File No: STD/1669
STD/1670

April 2019

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

STD/1669: Alkanes, C15-16-branched
STD/1670: Alkanes, C17-18-branched

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:

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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
STD/1669 STD/1670	Ixom Operations Pty Ltd	STD/1669: Alkanes, C15-16-branched STD/1670: Alkanes, C17-18-branched	Yes	STD/1679: ≤ 100 tonnes per annum STD/1670: ≤ 100 tonnes per annum	Cosmetic ingredient

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
Based on the available information, the notified chemicals are 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 table below.

Hazard classification	*Hazard statement*
Aspiration hazard (Category 1)	H304 – May be fatal if swallowed and enters airways

Human Health Risk Assessment
Under the conditions of the occupational settings described, the notified chemicals are not considered to pose an unreasonable risk to the health of workers.

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

Environmental Risk Assessment
On the basis of the low hazard and the assessed use pattern, the notified chemicals are not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemicals should be classified as follows:
  - H304 – May be fatal if swallowed and enters airways

The above should be used for products containing the notified chemicals, if applicable, based on the concentration of the notified chemicals 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 chemicals during reformulation:
  - Enclosed, automated processes, where possible
  - Local exhaust ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemicals during reformulation:
  - Avoid inhalation
  - Use in ventilated areas

- 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 chemicals during reformulation:
  - Respiratory protection

  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 chemicals 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

- As liquid hydrocarbons are included in Schedule 5 of the SUSMP, any labelling and/or packaging requirement for products containing the notified chemicals, which are available to the public, should be adhered to.

- To prevent the possibility of end user risks, formulators should consider the aspiration hazard of the notified chemicals when formulating cosmetic products containing these chemicals.

Storage

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

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified chemicals 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 chemicals 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 chemicals, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemicals are 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 final use concentration of the notified chemicals exceed 50% in cosmetic products;

or

(2) Under Section 64(2) of the Act; if

- the function or use of the chemicals has changed from a cosmetic ingredient, or is likely to change significantly;
- the amount of the chemicals being introduced has increased, or is likely to increase, significantly;
- the chemicals have begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemicals 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 documents of the notified chemicals provided by the notifier were 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
Ixom Operations Pty Ltd (ABN: 51 600 546 512)
70 Marple Avenue
VILLAWOOD NSW 2163

NOTIFICATION CATEGORY
STD/1669: Standard: Chemical other than polymer (more than 1 tonne per year)
STD/1670: 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, analytical data, degree of purity, use details, import volume, identity of analogue chemicals and identity of manufacturer/recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for water solubility, hydrolysis as a function of pH, partition coefficient, absorption/desorption, dissociation constant, flammability, acute oral toxicity, acute dermal toxicity, repeated dose toxicity and all ecotoxicity endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
STD/1669: Europe (2017)
STD/1670: Europe (2017)

2. IDENTITY OF CHEMICAL

MARKETING NAMES
STD/1669: EMOGREEN L15
STD/1670: EMOGREEN L19

CAS NUMBER
STD/1669: 2081854-13-7
STD/1670: 2081854-12-6

CHEMICAL NAME
STD/1669: Alkanes, C15-16-branched
STD/1670: Alkanes, C17-18-branched

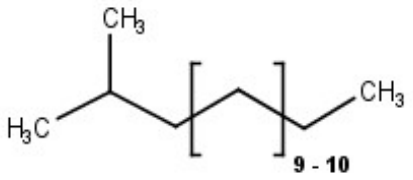
OTHER NAME(S)
STD/1669: Renewable hydrocarbons, C15-16, branched alkanes (IUPAC/REACH name)
DEV 1763

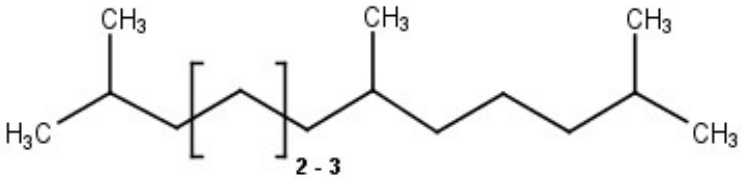
STD/1670: Renewable hydrocarbons, C17-18, branched alkanes (IUPAC/REACH name)

MOLECULAR FORMULA
STD/1669: Unspecified
STD/1670: Unspecified

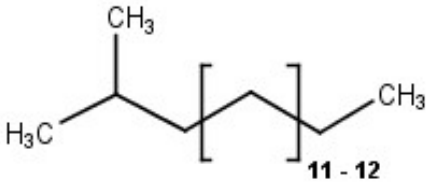
STRUCTURAL FORMULA

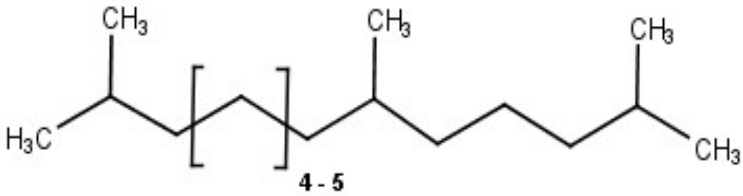
STD/1669:
Representative structure:





STD/1670:
Representative structure:





MOLECULAR WEIGHT
STD/1669: 212-226 g/mol
STD/1670: 240-254 g/mol

ANALYTICAL DATA
Reference IR, GC, UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
STD/1669: > 95%
STD/1670: > 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless liquids

Property	*Value*	*Data Source/Justification*
Pour Point	STD/1669: -81 °C STD/1670: -45 °C	Measured
Boiling Point	STD/1669: 247 - 269 °C at 101.3 kPa STD/1670: 293 – 324 °C at 101.3 kPa	Measured
Density	STD/1669: 776 kg/m^3 at 15 °C STD/1670: 787 kg/m^3 at 15 °C	Measured
Vapour Pressure	STD/1669: 2×10^{-3} kPa at 20 °C STD/1670: 1×10^{-3} kPa at 20 °C	Calculated using distillation range and total volume percent of saturates, olefins, and aromatics of the test substance
Water Solubility	STD 1669: 0.0033 mg/L at 25 °C STD 1670: 0.0001 mg/L at 25 °C	Estimated by WSKOW v1.43
Hydrolysis as a Function of pH	Not determined	Contains no hydrolysable functionalities
Partition Coefficient (n-octanol/water)	STD 1669: log P_{ow} = 7.63 STD 1670: log P_{ow} = 9.11	Estimated by KOW v1.68
Adsorption/Desorption	STD 1669: log K_{oc} = 4.39 – 6.62 STD 1670: log K_{oc} = 5.17 – 7.91	Estimated by KOCWIN v2.00
Dissociation Constant	Not determined	Contains no dissociable functionalities
Flash Point	STD/1669: 115 °C STD/1670: 149 °C	Measured
Flammability	Combustible liquids#	Based on flash points
Autoignition Temperature	STD/1669: 193 °C at 101.3 kPa STD/1670: 204 °C at 101.3 kPa	Measured
Kinematic Viscosity	STD/1669: 2.5 mm^2/s at 40 °C STD/1670: 3.9 mm^2/s at 40 °C	Measured
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

Based on *Australian Standard AS1940 definitions*

DISCUSSION OF PROPERTIES

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

Reactivity

The notified chemicals are 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 chemicals are 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.

The notified chemical for STD/1669 has a flash point of 115 ºC which is greater than 93 °C but less than its boiling point (247 - 269 ºC). Based on *Australian Standard AS1940* definitions for combustible liquid, the notified chemical may be considered as a Class C2 combustible liquid.

The notified chemical for STD/1670 has a flash point of 149 ºC which is greater than 93 °C but less than its boiling point (293 – 324 ºC). Based on *Australian Standard AS1940* definitions for combustible liquid, the notified chemical may be considered as a Class C2 combustible liquid.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemicals will be introduced into Australia neat for reformulation or as a component of finished cosmetic products at ≤ 50% concentration for each chemical.

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

STD/1669

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 100	≤ 100	≤ 100	≤ 100	≤ 100

STD/1670

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 100	≤ 100	≤ 100	≤ 100	≤ 100

PORT OF ENTRY
Melbourne and Sydney

TRANSPORTATION AND PACKAGING
The notified chemicals will be imported neat in 216 L drums. The finished cosmetic products containing the notified chemicals at ≤ 50% concentration will be imported in containers suitable for retail sale (≤ 500 mL plastic/HDPE or glass bottles).

