File No: EX/178 (STD/1331)

December 2012

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Sodium Laurylglucosides Hydroxypropylsulfonate

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

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

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

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Director
NICNAS

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FULL PUBLIC REPORT

This assessment report is for an extension of the original assessment certificate for Sodium Laurylglucosides Hydroxypropylsulfonate. Based on the submission of new information by the extension notifier, some sections of the original assessment report for Albright & Wilson Pty Ltd have been modified. These modifications have been made under the heading *'Extension Application'* in the respective sections.

SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
EX/178 (STD/1331)	Capitol Ingredients Australia Pty Ltd	Sodium Laurylglucosides Hydroxypropylsulfonate	Yes	100 tonnes per annum	A component of personal care products and surface cleaning products

Hazard classification

The notified chemical is not able to be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). However, based on the reported irritation effects of structurally related chemicals (APGs and sulfonates) as irritating to the eyes and skin (R36/38), the notified chemical should be considered as though classified as:

R36/38 Irritating to eyes and skin.

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*
Acute aquatic toxicity	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 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 considered to pose an unreasonable risk to the environment.

Risk assessment relating to extension applicant

The use and environmental fate described in the extension application are not expected to impact the outcomes of the original human health and environment risk assessment and recommendations.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- The introducers of the notified chemical should consider the following health hazard classification:
  - R36/38: Irritating to eyes and skin

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥ 20%: R36/38: Irritating to eyes and skin

CONTROL MEASURES
Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to the notified chemical:
  - Avoid contact with skin and eyes

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced at ≤ 40%:
  - Wear eye/face protection
  - Wear impervious gloves, coveralls and enclosed footwear

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- The MSDS and label for the imported product containing the notified chemical at ≤ 40% should be revised to include the following risk phrases:
  - R36/38: Irritating to eyes and skin.

- 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.

Disposal

- The notified chemical should be disposed of to landfill

Storage

- The following precautions should be taken regarding storage of the notified chemical:
  - Keep in a cool place away from strong oxidizing agents

Emergency procedures

- Spills and/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(1) of the Act; if
- the chemical is intended for use in consumer products at concentrations > 14%;
- the chemical is intended for use in products that are not rinse-off

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from an anionic surfactant component of personal care products and hard surface cleaning products at concentrations up to 14%, or is likely to change significantly;
- the amount of chemical being introduced has increased from 200 tonnes, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

Material Safety Data Sheet
The MSDS of the 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.

Extension Application
The extension applicant has provided an MSDS for the notified chemical which was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the extension applicant.

ASSESSMENT DETAILS

Sodium Laurylglucosides Hydroxypropylsulfonate

1. APPLICANT AND NOTIFICATION DETAILS

Holder of Original Assessment Certificate (STD/1331)
Albright & Wilson Pty Ltd (ABN 36 004 234 137)
295 Whitehall Street
YARRAVILLE VIC 3013

Applicant for Extension of the Original Assessment Certificate
Capitol Ingredients Australia Pty Ltd (ABN 30 055 147 567)
Unit 9, 7 Meridian Place
BELLA VISTA NSW 2153

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

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
vapour pressure, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, acute dermal toxicity, acute inhalation toxicity, skin irritation, eye irritation, skin sensitisation, repeated dose toxicity, chromosome damage and bioaccumulation.

NOTIFICATION IN OTHER COUNTRIES
USA (2007)

2. IDENTITY OF CHEMICAL

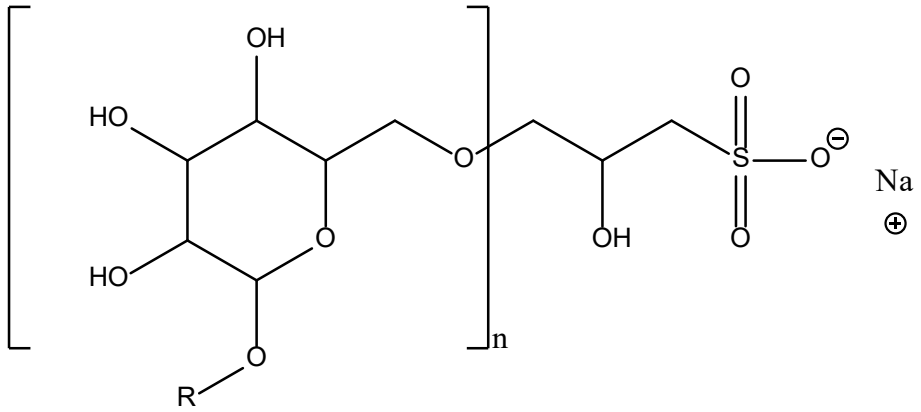
MARKETING NAME(S)
Suga*Nate 160 (≤ 40% solution of notified chemical)
Sodium Laurylglucosides Hydroxypropylsulfonate (INCI Name)

CHEMICAL NAME
D-Glucopyranose, oligomeric, C10-16-alkyl glycosides, 2-hydroxy-3-sulfopropyl ethers, sodium salts

CAS NUMBER
742087-49-6

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA



R = $C_{12}H_{25}$, $C_{13}H_{27}$ or $C_{14}H_{29}$
n = 1 or 2

MOLECULAR WEIGHT*
≥ 508 Da.
* Assumes R = $C_{12}H_{25}$ and n = 1

ANALYTICAL DATA

METHOD	Infra-red Spectrometry
Remarks	Major peaks at: ~ 3400, 1600, 1000 and 700 cm^{-1}

3. COMPOSITION

DEGREE OF PURITY > 94%

KNOWN HAZARDOUS IMPURITIES

Chemical Name D-Glucopyranose, oligomeric, C_{10-16}-alkyl glycosides
CAS No. 110615-47-9 *Weight %* 1.72%
Hazardous Properties ≥ 20% Xi; R36/38 Irritating to eyes/skin.

