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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Ethanol, 2-amino-, compds, with polyethylene glycol hydrogen sulfate C_{12-15}-alkyl ethers

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 and Energy.

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

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

Director
NICNAS

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SUMMARY

The following details will be published on our website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1706	Procter & Gamble Australia Pty Ltd Costco Wholesale Australia Pty Ltd	Ethanol, 2-amino-, compds, with polyethylene glycol hydrogen sulfate C_{12-15}-alkyl ethers	Yes	≤ 10 tonnes per annum	Ingredient in laundry detergent

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

Hazard Classification	*Hazard Statement*
Skin irritation/corrosion (Category 2)	H315 - Causes skin irritation
Serious Eye Damage/Eye irritation (Category 2)	H319 - Causes serious eye irritation

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard Classification	*Hazard Statement*
Hazard classification	***Hazard statement***
Acute Category 1	H400 - Very toxic to aquatic life
Chronic Category 3	H412 - Harmful to aquatic life with long lasting effects

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, 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:
  - Skin irritation/corrosion (Category 2): H315 - Causes skin irritation

- Serious Eye Damage/Eye irritation (Category 2): H319– Causes serious eye irritation

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

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 formulation:
  - Enclosed, automated processes, where possible

- 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:
  - 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:
  - Impervious gloves
  - Safety glasses
  - Protective clothing- coveralls

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

- A copy of the 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

- Formulators should take into account the potential for the notified chemical to cause serious eye damage when manufacturing consumer products containing the notified chemical.

Emergency procedures

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

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.

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 concentration of the notified chemical in laundry detergent exceeds, or is intended to exceed 15% in laundry detergent;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from an ingredient in laundry detergent, 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.

Safety Data Sheet
The SDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Procter & Gamble Australia Pty Ltd (ABN: 91 008 396 245)
Level 4, 1 Innovation Road
MACQUARIE PARK NSW 2113

Costco Wholesale Australia Pty Ltd (ABN: 57 104 012 893)
17-21 Parramatta Road
LIDCOMBE NSW 2141

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details exempt from publication include: other names, degree of purity, impurities, additives/adjuvants, and manufacture/import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for hydrolysis as a function of pH, dissociation constant, particle size, flammability, auto-ignition temperature, explosive properties, oxidising properties, reactivity, acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, skin sensitisation, repeat dose toxicity, genotoxic damage in vivo, genotoxic chromosome damage in vitro, fish acute toxicity, bioaccumulation, daphnia acute toxicity and algal toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2011)

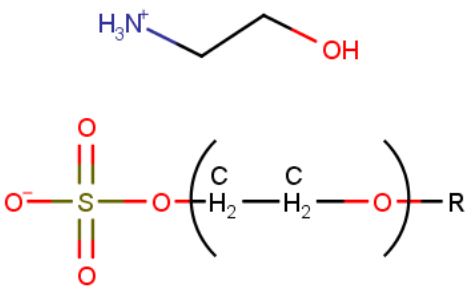
2. IDENTITY OF CHEMICAL

CHEMICAL NAME
Ethanol, 2-amino-, compds, with polyethylene glycol hydrogen sulfate C_{12-15}-alkyl ethers

CAS NUMBER
162201-45-8

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA



Where R = C_{12-15} alkyl group

MARKETING NAME(S)
Chemical in Tide Detergent

MOLECULAR WEIGHT
437.6 g/mol (for R = C_{12} and polyethylene glycol = 2.5)
479.7 g/mol (for R = C_{16} and polyethylene glycol = 2.5)

ANALYTICAL DATA
Reference IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90 %

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Pale amber liquid/paste with a mild chemical odour

Property	*Value*	*Data Source/Justification*
Melting Point/Freezing Point	8 °C	Measured
Boiling Point	Decomposed at 150 °C at 101.3 kPa	Measured
Density	1.08 kg/m^3 at 20 °C	Measured
Vapour Pressure	< 1.47 × 10^{-6} Pa at 20 °C (or < 1.10 × 10^{-5} mmHg at 20 °C)	Measured
Water Solubility	> 1000 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical is water soluble and contains functionalities that may slowly hydrolyse under environmental conditions (pH 4-9).
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to phase boundaries based on its surface activity.
Adsorption/Desorption	Not determined	Expected to sorb to soil, sediment and sludge.
Dissociation Constant	Not determined	The notified chemical is a salt and will be dissociated in environmental conditions (pH 4-9).
Flash Point	> 93 °C	SDS
Flammability	Not determined	Expected to be of low flammability based on the flash point.
Autoignition Temperature	Not determined	Not expected to auto ignite under normal conditions of use
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

DISCUSSION OF PROPERTIES
For 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.

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 in Australia. It will be imported into Australia as an ingredient of detergent formulations at up to 15% concentration.

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

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

PORT OF ENTRY
Sydney

TRANSPORTATION AND PACKAGING
Formulations containing the notified chemical at ≤ 15% concentration will be imported into Australia by sea in 20 kg plastic bags in cardboard cartons on pallets. End use containers, up to 1000 mL in size, may be bottles or tubes made mainly of HDPE plastic.

