File No: LTD/1912

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Ethanaminium, *N,N*-dimethyl-2-[(1-oxooctadecyl)oxyl]-*N*-[2-[(1-oxooctadecyl)oxy]ethyl-, chloride (1:1) (INCI Name: Distearoylethyl dimonium chloride)

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.

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(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1912	L'Occitane Australia Pty Ltd	Ethanaminium, *N,N*-dimethyl-2-[(1-oxooctadecyl)oxyl]-*N*-[2-[(1-oxooctadecyl)oxy]ethyl-, chloride (1:1) (INCI Name: Distearoylethyl dimonium chloride)	No	≤ 1 tonne per annum	Cosmetic ingredient

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

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

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

Human health risk assessment
Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

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

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

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified chemical itself. However, these should be selected on the basis of all ingredients in the formulation.

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

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

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

Disposal

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

Storage

- The handling and storage of the notified chemical should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
  – the importation volume exceeds one tonne per annum notified chemical;

or

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

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

(Material) Safety Data Sheet
The (M)SDS of the notified chemical (and products containing the notified chemical) provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
L'Occitane Australia Pty Ltd (ABN: 32 093 616 043)
Level 8
157 – 159 Walker Street
NORTH SYDNEY NSW 2060

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: spectral data.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Varisoft EQ 65 Pellets

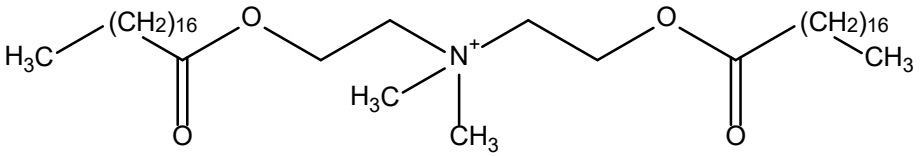
CAS NUMBER
67846-68-8

CHEMICAL NAME
Ethanaminium, *N,N*-dimethyl-2-[(1-oxooctadecyl)oxyl]-*N*-[2-[(1-oxooctadecyl)oxy]ethyl-, chloride (1:1)

OTHER NAME(S)
Distearoylethyl dimonium chloride (INCI Name)

MOLECULAR FORMULA
$C_{42}H_{84}NO_4.Cl$

STRUCTURAL FORMULA



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MOLECULAR WEIGHT
702.6 Da

ANALYTICAL DATA
None provided.

3. COMPOSITION

DEGREE OF PURITY
65%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	1-Tetradecanol		
CAS No.	112-72-1	*Weight %*	1 – 2.5%
Hazardous Properties	H319 Causes serious eye irritation		

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)

Chemical Name	1-Hexadecanol		
CAS No.	36653-82-4	*Weight %*	25 – 50%
Chemical Name	1-Octadecanol		
CAS No.	112-92-5	*Weight %*	25 – 50%

ADDITIVES/ADJUVANTS

Chemical Name	Alcohols, C_{16-18}		
CAS No.	67762-27-0	*Weight %*	35%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellow solid

Property	Value	Data Source/Justification
Pour Point	55 °C	Measured; ISO 3016
Boiling Point	802.35 °C at 101.3 kPa	Estimated using USA EPI Suite™ v.4.11, MPBVP v1.43 (adapted Stein and Brown Method).
Density	870 kg/m^3 at 90 °C	(M)SDS
Vapour Pressure	< 7.33 x 10^{-21} kPa at 25 °C	Estimated using USA EPI Suite™ v.4.11, MPBVP v1.43 (modified Grain Method).
Water Solubility	< 1 × 10^{-6} g/L*	Measured; not expected to be high based on predominantly hydrophobic molecular structure

Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities; however, not expected to rapidly hydrolyse under environmental conditions (pH 4-9)
Partition Coefficient (n-octanol/water)	log Pow = 3.1*	Analogue data; expected to partition to phase boundaries based on surface activity
Adsorption/Desorption	log K_{oc} = 11.78-12.84*	Measured; expected to adsorb to soil and sediment based on surface activity and cationic properties
Dissociation Constant	Not determined	Expected to be ionised under environmental conditions (pH 4-9)
Flash Point	> 99 °C	(M)SDS
Autoignition Temperature	Not determined	Expected to be high based on the flash point
Explosive Properties	Not determined	Not expected to be explosive based on chemical structure.
Oxidising Properties	Not determined	Not expected to be oxidising based on chemical structure.