Chemical Name Alcohols, C_{10-16}
CAS No. 67762-41-8 *Weight %* < 0.5%
Hazardous Properties ≥ 20% Xi; R36/38 Irritating to eyes/skin.

IMPURITIES (> 1% by weight)

Chemical Name Sodium chloride
CAS No. 7647-14-5 *Weight %* 3.3%

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance of the notified chemical: Soft, yellowish, waxy solid.
Appearance of the product Suga*Nate 160 containing the notified chemical at ≤ 40% at 20 °C and 101.3 kPa: Clear yellow viscous liquid.
The following values are for the product Suga*Nate 160 containing the notified chemical at ≤ 40% unless otherwise stated.

Property	Value	Data Source/Justification
Melting Point/Freezing Point	250 °C	Estimated for notified chemical
Boiling Point	105 °C	Estimated
Density	1130 kg/m^3	Measured
Vapour Pressure	Not determined	The notified chemical will not be isolated from solution which has a vapour pressure similar to water.
Water Solubility	816 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Stable	MSDS
Partition Coefficient (n-octanol/water)	Expected to be low, based on the water solubility.	The property cannot be measured as the notified chemical is a surfactant.
Adsorption/Desorption	Sorption to soil is expected to be weak.	The notified chemical is highly water soluble.
Dissociation Constant	Fully dissociated in aqueous solution.	Sulfonic acids are strong acids (methanesulfonic acid pKa ~ -3).
Viscosity	6900 cps at 25 °C	Measured
pH at 10% concentration	7.3	Measured
Flash Point	> 93 °C	Measured
Flammability	Not expected to be flammable	Estimated
Autoignition Temperature	Not expected to autoiginite	Estimated
Explosive Properties	Not expected to be explosive	Does not contain explosophores

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

Reactivity
May react at high temperatures or in the presence of strong oxidizing agents.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported at ≤ 40% in the product Suga*Nate 160 in 200 L drums for reformulation.

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

Original Notifier

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10 – 100	10 – 100	10 – 100	10 – 100	10 – 100

Extension Application

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10 – 100	10 – 100	10 – 100	10 – 100	10 – 100

Total Import Volume

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	20 – 200	20 – 200	20 – 200	20 – 200	20 – 200

PORT OF ENTRY
Sydney, Melbourne, Brisbane

IDENTITY OF RECIPIENTS
The notified chemical will be manufactured by Colonial Chemicals, Inc., 225 Colonial Drive, South Pittsburg, TN 37380 USA and imported into Australia by Albright & Wilson (Australia) Limited.

Extension Application
The notified chemical will be manufactured by Colonial Chemicals, Inc., 225 Colonial Drive, South Pittsburg, TN 37380 USA and imported into Australia by Capitol Ingredients Australia Pty Limited.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported as a component of the product Suga*Nate 160 in 200 L steel drums before being transported to various customers across Australia for reformulation into personal care products and industrial cleaners in packages ranging up to 500 mL in size for sale in various stores and outlets.

USE
The notified chemical will be used as an anionic surfactant component of personal care products and hard surface cleaning products at concentrations up to 14%.

OPERATION DESCRIPTION
Reformulation
The notified chemical will be imported as an aqueous solution (containing ≤ 40% notified chemical). It will be transported to a reformulation site where it will be weighed and added to a blending tank with other ingredients for formulation into finished products. Sampling and quality control testing of the formulated product will be conducted prior to packaging. The finished product will then be transferred into product containers which will be sealed and packaged for retail sale.

End-use
Personal care products containing the notified chemical (≤ 14%) such as soaps, detergents and shampoos will be used daily in hair and beauty salons and by members of the public. The notified chemical will also be used by cleaners in hard surface cleaners at ≤ 14%.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hrs/day)*	*Exposure Frequency (days/year)*
Transport	1-2	1	4-6
Storage	1	1	4-6
Reformulation	1-3	0.5	4-6
Laboratory Technician	1	0.5	4-6

EXPOSURE DETAILS

Transport and Storage

Exposure to the notified chemical during transport and storage is not anticipated except in case of an accident leading to release.

Reformulation

Accidental dermal and ocular exposure to drips, spills and splashes of the notified chemical (≤ 40%) may occur during weighing, charging of mixing vessels, blending, quality assurance testing and filling of product packaging. Dermal and ocular exposure may also occur during cleaning and washing of equipment used in reformulation with appropriate solvents. The notifier states exposure is expected to be minimised given the anticipated use of closed systems for reformulation and personal protective equipment (PPE), such as safety goggles, impervious gloves, overalls and enclosed footwear.

Inhalation exposure to aerosols is not expected due to the anticipated high viscosity of Suga*Nate 160.

Use of finished personal care products

Occupational exposure is possible for workers in hair and beauty salons using products containing the notified chemical (≤ 14%). Dermal exposure is expected to be extensive given that shampoo and personal care products containing the notified chemical will be applied directly to the skin and hair. Accidental ocular exposure and oral ingestion may also occur.

Although the level and route of exposure will vary depending on the method of application and work practices employed, extensive dermal exposure is expected in some occupational settings. This exposure is likely to be greater than that expected for the public (see below).

Use of hard surface cleaners

Workers using hard surface cleaning products containing the notified chemical (≤ 4%) are expected to experience extensive dermal exposure during application of the products and rinsing. Accidental eye exposure to aerosols of the product is also possible during cleaning. Gloves may be worn when handling the cleaning solution but eye protection is unlikely to be used.

