



PRODUCT INFORMATION DOSSIER (PI)

PRODUCT

ARGIRELINE® *peptide solution C*

Date

February 2018

Version

9

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PRODUCT INFORMATION

Trade Name & Code

| Trade Name | Code |
|---------------------------------------|-----------|
| ARGIRELINE® <i>peptide solution C</i> | P06-PD010 |

Manufacturer

LIPOTEC S.A.U.

C/ ISAAC PERAL 17, POL. IND. CAMÍ RAL

08850 GAVÀ (BARCELONA) – SPAIN

INCI name

WATER (AQUA), ACETYL HEXAPEPTIDE-8, CAPRYLYL GLYCOL.

Composition

| INGREDIENT | %* | CAS | EINECS |
|----------------------|---------------|-----------|-----------|
| Water (Aqua) | Up to 100 | 7732-18-5 | 231-791-2 |
| Acetyl Hexapeptide-8 | 0.045 – 0.055 | - | - |
| Caprylyl Glycol | 0.45 -0.55 | 1117-86-8 | 214-254-7 |

* Target value concentration can be calculated as the mean value between maximum and minimum concentration. Please note that target value is not a sales specification of the product.

Additional information on ingredients

| INGREDIENT | FUNCTION |
|----------------------|-------------------------------------|
| Water (Aqua) | Solvent |
| Acetyl Hexapeptide-8 | Active Ingredient |
| Caprylyl Glycol | Skin-conditioning agent - Emollient |

- vegetal origin: none.
- biosynthetic origin: none.
- animal origin: none.
- synthetic origin: Acetyl Hexapeptide-8, Caprylyl Glycol;
- mineral origin: Water (Aqua).

Specifications

Analytical Data

| TEST | SPECIFICATION | METHOD |
|-----------------------|---------------------------------------------------|--------------|
| Physical appearance | Translucent solution | CC-10-01-B6 |
| Colour | Colourless | CC-10-01-B6 |
| Specific gravity | N.A. | - |
| pH | 3.0 – 6.0 | CC-10-01-B1 |
| Viscosity (cPs) | N.A. | - |
| Particle size (mm) | N.A. | - |
| Refractive index | N.A. | - |
| Dry residue (%) | N.A. | - |
| Identification (HPLC) | Similar retention time as in-house ref. standard. | CC-10-01-B19 |

Microbiological Data

| TEST | SPECIFICATION | METHOD |
|-------------------------------|---------------|--------------|
| TOTAL AEROBIC MICROBIAL COUNT | < 100 cfu/g | MI-10-01-D09 |
| TOTAL YEAST AND MOULD COUNT | < 10 cfu/g | MI-10-01-D09 |
| SPECIFIC MICROORGANISMS: | | |
| <i>Escherichia coli</i> | ABSENCE/0.5 g | MI-10-01-D09 |
| <i>Pseudomonas aeruginosa</i> | ABSENCE/g | MI-10-01-D09 |
| <i>Staphylococcus aureus</i> | ABSENCE/g | MI-10-01-D09 |
| <i>Candida albicans</i> | ABSENCE/g | MI-10-01-D09 |

Storage

ARGIRELINE® peptide solution C should be stored in a clean, cool and dark place.

Shelf life

If stored as recommended, shelf life is 24 months.

Impurities

| ANALYSIS | AVAILABLE | EXPECTED | RESULT/COMMENTS |
|-------------------|-----------|----------|------------------------------------------|
| Heavy metals | YES | - | Heavy metals <20 ppm Arsenic < 2 ppm |
| Diethylene Glycol | NO | NO | Not expected based on product knowledge. |
| Other impurities | NO | - | Not analyzed. |

Regulatory status

Information on the regulatory status of ARGIRELINE® peptide solution C is given to the best of our knowledge in the chart below:

| REGION | STATUS |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| European Union | In accordance with Regulation 1223/2009 on cosmetic products. |
| USA | No ingredients restricted by applicable cosmetic regulations. No ingredients listed in California's Proposition 65. |
| Japan | No ingredient restrictions known on the Standards for Cosmetics, Notification No. 331/2000, as amended in April 2016 |
| Brazil | In accordance with article 11 from Resolution RDC No.7 of February 10, 2015. |
| Australia | All ingredients listed in AICS ¹ schedule Exception: Acetyl Hexapeptide-8* No ingredients listed in SUSMP ² |
| China | All ingredients listed in IECIC schedule. |
| Canada | No ingredient listed in HOTLIST schedule. |

¹AICS: Australian Inventory of Chemical Substances

²SUSMP: Standard for the Uniform Scheduling of Medicines and Poisons

*The obligation to notify to NICNAS applies only to import volumes over 10 kg of substance/year.

