COSMETIC PRODUCT SAFETY REPORT - REGULATION (EC) 1223/2009, COSMETIC PRODUCTS

SHOWER GEL

SUMMARY & CONCLUSIONS
This product is a fragranced Shower gel in a single use, 7 gram, sachet.


All ingredients satisfy legislation requirements and, taking into consideration the physical-chemical and toxicological properties of each ingredient, exposure to the product and to each ingredient, the type of usage and the intended user, it is concluded that this product satisfies legislation requirements and will be safe to use as instructed and under other reasonably foreseeable conditions of use.

Note: Corrections required to product label (see section 11).

If product enters the eye, temporary irritation may be experienced and, if skin is sensitive or damaged, it may cause slight skin irritation. The product is not expected to cause skin sensitization, to be harmful if ingested in small amounts or to adversely affect the respiratory system. Long term adverse effects are not expected.

CONDITIONS OF USE
Avoid eye contact. In the event of eye irritation, rinse thoroughly with water.

WARNINGS
Regulation 1223/2009 requirements: None.

Digitally signed by R A J Priston
Reason: I am the author of this document
Location: 
Date: 2014-11-13 12:02Z

R A J Priston
B.Sc. Ph.D. MSB. MSCS., Chartered Biologist (CBiol.), UK & EUROTOX Registered Toxicologist.
Toxicologist / Cosmetic Safety Assessor - authorised under the Cosmetic Products (Safety) Regulations 2004 (Statutory Instrument, SI No. 2152), as amended, to conduct and take responsibility for the safety assessment of cosmetic products. The statement above has been prepared in accordance with those Regulations and, in particular, paragraphs 4, 9(1)(d), 9(1)(e), 9(1)(f), 9(2) and 9(5).

If this product is reported to cause significant adverse reaction amongst consumers the undersigned should be informed for a further review of this product.

For assessor’s credentials, see section 12.

1 NB. This conclusion is valid only when, on-going, the same or equivalent ingredients are used as reviewed for this assessment.
1. PURPOSE OF ASSESSMENT


This report contains a summary of the information that is required in the Product Information File (PIF) as Part 1A of the complete Cosmetic Product Safety Report (Annex 1 of Regulation 1223/2009) and a safety assessment, representing Part 1B. The summarized information includes, for example, reports on stability, microbiological challenge, the product MSDS, ingredient MSDS’ and specifications, statements on the absence of animal testing and clinical reports. External, typical, information has also been referred to as appropriate.

The client should ensure that Part 1A documents (several of which are referred to in this assessment) are lodged in the PIF with the Responsible Person.

ANNEX 1, PART A, SUMMARISED MAIN POINTS

2. QUANTITATIVE & QUALITATIVE COMPOSITION

The composition of this product with ingredient trade names and breakdown is in Appendix 1. The following table lists ingredients in order of decreasing concentration.

<table>
<thead>
<tr>
<th>EU INCI NAME, CI No</th>
<th>CAS No</th>
<th>Function(s) as listed in COSING</th>
<th>Conc. (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aqua</td>
<td>7732-18-5</td>
<td>Solvent</td>
<td>73.411</td>
</tr>
<tr>
<td>Sodium Lauroyl Sarcosinate</td>
<td>137-16-6</td>
<td>Antistatic, Cleansing, Emulsifying, Conditioning</td>
<td>14.00</td>
</tr>
<tr>
<td>Cocamide MEA</td>
<td>68140-00-1</td>
<td>Emulsifying, Stabilising, Surfactant</td>
<td>5.00</td>
</tr>
<tr>
<td>Cocamidopropyl Betaine</td>
<td>61789-40-0</td>
<td>Surfactant, Foam booster</td>
<td>4.00</td>
</tr>
<tr>
<td>Parfum</td>
<td>Mixture</td>
<td>Parfum</td>
<td>3.00</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>7647-14-5</td>
<td>Bulking, Masking, Viscosity controlling</td>
<td>0.30</td>
</tr>
<tr>
<td>Diazolidinyl Urea</td>
<td>78491-02-8</td>
<td>Preservative</td>
<td>0.10</td>
</tr>
<tr>
<td>Citric Acid</td>
<td>77-92-9</td>
<td>Buffering, Chelating</td>
<td>0.10</td>
</tr>
<tr>
<td>Alpha-isomethyl Ionone</td>
<td>127-51-5</td>
<td>Fragrance ingredient</td>
<td>0.096</td>
</tr>
<tr>
<td>Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde</td>
<td>31906-04-4</td>
<td>Fragrance ingredient</td>
<td>0.039</td>
</tr>
<tr>
<td>Magnesium Nitrate</td>
<td>10377-60-3</td>
<td>Stabilizer, Conditioning</td>
<td>0.018</td>
</tr>
<tr>
<td>Linalool</td>
<td>78-70-6</td>
<td>Denaturant, Perfuming</td>
<td>0.012</td>
</tr>
<tr>
<td>Magnesium Chloride</td>
<td>7786-30-3</td>
<td>Viscosity controlling</td>
<td>0.004</td>
</tr>
<tr>
<td>Mixture of 5-Chloro-2-methyl-Isothiazol-3(2H)-one and 2-Methylisothiazol-3(2H)-one</td>
<td>55965-84-9</td>
<td>Preservative</td>
<td>0.0012</td>
</tr>
</tbody>
</table>

*: SCCNFP allergens originating from the Parfum and present in product at ≥0.01%. They must be included in the list of ingredients on the label.

3. ORDER OF INGREDIENTS FOR LABEL (EC)

Preface with "INGREDIENTS"

List in this order: Aqua, Sodium Lauroyl Sarcosinate, Cocamide MEA, Cocamidopropyl Betaine, Parfum, Follow this in any order with: Sodium Chloride, Diazolidinyl Urea, Citric Acid, Alpha-isomethyl Ionone, Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde, Magnesium Nitrate, Linalool, Magnesium Chloride, methylchloroisothiazolinone, methylisothiazolinone.

4. PHYSICAL-CHEMICAL CHARACTERISTICS & STABILITY

- Product –
  i. Physical chemical properties

  The product is a colourless, slightly perfumed, viscous liquid. It is miscible with water.
The stability test report provided (see below) states that the pH is 4.00-10.00 with the range in the stability test being 6-6.2. Further information is in the PIF.

ii. Stability/Biocompatibility:

Report details: See appendix 1.