6.1.2. Public exposure

Public exposure to the notified chemical is expected to be widespread and frequent through daily use of personal care products containing the notified chemical at concentrations up to 14%. Exposure to the notified chemical will vary depending on individual use patterns. The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible, particularly if products are applied by spray. Accidental ingestion from the use of these types of products is also possible from facial use.

Public exposure to the notified chemical in Australia has been estimated using the Scientific Committee on Consumer Products' (SCCP's) Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation and applying the following assumptions:

- Bodyweight of 60 kg for females (SCCP, 2006);
- The concentration of the notified chemical in all cosmetic and household products is 14%;
- 100% dermal absorption (SCCP, 2006);

- An individual uses all product types containing the notified chemical.

Product(s) used	*Use level for each product*	*Retention factor*	*Systemic Exposure (mg/kg bw/day)*
Facial cleanser	0.8 g x 0.5 applications/day	0.01	0.07
Shampoo	10.46 g per day	0.01	1.74
Conditioner	14.00 g x 0.28 applications/day	0.01	0.65
Shower gel	5.00 g x 2 applications/day	0.01	1.67
Laundry detergent(1)	230 g x 1 use/day	0.00095	3.64
Dishwashing liquid(1)	5.34 mg(2) x 3 uses/day	1.0	0.27
Liquid soap(1)	1.6 g x 7 applications/day	0.005	0.93
Total product exposure =			8.97

Total exposure to the notified chemical at 14% in each of the products above = 8.97 mg/kg bw/day x 14%

Total	**1.26**

(1) Exposure estimates by the Soap & Detergent Association's (SDA) (2005).
(2) Amount in contact with skin per use

This exposure estimate was produced using highly conservative assumptions and is expected to reflect a worst-case scenario. In reality, the level of exposure is expected to be lower than 1.26 mg/kg bw/day as it is assumed that consumers would not use all these products to the extent shown above, and dermal absorption may be less than 100%.

6.2. Human health effects assessment

A summary of the results from toxicological investigations conducted on the notified chemical and structurally related chemicals: Alkyl polyglucosides (APGs), Secondary alkane sulfonates (SAS) (CAS No. 68037-49-0) and Linear alkylbenzene sulphates (LAS) (CAS No. 68411-30-3, CAS No. 1322-98-1, 25155-30-0, CAS No. 90194-45-9, CAS No. 85117-50-6) are summarised in Table 1 below. Details of studies on the notified chemical can be found in Appendix B.

Table 1: Physico-chemical and toxicological properties of the notified chemical and 3 structurally related chemicals

Endpoint	*Notified chemical[1] (CAS No. 742087-49-6)*	*Alkyl Polyglucosides (APGs)[2]*	*Secondary Alkane Sulfonate (SAS)[3] (CAS No. 68037-49-0)*	*Linear Alkylbenzene Sulpohonate (LAS)[4] (CAS No. 68411-30-3, CAS No. 1322-98-1, 25155-30-0, CAS No. 90194-45-9, CAS No. 85117-50-6)*
Molecular weight (Da.)	508****	~ 334*	328**	342.4***
Melting point/Freezing Point (°C)	250	- 10[5]	< 200	277 (C_{12})
Boiling point (°C)	105	100[5]	-	637^
Density (kg/m^3)	1130	1050 – 1150[5]	-	1060
Vapour pressure at 20°C (kPa)	-	-	$5.3x10^{-14}$^^	$3\text{-}17x10^{-16}$^
Water solubility	816	Water-soluble[5]	350	250
Log K_{OW}	-	-	2.76	3.32 (ave.)
Rat, acute oral toxicity (LD50) (mg/kg bw)	> 2000	> 2000	2130 (M), 2890 (F)	≥ 1086 - 1980
Rabbit, acute dermal toxicity (LD50) (mg/kg bw)	-	> 2000	-	> 1000
Rat, acute inhalation toxicity (LD50) (mg/kg bw)	-	-	-	-
Rabbit, skin irritation	-	R38 at ≥ 40%	R38 at ≥ 30%	R38 at 5 - 47%
Skin irritation – human volunteers	non-irritating at 4%	-	-	-
Rabbit, eye irritation		R36 at ≥ 50%	R36 at ≥ 30%	R36 at 5 - 47%
Hen's Egg Test – Chorio-allantoic Membrane (HET-CAM)	non-irritating at 2%	-	-	-
In vitro eye irritation – EpiOcular Test	non-irritating at 0.8%	-	-	-
Guinea pig, skin sensitisation – Magnusson & Kligman or Buehler Method	-	Not sensitising at ≤ 20%	Not sensitising at ≤ 60%	Not sensitising at ≤ 6.5%
Rat, Repeat dose oral toxicity (mg/kg bw/day)	-	90 days, NOAEL = 1000	52 weeks, NOEL = 200	9 months, NOAEL = 85 LOAEL = 145
Rat, Repeat dose dermal toxicity	-	-	4-5 weeks, NOAEL = 32% conc.	15 days, LOAEL = 286 mg/kg bw/day
Genotoxicity – bacterial reverse mutation test	negative	negative	negative	negative
Genotoxicity – In vitro (Chromosome aberration test)	-	negative	-	-
Genotoxicity – In vivo	-	-	negative	negative

[1] See section 6.2 Human health effects assessment and Appendices A and B for details. **** Assumes R = $C_{12}H_{25}$ and n = 1

[2] Detergency of Specialty Surfactants (2001). [3] HERA (2005)

[4] HERA (2007) [5] MSDS for Alkylpolyglucoside (CAS No. 68515-73-1) available online [6 July 2009]: www.trade-chem.com/products/MSDS/APG%20MSDS.pdf

^ Calculated for C_{12}

^^ Calculated for C_{16}

** Average molecular weight

*** Calculated based on an average $C_{11.6}$ linear alkyl chain

Toxicokinetics, metabolism and distribution
Limited data is available to describe the likely toxicokinetic properties of the notified chemical. Given its high water solubility and molecular weight of < 1000 Da., absorption might be expected following ingestion, or inhalation exposure (EC, 2003). Studies on LAS indicated ready absorption (80-90%) via the gastrointestinal tract and distribution to most organs except the uterus. Limited information indicates LAS have limited dermal absorption (HERA, 2007). It is unknown to what extent the differences in structure between LAS and the notified chemical have on its toxicokinetics. However, the metabolism of the notified chemical is thought to be markedly different to LAS due to the presence of an aromatic ring in the latter.

