



PRODUCT INFORMATION DOSSIER (PI)

PRODUCT

EYESERYL® *peptide solution B*

Date

March 2018

Version

4

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PRODUCT INFORMATION

Trade Name & Code

Trade Name	Code
EYESERYL® peptide solution B	P08-PD070

Manufacturer

LIPOTEC S.A.U.

C/ ISAAC PERAL 17, POL. IND. CAMÍ RAL

08850 GAVÀ (BARCELONA) – SPAIN

INCI name

WATER (AQUA), BUTYLENE GLYCOL, ACETYL TETRAPEPTIDE-5.



Composition

INGREDIENT	%*	CAS	EINECS
Water (Aqua)	Up to 100	7732-18-5	231-791-2
Butylene Glycol	44.955 – 54.945	107-88-0	203-529-7
Acetyl Tetrapeptide-5	0.09 – 0.11	-	-

* 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
Butylene Glycol	Solvent
Acetyl Tetrapeptide-5	Active ingredient

- vegetal origin: none.
- biosynthetic origin: none.
- animal origin: none
- synthetic origin: Butylene Glycol, Acetyl Tetrapeptide-5.
- mineral origin: Water (Aqua).

Specifications

Analytical Data

TEST	SPECIFICATION	METHOD
Physical appearance	Transparent solution	CC-10-01-B6
Colour	Colourless	CC-10-01-B6
Specific gravity	N.A.	-
pH	2.0 – 6.0	CC-10-01-B1
Viscosity (cPs)	N.A.	CC-10-01-B2
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

EYESERYL® peptide solution B 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 < 10 ppm Arsenic < 0.5 ppm
Diethylene Glycol	NO	NO	Not expected based on product knowledge
Other impurities	NO	-	Not analyzed

Regulatory status

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

REGION	STATUS
European Union	In accordance with Regulation (EC) 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 Tetrapeptide-5* 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)	-
Butylene glycol	Registered by supplier	01-2119455875-25-XXXX
Acetyl Tetrapeptide-5	Exempt (< 1 Tonne/year)	-

Statements

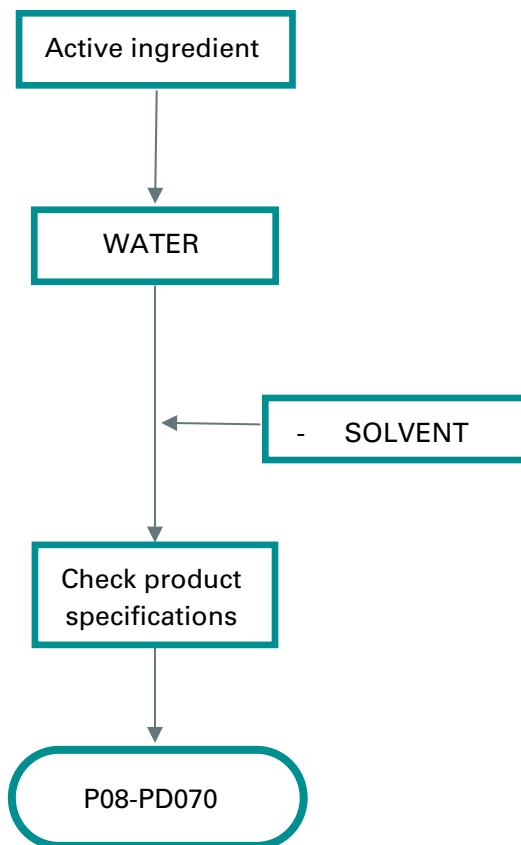
STATEMENT	YES/NO	COMMENTS
Does the product contain any genetically modified ingredient?	NO	-
Does the product contain as an ingredient any of the 26 substances listed in Annex III of Cosmetics Regulation (EC) 1223/2009 and identified by the SCCNFP as likely to cause allergenic reactions?	NO	-
Has the product undergone animal tests sponsored by Lipotec S.A.U.?	YES	The active ingredient with INCI name Acetyl Tetrapeptide-5 contained in EYESERYL® peptide solution B has undergone animal tests for safety purposes. The last test was performed in 2004.
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) 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	-

*According to the information provided by our suppliers, the following ingredient falls under the definition of "Volatile Organic Compound (VOC)" as described in Directive 2004/42/CE: Butylene Glycol. Please, note that this ingredient is not listed in Annex I of the Swiss Ordinance 814.018.

MANUFACTURING FLOWCHART

The product EYESERYL® peptide solution B is manufactured according to the manufacturing standard protocol:





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