Product Information Dossier (PI)

Product

BI010

HYADISINE® *marine ingredient*

Date

January 2017

Revision

7

Lipotec

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Contents

Product Information

Trade Name & Code

TRADE NAME	CODE
HYADISINE® *marine ingredient*	BI010

Manufacturer

LIPOTEC S.A.U.

C/ ISAAC PERAL 17, POL. IND. CAMÍ RAL

08850 GAVÀ (BARCELONA) – SPAIN

INCI name

WATER (AQUA), PSEUDOALTEROMONAS EXOPOLYSACCHARIDES, CITRIC ACID, SODIUM SALICYLATE.

Composition

INGREDIENT	% *	CAS	EINECS
Water (Aqua)	Up to 100%	7732-18-5	231-791-2
Pseudoalteromonas Exopolysaccharides	0.9 – 1.1%	-	-
Citric Acid	q.s.	5949-29-1	201-069-1
Sodium Salicylate	0.45 – 0.55%	54-21-7	200-198-0

* 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
Pseudoalteromonas Exopolysaccharides	Active ingredient
Citric Acid	pH adjuster
Sodium Salicylate	Preservative

- vegetal origin:
  (none)

- biosynthetic origin:
  Pseudoalteromonas Exopolysaccharides, Citric Acid;

INGREDIENT	NATURE	SPECIES	OBTENTION
PSEUDOALTEROMONAS EXOPOLYSACCHARIDES	Exopolysaccharide	*Pseudoalteromonas spp.*	Fermentation

- animal origin:
  (none)

- synthetic origin:
  Sodium Salicylate;

- mineral origin:
  Water (Aqua).

Specifications

Analytical Data

TEST	SPECIFICATION	METHOD
Physical appearance	Transparent solution	CC-10-01-B6
Colour	Colourless to Light yellow	CC-10-01-B6
Specific gravity (g/mL)	0.96 – 1.06	CC-10-01-B3
pH	3.3 – 4.3	CC-10-01-B1
Viscosity (cPs)	N.A.	
Particle size (mm)	N.A.	
Refractive index	1.316 – 1.356	CC-10-01-B4
Dry residue (%)	N.A.	

Microbiological Data

TEST	SPECIFICATION	METHOD
Total aerobic microbial count	< 1000 cfu/g	MI-10-01-D09
Total yeast and mould count	< 100 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

Remarks

The product may have a starting pale color that could darken with time.
Filaments may be present. However, none of these factors affect its integrity or efficacy.

Storage

HYADISINE® *marine ingredient* 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	-	-
Diethylene Glycol	NO	NO	Not expected based on product knowledge
Other impurities	NO	-	-

Regulatory status

Information on the regulatory status of HYADISINE® *marine ingredient* 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 ingredient restrictions known on cosmetic regulations
Brazil	In accordance with Resolution RDC No.3 of January 18, 2012
Australia	All ingredients listed in AICS[1] schedule Exception: Pseudoalteromonas Exopolysaccharides No ingredients listed in SUSMP[2]
China	All ingredients listed in IECIC schedule Exception: Pseudoalteromonas Exopolysaccharides
Canada	No ingredient listed in HOTLIST schedule Exception: Citric Acid[†]

[1]AICS: Australian Inventory of Chemical Substances

[2]SUSMP: Standard for the Uniform Scheduling of Medicines and Poisons

[†] Permitted at total concentrations ≤ 10%, with a pH ≥ 3.5

REACH

INGREDIENT	STATUS	COMMENTS
Water (Aqua)	Exempt (Annex IV/V)	-
Pseudoalteromonas Exopolysaccharides	Exempt (< 1 Tonne/year)	-
Citric Acid	Registered by supplier	-
Sodium Salicylate	Pre-registered by supplier	-