USE
The notified chemical will be used as a component of laundry detergents at up to 15% concentration.

OPERATION DESCRIPTION

Reformulation and Repackaging
The reformulation procedure will likely vary depending on the nature of the formulated products, and may involve both automated and manual transfer steps. However, in general, it is expected that the reformulation processes will involve blending operations that will be highly automated and use closed systems with adequate ventilation, followed by automated filling (using sealed delivery systems) of the reformulated products into containers of various sizes.

End-use
Consumers will open the product container and manually measure out the required volume of the laundry detergent using the cap of the container or a plastic measuring/dispensing cup before adding the detergent to the washing machine.

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	4	12
Professional compounder	8	12
Chemist	3	12
Packers (Dispensing & Capping)	8	12
Store Persons	4	12
End Users	8	365

EXPOSURE DETAILS
Transport, storage and retail workers may come in contact with the notified chemical at ≤ 15% concentration, only in the event of accidental spills.

Reformulation
Dermal and ocular exposure of workers to the notified chemical at < 15% concentration may occur during connection and disconnection of transfer lines, quality control and cleaning and maintenance of equipment. Exposure is expected to be limited through the use of enclosed systems and personal protective equipment (PPE)

such as coveralls, eye protection and impervious gloves, as stated by the notifier. Inhalation exposure is not expected given the low vapour pressure of the notified chemical.

End-use
Exposure of professional laundry workers to the notified chemical is expected to be of a similar extent to that experienced by consumers using laundry detergents containing the notified chemical in washing machines (see section 6.1.2).

6.1.2. Public Exposure
There will be repeated exposure of the public to the notified chemical at ≤ 15% concentration through the use of a wide range of laundry products. The main route of exposure will be dermal, while ocular exposure is also possible.

Data on typical use patterns of products (SCCS, 2012; Cadby *et al.*, 2002; ACI, 2010; Loretz *et al.,* 2006) in which the notified chemical may be used are shown in the following tables. For the purposes of the exposure assessment, Australian use patterns for the various product categories are assumed to be similar to those in Europe. A dermal absorption (DA) of 2.4% was used for the notified chemical (for details of dermal absorption, see Section 6.2 Toxicokinetics). A lifetime average female body weight (BW) of 64 kg (enHealth, 2012) was used for calculation purposes.

Household products (Indirect dermal exposure –from wearing clothes):

Product type	Amount	C	Product Retained (PR)	Percent Transfer (PT)	Daily systemic exposure
	(g/use)	(%)	(%)	(%)	(mg/kg bw/day)
Laundry liquid	230	15	0.95	10	0.0123
Total					**0.0123**

C = maximum intended concentration of notified chemical
Daily systemic exposure = (Amount × C × PR × PT × DA)/BW

Household products (Direct dermal exposure):

Product type	Frequency	C	Contact Area	Product Use C	Film Thickness	Time Scale Factor	Daily systemic exposure
	(use/day)	(%)	(cm^2)	(g/cm^3)	(cm)	(unitless)	(mg/kg bw/day)
Laundry liquid	1.43	15.00	1980	0.01	0.01	0.007	0.0001
Total							**0.0001**

C = maximum intended concentration of notified chemical
Daily systemic exposure = (Frequency × C × Contact area × Product Use Concentration × Film Thickness on skin × Time Scale Factor × DA)/BW where C = concentration, DA = Dermal absorption rate, BW = Average bodyweight

The worst case scenario estimation using these assumptions is for a person who is a user of laundry detergents that contains the notified chemical at the maximum intended concentration. This would result in a combined internal dose of 0.0124 mg/kg bw/day for the notified chemical.

6.2. Human Health Effects Assessment
Limited toxicity data were provided for the notified chemical. The results from an acute oral toxicity study conducted on the notified chemical are summarised in the following table. For full details of the study, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Acute oral toxicity – rat (notified chemical)	LD50 > 5,000 mg/kg bw; low toxicity

Use of Analogue Data in Human Health Effects Assessment
Only limited toxicological data were provided for the notified chemical. Therefore, data on analogous alcohol ethoxysulphates (AES) were used to derive an estimate of the hazard of the notified chemical. As the notified chemical contains a range of alkyl chains (C12-15) with the average number of ethoxy (EO) groups being 2.5, analogues with an alkyl chain ranging from C12 to C16 and an average number ethoxy (EO) groups of 2 or 3 were considered most relevant for assessment of the toxicological effects of the notified chemical. Salts of AES are expected to be dissociated in any product formulation independent of whether the identity of the cation (CIR,

2010). Toxicity data on the cation, ethanol, 2-amino- (CAS number 141-43-5) also known as monoethanolamine (MEA), has also been included.

