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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL 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 Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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**Glycine, N-coco acyl derivs., sodium salts (INCI name: Sodium Cocoyl Glycinate)****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

NOTIFICATION CATEGORY

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: spectral data, purity, impurities

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)

None

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)

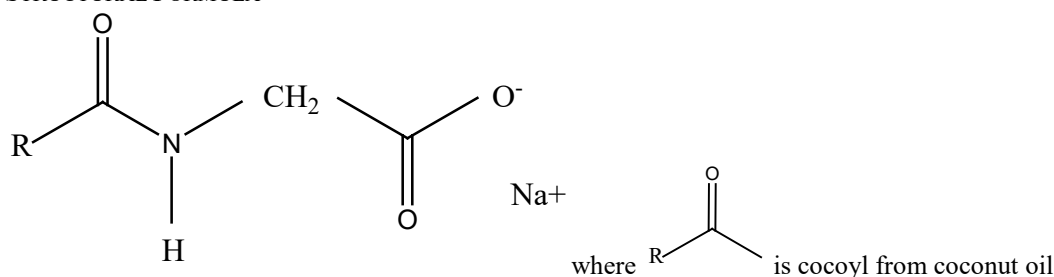
INCI name: Sodium Cocoyl Glycinate
N-Cocoyl glycine sodium salt

MOLECULAR FORMULA

Unspecified

The main component, C₁₂ derivative: C₁₄H₂₆NO₃Na

STRUCTURAL FORMULA



MOLECULAR WEIGHT

Unspecified

The main component, C₁₂ derivative: 279.4 Da

ANALYTICAL DATA

Reference ¹H 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 > 350°C 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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	1	1	1	1	1

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 as a raw material for the manufacture of 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 or to generate airborne dust. 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 consumers.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
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
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 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.

Sales workers can have frequent dermal and ocular exposure to the notified chemical if involved in demonstration to consumers of cosmetic products containing the notified chemical. However, exposure for sales workers is less likely for body and hair cleansing products which are the intended end use of 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.

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.

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 not a likely route of exposure and 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 Hostapon SG (containing approximately 25% 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) 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.

<i>Endpoint</i>	<i>Result for 25% of Notified Chemical</i>
Rat, acute oral 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

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 are 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.

No data were provided on the acute dermal toxicity of the notified chemical. 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. This suggests that the notified chemical is of low acute dermal toxicity.

The acute inhalation toxicity or potential for respiratory irritation of the notified chemical is unknown. In addition, there is no data available on the inhalation toxicity 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. The notified chemical at 100% is expected to have severe 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.

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 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, overalls, 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 (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 of exposure. Skin irritation effects from formulated products containing up to 5% of the notified chemical are not expected. However, it is noted that 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 level of 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 can therefore be expected to degrade during sewage treatment and if discharged to aquatic environments. Degradation in landfill can also be expected, based on the ready biodegradability and chemical structure of the notified chemical. The notified chemical has a low potential for bioaccumulation based on its ready biodegradability and surface activity. For the details of the environmental fate studies refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

A PEC for discharge of the notified chemical to surface waters has been calculated assuming that all of the imported quantity of the chemical is discharged to sewers nation wide and that no removal occurs in sewage treatment. The details of this worst case scenario are 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)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.65	µg/L
PEC - Ocean:	0.07	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/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/m³). Using these assumptions, irrigation with a concentration of 0.647 µg/L may potentially result in a soil concentration of approximately 4.316 µg/kg.

Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 21.58 µg/kg and 43.16 µg/kg, respectively. However, due to the ready biodegradability of the notified chemical, these calculated values represent maximum concentrations only.

7.2. Environmental effects assessment

The results from an ecotoxicological study of the acute effects of the notified chemical on fish are summarised in the table below. Details of this study can be found in Appendix C.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity (96 hour)	LC50 > 25 mg/L	Potentially harmful to fish

The notified chemical is classified as harmful to aquatic life under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009). This classification is based on the known acute aquatic toxicity end points of related anionic surfactants which are in the range 10–100 mg/L (Madsen et al., 2001), and the fish acute toxicity test result for the notified chemical which sets a lower limit on the acute effects that is within this concentration range. 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 lower limit for the fish acute toxicity and an assessment factor of 1000. The most conservative assessment factor has been applied as acute ecotoxicity data for the notified chemical are only available for one trophic level.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment			
LC50 (Fish)	> 25	mg/L	
Assessment Factor	1,000		
PNEC:	> 25	µg/L	

7.3. Environmental risk assessment

The Risk Quotient ($Q = \text{PEC}/\text{PNEC}$) values have been calculated as follows:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.65	> 25	< 0.026
Q - Ocean	0.06	> 25	< 0.003

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 expected to pose an unacceptable risk to the aquatic environment from its proposed use pattern.

8. 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.

<i>Hazard category</i>	<i>Hazard statement</i>
------------------------	-------------------------

Skin irritation	2	Causes skin irritation
Eye irritant	2A	Causes serious eye irritation
Acute hazards to the aquatic environment	3	Harmful to aquatic life

Human health risk assessment

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

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

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemical is not expected to pose a 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 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 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 formulating the consumer products:
 - Protective eye wear such as goggles
 - Impermeable gloves
 - Coveralls

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 of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) 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 $\leq 5\%$, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 1 tonne 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.

No additional secondary notification conditions are stipulated.

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.

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

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
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.
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TEST FACILITY	Harlan Laboratories Ltd (2008a)
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B.2. 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

<i>Lesion</i>	<i>Mean Score* Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	1.3	1.7	2	2	< 10 days	0
<i>Oedema</i>	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
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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.3. 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*			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.4. 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

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

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

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

<i>Test substance</i>		<i>Sodium benzoate</i>	
<i>Day</i>	<i>% degradation</i>	<i>Day</i>	<i>% degradation</i>
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.
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CONCLUSION	The notified chemical is readily biodegradable
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TEST FACILITY	Clariant Analytical Services (2009)
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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 (<i>Danio rerio</i>)
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

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

LC50 > 25 mg/L at 96 hours (adjusted for notified chemical in test substance)
 NOEC 25 mg/L at 96 hours
 Remarks – Results LC50 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 LC50 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)

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