Conditions & observations:
- Ambient, 3 month: Examined every 10 days for appearance, colour, fragrance and pH.
- 41+/-1°C, 24h then returned to ambient. Observed for separation.
- -5-10°C, 24h, then returned to ambient. Observed for separation.

Results/conclusion: No significant changes.

Other: Total bacterial count to be ≤1000cfu/gram. All measurements <10cfu/gram. Fecal Coliform: Not detected.

Ingredients:
- For details of ingredients, see Appendix 2.

5. MICROBIOLOGY

This shower gel is a water-based liquid. It contains more than 70% water.

Quality

For a product of this type (category 2), manufactured product should meet the following standards:

- Products not intended for use on babies, the vicinity of the eyes or on mucous membranes – total viable count (TVC) for aerobic mesophilic microorganisms should not exceed 1000cfu/g (ml) in 0.1g (ml) of product.
- The following organisms are required to be absent in 1g (ml) of the product: Pseudomonas aeruginosa; Staphylococcus aureus; Candida albicans.

Quality was measured (report no: 13/0164; date of test: 2013/03/22). Counts were all <10cfu/ml (see Appendix 2). Similar findings are reported in the Stability study report.

Preservation:

A challenge test was conducted to determine effectiveness to control the growth of standard tester strains (Report no. 13-0164-1, date of test: 2013/03/21). Details are shown in Appendix 2.

Conclusion: The product satisfies the criteria for a dermally applied product.

6. IMPURITIES & PACKAGING MATERIAL

It is understood that this product is manufactured following Good Manufacturing Procedures (e.g. ISO 22716:2007) and that ingredients used throughout will be of a suitable quality. The information provided in MSDS' and indicates that all ingredients are acceptable. Ingredient names are shown in Appendix 1, full documentation must be held in the Product Information File.

The product is packaged in a 7 g single use sachets.

7. NORMAL & REASONABLY FORESEEABLE USE

This product is intended for the general public, both sexes. It will be applied to the whole body in the shower and removed by rinsing with copious amounts of water. It is a rinse-off product.

Exposure to whole product is calculated for an adult using the approach recommended by the Scientific Committee on Consumer Safety (SCCS) and the content of the sachet as the amount applied:

whole product:

<table>
<thead>
<tr>
<th>Skin Exposure</th>
<th>Systemic Exposure Dose (SED): [Exposure/body weight (kg)]*retention factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application site:</td>
<td>Head &amp; hands</td>
</tr>
<tr>
<td>Surface area:</td>
<td>1750 cm²</td>
</tr>
<tr>
<td>Total amount applied:</td>
<td>7g (7,000mg)</td>
</tr>
<tr>
<td>Typical body weight:</td>
<td>60kg</td>
</tr>
<tr>
<td>Retention factor:</td>
<td>0.01 (1%)</td>
</tr>
<tr>
<td>Total amount applied:</td>
<td>7g (7,000mg)</td>
</tr>
</tbody>
</table>

The SCCS' Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation, 8th revision. SCCS/1501/12, 11 Dec 2012

All results relate only to the sample received for assessment
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**8. TOXICOLOGY PROFILE OF INGREDIENTS**

Sources of information for this review include the client peer reviewed literature and internet providers such as COSING. For key toxicological findings of all ingredients, see Appendix 3.

The available physical-chemical and toxicological properties of all ingredients were reviewed with particular attention to potential effects on normal and sensitive skin. Intended and reasonably foreseeable use of the complete formulation and any agreed limits/restrictions such as those imposed by cosmetics legislation were taken into consideration.

All ingredients are allowed in this type of product according to current legislation. None of them are, or are known to contain, a CMR (carcinogen, mutagen or reproductive toxicant). None of them are nanoparticles as defined by the Scientific Committee on Consumer Safety (SCCS/1484/12). All ingredients are at a concentration that is below any limits in legislation.

This product contains a single fragrance (details below) in which several of the SCCNFP allergens are present. The concentrations of these in the final product are highlighted. Those at ≥0.01% must be included in the list of ingredients on pack.

**Hbrid Lily, RH81516**

<table>
<thead>
<tr>
<th>EU INCI NAME</th>
<th>CAS No.</th>
<th>EC C&amp;L</th>
<th>CLP</th>
<th>Conc. (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Lauroyl Sarcosinate</td>
<td>137-16-6</td>
<td>R23, 36/38, H330, H315, H319</td>
<td>14.00</td>
<td></td>
</tr>
<tr>
<td>Cocamidopropyl Betaine</td>
<td>61789-40-0</td>
<td>R41</td>
<td>H318</td>
<td>4.00</td>
</tr>
<tr>
<td>Dizodiolindinyl Urea</td>
<td>78491-02-8</td>
<td>R43</td>
<td>H317</td>
<td>0.10</td>
</tr>
<tr>
<td>Citric Acid</td>
<td>77-92-9</td>
<td>R36</td>
<td>H319</td>
<td>0.10</td>
</tr>
<tr>
<td>Alpha-Isomethyl Ionone</td>
<td>127-51-5</td>
<td>R43, 51/53, H319, H411, H315</td>
<td>0.096</td>
<td></td>
</tr>
<tr>
<td>Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde</td>
<td>31906-04-4</td>
<td>R43, 41, 52/53, H317, H319, H412</td>
<td>0.039</td>
<td></td>
</tr>
<tr>
<td>Linalool</td>
<td>78-70-6</td>
<td>R36/38, 43, H315, H319</td>
<td>0.012</td>
<td></td>
</tr>
</tbody>
</table>

**FOOTNOTE:**

-хохтоно: *: NESIL: No Expected Sensitization Induction Level; MoS: Margin of Safety; IFRA: International Fragrance Research Association. Entries in yellow are ≥0.01%.

Of the ingredients, a number are classified for physical, health and/or environmental hazards under EC Chemicals legislation. The information in the following table is indicative of the classification of these chemicals. The other ingredients are not to be considered significantly hazardous.

Based on this information, this product may cause skin and eye irritation. It is not expected to cause skin sensitization or to be harmful to health (Because it is a liquid, inhalation is not expected to be a route of exposure and, therefore, toxic by inhalation (R23) does not apply.

**Ingredients:**

Exposure to each ingredient/raw material is expected to be in proportion to their concentration in the product.