Alkyl chain length	Structure	Short name
C12	$CH_3(CH_2)_{10}CH_2(OCH_2CH_2)_nOSO_3$	C12AE2S
		C12AE3S
C12-C14	$CH_3(CH_2)_{10\text{-}12}CH_2(OCH_2CH_2)_nOSO_3$	C12-C14AE2S
C12-C15	$CH_3(CH_2)_{10\text{-}13}CH_2(OCH_2CH_2)_nOSO_3$	C12-15AE3S

Toxicokinetics
Dermal absorbtion of the notified chemical is expected to be relatively poor as expected from ionic molecules. In a study conducted in rats, C12AE3S had a low percutaneous absorption rate of 0.0163 µg/cm^2/h (HERA, 2003). In a dermal absorption study conducted in guinea pigs, 2.4% of a ^{14}C labelled sodium laureth sulphate applied cutaneously penetrated the skin during 24 hours exposure (CIR, 1983).

Acute Toxicity
The notified chemical is of low acute oral toxicity based on a study conducted in rats (LD50 >5000 mg/kg bw).

C12-C14AE2S (triisopropanolamine salt, 90% active material) and MEA also showed low dermal toxicity in rats (LD50 > 2,000 mg/kg bw and 1700 mg/kg bw, respectively (HERA, 2003; IUCLID, 2000). Based on the analogue data, the notified chemical is not expected to be acutely toxic via the dermal route.

The lethal concentration of MEA following inhalation in rats was 1.37 mg/L (7 h exposure) or > 2.42 mg/L (2 h exposure), in mice it was 0.619 mg/L with no mortality seen at 0.215 mg/L (35 h exposure) (IUCLID, 2000).

Irritation
The skin irritation potential of AES is concentration dependent. C12-C14AE2S (triisopropanolamine at 90% concentration) was found to be moderately irritating in rabbits (HERA 2003). NaC12-14AE2S (70%) showed moderate to severe irritation in two skin irritation studies conducted in rabbits (HERA, 2003). At 10-30% concentrations AES are slight to moderately irritating and at < 1% concentrations AES are non-irritating (HERA, 2003). MEA was found to be corrosive to skin at a concentration of 30% in semi occluded patch tests and at > 10% concentration in ten open applications over a period of 14 days (CIR, 1983; IUCLID, 2000).

The eye irritation potential of AES is also concentration dependent. C12-C14AE2S (triisopropanolamine at 90% concentration) and C12-14AE2S (28%) were found to be moderately to severely irritating in two independent eye irritation studies conducted in rabbits (HERA 2003). AES at 1-10% concentrations are slightly to moderately irritating to eyes and at < 1% concentrations AES are non-irritating (HERA, 2003). MEA was found to be irritating the rabbit eye at 5% (CIR, 1983; IUCLID, 2000). Moderate eye irritation effects were observed with the notified chemical (17.84% concentration) in an isolated chicken eye (ICE) test resulting in a Cat 2/2A eye irritation classification (Triskelion, 2018).

Mild skin irritation effects were observed in a skin irritation study conducted in 12 human subjects with a detergent formulation containing 11.4% of NaC12-14ES (CAS No. 68891-38-3) (HERA, 2003).
The skin and eye irritation potential of the notified chemical is expected to be concentration-dependent, similar to other AES. The notified chemical is classified as a skin irritant (GHS Cat 2) and a severe eye irritant (GHS Cat 2) by the notifier in the SDS provided.

Sensitisation
In a human repeat insult patch test (HRIPT) completed in 25 subjects, the notified chemical at 5% concentration was found to be non-sensitising. Analogue NaC12-14AE2S (27% or 28%) did not cause skin sensitisation in guinea pigs in either of two studies according to the Magnusson-Kligman protocol (HERA 2003). MEA showed no sensitising effects on guinea pigs when tested according to the Buehler method at a challenge concentration of 1-20% (CIR, 1983; IUCLID, 2000). Although weak skin sensitisation responses have been reported, AES are not considered to be skin sensitisers based on the weight of evidence (14 out of 15 AES studies according to Magnusson-Kligman protocol and 6 out of 8 studies according to the Buehler method revealed no evidence of sensitisation) (HERA, 2003). Based on the analogue data, the notified chemical is expected to be non-sensitising.

Repeated Dose Toxicity
A number of close analogues (with an alkyl chain ranging from C12 to C16 and average EO groups of 3) of the notified chemical were evaluated in repeated dose oral toxicity studies (HERA, 2003).

