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January 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Stearalkonium Bentonite

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

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

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

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Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
STD/1414	Coty Australia Pty Ltd L'Oreal Australia Pty Ltd	Stearalkonium Bentonite	ND*	< 10 tonnes per annum	A component of cosmetic products

* ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the data provided, the notified chemical is not classified as hazardous according to the Approved Criteria for Classifying Hazardous Substances (NOHSC, 2004). However, the notified chemical contains an impurity at up to 5% concentration that has been associated with carcinogenic effects via the inhalation route.

Human health risk assessment
Provided that control measures are in place to minimise worker exposure to the notified chemical, including the use of PPE (particularly respiratory protection), ventilated environments and automated reformulation processes, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

The notified chemical is not considered to pose an unreasonable risk to public health when used in cosmetic products at up to 5% concentration.

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

Recommendations

REGULATORY CONTROLS
Material Safety Data Sheet

- The MSDS of the notified chemical should reflect the presence of the impurity and the potential health hazards associated with it.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following isolation and engineering controls to minimise occupational exposure to the notified chemical during reformulation processes:
  - Enclosed, automated processes, where possible
  - Local exhaust ventilation and/or appropriate dust extraction systems

- Employers should implement the following safe work practices to minimise occupational exposure while handling the notified chemical during reformulation processes:
  - Avoid contact with skin and eyes
  - Use of low-dust handling techniques
  - Ensuring that relevant exposure standards (e.g. for silica or atmospheric dust) are observed

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during reformulation processes:
  - Coveralls, impervious gloves, goggles

- Respiratory protection during manual handling tasks involving the notified chemical (powder form)

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

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Public Health

- Suppliers should ensure that the level of quartz present in the notified chemical is minimised.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

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

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act, if
- the notified chemical is intended to be introduced in a form that meets the NICNAS definition of a nanomaterial;
- the notified chemical is intended to be used in cosmetic products at > 5% concentration;
- further information has become available on the hazard of the quartz impurity in the notified chemical;
- information becomes available on the presence of other forms of crystalline silica as impurities in the notified chemical;
- information becomes available on restrictions on cosmetic products related to crystalline silica impurities in ingredients.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a component in cosmetic products, or is likely to change significantly;
- the amount of chemical being introduced has increased from 10 tonne per annum, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

Material Safety Data Sheet
The MSDS of the notified chemical and a product containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Coty Australia Pty Ltd (ABN 96 058 696 549)
Level 31, 1 Market Street, Sydney NSW 2000

L'Oreal Australia Pty Ltd (ABN 40 004 191 673)
564 St Kilda Road, Melbourne VIC 3004

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: use details, import volume, site of manufacture

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Melting Point/Freezing Point, Boiling Point, Vapour Pressure, Density, Dissociation Constant, Flash Point, Flammability, Autoignition Temperature, Explosive Properties and Oxidising Properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

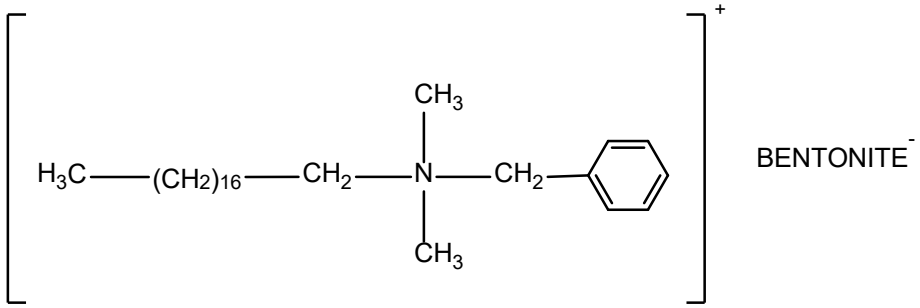
MARKETING NAME(S)
Stearalkonium Bentonite, Tixogel VZ-V, Tixogel LG-M, Tixogel MP 250, Tixogel VZ
Miglyol-Gel T (containing the notified chemical at 10-25%)

CAS NUMBER
130501-87-0

CHEMICAL NAME
Stearalkonium Bentonite

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA



MOLECULAR WEIGHT
Unspecified

ANALYTICAL DATA
Reference IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY 95%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	Quartz (SiO_2)		
CAS No.	14808-60-7	*Weight %*	up to 5%
Hazardous Properties	Exposure Standard TWA 0.1 mg/m^3 Crystalline silica in the form of quartz is carcinogenic to humans (Group 1; IARC, 2012).		
Chemical Name	Benzenemethanol		
CAS No.	100-51-6	*Weight %*	Up to 0.005%
Hazardous Properties	Classification Xn; R20/22 Concentration cutoffs Conc>=25%: Xn; R20/22		

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None.

