File No: LTD/1768

February 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Firascone

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	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1768	Firmenich Limited	Firascone	Yes	≤ 1 tonne per annum	Fragrance ingredient

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

The environmental hazard classification according to the *Globally Harmonised System for the 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*
Acute Category 3	H402 – Harmful 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 setting 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

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:
  - Enclosed, automated processes, where possible;
  - Local exhaust ventilation, if significant inhalation potential is anticipated;

- 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 as introduced:
  - Avoid skin and eye contact

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by reformulation workers to minimise occupational exposure to the notified chemical:

- Coveralls
- Safety goggles
- Impervious gloves
- Respirators, if significant inhalation exposure is expected

- 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 for the 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.

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 importation volume exceeds one tonne per annum notified chemical;
- the concentration of the notified chemical exceeds or is intended to exceed 2.0% in fine fragrances and air fresheners and 0.3% in other cosmetic and household products;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a fragrance ingredient, 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 (and products containing the notified chemical) provided by the notifier was (were) 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)
Firmenich Limited (ABN: 86 002 964 794)
73 Kenneth Road
BAGOWLAH NSW 2093

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants and use details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: dissociation constant, flammability limits, explosive properties, oxidizing properties and reactivity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2010), EU (2008), Switzerland (2008), China (2010) and Philippines (2007)

2. IDENTITY OF CHEMICAL

MARKETING NAME
Firascone

MOLECULAR WEIGHT
< 200 Da

ANALYTICAL DATA
Reference NMR, IR, GC, GC-MS and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: colourless liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< -20 °C	Measured
Boiling Point	206 ± 2 °C at 96.6 kPa	Measured
Density	958 kg/m^3 at 20 °C	Measured
Vapour Pressure	0.151 kPa at 25 °C	Measured
Vapour Pressure	3.5 x 10^{-2} kPa at 25 °C	Measured
Water Solubility	0.119 g/L at 20 ± 0.5 °C	Measured
Hydrolysis as a Function of pH	$t_{½}$ = 150 – 179 days, at 25 ± 0.5 °C pH 4 - 9	Measured
Partition Coefficient (n-octanol/water)	log Kow = 3.92	Measured
Surface Tension	65.8 mN/m at 22.4 °C	Measured
Adsorption/Desorption	log K_{oc} = 2.80	Measured

Dissociation Constant	Not determined	No dissociable functionality
Flash Point	74 ± 2 °C at 101.3 kPa	Measured
Flammability	Not determined	Not expected to be flammable based on flash point
Autoignition Temperature	354 ± 5 °C	Measured
Explosive Properties	Predicted negative	Estimated
Oxidising Properties	Predicted negative	Estimated

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.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	***Hazard statement***
Flammable Liquids (Category 4)	H227 – Combustible liquid

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. The notified chemical will be imported into Australia in the following forms: as the pure chemical to be blended into fragrance formulations or end-use products, as a component of fragrance formulations to be blended into end-use products, or as a component of end-use products.

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

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

PORT OF ENTRY
Sydney NSW

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in lacquered drums of varying sizes ranging from 5 kg to 180 kg. Transport from notifier's site to the customer's site will be by road. End-use products containing the notified chemical will be packaged in a variety of container sizes depending on the product and transported by road to retail outlets for sale to public.

USE
The notified chemical will be used as a fragrance ingredient in a wide variety of cosmetic and household products. The content in the final consumer products will vary, with the following proposed usage concentrations: ≤ 2% in fine fragrances and air fresheners and ≤ 0.3% in other cosmetic and household products.

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

Reformulation
The notified chemical will be formulated into either a fragrance formula or fragranced end-products. The procedures for incorporating the notified chemical into end-use products will likely vary depending on the nature of the cosmetic and household 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 occur in a fully enclosed environment, followed by automated filling of the reformulated products

into containers of various sizes. During the reformulation processes, samples of the notified chemical and the finished cosmetic products may be taken for quality control testing.

End-use
The finished products containing the notified chemical may be used by consumers and professionals such as hairdressers, workers in beauty salons or cleaners. Depending on the nature of the product, these could be applied in a number of ways, such as by hand, using an applicator or sprayed.

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 warehouse workers	Unknown	Unknown
Plant operators – mixing/compounding	4	2
Plant operators – drum handling	4	2
Plant operators – drum cleaning/washing	4	2
Plant operators – equipment maintenance	4	2
Plant operators – quality control	0.5	1
Plant operators – Packaging	4	2

EXPOSURE DETAILS
Transport and storage
Transport and storage workers may come into contact with the notified chemical at a concentration of ≥ 90% only in the event of accidental rupture of the drum containers.