USE
The notified chemicals will be used as a cosmetic ingredient. The proposed end use concentration for each chemical is ≤ 50% concentration.

OPERATION DESCRIPTION
The notified chemicals will not be manufactured in Australia. The notified chemicals will be introduced into Australia in their neat form for reformulation into cosmetic products. The notified chemicals will also be introduced as components of finished cosmetic products at ≤ 50% concentration.

Reformulation
The procedures for incorporating the notified chemicals into end-use products 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 for the reformulation process, the notified chemicals will be weighed and added to the mixing tank where it will be blended with additional additives to form the finished cosmetic products. This will be followed by automated filling of the reformulated products into containers of various sizes. The blending operations are expected to be highly automated and use closed systems and/or adequate ventilation. During the reformation process, samples of the notified chemicals and the finished end-use products will be taken for quality control testing.

End Use
The finished cosmetic products containing the notified chemicals at ≤ 50% concentration will be used by consumers and professionals (such as beauticians and hair dressers). Depending on the nature of the products, application could be by hand, sprayed or through the use of an applicator.

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	2	50
Reformulation	4	50
Quality control	1	50
Retail	1	250
Professional end users	2	250

EXPOSURE DETAILS
Transport and storage

Transport, storage and warehouse workers may come into contact with the notified chemicals in neat form or as a component of imported preparations, only in the unlikely event of accidental rupture of containers.

Reformulation
During reformulation, dermal, ocular and perhaps inhalation exposure of workers to the notified chemicals at ≤ 100% concentration may occur during handling of drums, during weighing and transfer stages, blending, quality control analysis, and cleaning and maintenance of equipment. The notifier stated that the exposure will be minimised through the use of mechanical ventilation and/or enclosed systems, and through the use of personal protective equipment (PPE) such as protective clothing, eye protection, respirator and impervious gloves.

End-use
Exposure to the notified chemicals in end-use products at ≤ 50% concentration may occur in professions where the services provided involve in the application of cosmetics to clients (e.g. hair dressers and workers in beauty salons). 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, and 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 the products containing the notified chemicals.

6.1.2. Public Exposure
There will be widespread and repeated exposure of the public to the notified chemicals at ≤ 50% concentration through the use of a wide range of cosmetic products. The principal route of exposure will be dermal, while ocular and inhalation exposure (e.g. through the use of spray products) are also possible.

6.2. Human Health Effects Assessment
The results from toxicological investigations conducted on the notified chemicals and acceptable analogues of the notified chemicals (analogue chemicals 1 and 2) are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Test substance*	*Result and Assessment Conclusion*
Acute oral toxicity – rat	Analogue chemical 1	LD50 > 2,000 mg/kg bw; low toxicity
Acute dermal toxicity – rat	Analogue chemical 1	LD50 > 2,000 mg/kg bw; low toxicity
Skin irritation – *in vitro* reconstructed human epidermis model (EpiSkin)	Notified chemical (STD/1669)	not a skin irritant
	Notified chemical (STD/1670)	not a skin irritant
Skin irritation – *in vitro* reconstructed epithelium model (vaginal mucosa)	Notified chemical (STD/1669)	not a skin irritant
	Notified chemical (STD/1670)	not a skin irritant
Skin compatibility – human volunteers	Notified chemical (STD/1669)	good compatibility at 60% concentration
	Notified chemical (STD/1670)	good compatibility at 60% concentration
Eye irritation – *in vitro* BCOP test	Notified chemical (STD/1669)	not an eye irritant
	Notified chemical (STD/1670)	not an eye irritant
Skin sensitisation – *in vitro* SENS-IS test	Notified chemical (STD/1669)	not a skin irritant or sensitiser at 100% concentration
Skin sensitisation – HRIPT	Notified chemical (STD/1669)	no evidence of sensitisation at 50% concentration
	Notified chemical (STD/1670)	no evidence of sensitisation at 50% concentration
Repeat dose dermal toxicity – rat, 90 days	Analogue chemical 2	NOAEL > 495 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	Notified chemical (STD/1669)	non mutagenic
Genotoxicity – *in vitro* mammalian cell micronucleus test	Notified chemical (STD/1669)	non genotoxic
Reproductive and developmental toxicity - rat	Analogue chemical 1	NOAEL > 1,000 mg/kg bw/day (reproductive and systemic)

Toxicokinetics
Given the low molecular weight of the notified chemicals (< 300 g/mol), absorption across the respiratory or gastrointestinal tract may occur. However, based on the low water solubility (< 0.005 mg/L) and high partition coefficient (log Pow > 7.5), indicating high lipophilicity of the notified chemicals, percutaneous absorption is expected to be limited.

Acute Toxicity
No studies were submitted on the acute toxicity of the notified chemicals.

Analogue chemical 1 was found to be of low acute oral and dermal toxicity in rats.

The notified chemicals are liquid `hydrocarbons and have a kinematic viscosity ≤ 20.5 mm^2/s at 40 °C. The notified chemicals are therefore considered to be Category 1 aspiration toxicants (H304 − May be fatal if swallowed and enters airways).

Irritation and Sensitisation
In *in vitro* studies using reconstructed human epidermal (EpiSkin) or epithelium (vaginal mucosa) models, the notified chemicals were determined not to be skin irritants. The notified chemicals were also found to be well tolerated in skin compatibility tests using human volunteers at 60% concentration.

In *in vitro* bovine corneal opacity and permeability (BCOP) tests, the notified chemicals were determined not be eye irritants.

In human repeat insult patch tests (HRIPT) the notified chemicals at ≤ 60 concentration showed no evidence of skin sensitisation. The notified chemical (STD/1669) was also determined to be a non-sensitiser in an *in vitro* skin sensitisation study (SENS-IS test) using the human reconstituted epidermis model (EpiSkin).

Repeated Dose Toxicity
No data were submitted for the notified chemicals.

In a 90 day repeated dose dermal toxicity study in rats with analogue chemical 2 at 165, 330 and 495 mg/kg bw/day, the No Observed Adverse Effect Level (NOAEL) was established as > 495 mg/kg bw/day, based on the absence of treatment related effects up to the highest dose tested.

Mutagenicity/Genotoxicity
The notified chemical (STD/1669) was found to be negative in a bacterial reverse mutation assay and in an *in vitro* mammalian cell micronucleus assay. No data was submitted for the notified chemical (STD/1670).

Toxicity for reproduction
In a two-generation reproductive study, rats were administered the notified chemical by gavage at 0, 50, 250 or 1,000 mg/kg bw/day and mated to produce subsequent generations. There were no treatment related effects on reproductive performance or on pups. Effects in the kidneys were attributed to α2-microglobulin accumulation and, in the absence of associated effects, were not considered by the study authors to be adverse. Increased liver weights and hepatocellular hypertrophy were observed and were considered to be an adaptive effect. The NOAEL for reproductive and systemic toxicity was established as > 1,000 mg/kg bw/day in this study, based on the lack of adverse effects.

Health Hazard Classification
Based on the available information, the notified chemicals are 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 table below.

Hazard classification	*Hazard statement*
Aspiration hazard (Category 1)	H304 – May be fatal if swallowed and enters airways

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the information available, the critical health effect of the notified chemicals is as an aspiration hazard. Local and systemic effects from acute or repeated exposure are not expected.

Reformulation
During reformulation workers may be at risk of aspiration when handling the neat notified chemicals as introduced. It is stated by the notifier that engineering controls such as enclosed and automated processes and local ventilation will be implemented where possible and appropriate PPE (coveralls, imperious gloves, eye protection and respiratory protection) will be used to limit worker exposure.
Therefore, under the conditions of the occupational settings described, the notified chemicals are not considered to pose an unreasonable risk to the health of workers.

End-use
Workers involved in professions where the services provided involve the application of cosmetic products containing the notified chemicals to clients (such as beauticians and hairdressers) may be exposed to the notified chemicals at ≤ 50% concentration. Such professionals may use PPE 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 the various products containing the notified chemicals (for details of the public health risk assessment, see Section 6.3.2).

