

PRODUCT NAME: Acetyl Hexapeptide-8 Solution

CODE: CM9010

REVISION 8

DATE 12/09/2022



## ACETYL HEXAPEPTIDE-8 Solution

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#### PRODUCT IDENTIFICATION

**Product name** Acetyl Hexapeptide-8 Solution

**Code** CM9010

#### INCI NAME

Water (Aqua), Caprylyl Glycol, Acetyl Hexapeptide-8

| INCI                 | COMPOSITION    | CAS         | EINECS    | FUNCTIONS         | ORIGIN    |
|----------------------|----------------|-------------|-----------|-------------------|-----------|
| Water (Aqua)         | Up to 100%     | 7732-18-5   | 231-791-2 | Solvent           | Mineral   |
| Caprylyl Glycol      | 0.45 - 0.55%   | 1117-86-8   | 214-254-7 | Skin Conditioning | Synthetic |
| Acetyl Hexapeptide-8 | 0.045 - 0.055% | 616204-22-9 | -         | Active Ingredient | Synthetic |

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#### SPECIFICATIONS

|                                       |                        |          |
|---------------------------------------|------------------------|----------|
| <b>Appearance</b>                     | Translucent solution   | AM-P-006 |
| <b>Color</b>                          | Colorless              | AM-P-005 |
| <b>pH</b>                             | 3.0 - 6.0              | AM-P-004 |
| <b>Density (g/mL)</b>                 | 0.98 - 1.02            | AM-P-001 |
| <b>Refraction Index</b>               | 1.31 - 1.35            | AM-P-002 |
| <b>Peptide Identification (HPLC)*</b> | According to standards | AM-P-007 |

\*The purity value refers to the purity of the peptide

#### MICROBIOLOGICAL DATA

|                                      |            |                  |
|--------------------------------------|------------|------------------|
| <b>Total aerobic microbial count</b> | <100 CFU/g | UNE-EN ISO 21149 |
| <b>Total yeast and mould count</b>   | <10 CFU/g  | UNE-EN ISO 16212 |
| <b>Escherichia coli</b>              | Absence/g  | UNE-EN ISO 21150 |
| <b>Staphylococcus aureus</b>         | Absence/g  | UNE-EN ISO 22718 |
| <b>Pseudomonas aeruginosa</b>        | Absence/g  | UNE-EN ISO 22717 |
| <b>Candida albicans</b>              | Absence/g  | UNE-EN ISO 18416 |

#### HEAVY METALS

Pb < 0.1 ppm

Cd < 0.1 ppm

Hg < 0.1 ppm

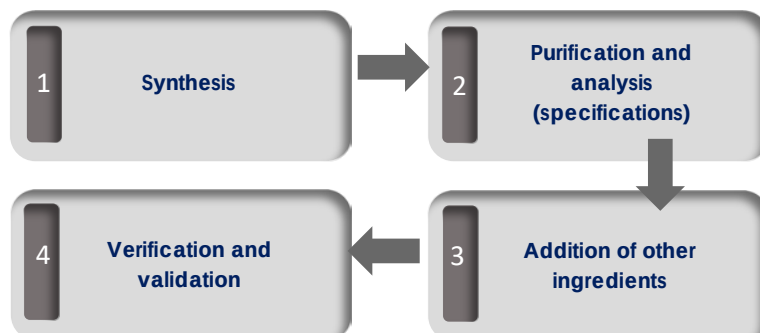
As < 0.1 ppm

Sb < 0.1 ppm

#### MOLECULAR WEIGHT

MW= 889.0 g/mol

## MANUFACTURING FLOWCHART



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## MANUFACTURING COUNTRY

Spain

## SHELF LIFE AND STORAGE

24 months, if the product is kept in the original sealed container in a clean, cool and dark place

## RECOMMENDED DOSAGE

2-10%

## SOLUBILITY

Water

## APPLICATION DATA

Add into the aqueous phase during the final step of the manufacturing process provided that the temperature is below 40°C although it can be stable for 2h at 80 °C

Recommended pH range between 3 and 8 to avoid conformational changes

## INCOMPATIBILITIES

Oxidants, electrophiles and tannins

## GENETICALLY MODIFIED ORGANISMS (GMO)

The product does not contain any ingredient genetically modified

## ANIMAL TESTS

This product has not undergone any animal test by or on behalf of LipoTrue S.L. according to the European Regulation (EC) No. 1223/2009