Test Material	Study summary and Estimated LOEL/NOAEL/NOEL
NaC12-15AE3S	21 Day dietary rat study at 0.023%, 0.047%, 0.094%, 0.188%, 0.375%, 0.75%, 1% and 1.5%. No effects were noted at or below 0.188% level (254 mg/kg bw/day). The Lowest Observed Effect Level (LOEL) was established as 0.375% (487 mg/kg bw/day) based on hepatocyte hypertrophy. Significantly increased organ weights (liver, kidney, brain) were noted at doses equal to or higher than the LOEL.
NH4C12-15E3S	21 Day dietary rat study at 0.023%, 0.047%, 0.094%, 0.188%, 0.375%, 0.75%, 1% and 1.5%. No effects were noted at or below 0.188% (232 mg/kg bw/day). The LOEL was established as 0.375% (465 mg/kg bw/day) based on significant increases in plasma alkaline phosphatase activity. Significantly increased liver weight was noted at doses higher than the LOEL.
NaC12-15E3S	21 Day dietary rat study at 0.023%, 0.047%, 0.094%, 0.188%, 0.375%, 0.75%, 1% and 1.5%. No effects were noted at or below 0.094% level (108 mg/kg bw/day). The LOEL was established as 0.188% (217 mg/kg bw/day) based on significant increases in plasma alkaline phosphatase activity. Significantly increased liver weight was noted at doses equal to or higher than the LOEL.
NH4C13-15E3S	21 Day dietary rat study at 0.023%, 0.047%, 0.094%, 0.188%, 0.375%, 0.75%, 1% and 1.5%. No effects were noted at or below 0.375% (461 mg/kg bw/day). The LOEL was established as 0.75% (857 mg/kg bw/day) based on hepatocyte hypertrophy. Significantly increased organ weights (liver, testes, brain) were noted at doses higher than the LOEL.
C12AE3S	2-Year rat study at 0.1% or 0.5% in the diet. The results suggested a NOAEL of greater than 250 mg/kg bw/day.
C12AE3S	2-Year rat study at 0.1% in the drinking water. The NOAEL was estimated as greater than 75 mg/kg bw/day (equivalent to tested dose of 0.1% in the drinking water).

The NOAEL for a 90-day repeat dose oral feeding study conducted on rats using MEA at concentrations up to 2,670 mg/kg/day was 320 mg/kg bw/day (CIR, 1983; IUCLID, 2000).

Repeated dose dermal studies on two liquid dishwashing detergents containing C12-14AES at 23% and 27% concentrations were conducted in rabbits, in which the test substance was administered at 0.5%, 1%, 2.5% for 6 hours per day and 5 days a week for a total of 91 days. The test substance caused no adverse systemic effects, slight to moderate dermal irritation was observed at the detergent application sites in both studies (HERA, 2003).

Mutagenicity/Genotoxicity
A structure activity analysis on AES didn't reveal functional groups that were associated with mutagenic or genotoxic properties (HERA, 2003). In all available in vitro and in vivo mutagenicity/genotoxicity assays on AES (analogues of the notified chemical), there is no indication of mutagenic/genotoxic potential (HERA, 2003). Various in vitro and in vivo studies showed that MEA was negative for mutagenicity (CIR, 1983; IUCLID, 2000) Therefore, the notified chemical is expected to be non-genotoxic.

Carcinogenicity
A close analogue of the notified chemical, C12AE3S, was evaluated in carcinogenicity studies (HERA, 2003).

C12AE3S	2-year rat study with 0.1% in the drinking water. The only unusual finding was slight but consistently higher water consumption by test-substance treated rats and a significant difference on the empty cecum to body weight ratio of female animals. Various types of benign and malignant tumours were found in both treatment and control groups, with no significant difference in frequency of tumours between the groups.
C12AE3S	2-year rat feeding study at 0.1 or 0.5% in the diet. No indications of an increased incidence in tumours were reported.
C12AE3S	Applied as a 5% aqueous solution twice weekly on the skin of 30 female mice with no papillomas or other tumours observed.

It is concluded in the HERA report (HERA, 2003) that there is sufficient evidence that AES is not carcinogenic in the tested species under the conditions described.

Toxicity for reproduction

In available studies on various AES (NaC12-14AE2S, C12-CaC15AE3S, C12AE3S), the primary sex organs of the animals did not show evidence of treatment-related adverse effects at the highest tested exposure level of 250 mg/kg bw/day (HERA, 2003).

Developmental toxicity/teratogenicity
A number of close analogues (with an alkyl chain ranging from C12 to C16 and average EO groups of 3) of the notified chemical were evaluated in developmental toxicity/teratogenicity studies (HERA, 2003).

NaC12-15AE3S	Gavage administration to pregnant rats at 375 and 750 mg/kg bw/day once daily from day 6 to 15 of gestation. The NOAEL for maternal toxicity was established as 375 mg/kg bw/day and the NOAEL for teratogenic effects or developmental toxicity was estimated to be greater than 750 mg/kg bw/day.
NaC12-14AE3S	Gavage administration to pregnant rats at 93, 187, 375 and 750 mg/kg bw/day once daily from day 6 to 15 of gestation. The NOAEL for maternal toxicity was established as 375 mg/kg bw/day and the NOAEL for teratogenic effects or developmental toxicity was estimated to be greater than 750 mg/kg bw/day.
NaC12-15E3S	Gavage administration to pregnant rats at 125, 250, 500 and 1000 mg/kg bw/day once daily from day 6 to 15 of gestation. Maternal toxicity indicated by a significant reduction in body weight gain was noted at 1000 mg/kg bw/day but no evidence of treatment-related developmental toxicity or teratogenic effects were noted.

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

Hazard Classification	***Hazard Statement***
Skin irritation/corrosion (Category 2)	H315 - Causes skin irritation
Eye irritation/corrosion (Category 2A)	H319 - Causes serious eye irritation

6.3. Human Health Risk Characterisation
Based on the available toxicological information on the notified chemical and analogues, the notified chemical may cause skin irritation and severe eye irritation. Systemic toxicity effects are not expected from exposure to the notified chemical.