Acute toxicity
A formulation containing the notified chemical at a concentration of 36.2% was found to be of low acute oral toxicity (LD50 > 742 mg/kg bw/day) in 5 female rats according to the method described by OECD TG 420 Acute Oral Toxicity - Fixed Dose Method (Consumer Product Testing Co., 2008).

The notified chemical was not tested for acute toxicity via the dermal or inhalation routes. However, acute dermal toxicity studies on structurally related chemicals: APGs (LD50 > 2000) and LAS (LD50 > 1000) indicate that the notified chemical is unlikely to be toxic following acute dermal exposure. The acute inhalation toxicity potential of the notified chemical is unknown.

Irritation and Sensitisation
The notified chemical was not tested for skin or eye irritation at concentrations greater than 4%. However, tests on rabbits using structurally related chemicals resulted in irritant effects sufficient for classification with R36/38 Irritating to eyes and skin (see Table 1). Based on this information, the notified chemical may be considered as irritating to the eyes and skin.

A 48-hour semi-occlusive patch test to determine the potential for skin irritation in human volunteers was conducted using 0.2 mL of a solution diluted to a concentration of 4% notified chemical in distilled water. The treated skin sites of 53 adult volunteers (11 Males, 42 Females) were observed for signs of irritation 48 hrs and 72 hrs after application. No signs of irritation were observed in any of the test subjects at either of the observation points (see Appendix B for details). Based on the results of the patch test in human volunteers using the notified chemical at 4%, the notified chemical is not considered to be irritating at ≤ 4% in surfactant containing formulations.

The eye irritation potential of dilute solutions of the notified chemical was investigated in a Hen's Egg Test-Chorioallantoic Membrane (HET-CAM) assay. A solution (0.3 mL) of the notified chemical, diluted to a concentration of 2% in distilled water, was applied to the chorio-allantoic membrane of 4 Leghorn hens' eggs according to a modification of the method described by Kemper and Luepke (1986). No signs indicative of hyperaemia, haemorrhage or coagulation were observed in any of the membranes tested. Therefore, the notified chemical at 2% was not considered an eye irritant under the conditions of the test (see Appendix B for details).

The HET-CAM assay has not yet been validated as a replacement test for the *in vivo* Draize test, however validation of this assay is currently being considered by the US National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods and the Interagency Coordinating Committee on the Validation of Alternative Methods (NICEATM-ICCVAM). The draft ICCVAM recommendations from this validation process were released in April 2009 and recommended that the Hen's Egg Test-Chorioallantoic Membrane (HET-CAM) not be used for regulatory hazard classification purposes based on a lack of adequate data (ICCVAM, 2009a). The draft recommendations also included a recommendation that the HET-CAM test method could be useful for certain substances such as the notified chemical in formulations at low concentrations:

"Based on an analysis of 60 compounds (25 surfactant based formulations, 18 oil/water emulsions and 17individual substances), the HET-CAM IS(A) test method can be used as a screening test to identify substances as not labelled as irritants from all other hazard categories (R36 or R41). This recommendation is limited to cosmetic and personal care formulations that are oil/water emulsions or surfactant containing formulations."

However, at their recent meeting the Independent Scientific Peer Review Panel (ICCVAM, 2009b) did not agree with all the draft recommendations put forward by ICCVAM:

"The Panel did not support the ICCVAM draft recommendation (with one minority opinion) that based on the

available data, the HET-CAM IS(A) test method can be used as a screening test to identify substances as not labelled as irritants from all other hazard categories when results are to be used for EU or GHS hazard classifications. The Panel concluded that there were too few surfactants or oil/water emulsions in the mild to moderate irritant categories to have sufficient confidence in the ability of the test to distinguish them from the not labelled as irritant category."

Therefore the validity of the HET-CAM assay for determining the irritancy potential for a chemical or formulation has not yet been confirmed. However given the complete absence of response in the HET-CAM assay for the notified chemical solution, and the tendency for the HET-CAM assay to over-predict the irritancy potential in the validation studies of surfactant formulations, it is likely that the HET-CAM results indicate a low irritancy potential for the notified chemical at a concentration of 2%.

An *in vitro* eye irritation test was performed on a solution of the notified chemical diluted to 0.8% using the EpiOcular Tissue Model (see Appendix B for details). This test method is not a validated alternative to the *in vivo* animal test, although efforts towards validation are underway. The test method protocol used for the notified chemical solution varies from the method currently undergoing validation (Harbell et al, 2009). The EpiOcular Tissue Model has previously been shown to provide information on the ocular irritation potential of a cosmetic ingredient (Stern et al 1998; Sheasgreen et al 2003). The study authors concluded that the notified chemical did not elicit any signs of irritancy at the concentration tested under the conditions of the test, as there was only minimal reduction in cell viability after 4 hours treatment with the notified chemical.

Therefore although the notified chemical itself is considered to be an eye irritant, based on consideration of the data from the *in vitro* studies, in which no or very minimal irritancy responses were observed, dilute solutions of the notified chemical are unlikely to cause significant eye irritation.