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Footnote: *: NESIL: No Expected Sensitization Induction Level; MoS: Margin of Safety; IFRA: International Fragrance Research Association. Entries in yellow are ≥0.01%.
Calculations of Margin of Safety (MoS) have been determined for all ingredients where this is possible from published toxicity information. The method used to do this is:

\[
\text{SED (whole product)} \times \% \text{ ingredient} = \text{SED (ingredient)} \\
\text{MoS} = \frac{\text{Oral NOEL (ingredient)}}{\text{SED (ingredient)}}.
\]

In every case at the highest concentration present (see following table), the MoS is >100 which is considered to be acceptable.

<table>
<thead>
<tr>
<th>EU INCI NAME, CI No</th>
<th>Conc. (%)</th>
<th>SED</th>
<th>Oral NOEL mg/kg/day</th>
<th>MoS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aqua</td>
<td>73.411</td>
<td>0.8589087</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sodium Lauroyl Sarcosinate</td>
<td>14</td>
<td>0.1638</td>
<td>30</td>
<td>183.15</td>
</tr>
<tr>
<td>Cocamide MEA</td>
<td>5</td>
<td>0.0585</td>
<td>75</td>
<td>1282.05</td>
</tr>
<tr>
<td>Cocamidopropyl Betaine</td>
<td>4</td>
<td>0.0468</td>
<td>150</td>
<td>3205.13</td>
</tr>
<tr>
<td>Parfum</td>
<td>3</td>
<td>0.0351</td>
<td>Not available</td>
<td>-</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>0.3</td>
<td>0.00351</td>
<td>1330</td>
<td>378917.38</td>
</tr>
<tr>
<td>Diazolidinyl Urea</td>
<td>0.1</td>
<td>0.00117</td>
<td>100</td>
<td>85470.09</td>
</tr>
<tr>
<td>Citric Acid</td>
<td>0.1</td>
<td>0.00117</td>
<td>1200</td>
<td>1025641.03</td>
</tr>
<tr>
<td>Alpha-isomethyl Ionone</td>
<td>0.096</td>
<td>0.0011232</td>
<td>10</td>
<td>8903.13</td>
</tr>
<tr>
<td>Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde</td>
<td>0.039</td>
<td>0.0004563</td>
<td>120</td>
<td>262984.88</td>
</tr>
<tr>
<td>Magnesium Nitrate</td>
<td>0.018</td>
<td>0.0002106</td>
<td>1500</td>
<td>7122507.12</td>
</tr>
<tr>
<td>Linalool</td>
<td>0.012</td>
<td>0.0001404</td>
<td>160</td>
<td>1139601.14</td>
</tr>
<tr>
<td>Magnesium Chloride</td>
<td>0.004</td>
<td>0.0000468</td>
<td>1000</td>
<td>2136752.37</td>
</tr>
<tr>
<td>Mixture of 5-Chloro-2-methyl-Isothiazol-3(2H)-one and 2-Methylisothiazol-3(2H)-one</td>
<td>0.0012</td>
<td>0.00001404</td>
<td>Not available</td>
<td>-</td>
</tr>
</tbody>
</table>

Footnote: SED = Systemic Exposure Dose; NOEL(NOAE) = No Effect of No Actual Effect Level established by experiment or assumed by read-across to similar ingredients; MoS = Margin of Safety. Calculation assumes 100% absorption through skin.

In addition, calculations are also presented to compare the concentration of each ingredient with the recommendations of industry (CTFA) and any limits in European cosmetic legislation. All ingredients fall below any recommended limits.

9. UNDESIRABLE EFFECTS & SERIOUS UNDESIRABLE EFFECTS

None have been reported to this assessor. Rarely, reports of skin and eye irritation may be received on this type of product.

10. OTHER INFORMATION

ANNEX I, PART B — COSMETIC PRODUCT SAFETY ASSESSMENT

11. REASONING

This product is a single use, fragranced shower gel. It is intended for occasional use. It is not specifically intended for children under 3 years of age.

The available physical-chemical and toxicological properties of all ingredients were reviewed. Intended and reasonably foreseeable use of the complete formulation and any agreed limits/ restrictions such as those imposed by Cosmetics legislation were taken into consideration.

All ingredients are suitable for this application. They have a history of safe use in cosmetic products. As a consequence, there is no reason to expect this product to be hazardous to health.
It does not contain carcinogens, mutagens, chemicals that are toxic to reproduction or nanoparticles. The preservative present is allowed. The product is able to control the growth of microorganisms as demonstrated in a challenge test. It is calculated that the amount of formaldehyde is less than 0.05%. Thus there is no requirement for a warning for formaldehyde content to be included on label.

The product has been shown to be stable at temperatures up to 40°C for 12 weeks and not to separate in the cold. These conditions represent those of transport, storage and use.

This product satisfies legislation requirements and is expected to be safe to use as instructed and under other reasonably foreseeable conditions of use.

The list of ingredients for the label as provided is incorrect. It should be amended according to section 3 of this report.

If product enters the eye, temporary irritation may be experienced and, if skin is sensitive or damaged, it may cause slight skin irritation. The product is not expected to cause skin sensitization, to be harmful if ingested in small amounts or to adversely affect the respiratory system. Long term adverse effects are not expected.
12. ASSESSOR’S CREDENTIALS

This is to certify that

Robert Priston
has been admitted as a
Chartered Biologist
by resolution of the Council

Membership Number 055297
Council Date 04 March 2010

Professor David Coates
Honorary Secretary

This is to certify that

Robert Priston
has been admitted as a
Member
by resolution of the Council

Membership Number 000967
Council Date 16 December 2009

Professor David Coates
Honorary Secretary

This is to certify that

Robert Anthony John Priston
may use the title
EUROTOX REGISTERED TOXICOLOGIST
whilst registered with the
UK Register of Toxicologists

EUROTOX Secretary General
BAILI COURT, LONDON

UNIVERSITY OF LONDON

Robert Anthony John Priston

London. School of Hygiene & Tropical Medicine
and Animal Venoms Research Institute

Having completed the course of study approved by the University and
passed the prescribed examinations as an Internal Student has
also been awarded by the Senate to the degree of

DOCTOR OF PHILOSOPHY

26 February 1999

Academic Registrar
This is to certify that Robert Anthony John Priston has been registered with the UK Register of Toxicologists and is bound by the codes of conduct of the Society of Biology and British Toxicology Society for the period 17th October 2011 to 17th October 2016.

S. C. Davis
Director Chair

Robert Anthony John Priston - Curriculum Vitae

14 Aug 2013

Technology Advisor. Coverage included specialty and agricultural chemicals, lower depletions, DODSALES, PMP, pesticides, phytotoxicants and their effects, nanomaterials, text chemicals, biocides and other products and pesticides.