6.3.1. Occupational Health and Safety

Reformulation
During reformulation, workers may be exposed to the notified chemical introduced at ≤ 15% concentration. At this concentration, workers may be at risk of skin or eye irritation. According to the notifier engineering controls such as enclosed automated process and local ventilation will be implemented where possible and appropriate PPE (coveralls, impervious gloves and eye protection) will be used to limit worker exposure to the notified chemical. Therefore provided the control measures are in place to minimise worker exposure, under the occupational settings described, the risk to the health of workers from use of the notified chemical is not considered to be unreasonable.

End-use
Workers involved in professions where the services provided involve use of household products such as laundry detergent may be exposed to the notified chemical at ≤ 15% concentration. Products containing the chemical at ≥ 3% are classified as severe eye irritants according to the GHS criteria. Professional workers may use PPE such as gloves to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used the risk to such workers is expected to be of a similar or lesser extent than that experienced by consumers using various products containing the notified chemical.

6.3.2. Public Health
Members of the public will experience frequent exposure to the notified chemical at < 15% concentration through daily use of laundry detergents. The main route of exposure is expected to be dermal, while ocular and inhalational exposures are also possible.

Based on the available information on the notified chemical and analogues, the potential to cause skin and eye irritation effects at up to 15% concentration cannot be ruled out. The irritation potential is expected to vary depending on the detergent formulation.

The notified chemical is a serious eye irritant at concentrations ≥ 10% according to the GHS criteria and therefore consumer products in retail containers should be labelled with appropriate safety directions for use. However, accidental ocular exposure to the notified chemical in laundry detergents is expected to be an infrequent event and therefore the risk to the public is not expected to be unreasonable at the proposed use concentration.

When used for hand washing the notified chemical will be diluted at least 10 times to concentrations where irritant effects are expected to be negligible.

Repeated dose toxicity
The repeated dose toxicity potential was estimated by calculation of the margin of exposure (MoE) of the notified chemical using the worst case exposure scenario from use of multiple products containing the notified chemical (0.0124 mg/kg bw/day) (see Section 6.1.2). Using a NOAEL of 375 mg/kg bw/day derived from reproductive toxicity studies in rats (HERA, 2003), the margin of exposure (MoE) was estimated to be 30,242. A MoE value greater than or equal to 100 is generally considered acceptable to account for intra- and inter-species differences.

Based on the information available, the risk to the public associated with use of the notified chemical at < 15% concentration in laundry products is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will not be manufactured in Australia; therefore, there is no release of the notified chemical to the environment from this activity. Environmental release during importation, transport and distribution may occur as a result of accidental spills. In the event of a spill, the notified chemical is expected to be contained and collected with an inert absorbent material and disposed of in accordance with local regulations.

Products containing the notified chemical will be blended locally to prepare laundry detergent products. The blending and packing processes are semi-automatic and will occur in enclosed systems. Therefore, significant release of the notified chemical to the environment from accidental splashes, drips and spills is not expected during reformulation/packing processes. A total of up to 4% of the import volume is estimated to be generated as waste from residues in empty containers and spills during reformulation. Empty containers containing the notified chemical will either be recycled or disposed of through an approved waste management facility.

RELEASE OF CHEMICAL FROM USE
During use as a component of laundry detergent products, almost the entire volume of the notified chemical is expected to be released to sewers. Spills are expected to be cleaned up with an appropriate absorbent material, which is expected to be disposed of to landfill, or spills may be washed to sewers. Residues of the notified chemical in the empty containers are likely to be rinsed and be added into the washing machine or domestic wastewater via the sink or disposed of to landfill with the empty containers.

RELEASE OF CHEMICAL FROM DISPOSAL
It is expected that some of the product containing the notified chemical will remain in end-use containers. Empty containers containing the notified chemical will either be recycled or disposed of through an approved waste management facility. During these processes residues of the notified chemical will either be washed to sewer or be disposed of to landfill.

7.1.2. Environmental Fate
The notified chemical is part of a group of chemicals known as alcohol ethoxysulfates (AES) and is a subset of the UVCB substance used as the analogue with alkyl chain-lengths ranging from C12-15 and average ethoxylate chain-length (EO) ranging from zero to eight ($C_{12\text{-}15}EO_{0\text{-}8}S$).

The analogue of the notified chemical achieved 87% biodegradation over 28 days and the 10-day window was satisfied. As a class of compounds, linear AES used in detergent products (alkyl chain lengths C12-16 and average ethoxylate chain length (EO 1-4) undergo rapid primary and ultimate biodegradation (BKH 1994, Little 1991, Kravetz et al., 1982). Neither the length of the alkyl chain per mole nor the ethoxylate portion of the molecule had a significant effect on the rate of degradation. Therefore, the notified chemical is expected to rapidly biodegrade and is not expected to persist in the environment. For the details of the environmental fate study please refer to Appendix C.