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 ºC AND 101.3 kPa: off white odourless powder

Property	Value	Data Source/Justification
Melting Point/Freezing Point	> 390 ºC	MSDS
Boiling Point	> 500 ºC at 101.3 kPa	Analogue data for stearalkonium hectorite (hectorite is a form of bentonite).
Density	330-480 kg/m^3 at 25 ºC	MSDS
Vapour Pressure	Not determined	Anticipated to be low based on structure.
Water Solubility	< 0.04 x 10^{-3} g/L at 20 ºC	Measured
Hydrolysis as a Function of pH	Not determined	Hydrolysis of the notified chemical is unlikely given no hydrolysable functionality is present in the chemical.
Partition Coefficient (n-octanol/water)	log Kow = 5.87 at 25 ºC	Estimated from stearalkonium chloride, an analogue of the organic component of the notified chemical, using KOWWIN v1.68, EPI Suite v4.1 (US EPA, 2011).
Adsorption/Desorption	log K_{oc} = 4.08 at 25 °C	Estimated from stearalkonium chloride, an analogue of the organic component of the notified chemical, using KOCWIN v2.00, EPI Suite v4.1 (US EPA, 2011).
Dissociation Constant	Not determined	The notified chemical is a salt but it is

		not expected to significantly dissociate due to low water solubility.
Particle Size	Inhalable fraction < 100 µm: ~90%. Respirable fraction (< 10 µm): 30% < 0.5 µm: 0.02%	Measured
Flash Point	Not determined	-
Autoignition Temperature	> 150 ºC	MSDS
Explosive Properties	Unlikely to be explosive	Based on structural information.
Oxidising Properties	Not expected to have oxidative properties	Based on structural information.

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.

Dangerous Goods classification
Based on the submitted physical-chemical data in the above table the notified chemical is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However, the data above do not address all Dangerous Goods endpoints. Therefore, consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical is manufactured outside Australia and will be imported in formulated finished cosmetic products. The notified chemical may be imported as a raw material in the future.

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

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

PORT OF ENTRY
Sydney or Melbourne by wharf

IDENTITY OF RECIPIENTS
Coty Australia Pty Ltd
L'Oreal Australia Pty Ltd

TRANSPORTATION AND PACKAGING
Products containing the notified chemical will generally be shipped to Australia by sea in containers. The products will be packed in dozens inside a shipper, with multiple shippers per pallet and multiple pallets per container. The containers will be taken from the wharf in Sydney or Melbourne and transported to the appropriate central distribution centres. They will then be packed into individual orders for delivery to major retailer warehouses. The end use containers will be the usual cosmetic containers (e.g. 0-500 mL bottles or tubes.

USE
The notified chemical will be used as a component of cosmetic products at up to 5% concentration.

OPERATION DESCRIPTION
The notified chemical will be imported as a component in finished cosmetic products.

The notified chemical may be also imported (at ≤ 100% concentration) and used in the reformulation of cosmetic products. If reformulation occurs, the process will likely involve a blending operation which will be mainly automated and occur in an enclosed environment, followed by automatic filling into containers of various sizes.

The finished consumer products will be distributed to retail outlets, displayed and sold to the public.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and Storage	4	12
Professional Compounder	8	12
Chemist	3	12
Packaging	8	12
Store Persons	4	12
Salon Workers	unspecified	365

EXPOSURE DETAILS
Transport and distribution workers are not expected to be exposed to the notified chemical except in an unlikely event of an accident. In the case of such accidental exposure, the main routes of exposure would be dermal and ocular (and inhalation if the notified chemical is introduced at ≤ 100% concentration in powder form). However, the likelihood of such an accidental exposure is minimal.

In the case of import of the notified chemical for reformulation into consumer products, dermal and ocular exposure of workers to the notified chemical (at up to 100%) may occur during manual transfer from the drums and pails into the mixing vessel. However, this exposure could be minimised by the use of personal protective equipment (PPE) for skin and eye protection by the workers (e.g. safety glasses and impervious gloves). As the notified chemical is a powder (with ~30% of particles in the respirable size range), workers may also experience inhalation exposure to the notified chemical. Such exposure is expected to be minimised through the use of respiratory protection by workers and the conduct of reformulation activities in ventilated environments.

Packing workers may also have dermal and ocular exposure to the notified chemical at up to 5%. However, exposure is likely to be minimised through the automation of the processes and the use of PPE.

Exposure to the notified chemical in end-use products (at ≤ 5% concentration) may occur in professions where the services provided involve the application of cosmetic products to clients (e.g. hairdressers and workers in beauty salons). Such professionals may use some PPE to minimise repeated exposure and good hygiene practices as expected to be in place. If PPE is used, exposure of workers is expected to be a similar or lesser extent to 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 ≤ 5% concentration) through the use of the cosmetic products. While the principal route of exposure will be dermal, ocular exposure is also possible. Where the products are applied by spray, or are in powder form, inhalation exposure may also occur.

6.2. Human Health Effects Assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 5000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	severely irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days	NOEL = 1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vivo* micronucleus test	non genotoxic

Toxicokinetics
Similar to other organoclay compounds (OECD, 2007), absorption of the notified chemical following oral or dermal exposure is not expected. Given that the notified chemical contains particles in the respirable size range, there is potential for accumulation following inhalation exposure.

Acute toxicity
The notified chemical was of low acute toxicity via the oral and dermal routes in rats.

