File No: STD/1554

November 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

D-Glucopyranose, oligomeric, heptyl glycosides (INCI Name: Heptyl glucoside)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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.

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

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

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Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1554	Bronson & Jacobs Pty Ltd	D-Glucopyranose, oligomeric, heptyl glycosides (INCI Name: Heptyl glucoside)	Yes	≤ 5 tonne/s per annum	Ingredient in cosmetic and cleaning products

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Eye Damage (Category 1)	H318 – Causes serious eye damage

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R41: Risk of serious damage to eyes

Human health risk assessment

Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

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

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

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - Eye Damage (Category 1): H318 – Causes serious eye damage

The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present and the intended use/exposure scenario.

- The Delegate (and/or the Advisory Committee on Chemicals Scheduling) should consider the notified chemical for listing on the SUSMP.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical during reformulation processes:
  - Enclosed, automated processes, where possible
  - Ventilation system including local exhaust ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical during reformulation processes:
  - 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 during reformulation processes:
  - Impervious gloves
  - Coveralls
  - Eye protection such as safety glasses or goggles

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

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Public Health

- Product formulators should take into account the potential for the notified chemical to cause eye damage when manufacturing cosmetic products containing the notified chemical.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

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(1) of the Act; if
- The notified chemical is proposed to be used at a concentration > 15% in cosmetic or cleaning products;
- additional information has become available to the person as to the eye irritation of the chemical.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from an ingredient in cosmetic and cleaning products, or is likely to change significantly;
- the amount of chemical being introduced has increased, 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 (M)SDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Bronson & Jacobs Pty Ltd (ABN: 81 000 063 249)
70 Marple Avenue
VILLAWOOD NSW 2163

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants, analogue chemicals, use details (concentration in products), import volume, and references.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: water solubility, hydrolysis as a function of pH, absorption/desorption, dissociation constant, particle size, explosive and oxidising properties, reactivity, acute inhalation toxicity, genotoxicity (in vitro and in vivo), bioaccumulation, acute aquatic toxicity (fish).

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
ECHA (2015)

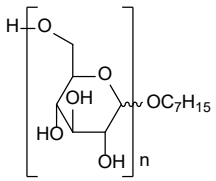
2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
SEPICLEAR G7
SIMULSOL SL 7 G

CHEMICAL NAME
D-Glucopyranose, oligomeric, heptyl glycosides

OTHER NAME(S)
Heptyl glucoside (proposed INCI name)

STRUCTURAL FORMULA
Basic structure:



MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
Reference IR spectra were provided. (SEPPIC (2014d))

3. COMPOSITION

DEGREE OF PURITY
≥ 98%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: amber viscous liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Could not be determined.	Begins melting at ≥ 250–275 °C. Decomposition was noted during the reaction.
Boiling Point	Could not be determined	Begins melting at ≥ 250–275 °C. Decomposition was noted during the reaction.
Density	967 ± 10 kg/m^3 at 20 ± 4 °C	Measured
Vapour Pressure	7.2 × 10^{-8} kPa at 20 °C	Measured
Water Solubility	Soluble	(M)SDS
Hydrolysis as a Function of pH	Not determined	Contains no hydrolysable functionalities.
Partition Coefficient (n-octanol/water)	log Pow = -1.6 to -1.0 at 20 °C	Measured
Adsorption/Desorption	log K_{oc} ≤ 0.325	Calculated for the most representative species of the notified chemical (KOCWIN v2.00; US EPA, 2011). The notified chemical is not expected to adsorb strongly to soil and sediment based on its high water solubility and low log P_{OW}.
Dissociation Constant	Not determined	Contains no dissociable functionalities.
Surface tension	30.5 mN/m at 1 g/L (active ingredient) at 20 °C	Measured, not surface active.
Autoignition Temperature	No relative self-ignition temperature up to 400°C	Measured
Explosive Properties	Not determined.	Contains no functional groups that would imply explosive properties.
Oxidising Properties	Not determined.	Contains no functional groups that would imply oxidising properties.

* Based on the reported characteristics of the products SEPICLEAR G7 and SIMULSOL SL 7 G (containing the notified chemical)

DISCUSSION OF PROPERTIES

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

Reactivity

The notified chemical is expected to be stable under normal conditions of use. Crystallisation of the notified chemical in the liquid product may occur during storage, whereby the notifier has given instructions for a rehomogenisation process in the (M)SDS.