## STATEMENTS ABOUT INGREDIENTS

|                                                     |                                                                                                                                                                                                                           |
|-----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Bovine spongiform encephalopathy (BSE)</b>       | There are no ingredients from animal origin                                                                                                                                                                               |
| <b>Cosmetic allergens</b>                           | This product is not expected to contain any of the 26 substances introduced into Annex III of the European Cosmetics Regulation by the 7 <sup>th</sup> amendment (EC) No. 2003/15 on the basis of the SCCNFP opinion      |
| <b>Food allergens</b>                               | This product is not expected to contain any food allergen listed in Annex IIIa of Directive 2003/89/EC and is in compliance with Annex II of Reg 1169                                                                     |
| <b>Gluten</b>                                       | To the best of our knowledge, regarding the manufacturing process and information provided by our suppliers, this product is not expected to contain traces of gluten                                                     |
| <b>Pesticides</b>                                   | To the best of our knowledge, pesticides are not expected                                                                                                                                                                 |
| <b>Palm oil</b>                                     | This product does not contain palm oil                                                                                                                                                                                    |
| <b>Phthalates, sulfates</b>                         | To the best of our knowledge, phthalates and sulfates are not expected                                                                                                                                                    |
| <b>Dioxin, 1.4 dioxane</b>                          | To the best of our knowledge dioxin and 1.4 dioxane are not expected                                                                                                                                                      |
| <b>Cyclosiloxanes (D4, D5, D6)</b>                  | To the best of our knowledge cyclosiloxanes (D4, D5, D6) are not expected                                                                                                                                                 |
| <b>Glycol ethers</b>                                | This product does not contain the following glycol ethers as an ingredient: DEG, EDGME, DEDGME, TEDGME, EGBE, DEGBE, DEGEE                                                                                                |
| <b>Volatile organic compound (VOC)</b>              | To the best of our knowledge, this product, is not expected to contain any ingredient considered as VOC                                                                                                                   |
| <b>Substance Very high Concern (SVHC)</b>           | To the best of our knowledge, this product is not expected to contain any ingredient considered as SVHC                                                                                                                   |
| <b>CMR</b>                                          | To the best of our knowledge, this product does not contain any ingredient classified as carcinogenic, mutagenic, or toxic for the reproduction (CMR) of category 1A, 1B, or 2 according to Regulation (EC) No. 1272/2008 |
| <b>Nanomaterials</b>                                | To the best of our knowledge, this product is not expected to contain any nanomaterial as defined in Regulation (EC) No. 1223/2009 and French decree n° 2012-232 of 17 February 2012                                      |
| <b>EWG's skin Deep® cosmetic database reference</b> | The ingredients contained in this product are included in EWG's skin Deep® cosmetic database                                                                                                                              |

*\*Information provided according to our manufacturing process and our supplier's information.*

#### TOXICOLOGICAL INFORMATION

|                          |                                                                                                                                                                                                 |
|--------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>OCULAR IRRITATION</b> | Method: <i>In vitro</i> the study of cytotoxicity according to the neutral red release method on SIRC cell line<br>Concentration: up to 5% of active ingredient<br>Results: <b>non irritant</b> |
| <b>SENSITIZATION</b>     | Method: <i>In vitro</i> H-CLAT<br>Concentration: 1200/600/335/60 µg/mL of active ingredient<br>Results: <b>non sensitizing</b>                                                                  |
| <b>PHOTOTOXICITY</b>     | Method: <i>In vitro</i> 3T3 NRU<br>Concentration: 1/0.5/0.250/0.125/0.063/0.031/0.016/0.008 mg/mL of active ingredient<br>Results: <b>non phototoxic</b>                                        |
| <b>MUTAGENICITY</b>      | Method: <i>In vitro</i> Ames test<br>Concentration: 1.85/0.93/0.46/0.23/0.12 mg/mL of active ingredient<br>Results: <b>non mutagenic</b>                                                        |

#### ECOTOXICITY

|                                          |                                                                                                                                                                                                                                                                                                                                                                                         |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Reference</b>                         | OECD Guideline for the testing of chemicals – OECD 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test                                                                                                                                                                                                                                                                       |
| <b>Objective of the study</b>            | Determine the effects of a substance on the growth of a unicellular green algal species after 72 h of exposure without changing the medium (static assay)                                                                                                                                                                                                                               |
| <b>Concentration of tested substance</b> | 100 mg/L, 32 mg/L, 10 mg/L, 3.2 mg/L, 1 mg/L, 0.32 mg/L, 0.1 mg/L of Acetyl Hexapeptide-8 Solution                                                                                                                                                                                                                                                                                      |
| <b>Results</b>                           | EC (50r-72h) & (20r-72h) & (10r-72h) >100 mg/L<br>Effective concentration resulting in X per cent reduction in the growth rate of the population compared to control. The lower the EC <sub>x</sub> , the higher the toxicity<br>NOEC = 100 mg/L<br>“No Observed Effect Concentration”; the highest tested concentration without any effect on test organisms, compared to the controls |
| <b>Conclusion</b>                        | The product Acetyl Hexapeptide-8 Solution is <b>not ecotoxic</b> according to OECD 201 (Freshwater Alga and Cyanobacteria, Growth Inhibition Test)                                                                                                                                                                                                                                      |