The notified chemical does not contain any structural alerts for skin sensitisation (Barratt *et al*, 1994). In addition, information on structurally related chemicals indicate the potential for skin sensitisation is unlikely (see Table 1).

Repeated Dose Toxicity

The notified chemical was not tested for repeated dose toxicity. Information on chemicals with glucoside functionality suggests this functional group is unlikely to cause toxicity following repeated oral exposure.

Information provided by the notifier on the chemicals with sulfonate functionality indicates that the systemic toxicity following repeated exposure is varied, depending on the other functional groups within the molecules. In studies on LAS, which contains an aromatic group and was shown to be rapidly metabolised to sulfophenyl carboxylic acids, possible adverse effects on the liver and kidneys were observed. A NOAEL of 85 mg/kg bw/day was suggested based on the weight of evidence from a number of studies (HERA, 2007). However, given the absence of aromatic groups in the notified chemical, and therefore the different metabolite profiles expected, the relevance of these results on LAS to the systemic toxicity of the notified chemical is questionable.

In studies on SAS, which contains alkyl groups, unspecific effects (impaired grooming activity and retarded weight gain) were seen at the highest dose tested in a feeding study (HERA, 2005). The NOAEL from this study was estimated to be 200 mg/kg bw/day. No information was provided on the metabolism of SAS.

No conclusion can be made on the systemic toxicity of the notified chemical. However, based on the information provided on structurally related chemicals it is unlikely to be a significant toxicant after repeated systemic exposure.

Mutagenicity and Genotoxicity

The notified chemical was found not to be mutagenic up to the levels of cytotoxicity in a bacterial reverse mutation assay conducted according to OECD TG 471 (see Appendix B for further details).

No data is available on the potential for the notified chemical to cause chromosome aberrations *in vitro*. However, there was no evidence of genotoxicity or carcinogenicity in studies on APGs (Friedli, F., 2001), SAS (HERA, 2005) and LAS (HERA, 2007).

Based on this information, the notified chemical is not expected to be genotoxic or carcinogen.

Health hazard classification
Based on the reported irritation effects of structurally related chemicals (APGs and sulfonates) as irritating to the eyes and skin (R36/38), the notified chemical should be considered as if it is classified as R36/38: Irritating to eyes and skin.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Reformulation
Based on the available data, the main concern for human health following exposure to the notified chemical is eye and skin irritation. The concentration cut-off level for mixtures containing eye and skin irritants is ≥ 20% for classification as R36/38: Irritating to eyes and skin (NOHSC, 2004). This cut-off level would be considered to apply to the notified chemical as imported (≤ 40%) but not in the formulated personal care or hard surface cleaner products (≤ 14%).

Transport and warehouse workers and workers involved in the handling and reformulation of the imported product into personal care or hard-surface cleaner products are expected to be at a high risk of irritation, following direct ocular or dermal exposure. However, these workers are expected to wear PPE including, safety glasses or face shield, overalls, rubber gloves and enclosed footwear which is anticipated to minimise exposure. Therefore the risk of significant irritation effects in these workers wearing PPE is not considered to be unacceptable.

Quality assurance, maintenance and professional use of personal care and hard surface cleaning products
Laboratory technicians, maintenance workers and end-users working in the hair, beauty and cleaning industries will experience dermal and potentially accidental ocular exposure to personal care or hard surface cleaning products containing the notified chemical (≤ 14%). Laboratory technicians and maintenance workers are expected to wear safety gloves and possibly eye protection to minimise the potential for exposure and therefore the risk of irritation is expected to be minimal for these workers.

The use of PPE is not considered to be common place for workers using personal care or cleaning products containing the notified chemical at ≤ 14% in the health and beauty or cleaning industries and therefore there is some risk of irritation. However, the risk is not considered to be unreasonable based on the following mitigating factors:

(1) At < 20% concentration, the products would not be classified as skin or eye irritants according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

(2) The skin and eye irritation potential of the notified chemical was not tested at 14%. However, chemicals with the same functional groups, such as APGs and SAS were not found to be irritating at this concentration indicating that the notified chemical is unlikely to present a significant risk of irritation at 14%.

(3) The notified chemical will be used in rinse-off products such as shampoos and detergents. Therefore, the concentration which workers are likely to experience exposure is assumed to be less than 14%. Tests on diluted formulations of the notified chemical indicated that significant irritation is unlikely at low concentrations. Based on these results, the notified chemical is not considered to present an unacceptable risk once diluted for use.

Although the irritation potential of the notified chemical is unknown at 14%, it is not thought to present an unreasonable risk to occupational health and safety when used in rinse-off products.

6.3.2. Public health
Members of the public will experience widespread and frequent exposure to the notified chemical through daily use of personal care products (≤ 14%) which will be applied directly to the skin and hair. Frequent dermal exposure to cleaning products containing the notified chemical at ≤ 14% is also expected.

The level of dermal and accidental ocular exposure resulting from the application of personal care products containing the notified chemical (≤ 14%) to the skin and hair and the use of cleaning products containing the notified chemical at ≤ 14% is not expected to lead to irritation for similar reasons to those outlined above for workers in the health, beauty and cleaning industries. Namely: The products would not be considered to be classified as skin and eye irritants; tests on chemicals with the same functional groups did not indicate irritation

effects at that concentration; and the rinse-off nature of the products is thought to lead to exposure at lower concentrations, shown not to be irritating in tests on diluted formulations of the notified chemical.