At the notifier facility, the primary work activity undertaken by transport and warehouse workers will include the handling, loading and off-loading of drums containing the notified chemical at ≥ 90% concentration. Exposures of these workers will be limited to situations involving products sampling for quality control or, in the event of a discharge, clean up from a spill or leaking drum. If such an event occurs, a worker may be exposed through dermal or ocular contact. Such exposures will be minimised to the extent possible through the use of personal protective equipment (PPE) including protective overalls, hard hats, chemical resistant gloves and safety glasses.

Formulation of end products
During reformulation, dermal, ocular and perhaps inhalation exposure of workers to the notified chemical (at ≥ 90% concentration) may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. The notifier states that exposure is expected to be minimised through high degree of automation and the use of mechanical ventilation, local exhaust ventilation and/or enclosed systems, and the use of PPE such as coveralls, goggles and impervious gloves.

Beauty care and cleaning professionals
Exposure to the notified chemical in end-use products (at ≤ 2% 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 the use of household products in the cleaning industry. 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 use is not expected. 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 ≤ 2% concentration in individual products, through the use of a wide range of cosmetic, personal care and household products. The principal routes of exposure will be dermal, while ocular, oral (during facial use), and inhalation exposures (through the use of spray products) are also possible.

Data on typical use patterns of cosmetic and household cleaning product categories in which the notified chemical may be used are shown in the following tables (SCCS, 2012; Cadby *et al.*, 2002; SDA, 2005). 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. In the absence of dermal absorption data, the default dermal absorption of 100% was assumed for calculation purposes (European Commission, 2003). For the inhalation exposure assessment (European Commission, 2003; SDA, 2005), an adult inhalation rate of 23 m^3/day (enHealth, 2004) was used and it was assumed that the bioavailability of the notified chemical via the inhalation route is 100%. An adult bodyweight of 60 kg was used for calculation purposes.

Cosmetic products (Dermal exposure)

Product type	Amount (mg/day)	C (%)	RF (unitless)	Daily systemic exposure (mg/kg bw/day)
Body lotion	7820	0.300	1	0.3910
Face cream	1540	0.300	1	0.0770
Hand cream	2160	0.300	1	0.1080
Fine fragrances	750	2.000	1	0.2500
Deodorant spray	1430	0.300	1	0.0715
Shampoo	10460	0.300	0.01	0.0052
Conditioner	3920	0.300	0.01	0.0020
Shower gel	18670	0.300	0.01	0.0093
Hand soap	20000	0.300	0.01	0.0100
Hair styling products	4000	0.300	0.1	0.0200
Total				**0.9440**

C = concentration (%); RF = retention factor.
Daily systemic exposure = Amount x C x RF x dermal absorption /body weight

Household products (Indirect dermal exposure - from wearing clothes)

Product type	Amount (g/use)	C (%)	Product Retained (PR) (%)	Percent Transfer (PT) (%)	Daily systemic exposure (mg/kg bw/day)
Laundry liquid	230	0.30	0.95	10	0.0109
Fabric softener	90	0.30	0.95	10	0.0043
Total					**0.0152**

Daily systemic exposure = Amount x C x PR x PT x dermal absorption /body weight

Household products (Direct dermal exposure)

Product type	Frequency (use/day)	C (%)	Contact Area (cm^2)	Product Use C (g/cm^3)	Film Thickness (cm)	Time Scale Factor	Daily systemic exposure (mg/kg bw/day)
Laundry liquid	1.43	0.30	1980	0.01	0.01	0.007	0.0001
Dishwashing liquid	3	0.30	1980	0.009	0.01	0.03	0.0008
All-purpose cleaner	1	0.30	1980	1	0.01	0.007	0.0069
Total							**0.0078**

Daily systemic exposure = Frequency x C x Contact area x Product Use Concentration x Film Thickness on skin x Time Scale Factor x dermal absorption /body weight

Cosmetic and household products (Inhalation exposure)

Product type	Frequency (use/day)	Amount (g/use)	C (%)	Inhalation rate (m^3/day)	Exposure duration (mins)	Airspace volume (m^3)	Daily systemic exposure (mg/kg bw/day)
Hairspray	2	10	0.3	23	15	2	0.1198
Air freshener	4	10	2.0	23	15	20	0.1597
Total							**0.2795**