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 of 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 not be manufactured within Australia. The notified chemical will be imported into Australia either as a blended bulk raw material (≤ 100% concentration) for reformulation into cosmetics (at ≤ 15% concentration) and cleaning products (at ≤ 15% concentration), or as a component of finished cosmetic products (at ≤ 15% concentration) and cleaning products (at ≤ 15% concentration).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 5	≤ 5	≤ 5	≤ 5	≤ 5

PORT OF ENTRY
Melbourne and Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS
SEPPIC SA. France (Manufacturer)

TRANSPORTATION AND PACKAGING
When imported as a blended bulk raw material for reformulation into cosmetics or cleaning products (at ≤ 15% concentration), the notified chemical will be transported by ship into Australia in 100 kg PEHD plastic drums. The notified chemical will also be imported as a component of finished cosmetic products (at ≤ 15% concentration) and cleaning products containing (at ≤ 15% concentration) in ≤ 500 mL plastic/HDPE bottles or tubes suitable for retail sale. The products containing the notified chemical will be circulated to distribution centres/reformulation sites and retail outlets within Australia by road.

USE
The notified chemical (as SEPICLEAR G7) will be used as a surfactant ingredient and will be sold to industrial customers to be incorporated into cosmetic and personal care products. The concentration of the notified chemical in end-use cosmetic products will be ≤ 15%.

The notified chemical will be used as a component of both leave-on and rinse-off cosmetic products including products with spray applications. Products will be applied to both the face and body. Product categories include creams, deodorant, body washes, hair care, moisturisers, and makeup (including foundation, eye make-up and lip care).

The notified chemical will also be imported as a component of finished cleaning products (containing SIMULSOL SL 7 G). Cleaning products containing SIMULSOL SL 7 G (containing the notified chemical at ≤ 15% concentration) will include floor detergents, aluminium cleaner/brightener and automatic bottle washing formulations. The notified chemical functions as a hydrotropic agent, viscosity reducer and co-solvent of surfactants for non-foaming cleaning products.

OPERATION DESCRIPTION
The notified chemical will not be manufactured within Australia.

Reformulation
Where imported as a blended bulk raw material (≤ 100% concentration) for reformulation, the notified chemical will be weighed and added to the mixing tank where it will be blended with additional additives to form the finished cosmetic products. The notifier states that the mixing facilities are expected to be mostly automated, well ventilated (local exhaust ventilation) and use closed systems. After being reformulated, the finished products containing the notified chemical will be transferred into the retail packaging.

End use
The finished cosmetic products containing the notified chemical may be used by consumers and professionals, such as workers in beauty and hair salons. Application of products could be by hand, spray or through the use of an applicator. Cleaning products may be used by consumers and workers in home and industrial settings.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage workers	4	12
Plant operators – mixing/compounding	8	12
Plant operators – chemist	3	12
Plant operators – packing (dispensing/capping)	8	12
Professional users – (e.g. hair and beauty salon workers, cleaners)	8	365

EXPOSURE DETAILS

Transport and storage

The notified chemical will be transported and stored in sealed HDPE closed head pails or consumer packaging (plastic tubes, jars, bottles, sticks) protected by cartons and on secure pallets. Therefore, exposure to the notified chemical during transport and storage is expected only in the unlikely event of an accident where a container is damaged. In case of such accidental exposure, the main route of exposure would be dermal and ocular.

The notifier states that dockside and warehouse workers routinely wear personal protective equipment (PPE) such as impervious gloves, coveralls, safety glasses and boots to minimise exposure to the notified chemical.

Reformulation

Limited dermal and ocular exposure of workers to the notified chemical (≤ 100% concentration) may occur during transfer from the transport containers to the manufacturing equipment. Exposure to the notified chemical (at ≤ 15% concentration) may occur during manufacturing (connection and disconnection of transfer filling lines) by the compounders and chemists.

During the final stages of reformulation (quality control and repackaging), workers involved in the dispensing and capping of the end product containers, as well as during maintenance and cleaning of equipment, may be exposed to the notified chemical (at ≤ 15% concentration).

The notifier states that exposure to the notified chemical during reformulation is expected to be minimised by the use of automated equipment and closed systems for reformulation, as well as the requirement for PPE such as safety glasses, safety shoes, impervious gloves and coveralls. Local exhaust ventilation is recommended and assumed to be used at exposure points. Overall the exposure of workers to the notified chemical is expected to be low.

Retail workers

Retail workers will unpack shippers and place the consumer-packaged products (containing ≤ 15% w/w notified chemical) on retail shelves. There will be no exposure during this task, except for any unexpected spills from damaged packaging.

End-use

Exposure to the notified chemical in end-use products (at ≤ 15% concentration) may occur in professions where the services provided involve the application of cosmetic and personal care products to clients (e.g. hair dressers, workers in beauty salons) or use of the cleaning products (e.g. cleaners). The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible. Such professionals may use some PPE to minimise repeated exposure, but this is not expected to occur in all workplaces. However, good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical.