Acute inhalation toxicity data were not provided for the notified chemical. However, studies on other organoclay compounds indicate a low level of toxicity, with reported clinical signs including transient weight loss and respiratory irregularity (OECD, 2007).

Irritation
The notified chemical was slightly irritating to the skin of rabbits under the conditions of the test, with slight erythema and oedema noted following treatment at abraded skin sites.

In an eye irritation study in rabbits, severe ocular irritation effects were noted, which persisted in some animals until the end of the observation period. In a second (more recent) study, only mild to moderate conjunctival effects were noted, with the irritation scores not warranting classification of the chemical as an eye irritant. It is noted that in the former study, a significantly larger amount of test substance was instilled into the eyes of the treated animals (0.1 g versus 0.1 mL/~0.03 g in the latter study) and that the protocol required any residual solid substance to remain in the eyes for 24 hours prior to rinsing. Therefore, based on the studies provided, it is considered that the notified chemical has the potential to be only slightly irritating to eyes. This is consistent with the eye irritation effects expected from similar organoclay compounds (OECD, 2007)

Sensitisation
The notified chemical did not cause skin sensitisation in guinea pigs (adjuvant test using the Magnusson and Kligman method).

Repeated dose toxicity
The No Observed Effect Level (NOEL) was established by the study authors as 1000 mg/kg bw/day in rats (the highest dose tested) based on the absence of test substance related toxicologically significant effects at any of the doses administered.

Mutagenicity
The notified chemical was not mutagenic in a bacterial reverse mutation study and not genotoxic in an *in vivo* micronucleus test.

Carcinogenicity
The notified chemical contains up to 5% quartz as an impurity, originating from the bentonite precursor of the notified chemical. Crystalline silica in the form of quartz or cristobalite dust causes cancer of the lung. (IARC, 2012). A recent Canadian evaluation of quartz and cristabolite considered that adequate data exists for a threshold approach to risk characterisation (Environment Canada, 2011).

For forms of crystalline silica, there may be differences in the toxicity potential depending on their physico-chemical features, such as polymorph characteristics (IARC, 2012), and association with other minerals (Miles, 2008).

It has been suggested that association with clay or other aluminium containing compounds (as occurs with the notified chemical) inhibits adverse effects (Duffin et al., 2001 as cited in IARC, 2012). IARC (2012) notes that the effects after long residency in the lung have not been systematically assessed.

Health hazard classification
Based on the data provided, the notified chemical is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Reformulation
There is the potential for exposure to the notified chemical at up to 100% concentration during reformulation processes. Given that the notified chemical is a powder (with particle sizes in the inhalable and respirable size range) that has potential for accumulation in the lung and that the chemical contains an impurity that has been associated with carcinogenic effects following inhalation exposure, the greatest concern for the health of workers relates to inhalation. Therefore, steps should be taken to avoid exposure to the notified chemical, particularly via the inhalation route.

Therefore, provided that control measures are in place to minimise worker exposure to the notified chemical, including the use of PPE (particularly respiratory protection), ventilated environments and automated reformulation processes, the risk to the health of workers from use of the notified chemical is not considered to be unreasonable.

End-use
Workers involved in professions where the services provided involve the application of cosmetic products containing the notified chemical to clients (e.g. hairdressers and beauty salon workers) may be exposed to the notified chemical. 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 (for details of the public health risk assessment, see Section 6.3.2.).

6.3.2. Public Health
The public may come into contact with the notified chemical (at up to 5% concentration) through the use of a range of cosmetic products.

At the proposed usage concentration, local toxicity effects are not expected. While members of the public may experience repeated dermal exposure, as noted in section 6.1.2, absorption via the dermal (and oral) routes is not expected. Therefore, systemic toxicity effects from exposure to the notified chemical via these routes, is not expected. This is supported by the results of a 28-day repeated dose oral toxicity study in rats, in which the notified chemical was determined to be of low toxicity (NOEL was established as 1000 mg/kg bw/day, the highest dose tested).

There are uncertainties related to the inhalation hazard of the notified chemical to consumers during use of spray or powder products, e.g antiperspirants. The key uncertainty relates to the potential carcinogenicity of the quartz impurity in the notified chemical due to its association with bentonite, and the level of exposure to this impurity that is likely to cause adverse health effects. Other uncertainties relate to the respirable particle size, potential to accumulate following inhalation exposure, and lack of data regarding the effects of the notified chemical following repeated inhalation exposure. It is noted that the maximum concentration of the impurity in consumer products will be 0.25%, based on up to 5% of the impurity in the notified chemical, and up to 5% of the notified chemical in the products. It is considered that this low concentration would limit the potential risk. As a further precaution, suppliers should ensure that the level of quartz impurity in the notified chemical is minimised.

