

Product Information Dossier (PI)



Product

**PD280**

**REPROAGE™ peptide  
solution**

Date

**November 2016**

Revision

**0**



Pol. Ind. Camí Ral C/ Isaac Peral, 17  
08850 Gavà Barcelona (Spain)  
Tel. +34 93 638 80 00  
www.lipotec.com  
commercial@lipotec.com

## Contents

PRODUCT INFORMATION		
	Trade name & Code	3
	Manufacturer	3
	INCI name	3
	Composition	4
	Additional information on ingredients	4
	Specifications	5
	Storage	6
	Shelf life	6
	Impurities	6
	Regulatory status	6
	REACH	7
	Statements	7
MANUFACTURING FLOWCHART		9
SAFETY		10
ADDITIONAL INFORMATION		11

PD280

**REPROAGE™** *peptide solution*

## Product Information

### Trade Name & Code

TRADE NAME	CODE
REPROAGE™ <i>peptide solution</i>	PD280

### Manufacturer

LIPOTEC S.A.U.

C/ ISAAC PERAL 17, POL. IND. CAMÍ RAL

08850 GAVÀ (BARCELONA) – SPAIN

### INCI name

WATER (AQUA), DISODIUM PHOSPHATE, ACETYL HEXAPEPTIDE-8, SODIUM PHOSPHATE, CAPRYLYL GLYCOL.

## Composition

INGREDIENT	% *	CAS	EINECS
Water (Aqua)	Up to 100	7732-18-5	231-791-2
Disodium Phosphate	1.8594 – 2.2726	10039-32-4	231-448-7
Acetyl Hexapeptide-8	0.045 – 0.055	-	-
Sodium Phosphate	0.594 – 0.726	13472-35-0	231-449-2
Caprylyl Glycol	0.45 – 0.55	1117-86-8	214-254-7

\* 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
Disodium Phosphate	Buffering Agent
Acetyl Hexapeptide-8	Active Ingredient
Sodium Phosphate	Buffering Agent
Caprylyl Glycol	Skin-conditioning Agent

- **vegetal origin:**  
(none)
- **biosynthetic origin:**  
(none)
- **animal origin:**  
(none)
- **synthetic origin:**  
Disodium Phosphate, Acetyl Hexapeptide-8, Sodium Phosphate, 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	0.96 – 1.06	CC-10-01-B3
pH	5.5 – 8.0	CC-10-01-B1
Viscosity (cPs)	N.A.	
Particle size (mm)	N.A.	
Refractive index	1.315 – 1.355	CC-10-01-B4
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

REPROAGE™ *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	NO	-	Heavy Metals < 10 ppm Arsenic < 0.5 ppm
Diethylene Glycol	NO	NO	Not expected based on product knowledge
Other impurities	NO	-	-

## Regulatory status

Information on the regulatory status of REPROAGE™ *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 <sup>1</sup> schedule Exception: Acetyl Hexapeptide-8* No ingredients listed in SUSMP <sup>2</sup> Exception: Sodium Phosphate <sup>§</sup>
China	All ingredients listed in IECIC schedule
Canada	No ingredient listed in HOTLIST schedule

<sup>1</sup>AICS: Australian Inventory of Chemical Substances

<sup>2</sup>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

<sup>§</sup> Please note that the type of preparations described in Schedule 3 and 4 regarding this substance do not apply to REPROAGE™ *peptide solution*

## REACH

INGREDIENT	STATUS	COMMENTS
Water (Aqua)	Exempt (Annex IV)	
Disodium Phosphate	Exempt (Annex IV/V)	
Acetyl Hexapeptide-8	Exempt (< 1 Tonne/year)	
Sodium Phosphate	Exempt (Annex IV/V)	
Caprylyl Glycol	Registered by supplier	