6.3.2. Public Health
Members of the public may experience repeated exposure to the notified chemicals through the use of cosmetic products containing the notified chemicals at ≤ 50% concentration in cosmetic products. Based on the available information, the notified chemicals could pose an aspiration hazard through ingestion or inhalation of aerosols. At the proposed end-use concentrations in cosmetic products the risk of aspiration hazard cannot be ruled out. Therefore cosmetic products containing the notified chemicals should be formulated in a manner that addresses the aspiration hazard of the notified chemicals, to prevent any risks from aspiration. Local and systemic effects from acute or repeated exposure are not expected.

The notified chemicals are liquid hydrocarbons. Liquid hydrocarbons are included in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), with packaging/labelling requirements for products containing liquid hydrocarbons available to the public.

Therefore, when used in the proposed manner with appropriate labelling and recommendation for formulators, the notified chemicals are not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemicals will be introduced into Australia in their neat form for reformulation into cosmetic products. In general, the reformulation processes are expected to involve blending operations that will be highly automated and occur in an enclosed system, followed by automated filling of the finished products into end-use containers. Waste generated during the reformulation process is expected to be disposed of in accordance with local government regulations. Release of the notified chemicals to the environment in the event of accidental spills or leaks during reformulation, storage and transport is expected to be absorbed on suitable materials and disposed of to landfill in accordance with local government regulations. The notifier estimated up to 1% of the import volume of the notified chemicals may remain as residue in empty import containers, which are expected to be disposed of, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE
The majority of the notified chemicals are expected to be released to sewers across Australia as a result of its use in cosmetics, which are washed off hair and skin of consumers.

RELEASE OF CHEMICAL FROM DISPOSAL
The notifier estimated up to 3% of the import volume of the notified chemicals may remain as residue in empty end-use containers. The notified chemical residuals are likely to either share the fate of the containers and be disposed of to landfill, or be released to the sewer system when containers are rinsed before recycling through an approved waste management facility.

7.1.2. Environmental Fate

The majority of the notified chemicals are expected to enter sewers across Australia as a result of its use in cosmetics. The biodegradation in seawater tests conducted on the notified chemicals (80-83% degradation over 28 days in OECD 306 tests) indicate that they would also likely to be biodegradable in sewage treatment plants (STPs). The notified chemicals are expected to sorb significantly to sludge at sewage treatment plants (STPs) based on its estimated low water solubility (0.0001-0.0033 mg/L) and high partition coefficient (log P_{ow} = 7.63-9.11). As a result, the notified chemicals are expected to be effectively removed at STPs through biodegradation and adsorption to sludge before potential release to surface waters nationwide. A proportion of the notified chemicals may be applied to land when effluent is used for irrigation or when sewage sludge is used for soil remediation, or disposed of to landfill. The notified chemical residues in sludge, landfill and soils are expected to have very low mobility based on their estimated high soil adsorption coefficient (log K_{oc} = 5.17-6.62). In the aquatic and soil compartments, the notified chemicals are expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume the worst case scenario with 100% release of the notified chemicals into sewer systems nationwide over 365 days per annum. It is also assumed under the worst-case scenario that there is no removal of the notified chemicals during sewage treatment processes. The resultant PEC for each of the notified chemicals in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	100,000	kg/year
Proportion expected to be released to sewer	100	%
Annual quantity of chemical released to sewer	100,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	273.97	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	24.386	Million
Removal within STP	0	%
Daily effluent production:	4,877	ML
Dilution Factor – River	1	
Dilution Factor – Ocean	10	
PEC – River:	56.18	µg/L
PEC – Ocean:	5.62	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m^2/year (10 ML/ha/year). The notified chemicals in this volume are assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 56.18 µg/L may potentially result in a soil concentration of approximately 0.37 mg/kg. Due to the notified chemicals biodegradability, annual accumulation is not expected.

7.2. Environmental Effects Assessment

The results from ecotoxicological studies conducted on acceptable analogues of the notified chemicals are summarised in the table below. The endpoints are based on nominal Water Accommodated Fraction (WAF) concentrations. Details of studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity of Analogue chemical 3	96h EC50 > 1,028 mg WAF/L	Not harmful to fish up to water solubility limit
Acartia tonsa Toxicity of Analogue chemical 3	48h EC50 > 69,155 mg WAF/L	Not harmful to aquatic invertebrates up to water solubility limit
Algal Toxicity of Analogue chemical 3	72h EC50 > 3,200 mg WAF/L	Not harmful to alga up to water solubility limit
Inhibition of Bacterial Respiration of Analogue chemical 1	3h IC50 > 1,000 mg/L	Not inhibitory to microbial respiration at sewage treatment plants

Based on the above ecotoxicological endpoints for acceptable analogues, the notified chemicals are not expected to be harmful to aquatic life up to the limit of their water solubility under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) for acute and chronic toxicities (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) for the aquatic compartment has not been calculated as the notified chemicals are not expected to be harmful to aquatic organisms up to their water solubility limit.

7.3. Environmental Risk Assessment

A Risk Quotient (PEC/PNEC) has not been calculated as the notified chemicals are not expected to be harmful to aquatic organisms up to their water solubility limit. Therefore, based on the low hazard and the assessed use pattern, the notified chemicals are not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

STD/1669

Pour Point -81 °C

Method	ISO 3016: Petroleum products -- Determination of pour point
Test Facility	Confidential (2018a)

Boiling Point 247 - 269 °C at 101.3 kPa

Method	ISO 3405: Petroleum products -- Determination of distillation characteristics at atmospheric pressure
Test Facility	Confidential (2018b)

Density 776 kg/m^3 at 15 °C

Method	ISO 12185: Crude petroleum and petroleum products -- Determination of density -- Oscillating U-tube method
Test Facility	Confidential (2018c)

Vapour Pressure 2×10^{-3} kPa at 20 °C

Method	Vapour pressure calculated using European Solvents Industry Group (ESIG) VP Tool software
Remarks	ESIG VP tool calculates vapour pressure using test substance data including distillation range (determined using Test Method ISO 3405) and total volume percent of saturates, olefins, and aromatics (determined using Test Method ASTM D1319).
Test Facility	Confidential (2018d)

Flash Point 115 °C

Method	ISO 2719: Determination of flash point -- Pensky-Martens closed cup method
Test Facility	Confidential (2018e)

Autoignition Temperature 193 °C

Method	ASTM E659 - Standard Test Method for Autoignition Temperature of Chemicals
Test Facility	Confidential (2018f)

Kinematic Viscosity 2.5 mm^2/s at 40 °C

Method	ISO 3014: Petroleum products -- Transparent and opaque liquids -- Determination of kinematic viscosity and calculation of dynamic viscosity
Remarks	None
Test Facility	Confidential (2018g)

STD/1670

Pour Point -45 °C

Method	ISO 3016: Petroleum products -- Determination of pour point
Test Facility	Confidential (2018h)

Boiling Point 293 - 324 °C at 101.3 kPa

Method	ISO 3405: Petroleum products -- Determination of distillation characteristics at atmospheric pressure
Test Facility	Confidential (2018i)

Density 787 kg/m^3 at 15 °C

Method	ISO 12185: Crude petroleum and petroleum products -- Determination of density -- Oscillating U-tube method
Test Facility	Confidential (2018j)

Vapour Pressure 1×10^{-3} at 20 °C

Method	Vapour pressure calculated using European Solvents Industry Group (ESIG) VP Tool software
Remarks	ESIG VP tool calculates vapour pressure using test substance data including distillation range (determined using Test Method ISO 3405) and total volume percent of saturates, olefins, and aromatics (determined using Test Method ASTM D1319).
Test Facility	Confidential (2018k)

Flash Point 149 °C

Method	ISO 2719: Determination of flash point -- Pensky-Martens closed cup method
Test Facility	Confidential (2018l)

Autoignition Temperature 204 °C

Method	ASTM E659 - Standard Test Method for Autoignition Temperature of Chemicals
Test Facility	Confidential (2018m)

Kinematic Viscosity 3.9 mm^2/s at 40 °C

Method	ISO 3014: Petroleum products -- Transparent and opaque liquids -- Determination of kinematic viscosity and calculation of dynamic viscosity
Test Facility	Confidential (2018l)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute Oral Toxicity – Rat

TEST SUBSTANCE	Analogue chemical 1
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method
Species/Strain	Rat/Sprague-Dawley CD
Vehicle	None
Remarks – Method	No significant protocol deviations