* Representative values for diethyloxyester dimethylammonium chloride (DEEDMAC) group of esterquat surfactants (HERA, 2008).

DISCUSSION OF PROPERTIES

Reactivity
The notified chemical is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. The notified chemical will be imported into Australia as a component of end-use cosmetic products at ≤ 6% concentration.

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

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

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Manufacturer:
Evonik Goldschmidt GmBH

Recipient:
L'Occitane Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical will be imported as a component of finished cosmetic and personal care products (at ≤ 6% concentration) in ≤ 500 mL containers suitable for retail sale.

USE
The notified chemical will be used as an ingredient in cosmetic and personal care products at ≤ 6% concentration.

OPERATION DESCRIPTION
The notified chemical will be imported into Australia (at ≤ 6% concentration) as a component of finished cosmetic and personal care products which will be sold to the public in the same form in which they are imported.

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

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

EXPOSURE DETAILS
Transport, storage and retail workers may come into contact with the notified chemical at ≤ 6% concentration, only in the event of accidental rupture of packages.

Exposure to the notified chemical in end-use products (at ≤ 6% concentration) may occur in professions where the services provided involve the application of cosmetic and personal care products to clients (e.g. hairdressers, workers in beauty salons). The principal route of exposure will be dermal, while oral, ocular and inhalation exposure is also possible. Such professionals may use 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 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 concentrations ≤ 6%) through the use of both rinse-off and leave-on cosmetic and personal care products. The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible particularly if products are applied by spray.

6.2. Human Health Effects Assessment

The results from toxicological investigations provided on the notified chemical and an analogue are summarised in the following table. For full details of the studies, refer to Appendix A.

Endpoint	*Result and Assessment Conclusion*
Eye irritation (in vivo) – HET-CAM	non-irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation (analogue)

Toxicokinetics, metabolism and distribution
In an *in vivo* study using ^{14}C radio labelling in rats, the notified chemical was dermally applied to the skin under occlusive conditions, dermal absorption was 0.2% (HERA, 2009). Following oral exposure of using ^{14}C radio labelled notified chemical up to 63% was absorbed, with 4.5% of the dose remaining within the body after 48 hours (HERA, 2009). The radiolabelled carbon of the notified chemical in the oral study was in the dimethyldiethanolammonium moiety, in other studies with esterquats where the fatty acid component was radiolabelled a significantly higher portion of the radiolabelled carbon remained within the test animals after 48 hours (HERA, 2009).

Acute toxicity
The acute oral and dermal toxicity of esterquats is low (> 2,000 mg/kg bw) and subsequently the notified chemical is not expected to be acutely toxic via the oral and dermal route (HERA, 2009). There is no data available on the inhalation toxicity of the notified chemical or suitable analogues.

Irritation
The notified chemical has a quaternary ammonium functional group which is a structural alert for corrosion and sensitisation (Hulzebos *et al*., 2005 and Tsakovska *et al*., 2007). However, the notified chemical exhibited only

slight skin irritation effects in rabbits, although the concentration of the test substance was not provided (HERA, 2009).

The notified chemical was non-irritating at 65% concentration in an *in vitro* eye (HET-CAM) irritation study. The notified chemical was also found to be non-irritating to the rabbit eye in low volumes (0.01 ml of undiluted test substance) in a study similar to OECD TG 405 (HERA, 2009).

Based on the available information, the notified chemical is not expected to be irritating to the eye. The potential for the notified chemical to be irritating to the skin cannot be excluded.

Sensitisation
Test data for an analogue to the notified chemical was provided (Dihydrogenated tallowethyl hydroxyethylmonium methosulfate a triethanolamine (TEA) based esterquat; substance details not provided). The study results indicated that the analogue chemical did not induce a sensitisation reaction in guinea pigs at a challenge concentration of 10%. Other data available on esterquats indicate they are not expected to induce a skin sensitisation reaction, including the close analogue ethanaminium, *N,N*-dimethyl-2-[(1-oxohexadecyl)oxy]-*N*-[2-[(1-oxohexadecyl)oxy]ethyl]-, chloride (1:1) (CAS number 97158-31-1) which showed no evidence of sensitisation in guinea pigs at a challenge concentration of 50% (HERA, 2009). The notified chemical tested as 1.5% and 2% aqueous solutions was not sensitising to the skin in human repeat insult patch studies (HERA, 2009).