6.1.2. Public Exposure

There will be widespread and repeated exposure of the public to the notified chemical (at ≤ 15% concentration) through the use of a wide range of cosmetic and cleaning products. The principal routes of exposure will be dermal, while ocular and inhalation exposures (e.g. through the use of spray products) are also possible.

Data on typical use patterns of cosmetic product categories in which the notified chemical/polymer may be used are shown in the following table (SCCS, 2012). For the purposes of the exposure assessment via the dermal route, Australian use patterns for the various product categories are assumed to be similar to those in Europe. A lifetime average female body weight (BW) of 64 kg (enHealth, 2012) was used for calculation purposes.

A dermal absorption of 100% is recommended (European Commission, 2003) for chemicals with molecular weight < 500 Da, in the absence of chemical-specific data. An in vitro dermal absorption study (to OECD TG 428) was submitted (dossier summary only) by the notifier on an analogue chemical (analogue 1 – exempt information), with a dermal absorption of 0.01%. Based on the higher molecular weight of the analogue chemical compared with the notified chemical, and the lack of a full study report, a dermal absorption value of 10% was considered reasonable to derive the margin of exposure for the notified chemical.

Product type	**Amount** (mg/day)	**C** (%)	**RF**	**Daily systemic exposure** (mg/kg bw/day)
Body lotion	7,820	15	1	1.8328
Face cream	1,540	15	1	0.3609
Hand cream	2,160	15	1	0.5063
Deodorant (non-spray)	1,500	15	1	0.3516
Liquid Foundation	510	15	1	0.1195
Mascara	25	15	1	0.0059
Eyeliner	5	15	1	0.0012
Eye shadow	20	15	1	0.0047
Makeup remover	5,000	15	0.1	0.1172
Hair styling products	4,000	15	0.1	0.0938
Shower gel	18,670	15	0.01	0.0438
Hand wash soap	20,000	15	0.01	0.0469
Shampoo	10,460	15	0.01	0.0245
Hair conditioner	3,920	15	0.01	0.0092
Facial cleanser	800	15	0.01	0.0019
Total				**3.5199**

C – concentration; RF – retention factor.
Daily systemic exposure = Amount × C × RF × dermal absorption/body weight

The worst case scenario estimation using these assumptions is for a person who is a simultaneous user of all products listed in the above table that contain the notified chemical. This would result in a combined internal dose of 3.52 mg/kg bw/day heptyl glucoside. The notified chemical is also proposed to be used in lipstick/gloss products. For these, exposure is mainly through the oral route. The data is shown below (SCCS, 2012). A conservative 100% ingestion rate was assumed for calculation purposes.

Cosmetic products (Oral exposure):

Product type	**Amount** (mg/day)	**C** (%)	**Daily systemic exposure** (mg/kg bw/day)
Lipstick/gloss	57	5	0.048

The worst case scenario estimation using these assumptions is for a person who is a simultaneous user of all products listed in the above tables that contain the notified chemical. This would result in a combined internal dose of 3.57 mg/kg bw/day.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical or a suitable analogue chemical are summarised in the following table. For full details of the studies, refer to Appendix B. Analogues (identities claimed exempt information) were considered to be structurally similar to the notified chemical.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2,000 mg/kg bw; low toxicity (analogue 2)
Skin irritation (in vitro)	non-irritating
Rabbit, eye irritation	severely irritating
Eye irritation (in vitro HET-CAM Test (Tolerance on the chorio allantoic membrane of a hen's egg)*	irritant
Eye irritation (in vitro Bovine corneal opacity protocol)	non-irritating at 1% concentration
Guinea pig, skin sensitisation – adjuvant test.	no evidence of sensitisation
Rat, repeat dose oral toxicity – 90 days.*	NOAEL = 1,000 mg/kg bw (analogue 2)
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vivo Mammalian Erythrocyte Micronucleus Test	non genotoxic (analogue 2)

* Summary report only

Use of analogue data in human health effects assessment
Limited toxicological data were provided for the notified chemical. Therefore, analogue data were used for the human health effects assessment of some toxicological endpoints (Testing Laboratory 7, 2014a). The notified chemical is structurally similar to chemicals evaluated by the Cosmetic Ingredient Review (CIR) panel (CIR 2013). The notifier submitted summary data and some toxicological study reports for analogues of the notified chemical which consisted of a category of similar chemicals. The chemicals are all D-glucopyranose oligomers substituted with alkyl chains between 4 and 16 carbon units.

Based on the summary data provided from studies on the analogue chemicals, the chemicals in this category were not acutely toxic by the oral or dermal routes; not skin sensitisers; not clastogenic or mutagenic; and were not systemically toxic by repeated oral exposure.

