Po8-PD070



PRODUCT INFORMATION DOSSIER (PI)

PRODUCT

EYESERYL® *peptide solution B*

Date

October 2017

Version

3

Aimtec®
peptides and synthetic molecules

Lipotec
A Lubrizol Company

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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:		
Escherichia coli	ABSENCE/0.5 g	MI-10-01-D09
Pseudomonas aeruginosa	ABSENCE/g	MI-10-01-D09
Staphylococcus aureus	ABSENCE/g	MI-10-01-D09
Candida albicans	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.

[1]AICS: Australian Inventory of Chemical Substances

[2]SUSMP: 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

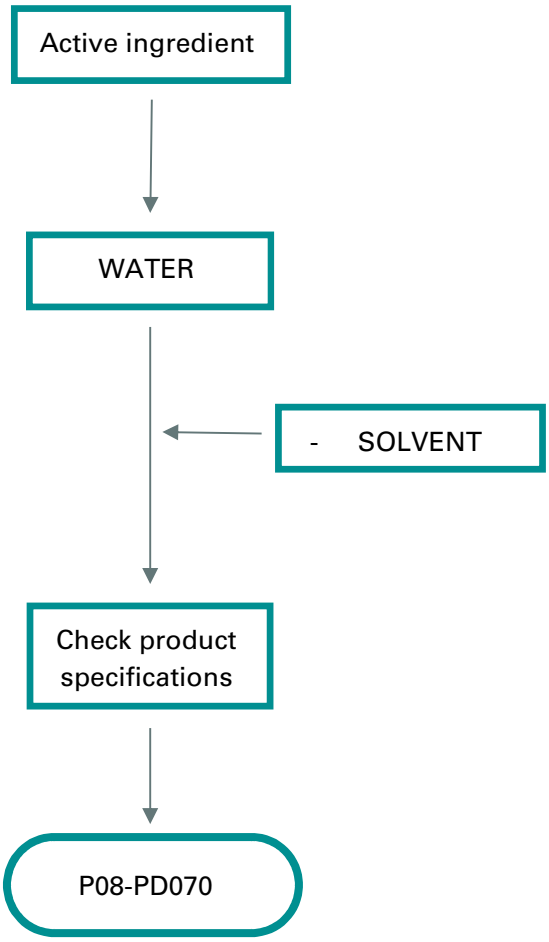
STATEMENT	YES/NO	COMMENTS
Does the product contain any genetically modified ingredient?	NO	-
Does the product contain as an ingredient any of the 26 substances listed in Annex III of Cosmetics Regulation (EC) 1223/2009 and identified by the SCCNFP as likely to cause allergenic reactions?	NO	-
Has the 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 nº 110-71-4) DEDGME (CAS nº 111-96-6) TEDGME (CAS nº 112-49-2) EGBE (CAS nº 111-76-2) DEGBE (CAS nº 112-34-5) DEGEE (CAS nº 111-90-0)	NO	-
Does the product contain, as an ingredient, any phthalate?	NO	-

Is the product expected to contain any nanomaterial meaning *an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm*, 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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