C = concentration.
Daily systemic exposure = Frequency x Amount x C x Inhalation rate x Exposure duration x bioavailability via the inhalation route/(Airspace volume x 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 tables that contain the notified chemical. This would result in a combined internal dose of 1.247 mg/kg bw/day. It is acknowledged that inhalation exposure to the notified chemical from use of other cosmetic and household products (in addition to hair spray & air fresheners) may occur. However, it is considered that the combination of the conservative inhalation exposure assessment parameters and the aggregate exposure from use of the dermally applied products, which assumes a conservative 100% absorption rate, is sufficiently protective to cover additional inhalation exposure to the notified chemical from use of other spray cosmetic and household products with lower exposure factors.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the following table. For full details of the studies, refer to Appendix B.

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
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Human, skin sensitisation – RIPT (5%)	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 150 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Mammalian Chromosome Aberration Test	non genotoxic

Toxicokinetics, metabolism and distribution.
No toxicokinetic, metabolism and distribution studies were submitted for the notified chemical. Based on the low molecular weight (< 200 Da) and the moderate water solubility (0.119 g/L at 20 ± 0.5 °C) and partition coefficient (log Pow = 3.92) there is a high probability for the chemical to be dermally absorbed (ECHA, 2012). This is also supported by the fact that the chemical causes skin irritation. Absorption across the gastrointestinal tract in rats was confirmed by the systemic effects seen in the 28-day repeated dose toxicity study.

Acute toxicity.
The notified chemical was found to have low acute toxicity by both the oral and dermal routes in studies conducted in rats.

No acute inhalation toxicity data were provided for the notified chemical.

Irritation and sensitisation.
The notified chemical was found to be slightly irritating to the skin and eyes of rabbits.

A local lymph node assay (LLNA) in mice and a human repeated insult patch test (HRIPT) were carried out to assess the skin sensitizing potential of the notified chemical. There was no evidence of skin sensitisation observed in either study, at the concentrations tested.

Repeated dose toxicity.
In a 28-day oral toxicity study on rats the notified chemical was administered at 15, 150 and 1,000 mg/kg bw/day. There were no mortalities, although test subjects showed treatment related effects at the highest dose tested, including enlargement of liver and associated histopathological and biochemical changes. Only liver weight changes were observed at the dose of 150 mg/kg bw/day, which were considered by the study authors not to be adverse in nature. The NOAEL was therefore established as 150 mg/kg bw/day.

Mutagenicity/Genotoxicity.
The notified chemical was not mutagenic in an *in vitro* bacterial mutation test. The notified chemical did not demonstrate clastogenic potential to human lymphocytes in an *in vitro* chromosome aberration test.

Health hazard classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Reformulation

The notified chemical has the potential to cause slight skin and eye irritation effects. In addition, due to the absence of relevant information, the risk to workers following inhalation exposure to the notified chemical cannot be ruled out.

Workers may experience dermal and accidental ocular and perhaps inhalation exposure to the notified chemical (at up to > 90% concentration) during reformulation processes. The recommended use of enclosed, automated processes and PPE (impervious gloves, goggles, coveralls and respiratory protection, if significant inhalation exposure is expected) by the workers should minimise the potential for exposure.

Therefore, given the expected low toxicity of the notified chemical, it is not considered to pose an unreasonable risk to the health of workers.

End-use

Cleaners and beauty care professionals will handle the notified chemical at a concentration similar to public use. 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 of cosmetic, hair care, personal care, air-care and household products containing the notified chemical at concentrations up to 2%.

The potential systemic exposure to the public from the use of the notified chemical in cosmetic and household products was estimated to be 1.247 mg/kg bw/day. Using a NOAEL of 150 mg/kg bw/day from a 28 day repeated dose toxicity study on the notified chemical, the margin of exposure (MOE) was estimated to be 120. A MOE value greater than or equal to 100 is considered acceptable to account for intra- and inter-species differences.

Based on the information available, the risk to the public associated with the use of the notified chemical at ≤ 2.0% in fine fragrances and air fresheners, and ≤ 0.3% in household other cosmetic 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 be imported as a component of fragrance preparations for local reformulation into a variety of consumer products (cosmetics and household products). Release during reformulation in Australia is expected to arise from spills (approximately 0.1% of the annual import volume), formulation equipment cleaning (no release estimate as cleaning water is expected to be recycled) and residues in import containers (approximately 0.1% of the annual import volume). Accidental spills during transport or reformulation are expected to be collected with inert material and disposed of to landfill. Import containers will either be recycled or disposed of through an approved waste management facility. Therefore, up to 0.2% of the import volume is estimated to be released to landfill as a result of reformulation in Australia.