Therefore the risk to public health from exposure to the notified chemical at up to 5% concentration in 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 is imported in finished cosmetic products and may potentially be imported as a raw material for reformulation. In the case of reformulation and mixing processes, release of notified chemical to the environment is expected to be negligible as these processes are likely to occur in a closed system in industrial settings. The concentration of the notified chemical in formulated cosmetic products will be up to 5%. Residues in empty import containers are estimated to be 1% of the annual import volume and are expected to be disposed of to landfill or through a licensed waste contractor. Accidental spills during transport or reformulation are expected to be collected with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemical is expected to be released to sewers in domestic situations across Australia as a result of its use in cosmetic products. The notified chemical may also be disposed of to landfill when certain cosmetics are removed from the body with cotton wool or tissues and disposed of via domestic garbage.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues of the notified chemical in end use containers (≤ 3%) are likely to share the fate of the container and be disposed of to landfill as domestic garbage, or to be washed to sewer when containers are rinsed before recycling.

7.1.2. Environmental Fate

The majority of the notified chemical is expected to be disposed of to sewer following its use in cosmetic products. The notified chemical does not dissociate up to 500 ^{o}C according to commentary on Quaternium 18-Bentonite, a representative component of the notified chemical (CIR, 2000). The notified chemical is not readily biodegradable (23-33% biodegradation after 28 days, OECD TG 301 B; Institut Fresenius, 2000), and based on the predicted high absorption coefficient (log Koc = 4.08), it is likely to partition to sludge in Sewage Treatment Plant (STP) processes and eventually be disposed of to landfill. In landfill or in soil, the notified chemical is expected to have low mobility, due to its low water solubility and anticipated high sorption to soil and sediment. It is expected to degrade by abiotic and biotic processes to water, oxides of carbon and nitrogen, and clay minerals. The notified chemical is not expected to be bioavailable due to its limited water solubility and the organic component has low potential to bioaccumulate based on its low bioconcentration factor (log BCF = 1.85) predicted by a regression-based method using estimated log Kow (BCFBAF v3.01; log Kow = 5.87, KOWWIN; USEPA, 2011). For the details of the environmental fate study please refer to Appendix C.

7.1.3. Predicted Environmental Concentration (PEC)

Since most of the notified chemical will be washed into the sewer, under a worst case scenario, with no removal of the notified chemical in the STP, the resultant Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import Volume	10,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	10,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	27.40	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.61	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	6.06	µg/L
PEC - Oceann:	0.61	µg/L

The notified chemical that is not removed from waste water during STP processes may be released to the environment in STP effluent. 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 6.06 µg/L may potentially result in a soil concentration of approximately 40.39 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 201.9 µg/kg and 403.9 µg/kg, respectively. The ready biodegradability test of the notified chemical indicates up to 33% biodegradation in 28 days. Due to biodegradation and expected sorption of the notified chemical to sludge, these calculated values represent theoretical maximum concentrations only.

7.2. Environmental Effects Assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 > 100 mg/L	Not harmful to fish up to the limit of water solubility
Daphnia Toxicity	48 h EC50 > 100 mg/L	Not harmful to aquatic invertebrates up to the limit of water solubility
Algal Toxicity	72 h E_rC50 > 100 mg/L	Not harmful to algae up to the limit of water solubility

Classification should be based only on toxic responses observed in the soluble range of the notified chemical. The notified chemical was not harmful to aquatic life up to its limit of solubility in water and is not classified for acuate aquatic hazard under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the lower limit of the endpoints of the aquatic organisms. An assessment factor of 100 has been used as acute toxicity endpoints are available for three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment	
Acute toxicity to aquatic organisms	100 mg/L
Assessment Factor	100
PNEC:	1000 µg/L

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC, the following Risk Quotient has been calculated.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	6.06	1000	**0.006**
Q - Ocean	0.61	1000	**0.001**

The risk quotient for discharge of effluents containing the notified chemical to the aquatic environment, assuming a worst case with no removal during STP processes, indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations in surface waters based on its maximum annual use quantity. The notified chemical has a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio, maximum annual use volume and assessed use pattern in cosmetic products, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility $< 0.04 \times 10^{-3}$ g/L at 20 ºC

Method	OECD TG 105 Water Solubility. EC Directive 92/69/EEC, Method A.6 Water Solubility.
Remarks	The flask method was used to disperse an amount of five times the expected concentration of the notified chemical in water at 20 ºC. At saturation, the mass concentration of three clay elements in the aqueous solution without any undissolved particles was determined by HPLC. The water solubility of notified chemical equivalents was < 1 mg/L for aluminium (Al) and silicon (Si) concentrations, but 11 mg/L for magnesium (Mg). The mean concentration of aluminium in deionised water at 20 and 30 ºC was ≤ 0.04 mg/L which is considered equivalent to water solubility of the notified chemical.
Test Facility	ARC (2005a)

Hydrolysis as a Function of pH Not determined

Method	OECD TG 111 Hydrolysis as a Function of pH. EC Council Regulation No 440/2008 C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.
Remarks	Based on OECD guidelines, the method is only applicable for pure and commercial grade compounds that are water soluble. Estimating the rate constants using an atom/fragment contribution method is not possible, as the available program is not applicable to the notified chemical. Both components of the notified chemical, stearalkonium and bentonite clay are not chemically uniform substances. However, due to absence of hydrolysable functionality, the notified chemical is expected to be hydrolytically stable in the environmental conditions.
Test Facility	ARC (2005b)