Repeated dose toxicity
Toxicity studies in rats on either the notified chemical or the close analogue ethanaminium, *N,N*-dimethyl-2-[(1-oxohexadecyl)oxy]-*N*-[2-[(1-oxohexadecyl)oxy]ethyl]-, chloride (1:1) (CAS number 97158-31-1), it was not specified which, indicated no treatment related major clinical or histopathological effects at up to 1,000 mg/kg bw/day (HERA, 2009). In other studies on esterquats local effects were observed in the forestomach and urinary bladder in animals in the high-dose group in one chronic study and in a separate study males in the high dose group (3,860 mg/kg bw/day) exhibited diarrhoea with weight loss, a slightly increased kidney-to-bodyweight ratio (no concurrent histopathological effects) and some functional effects of mild dehydration (HERA, 2009). A 13-week neurotoxicity study on an esterquat analogue, using oral gavage doses of up to 1,000 mg/kg bw/day, showed no signs of neurotoxicity (HERA, 2009).

Mutagenicity/Genotoxicity
No genotoxic effects were seen in an *in vitro* mammalian cell mutation study using Chinese Hamster V79 cells involving either the notified chemical or the close analogue ethanaminium, *N,N*-dimethyl-2-[(1-oxohexadecyl)oxy]-*N*-[2-[(1-oxohexadecyl)oxy]ethyl]-, chloride (1:1) (CAS number 97158-31-1), it was not specified which (HERA, 2009). Additional *in vivo* and *in vitro* studies on other esterquats (HERA, 2009) did not indicate genotoxic properties. The notified chemical is not expected to be genotoxic based on the results of these studies.

Developmental Toxicity
A study on the notified chemical was conducted where female rats were orally dosed at concentrations of up to 1,000 mg/kg bw/day from day 6 to 15 post mating before being sacrificed on day 21 (HERA, 2009). A slight but statistically significant post-implantation loss was noted in the high dose group, although the rate was still within that seen in the historical controls. No other adverse effects were noted in either study and the NOAEL was determined as 1,000 mg/kg bw/day (HERA, 2009).

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

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Hairdressers and beauty care professionals will handle the notified chemical at ≤ 6% concentration, similar to public use. Therefore, the risk to workers who regularly use the notified chemical is expected to be of a similar or lesser extent that that experienced by members of the general public who use such products on a regular basis. For details of the public health risk assessment see section 6.3.2.

Based on the information available, the risk to workers associated with the use of the notified chemical at ≤ 6% in cosmetic and personal care products, is not considered to be unreasonable.

6.3.2. Public Health

The public will be exposed to the notified chemical at ≤ 6% concentration in cosmetic and personal care products. The main route of exposure is expected to be dermal with some potential for oral and inhalation exposure.

The notified chemical may be slightly irritating to the skin; however eye and skin irritation effects are not expected from use of the notified polymer at the proposed concentration.

The notified chemical is of low systemic toxicity, with minimal dermal absorption expected. In addition the notified chemical is not expected to be sensitising, genotoxic or a reproductive or developmental toxicant.

Therefore, based on the expected low hazard, the risk to the public associated with the use of the notified chemical at < 6% 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 will be imported as a component of finished cosmetic products; no reformulation or repackaging will occur in Australia. Therefore, no environmental release is expected from manufacturing or reformulation in Australia. Environmental release of the notified chemical during importation, transport and storage is likely to be limited to accidental spills and leaks. In the event of spills, the product containing the notified chemical is expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The notified chemical is expected to be released to the aquatic compartment through sewers during its use in various cosmetic products.

RELEASE OF CHEMICAL FROM DISPOSAL

It is estimated by the notifier that a maximum of 3% (or up to 30 kg) of the notified chemical may remain in end-use containers once the consumer products are used up. Wastes and residues of the notified chemical in empty containers are likely to share the fate of the container, and be disposed of to landfill. Residues of the notified chemical may also be released to sewer when containers are rinsed before recycling through an approved waste management facility.

7.1.2. Environmental Fate

Following its use in Australia, the majority of the notified chemical is expected to enter the sewer system through its use in cosmetic products, before potential release to surface waters nationwide. Based on the results of a ready biodegradability study, the notified chemical is considered readily biodegradable (≥ 75% in 28 days). For details of the environmental fate study, please refer to Appendix B. Based on its surfactant properties and cationicity, release to surface waters is unlikely occur, as partitioning to sludge and sediment is expected under environmental pH. The notified chemical is not expected to bioaccumulate due to its surfactant properties and ready biodegradability. Therefore, in surface waters the notified chemical is expected to disperse and degrade through biotic and abiotic processes to form water and oxides of carbon and nitrogen.