RELEASE OF CHEMICAL FROM USE

The notified chemical is expected to be released to sewers in domestic situations across Australia as a result of its use in cosmetic and household cleaning products, which are either washed off the hair and skin of consumers, or disposed of following cleaning activities.

RELEASE OF CHEMICAL FROM DISPOSAL

It is estimated that a maximum of 3% of the consumer products containing the notified chemical will remain in end-use containers. These are likely to be disposed of through domestic garbage disposal and enter landfill or be recycled.

7.1.2. Environmental Fate

Following its use in Australia, the majority of the notified chemical is expected to enter the sewer system. During sewage treatment processes, a portion of the notified chemical is expected to be removed from effluent by partitioning to sludge and sediment, and biodegradation. The notified chemical is expected to partition to soil and sludge based on its moderately high soil adsorption coefficient and n-octantal/water partition coefficient. Whilst the notified chemical cannot be classified as readily biodegradable, it has potential to biodegrade based on the results of a ready biodegradation test study. For the details of the environmental fate studies please refer to Appendix C.

The notified chemical is not expected to be entirely removed from effluent by sewage treatment processes, and some notified chemical may be released as treated effluent to surface waters. In the case of release to surface waters, the notified chemical is expected to disperse and slowly degrade. The provided study indicates that slow hydrolysis may occur under ambient environmental conditions. On the basis of its potential to degrade biotically and abiotically, forming water and oxides of carbon, the notified chemical is unlikely to persist in the aquatic environment. The notified chemical is not likely to bioaccumulate in aquatic organisms, based on its measured n-octanol/water partition coefficient.

The notified chemical is volatile and may volatilise to air during use or sewage treatment. The half-life of the notified chemical in air is calculated to be 2.1 h and 1.4 h, based on reactions with hydroxyl radicals and ozone respectively (AOPWIN, v1.29, US EPA, 2011). Therefore, in the event of release to atmosphere, the notified chemical is not expected to persist in the air compartment.

Notified chemical may be applied to land when treated sewage effluent is used for irrigation or when sewage sludge is used for soil remediation, or disposed of to landfill. Notified chemical residues in landfill, soil and sludge are expected to have low mobility based on its measured soil adsorption coefficient and are expected to degrade to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The following predicted environmental concentrations (PEC) have been calculated assuming that all of the imported quantity of notified chemical will be released to sewer, nationwide, over 365 days. It has been assumed for the worst case that there is no removal of the notified chemical during sewage treatment processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	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:	0.61	µg/L
PEC - Ocean:	0.06	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 0.61 µg/L may potentially result in a soil concentration of approximately 4.04 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 20.2 µg/kg and 40.4 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	48 h EC50 = 15 mg/L	Harmful to aquatic invertebrates
Algal Toxicity	72 h EC50 = 20 mg/L	Harmful to alga
Inhibition of Bacterial Respiration	3 h IC50 = 700 mg/L	Not expected to inhibit microbial respiration

Based on the available measured endpoints the notified chemical is considered to be harmful to aquatic invertebrates and alga. Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified chemical is formally classified as 'Acute Category 3: Harmful to aquatic life'. The long-term hazard of the notified chemical is formally classified under the GHS, on the basis of its measured acute toxicity to aquatic biota and its lack of rapid degradability, as 'Chronic Category 3: Harmful to aquatic life with long lasting effects'.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) for the notified chemical was calculated from the endpoint of the most sensitive species (invertebrates) and an assessment factor of 1000. A conservative assessment factor of 1000 is appropriate in this case as only endpoints from species representing two trophic levels were available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Invertebrates).	15.0	mg/L
Assessment Factor	1,000.00	
PNEC:	15.0	µg/L

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC values, the following risk quotients (Q) have been calculated:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.61	15	0.040
Q - Ocean	0.06	15	0.004

The risk quotient for discharge of effluents containing the notified chemical indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations in aquatic environments based on its annual import quantity. The notified chemical is neither likely to bioaccumulate in aquatic organisms nor persist in surface waters, air or soils. Therefore, on the basis of the PEC/PNEC ratio, maximum annual import volume and assessed use pattern in cosmetic and household cleaning products, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point < -20 °C