Partition Coefficient (n-octanol/water) log Kow = 5.87 at 25 ºC (estimated from stearalkonium chloride)

Method	OECD TG 117 Partition Coefficient (n-octanol/water). EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks	Both HPLC Method and Flask Method are inappropriate for the notified chemical. The HPLC method is not applied because the notified chemical is not soluble in suitable solvents. The flask method is not suitable for the notified chemical which contains both organic and inorganic components. Log Kow of the organic component was modelled using stearalkonium chloride, an analogue component of the notified chemical. The above log Kow was estimated using KOWWIN v1.68, EPI Suite v4.10 (US EPA, 2011).
Test Facility	ARC (2005c)

Adsorption/Desorption Log Koc = 4.08 at 25 ºC (estimated from stearalkonium chloride)

Method	EEC/Directive 2001/59/EG Method C19. OECD TG 121 Estimation of the Adsorption Coefficient Koc using HPLC
Remarks	No single method is available for the complete notified chemical. Both components of the notified chemical, stearalkonium and bentonite clay, are not chemically uniform substances. Therefore, no adsorption coefficient log Koc was calculated for the notified chemical. Log Koc of the organic component was modelled using stearalkonium chloride, an analogue component of the notified chemical. The above log Koc value was calculated using KOCWIN v2.00, EPI suite v4.10 (US EPA, 2011).
Test Facility	ARC (2005d)

Particle Size

Method The Malvern laser diffraction analyser was used.

Range (μm)	*Mass (%)*
100	90.58
10	30.06
1	2.64
0.5	0.02

Remarks Results for Tixogel VZ-V with the smallest particle size were presented.
Test Facility Sud-Chemie AG (2000)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 401 Acute Oral Toxicity – Limited Test.
Species/Strain	Rat/Wistar albino
Vehicle	Corn oil
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	5000	1 M

LD50	> 5000 mg/kg bw
Remarks – Signs of Toxicity	Hair matted and unkempt was noted for all animals on days 1 and 2. One male animal showed slight depression on day 4 prior to its death on day 5. Slightly reddened gastric mucosa was noted in a single animal at necropsy.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Consumer Product Testing (1981)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity. EC Council Regulation No 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain	Rat/Sprague Dawley
Vehicle	Deionised water
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity	None
Effects in Organs	None
Remarks - Results	The study authors noted that body weight variations in 2/5 female animals may have been due to the discomfort caused by the dressing and were not considered to be toxicologically relevant.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	ARC (2004a)

B.3. Irritation – skin

TEST SUBSTANCE	Notified chemical

METHOD
Species/Strain: Rabbit/New Zealand White
Number of Animals: 6
Vehicle: None
Observation Period: 72 hours
Type of Dressing: Occlusive
Remarks - Method: Abraded skin and intact skin sites on each animal were tested using a 24 hour exposure period. It is not indicated in the study report if the test substance was moistened prior to application. Observations were recorded at 24 and 72 hours after patch removal only.

RESULTS

Lesion	*Mean Score**	*Maximum Value***	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Intact sites				
Erythema/Eschar	0	0	-	0
Oedema	0	0	-	0
Abraded sites				
Erythema/Eschar	0.3	0	< 72 hours	0
Oedema	0.25	0	< 72 hours	0

*Calculated on the basis of the scores at 24 and 72 hours for ALL animals.
**Observations recorded at 24 and 72 hours only.

Remarks - Results: At 24 hours, observations of very slight erythema (barely perceptible;4 out 6 animals) and very slight oedema (barely perceptible; 3 out 6 animals) were noted for the abraded skin sites.

CONCLUSION: The notified chemical was slightly irritating to the skin under the conditions of the test.

TEST FACILITY: Consumer Product Testing (1981)

B.4. Irritation – eye

TEST SUBSTANCE: Notified chemical

METHOD
Species/Strain: Rabbit/New Zealand White
Number of Animals: 6
Observation Period: 7 days
Remarks - Method: 0.1 g of test substance was instilled into a single eye of the test animals. It is noted that if the test substance remained in the eye at the 24 hour observation point, then the eye was rinsed with lukewarm water.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	2.44	3	> 7 days	2
Conjunctiva: chemosis	2.72	4	> 7 days	2
Conjunctiva: discharge	1.5	3	< 7 days	0
Corneal opacity	0.72	4	> 7 days	4
Iridial inflammation	0.61	1	> 7 days	1

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

Remarks - Results: *Conjunctiva: redness*
The most severe observation (grade 3: diffuse beefy red) was noted for all animals at 24 hours. One animal still exhibited a grade 2 response (more

diffuse, crimson red, individual vessels not easily discernible) on day 7.

Conjunctiva: chemosis
The most severe observation (grade 4: swelling with lids about half-closed to completely closed) was noted for 5 out of 6 animals at 24 hours. One animal still exhibited a grade 2 response (obvious swelling with partial eversion of the lids) on day 7.