A traditional occupational toxicologist and a risk assessor for new and existing products. Responsibilities included working globally as a member of a multidisciplinary and multidisciplinary team.

External representation, high profile national activities in Europe and the USA. Product stewardship such as placardisation, hazard and risk assessment and occupational and consumer exposure. Sensitivity to research and programs developed, managed and reported.

An essential part of the work was to maintain a thorough knowledge of toxicology and its applications, including REACH, GHS, REACh, etc. (alternatives to animal testing).

SHELL RESEARCH LIMITED (1974 - 1985)

Business liaison manager in the strategic and operational group Management of operations, strategic and business planning and development, product and market analysis, and internal audit.

ANIMAL VIRUS RESEARCH INSTITUTE (1975 - 1978)

Business advisor in the strategic and operational group. Management of operations, strategic and business planning and development, product and market analysis, and internal audit.

PERSONAL

Education: B.Sc., Honors, Zoology and Botany (University of Hull), BSc (London University, England)

Languages: English, Working knowledge in French and Dutch.

AFFILIATIONS

Society of Biology (NSB), Chartered Biologist (C. Biol.), British Toxicology Society (BTS), UK & London Registered Toxicologist, Society of Cosmetic Chemists (UK), UK Environmental Protection Society (UKEPS)

COMMENTS

Anthem - CTPA, Toxicology Advisory Panel (TAP)

PAST TOXICOLOGY COMMITTEES/STAFF FORCES

European Centre for Ecotoxicology and Toxicology of Chemicals (ECCETOC)
European Chemical Industry Council (CEFIC)
Chemical Industries Association (UK CIA)
Oil companies: European Association for Environment, Health and Safety, Refining and Distribution (COFRED)
International Cooperation Institute (ICI)
International Institute of Synthetic Rubber Producers (ISRP)
European Disposables and Polystyrene Association (EDPA)
UK Department of Health, Safety and Environment (DSE) Centers for Alternatives to Animal Testing (CAAT)
European Responsible and Nonvertiser's Association (EIRWA)
European Partnership for Alternative Approaches to Animal Testing (EPATA)

Fund for the Replacement of Animals in Medical Experiments (PRAME)
Institute of Vitro Sciences (IVS, Science Advisory Committee)
Cosmetic Toxology & Parfumery Association (CTPA)

SUMMARY

- A toxicologist with more than 35 years in the Chemical and Consumer Product industries.
- Experienced in risk management and risk assessment, both internal and external, on various substances.
- Working knowledge of Chemical requirements in Europe and the USA, particularly in Cosmetics, Medical Devices and REACH.
- Experienced in Trade Assessments in the EU and the USA.
- Strong written and verbal skills, good team player.
- Management and leadership strengths.
# APPENDIX 1: PRODUCT COMPOSITION

<table>
<thead>
<tr>
<th>Raw material (supplier)</th>
<th>Ingredient</th>
<th>CAS</th>
<th>Conc. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>Aqua</td>
<td></td>
<td>73.35</td>
</tr>
<tr>
<td>(Chatten Chemical Inc)</td>
<td>Sodium Lauroyl Sarcosinate</td>
<td></td>
<td>14</td>
</tr>
<tr>
<td>cocamide MEA (Cognis)</td>
<td>Cocamide MEA</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Amphosolm CA (Stepan)</td>
<td>Cocamidopropyl Betaine</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Maxim Group</td>
<td>Hibrid Lily, RH81516</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Various (Science Lab)</td>
<td>Sodium Chloride</td>
<td></td>
<td>0.3</td>
</tr>
<tr>
<td>Various (Science Lab)</td>
<td>Citric Acid</td>
<td></td>
<td>0.1</td>
</tr>
<tr>
<td>Various (Science Lab)</td>
<td>Diazolidinyl Urea</td>
<td></td>
<td>0.1</td>
</tr>
<tr>
<td>Isocil PC (Lonza)</td>
<td>MI/CMI mix</td>
<td></td>
<td>0.001*</td>
</tr>
<tr>
<td>-</td>
<td>Linalool</td>
<td>78-70-6</td>
<td>0.0120</td>
</tr>
<tr>
<td>-</td>
<td>Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde</td>
<td>31906-04-4</td>
<td>0.0390</td>
</tr>
<tr>
<td>-</td>
<td>alpha-isomethyl ionone</td>
<td>127-51-5</td>
<td>0.0960</td>
</tr>
</tbody>
</table>

* This mixture also contains Aqua, Magnesium Nitrate, and Magnesium Chloride.
### Appendix 3: Ingredient Summaries

**Product:** SHOWER GEL

#### Agua

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS No</td>
<td>7732-18-5</td>
</tr>
<tr>
<td>EINECS/ELINC</td>
<td>231-791-2</td>
</tr>
<tr>
<td>Function</td>
<td>Solvent</td>
</tr>
<tr>
<td>Other name</td>
<td>Water (USA)</td>
</tr>
</tbody>
</table>

**Physical Properties:***

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular weight</td>
<td>18.15</td>
</tr>
<tr>
<td>Formula</td>
<td>H2O</td>
</tr>
<tr>
<td>Solubility</td>
<td>Completely miscible</td>
</tr>
<tr>
<td>Flash point</td>
<td>-</td>
</tr>
<tr>
<td>Melting point</td>
<td>0°C</td>
</tr>
<tr>
<td>Boiling point</td>
<td>100°C</td>
</tr>
</tbody>
</table>

**Summary:**

Water is a clear liquid used as a universal solvent. Freezing and boiling points, 0°C and 100°C respectively. The quality of water must be monitored according to Good Manufacturing Procedures (GMP) and/or must comply with international Pharmacopoeia standards for water purity used in drugs, devices and diagnostics. Oral LD50 (rat) >90ml/kg. It represents no significant toxicological hazard in this application.