Method OECD TG 102 Melting Point/Melting Range.
Remarks BS4633 method for determination of crystallizing point. The data is derived from two independent determinations.
Test Facility Firmenich (2003)

Boiling Point 206 ± 2 °C at 96.6 kPa

Method OECD TG 103 Boiling Point.
Remarks Siwoloboff method. The data is derived from three independent determinations.
Test Facility Firmenich (2003)

Density 958 kg/m^3 at 20 °C

Method OECD TG 109 Density of Liquids and Solids.
Remarks Oscillating density meter method. The data is derived from three independent determinations.
Test Facility Firmenich (2003)

Vapour Pressure 0.151 kPa at 25 °C

Method OECD TG 104 Vapour Pressure.
Remarks The vapour pressure was measured using an isoteniscope system.
Test Facility Harlan (2009a)

Vapour Pressure 3.5 x 10^{-2} kPa at 25 °C

Method OECD TG 104 Vapour Pressure.
Remarks The vapour pressure was determined using the gas saturation method.
Test Facility Harlan (2009b)

Water Solubility 0.119 g/L at 20 ± 0.5 °C

Method EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks Flask Method. The test material concentration decreased by approximately 6% over the course of the test, which was attributed to hydrolysis.
Test Facility Safepharm (2004e)

Hydrolysis as a Function of pH $t_{½}$ = 150 – 179 days, at 25 ± 0.5 °C pH 4 - 9

Method OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ <hours or days>*
4	25	162 days
7	25	179 days
9	25	150 days

Remarks A 1% co-solvent of acetonitrile was used to aid solubility of the test solutions. The results from the preliminary test showed it was necessary to undertake further testing at pH 4, pH 7 and pH 9, with solutions being maintained at 25 ± 0.5 °C for a period of 30 days. Sample solutions at pH 1.2 were maintained at 37.0 ± 0.5 °C for a period of 24 hours. Sample solution concentrations were analysed by HPLC. The percentage of the test substance remaining after 30 days at 25 °C was approximately 88% for the test solutions at pH 4 – 9. Under the physiologically relevant conditions of pH 1.2, 37 ± 0.5 °C, the test substance was determined not to show significant hydrolysis after 24 hours.
Test Facility Harlan (2009c)

Partition Coefficient (n-octanol/water) log Pow = 3.92

Method	OECD TG 117 Partition Coefficient (n-octanol/water), HPLC method
Remarks	HPLC Method. In the absence of any dissociating groups present on the test substance, no manipulation of the mobile phase pH was required to ensure a non-ionised form of the test substance.
Test Facility	Safepharm (2004e)

Surface Tension 65.8 mN/m at 22.4 °C

Method	OECD TG 115 Surface Tension of Aqueous Solutions.
Remarks	Concentration: 106 mg/L solution; ISO 304 standard ring method.
Test Facility	Harlan (2009c)

Adsorption/Desorption log K_{oc} = 2.80
– screening test

Method	OECD TG 121 Estimation of the adsorption coefficient (K_{oc}) on soil and sewage sludge using HPLC
Remarks	HPLC method. The test was conducted at pH 7 as the test material has no modes of dissociation and will be unionised at this pH.
Test Facility	Harlan (2009c)

Flash Point 74 ± 2 °C at 96.7 kPa

Method	EC Council Regulation No 440/2008 A.9 Flash Point.
Remarks	Closed cup equilibrium method. The data is derived from three independent determinations.
Test Facility	Firmenich (2003)

Autoignition Temperature 354 ± 5°C

Method	EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases)
Remarks	Atmospheric pressure was between 103.56 – 103.92 kPa.
Test Facility	Harlan (2009a)

Explosive Properties Predicted negative

Method	EC Council Regulation No 92/69/EEC A.14 Explosive Properties.
Remarks	The test substance was assessed for chemical groups that would imply explosive properties, and combined with a calculated oxygen balance of -254.6 the study authors came to a negative prediction for explosive properties.
Test Facility	Harlan (2009a)

Oxidizing Properties Predicted negative

Method	EC Council Regulation No 440/2008 A.17 Oxidizing Properties (Solids).
Remarks	The test substance was assessed for chemical groups that would imply oxidising properties, the study authors came to a negative prediction.
Test Facility	Harlan (2009a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Sprague-Dawley CD
Vehicle	None
Remarks - Method	No significant deviations from the OECD protocol. Due to the liquid nature of the notified chemical, specific gravity of the notified chemical was determined and used to calculate the appropriate dose volume for the required dose level.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 Female	2,000	0/3
2	3 Female	2,000	0/3