## Statements

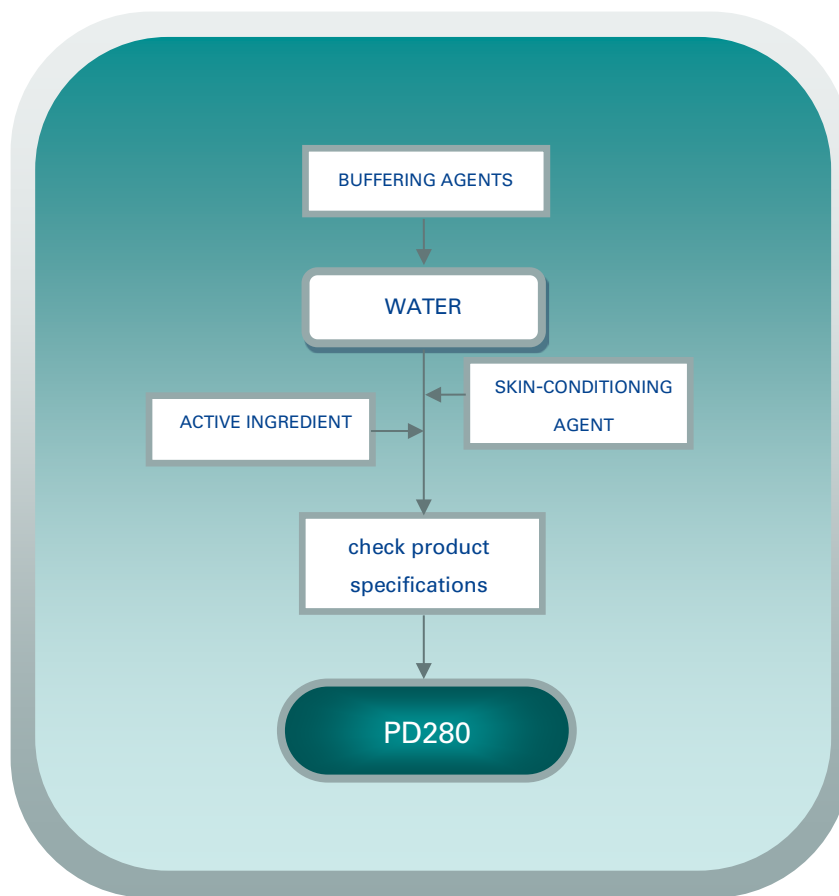
STATEMENT	YES/NO	COMMENTS
Does the product contain any genetically modified ingredient?	NO	-
Does the product contain as an ingredient any of the 26 substances listed in Annex III of Cosmetics Regulation (EC) 1223/2009 and identified by the SCCNFP as likely to cause allergic reactions?	NO	-
Has the product undergone animal tests sponsored by Lipotec S.A.U.?	NO	-
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 REPROAGE™ peptide solution is manufactured according to the manufacturing standard protocol:



## Safety

### IN VITRO TESTS

The toxicological profile of the ingredient REPROAGE™ peptide (INCI Acetyl Hexapeptide-8) for cosmetic purposes was assessed in vitro. All tests were performed using solutions of REPROAGE™ peptide at the desired concentrations.

#### **Cytotoxicity test on human epidermal keratinocytes**

The results showed no significant cytotoxic effects at the concentrations assayed.

#### **Cytotoxicity test on 3T3 fibroblasts**

The results showed no significant cytotoxic effects at the concentrations assayed.

#### **Ocular irritation (HET-CAM test)**

The results showed no ocular irritation.

#### **NRU phototoxicity test**

The results showed no phototoxicity on 3T3 fibroblast cell cultures, showing a PIF (Photo-Irritation Factor) = n.d. and a MPE (Mean Photo Effect) = -0.005.

#### **Bacterial reverse mutation test (Ames test)**

The results showed no mutagenicity at the concentrations assayed.

### IN VIVO TESTS

#### **Human Repeated Insult Patch Test (HRIPT)**

REPROAGE™ peptide solution is considered to have very good skin compatibility. No allergic reactions were detected.

*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	
Safety Data Sheet	X	

*The trademarks referenced herein are owned by The Lubrizol Corporation or its affiliates.*

*Disclaimer:*

*The information including the claims and supporting data provided in this document are provided for informational purposes only, upon the express condition that the User make its own assessment of the appropriate use of such information. While the information contained herein is believed to be reliable, there are no representations, guarantees, or warranties of any kind made as to its accuracy, suitability for particular applications, how the product(s) will perform in combination with other substance or in the User's process or the results obtained. All expressed and implied warranties are disclaimed. Lubrizol and its affiliates MAKE NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. The User is solely responsible for ensuring that products marketed to consumers comply with all relevant laws and regulations and assumes all risk and liability of any use or handling of any materials. User agrees to indemnify and hold harmless Lubrizol and its affiliates for any and all actions arising from User's use of any information including claims in this publication, including, but not limited to, use in advertising and finished product label claims, and not present this publication as evidence of finished product claim substantiation to any regulatory authority. It is the User's sole responsibility to determine if there are any issues relating to patent infringement relating to the supplied information. Nothing contained herein is to be considered as permission, recommendation, nor as an inducement to practice any patented invention without permission of the patent owner.*

© 2016 The Lubrizol Corporation. All Rights Reserved.