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

7.1.3. Predicted Environmental Concentration (PEC)

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

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.606	µg/L
PEC - Ocean:	0.061	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m2/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 1,500 kg/m3). Using these assumptions, irrigation with a concentration of 0.61 µg/L may potentially result in a soil concentration of approximately 4.04 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of the notified chemical in the applied soil in 5 and 10 years may be approximately 20.19 µg/kg and 40.39 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below (HERA, 2008). However, as the full study reports have not been provided, these results should be treated with caution.

Endpoint	*Result*	*Assessment Conclusion*
Acute toxicity		
Fish		
Danio rerio	96 h LC50 = 2.8 mg/L	Toxic to fish
Daphnia		
Daphnia magna	48 h EC50 = 4 mg/L	Toxic to aquatic invertebrates
Algae		
Selenastrum capricornutum	72 h EC50 = 0.93 mg/L	Very toxic to algae
Inhibition of Bacterial Respiration	3 h NOEC = 48.6 mg/L	Not inhibitory to microbial respiration
Earthworm		
Eisenia fetida	14 d EC50 > 47.4 mg/kg dry weight of soil	Potentially harmful to terrestrial invertebrates
Terrestrial plants		
Avena sativa	17 d NOEC > 47.4 mg/kg dry weight of soil	Not expected to be harmful to terrestrial plants
Lactuca sativa	17 d NOEC > 47.4 mg/kg dry weight of soil	Not expected to be harmful to terrestrial plants

Chronic toxicity		
Fish		
Pimephales promelas	35 d NOEC = 0.63 mg/L	Harmful to fish with long lasting effects
Daphnia		
Daphnia magna	21 d NOEC = 1 mg/L	Harmful to aquatic invertebrates with long lasting effects
Algae		
Selenastrum capricornutum	72 h E_rC10 = 0.48 mg/L	Harmful to algae with long lasting effects

Based on the above acute ecotoxicological endpoints for the notified chemical, it is expected to be very toxic to algae, and toxic to fish and aquatic invertebrates. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified chemical is formally classified as "Acute Category 1; Very toxic to aquatic life". Based on the above chronic ecotoxicological endpoints and ready biodegradability of the notified chemical, it is expected to be harmful to aquatic life on a chronic basis. Therefore under the GHS, the notified chemical is formally classified as "Chronic Category 3; Harmful to aquatic life with long lasting effects".

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the most sensitive endpoint for algae. A safety factor of 10 was used given acute and chronic endpoints for three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E_rC10 (Algae, 72 h)	0.48	mg/L
Assessment Factor	10	
Mitigation Factor	1.00	
PNEC:	48	µg/L

7.3. Environmental Risk Assessment

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

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q – River	0.606	48	**0.013**
Q – Ocean	0.061	48	**0.001**

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

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Irritation – eye (in vivo)

TEST SUBSTANCE: Notified chemical (65%)

METHOD: The Hen's Egg Test on the Chorioallantoic Membrane (HET-CAM) method used is based on publications by Prof. Dr. N.-P. Lüpke, Institute for Pharmacology and Toxicology, University of Münster.

Vehicle: None

Remarks - Method: Fresh eggs (2 days post laying) were stored for 24 h at 15 - 22 °C with blunt ends upwards to adjust air space. Eggs were incubated at 37 °C and a relative humidity of 60–70% in an automatic, rotating incubator for 9 days. Eggs were illuminated on incubation day 6 and 8 with a candeling lamp. Unfertilized or not-developed eggs were rejected. Nine days after the eggs were added to the incubator, the shell over the air sac of each egg was removed. The inner egg membrane sack was wetted with physiological saline and the inner egg membrane removed to reveal the CAM. Eggs with small lesions or haemorrhages after preparation were rejected.

A 200 mg sample of the ground test substance was applied onto the CAM of each of six eggs. Six positive and six negative controls were also included. All CAMs were exposed to the test substance or control for the length of the observation period (5 min). Observations were made at 0.5, 2 and 5 min post-application.

Exposure periods of 30 seconds and 2 minutes were not required.