The risk of eye exposure is thought to be greater for members of the public applying shampoos in the shower compared to workers applying shampoos standing up in a hairdressing salon. However, the concentration of the notified chemical that could enter the eye is thought to be less than 14% due to the rinse-off nature of shampoos. Although the potential for eye irritation cannot be ruled out, at the diluted concentrations in use it is unlikely to cause significant eye irritation.

A maximum systemic exposure of 1.26 mg/kg bw/day was estimated. As no repeat dose toxicity studies have been conducted, a NOAEL could not be established for the notified chemical. Therefore a quantitative risk assessment cannot be conducted. However, given the expected low systemic toxicity after repeated use, the notified chemical is not expected to pose an unacceptable risk of systemic toxicity to the public when used in personal care and cleaning products at ≤ 14%. Overall, based on the available data, the notified chemical is not considered to pose an unreasonable risk to public health at concentrations up to 14% in personal care and cleaning products.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical is manufactured overseas and imported as a ≤ 40% aqueous solution for blending into finished products. Releases from blending are expected to be very low. Empty drums will be rinsed and the aqueous rinsate used for production. Spilt material will be recovered, or contained with material such as sand or cat litter prior to disposal.

RELEASE OF CHEMICAL FROM USE
The notified chemical will be washed to sewer after use in personal care and cleaning products.

RELEASE OF CHEMICAL FROM DISPOSAL
Spilt material will be disposed of to landfill as solid waste after containment as outlined above.

7.1.2 Environmental fate

The notified chemical is likely to pass through sewage treatment works and enter receiving waters as it is water soluble. However, some degradation can be assumed, as the notified chemical is readily biodegradable, and a portion may also partition to sludge as the notified chemical is surface active. The SimpleTreat model predicts 87% removal by biodegradation during sewage treatment. Residues discharged to waterways can be expected to disperse and degrade. The notified chemical is not expected to bioaccumulate in fish as it is water soluble and readily biodegradable.

7.1.3 Predicted Environmental Concentration (PEC)

The PEC can be estimated as outlined below, with allowance for 87% removal during sewage treatment as predicted by the SimpleTreat model.

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:	274	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.374	million
Removal within STP	87%	
Daily effluent production:	4,275	ML

Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	8.3	µg/L
PEC - Ocean:	0.83	µg/L

7.2. Environmental effects assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	EC50 = 10.9 mg/L	Harmful
Daphnia Toxicity	LC50 = 6.5 mg/L	Toxic
Algal Toxicity	IC50 = 21.2 mg/L	Harmful

The fish test used imbalance rather than lethality as the endpoint. Results indicate that the notified chemical is harmful to fish and green algae, and toxic to daphnids.

7.2.1 Predicted No-Effect Concentration

The PNEC can be determined by application of an assessment factor of 100 to the most sensitive aquatic toxicity endpoint, as data are available for three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Daphnia toxicity	6.5	mg/L
Assessment Factor	100	
PNEC:	65	µg/L

7.3. Environmental risk assessment

The risk quotients (Q = PEC/PNEC) are tabulated below.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	8.3	65	**0.13**
Q - Ocean	0.83	65	**0.01**

The risk quotients are less than one, indicating that the notified chemical is not expected to pose a risk to the environment when it is used as proposed.

Extension Application

The proposed increase in volume under the extension application is not expected to impact on the current environmental risk assessment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point 250 °C

Remarks Estimated value of the notified chemical provided by notifier.

Boiling Point 105 °C

Remarks Estimated value of the product Suga*Nate 160 (≤ 40% notified chemical) provided by notifier

Density 1,130 kg/m^3

Method Not provided
Remarks Measurement of the product Suga*Nate 160 (≤ 40% notified chemical). Test report not provided.

Water Solubility 816 g/L at 20 °C

Method OECD TG 105 Water Solubility.
Remarks Flask Method. The aqueous solution was dried to less than 5% water in a convection oven at 90°C. The dried material was added periodically over a 30 day period until no further dissolution occurred. Solubility was determined by a gravimetric method after centrifugation and drying as above.
Test Facility Colonial Chemicals (Undated)

Hydrolysis as a Function of pH Stable

Remarks The shelf life of the 40% aqueous solution as sold is in excess of 2 years, with a 12 month guarantee of stability being offered to customers from the date of delivery.
Samples of the aqueous solution were acidified to pH 3 with concentrated sulfuric acid and incubated on a boiling water batch for 12 or 24 hours. Recoveries as determined by HPLC were between 99.3 and 102.4%.
Test Facility Technical Consultancy Services (2009)

Partition Coefficient (n-octanol/water) Not measured, but expected to be low.

Remarks This property cannot be measured because the notified chemical is a surfactant. It is expected to be low, based on the high water solubility and ionic properties of the notified chemical.

Adsorption/Desorption Not measured, but expected to be low.

Remarks The notified chemical is expected to be mobile in soils based on its water solubility, but may undergo some sorption because of its surface activity.

Dissociation Constant pKa~ -3

Remarks The notified chemical is expected to be fully dissociated in aqueous solution by analogy with the sodium salt of methanesulfonic acid.

Flash Point > 93.3 °C

Method Pensky-Martens Closed Cup method.
Remarks Measurement on the product Suga*Nate 160 (≤ 40% notified chemical). Test report not provided.

pH 7.3

Method	Not provided
Remarks	Measurement on the product Suga*Nate 160 at 10% (4% notified chemical). Test report not provided.

Viscosity 6900 cps at 25 °C

Method	Not provided
Remarks	Measurement on the product Suga*Nate 160 (≤ 40% notified chemical). Test report not provided.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Skin Irritation in Human Volunteers

TEST SUBSTANCE: SugaSulfonate 160 diluted to 10% concentration (4% notified chemical)

METHOD

Remarks - Method: The solution was diluted with distilled water to a concentration of 4% notified chemical. 0.2 mL of the solution was applied to an absorbent pad (2.54 cm x 2.54 cm) of a clear adhesive dressing and secured to the upper back between the scapulae of 53 healthy human volunteers (11 Males, 42 Females).
After 48 hrs, the dressing was removed and the treated site examined for signs of irritation. Another examination was conducted at 72 hrs after application.