Toxicokinetics, metabolism and distribution
Absorption through the gastrointestinal tract of the notified chemical may occur, due to the molecular weight (< 500 Da) and water solubility. Alkyl polyglycosides similar to the notified chemical are completely absorbed following ingestion and are rapidly metabolised (Weber & Benning 1984).

Acute toxicity
The notified chemical was found to be of low acute oral toxicity with an LD50 > 2,000 mg/kg bw. An analogue chemical was found to be of low acute dermal toxicity with an LD50 > 2,000 mg/kg bw.

Irritation and sensitisation
The notified chemical was not a skin sensitiser in a Guinea pig maximisation test. In an in vitro skin irritation the notified chemical was reported as non-irritating to skin.

In an eye irritation study in rabbits, the notified chemical caused irreversible damage to the eyes. In an in vitro eye irritation study (HET-CAM test, summary only), the notified chemical was an irritant under the conditions of the test (based on an irritant score of 11.6). The notified chemical was not irritating in a bovine corneal opacity and permeability test (BCOP), at 1% concentration.

Repeated dose toxicity
No data on repeated dose toxicity was provided for the notified chemical. For analogue 1, a 90-day repeated dose oral toxicity study in rat reported a NOAEL of 1,000 mg/kg bw, based on no adverse effects observed up to the highest dose tested.

Mutagenicity/Genotoxicity
The bacterial reverse mutation test (Ames test) assessed the mutagenic potential of the notified chemical in several bacterial strains. Based on the results obtained in this study, it can be concluded that the test item does

not induce point mutations or frame-shifts in the genome of the bacterial strains with or without metabolic activation regardless of the procedure. Data provided for analogue 2 showed it to be non-genotoxic in an in vivo test.

Toxicity for reproduction
There was no data submitted to assess the toxicity for reproduction.

Observations on human exposure
There was no data submitted on human exposure to the notified chemical.

Health hazard classification
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	***Hazard statement***
Eye Damage (Category 1)	H318 – Causes serious eye damage

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):
R41: Risk of serious damage to eyes

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Transport
Workers may experience dermal and accidental ocular exposure to the notified chemical (at up to 100% concentration) during transportation and storage in the event of an accident such as a breakage or a spill. The notifier has stated that accidental release (spills) measures (which will include contacting emergency personnel, keeping unnecessary personnel away, using suitable protective equipment and following all firefighting procedures) should minimise the potential for exposure.

Therefore, under the expected scenarios for transport and reformulation, the risk to workers from use of the notified chemical is not considered to be unreasonable.

End-use
Workers involved in professions where the services provided involve the application of cosmetic products to clients (e.g. hairdressers or beauty salon workers), may be exposed to the notified chemical during their use. Workers may also be exposed to the notified chemical during the used of cleaning products in industrial workplaces. Such professionals may use PPE to minimise repeated exposure and good hygiene practices are expected to be in place. The risk to these workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical on a regular basis (for details of the public health risk assessment, see Section 6.3.2.).

6.3.2. Public Health
Members of the public may be repeatedly exposed to the notified chemical during the use in cosmetic, hair care and personal care products containing the notified chemical at the proposed concentration up to 15%. Members of the public may be exposed to the notified chemical through the use of cleaning products in the home or institutional industries (e.g. hospitals), but at a significant lesser extent than exposure from cosmetic products.

Local effects
A test conducted with undiluted notified chemical caused irreversible damage to the eye of rabbits. The maximum concentration of the notified chemical proposed by the notifier for use in cosmetic products is 15%, which is greater than the 1% concentration found to be non-irritating in the in vitro BCOP test. Therefore, there is uncertainty on the potential risk of eye irritation to consumers using the notified chemical at concentrations between 1% and 15%. The risk assessment recommends that formulators of cosmetic products containing the notified chemical take into account the potential for the notified chemical to cause eye damage in the cosmetics manufacturing process. Based on the confidential concentrations of the notified chemical proposed by the notifier in products to be used around the eyes (which are less than 15%), there is not expected to be a significant

risk for eye irritation. The Delegate (and/or the Advisory Committee on Chemicals Scheduling) should consider the notified chemical for listing on the SUSMP based on the uncertainty for eye irritation up to the maximum proposed used concentrations.