#### Sodium Lauroyl Sarcosinate

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS No</td>
<td>137-16-6</td>
</tr>
<tr>
<td>EINECS/ELINC</td>
<td>205-281-5</td>
</tr>
<tr>
<td>Function</td>
<td>Antistatic, Cleansing, Emulsifying, Conditioning</td>
</tr>
<tr>
<td>Other name</td>
<td>Sodium N-lauroylsarcosinate, Sarkosyl</td>
</tr>
</tbody>
</table>

**Physical Properties:***

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular weight</td>
<td>293.38</td>
</tr>
<tr>
<td>Formula</td>
<td>C15H29NO3 • Na</td>
</tr>
<tr>
<td>Solubility</td>
<td>40% in water at 20°C</td>
</tr>
<tr>
<td>Flash point</td>
<td>-</td>
</tr>
<tr>
<td>Melting point</td>
<td>-1°C</td>
</tr>
<tr>
<td>Boiling point</td>
<td>100°C</td>
</tr>
</tbody>
</table>

**Summary:**

Sodium lauroyl sarcosinate is a co-surfactant. The CIR Expert Panel has reviewed use in cosmetic products (1). They concluded that sarcosine derivatives, in general, are not significantly toxic and concluded that they can be used without limitation in rinse-off products. Sarcosine can be nitrosated, however, to form N-nitrosarcosine. With this in mind, they recommended a maximum of 5% in leave-on products.

Ref: (1) IJT 20 (1) 2001. REACH data.

**Cosmetics legislation:** not controlled.

| EU, R-phrases * | Not classified |
| Notified Classifications, CLP ** | Not classified |
| EU REACH status | Exempt |

**Ingredient Exposure Calculations:**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum conc. of ingredient in product (% w/w):</td>
<td>73.411000</td>
</tr>
<tr>
<td>Skin Exposure, ingredient (mg/cm²) - Oral NOAEL (mg/kg/day) -</td>
<td>2.93644</td>
</tr>
<tr>
<td>SED, ingredient (mg/kg/day) - ADI (mg/kg/day) -</td>
<td>0.85891</td>
</tr>
<tr>
<td>CIR, Safe level, Rinse-off max (%) - Reg.(EC)1223/2009, Rinse-off max (%) -</td>
<td>0.56000 0.16380 30.0 183.15</td>
</tr>
</tbody>
</table>
**Cocamide MEA**

CAS No 68140-00-1

EINECS/ELINC 268-770-2

Function Emulsifying, Stabilising, Surfactant

Other name Cocoyl Monoethanolamine; Amides, coco, Û-(hydroxyethyl)

**PHYSICAL PROPERTIES:**

- **Appearance:** Solid, wax pellets, white-off white
- **Molecular weight:** 243.22
- **Formula:** C14H29NO2
- **Solubility:** Readily soluble in water
- **Flash point:** >150°C
- **Melting point:** -2°C
- **Boiling point:** >100°C

**SUMMARY:**

Cocamide MEA is a wax with a low acute toxicity but is irritating to skin and severely irritating to eyes. A 28-day oral toxicity study in rat gave a NOAEL of 750mg/kg/d. This equates to 75g/kg for a 90-day study (1). The CIR Expert Panel (2) recommends a maximum of 10% in leave-on products but no restriction for rinse-off. Should not be used where N-nitroso compounds might be formed (76/768/EEC as amended) (Annex III/1, 60). Criteria are:

- Ingredient: Max Dialkanolamine content-5.0%; Max N-nitrosodialkanolamine - 50µg/kg. Final product: Dialkanolamine content, maximum of 0.5% in the product. Raw material must be stored in nitrite-free containers.


**Cosmetics legislation:** Allowed, not controlled, but see above.

EU, R-phrases *: Not classified

Notified Classifications, CLP **: Not classified

EU REACH status: Pre-registered, Amides, coco, N-(hydroxyethyl)

**INGREDIENT EXPOSURE CALCULATIONS:**

| Maximum conc. of ingredient in product (% w/w): | 5.000000 | Oral NOAEL (mg/kg/day) | 75.0 | 1282.05 |
| Skin Exposure, ingredient (mg/cm²) - | 0.200000 | ADI (mg/kg/day) - | 0.05850 |
| SED, ingredient (mg/kg/day) - | 0.04680 |

**Cocamidopropyl Betaine**

CAS No 61789-40-0

EINECS/ELINC 263-058-8

Function Surfactant, Foam booster

Other name Cocoamidopropyl betaine, Dehyton® K COS/BZ; Epigen BS/F

**PHYSICAL PROPERTIES:**

- **Appearance:** White-slightly yellow liquid
- **Molecular weight:** -
- **Formula:** -
- **Solubility:** Readily soluble in water
- **Flash point:** 110°C
- **Melting point:** -2°C
- **Boiling point:** >100°C

**SUMMARY:**

Cocamidopropyl Betaine is a co-surfactant and foam booster. It is a soluble, creamy-white liquid with a pH 4-5.5. The CIR Expert Panel (1) had no concerns over this ingredient in rinse-off products but in leave-on products they recommended a maximum of 3%, based on sensitization but these are thought to have been due to the presence of the impurity 3-dimethylaminopropylamine (DMAPA). Cocamidopropyl Betaine causes eye irritation in the rabbit at 4.5% and skin irritation at 10% but it is not acutely toxic (oral LD50 in rat of>1500mg/kg) and is not a mutagen. Systemic effects in feeding studies and a reproduction study. An oral NOEL for developmental toxicity - 150mg/kg/d (2). For cosmetic use, impurities should meet the following: Dichloroacetic acid <30ppm; Monochloroactic acid <5ppm; Cocaamidopropyldimethylamine (DMAPA)<5000ppm; 3-dimethylaminoptylamine (DMAPA) <15ppm. Nitrosamine level <50ppb.

Ref: (1) CIR review: JACT, 10(1) (2)1991; HPV test plan Sept 16, 2004. (Mackam 50ULT = 40-50% Cocamidopropyl Betaine; Surfac B4 MSDS (10-30%).

**Cosmetics legislation, EC:** Not restricted.

EU, R-phrases *: R41

Notified Classifications, CLP **: H318

EU REACH status: Pre-registered

**INGREDIENT EXPOSURE CALCULATIONS:**

| Maximum conc. of ingredient in product (% w/w): | 4.000000 | Oral NOAEL (mg/kg/day) | 150.0 | 3205.13 |
| Skin Exposure, ingredient (mg/cm²) - | 0.160000 | ADI (mg/kg/day) - | 0.04680 |
| SED, ingredient (mg/kg/day) - | 0.04680 |

**Ref:**

Appendix: Page 2 of 7
**Sodium Chloride**

CAS No 7647-14-5  
EINECS/ELINC 231-598-3  
Function Bulking, Masking, Viscosity controlling  
Other name Sodium Chloride  

**PHYSICAL PROPERTIES:**
- Appearance: solid, white, odourless  
- Molecular weight: 58.4428  
- Formula: NaCl  
- Solubility: very soluble (310g/L)  
- Flash point: Melting point: 801°C  
- Boiling point: 1465°C

**SUMMARY:**
Sodium chloride (common salt) has ubiquitous use throughout the food and non-food industry. It is commonly used in skin applications within the personal care industry and is regularly used as a thickener and gelling agent in shower gels and bubble baths at concentrations up to 5%. It is also used as an ingredient and condiment directly on food. The acute toxicity of sodium chloride is >2000mg/kg, it is not an irritant of skin sensitizer and there is no known systemic toxicity associated with its use at typical usage concentrations. It is acceptable in this application.