RESULTS

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

LD50	> 2,000 mg/kg bw
Signs of Toxicity	No clinical signs of toxicity were observed. All animals gained weight over the 14 day observation period.
Effects in Organs	None
CONCLUSION	The notified chemical is of low acute toxicity via the oral route.
TEST FACILITY	Confidential (2005)

B.2. Acute Dermal Toxicity – Rat

TEST SUBSTANCE	Analogue chemical 1
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 protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	5M/5F	2,000	0/10

LD50	> 2,000 mg/kg bw
Signs of Toxicity – Local	No irritation was noted in males. Hyperkeratinisation or crust formation was observed in females throughout the observation period, with scabs observed in some females. The study authors note that the scabs may have been attributed to the animals scratching the treatment site. The authors further note the observations in females may be due to a drying/defatting effect of the test substance.
Signs of Toxicity – Systemic	None
Effects in Organs	None
Remarks – Results	The use of semi-occlusive dressing may have resulted in loss of the applied test substance through volatilisation.
CONCLUSION	The notified chemical is of low acute toxicity via the dermal route.
TEST FACILITY	Confidential (2006a)

B.3. Skin Irritation – *In Vitro* Reconstructed Human Epidermis Model

TEST SUBSTANCE	Notified chemical (STD1669)
METHOD	OECD TG 439 *In vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method
Vehicle	None
Remarks – Method	No significant protocol deviations. The EpiSkin test system was used. Standard MTT assay was used to determine cell viability. The test substance (10 µL) was applied to the tissues in triplicate. The tissues were incubated for 42 hours at 37 °C following an exposure period of 15 minutes. Positive and negative controls were run in parallel with the test substance: – Negative control (NC): Phosphate buffered saline with Ca^{2+} and Mg^{2+} – Positive control (PC): sodium dodecyl sulphate (5% in sterile water)

RESULTS

Test Material	*Mean OD_{570} of Triplicate Tissues*	*Relative Mean Viability (%)*	*SD of Relative Mean Viability*
Negative control	0.728	100	3.9
Test substance	0.675	92.8	7.3
Positive control	0.126	17.4	3.7

OD = optical density; SD = standard deviation

Remarks – Results	The test substance did not show any chemically reducing properties of MTT. The criteria for acceptance of both the negative and positive controls were satisfied, as were the requirements for standard deviation between the replicates. As the mean tissue viability was > 50%, the test substance is considered a non-irritant under the conditions of the test.
CONCLUSION	Based on the mean tissue viability of > 50%, the notified chemical is not classified as a skin irritant according to the GHS criteria.
TEST FACILITY	Confidential (2016a)

B.4. Skin Irritation – *In Vitro* Episkin Reconstructed Human Epidermis Model

TEST SUBSTANCE	Notified chemical (STD1670)
METHOD	OECD TG 439 *In vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method
Vehicle	None
Remarks – Method	No significant protocol deviations. The EpiSkin test system was used. Standard MTT assay was used to determine cell viability. The test substance (10 µL) was applied to the tissues in triplicate. The tissues were incubated for 42 hours at 37 °C following an exposure period of 15 minutes.

Positive and negative controls were run in parallel with the test substance:
- Negative control (NC): Phosphate buffered saline with Ca^{2+} and Mg^{2+}
- Positive control (PC): sodium dodecyl sulphate (5% in sterile water)

RESULTS

Test Material	*Mean OD_{570} of Triplicate Tissues*	*Relative Mean Viability (%)*	*SD of Relative Mean Viability*
Negative control	0.728	100	3.9
Test substance	0.677	93.1	3.8
Positive control	0.126	17.4	3.7

OD = optical density; SD = standard deviation

Remarks – Results The test substance did not show any chemically reducing properties of MTT.

The criteria for acceptance of both the negative and positive controls were satisfied, as were the requirements for standard deviation between the replicates.

As the mean tissue viability was > 50%, the test substance is considered a non-irritant under the conditions of the test.

CONCLUSION Based on the mean tissue viability of > 50%, the notified chemical is not classified as a skin irritant according to the GHS criteria.

TEST FACILITY Confidential (2016b)

B.5. Skin Irritation – *In Vitro* Reconstructed Vaginal Mucosa

TEST SUBSTANCE Notified chemical (STD1669)

METHOD Not a guideline study

Vehicle None

Remarks – Method The test substance (30 µL) was applied to the epitheliums in duplicate. Following an exposure periods of 10±1 minutes and 1 hour±5 minutes at room temperature, the epitheliums were rinsed in PBS and then incubated in fresh medium for 3±1 hours. The tissues were then treated with MTT and incubated for 1 hour ±10 minutes. Following extraction, the optical densities were determined (570 nm).

Positive and negative controls were run in parallel with the test substance:
- Negative control: 0.9% sodium chloride in sterile water
- Positive control: 1.5% sodium dodecyl sulphate sterile water

RESULTS

Test Material	*Contact time point*	*Mean OD_{570} of Duplicate Tissues*	*Relative Viability (%)*
Negative control	180	0.996	100
Test substance	10	1.261	126.6
	60	1.040	104.4
	180	0.987	99.1
Positive control	10	0.79	79.3
	60	0.045	4.5

Remarks – Results The positive and negative controls gave satisfactory results, confirming the validities of the test systems.

CONCLUSION The notified chemical was not considered a skin irritant under the conditions of the test.

TEST FACILITY Confidential (2016c)

B.6. Skin Irritation – *In Vitro* Reconstructed Vaginal Mucosa

TEST SUBSTANCE Notified chemical (STD1670)

METHOD Not a guideline study
Vehicle None
Remarks – Method The test substance (30 µL) was applied to the epitheliums in duplicate. Following an exposure periods of 10±1 minutes and 1 hour±5 minutes at room temperature, the epitheliums were rinsed in PBS and then incubated in fresh medium for 3±1 hours. The tissues were then treated with MTT and incubated for 1 hour ±10 minutes. Following extraction, the optical densities were determined (570 nm).

Positive and negative controls were run in parallel with the test substance:
- Negative control: 0.9% sodium chloride in sterile water
- Positive control: 1.5% sodium dodecyl sulphate sterile water

RESULTS

Test Material	*Contact time point*	*Mean OD_{570} of Duplicate Tissues*	*Relative Viability (%)*	*SD of Relative Viability*
Negative control	180	0.996	100	0.017
Test substance	10	1.166	117	0.029
	60	1.075	107.9	0.035
	180	1.027	103.1	0.029
Positive control	10	0.79	79.3	0.107
	60	0.045	4.5	0.001

OD = optical density; SD = standard deviation

Remarks – Results The positive and negative controls gave satisfactory results, confirming the validities of the test systems.

CONCLUSION The notified chemical was not considered a skin irritant under the conditions of the test.

TEST FACILITY Confidential (2016d)

B.7. Skin Compatibility – Human Volunteers

TEST SUBSTANCE Notified chemical (STD1669) (tested at 60% concentration)

METHOD Single Patch Test (In-house method)
Study Design Patches containing 0.02 mL test substance (60% in Vaseline) were applied under occlusive conditions once for ~ 48 hours on 21 subjects. Thirty minutes after the removal of patches, skin reactions were graded by comparing with the negative control.

Irritation potential of the test substance was determined based on the Primary Cutaneous Index (PCI). The PCI was the mean of the weighted sum of scoring obtained on the whole subjects (erythema: factor 1, oedema: factor 2, dryness, detergent effect, reflectivity: 0.5).