Systemic effects
The potential systemic exposure to the public from the use of the notified chemical in cosmetic products was estimated to be 3.57 mg/kg bw/day. Using a NOAEL of 1,000 mg/kg bw/day, which was derived from a repeated dose toxicity study on analogue chemical 1, the margin of exposure (MOE) was estimated to be 280. A MOE value greater than or equal to 100 is considered acceptable to account for intra- and inter-species differences, therefore, the MOE is considered to be acceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported as a component of the product, SEPICLEAR G7, for reformulation into finished cosmetic products, or as a component of finished cosmetic formulations. The notified chemical will also be imported as a component of the product, SIMULSOL SL 7 G, for reformulation into finished cleaning products, or as a component of finished cleaning formulations. There is unlikely to be any significant release to the environment from transport and storage, except in the case of accidental spills. Accidental spills are unlikely, given the imported product containing the notified chemical will be containerised. In the event of spills, the product containing the notified chemical is expected to be collected with inert material, and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve blending operations that will be highly automated, and is expected to occur within a fully enclosed environment. Therefore, significant release of the notified chemical from this process to the environment is not expected. The process will be followed by automated filling of the formulated products into containers of various sizes suitable for retail. Wastes containing the notified chemical generated during reformulation include equipment wash water, spilt materials, and empty import containers. It is estimated by the notifier that up to 1% (or ≤ 50 kg) of the notified chemical will remain as residues in the import containers. Wastes may be collected and released to sewers in a worst case scenario, or disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE
The majority of the notified chemical in cosmetic and cleaning products is expected to be released to sewer during use.

RELEASE OF CHEMICAL FROM DISPOSAL
It is estimated that a maximum of 3% (or up to 150 kg) of the notified chemical may remain in end-use containers once the consumer products are used up. Wastes and residues of the notified chemical in empty containers are likely either to share the fate of the container and be disposed of to landfill, or be released to sewer when containers are rinsed before recycling through an approved waste management facility.

7.1.2. Environmental Fate

Following its use in cosmetic and cleaning products, the majority of the notified chemical is expected to enter the sewer system, before potential release to surface waters nationwide. Based on the results of a biodegradability study, the notified chemical is considered to be readily biodegradable (82.25% in 28 days). For details of the environmental fate study, please refer to Appendix C. Based on its very high water solubility and low calculated adsorption coefficient (log $K_{OC} \leq 0.325$), release to surface waters is expected as partitioning to sludge and sediment is unlikely. However, the notified chemical is not expected to bioaccumulate, due to its low n-octanol/water partition coefficient (log $P_{OW} \leq -1.0$) and ready biodegradability. This is supported by a low bioconcentration factor (BCF = 3.162), calculated using BCFBAF v3.01 (US EPA, 2011). Therefore, in surface waters the notified chemical is expected to disperse and degrade through biotic and abiotic processes to form water and oxides of carbon.

The majority of the notified chemical will be released to sewer after use. A small proportion of the notified chemical may be applied to land when effluent is used for irrigation, or when sewage sludge is used for soil remediation, or disposed of to landfill as collected spills and empty container residue. The notified chemical residues in landfill, soil and sludge are expected to eventually degrade to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume a worst case scenario, with 100% release of the notified chemical into sewer systems nationwide and no removal within sewage treatment plants (STPs).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	5,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	5,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	13.7	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	3.029	µg/L
PEC - Ocean:	0.303	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 3.029 µg/L may potentially result in a soil concentration of approximately 20.19 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of the notified chemical in the applied soil in 5 and 10 years may be approximately 101.0 µg/kg and 201.9 µg/kg, respectively.

7.2. Environmental Effects Assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Daphnia Toxicity	EC50 > 100 mg/L	Not harmful to *Daphnia*
Algal Toxicity	E_bC50 = 107.8 mg/L	Not harmful to algae
	NOE_bC = 44.5 mg/L	

Based on the ecotoxicological endpoints for the notified chemical, it is not expected to be harmful to daphnids and algae. Therefore, the notified chemical is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009) for acute and chronic toxicities.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the most sensitive endpoint for daphnids. A safety factor of 1000 was used given acute endpoints for two trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (*Daphnia*, 48 h)	> 100	mg/L
Assessment Factor	1000	
Mitigation Factor	1.00	
PNEC:	> 100	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	3.029	> 100	< 0.030
Q - Ocean	0.303	> 100	< 0.003

The risk quotient for discharge of treated effluents containing the notified chemical to the aquatic environment indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. The notified chemical is readily biodegradable, and is expected to have a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern in cosmetic formulations and detergents, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting/Boiling Point Not determined.