Conjunctiva: discharge
The most severe observation (grade 3: discharge with moistening of the lids and hairs and considerable area around eye) was noted for 2 out of 6 animals at 24 hours. All animals appeared normal on day 7.

Corneal opacity
The most severe observation (grade 2: easily discernible translucent areas, details of iris slightly obscured) was noted for 2 out of 6 animals at 24 hours. The most severe observation (grade 3: opalescent areas, no details of iris visible, size of pupil barely discernible) was noted for 1 out of 6 animals at 48 hours. One animal still exhibited the highest grade 4 response opaque, iris invisible on day 7.

Iridial inflammation
Five out of 6 animals exhibited a grade 1 iridial inflammation response (sluggish reaction is positive) with the effect persisting in one animal up to and including day 7.

CONCLUSION The notified chemical was severely irritating to the eye under the conditions of the test.

TEST FACILITY Consumer Product Testing (1981)

B.5. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 F
Observation Period	72 hours
Remarks - Method	0.1 mL (31-36 mg) of test substance was instilled into the right eyes of the test animals. Grading of conjunctiva discharge was not reported.

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	0	0.7	1	< 72 h	0
Conjunctiva: chemosis	0	0	0.3	2	< 48 h	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 Neither corneae nor irises were affected.
Slight conjunctiva redness [some blood vessels definitely hyperaemic (injected)] was noted for 2/3 animals from 1 hour until a maximum of 48 hour observation.
Slight to moderate conjunctiva chemosis [any swelling above normal (including nictating membranes) or obvious swelling with particle

	eversion of lids] was noted for 2/3 animals from 1 hour until a maximum of 24 hour observation. Ocular discharge was noted in 2/3 animals from 1 hour until a maximum of the 24 hour observation.
CONCLUSION	The notified chemical is slightly irritating to the eye under the conditions of the test.
TEST FACILITY	ARC (2005e)

B.6. Skin sensitisation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 406 Skin Sensitisation - Magnusson and Kligman. EC Directive 96/54/EC B.6 Skin Sensitisation - Magnusson and Kligman.
Species/Strain	Guinea pig/albino Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 1.25% in distilled water topical: 60% in distilled water
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group:10
INDUCTION PHASE	Induction Concentration: topical: 60% in distilled water
Signs of Irritation	Not reported (the test sites were treated with 10% lauryl sodium sulphate in vaseline, prior to the topical induction phase to create a local irritation)
CHALLENGE PHASE	Induction Concentration: topical: 60% and 30% in distilled water
Remarks - Method	The study report was translated from French to English. No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: challenge*	
		24 h	*48 h*
Test Group	60%	0	0
	30%	0	0
Control Group	60%	0	0
	30%	0	0

CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	EVIC-CEBA (1999)

B.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rats/Fischer, CDF(F344)/CRLBR, SPF
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	0.1% aqueous solution of Na-carboxymethylcellulose (CMC)
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5 per sex	0	0
low dose	5 per sex	100	0
mid dose	5 per sex	316	0
high dose	5 per sex	1000	0
control recovery	5 per sex	0	0
high dose recovery	5 per sex	1000	0

Mortality and Time to Death

No test substance related deaths occurred during the study.

Clinical Observations

There were no significant differences or dose related trends noted in the daily, detailed clinical or functional observations.

Chromodakryorrhoea was noted occasionally in both the control and treated animals.

It is reported that there were no notable differences in feed consumption or body weight gain in males. Decreased body weights were recorded for females in the high dose recovery group but these were determined by the study authors to be of no toxicological relevance.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

There were no significant differences or dose related trends noted in the haematology or clinical biochemistry data of both sexes

Effects in Organs

There were no significant differences or dose related trends noted in the necropsy or histopathology of both sexes, nor were there uncommon individual spontaneous lesions noted.

There were no significant organ weight changes in the males and the organ weight decreases in females (heart and brain) at the end of recovery period were determined by the study authors to be of no toxicological relevance, as there were no corresponding differences at the end of the dosing period noted.

CONCLUSION

The No Observed Effect Level (NOEL) was established by the study authors as 1000 mg/kg bw/day in rats, based on the absence of test substance related toxicological significant effects at any of the doses administered.

TEST FACILITY ARC (2003)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Test 1: plate incorporation procedure
Test 2: pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	Post-mitochondrial fraction (S9 fraction) from rats treated with Aroclor 1254.
Concentration Range in Main Test	a) With metabolic activation: 0, 3.16, 10, 31.6, 100, 316 µg/plate b) Without metabolic activation: 0, 3.16, 10, 31.6, 100, 316 µg/plate
Vehicle	Dimethyl sulfoxide (DMSO)
Remarks - Method	As concentrations of ≥ 1000 µg/plate resulted in precipitation of the test substance, 1000 µg/plate was chosen as the maximum concentration in the preliminary test (TA 100). In the preliminary test, a slight cytotoxic effect was noted at 100 µg/plate (and a pronounced cytotoxic effect was noted at concentrations of ≥ 316

µg/plate). Therefore, the highest concentration selected was 316 µg/plate.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:* *Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	≥ 100	> 316	negative
Test 2	≥ 31.6	> 316	negative
Present			
Test 1	≥ 316	> 316	negative
Test 2	≥ 316	> 316	negative

Remarks - Results

Cytotoxicity
In the main study, pronounced cytotoxicity was noted in all test strains at the top concentration of 316 µg/plate (without and with metabolic activation). In the tests without metabolic activation cytotoxicity was also noted in several strains at concentrations of 31.6 and/or 100 µg/plate.