LD50	> 2,000 mg/kg bw
Signs of Toxicity	Hunched posture, lethargy, ataxia, diarrhoea, pilo-erection, increased activity, pallor of the extremities, decreased respiratory rate and laboured respiration. The symptoms disappeared 2–3 days after dosing.
Effects in Organs	No macroscopic findings were observed at necropsy in any of the test animals.
Remarks - Results	There were no deaths and all animals gained weight over the course of the study.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Safepharm (2004a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rat/Sprague-Dawley CD
Vehicle	None
Type of dressing	Semi-occlusive.
Remarks - Method	No significant deviations from the OECD protocol. Due to the liquid nature of the notified chemical, specific gravity of the notified chemical was determined and used to calculate the appropriate dose volume for the required dose level.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	2000	0/10

LD50	> 2,000 mg/kg bw
Signs of Toxicity - Local	There were no test substance-related dermal reactions
Signs of Toxicity - Systemic	There were no death or test substance related clinical signs.
Effects in Organs	No macroscopic findings were observed at necropsy in any of the test animals
Remarks - Results	All animals gained weight over the course of the study The LD50 was

determined to be > 2,000 mg/kg bw, based on an absence of mortalities or adverse effects at this dose.

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

TEST FACILITY Safepharm (2008a)

B.3. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3 male
Vehicle None
Observation Period 7 days
Type of Dressing Semi-occlusive
Remarks - Method No significant deviations from the OECD protocol.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	1.0	1.7	2	< 7 days	0
Oedema	0	1.0	1.0	1	< 7 days	0

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

Remarks - Results There were no signs of irritation seen in one animal. In the remaining 2 test subjects very slight to well defined erythema and very slight oedema were observed, along with moderate desquamation and loss of skin elasticity.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY Safepharm (2004b)

B.4. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 72 hours
Remarks - Method No significant deviations from the OECD protocol.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.3	0.7	0.3	1	< 72 hours	0
Conjunctiva: chemosis	0	0	0	0	-	0
Conjunctiva: discharge	0.3	0.3	0.3	1	< 48 hours	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results	A single application of test substance resulted in conjuctival irritation in all test animals. The effects were reversed at the 48 h observation in 2 test subjects and at 72 h in the third subject.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	Safepharm (2004c)

B.5. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain	Mouse/CBA/J
Vehicle	Acetone / olive oil (4/1 v/v)
Remarks - Method	No significant deviations from the OECD protocol. Incorporation of ^{125}I labelled iododeoxyuridine into auricular lymphocytes was used as a measure of proliferation response.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	27.0 ± 4.9	–
1%	17.3 ± 5.3	0.6 ± 0.2
5%	22.3 ± 8.4	0.8 ± 0.3
10%	28.4 ± 4.4	1.1 ± 0.2
20%	29.6 ± 12.7	1.1 ± 0.5
40%	65.9 ± 10.6	2.4 ± 0.4
Positive Control		
Isoeugenol		
0.5%	16.9 ± 8.6	0.6 ± 0.3
1.0%	28.7 ± 14.3	1.1 ± 0.5
5.0%	326.7 ± 63.3	12.1 ± 2.3

Remarks - Results	One of the eight vehicle-control subjects died of injection trauma. No significant change (> 10%) in ear thickness was noted. With all stimulation index values less than 3 for the test substance, a reliable EC-3 potency value could not be calculated.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	BRT (2004)

B.6. Skin sensitisation – human volunteers

TEST SUBSTANCE	Notified chemical (5% in vehicle)
METHOD	Repeated insult patch test with challenge
Study Design	Induction Procedure: Patches containing 0.3 mL test substance were applied 3 times per week (Monday, Wednesday and Friday) for a total of 9 applications. Patches were removed by the applicants after 24 h and graded after an additional 24 h (or 48 h for patches applied on Friday). Rest Period: 10–15 days Challenge Procedure: A patch was applied to a naïve site. Patches were removed by the applicant after 24 h. sites were graded 24, 48 and 72 h post-patch removal.
Study Group	88 F, 25 M; age range 18–70 years

Vehicle	Mixture of diethyl phthalate & ethanol (3:1 ratio)
Remarks - Method	Occluded. The test substance was spread on a 2.5 cm × 2.5 cm patch.