Method	EC Council Regulation No 440/2008 A.1. Melting Temperature. EC Council Regulation No 440/2008 A.2. Boiling Temperature.
Remarks	Determined using differential scanning calorimetry (DSC). No boiling point was observed. Melting was initiated from 250–275°C, however, the melting point was not observed. Decomposition of the test item was noted during the reaction.
Test Facility	Testing Laboratory 2 (2013)

Relative Density 0.976 ± 0.01 kg/m^3 at 20 ± 4°C

Method	OECD TG 109 Density of Liquids and Solids.
Remarks	Determined using a gas comparison stereopycnometer.
Test Facility	Testing Laboratory 2 (2013)

Vapour Pressure 7.2×10^{-8} kPa at 20°C

Method	OECD TG 104 Vapour Pressure.
Remarks	Determined using the dynamic vapour pressure (Knudsen cell) effusion method.
Test Facility	Testing Laboratory 2 (2013)

Partition Coefficient (n-octanol/water) log Pow = -1.6 to -1.0 at 20 °C

METHOD	OECD TG 117 Partition Coefficient (n-octanol/water). EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks	Flask Method
Test Facility	Testing Laboratory 3 (2013a)

Surface Tension 30.5 mN/m at 1 g/L (active ingredient) at 20 °C

METHOD	OECD TG 115 Surface Tension of Aqueous Solutions.
Remarks	In-house study, full study report not provided.
Test Facility	Testing Laboratory 7 (2012)

Autoignition Temperature > 400 °C

Method	EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids.
Remarks	No self-ignition was observed at temperatures up to 400°C (corrected from 420°C) in 3 test runs.
Test Facility	Testing Laboratory 2 (2013)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method and test method B.1 tris of Council regulation No. 440/2008.
Species/Strain	Rat
Vehicle	Water
Remarks - Method	No deviation from the OECD guideline. GLP certificate

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
Treated	6 F	2,000 mg/kg	No mortality

LD50	> 2,000 mg/kg bw
Signs of Toxicity	None
Effects in Organs	None
Remarks - Results	The results showed that the test substance present low oral toxicity in rats.

CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Testing Laboratory 1 (2014a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Analogue 2
METHOD	OECD TG 402 Acute Dermal Toxicity.
Species/Strain	Rabbit/New Zealand White
Vehicle	No vehicle
Type of dressing	Semi-occlusive.
Remarks - Method	Summary data only from a REACH dossier on the analogue chemical was submitted.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
Male	5	2,000 mg/kg bw	No mortality
Female	5	2,000 mg/kg bw	No mortality

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	No treatment related changes
Signs of Toxicity - Systemic	No treatment related changes
Effects in Organs	No treatment related changes
Remarks - Results	The results showed that the test substance present low dermal toxicity in rabbits.

CONCLUSION	The analogue chemical is of low toxicity via the dermal route.
TEST FACILITY	ECHA (2010a)

B.3. Irritation – skin (in vitro)

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 439 In vitro Skin Irritation: Reconstructed Human *Epidermis* Test Method Reconstituted Human Epidermis SkinEthic Model
Vehicle	No vehicle used.
Remarks - Method	No deviation or amendment to the study plan was reported.

RESULTS

Test material	*Mean OD of triplicate tissues*	*Relative mean Viability (%)*	*SD of relative mean viability*
Negative control	1.413	100%	7.1%
Test substance	1.691	119.7% (corrected viability 114.8%)	12.3% (4.9%)
Positive control	0.041	2.9%	0.5%

OD = optical density; SD = standard deviation

Remarks - Results	All criteria were fulfilled for a valid test.
CONCLUSION	The notified chemical was non-irritating to the skin under the conditions of the test.
TEST FACILITY	Testing Laboratory 4 (2014)

B.4. Irritation – eye

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Council Regulation No 440/2008 B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	7 days
Remarks - Method	No deviation to the study plan has been registered during this study GLP certificate

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	2	2	2	2	72 hours	2
Conjunctiva: chemosis	1.7	1	1.7	3	72 hours	1
Corneal opacity	2	2	2	2	72 hours	2
Iridial inflammation	2	1	2	2	72 hours	2

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

Remarks - Results	A moderate redness of the conjunctivae was observed at 24 h and was reversible on day 7. A congestion or haemorrhage of the iris was observed at 1 h or 24 h, and was reversible between days 7 and 14. A moderate corneal opacity was observed in two animals at 24 h and in one animal on the last day of the test. A corneal neovascularisation was observed on day 14 and day 21 in one animal.
CONCLUSION	The notified chemical caused irreversible effects to the eye.

TEST FACILITY Testing Laboratory 5 (2014b)

B.5. Irritation – eye (in vitro)

TEST SUBSTANCE Notified chemical (1% w/v dilution)

METHOD OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants

Controls Vehicle: 0.9% sodium chloride
Positive: 10% sodium hydroxide

Remarks - Method GLP Certificate
No significant protocol deviations
Closed-chamber method
Vehicle and positive control items were tested concurrently. Opacity was determined by an opacitometer.