Mutagenicity
No significant increases in the frequency of revertant colonies were recorded for the test substance in any of the 5 test strains in two independent tests without and with metabolic activation.

The concurrent positive controls gave satisfactory responses confirming the validity of the test system.

CONCLUSION

The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

LPT (2000)

B.9. Genotoxicity – in vivo

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 2000/32/EC B.12 Mutagenicity - Mammalian Erythrocyte Micronucleus Test.

Species/Strain: Mice/Crl:NMRI BR
Route of Administration: Oral – gavage
Vehicle: 0.1% aqueous solution of Na-carboxymethylcellulose (CMC)
Remarks - Method: No significant protocol deviations.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5 per sex	0	24
	5 per sex	0	48
II (low dose)	5 per sex	1000	24
III (mid dose)	5 per sex	1500	24
IV (high dose)	5 per sex	2000	24
	5 per sex	2000	48
V (positive control, CP)	5 per sex	40	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity

All animals survived until the scheduled sacrifice and no adverse reactions were noted after administration of the test substance.

The ratios between the polychromatic and normochromatic erythrocytes

	in females (all dosage levels) were comparable to that of the control data. Statistically significant differences in this ratio were reported in males at all dosage levels at the 24 hour sacrifice time. However, as the values were within the historical negative control data ranges, the differences were not considered by the study authors to have been an adverse effect of the test substance.
Genotoxic Effects	The number of micronucleated polychromatic erythrocytes in the high dose groups (both sexes) was statistically significantly higher than the corresponding negative control group 48 hours after administration. However, as all figures were within the range of historical negative control data, the study author considered this not being attributed to a test substance effect. The amounts of microcleated polychromatic erythrocytes in the other dosed groups were not marked or statistically significant from the corresponding negative controls.
Remarks - Results	The concurrent negative/positive controls gave satisfactory responses confirming the validity of the test system. It is not clear that the notified chemical reached the bone marrow.
CONCLUSION	The notified chemical was not clastogenic under the conditions of this in vivo micronucleus test.
TEST FACILITY	ARC (2005f)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Activated sludge from the domestic sewage plant at Taunusstein-Bleidenstadt in Germany.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	pH and CO_2 analysis
Remarks - Method	The test was conducted for 28 days in accordance with the above guideline. The test substance was added to a liquid medium inoculated with sewage microorganisms and aerated with CO_2-free air at 4 L/h. Temperature was in the range of 19.2 to 25.4 ^oC. CO_2 production was analysed.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
Test 1			
10	8.2		
16	14.7		
23	18.6		
28	21.3	28	89
29	23.2		
Test 2			
10	10.4		
16	20.1		
23	26.2		
28	29.4	28	91
29	32.6		

Remarks - Results	The notified chemical consists of two different components: inorganic (bentonite) and organic (stearalkonium). Biodegradability of inorganic chemicals can't be assessed as it is not applicable to the guidelines. The organic content of the test substance and the measured carbon dioxide generation were used to calculate results of 23% and 33% of the theoretical carbon dioxide. The mean degradation value for the test substance after 28 days was 28%. The toxicity control was degraded 53% within 28 days and shows that no toxicity of the test substance has reduced the activity of the microorganisms. The control substance sodium benzoate was degraded 89 and 91% within 28 days. The notifier stated that threshold for classification as readily biodegradable of ≥ 60% was met within 6 days and therefore 10 day window as required by the OECD guideline was met for the reference substance. The CO_2 evolution measured in the blank was in the required range. All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is classified as not readily biodegradable.
TEST FACILITY	Institut Fresenius (2000)

C.1. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	EC Directive 92/69/EEC C.1 Acute Toxicity for Fish -96 hour static test.
Species	Zebrafish (*Brachydanio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	Not provided
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	pH, Oxygen and Silicon concentration; Inductively coupled plasma atomic emission spectrometry (ICP/AES).
Remarks – Method	According to above guideline, the test was conducted for the notified chemical with very low solubility (41 mg/L). The aqueous extracts of the different concentrations tested were prepared by loading at the designated concentrations and filtering after 24 hours of stirring. Seven fish per test solution were observed for mortality and behaviour changes after every 24 hours. Test conditions were: 20 ºC, pH 7.9-8.3, dissolved O_2 > 60% of the air saturation and 8 hours dark and 16 hours light period. The inductively coupled plasma atomic emission spectrometry (ICP/AES) technique was used to determine the concentrations of silicon in the test media and the control.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality (%)*				
Nominal		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	7	0	0	0	0	0
10	7	0	0	0	0	0
18	7	0	0	0	0	0
32	7	0	0	0	0	0
56	7	0	0	0	0	0
100	7	0	0	0	0	0