Study Group 20 subjects (sex not specified); age range 18-70 years
Vehicle Vaseline

Remarks – Method	Occlusive. The test substance was spread on a 5 cm × 5 cm patch.
RESULTS	
Remarks – Results	One subject had a history of atopy and this equates to ~5% of the subjects (maximum limit is 25%). All subjects completed the study. One subject showed moderate (grade 2) erythema and slight oedema (grade 1) and another 9 subjects showed slight (grade 1) erythema. The PCI was determined by the study authors as 0.71.
CONCLUSION	The notified chemical at 60% concentration showed good skin compatibility under the conditions of the test.
TEST FACILITY	Confidential (2016e)

B.8. Skin Compatibility – Human Volunteers

TEST SUBSTANCE	Notified chemical (STD1670) (tested at 60% concentration)
METHOD	Single Patch Test (In-house method)
Study Design	Patches containing 0.02 mL test substance (60% in Vaseline) were applied under occlusive conditions once for ~ 48 hours. Thirty minutes after the removal of patches, skin reactions were graded by comparing with the negative control (patch with a filter paper disc and Vaseline). Irritation potential of the test substance was determined based on the Primary Cutaneous Index (PCI). The PCI was the mean of the weighted sum of scoring obtained on the whole subjects (erythema: factor 1, oedema: factor 2, dryness, detergent effect, reflectivity: 0.5).
Study Group	21 subjects (sex not specified); age range 18-70 years
Vehicle	Vaseline
Remarks – Method	The test substance was spread over a 50 mm^2 area (occlusive patch "Small Finn Chambers on Scanpor".
RESULTS	
Remarks – Results	All subjects completed the study. Slight (grade 1) erythema was observed in two subjects. No skin reactions were observed in the remaining subjects. The PCI was determined by the study authors to be 0.1.
CONCLUSION	The notified chemical at 60% concentration showed good skin compatibility under the conditions of the test.
TEST FACILITY	Confidential (2016f)

B.9. Eye Irritation – *In Vitro* BCOP Test

TEST SUBSTANCE	Notified chemical (STD1669)
METHOD	OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants
Vehicle	None
Remarks – Method	Positive and negative controls were run in parallel with the test substance: Negative control: 0.9% sodium chloride in sterile water Positive control: 10% sodium hydroxide in sterile water

RESULTS

Test Material	*Mean Opacities of Triplicate Tissues (SD)*	*Mean Permeabilities of Triplicate Tissues (SD)*	*IVIS (SD)*
Vehicle control	0.3 (0.6)	0.011 (0.007)	0.5
*Test substance**	-0.3 (0.0)	-0.003 (0.001)	0.0
*Positive control**	122.7 (2.0)	7.059 (0.091)	228.6 (2.7)

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

Remarks – Results	The negative and positive controls gave satisfactory results confirming the validity of the test system. The IVIS for the test substance was ≤ 3.
CONCLUSION	The notified chemical was not considered an eye irritant under the conditions of the test.
TEST FACILITY	Confidential (2016g)

B.10. Eye Irritation – *In Vitro* BCOP Test

TEST SUBSTANCE	Notified chemical (STD1670)
METHOD	OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants
Vehicle	None
Remarks – Method	Positive and negative controls were run in parallel with the test substance: Negative control: 0.9% sodium chloride in sterile water Positive control: 10% sodium hydroxide in sterile water

RESULTS

Test Material	*Mean Opacities of Triplicate Tissues (SD)*	*Mean Permeabilities of Triplicate Tissues (SD)*	*IVIS (SD)*
Vehicle control	0.3 (0.6)	0.011 (0.007)	0.5
*Test substance**	0.0 (0.6)	0.004 (0.003)	0.1 (0.6)
*Positive control**	122.7 (2.0)	7.059 (0.091)	228.6 (2.7)

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

Remarks – Results	The negative and positive controls gave satisfactory results confirming the validity of the test system. The IVIS for the test substance was ≤ 3.
CONCLUSION	The notified chemical was not considered an eye irritant under the conditions of the test.
TEST FACILITY	Confidential (2016h)

B.11. Skin Sensitisation – *In Vitro* SENS-IS Test

TEST SUBSTANCE	Notified chemical (STD1669)
METHOD	Non-guideline study
Vehicle	Olive oil
Remarks – Method	In a non-guideline sensitisation/irritation study, 100%, 50% and 10% of the test substance (30 µl) was applied onto reconstituted epidermis (Episkin). After 15 minutes exposure, the Episkin were rinsed with potassium buffer

solution (PBS) and incubated at 37 °C for 6 hours. Following incubation, the Episkin was placed in RNAzol solution and the total RNA was isolated by homogenisation of the Episkin. Following reverse transcription, quantitative gene expression was measured.

The test substance is considered an irritant if it induces the overexpression of at least 15 genes among a group of 23 genes named IRRITATION.

The test substance is considered a sensitiser if it induces the over expression of at least 7 genes in either or both of two groups of 21 and 17 genes named SENS-IS (gathers biomarkers of sensitisation genes) and REDOX (gathers oxidative stress response genes), respectively. A test substance is classified as extreme, strong, moderate or weak sensitiser if found positive at 0.1%, 1%, 10% or 50%, respectively.

Negative controls: dimethyl sulfoxide (DMSO)
Positive control: 5% sodium lauryl sulfate (SLS) (for irritation study)
1% 2,4,6-trinitrobenzene sulfonic acid (TNBS) (for sensitisation study)

RESULTS

Following are the results of the number of genes over expressed in the 3 different groups (IRRITATION, SENS-IS and REDOX). Three tests were performed for the positive and negative controls.

Sample	*Concentration (%)*	*IRRITATION*	*SENS-IS*	*REDOX*
Negative Control	100	6, 9, 6	2, 3, 1	2, 2, 1
Test substance				
Dose Level 1	10	6	4	1
Dose Level 2	50	3	2	1
Dose Level 3	100	4	2	4
Positive control				
5% SLS	5	**23, 22, 23**	5, 1, 1	5, 4, 2
1% TNBS	1	8, 16, 11	3, 3, 4	**11, 12, 14**

Remarks – Results

At all tested concentrations the notified chemical was a non-irritant (the number of irritant genes overexpressed was < 15) and a non-sensitiser (the number of genes overexpressed in both the SENS-IS or the REDOX group was below 7).

The results of the positive and negative controls confirmed the validity of the test system.

CONCLUSION

The notified chemical was not considered a skin irritant or skin sensitiser under the conditions of the test.

TEST FACILITY

Confidential (2016i)

B.12. Skin Sensitisation – Human Volunteers (HRIPT)

TEST SUBSTANCE

Notified chemical (STD 1669) (tested at 50% concentration)

METHOD

Repeat Insult Patch Test (Shelanski Method)

Study Design

Induction procedure: Test substance in 50% Vaseline was applied to the upper back (between the scapulae and the waist to either side of the spinal midline) and allowed to remain in direct skin contact for 24 hours for a total of 113 subjects. Patches were applied on the same site on Monday, Wednesday and Friday for a total of 9 applications. Twenty four hours after the removal of patches by the subjects on Tuesday and Thursday and 48 hours after removal of the patches on Saturday, skin reactions were graded by a technician.

	Rest period: 10-21 days Challenge procedure: ~10-21 days after induction phase, challenge patches were applied to previously untreated test sites on the back of the subjects. The patches were removed by a technician 24 hours after the removal of patches and skin reactions were evaluated. The test sites were re-evaluated at 48 and 72 hours after the application. Subjects exhibiting reactions during challenge phase may have been asked to return for 96 hour evaluation.
Study Group	27 M and 86 F; age range 18-70 years.
Vehicle	Vaseline
Remarks – Method	Semi-occlusive method. The patch size or amount applied was not specified. Five subjects discontinued the study for reasons unrelated to the test material. Two subjects did not attend a challenge assessment (one at 24 hour and another at 48 hour challenge). However these subjects did attend a challenge assessment 96 hours after application.
RESULTS	
Remarks – Results	One hundred and eight subjects completed the study. One subject had mild erythema at the 72 and 96 hour assessment. No other skin reactions were observed during the study.
CONCLUSION	The notified chemical at 50% concentration was non-sensitising under the conditions of the test.
TEST FACILITY	Confidential (2016j)

B.13. Skin Sensitisation – Human Volunteers (HRIPT)

TEST SUBSTANCE	Notified chemical (STD 1669) (tested at 50% concentration)
METHOD	Repeat Insult Patch Test (Shelanski Method)
Study Design	Induction procedure: Test substance in 50% Vaseline was applied to the upper back (between the scapulae and the waist to either side of the spinal midline) and allowed to remain in direct skin contact for 24 hours for a total of 123 subjects. Patches were applied on the same site on Monday, Wednesday and Friday for a total of 9 applications. Twenty four hours after the removal of patches by the subjects on Tuesday and Thursday and 48 hours removal of the patches on Saturday, skin reaction was graded by a technician. Rest period: 10-21 days Challenge procedure: ~10-21 days after induction phase, challenge patches were applied to previously untreated test sites on the back. The patches were removed by a technician 24 hours after the removal of patches and skin reactions were evaluated. The test sites were re-evaluated at 48 and 72 hours after the application. Subjects exhibiting reactions during challenge phase may have been asked to return for 96 hour evaluation.
Study Group	37 M and 86 F; age range 18-70 years.
Vehicle	Vaseline
Remarks – Method	Occlusive method. The patch size or amount applied was not specified. Twenty six subjects discontinued the study for reasons unrelated to the test material. Three subjects were replaced. One subject did not attend the 48 hour challenge assessment, but attended the 72 hour assessment.
RESULTS	
Remarks – Results	Ninety seven subjects completed the study. No skin reactions were observed during the study.
CONCLUSION	The notified chemical at 50% concentration was non-sensitising under the

conditions of the test.