Ref: REACH dataset.

Cosmetic legislation, EC: Not restricted.
EU, R-phrases *: Not classified  
Notified Classifications, CLP **: Not classified  
EU REACH status: Full registration

**INGREDIENT EXPOSURE CALCULATIONS:**

| Maximum conc. of ingredient in product (% w/w): | 0.300000 | 1330.0 | 378917.38 |
| Skin Exposure, ingredient (mg/cm²) - | 0.01200 | Oral NOAEL (mg/kg/day) - | |
| SED, ingredient (mg/kg/day) - | 0.00351 | ADI (mg/kg.day) - | |
| | | CIR, Safe level, Rinse-off max (%) - | |
| | | Reg.(EC)1223/2009, Rinse-off max (%) - | |

**Citric Acid**

CAS No 77-92-9  
EINECS/ELINC 201-069-1, -  
Function Buffering, Chelating  
Other name 1,2,3-Propanetricarboxylic acid, 2-hydroxy-  

**PHYSICAL PROPERTIES:**
- Appearance: White granules, odourless  
- Molecular weight: 191  
- Formula: C6H8O7  
- Solubility: 60g/100ml at 20°C  
- Flash point: Melting point: 153°C  
- Boiling point: |

**SUMMARY:**
Citric Acid is a natural substance produced by citrus fruits. It is an alpha-hydroxy acid, similar is structure to lactic and glycolic acid but less widely used in cosmetic products. It is also a food ingredient (E330). In cosmetic products it is principally a buffering and chelating agent but it, as with the other AHA, is a defoliating agent at high concentrations, breaking down the bonds between live and dead cells. As such it is useful in skin creams to reduce wrinkles etc. Citric acid is of low acute toxicity. In the rat, the NOAEL for repeated dose toxicity is 1200mg/kg/day with effects limited to changes in blood chemistry and excretion (1). It is not a carcinogen or mutagen and the NOAEL for reproductive effects is 2500mg/kg/day. It is irritating to skin, eyes and the respiratory system but is not a skin sensitizer (1).


Cosmetics legislation, EC: Not restricted.
EU, R-phrases *: R36  
Notified Classifications, CLP **: H319  
EU REACH status: Registered

**INGREDIENT EXPOSURE CALCULATIONS:**

| Maximum conc. of ingredient in product (% w/w): | 0.100000 | 1200.0 | 1025641.03 |
| Skin Exposure, ingredient (mg/cm²) - | 0.00400 | Oral NOAEL (mg/kg/day) - | |
| SED, ingredient (mg/kg/day) - | 0.00117 | ADI (mg/kg.day) - | |
| | | CIR, Safe level, Rinse-off max (%) - | |
| | | Reg.(EC)1223/2009, Rinse-off max (%) - | |
### Diazolidinyl Urea

**CAS No**: 78491-02-8  
**EINECS/ELINC**: 278-928-2  
**Function**: Preservative  
**Other name**: 1-[1,3-bis(Hydroxymethyl)-2,5-dioxiimidazolidin-4-y]-1

#### PHYSICAL PROPERTIES:

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
<td>Molecular weight</td>
<td>278.22</td>
</tr>
<tr>
<td>Formula</td>
<td>C8H14N4O7</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble</td>
</tr>
<tr>
<td>Flash point</td>
<td>278.22°C</td>
</tr>
<tr>
<td>Melting point</td>
<td>Solid, white, odourless</td>
</tr>
<tr>
<td>Boiling point</td>
<td>122.1°C</td>
</tr>
</tbody>
</table>

#### SUMMARY:

Diazolidinyl urea is a substituted urea, typically used in cosmetic products at 0.2-0.4%. It is a formaldehyde donor. Use in cosmetics has been reviewed by the SCCNFP (1) and by the CIR Expert Panel (2). Diazolidinyl urea has low acute and long term toxicity (NOEL from a 90-day study reported to be 100mg/kg/day). Not an eye irritant at 5% but in 3 of 4 studies reported it was shown to cause skin sensitization. It is not mutagenic in bacteria or in cell cultures. In human volunteers, Diazolidinyl Urea at 0.4% was a mild cumulative skin irritant, not a skin sensitizer in an RRIPT but at 1%, 57 of 2385 patients developed an allergic reaction. It was not a photosensitizer at 0.25%. The CIR Expert Panel concluded that this ingredient is safe at 0.5%.

Under the EC Cosmetics Directive a warning "contains formaldehyde" is required to be stated on the labelling of the product if the free formaldehyde content in the finished product exceeds 0.05%. According to the SCCNFP, 1 molecule of Diazolidinyl Urea will give rise to 4 molecules of formaldehyde. Thus, a concentration of 0.1% will produce 0.043% free formaldehyde (1).

In the absence of any test data relating to the free formaldehyde content it would be prudent to include the warning "contains formaldehyde" to alert the consumer to the presence of this compound in the event of a known allergy to formaldehyde, thus allowing the consumer to avoid the product if necessary.

Ref: (1) SCCNFP/586/02(final), 17 December 2002; (2) JACT 9(2) 1990.

### Alpha-isomethyl Ionone

**CAS No**: 127-51-5  
**EINECS/ELINC**: 204-846-3  
**Function**: Fragrance ingredient  
**Other name**: Methyl Ionone, Mixed Isomers

#### PHYSICAL PROPERTIES:

<table>
<thead>
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<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular weight</td>
<td>206.32</td>
</tr>
<tr>
<td>Formula</td>
<td>C14H22O</td>
</tr>
<tr>
<td>Solubility</td>
<td>16 mg/L at 20°C (OECD 105)</td>
</tr>
<tr>
<td>Flash point</td>
<td>122.1°C</td>
</tr>
<tr>
<td>Melting point</td>
<td>265.3°C</td>
</tr>
</tbody>
</table>

#### SUMMARY:

Alpha-isomethyl Ionone is one of 21 ionone derivatives. It is GRAS and is approved for use in food by JECFA. Ionone derivatives occur mainly in plants containing beta-carotene and they are produced synthetically. This isomer does not possess significant toxicity but it has been identified as a weak allergen in human studies. According to IFRA Alpha-isomethyl Ionone is a weak skin sensitizer with a NOEL for induction in an HRIPT of 70.866mg/cm2. Based on this they set a NESIL (No Expected Sensitization Induction Level) of 70.00mg/cm2.

