fullinsdorf, Switzerland (unpublished report submitted by the notifier).

Harlan Laboratories Ltd (2008b) Hostapon SG: Primary Skin Irritation Study in Rabbits (4-Hour Semi-Occlusive Application) (Study No. C14281) for Clariant Produkte (Deutschland) GmbH 65926 Frankfurt am Main, Germany. Harlan Laboratories Ltd (former RCC Ltd) 4414 Fullinsdorf, Switzerland (unpublished report submitted by the notifier).

Harlan Laboratories Ltd (2008c) Hostapon SG: Primary Eye Irritation Study in Rabbits (Study No. C14292) for Clariant Produkte (Deutschland) GmbH 65926 Frankfurt am Main, Germany. Harlan Laboratories Ltd (former RCC Ltd) 4414 Fullinsdorf, Switzerland (unpublished report submitted by the notifier).

Harlan Laboratories Ltd (2008d) Hostapon SG: Contact Hypersensitivity in Albino Gunea Pigs. Maximisation-Test (Study No. C14314) for Clariant Produkte (Deutschland) GmbH 65926 Frankfurt am Main, Germany. Harlan Laboratories Ltd (former RCC Ltd) 4414 Fullinsdorf, Switzerland (unpublished report submitted by the notifier).

Harlan Laboratories Ltd (2008e) Hostapon SG: Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay (Study No. C14303) for Clariant Produkte (Deutschland) GmbH 65926 Frankfurt am Main, Germany. Harlan Laboratories Ltd (former RCC Ltd) 4452 Itingen, Switzerland (unpublished report submitted by the notifier).

Harlan Laboratories Ltd (2010) Hostapon SG: Acute Dermal Toxicity in Rats (Study No. D03324) for Clariant International Ltd, 4132 Muttenz, Switzerland. Harlan Laboratories Ltd, 4414 Fullinsdorf, Switzerland (unpublished report submitted by the notifier).

Harlan Cytotest Cell Research GmbH (2010) Hostapon SG: Cell Mutation Assay at the Thymidine Kinase Locus ($TK^{+/-}$) in Mouse Lymphoma L5178Y Cell (Study No. 1364600) for Clariant Products (Switzerland) Ltd, 4132 Muttenz 1, Switzerland. Harlan Cytotest Cell Research GmbH (Harlan CCR), 64380 Rossdorf, Germany (unpublished report submitted by the notifier).

Madsen T, Boyd HB, Nylén D, Pederson AR & Simonsen F (2001) Environmental and Health Assessment of Substances in Household Detergents and Cosmetic Detergent Products. CETOX, Miljøprojekt, 210 pp (Environmental Project No. 615).

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.