RESULTS

Test material	*Mean opacities of triplicate tissues*	*Mean permeabilities of triplicate tissues*	*IVIS*
Vehicle control	0 (1.0 SD)	-0.002 (0.009 SD)	
*Test substance**	-0.3 (1.2 SD)	0.000 (0.005 SD)	0 (1.1 SD)
*Positive control**	171.3 (36.1 SD)	4.936 (0.224 SD)	245 (37.1 SD)

SD = Standard deviation; IVIS = in vitro irritancy score
*Corrected for background values

Remarks - Results The test substance was provided at a 10% solid concentration, and was diluted in the vehicle at 10% concentration at the request of the notifier for an overall concentration of 1% of the test substance.

The positive control gave an in vitro irritation score that was reportedly within two standard deviations of the current historical mean confirming the validity of the test system.

The study authors concluded that the test substance does not require classification for eye irritation.

CONCLUSION The notified chemical was non-irritating under the conditions of the test.

TEST FACILITY Testing Laboratory 9 (2015)

B.6. Skin sensitisation

TEST SUBSTANCE Notified Chemical

METHOD OECD TG 406 Skin Sensitisation – Magnusson & Kligman Test Method.

Species/Strain Guinea pig

PRELIMINARY STUDY Maximum Non-irritating Concentration:
Intradermal induction
Topical induction

MAIN STUDY

Number of Animals Test Group: 20 Control Group: 10

Vehicle Deionised water

Positive control Not conducted in parallel with the test substance.

INDUCTION PHASE Induction Concentration:
intradermal: 5% (v/v)
topical: 25% (v/v)

Signs of Irritation	Only treated animals presented skin reactions in the intradermal induction application. However, these skin reactions observed were due to skin irritation rather than sensitisation. Treated and control animals presented no skin reactions in the topical induction and challenge applications.
CHALLENGE PHASE	
1st challenge	topical: 25% (v/v)
Remarks - Method	No deviation to the study plan has been registered during this study. GLP certificate

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		Topical induction		*Challenge*	
		48 h	*72 h*	*48 h*	*72 h*
Test Group	topical: 25% (v/v)	0	0	0	0
Control Group	0	0	0	0	0

Remarks - Results	The results showed that the test substance did not cause skin sensitisation in guinea pigs under the testing condition
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Testing Laboratory 1 (2012)

B.7. Repeat dose toxicity

TEST SUBSTANCE	Analogue chemical 2
METHOD	EC Directive 88/302/EEC B.26 Sub-Chronic Oral Toxicity Test: 90-Day Repeated Oral Dose Study using Rodent Species.
Species/Strain	Sprague Dawley Rat
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 90 days Dose regimen: 5 days per week Post-exposure observation period: 27 days
Vehicle	Water
Remarks - Method	A dossier summary was submitted. No ophthalmological examinations were performed prior to treatment, no information on detailed clinical examination.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	10 (M/F)	0	0
low dose (2.5% w/v)	10 (M/F)	250	0
mid dose (5% w/v)	10 (M/F)	500	0
high dose (10% w/v)	10 (M/F)	1,000	0
high dose recovery (10% w/v)	5 (M/F)	1,000	0

Mortality and Time to Death

There were three unscheduled deaths during the study due to mistakes in blood sampling and gavage errors.

Clinical Observations

No significant treatment related effects on body weight development, food and water consumption and functional performance were observed.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No significant treatment related changes in haematological, urinalysis and clinical chemistry parameters were observed.

Effects in Organs

There were inflammatory oedema of the submucosa and multiple ulcerations associated with acanthosis and proliferation of the mucous membrane of forestomach in animals in the mid- and high-dose groups.

Remarks – Results

Clinical observations did not indicate dose-related signs of intolerance during the experimental procedure. No statistically significant test substance related changes were observed. Any differences observed were considered to be incidental and unrelated to the test-substance.

CONCLUSION

The No Observed (Adverse) Effect Level (NO(A)EL) was established as 1,000 mg/kg bw/day in this study, based on test method.

TEST FACILITY ECHA (2015)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified Chemical

METHOD

	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2008/440/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure (Test 1) and pre incubation procedure (Test 2)
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2 (pKM101)
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 60–5,000 µg/plate b) Without metabolic activation: 60–5,000 µg/plate
Vehicle	MilliQ water
Remarks - Method	No deviation was recorded throughout the study period. GLP certificate. Positive controls: with S9 activation (2-Aminoanthracene) and without S9 activation: 2-nitrofluorene (TA98), Sodium azide (TA100, TA1535), 4-nitroquinoline-N-oxide (WP2(pKM101), 9-aminoacridine (TA1537)

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5,000	> 5,000	> 5,000	negative
Test 2		> 5,000	> 5,000	negative
Present				negative
Test 1	> 5,000	> 5,000	> 5,000	negative
Test 2		> 5,000	> 5,000	negative

Remarks - Results

In the dose finding tests and the main tests, increases in the number of revertant colonies or a dose-related response was not observed for any dose with or without metabolic activation.