96 h LC50	> 100 mg/L
96 h NOEC	≥ 100 mg/L
Remarks – Results	After 96 hours of exposure, there was no fish mortality in the control thereby validating the test for the criteria. There was also no fish mortality or other visible abnormalities in the test substance vessels. The test substance had no acute effects on zebra fish up to the solubility limit in test water. The concentration of the silicon as measured at the start of the test and at the end of the test were approximately the same in all test substance media and about 3-4 times higher than those of the reconstituted water. These results confirm that the test substance has slight solubility in the reconstituted water.
CONCLUSION	The notified chemical is not harmful to fish up to its limit of solubility in water.
TEST FACILITY	ARC (2005g)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Not provided

Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	pH, dissolved oxygen and silicon concentrations; ICP/AES.
Remarks - Method	According to above guideline, the test was conducted for the notified chemical with very low solubility (41 mg/L). The aqueous extracts of the different concentrations tested were prepared by loading at the designated concentration and filtering after 24 hours of stirring. Twenty daphnia (4 replicates of 5 animals) were exposed to six nominal concentrations from 0 to 100 mg/L. Immobilisation was observed after 24 and 48 hours. Test conditions were: 20 ºC, pH 7.7-8.0, 7.5-8.0 mg O_2/L and 8 hours dark and 16 hours light period. The inductively coupled plasma atomic emission spectrometry (ICP/AES) technique was used to determine the concentrations of silicon in the test media and the control.

RESULTS

Concentration mg/L Nominal	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
0	20	0	0
10	20	0	0
18	20	0	0
32	20	0	0
56	20	0	0
100	20	0	2

48 h LC50	> 100 mg/L
48 h NOEC	> 100 mg/L
Remarks - Results	Daphnia were not trapped at the water surface in the control. Two animals from twenty were immobilised in the 100 mg/L test substance group. The maximum limit of natural mortality tolerated according to the guidelines is 10%. Therefore, for evaluation of the EC0 of a test substance, 3 daphnia and 10% mortality is considered as possibly not related to test substance. The concentration of the silicon as measured at the start of the test and at the end of the test were approximately the same in all test substance media and about 3-4 times higher than those of the reconstituted water. These results confirm that the test substance has slight solubility in the reconstituted water.

CONCLUSION	The notified chemical is not harmful to aquatic invertebrates up to its limit of solubility in water.
Test Facility	ARC (2005h)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	pH; ICP/AES
Remarks - Method	According to above guideline, the test was conducted for the notified chemical with very low solubility (41 mg/L). The aqueous extracts of the different concentrations tested were prepared by loading at the designated concentration and filtering after 24 hours of stirring. The inductively coupled plasma atomic emission spectrometry (ICP/AES) technique was

used to determine the concentrations of silicon in the test media and the control.

RESULTS

Biomass		*Growth*	
EbC50	*NOEC*	*ErC50*	*NOEC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
> 100	≥ 100	> 100	≥ 100

Remarks - Results: During the 72 hours incubation period the cell density in the control cultures was increased by a factor of about 17. The algal growth rates of the test concentration at the highest concentration inhibition was 13.8% based on the area under the growth curves or 1.3% based on the average growth rates. At the other concentrations, algal growth was either marginally inhibited or slightly enhanced depending on the method of calculation. The concentration of the silicon as measured at the start of the test were equivalent to 0.03 to 0.27 mg/L and at the end of the test was equivalent to 0.08 to 0.38 mg/L. These results confirm that the test substance is not very soluble in the dilution water.

CONCLUSION: The notified chemical is not harmful to algae up to its limit of solubility in water.

TEST FACILITY: ARC (2005i)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test

Inoculum: Microbial activated sludge was collected from Sewage treatment plant in Baden near Vienna, Austria.

Exposure Period: 3 hours

Concentration Range: Nominal: 8.0, 22.4, 49.8, 120.4, 301.6 and 302.4 mg/L

Remarks – Method: The test substance was added directly to the sludge at the beginning of the incubation. This treatment is in accordance with the EPA Guidelines OPPTS 850.6800 as the test substance was not soluble in water. Additionally one sample of the highest nominal concentration of 300 mg/L was prepared by stirring the test substance in tap water for 24 hours. This stock solution was used without filtration.

RESULTS

IC50: > 300 mg/L at 3 hr

Remarks – Results: All validity criteria for the guideline were satisfied and no significant deviations from the guidelines were reported. The respiration rates of the two negative control samples were within 15% of each other, the actual values were 99 and 101% of their calculated mean value. The respiration of the positive control 3,5-dichlorophenol was in the accepted range of 5 to 30 mg/L with an actual EC50 of 14.5 mg/L. The respiration rates of all the samples with the notified chemical were in the range of 93.4 to 106.2% of the control value.

CONCLUSION: The notified chemical did not inhibit respiration rate of activated sludge microorganisms under the condition of the test.

TEST FACILITY: ARC (2004b)

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