

Product Information Dossier (PI)



Product

P06-PD017

SNAP-8™ *peptide solution C*

Date

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Revision

0



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Product Information

Trade Name & Code

TRADE NAME	CODE
SNAP-8™ <i>peptide solution C</i>	P06-PD017

Manufacturer

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

INCI name

WATER (AQUA), ACETYL OCTAPEPTIDE-3, CAPRYLYL GLYCOL.

Composition

INGREDIENT	%	CAS	EINECS
Water (Aqua)	Up to 100%	7732-18-5	231-791-2
Acetyl Octapeptide-3	0.045 – 0.055%	1253115-75-1	-
Caprylyl Glycol	0.45 – 0.55%	1117-86-8	214-254-7

Additional information on ingredients

INGREDIENT	FUNCTION
Water (Aqua)	Solvent
Acetyl Octapeptide-3	Active Ingredient
Caprylyl Glycol	Skin Conditioning

- **vegetal origin:**
(none)
- **biosynthetic origin:**
(none)
- **animal origin:**
(none)
- **synthetic origin:**
Acetyl Octapeptide-3, 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 (g/mL)	N.A.	
pH	3.0 – 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% SNAP-8™ peptide.

Storage

SNAP-8™ 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	-	-

Regulatory status

Information on the regulatory status of SNAP-8™ peptide solution C 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: Acetyl Octapeptide-3*. 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/V)	-
Acetyl Octapeptide-3	Exempt (< 1 Tonne/year)	-
Caprylyl Glycol	Registered by supplier	-

Statements

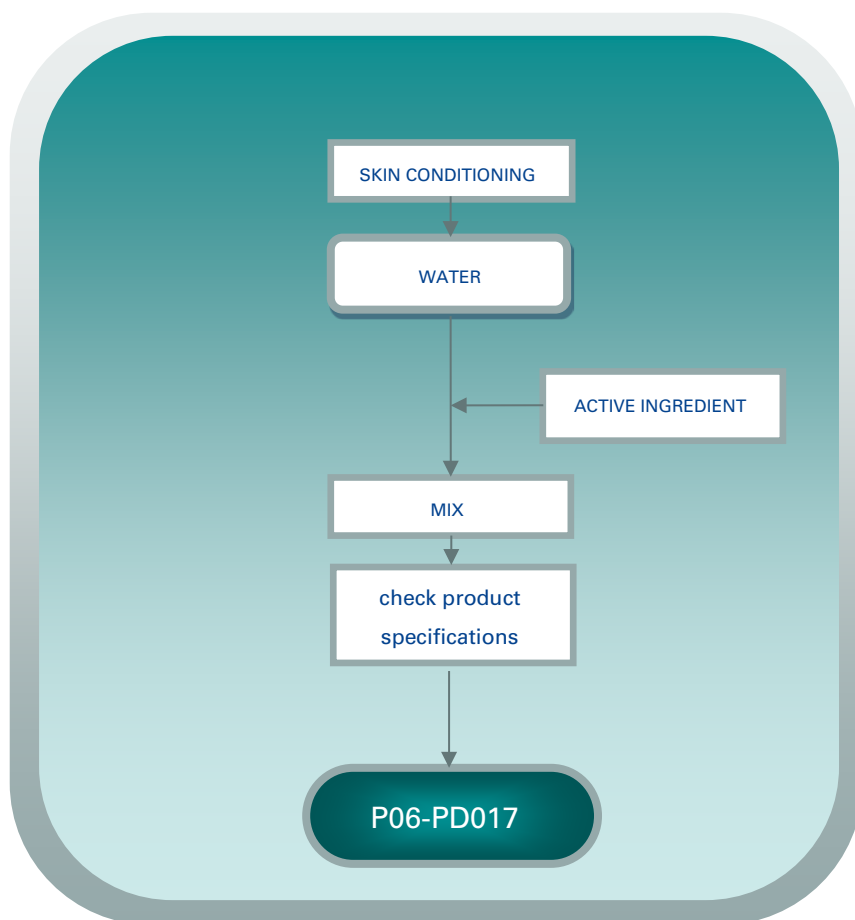
STATEMENT	YES/NO	COMMENTS
Does the product contain any genetically modified ingredient?	NO	-
Does the product contain as an ingredient any of the 26 substances listed in Annex III of Cosmetics Regulation (EC) 1223/2009 and identified by the SCCNFP as likely to cause allergenic reactions?	NO	-
Has the product undergone animal tests sponsored by Lipotec S.A.U.?	YES	The active ingredient with INCI name Acetyl Octapeptide-3 contained in SNAP-8™ <i>peptide solution C</i> has undergone animal tests for safety purposes. Last test was performed in 2003
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 SNAP-8™ *peptide solution C* is manufactured according to the manufacturing standard protocol:



Safety

The toxicological profile of SNAP-8™ *peptide* for cosmetic purposes was assessed *in vitro* and *in vivo*. All tests were performed using solutions of Snap-8™ *peptide* at the desired concentrations.

IN VITRO TESTS

Cytotoxicity test on human epidermal keratinocytes

SNAP-8™ *peptide* showed no significant signs of cytotoxicity at the concentrations assayed.

Cytotoxicity test on 3T3 fibroblasts

SNAP-8™ *peptide* proved not to have significant cytotoxic effects.

Ocular Irritation (NRU test)

SNAP-8™ *peptide* was potentially not irritating for the eyes.

NRU Phototoxicity test

SNAP-8™ *peptide* showed no signs of phototoxicity at the concentrations assayed.

Bacterial reverse mutation test (AMES test)

SNAP-8™ *peptide* produced no mutagenic or promutagenic activity in any of the bacterial strains tested.

IN VIVO TESTS

Skin sensitisation (HYPOALLERGENICITY)

SNAP-8™ *peptide* induced neither irritation nor any sensitising reaction.

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

Additional Information

DOCUMENTATION	AVAILABLE	NOT AVAILABLE
Technical Report	X	
Brochure	X	
Complete Tox	X	
Toxicity Summary	X	
Safety Dossier	X	
Material Safety Data Sheet	X	
Stability Report	X	

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Note: Graphs and photographs of efficacy tests are available for customer use provided that the final product contains the same concentration of active as the formulations in our tests. Customers must request written permission for use of the graphic material and/or ingredient tradenames to Lipotec. Customers are responsible for compliance with local and international advertising regulations.

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