RESULTS

Remarks - Results: No visible skin reactions were observed in any of the 53 human subjects at the 48-hour or 72-hour time points.

CONCLUSION: The notified chemical was found not to be irritating in skin at 4% concentration under the conditions of the test.

TEST FACILITY: Consumer Product Testing Co. (2004a)

B.2. Irritation – eye The Hen's Egg Test – Utilizing the Chorioallantoic Membrane (HET-CAM)

TEST SUBSTANCE: Colonial SugaSulfonate 160 – 10% Active diluted to 50% (2% notified chemical)

METHOD: Hen's Egg Test (HET) - Chorioallantoic Membrane (CAM) Test. Modification of that described by Kemper and Luepke (1986).

Species: White Leghorn chicken eggs

Number of eggs: 4 for each test substance

Observation period: Readings taken at 0.5, 2 and 5 mins

Treatment: After a 10-day incubation at 37.2 ± 1°C in a Kuhl incubator, the shell over the air sack of each egg was removed and following hydration for 2-5 mins, the inner membrane was removed to reveal the CAM. A 0.3 mL test solution was added to each CAM for a period of 20 secs and effects of hyperemia, haemorrhage (including minimal haemorrhage) and coagulation were observed over a period of 5 mins and scored according to the maximum scores shown in the following table.

Effect	*Scores at time (min):*		
	0.5	2	5
Hyperemia	5	3	1
Minimal Hemorrhage ("Feathering")	7	5	3
Hemorrhage (Obvious leakage)	9	7	5
Coagulation and/or Thrombosis	11	9	7

Each reaction type can be recorded only once for each CAM, therefore the maximum score per CAM is 32. The mean score was determined for all CAM's similarly tested.

Remarks - Method: No details of test substance preparation was included. Johnson's Baby Shampoo (50%) and Prell Shampoo Concentrate (50%) were the reference articles

included in the study.

RESULTS

Test Solution	*Average Irritation score*
Colonial SugaSulfonate 160 – 10% Active diluted to 50% concentration (2% notified chemical)	0.00
Johnson's Baby Shampoo (50 %)	11.00
Prell Shampoo Concentrate (50%)	24.25

Remarks - Results: The study authors state that previous studies have shown that the CAM of the hen's egg is 2 times more sensitive to liquid irritants than the rabbit eye. Therefore, the Colonial SugaSulfonate 160, Johnson's Baby Shampoo and the Prell Shampoo Concentrate were tested at 50% concentration to equate to the Draize results for those substances at 100% concentration. The Draft Updated ICCVAM Recommended HET-CAM Test Method Protocol (available online [20 July 2009]: http://iccvam.niehs.nih.gov/methods/ocutox/mildmod/HET-CAMProtocol11May09FD.pdf) recommends testing solutions undiluted unless dilution is justified.

CONCLUSION: Under the conditions of this test, the notified chemical is predicted to be non-irritating to the eye at a concentration of 4%.

TEST FACILITY: Consumer Product Testing Co. (2004b)

B.3. Irritation – eye (EpiOcular method)

TEST SUBSTANCE: Colonial SugaSulfonate 160 – 10% Active diluted to 20% (0.8% notified chemical)

METHOD: EpiOcular Tissue Model (MatTek Corporation) *in vitro* colorimetric test using MTT reduction.

Exposure Period: 20 mins, 1 hr, 4 hrs

Concentration: The test article 'Colonial SugaSulfonate 160 – 10% Active' was found to have a specific gravity greater than 0.95 g/mol. Therefore it was diluted to 20% (0.8% notified chemical) prior to dosing.

Remarks - Method: As the EpiOcular method has not yet been validated there is no Test Guideline. The method employed in this study was as follows:
100 µL of the test substance (0.8% notified chemical), reference (Triton X 100 (0.3%)) or negative control (distilled water) were incubated with the tissue samples in 6 well plates at 37°C, 5% CO_2 and ≥ 90% humidity. Three different exposure periods were used: 20 mins, 1hr and 4 hrs for the test article and 5 mins, 20 mins and 1 hr for the reference. After exposure for an unspecified period and rinsing with phosphate buffered saline (PBS), the samples were submerged in 5 mL of assay media for 10 mins at room temperature. After another 10 mins, excess liquid was removed and the samples were incubated for 3 hours with 300 µL (3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyl-tetrazolium bromide) (MTT) solution. After rinsing with PBS, the samples were then extracted overnight and the absorbance of each extractants at 570 nm was determined. The absorbance of the negative control was defined as 100% viability, and the percent viabilities of the samples determined proportionally.

This method varies from the method currently undergoing validation (Harbell et al., 2009) due to the multiple exposure times, no post-treatment incubation step, volume of test substance used, absorbance measured at 570 nm instead of 550 nm and the prediction model used.

RESULTS

Remarks - Results

The test substance demonstrated 84% tissue viability after 4 hrs when compared to the negative control (distilled water). In comparison, the positive control (Triton X 100 (0.3%)) demonstrated 26% tissue viability after 1 hr exposure.

	% viability after exposure		
	20 mins	1 hr	4hrs
Colonial SugaSulfonate 160 diluted to 20% (0.8% notified chemical)	101	115	84
Triton X 100 (0.3%)	100	74	26

A plot of a semi-log scale of the percentage tissue viabilities versus exposure time was constructed. Interpolation of the plot, revealed the time at which tissue viability would be 50% (ET-50) > 256 mins for the test substance and approximately 34.8 mins for the positive control.

