



PRODUCT INFORMATION DOSSIER (PI)

PRODUCT

ARGIRELINE® peptide solution NP

DATE

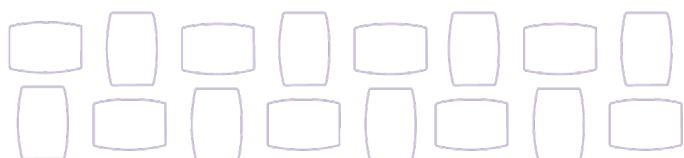
August 2022

VERSION

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PRODUCT INFORMATION

Trade Name & Code

Trade Name	Code
ARGIRELINE® peptide solution NP	05C037

Manufacturer

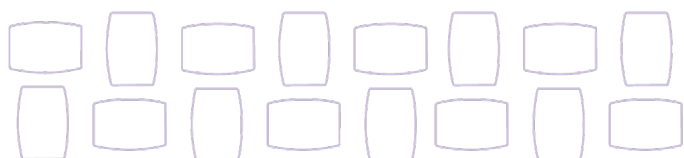
LIPOTEC S.A.U.

C/ ISAAC PERAL 17, POL. IND. CAMÍ RAL

08850 GAVÀ (BARCELONA) – SPAIN

INCI name

WATER (AQUA), ACETYL HEXAPEPTIDE-8, ACETIC ACID, PHENOXYETHANOL, POTASSIUM SORBATE.



Composition

INGREDIENT	%*	CAS	EINECS
Water (Aqua)	Up to 100%	7732-18-5	231-791-2
Acetyl Hexapeptide-8	0.045 – 0.055	-	-
Phenoxyethanol	0.45 – 0.55	122-99-6	204-589-7
Potassium Sorbate	0.09 – 0.11	24634-61-5	246-376-1
Acetic Acid	q.s.	64-19-7	200-580-7

* 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
Phenoxyethanol	Preservative
Potassium Sorbate	Preservative
Acetic Acid	pH adjuster

- vegetal origin: none.
- biosynthetic origin: none.
- animal origin: none.
- synthetic origin: Acetyl Hexapeptide-8, Phenoxyethanol, Potassium Sorbate, Acetic Acid.
- mineral origin: Water (Aqua).

Naturality (according to ISO 16128)

CONTENT	%
Natural origin content	99.39



Specifications

Analytical Data

TEST	SPECIFICATION	METHOD
Physical appearance	Transparent solution	CC-10-01-B6
Colour	Colourless	CC-10-01-B6
Specific gravity	0.94 – 1.04	CC-10-01-B3
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/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 NP 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*	-	Mercury < 1 ppm Lead < 10 ppm Arsenic < 2 ppm Cadmium < 3 ppm Antimony < 5 ppm
Diethylene Glycol	NO	NO	Not expected based on product knowledge
Other impurities	NO	-	-

*Data based on the results of the analysis of one representative batch of ARGIRELINE® peptide solution NP.

Regulatory status

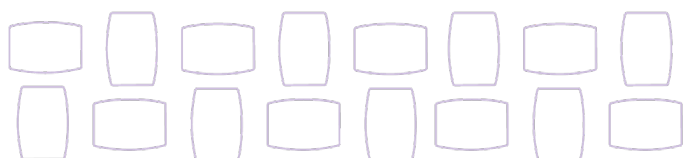
Information on the regulatory status of ARGIRELINE® peptide solution NP is given to the best of our knowledge in the chart below:

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 AIIC 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

¹ AIIC: Australian Inventory of Industrial Chemicals.

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

*Chemicals not listed on the AIIC must be categorized by the importer before importation into Australia.



REACH

INGREDIENT	STATUS	COMMENTS
Water (Aqua)	Exempt (Annex IV)	-
Acetyl Hexapeptide-8	Exempt (< 1 Tonne/year)	-
Phenoxyethanol	Registered by supplier	01-2119488943-21-XXXX
Potassium Sorbate	Registered by supplier	01-2119950315-41-XXXX
Acetic Acid	Registered by supplier	01-2119475328-30-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 in ARGIRELINE® peptide solution NP 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	-



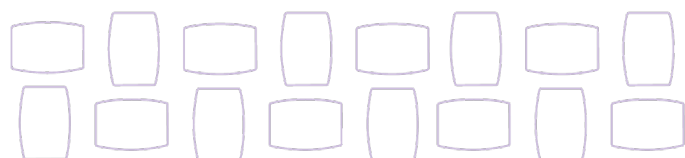
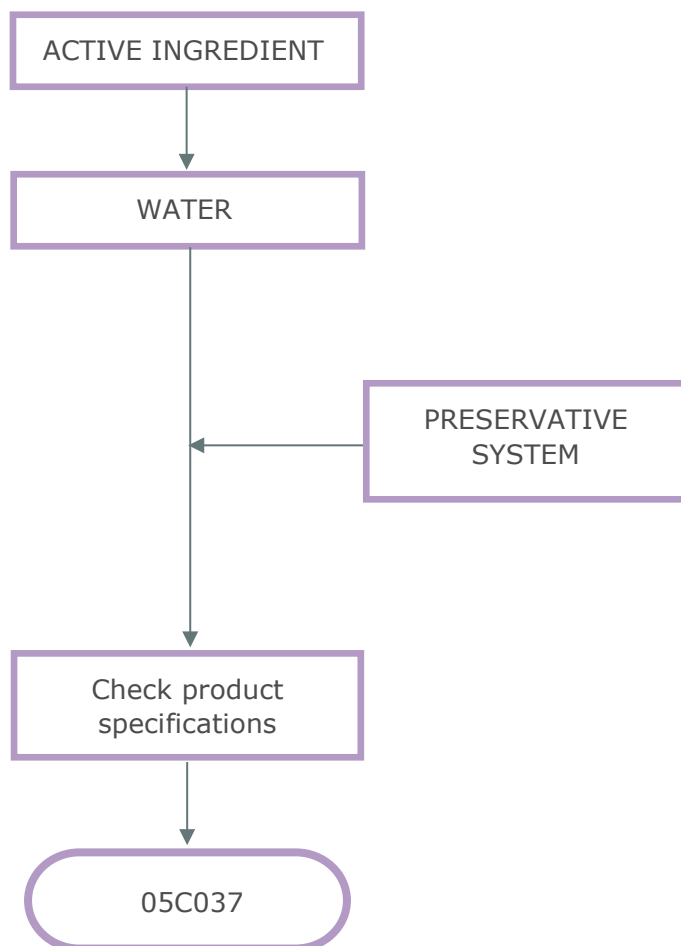
Does the product contain, as an ingredient, any phthalate?	NO	-
Is the product expected to contain any nanomaterial meaning <i>an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm</i> , as defined 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?	YES	*
Is there risk of contamination with Bovine Spongiform Encephalopathy (BSE) or Transmissible Spongiform Encephalopathy (TSE) through the use of this product?	NO	-
Is the product expected to contain, as an ingredient, 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	-

* According to the information provided by supplier, the following ingredients fall under the definition of "Volatile Organic Compound (VOC)" as described in Directive 2004/42/CE: Phenoxyethanol and Acetic Acid. Please, note that this ingredient is not listed in Annex I of the Swiss Ordinance 814.018.



MANUFACTURING FLOWCHART

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



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