TEST FACILITY Confidential (2016k)

B.14. Skin Sensitisation – Human Volunteers (HRIPT)

TEST SUBSTANCE Notified chemical (STD 1670) (tested at 50% concentration)

METHOD Repeat Insult Patch Test (Shelanski Method)

Study Design: Induction procedure: Test substance in 50% Vaseline was applied to the upper back (between the scapulae and the waist to either side of the spinal midline) and allowed to remain in direct skin contact for 24 hours for a total of 113 subjects. Patches were applied on the same site on Monday, Wednesday and Friday for a total of 9 applications. Twenty four hours after the removal of patches by the subjects on Tuesday and Thursday and 48 hours removal of the patches on Saturday, skin reaction was graded by a technician.
Rest period: 10-21 days
Challenge procedure: ~10-21 days after induction phase, challenge patches were applied to previously untreated test sites on the back. The patches were removed by a technician 24 hours after the removal of patches and skin reactions were evaluated. The test sites were re-evaluated at 48 and 72 hours after the application. Subjects exhibiting reactions during challenge phase may have been asked to return for 96 hour evaluation.

Study Group: 27 M and 86 F; age range 18-70 years.

Vehicle: Vaseline

Remarks – Method: Semi-occlusive method. The patch size or amount applied was not specified. Five subjects discontinued the study for reasons unrelated to the test material. Two subjects did not attend a challenge assessment (one at 24 hour and another at 48 hour challenge). However these subjects did attend a challenge assessment 96 hours after application.

RESULTS

Remarks – Results: One hundred and eight subjects completed the study.

No skin reactions were observed during the study.

CONCLUSION The notified chemical at 50% concentration was non-sensitising under the conditions of the test.

TEST FACILITY Confidential (2016l)

B.15. Repeat Dose Dermal Toxicity – Rats

TEST SUBSTANCE Analogue chemical 2

METHOD Similar to OECD TG 411 Subchronic Dermal Toxicity: 90-day Study

Species/Strain: Rats/Sprague-Dawley (CD)

Route of Administration: Dermal –non-occluded

Exposure Information: Total exposure days: 65 days
Dose regimen: 5 days per week
Duration of exposure (dermal): 6 hours/day
Post-exposure observation period: 28 days

Vehicle: Mineral oil

Remarks – Method: No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw/day)*	*Mortality*
Control	12M/12F	0	0/24

Low Dose	12M/12F	165	0/24
Mid Dose	12M/12F	330	0/24
High Dose	12M/12F	495	0/24
Control Recovery	12M/12F	0	0/24
High Dose Recovery	12M/12F	0	0/24

Mortality and Time to Death
No unscheduled mortalities occurred during the study.

Clinical Observations
Low, mid and high dose males showed erythema (mean scores of 0.17, 0.5 and 1.33, respectively) on Day 4. High dose males on Day 5 and females on Day 6 showed a mean score of 2 and 1.33, respectively. The study authors stated that these were the highest scores obtained during the study and indicate very slight to well defined erythema (data not provided). Very slight oedema was observed in high dose males (mean score 0.33) and females (mean score 0.04) on Day 10. Skin irritation receded as the study progressed. After the second week, no group mean erythema score exceeded 1.0 and no sign of oedema was observed after week 5.

Alopecia, abrasions/lesions and red eye discharge were observed (no further details provided) during dosing. The study authors stated that these effects were considered to be incidental and not treatment related.

Laboratory Findings – Clinical Chemistry, Haematology
Following statistically significant changes were observed:

- increase in neutrophils (97% increase than control group) in high dose females
- decreased in haematocrit values in high dose males
- increase mean corpuscular haemoglobin concentration values on Day 90
- changes in serum chemistry values in all treated groups
- increase in sorbitol dehydrogenase in mid dose males (on Day 90) and high dose recovery males (on Day 120)
- increase in chloride values on Day 90 in high dose males
- increase in sodium values in mid and high dose females on Day 90
- reduction in total protein, albumin and calcium in high dose recovery females on Day 120

Data was provided for neutrophil values only. The increase in the neutrophil count in high dose females was considered by the study authors to be treatment related. However given the relatively small increase the study authors did not consider this finding to be of toxicological significance. All other differences were considered by the study authors to be incidental to treatment based on the lack of a dose response, the small magnitude of difference, or biologically insignificant changes.

Effects in Organs
Statistically significant increase in spleen-to-body weight and spleen-to-brain weight in high dose females compare to control group was observed. The recovery high dose females also showed statistically significant increase in absolute spleen weight than control group. The study authors stated no relevant adverse histopathological findings were observed in the spleen, therefore these effects were not considered to be treatment related.

Remarks – Results
The test substance caused minimal skin irritation and no apparent target organ toxicity. There was no apparent test substance-related effects on neurobehavioral parameters and no gross or microscopic changes in peripheral or central nervous system tissues were observed. The haematological results did not indicate any test substance related effects with the possible exception of the neutrophil count in high dose females. However, the study authors did not consider this finding to be of toxicological significance given the relatively small increase.

CONCLUSION
The NOAEL was established by the study authors as > 495 mg/kg bw/day in this study, based on the absence of treatment related effects up to the highest dose tested.

TEST FACILITY Confidential (2014)

B.16. Genotoxicity – Bacteria

TEST SUBSTANCE	Notified chemical (STD1669)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test (1997) Pre incubation procedure
Species/Strain	*Salmonella typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	S9 mix from Aroclor1254-induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 0.46, 1.37, 4.11, 12.35, 37.05, 111.11, 333.33, 1,000, 2,000 and 4,000 µg/plate b) Without metabolic activation: 0.46, 1.37, 4.11, 12.35, 37.05, 111.11, 333.33, 1,000, 2,000 and 4,000 µg/plate
Vehicle	Ethanol
Remarks – Method	Negative control: ethanol Positive control: with S9-mix: 2-aminoanthracene (TA1535, TA1537, TA98 and TA100) and benzo(a)pyrene (TA102) without S9-mix: methylnitronitosoguanidine (TA1535 and TA100); 9-aminoacridine (TA1537); 2-nitro fluorene (TA98) and mitomycin C (TA102). Preliminary toxicity test was not conducted.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	-	> 4,000	> 4,000	negative
Test 2	-	> 4,000	> 4,000	negative
Present				
Test 1	-	> 4,000	> 4,000	negative
Test 2	-	> 4,000	> 4,000	negative

Remarks – Results	For tester strain TA102 a statistically significant increase in the number of revertants was noted at a dose of 1.37 µg/plate. However, this was not considered biologically significant by the study authors as the increase in revertants was within the historical control data and no dose response relationship was observed. For the remaining tester strains used in the study, no statistically or biologically relevant increases in the number of revertants were observed during the test, in either the presence or absence of metabolic activation. For the positive controls, statistically and biologically relevant increases in the number of revertants were noted, indicating the validity of the test system.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Confidential (2016m)

B.17. Genotoxicity – *In Vitro* Mammalian Cell Micronucleus Test

TEST SUBSTANCE	Notified chemical (STD1669)
METHOD	OECD TG 487 *In vitro* Mammalian Cell Micronucleus Test (2014)
Species/Strain	Human
Cell Type/Cell Line	TK6/Lymphoblastoid
Metabolic Activation System	S9 mix from Aroclor1254-induced rat liver

Vehicle	Ethanol
Remarks – Method	Preliminary test was not conducted. Negative control: ethanol Positive control: with S9-mix: cyclophosphamide without S9-mix: mitomycin C and Griseofulvin (27-hour treatment only)

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0.24, 0.49, 0.98, 1.95, 3.91, 7.81, 15.63, 31.25, 62.5, 125*, 250* and 500*	3 h	27 h
Test 2	0.24, 0.49, 0.98, 1.95, 3.91, 7.81, 15.63, 31.25, 62.5, 125*, 250* and 500*	27 h	27 h
Present			
Test 1	0.24, 0.49, 0.98, 1.95, 3.91, 7.81, 15.63, 31.25, 62.5, 125*, 250* and 500*	3 h	27 h
Test 2	250*, 375*, 500*, 750* and 1000*	3 h	27 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*		
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Genotoxic Effect*
Absent			
Test 1	-	> 500	negative
Test 2	-	> 500	negative
Present			
Test 1	-	> 500	negative
Test 2	-	> 1,000	negative

Remarks – Results

Statistically significant increase in the number of micronucleated cells (10 out of 2,000 mononucleated cells, whereas 2 out of 2,000 cells in the negative control) treated at 500 µg/mL of the test substance was observed in Test 1 (with S9). This value was above the historical control data (which is 3.71-4.97). The study authors stated that the increase may due to the low number of micronucleated cells in the negative control. As no dose response was observed, it was not considered biologically significant. Furthermore, a confirmatory test (Test 2 with S9) conducted at a concentration range of 250-1,000 µg/mL did not show a statistically or biologically significant increase in the number of micronucleated cells.