Cosmetics legislation: controlled.(Annex III/90). Fragrance allergen. Must be declared at 0.001% (leave-on, eyes) and 0.01% (rinse-off).

### INGREDIENT EXPOSURE CALCULATIONS:

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Margin of Safety</strong></td>
<td></td>
</tr>
<tr>
<td>Skin Exposure, ingredient (mg/cm2) -</td>
<td>0.00384 Oral NOAEL (mg/kg/day) - 10.0 8903.13</td>
</tr>
<tr>
<td>SED, ingredient (mg/kg/day) -</td>
<td>0.00112 ADI (mg/kg/day) -</td>
</tr>
<tr>
<td></td>
<td>CIR,Safe level,Rinse-off max (%) - 0.500 5.00</td>
</tr>
<tr>
<td></td>
<td>Reg.(EC)1223/2009, Rinse-off max (%) - 0.5000 5.00</td>
</tr>
</tbody>
</table>
**Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde**

**CAS No**  31906-04-4, 51414-25-6  
**EINECS/ELINC**  250-863-4, 257-187-9  
**Function**  Fragrance ingredient  
**Other name**  Hydroxy-methylpentylcyclohexenecarboxaldehyde; Lyral  

**PHYSICAL PROPERTIES:**

- **Appearance**  
- **Molecular weight:** 210.31  
- **Formula:** C13H22O2  
- **Solubility:** Very soluble  
- **Flash point:** 93°C  
- **Melting point:** 65-77.2 °C.  
- **Boiling point:** 85-122 °C  

**SUMMARY:**

Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde is one of the 26 fragrance allergens identified by SCCNFP. The SCCP has reviewed numerous animal and clinical studies and concluded that it is a common allergen in Europe. They tentatively concluded a NOEL for this effect of 4000ug/cm² and an EC3 value of 4272ug/cm². IFRA has not yet agreed a NESIL (No Expected Sensitization Induction Level) but form the above, 4000ug/cm² is assumed. IFRA has set maximum concentration levels on a pragmatic basis. A NOEL from a 90-day oral study in rat is reported in (1). This is 120mg/kg/day. From a 2 year study the equivalent reported is 250mg/kg/day.  


**Cosmetics legislation:** Must be declared at 0.001% (leave-on, eyes) and 0.01% (rinse-off) (Annex III/79).

**EU, R-phrases:**  
R43, 41, 52/53  
**Notified Classifications, CLP:**  
H317, H319, H412  
**EU REACH status:**  
Pre-registered  

**INGREDIENT EXPOSURE CALCULATIONS:**

<table>
<thead>
<tr>
<th>Skin Exposure, ingredient (mg/cm²)</th>
<th>Oral NOAEL (mg/kg/day)</th>
<th>Margin of Safety</th>
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<tbody>
<tr>
<td>SED, ingredient (mg/kg/day) -</td>
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<td>120.0</td>
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<tr>
<td>0.039000</td>
<td>0.00156</td>
<td>262984.88</td>
</tr>
<tr>
<td>0.00046</td>
<td>ADI (mg/kg.day) -</td>
<td></td>
</tr>
<tr>
<td>CIR, Safe level, Rinse-off max (%) -</td>
<td>Reg.(EC)1223/2009, Rinse-off max (%) -</td>
<td></td>
</tr>
</tbody>
</table>

---

**Magnesium Nitrate**

**CAS No**  10377-60-3  
**EINECS/ELINC**  233-826-7  
**Function**  Stabilizer, Conditioning  
**Other name**  -  

**PHYSICAL PROPERTIES:**

- **Appearance**  Colourless crystals  
- **Molecular weight:** 143.31  
- **Formula:** HNO₃·1/2Mg  
- **Solubility:** Very soluble  
- **Flash point:** 129°C  
- **Boiling point:**  

**SUMMARY:**

Magnesium nitrate is a natural salt that is used as a fixative in shampoos and hair conditioners. It is also one of the components of preservative mixtures that contain methylchloroisothiazolinone and methylisothiazolinone in which it is a carrier. When neat it has the form of colourless crystals with a melting temperature of 129°C. It is soluble in water with a pH 7.00. Toxicologically, It has low toxicity, is not irritating and in not a skin sensitizer. In a 28 day oral study in rat at 0, 250, 750 and 1,500 mg/kg/day the were no significant findings at th highest dose level ( NOAEL => 1500mg/kg/d. It is acceptable as proposed.  

Ref: REACH database.

**Cosmetics legislation:** Not controlled.

**EU, R-phrases:**  
Not classified  
**Notified Classifications, CLP:**  
Not classified  
**EU REACH status:**  
Registered  

**INGREDIENT EXPOSURE CALCULATIONS:**

<table>
<thead>
<tr>
<th>Skin Exposure, ingredient (mg/cm²)</th>
<th>Oral NOAEL (mg/kg/day)</th>
<th>Margin of Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>SED, ingredient (mg/kg/day) -</td>
<td></td>
<td>1500.0</td>
</tr>
<tr>
<td>0.018000</td>
<td>0.00072</td>
<td>7122507.12</td>
</tr>
<tr>
<td>0.00021</td>
<td>ADI (mg/kg.day) -</td>
<td></td>
</tr>
<tr>
<td>CIR, Safe level, Rinse-off max (%) -</td>
<td>Reg.(EC)1223/2009, Rinse-off max (%) -</td>
<td></td>
</tr>
</tbody>
</table>
## Linalool

**CAS No**: 78-70-6  
**EINECS/ELINC**: 201-134-4  
**Function**: Denaturant, Perfuming  
**Other name**: 3,7-Dimethylocta-1,6-dien-3-ol

### PHYSICAL PROPERTIES:
- **Appearance**: Colourless liquid with a pleasant, floral odour  
- **Molecular weight**: 154.25  
- **Formula**: C10H18O  
- **Flash point**: 77.2 °C  
- **Melting point**: > -74 °C  
- **Boiling point**: 198°C  
- **Solubility**: Soluble in water (1000-10000 mg/L)

### SUMMARY:
Linalool is a naturally occurring terpene alcohol found in many flowers and spice plants and, according to the EU Scientific Committee (1), the largest exposure is from its use as a fragrance component, especially in lavender oil. It has other names such as β-linalool, linalyl alcohol, linaloyl oxide, p-linalool, allo-ocimenol, and 2,6-dimethyl-2,7-octadien-6-ol.