REACH

| INGREDIENT | STATUS | COMMENTS |
|----------------------|-------------------------|-----------------------|
| Water (Aqua) | Exempt (Annex IV) | - |
| Acetyl Hexapeptide-8 | Exempt (< 1 Tonne/year) | - |
| Caprylyl Glycol | Registered by supplier | 01-2119966905-22-XXXX |

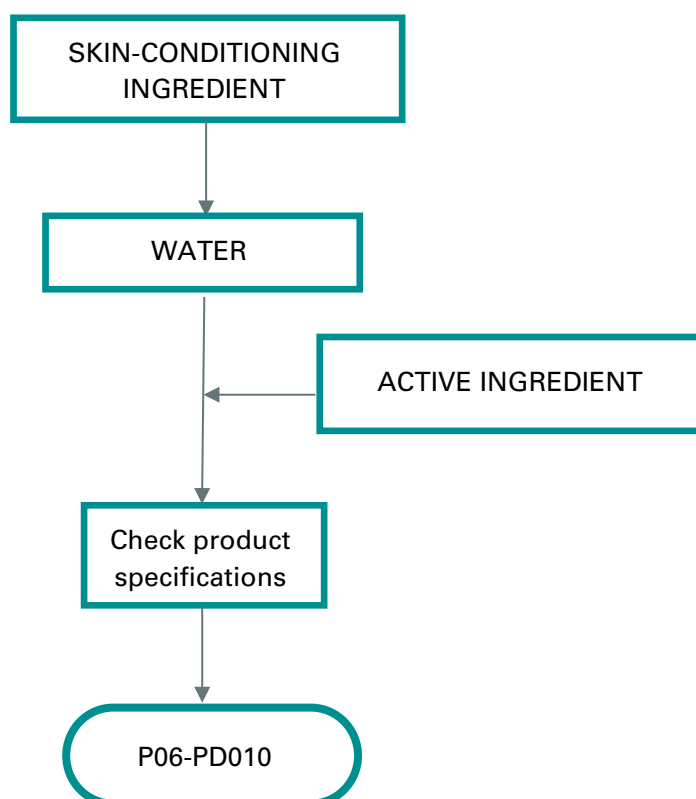
Statements

| STATEMENT | YES/NO | COMMENTS |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Does the product contain any genetically modified ingredient? | NO | - |
| Does the product contain as an ingredient any of the 26 substances listed in Annex III of Cosmetics Regulation (EC) 1223/2009 and identified by the SCCNFP as likely to cause allergenic reactions? | NO | - |
| Has the product undergone animal tests sponsored by Lipotec S.A.U.? | YES | The active ingredient with INCI name Acetyl Hexapeptide-8 contained in ARGIRELINE® peptide solution C has undergone animal tests for safety purposes. The last test was performed in 2002. |
| Is the product expected to contain any pesticide? | NO | - |
| Does the product contain as an ingredient any substance classified as CMR (Carcinogenicity, Germ Cell Mutagenicity and Reproductive Toxicity) from classes 1A, 1B or 2 in accordance with CLP Regulation 1272/2008 and its subsequent amendments? | NO | - |
| Does the product contain, as an ingredient, any of the following glycol ethers? EDGME (CAS n° 110-71-4) DEDGME (CAS n° 111-96-6) TEDGME (CAS n° 112-49-2) EGBE (CAS n° 111-76-2) DEGBE (CAS n° 112-34-5) DEGEE (CAS n° 111-90-0) | NO | - |
| Does the product contain, as an ingredient, any phthalate? | NO | - |

| | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|---|
| Is the product expected to contain any nanomaterial meaning <i>an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm</i> , as defined in Regulation (EC) No 1223/2009 on cosmetic products? | NO | - |
| Is the product expected to contain gluten? | NO | - |
| Does the product contain any ingredient that, according to the information provided by our suppliers, falls under the definition of Volatile Organic Compound (VOC) as described in Directive 2004/42/CE? | NO | - |
| Is there risk of contamination with Bovine Spongiform Encephalopathy (BSE) through the use of this product? | NO | - |
| Is the product expected to contain any dioxin? | NO | - |
| Does the product contain ethanol as an ingredient? | NO | - |
| Is the product suitable for vegetarians? | YES | - |
| Is the product suitable for vegans? | YES | - |

MANUFACTURING FLOWCHART

The product ARGIRELINE® *peptide solution C* is manufactured according to the manufacturing standard protocol:



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