The majority of the notified chemical is expected to be released to sewage treatment plants (STPs) via domestic wastewater. In wastewater treatment processes, a high proportion of the notified chemical is expected to be removed from STP influent due to its rapid biodegradation. In fact, a monitoring study of AES in wastewater found that it degraded extensively in-sewer (95-98%) before it even enters STPs (Sanderson et al. 2006).

The sludge containing the notified chemical may be sent to landfill or applied to soils for land remediation. Notified chemical released to surface waters is expected to partition to suspended solids and organic matter, or to disperse and degrade. Consequently, the notified chemical is not expected to be significantly bioavailable. The potential for the notified chemical to bioaccumulate is low based on its surfactant properties and rapid degradability, and this has been confirmed experimentally in common carp for ^{35}S-labelled $C_{12}EO_3S$ and $C_{12}EO_5S$ with whole-body bioconcentration factors of 18 and 4.7, respectively (Kikuchi et al., 1980).

7.1.3. Predicted Environmental Concentration (PEC)

The use pattern will result in most of the notified chemical being washed into the sewer. The predicted environmental concentration (PEC) has been calculated assuming the realistic worst-case scenario with 100% release of the notified chemical into sewer systems nationwide over 365 days per annum. The extent to which the notified chemical is removed from the effluent in STP processes based on the properties of the notified chemical has not been considered for this scenario, and therefore no removal of the notified chemical during sewage treatment processes, is assumed. The PEC in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	10,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	27.40	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	0%	
Daily effluent production:	4,877	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	5.62	µg/L
PEC - Ocean:	0.56	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 5.618 µg/L may potentially result in a soil concentration of approximately 0.037 mg/kg. Accumulation is not expected as the notified chemical is readily biodegradable.

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	LC50 (96 h) = 4.3 mg/L	Toxic to fish
	LC50 (96 h) = 10.42 mg/L	Harmful to fish
Daphnia Toxicity	EC50 (48 h) = 6.4 mg/L	Toxic to aquatic invertebrates

Algal Toxicity	EC50 (72 h) = 6.9 mg/L	Toxic to algae
	NOEC = 1.6 mg/L	Toxic to algae
	EC50 (72 h) = 2.8 mg/L	Toxic to algae
	NOEC = 0.42 mg/L	Very toxic to algae
	EC50 (72 h) = 0.9 mg/L	Very toxic to algae
	NOEC = 0.42 mg/L	Very toxic to algae

Under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009) the notified chemical is classified as toxic to fish, aquatic invertebrates and algae. Based on the toxicity to aquatic biota the notified chemical is formally classified as "Acute category 1 (H400); Very toxic to aquatic life". One or two adequate chronic endpoints are available. The long-term hazard is determined on both the chronic and acute endpoints and the most stringent outcome was taken. Based on this the notified chemical is formally classified as "Chronic Category 3(H412): Harmful to aquatic life with long lasting effects".

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) was calculated using the algal toxicity EC50 (72 h) value and an assessment factor of 100, as the endpoints for three trophic levels, are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (algae)	0.9	mg/L
Assessment Factor	100	
Mitigation Factor	1.00	
PNEC	9.0	µg/L

Mesocosm studies on AES have found NOECs of ≥ 75 µg/L [HERA 2004, Van de Plassche et al (1999), Belanger et al (2009) and Belanger et al (1995) noting that HERA (2004) cites Belanger et al (1995)], suggesting that the calculated PNEC for the notified chemical is a conservative estimate.

7.3. Environmental Risk Assessment

Insert the Risk Quotient Table (PEC/PNEC)

Risk Assessment	PEC (µg/L)	PNEC (µg/L)	Q
Q – River	5.62	9	**0.62**
Q – Ocean	0.56	9	**0.006**

As a result of its use pattern, the majority of the total annual import volume is expected to be disposed of to the sewer. In sewage treatment plants the notified chemical is expected to degrade rapidly. Notified chemical released to surface waters has a low potential to bioaccumulate and is not expected to persist in the environment. As a conservative estimate of the risk quotient is below 1, the notified chemical is not expected to pose an unacceptable risk to the environment on the basis of the PEC/PNEC ratio.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point 8 °C

Method	OECD TG 102 Melting Point/Melting Range EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature
Remarks	Determined using differential scanning calorimetry
Test Facility	NOTOX (2010)

Boiling Point Decomposed at 150 °C at 101.3 kPa

Method	OECD TG 103 Boiling Point EC Council Regulation No 440/2008 A.2 Boiling Temperature
Remarks	Determined using differential scanning calorimetry
Test Facility	NOTOX (2010)

Relative Density 1.08 kg/m^3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids EC Council Regulation No 440/2008 A.3 Relative Density
Remarks	Gas pycnometer method was used
Test Facility	NOTOX (2010)

Vapour Pressure < 1.47×10^{-6} kPa at 20 °C (< 1.10×10^{-5} mmHg at 20 °C)

Method	OECD TG 104 Vapour Pressure EC Council Regulation No 440/2008 A.4 Vapour Pressure
Remarks	Isothermal thermogravimetric effusion method was used
Test Facility	NOTOX (2010)