The positive controls used in the test induced marked increases in the frequency of revertant colonies confirming the activity of the S9 mix and sensitivity of bacterial strains.

CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Testing Laboratory 8 (2012)

B.9. Genotoxicity – in vivo

TEST SUBSTANCE	Analogue Chemical 2
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test. EC Directive 2000/32/EC B.12 Mutagenicity – Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mouse Crl;CD-1^{TM}(ICR)BR, Male
Route of Administration	Intraperitoneal
Vehicle	Sterile water
Remarks - Method	No deviation from the test method.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	7 M	0	48
II (low dose)	7 M	62.5	24
III (mid dose)	7 M	125	24
IV (high dose)	7 M	250	24
V (high dose)	7 M	250	48
V (positive control, CP)	5 M	50	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity	Premature death occurred at and above 500 mg/kg, clinical signs were observed at and above 250 mg/kg including hunched posture, lethargy, pilo-erection, decreased respiratory rate, ptosis, ataxia, splayed gait, prostration, laboured respiration and pallor of the extremities.
Genotoxic Effects	There was a statistically significant increase in the incidence of micronucleated polychromatic erythrocytes in the mid-dose group but was within the historical range for vehicle controls. There was a statistically significant decrease in the PCE/NCE ratio in the 24 h high dose group. The response was considered part of a dose related effect indicating exposure of the bone marrow to the test material.
Remarks - Results	The test material was considered to be non-genotoxic under the condition of the test.
CONCLUSION	The test substance was not genotoxic under the conditions of this in vivo Micronucleus Test in Mouse.
TEST FACILITY	Testing Laboratory 6 (2000)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Aerated activated sludge from a local domestic wastewater treatment plant (Bordeaux, France).
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Theoretical Oxygen Demand (ThOD)
Remarks - Method	No significant deviation in protocol.
RESULTS	
Remarks - Results	All validity criteria for the test were satisfied. Only a graphical summary of the study results was supplied in the report, with no tabulated measured data points. The percentage degradation of the reference compound, sodium benzoate, surpassed the threshold level of 60% by 7 days (> 65%) and neared 80% degradation by 14 days. Therefore, the test indicates the suitability of the inoculums. The notified chemical attained 82.25% degradation by 28 days, and attained the threshold level of 60% within the 10-day window. Therefore, the notified chemical can be classified as readily biodegradable according to the OECD (301F) guideline.
CONCLUSION	The notified chemical is readily biodegradable.
TEST FACILITY	Testing Laboratory 3 (2011)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	240 mg $CaCO_3$/L
Analytical Monitoring	GC/FID
Remarks - Method	No significant deviation in protocol.

RESULTS

Concentration mg/L		*Number of D. magna*	*Cumulative Immobilised (%)*	
Nominal	*Actual*		*24 h*	*48 h*
Control	Control	30	0	3.3
100	88.6–100.7	31	3.2	9.7

LC50	> 100 mg/L at 48 hours
NOEC (or LOEC)	Not determined.
Remarks - Results	All validity criteria for the test were satisfied. The actual concentrations of the notified chemical were measured at 0 and 48 hours within the 48 h test period. The test solutions were not renewed during the 48 h test period.

	The 48 h EC50 for daphnids was determined to be > 100 mg/L, based on measured concentrations.
CONCLUSION	Under the study conditions, the notified chemical is not considered to be harmful to daphnids.
TEST FACILITY	Testing Laboratory 3 (2013b)

C.2.2. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Freshwater Alga and Cyanobacteria, Growth Inhibition Test.
Species	*Pseudokirchneriella subcapitata* (green alga)
Exposure Period	72 hours
Concentration Range	Nominal: 30.0–150.0 mg/L Actual: 33.2–152.1 mg/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	GC/FID
Remarks - Method	No significant deviation in protocol.

RESULTS

Biomass		*Growth*	
E_bC50 *mg/L at 72 h*	NOE_bC *mg/L*	E_rC50 *mg/L at 72 h*	NOE_rC *mg/L*
107.8 (95% CL 95.3–120.5)	44.5	> 150	44.5

Remarks – Results	All validity criteria for the test were satisfied. The actual concentrations of the notified chemical were measured at 0 and 72 hours within the 72 h test period. The test solutions were not renewed during the 72 h test period. The 72 h E_bC50 and NOE_bC were determined to be 107.8 mg/L (95% Cl 95.3–120.5 mg/L) and 44.5 mg/L, respectively, based on measured concentrations.
CONCLUSION	Under the study conditions, the notified chemical is not considered to be harmful to algae.
TEST FACILITY	Testing Laboratory 3 (2014)

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