Based on ET-50 > 256 mins, and the estimation method from Kay and Calandra (1962) the draize score for the test substance was estimated at 0, with a "non-irritating" irritancy classification.

CONCLUSION

Under the conditions of this test, the notified chemical is predicted to be non-irritating to the eye at a concentration of 0.8%.

TEST FACILITY

Consumer Products Testing Co. (2004c)

B.4. Genotoxicity – bacteria

TEST SUBSTANCE

Suga*Nate 160

METHOD

Equivalent to: OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure

Species/Strain

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

Metabolic Activation System

S9 fraction from Aroclor 1254-induced rat liver.

Concentration Range in Main Test

a) With metabolic activation: 50 – 5000 µg/plate
b) Without metabolic activation: 50 – 5000 µg/plate

Vehicle

DMSO

Remarks - Method

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	-	≥ 1000	None	Negative
Present				
Test 1	-	≥ 1000	None	Negative

Remarks - Results

No visible reduction in the background lawn was observed following treatment with the test substance.

No substantial increase in revertant colony numbers of any of the tester strains were observed following treatment with the test substance at any dose level, with and without metabolic activation.

The concurrent positive control compounds (Sodium Azide, 2-Nitrofluorene, CR 191 Acridine, Methyl Methanesulfonate (-S9), 2-

	Aminoanthracene (+S9)) demonstrated the sensitivity of the assay and the metabolising activity of the liver preparations. Cytotoxicity was observed in the TA1537, TA100 and TA98 strains at 1000 and 5000 µg/plate without metabolic activation and the TA1535 strain at 5000 µg/plate without metabolic activation. Cytotoxicity was also observed in the TA1537, TA1535 and TA100 strain at 1000 and 5000 µg/plate and in the TA98 strain at 5000 µg/plate in the presence of metabolic activation.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Consumer Product Testing Co. (2009)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability (1)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 E Ready Biodegradability: Modified OECD Screening Test.
Inoculum	Mixed activated sludge and secondary effluent
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved organic carbon
Remarks - Method	

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
3	48		
7	81		
14	82	Data not reported	
21	80		
28	81		

Remarks - Results	The inhibition control found no inhibitory effects from the test substance.
CONCLUSION	The notified chemical is readily biodegradable.
TEST FACILITY	Silliker (2008)

C.1.2. Bioaccumulation

Remarks	The notified chemical is not expected to bioaccumulate in fish as it is water soluble and readily biodegradable.

Extension Application

C.1.3. Ready biodegradability (2)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Activated sludge

Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved organic carbon
Remarks - Method	The test chamber temperature was not recorded on Days 2, 3, 10 and 17. The test temperature exceeded the protocol range on Day 19.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	59.4	7	27.7
14	75.2	14	63.6
21	96.6	21	70.1
28	83.4	28	64.7

Remarks - Results	The inhibition control found no inhibitory effects from the test substance. The control substance aniline was degraded 64.7% within 28 days. The threshold of readily biodegradability of ≥ 60% for the control substance was met within 14 days. All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is readily biodegradable.
TEST FACILITY	Stillmeadow (2011)

C.2.

Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical (40% aqueous solution).
METHOD	In house method based on US EPA protocol
Species	Eastern rainbowfish (*Melanotaenia splendid*a)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	None
Remarks – Method	Imbalance was used as endpoint, rather than mortality. The concentrations tabulated below are of the test substance (40% solution).

RESULTS

Concentration mg/L		*Number of Fish*	*Imbalance %*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0		Not reported					0
10		Not reported					0
20		Not reported					25
40		Not reported					80
80		Not reported					100
120		Not reported					100

EC50	10.9 mg/L at 96 hrs.
NOEC	4 mg/L at 96 hrs.
Remarks – Results	The results have been corrected to reflect the concentration (40%) of the notified chemical in the test substance.
CONCLUSION	The notified chemical is harmful to fish.
TEST FACILITY	Ecotox Services Australia (2008a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical (40% aqueous solution).
METHOD	In house method based on US EPA protocol
Species	*Ceriodaphnia dubia*
Exposure Period	48 hrs
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	None
Remarks - Method	Mortality was used as endpoint. The concentrations tabulated below are of the test substance (40% solution).

RESULTS

Concentration mg/L		*Number of C dubia*	*Percentage Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0		Not reported		0
0.6		Not reported		0
1.25		Not reported		0
2.5		Not reported		0
5		Not reported		0
10		Not reported		0
20		Not reported		80
40		Not reported		100

LC50	6.5 mg/L at 48 hrs
NOEC	4.0 mg/L at 48 hrs
Remarks – Results	The results have been corrected to reflect the concentration (40%) of the notified chemical in the test substance.
CONCLUSION	The notified chemical is toxic to daphnids.
TEST FACILITY	Ecotox Services Australia (2008b)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical (40% aqueous solution).
METHOD	In house method based on US EPA protocol
Species	*Selenastrum capricornutum*
Exposure Period	72 hrs
Concentration Range	Nominal: 0, 14, 29, 57.5, 115 and 230 mg/L test substance (40% solution)
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	None
Remarks - Method	

RESULTS

Biomass		*Growth*	
EC50> mg/L at 72 h	*NOEC mg/L*	*IC50> mg/L at72 h*	*NOEC mg/L*
		21.2	11.6

Remarks - Results	The results have been corrected to reflect the concentration (40%) of the notified chemical in the test substance.

CONCLUSION	The notified chemical is harmful to green algae.
TEST FACILITY	Ecotox Services Australia (2008c)

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