The reactions of the CAM, the blood vessels, including the capillaries, and the albumin were examined and the following scores for irritant effects were applied as described below:

	Scores at time (min)		
Effect	0.5	2	5
Vascular injection	5	3	1
Haemorrhage	7	5	3
Coagulation	9	7	5

Each reaction type can be recorded only once for each CAM. Scoring is according to the severity and time needed for the effect to occur. The earlier a symptom is recorded the higher the numerical value assigned to it. The severity of the endpoints is ordered as follows: Coagulation > haemorrhage > vascular injection.

The recorded scores for every possible reaction were summed for each egg, with the average score for the tested eggs corresponding to the irritation index of the test substance. This was then used to classify in analogy to the Draize eye irritation test as described below:

Irritation index	*Classification*
0 – 0.9	not irritating
1 – 4.9	slightly irritating
5 – 8.9	moderately irritating
9 – 21.0	strongly irritating

Positive control: 5% Texapon ASV 70 Spezial (sodium magnesium lauryl-myristyl-6-ethoxy-sulfate).
Negative control: Tap water.

The testing laboratory is GLP compliant.

RESULTS

Test substance	*Total scores of samples*			*Average*
	0.5 min	2 min	5 min	
Negative control	0	0	0	0
Test substance	0	0	0	0
Positive control	20	28	3	8.5

Remarks - Results: No effects were observed in those CAMs exposed to the test substance for a period of 5 minutes.

Positive and negative controls performed as expected.

CONCLUSION: Under the conditions of the test the notified chemical is predicted to be non-irritating to the eye.

TEST FACILITY: Evonik (2009)

A.2. Skin sensitisation

TEST SUBSTANCE: Analogue (Dihydrogenated Tallowethyl Hydroxyethylmonium Methosulfate)

METHOD: OECD TG 406 Skin Sensitisation - adjuvant

Species/Strain: Guinea pig/Pirbright white

PRELIMINARY STUDY: Maximum Non-irritating Concentration: 10%
intradermal: 5%
topical: 10%, 25%, 50%, 75%, 100%

MAIN STUDY

Number of Animals: Test Group: 20 Control Group: 20

Vehicle: Water

Positive control: Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using 2,4-dinitrochlorobenzene and benzocaine.

INDUCTION PHASE: Induction Concentration:
intradermal: 5%
topical: 25%

Signs of Irritation: None

CHALLENGE PHASE

1st challenge: topical: 10%

Remarks - Method: In the preliminary study, following topical exposure, very slight to well-defined erythema with slight oedema was observed in animals exposed to the notified chemical at concentrations ≥ 50%; slight to well-defined erythema was observed in animals exposed to the notified chemical at 25% concentration, and no erythema or oedema was observed in those animals exposed to the notified chemical at 10% concentration. No irritation effects were observed for those animals exposed to the notified chemical at 5% concentration by intradermal injection.

Occlusive dressing used.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	10%	0/20	0/20
Control Group	10%	0/20	0/20

Remarks - Results None.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY IBR (1992)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Environmental Fate

B.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	Ethanol
Analytical Monitoring	Theoretical Carbon Dioxide ($ThCO_2$)
Remarks - Method	The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Test substance		*Toxicity control*		*Solvent control*		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*	*Day*	*% Degradation*	*Day*	*% Degradation*
7	30.3-31.9	7	71.4-73.9	7	81.7-82.9	7	82.0-84.4
14	53.1-60.2	14	84.3-84.7	14	87.4-88.0	14	88.6-89.2
21	68.3-77.1	21	88.0-88.4	21	90.4	21	91.0-92.8
28	75.6-81.4	28	90.3-92.0	28	92.5	28	92.5-95.5

Remarks - Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound surpassed the threshold level of 60% by 3 days (mean 70.6%) and reached ≥ 92% degradation by 28 days. Therefore, the test indicates the suitability of the inoculums. The percentage degradation of the toxicity control surpassed the threshold level of 25% by 1 day (mean 27.9%), indicating that toxicity was not a factor inhibiting the biodegradability of the test substance. The solvent control reached 92.5% degradation by 28 days. The test substance attained ≥ 75% degradation by 28 days. As the test substance is surface active, the 10-day window is not applicable. Therefore, the test substance is considered to be readily biodegradable according to the OECD (301 F) guideline.
CONCLUSION	The notified chemical is readily biodegradable.
TEST FACILITY	Fraunhofer (2007)

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