Water Solubility > 1000 g/L at 20 °C

Method	OECD TG 105 Water Solubility EC Council Regulation No 440/2008 A.6 Water Solubility
Remarks	Flask Method. The solution turned to a gel.
Test Facility	NOTOX (2010)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute Oral Toxicity – Rat

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure EC Council Regulation No 440/2008 B.1 Acute Toxicity (Oral)
Species/Strain	Rat/Sprague Dawley Crl:CD(SD)
Vehicle	Administered undiluted
Remarks – Method	GLP compliant No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)active test substance*	*Mortality*
1	1F	2600	0/1
2	2F	3900	0/2
3	6F	5000	1/6

LD50	> 5000 mg/kg bw (active substance)
Signs of Toxicity	Signs of systemic toxicity included soft stools, urine/faecal staining, rough coat, unkempt appearance, dark material around facial area and piloerection in all treated animals dosed with 5000 mg/kg bw (active substance). Animals dosed with 3900 mg/kg bw (active substance) showed piloerection, salvation and soft stools. The animals dosed with 2600 mg/kg bw (active substance) was noted to have soft stools.
Effects in Organs	In the animals that survived until the end of the study no abnormal gross pathology findings were noted. In the one animal that died abnormal contents of the trachea and stomach were noted.
CONCLUSION	The notified chemical is of low acute toxicity via the oral route.
TEST FACILITY	CRL (2010)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready Biodegradability

TEST SUBSTANCE	Analogue chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Total Organic Carbon (TOC)
Remarks – Method	No major deviations from the test guidelines were reported.

RESULTS

Test Substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	45.3	7	57.2
16	72.9	16	81.3
22	78.8	22	83.8
28	86.4	28	86.4

Remarks – Results	The validity criteria for the test were satisfied. The total CO_2 production in the inoculum blank at the end of the test did not exceed 40 mg/L. The difference between the degradation results of the replicates with the test substance was less than 20% at the end of the test.
CONCLUSION	The notified chemical is readily biodegradable.
TEST FACILITY	LISEC (2000a)

C.2. Ecotoxicological Investigations

C.2.1. Acute Toxicity to Fish

TEST SUBSTANCE	Analogue chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Semi static EC Council Regulation No 440/2008 C.1 Acute Toxicity for Fish - Semi static test
Species	Zebra fish *(Brachydanio rerio)*
Exposure Period	96 hours
Auxiliary Solvent	1,2 Propane diol
Water Hardness	49 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks – Method	A solvent control containing 50 mg/L of 1,2 propanediol was also tested.

RESULTS

Concentration (mg/L)	*Number of Fish*	*Mortality*			
Nominal		*24 h*	*48 h*	*72 h*	*96 h*
Control	10	0	0	0	0
Solvent	10	0	0	0	0
1.0	10	0	0	0	0
1.5	10	0	0	0	0
3	10	0	0	0	0
6	10	0	3	9	9
12	10	10	10	10	10

LC50	4.3 mg/L at 96 hours
NOEC	3.0 mg/L at 96 hours
Remarks – Results	The validity criteria for the test were satisfied. The dissolved oxygen in the test solutions were maintained at 69.69%. Statistical evaluation was conducted by TOXDAT program. Analytical monitoring was not done. Therefore, the report is based on nominal concentrations.

CONCLUSION The notified chemical is toxic to fish

Test Facility LISEC (1994)

C.2.2. Acute Toxicity to Fish

TEST SUBSTANCE Analogue chemical

METHOD OECD TG 203 Fish, Acute Toxicity Test – Semi static
EC Council Regulation No 440/2008 C.1 Acute Toxicity for Fish - Semi static

Species	Zebra fish *(Brachydanio rerio)*
Exposure Period	96 hours
Auxiliary Solvent	Propane diol
Water Hardness	10 - 250 mg $CaCO_3$/L
Analytical Monitoring	UV/VIS spectrophotometer
Remarks – Method	The definitive test concentrations were selected based on a preliminary test result. No major deviations from the test guidelines were reported. Fresh stock solution and test concentrations were made daily.

RESULTS

Concentration (mg/L)		*Number of Fish*	*Mortality*			
Nominal	*Measured*		*24 h*	*48 h*	*72 h*	*96 h*
Control	0.01	7	0	0	0	0
3.7	2.69	7	0	0	0	0
8.1	5.85	7	0	0	0	0
17.9	14.46	7	3	5	6	6
40	30.5	7	7	7	7	7
86	68.01	7	7	7	7	7

LC50	10.42 mg/L at 96 hours
Remarks – Results	The validity criteria for the test were satisfied. The dissolved oxygen concentration was maintained at 91.6%. Statistical evaluation was conducted by TOXDAT program. The results are based on geometrically mean measured concentrations.