Commercially available Linalool (97%) is a weak sensitizer but it is readily oxidised upon storage to strong sensitizers such as linalyl hydroperoxide. Oxidized linalool and its hydroperoxide gave positive reactions in 1.8% of more than 1000 patients tested in a European multi-centre study. Linalool is one of the 26 fragrance allergens identified by the SCCNFP (2).

Ref: (1) SCCNFP/0760/03; (2) SCCNFP/0017/98; REACH.

### Cosmetics legislation, EC:
- Restricted (Regulation Annex III/84).
- The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on products, 0.01% in rinse-off products.

EU, R-phrases *: R36/38, 43  
Notified Classifications, CLP **: H315, H319  
EU REACH status: Full registration, Linalool

### INGREDIENT EXPOSURE CALCULATIONS:

<table>
<thead>
<tr>
<th></th>
<th>Skin Exposure, ingredient (mg/cm²)</th>
<th>SED, ingredient (mg/kg/day)</th>
<th>Margin of Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum conc. of ingredient in product (% w/w):</td>
<td>0.012000</td>
<td>0.0048</td>
<td>Oral NOAEL (mg/kg/day) - 160.0 1139601.14</td>
</tr>
<tr>
<td>CIR, Safe level, Rinse-off max (%) - Reg.(EC)1223/2009, Rinse-off max (%) -</td>
<td>0.00014 ADI (mg/kg/day) -</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Magnesium Chloride

**CAS No**: 7786-30-3  
**EINECS/ELINC**: 232-094-6  
**Function**: Viscosity controlling

### PHYSICAL PROPERTIES:
- **Appearance**: Solid, crystalline  
- **Molecular weight**: Cl₂Mg  
- **Formula**: 95.206  
- **Flash point**: 712 °C  
- **Melting point**: 468.7 g/L  
- **Boiling point**: 198°C  
- **Solubility**: Soluble in water (1000-10000 mg/L)

### SUMMARY:
Magnesium Chloride is a natural dietary component. It is not significantly hazardous. The oral LD50 (rat) is 5000mg/kg, it is not an irritant or a skin sensitizer and the NOAEL was found to be 1000mg/kg in the rat (1), the highest concentration tested. This raw material is acceptable in this application.

Ref: (1) REACH.

### Cosmetics legislation, EC:
- Not restricted.

EU, R-phrases *: Not classified  
Notified Classifications, CLP **: Not classified  
EU REACH status: Full registration, magnesium chloride

### INGREDIENT EXPOSURE CALCULATIONS:

<table>
<thead>
<tr>
<th></th>
<th>Skin Exposure, ingredient (mg/cm²)</th>
<th>SED, ingredient (mg/kg/day)</th>
<th>Margin of Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum conc. of ingredient in product (% w/w):</td>
<td>0.004000</td>
<td>0.00016</td>
<td>Oral NOAEL (mg/kg/day) - 1000.0 21367521.37</td>
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<tr>
<td>CIR, Safe level, Rinse-off max (%) - Reg.(EC)1223/2009, Rinse-off max (%) -</td>
<td>0.00005 ADI (mg/kg/day) -</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Mixture of 5-Chloro-2-methyl-Isothiazol-3(2H)-one and 2-Methylisothiazol-3(2H)-one**

<table>
<thead>
<tr>
<th>CAS No</th>
<th>55965-84-9</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS/ELINC</td>
<td>-</td>
</tr>
<tr>
<td>Function</td>
<td>Preservative</td>
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</table>

**PHYSICAL PROPERTIES:**

<table>
<thead>
<tr>
<th>Appearance</th>
<th>Formula:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flash point</td>
<td>Melting point:</td>
</tr>
<tr>
<td>Solubility</td>
<td>Boiling point:</td>
</tr>
</tbody>
</table>

**SUMMARY:**

Mixture of MCIT and MIT in the ratio 3:1. All ingredients in these mixtures are typically:
- 5-Chloro-2-methyl-4-isothiazolin-3-one (CAS: 26172-55-4; 1.05 - 1.2%) & 2-Methyl-4-isothiazolin-3-one (CAS: 2682-20-4; 0.3 - 0.45%).
- May also contain Magnesium Chloride (CAS: 7786-30-3; 0.5 - 1.0%); Magnesium nitrate (CAS: 10377-60-3 2; 1.0 - 23.5%); Water (CAS: 7732-18-5; 74.0 - 77.0%).

Both preservatives are irritating and skin sensitizers and their maximum concentration in consumer products are strictly controlled. Cosmetic legislation: The mixture of CMIT and MIT restricted to 0.0015%.

**EU, R-phrases *:** R23/24/25, R34, R43, R50/53

**Notified Classifications, CLP **:** H300, H310, H314, H317, H318, H330, H400

**EU REACH status:** Both ingredients pre-registered

**INGREDIENT EXPOSURE CALCULATIONS:**

| Maximum conc. of ingredient in product (% w/w): | 0.001200 |
| Skin Exposure, ingredient (mg/cm²) - | - |
| SED, ingredient (mg/kg/day) - | 0.00005 Oral NOAEL (mg/kg/day) - |
| - | 0.00001 ADI (mg/kg.day) - |
| - | CIR, Safe level, Rinse-off max (%) - |
| - | Reg.(EC)1223/2009, Rinse-off max (%) - |

**Margin of Safety**

Abreviations: CIR: The highest concentration reviewed or agreed to by the Cosmetic Ingredient Expert Panel; IFRA: Recommended maximum level, International Fragrance Research Association; EC: Limits in Annexes of Regulation (EU) 1223/2009; ADI: Acceptable Daily Intake agreed by USFDA and/or WHO JECFA; NOAEL: No Observable Actual Effect Level; SED: Systemic Exposure Dose. *:
http://sitem.herts.ac.uk/aeru/iupac/docs/EU_Risk_Phases_UH.pdf; **: http://www.uni-muenster.de/imperia/md/content/physikalische_chemie/praktikum/h_p_phrases.pdf