



Product

PD080

LEUPHASYL® *peptide*
solution

Date

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Revision

1

 **Lipotec**
A Lubrizol Company



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PD080
LEUPHASYL® *peptide solution*



Product Information

Trade Name & Code

TRADE NAME	CODE
LEUPHASYL® <i>peptide solution</i>	PD080

Manufacturer

LIPOTEC S.A.U.
C/ ISAAC PERAL 17, POL. IND. CAMÍ RAL
08850 GAVÀ (BARCELONA) – SPAIN

INCI name

WATER (AQUA), GLYCERIN, PENTAPEPTIDE-18, CAPRYLYL GLYCOL.

Composition

INGREDIENT	%	CAS	EINECS
Water (Aqua)	Up to 100%	7732-18-5	231-791-2
Glycerin	9.0 – 11.0%	56-81-5	200-289-5
Pentapeptide-18	0.045 – 0.055%	64963-01-5	-
Caprylyl Glycol	0.45 – 0.55%	1117-86-8	214-254-7

Additional information on ingredients

INGREDIENT	FUNCTION
Water (Aqua)	Solvent
Glycerin	Solvent
Pentapeptide-18	Active ingredient
Caprylyl Glycol	Skin conditioning

- vegetal origin:
Glycerin;

INCI	PLANT (SPECIES)	PART OF THE PLANT	COUNTRY OF ORIGIN	CITES
Glycerin	<i>Elaeis guineensis</i>	Fruit	Malaysia, Indonesia, EU, Brazil or Argentina*	N/A
	<i>Brassica napus</i>	Seed	EU, Brazil or Argentina*	N/A
	<i>Brassica campestris</i>	Seed	EU *	N/A
	<i>Helianthus annuus</i>	Seed	EU, Brazil or Argentina*	N/A
	<i>Cocos nucifera</i>	Fruit	EU, Brazil or Argentina*	N/A
	<i>Glycine max</i>	Seed	EU, Brazil or Argentina*	N/A

*according to information from supplier

- biosynthetic origin:
(none)
- animal origin:
(none)

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- synthetic origin:
Pentapeptide-18, 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	0.97 – 1.07	CC-10-01-B3
pH	2.0 – 5.0	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

Remarks

Contains 0.05% LEUPHASYL® peptide.

If the product is frozen and defrosted, the preservative may appear as a precipitate.

It can be redissolved by heating gently.

This does not affect the integrity of the product.

Storage

LEUPHASYL[®] *peptide solution* 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	-	-

Regulatory status

Information on the regulatory status of LEUPHASYL[®] *peptide solution* 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
U.S.A.	No ingredients restricted by applicable cosmetic regulations No ingredients listed in California's Proposition 65
Japan	No ingredients restricted by applicable cosmetic regulations
Brazil	In accordance with Resolution RDC No.3 of January 18, 2012
Australia	All ingredients listed in AICS ¹ schedule Exception: Pentapeptide-18*
	No ingredients listed in SUSMP ²
China	All ingredients listed in IECIC schedule Exception: Pentapeptide-18
Canada	No ingredient listed in HOTLIST schedule Exception: Glycerin [†]

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

[†]The raw material used is within the specifications of an accepted pharmacopoeia with respect to diethylene glycol (DEG) impurities.

REACH

INGREDIENT	STATUS	COMMENTS
Water (Aqua)	Exempt (Annex IV/I)	-
Glycerin	Exempt (Annex V/II)	-
Pentapeptide-18	Exempt (< 1 Tonne/year)	-
Caprylyl Glycol	Registered by supplier	-

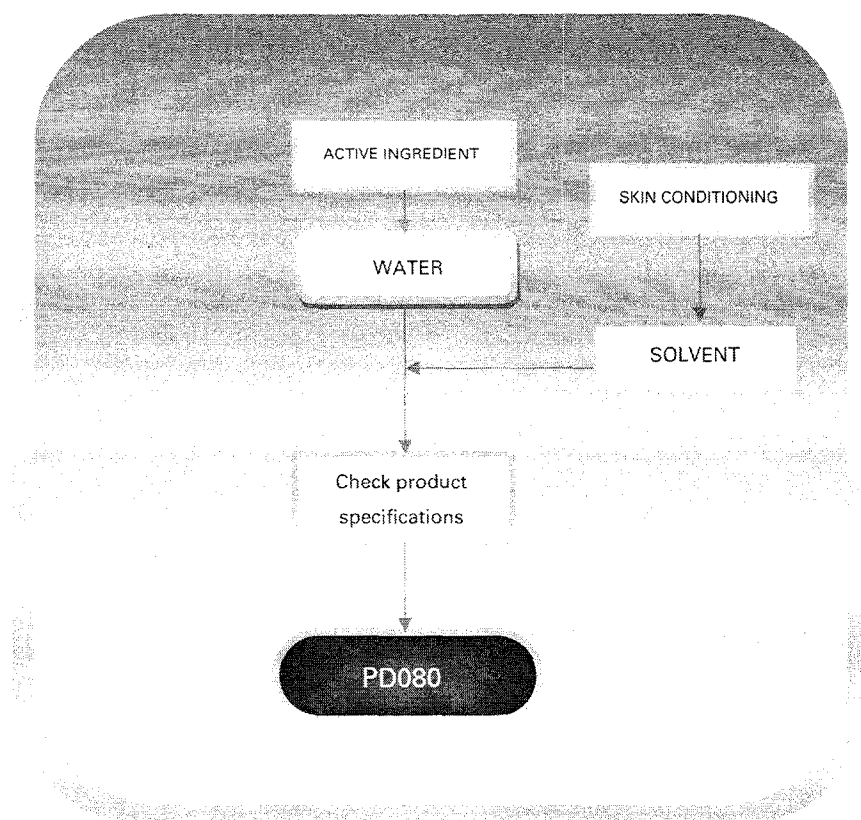
Statements

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 Pentapeptide-18 contained in LEUPHASYL® <i>peptide solution</i> has undergone animal tests for safety purposes. The last test was performed in 2005.
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 LEUPHASYL® *peptide solution* is manufactured according to the manufacturing standard protocol:



Safety

The toxicological profile of LEUPHASYL® *peptide* for cosmetic purposes was assessed *in vitro*. All tests were performed using solutions of LEUPHASYL® *peptide* at the desired concentrations.

IN VITRO TESTS

Cytotoxicity test on human epidermal keratinocytes

The results showed no signs of cytotoxicity at the concentrations assayed.

Cytotoxicity test on human 3T3 fibroblasts

No signs of cytotoxicity were observed.

Ocular Irritation (HET-CAM Test)

The product did not present ocular irritation under the concentrations assayed.

Genotoxicity test (Ames test)

The results showed no genotoxicity in the conditions assayed.

IN VIVO TESTS

Skin compatibility test

The product showed good skin compatibility under the experimental conditions assayed.

Skin sensitisation

LEUPHASYL® *peptide* 0.05% did not cause sensitisation or contact dermatitis in humans under the conditions tested.

A full toxicological report and a summary of all the safety tests performed are available on request.