Apart from this observation, the test substance did not induce a statistically or biologically significant increase in the number of micronucleated cells at all other test concentrations in each exposure group, with or without metabolic activation.

The positive controls behaved as expected, confirming the validity of the test system

CONCLUSION

The notified chemical was not genotoxic to human lymphoblastoid cells treated *in vitro* under the conditions of the test.

TEST FACILITY

Confidential (2016n)

B.18. Reproductive toxicity – two generation study

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 416 Two-Generation Reproduction Toxicity
Species/Strain	Rat/Wistar
Route of Administration	Oral – gavage
Exposure Information	Exposure period: approximately 11-18 weeks
Vehicle	Arachis Oil BP
Remarks – Method	In a preliminary range-finding study, rats (3/sex/dose) were administered the test substance by gavage for 21-days at 0, 200, 600 or 1000 mg/kg bw/day. There were no treatment-related clinical signs of toxicity or effects on body weight gain. There were no treatment-related findings reported at necropsy. In the main study, parental (P) generation rats (28/sex/dose) were administered the test substance by gavage at 0, 50, 250 or 1000 mg/kg bw/day for 18 weeks. A subset of the P generation (10/sex/dose) was subject to examinations, which included functional observations (behavioural, functional performance tests and sensory reactivity), body weight and feed consumption. Ophthalmological examination was conducted pre-treatment and again at week 10, and haematology and clinical chemistry analyses, and histopathological analyses, were conducted during week 11 of the study. Animals were paired and mated at week 11 until pregnancy was detected. The litters were maintained until weaning on day 21 postpartum, followed by culling to the F1 generation (24/sex/dose). Remaining F1 pups and the P generation females were sacrificed and subject to necropsy at this time. All P generation males were terminated during week 18. Selected tissues were subject to histopathological examination and epididymal spermatozoa were analysed for performance. Following weaning, the F1 pups were administered appropriate doses of the test substance for 11 weeks before mating. Subsequent F2 litters were maintained before study completion on day 21 postpartum. Histopathological analyses were conducted on P and F1 parental animals.

RESULTS

Mortality and Time to Death

There were no treatment related mortalities during the study. Incidental deaths (that were considered by the study authors to be unrelated to treatment) included one P generation male treated at 250 mg/kg bw/day which was found dead on day 76 and one P generation female treated at 25 mg/kg bw/day which was killed *in extremis* on day 106 following complete litter loss and signs of poor health.

Subchronic study

There were no mortalities in the subchronic groups. Clinical observations included increased salivation post-dosing in animals treated at 250 and 1000 mg/kg bw/day and red/brown staining around the mouth in the animals treated at 1000 mg/kg bw/day. These effects were attributed by the study authors to gavage administration of an unpleasant tasting and/or irritant test material. There were no treatment related observations in behavioural, functional or sensory reactivity assessments.

There were no treatment related effects on bodyweight gains. Mean food consumption was statistically significantly increased during weeks 7, 8 and 10 in males treated at 1000 mg/kg bw/day. Additionally, there were some statistically significant increases in mean water consumption in males treated at 250 and 1000 mg/kg bw/day.

There were statistically significant increases in neutrophil counts in males treated at 250 and 1000 mg/kg bw/day (↑81% and ↑71%, respectively). There was a statistically significant decrease in alkaline phosphatase levels in females treated at 1000 mg/kg bw/day (↓47%). The relevance of these effects is unclear, but these are unlikely to be treatment related in the absence of associated pathological findings.

There was a statistically significant increase in the relative liver weights in males treated at 1000 mg/kg bw/day (↑13%). Histopathological findings in the liver (females only) included minimal to slight generalised hepatocyte enlargement (hypertrophy), particularly in animals treated at 250 and 1000 mg/kg bw/day. These changes were not considered to be of toxicological concern based on the lack of associated effects.

There were globular accumulations of eosinophilic material in the tubular epithelium in all males treated at 1000 mg/kg bw/day, with minimal occurrences at 50 and 250 mg/kg bw/day. The study authors note that this effect is consistent with hydrocarbon nephropathy, resulting from excessive accumulation of α2-microglobulin and that humans do not synthesise this protein. The presence of α2-microglobulin was confirmed by Mallory Heidenhain staining. In the absence of degenerative changes, this finding was not considered by the study authors to represent an adverse effect of treatment.

Effects on Parental (P) and F1 Generation Animals
Effects were similar in P and F1 animals. Clinical observations were similar to the subchronic groups (salivation and red/brown staining around the mouth). There were no treatment-related effects on bodyweight gains. Feed consumption increases were observed in both generations and in both sexes treated at 1000 mg/kg bw/day with statistical significance at some observation points. Mean water intake was also statistically significantly increased, mostly in the 1000 mg/kg bw/day groups.

There were no treatment related changes to oestrous cycle. There was a slight non-statistically significant decrease in pregnancy rate in P generation animals treated at 1000 mg/kg bw/day, but this was not considered to be treatment related as there was no change in the F1 generation.

Pre-implantation losses were increased in the F1 generation treated at 250 and 1000 mg/kg bw/day, and post-implantation losses were increased in the F1 generation in the 1000 mg/kg bw/day group. These increases were not statistically significant and were of a similar rate to that of the controls in the P generation. Mating and pregnancy indices, gestation length, the number of litters per treatment level, total number of corpora lutea and implantation sites, litter size, live birth, and viability indices, and sex ratio were all similar to control groups.

There was an increase in the homogenisation resistant testicular spermatid counts in males treated at 1000 mg/kg bw/day in the F1 generation (↑49%), but this was not considered by the study authors to be toxicologically significant due to the lack of associated changes to reproductive performance. There were no treatment related effects in the proportion of pre-antral, antral and pre-ovulatory phases of follicular development.

Statistically significant increases in relative liver weights were observed in both generations in males treated at 1000 mg/kg bw/day. A statistically significant increase in absolute spleen weights in P generation males treated at 1000 mg/kg bw/day was not considered by the study authors to be treatment related due to the lack of an increase in the F1 generation and the lack of associated histopathological findings.

Statistically significant increases in the incidence of generalised hepatocyte enlargement (hypertrophy) was observed in P and F1 females treated at 1000 mg/kg bw/day, and in P generation females treated at 250 mg/kg bw/day. In the kidney, globular accumulation of eosinophilic material in the tubular epithelium was noted (α2-microglobulin presence confirmed by Mallory-Heidenhain staining). This effect primarily occurred in P and F1 generation males treated at 1000 mg/kg bw/day, with minimal observations at 50 and 250 mg/kg bw/day. The study authors note the absence of other, more severe effects in the kidney.

Effects on Pups (F1 and F2)
There were no treatment related clinical signs in pups, and pup body weights and body weight gains were not affected by treatment. Sexual development and ano-genital distance were not significantly affected by treatment. There were no treatment related organ weight changes.

Remarks – Results
Treatment related effects were observed in the liver and kidneys. The effects in the kidneys were not considered adverse due to the absence of associated degenerative changes. In the liver, increased liver weights and

hypertrophy were observed. These effects may be adaptive in nature and were not considered to be adverse based on the lack of associated effects.