RESULTS

Remarks - Results	105/113 subjects completed the study. One subject did not participate in the study. Five subjects were discontinued for failure to keep the scheduled visits (1–7 induction observations recorded). One subject was discontinued for violation of protocol and one subject was discontinued due to non-product related adverse event. No signs of irritation or adverse effects were noted in any of the test subjects at any stage.
CONCLUSION	The test substance was non-sensitising under the conditions of the test.
TEST FACILITY	TKL (2009)

B.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rats/Sprague-Dawley Crl:CD® (SD) IGS BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week
Vehicle	Arachis oil BP
Remarks - Method	No significant deviations from the OECD protocol.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
Control (Vehicle only)	5 per sex	0	0/10
low dose	5 per sex	15	0/10
mid dose	5 per sex	150	0/10
high dose	5 per sex	1,000	0/10

Mortality and Time to Death

There were no unscheduled deaths during the study.

Clinical Observations

Clinical signs noted during the study included salivation in both male and female in the medium and high dose groups throughout the treatment. A statistically significant reduction in body weight gain during week one and increased food consumption was noted for males in high dose group. Food efficiency (the ratio of bodyweight to dietary intake) was reduced for males in high dose group throughout the treatment period and for females in high dose group from week 2 onwards when compared to control.

A 22% increase in water intake was noted for males and a 67% increase in water intake was noted for females in high dose group throughout the study period.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Females from high dose group showed a statistically significant reduction in lymphocyte counts when compared to control animals. Males from high dose group showed a statistically significant increase in blood calcium and a statistically significant reduction in inorganic phosphate. Males from all treatment groups showed a statistically significant increase in plasma creatinine levels when compared to control.

Effects in Organs

Males from the medium and high dose groups showed statistically significant increases in liver weights, both absolute (4.8% and 15.7% respectively) and relative to terminal body weight. Females from the high dose group showed statistically significant increases in liver (35.8%) and kidney weights, both absolute and relative to

terminal body weight. Sloughing of the stomach was detected in one female from the high dose group.
Centrilobular hepatocyte enlargement was observed in relation to treatment for animals of either sex in the high dose group and in addition in males in medium dose group. . As hepatocyte enlargement is often seen in the rodent liver following treatment with xenobiotics, in the absence of any associated degenerative or inflammatory changes, the study authors considered this to be an adaptive change.
A lower incidence of higher grades of severity of extra-medullary haemopoiesis of spleen was seen in relation to treatment for males from high dose group, the study authors considered these changes to be marginal and non-adverse.

Remarks – Results
The > 10% increase in liver weights of both male and female animals in the 1,000 mg/kg/day dose groups along with the accompanying histopathological and biochemical changes are considered to be adverse. Therefore, the lower dose of 150 mg/kg/day was the dose where no adverse treatment related effects were observed.

CONCLUSION
Based on the adverse effects seen at high dose of 1,000 mg/kg bw/day, a No Observed (Adverse) Effect Level (NO(A)EL) was established as 150 mg/kg bw/day in this study.

TEST FACILITY Safepharm (2008b)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE

METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 and TA102
Metabolic Activation System	S9 fraction from phenobarbitone/β-naphtoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 5 – 5,000 µg/plate b) Without metabolic activation: 5 – 5,000 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks - Method	No significant deviations from OECD protocol. N-Ethyl-N'-nitro-N-nitrosoguanidine, 9-aminoacridine, mitomycin C and 4-nitroquinoline-1-oxide were used as positive controls in test without metabolic activation and 2-aminoanthracine, benzo(*a*)pyrene and 1,8-dihydroxyanthraquinone were used as positive controls for test with metabolic activation.

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				
Test 1	≥ 1,500	≥ 1,500	> 5,000	Negative
Test 2		≥ 1,500	> 5,000	Negative

Remarks - Results	No significant increase in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose, either with or without metabolic activation. The positive controls produced satisfactory responses, thus confirming the activity of S9-mix and the sensitivity of the bacterial strain.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Safepharm (2004d)

B.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.