#### BIODEGRADABILITY TEST

|                                          |                                                                                                                                                    |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Reference</b>                         | Evaluation of ready biodegradability: Dissolved Organic Carbon Die-Away following the OECD 301A Guideline                                          |
| <b>Concentration of tested substance</b> | 882.4 mg/L of Acetyl Hexapeptide-8 Solution                                                                                                        |
| <b>Results</b>                           | The product “Acetyl Hexapeptide-8 Solution” is <b>readily biodegradable</b> . Acetyl Hexapeptide-8 Solution is biodegradable at 100% after 28 days |

#### REACH

|                      |                         |
|----------------------|-------------------------|
| Water (Aqua)         | Exempt (Annex IV)       |
| Caprylyl Glycol      | 01-2119966905-22-XXXX   |
| Acetyl Hexapeptide-8 | Exempt (< 1 Tonne/year) |

## REGULATIONS

|                       |                                                                                                                                                                                                                                                                                                                                       |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>European Union</b> | This product is in accordance with Regulation (EC) No. 1223/2009                                                                                                                                                                                                                                                                      |
| <b>US</b>             | None of the ingredients contained in this product is prohibited nor restricted by FDA regulations<br>None of the ingredients contained in this product is included in California's Proposition 65                                                                                                                                     |
| <b>Canada</b>         | None of the ingredients contained in this product is included in the Cosmetic Ingredient Hotlist (2015) of prohibited and restricted ingredients for use in Cosmetic Products<br>The ingredients are present in Domestic Substance List (DSL). Acetyl Hexapeptide-8 is exempt (<1000 kg of imported substance/year)                   |
| <b>China</b>          | All the INCI names are included in the last version of the IECIC list (2021)<br>Acetyl Hexapeptide-8 Solution has been registered according to the Cosmetic Supervision and Administration Regulation (CSAR) guidelines of the China's National Medical Products Administration (NMPA) with the code number: <b>100622-02702-5326</b> |
| <b>Japan</b>          | None of the ingredients contained in this product is included in none of the Appendix of the Standards for Cosmetics published by the Ministry of Health and Welfare Notification No. 331 of 2000                                                                                                                                     |
| <b>Korea</b>          | All the INCI names are in compliance with Korean Existing Chemical List.<br>Acetyl Hexapeptide-8 is exempt (<1 tonne/year of imported substance) and is identified as cosmetic ingredient following the cosmetic regulation                                                                                                           |
| <b>Australia</b>      | This product is in accordance with Australian Inventory of Chemical Substances – AICS (Inventory). Acetyl Hexapeptide-8 is exempt (<100 kg of imported substance/year)                                                                                                                                                                |

## NAGOYA STATEMENT

Taking into account the origin of the different ingredients included in this product, and the information provided by our suppliers, we can conclude that our product is outside the scope of the Nagoya Protocol.

## ISO 16128-1:2016

According to the guidelines on definitions for natural and organic cosmetics ingredients, we certify regarding the information provided by our supplier and our manufacturing process, the following information for our product:

- Natural origin content = 99.45%

| <b>Ingredients</b>   | <b>Natural index</b> | <b>Natural origin index</b> | <b>Organic index</b> | <b>Organic origin index</b> |
|----------------------|----------------------|-----------------------------|----------------------|-----------------------------|
| Water (Aqua)         | 1                    | 1                           | 0                    | 0                           |
| Acetyl Hexapeptide-8 | 0                    | 0                           | 0                    | 0                           |
| Caprylyl Glycol      | 0                    | 0                           | 0                    | 0                           |

## HALAL CERTIFIED



Acetyl Hexapeptide-8 Solution is a “product elaborated according to Islamic law” and is associated with the license number IH-822/2.1/B94

Customer service telephone number: +34 957 634 071

## VEGAN CERTIFIED



Acetyl Hexapeptide-8 Solution is certified by The Vegan Society's Vegan Trademark

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The information provided in this Technical Dossier is correct to the best of our knowledge, information and belief at the date of this publication