CONCLUSION
The NOAEL for reproductive and systemic toxicity was established as > 1,000 mg/kg bw/day, due to the lack of adverse effects at the tested doses.

TEST FACILITY Confidential (2009)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready Biodegradability 1

TEST SUBSTANCE	Notified chemical (STD/1669)
METHOD	OECD TG 306 Biodegradability in Seawater – Closed Bottle Method
Inoculum	Seawater was sampled from coastal water near Oosterscheldedam (approximate latitude of 51.5°N and longitude of 3.9°E), the Netherlands at high tide, and aerated for 7 days.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved oxygen (DO) concentration was determined using an oxygen electrode
Remarks – Method	No major deviations from the test guidelines were reported. The test substance was directly added to the test bottles. A toxicity control was run.

RESULTS

Test Substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	26	7	69
14	60	14	74
21	74	21	80
28	80	28	81

Remarks – Results	All validity criteria for the test were satisfied. The blank respiration did not exceed 30% of the oxygen in the test bottles. The test substance did not cause a reduction in the endogenous respiration and therefore considered to be non-inhibitory to the inoculum. DO in the test bottles was ≥ 2.1 mg/L during the test. The degree of degradation of the test substance after 28 days was 80%.
CONCLUSION	The test substance is biodegradable in seawater.
TEST FACILITY	Confidential (2014a)

C.1.2. Ready Biodegradability 2

TEST SUBSTANCE	Notified chemical (STD/1670)
METHOD	OECD TG 306 Biodegradability in Seawater – Closed Bottle Method
Inoculum	Seawater was sampled from coastal water near Oosterscheldedam, the Netherlands at high tide, and aerated for 7 days.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	DO concentration was determined using an oxygen electrode
Remarks – Method	No major deviations from the test guidelines were reported. The test substance was directly added to the test bottles. A toxicity control was run.

RESULTS

Test Substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	31	7	69
14	71	14	74
21	80	21	80
28	83	28	81

Remarks – Results	All validity criteria for the test were satisfied. The blank respiration did not exceed 30% of the oxygen in the test bottles. The test substance did not cause a reduction in the endogenous respiration and therefore considered to be non-inhibitory to the inoculum. DO in the test bottles was ≥ 2.1 mg/L during the test. The degree of degradation of the test substance after 28 days was 83%.
CONCLUSION	The test substance is biodegradable in seawater.
TEST FACILITY	Confidential (2014b)

C.2. Ecotoxicological Investigations

C.2.1. Acute Toxicity to Fish

TEST SUBSTANCE	Analogue chemical 3
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Semi-static
Species	Juvenile turbot (*Psetta maxima = Scopthalmus maximus*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not determined
Analytical Monitoring	None
Remarks – Method	No major deviations from the test guidelines were reported. Water Accommodated Fraction (WAF) of different loading were prepared by slow mixing of different amount of test substance with dilution water for 20 hours. The mixture was settled for at least 2.5 hours before the WAF were siphoned into individual test vessels. The test medium was renewed after 48 hours. A sensitivity control was run.

RESULTS

Nominal concentration (mg WAF/L)	*Number of Fish*	*Mortality at 96 h*
Control	10	0
27	7	0
66	7	0
165	7	0
410	7	0
1,028	7	0

LC50	> 1,028 mg WAF/L (nominal concentration) at 96 hours
Remarks – Results	All validity criteria for the test were satisfied. During the test, DO was ≥ 85%. The fish evaluated by a sensitivity control series exposed to 0.53 mg/L of 3,5-dichlorophenol showed 20% immobilisation after 96 hours exposure. The fish evaluated by a sensitivity control series exposed to 0.67 mg/L of 3,5-dichlorophenol showed 100% immobilisation after 48 hours exposure.
CONCLUSION	The test substance is not harmful to fish up to its water solubility limit.
TEST FACILITY	Confidential (2002)

C.2.2. Acute Toxicity to Aquatic Invertebrates

TEST SUBSTANCE	Analogue chemical 3
METHOD	UK proposal to ISO TC147/SC5/WG2, Second Draft 1990: Water Quality – Determination of Acute Lethal Toxicity to Marine Copepods.

Species	*Acartia tonsa* (Copepods)
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not determined
Analytical Monitoring	None
Remarks – Method	No major deviations from the test guidelines were reported. WAF of different loading were prepared by slow mixing of different amount of test substance with dilution water for 20 hours. The mixture was settled for 1.5 hours before the WAF were separated by a separatory funnel for 30 minutes. A sensitivity control was run.

RESULTS

Nominal concentration (mg WAF/L)	*Number of Acartia tonsa*	*Number Immobilised at 48 h*
Control	20	1
2,601	20	1
4,378	20	3
7,745	20	3
13,468	20	3
23,461	20	5
41,107	20	10
72,836	20	10

LC50	69,155 mg WAF/L (nominal concentration) at 48 hours
Remarks – Results	All validity criteria for the test were satisfied. DO in the control was 93% after 48 hours exposure. The LC50 value was calculated based on the non-linear model: $Y = aX + blogX + c$ ($R^2 = 0.90$), indicating the proportion of variability in response Y explained by the exposure X. The copepods evaluated by a sensitivity control series exposed to approximately 1 mg/L of 3,5-dichlorophenol showed 70% immobilisation after 48 hours exposure.

CONCLUSION The test substance is not harmful to aquatic invertebrates up to its water solubility limit.

TEST FACILITY Confidential (1998)

C.2.3. Algal Growth Inhibition Test

TEST SUBSTANCE Analogue chemical 3

METHOD NS-EN ISO 10253, 1998: Water Quality – Marine Algal Growth Inhibition Test with *Skeletonema costatum* and *Phaeodactylum tricornutum*.

Species	*Skeletonema costatum*
Exposure Period	72 hours
Concentration Range	Nominal: control, 2.4; 9.7; 32.2; 99.1; 320; 993; 3,200 mg WAF/L
Auxiliary Solvent	None
Water Hardness	Not determined
Analytical Monitoring	None
Remarks – Method	No major deviations from the test guidelines were reported. WAFs were prepared by stirring the test substance in growth medium for 20 hours, followed by standstill for 4 hours. Samples for testing were taken from the middle of the water phase. A reference substance was run.

RESULTS

EC50	> 3,200 mg WAF/L (nominal concentration) at 72 hours
Remarks – Results	All validity criteria for the test were satisfied, the biomass factor increased by 106 times. A significant inhibition of growth rate was observed at 32.2 and 99.1 mg WAF/L; however, it was not dose responsive. The alga

	evaluated by the reference test exposed to 1.5 mg/L 3,5-dichlorophenol showed 21% inhibition after 72 hours exposure.
CONCLUSION	The test substance is not harmful to alga up to its water solubility limit.
TEST FACILITY	Confidential (2006b)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Analogue chemical 1
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 87/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test.
Inoculum	Activated sewage sludge microorganism from local domestic sewage treatment plant
Exposure Period	3 hours
Concentration Range	Nominal: 1000 mg/L
Remarks – Method	Following a range finding test, a limited test was performed at 1000 mg/L in triplicate at 21 ºC with the addition of a synthetic sewage as a respiratory substrate. Lab tap water was sued as the test water after being dechlorinated by passage through an activated carbon filter and partially softened, giving water a total hardness of 1401 mg/L as $CaCO_3$. The notified chemical was dispersed with the aid of ultrasonication in the test diluents for approximately 15 minutes prior to the addition of synthetic sewage, activated sewage sludge and water. Furthermore, each vessel was aerated to ensure that there was maximum contact between the test substance and activated sewage sludge. At the test concentration of 1000 mg/L a thick layer of test substance was visibly dispersed on the surface throughout the exposure period. This was considered to be due to the insoluble nature of the notified chemical in the test media. A blank control and a reference control using 3,5-dichlorophenol were also conducted.
RESULTS	
IC50	> 1000 mg/L (nominal) for 3 hour
NOEC	1000 mg/L (nominal) for 3 hour
Remarks – Results	All the test guideline criteria were met. No significant inhibitory effects were observed for the test group comparing to the control. The notified chemical is not considered to be inhibitory harmful to sludge bacteria based on the test results.
CONCLUSION	The test substance is not inhibitory harmful to sludge bacteria.
TEST FACILITY	Confidential (2006c)

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