Cell Type/Cell Line	Human lymphocytes isolated from blood donated by a volunteer
Metabolic Activation System	S9 fraction from phenobarbitone/β-naphtoflavone induced rat liver
Vehicle	Dimethyl sulfoxide
Remarks - Method	No significant deviations from OECD protocol. Mitomycin C was used as positive control in tests without metabolic activation and cyclophosphamide was used as positive control in tests with metabolic activation.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Selection Time*
Absent			
Test 1	0*, 30, 60*, 90*, 120*, 150*, 180	4 h	24 h
Test 2	0, 0*, 30, 60, 90*, 120*, 150*, 180	24 h	24 h
Present			
Test 1	0*, 30, 60, 90*, 120*, 150*, 180*	4 h	24 h
Test 2	0*, 60, 90*, 120*, 150*, 180, 210	4 h	24 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 228	≥ 150	> 180	Negative
Test 2	≥ 114	≥ 180	> 180	Negative
Present				
Test 1	≥ 228	> 180	> 180	Negative
Test 2	-	≥ 180	> 210	Negative

Remarks - Results No toxicologically significant increases in the number of cells with aberrations were noted, with or without metabolic activation.
The positive control showed a statistically significant increase in mutation frequency, confirming the validity of the test system.

CONCLUSION The notified chemical was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY Safepharm (2008c)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
- Inoculum: Activated sludge
- Exposure Period: 28 days
- Auxiliary Solvent: Not reported
- Analytical Monitoring: Total organic carbon (TOC)
- Remarks - Method: Conducted according to the guidelines above and in accordance with GLP principles.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
3	14	3	59
12	38	12	71
21	42	21	83
28	43	28	86

- Remarks - Results: All validity criteria were met, and no deviations to protocol were reported The toxicity control attained 25% biodegradation by day 14 of the study, thereby confirming that the test material was not toxic to the sewage treatment micro-organisms used in the study. The reference material, sodium benzoate, attained 86% biodegradation after 28 days thereby confirming the suitability of the test method and culture conditions.

CONCLUSION: The notified chemical is not readily biodegradable

TEST FACILITY: Safepharm (2004f)

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 - Static
- Species: *Daphnia magna*
- Exposure Period: 48 hours
- Auxiliary Solvent: None reported
- Water Hardness: 250 mg $CaCO_3$/L
- Analytical Monitoring: HPLC
- Remarks - Method: Conducted according to the guidelines above and in accordance with GLP principles.

RESULTS

Concentration (mg/L) Time-weighted mean measured concentration	*Number of D. magna*	*Number Immobilised (%)*	
		24 h	*48 h*
Control	20	0	5
0.282	20	0	5
0.529	20	0	0

0.889	20	0	0
1.52	20	0	0
2.55	20	20	35
4.47	20	10	15
7.87	20	5	5
13.8	20	10	50
22.6	20	45	85

LC50	15 mg/L (95% CI: 10 – 19 mg/L) at 48 hours
NOEC (or LOEC)	1.5 mg/L at 48 hours
Remarks - Results	All validity criteria were met and no significant deviations from protocol were reported. Analysis of the test solutions showed a slight decline in measured concentrations over the test duration. It was therefore considered justifiable to base the results on time-weighted mean measured test concentrations.

CONCLUSION The notified chemical is harmful to aquatic invertebrates

TEST FACILITY Safepharm (2008d)

C.2.2. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species	*Desmodesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 1.0, 3.2, 10, 32 and 100 mg/L Actual: 0.83, 3.0, 8.4, 32 and 102 mg/L
Auxiliary Solvent	None reported
Water Hardness	0.15 mmol Ca^{2+} & Mg^{2+}
Analytical Monitoring	HPLC
Remarks - Method	Conducted according to the guidelines above and in accordance with GLP principles.

RESULTS

Biomass		*Growth*	
EyC50	*NOEC*	*ErC50*	*NOEC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
13	8.4	20	8.4

Remarks - Results	All validity criteria were met and no significant deviations to protocol were reported. Analysis of the test solutions showed a decline in measured concentrations over the test duration. It was therefore considered justifiable to base the results on time-weighted mean measured test concentrations.

CONCLUSION The notified chemical is harmful to alga

TEST FACILITY Harlan (2008)

C.2.3. Inhibition of microbial activity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test.

Inoculum	Activated sewage sludge
Exposure Period	3 hours
Concentration Range	Nominal: 180, 320, 560, 1000 and 1800 mg/L

Remarks – Method	Conducted according to the guidelines above and in accordance with GLP principles.
RESULTS	
IC50	700 mg/L
NOEC	180 mg/L
Remarks – Results	All validity criteria were met and no significant deviations from protocol were reported. Total hardness of the test water was measured as 140 mg/L $CaCO_3$.
CONCLUSION	The notified chemical is not expected to inhibit microbial respiration at concentrations <700 mg/L.
TEST FACILITY	Safepharm (2008e)

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