CONCLUSION The notified chemical is toxic to fish

TEST FACILITY LISEC (2000b)

C.2.3. Acute Toxicity to Aquatic Invertebrates

TEST SUBSTANCE Analogue chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Semi static

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not measured

Analytical Monitoring	UV/VIS spectrophotometer
Remarks – Method	The definitive test concentrations were selected based on a preliminary test result. No major deviations from the test guidelines were reported. Stock solutions of the test substance was prepared in reconstituted water.

RESULTS

Concentration (mg/L)		*Number of D. magna*	*Number Immobilised (%)*	
Nominal	*Measured*		*24 h*	*48 h*
Control	0	20	0	0
1.2	1.0	20	0	0
2.6	2.2	20	0	0
5.7	4.6	20	0	5
12.5	9.7	20	45	100
27.6	21.3	20	100	100

LC50	6.4 mg/L at 48 hours (95% confidence = 5.7 – 12.5 mg/L)
NOEC	2.6 mg/L at 48 hours
Remarks – Results	The validity criteria for the test were satisfied. The dissolved oxygen in the test solutions and control was maintained at ≥8.32 mg/L. Statistical evaluation was conducted by TOXDAT program. The results are based on geometrically mean measured concentrations.
CONCLUSION	The notified chemical is toxic to aquatic invertebrates.
TEST FACILITY	LISEC (2000c)

C.2.4. Algal Growth Inhibition Test

TEST SUBSTANCE	Analogue chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test EC Council Regulation No 440/2008 C.3 Algal Inhibition Test
Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 0.2, 0.4, 0.8, 1.6, 3.2 and 6.4 mg/L
Auxiliary Solvent	1,2 Propanediol
Water Hardness	49 mg $CaCO_3$/L
Analytical Monitoring	UV/VIS Spectrophotometer
Remarks – Method	A stock solution of 1g/L was prepared and test solution prepared by dilution of this stock solution. A solvent control containing 1,2 Propanediol was also tested. River water was used after sterilization to avoid biodegradation.

RESULTS

Biomass		*Growth*	
E_bC50 (mg/L at 72 h)	*NOEC (mg/L)*	*E_rC50 (mg/L at 72 h)*	*NOEC (mg/L)*
5.2	1.6	6.9	1.6

Remarks – Results	The extrapolated E_rC50 was determined to be 77 mg/l as there was no growth rate inhibition higher than 50%. However, The E_rC50 in range finding test (not extrapolated) was 6.9 mg/L. Therefore, this value was preferred over the definite test value. The solvent control showed no inhibition like control. Validity criteria for the test were satisfied. The mean cell density in the control increased 91 times within 72 hours. The results are based on nominal concentrations.

CONCLUSION	The notified chemical is toxic to algae
TEST FACILITY	LISEC (1993)

C.2.5. Algal Growth Inhibition Test

TEST SUBSTANCE	Analogue chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test EC Council Regulation No 440/2008 C.3 Algal Inhibition Test
Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range	Nominal: 0.625, 1.25, 2.5, 5, and 10 mg/L Measured: 0.4, 1.0, 1.8, 3.0 and 6.2 mg/L
Auxiliary Solvent	None
Water Hardness	28 mg $CaCO_3$/L
Analytical Monitoring	UV/VIS Spectrophotometer
Remarks – Method	A stock solution of 1g/L was prepared and test solution prepared by dilution of this stock solution. River water was used for dilution after sterilization (to avoid biodegradation).

RESULTS

Biomass		*Growth*	
E_bC50 (mg/L at 72 h)	*NOEC (mg/L)*	*E_rC50 (mg/L at 72 h)*	*NOEC (mg/L)*
1.4	0.42	2.8	0.42

Remarks – Results	Validity criteria for the test were satisfied. The mean cell density in the control increased 44 times within 72 hours. The EC50 and NOEC was calculated by SAS program. The results are based on geometrical mean measured concentrations.
CONCLUSION	The notified chemical is toxic to algae
TEST FACILITY	LISEC (2000d)

C.2.6. Algal Growth Inhibition Test

TEST SUBSTANCE	Analogue chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test EC Council Regulation No 440/2008 C.3 Algal Inhibition Test
Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range	Nominal: 0.25, 0.5, 1, 2, and 4 mg/L Measured: 0.14, 0.3, 0.6, 1.1 and 2.2 mg/L
Auxiliary Solvent	None
Water Hardness	28 mg $CaCO_3$/L
Analytical Monitoring	UV/VIS Spectrophotometer
Remarks – Method	A stock solution of 1g/L was prepared by dissolving 256.2 mg of the test substance in 200 ml of deionised water. River water was used for dilution after sterilization to avoid biodegradation.

RESULTS

Biomass		*Growth*	
E_bC50 (mg/L at 72 h)	*NOEC (mg/L)*	*E_rC50 (mg/L at 72 h)*	*NOEC (mg/L)*
0.5	0.42	0.9	0.42

Remarks – Results	Validity criteria for the test were satisfied. The mean cell density in the control increased 40 times within 72 hours. The results are based on geometrical mean measured concentrations. The EC50 and NOEC was calculated by SAS program.
CONCLUSION	The notified chemical is toxic to algae
TEST FACILITY	LISEC (2000e)

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