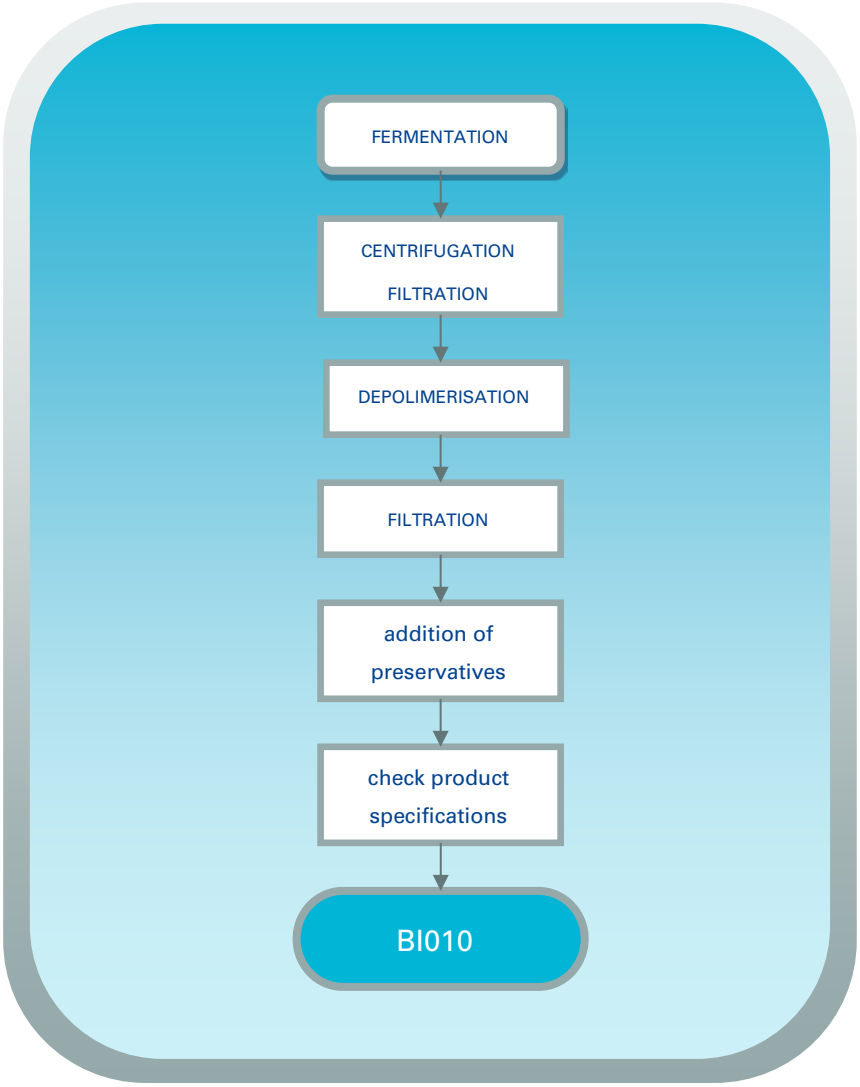
Statements

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.?	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 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?	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 HYADISINE® *marine ingredient* is manufactured according to the manufacturing standard protocol:



Safety

The toxicological profile of the ingredient Pseudoalteromonas Exopolysaccharides for cosmetic purposes was assessed *in vitro* and *in vivo.* All tests were performed using solutions of Pseudoalteromonas Exopolysaccharides at the desired concentrations.

IN VITRO TESTS

Cytotoxicity test on human epidermal keratinocytes
The results showed no significant signs of cytotoxicity at the concentrations assayed.

Cytotoxicity test on 3T3 fibroblasts
The results showed no significant signs of cytotoxicity at the concentrations assayed.

Ocular Irritation (HET-CAM test)
The results showed no ocular irritation at the concentrations assayed.

Phototoxicity (NRU test)
The results showed no signs of phototoxicity at the concentrations assayed.

Bacterial reverse mutation (Ames test)
The product produced no mutagenic activity in any of the bacterial strains used.

IN VIVO TEST

Skin sensitisation
A HRIPT (Human Repeated Insult Patch Test) was performed on 108 volunteers aged 18 to 70. Pseudoalteromonas Exopolysaccharides at 0.25% induced neither irritation nor allergic reaction and showed very good skin compatibility.

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	
Efficacy Reports	X	
Material Safety Data Sheet	X	
Stability Report	X	