Product Information Dossier (PI)

Product

BI030

HYANIFY™ ***marine ingredient***

Date

April 2015

Revision

5

Lipotec

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Product Information

Trade Name & Code

TRADE NAME	CODE
HYANIFY™ *marine ingredient*	BI030

Manufacturer

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

INCI name

WATER (AQUA), PROPANEDIOL, DISODIUM PHOSPHATE, XANTHAN GUM, SACCHARIDE ISOMERATE, SODIUM PHOSPHATE, GLYCERYL CAPRYLATE.

Composition

INGREDIENT	%	CAS	EINECS
Water (Aqua)	Up to100%	7732-18-5	231-791-2
Propanediol	22.05 – 26.95%	504-63-2	207-997-3
Disodium Phosphate	1.314 - 1.606%	10039-32-4	231-448-7
Xanthan Gum	0.9 - 1.1%	11138-66-2	234-394-2
Saccharide Isomerate	0.675 - 0.825%	-	-
Sodium Phosphate	0.81 - 0.99%	13472-35-0	231-449-2
Glyceryl Caprylate	0.45 - 0.55%	26402-26-6	247-668-1

Additional information on ingredients

INGREDIENT	FUNCTION
Water (Aqua)	Solvent
Propanediol	Solvent
Disodium Phosphate	Buffering agent
Xanthan Gum	Viscosity-controlling agent
Saccharide Isomerate	Active ingredient
Sodium Phosphate	Buffering agent
Glyceryl Caprylate	Emollient

- vegetal origin:
  Glyceryl Caprylate;

INCI	PLANT (SPECIES)	PART OF THE PLANT	GEOGRAPHIC ORIGIN	CITES
Glyceryl Caprylate	*Elaeis guineensis, Cocos nucifera*	Kernel	South-East Asia	N/A

- ## biosynthetic origin:
  Propanediol, Xanthan Gum, Saccharide Isomerate;

INGREDIENT	NATURE	SPECIES	MANUFACTURING
Propanediol	Fermentation product	*Escherichia coli K-12*	Fermentation + processing
Xanthan Gum	Polysaccharide	*Xanthomonas campestris*	Fermentation
Saccharide Isomerate	Saccharide	*Pseudoalteromonas sp.*	Fermentation + processing (see Manufacturing flowchart)

- ## animal origin:
  (none)

- ## synthetic origin:
  Disodium Phosphate, Sodium Phosphate;

- ## mineral origin:
  Water (Aqua).

Specifications

Analytical Data

TEST	SPECIFICATION	METHOD
Physical appearance	Opaque gel	CC-10-01-B6
Colour	Off white to yellow	CC-10-01-B6
Specific gravity (g/mL)	N.A.	
pH	5.8 – 7.8	CC-10-01-B1
Viscosity (cPs)	N.A.	
Particle size (mm)	N.A.	
Refractive index	N.A.	
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

Contains 0.75% SACCHARIDE ISOMERATE

Storage

HYANIFY™ *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 HYANIFY™ *marine ingredient* is given to the best of our knowledge in the chart below:

REGION	STATUS
European Union	In accordance with Regulation 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 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

REACH

INGREDIENT	STATUS	COMMENTS
Water (Aqua)	Exempt (Annex IV/V)	-
Propanediol	Registered by our suppliers	-
Disodium Phosphate	Pre-registered by our suppliers	-
Xanthan Gum	Exempt (Polymer)	-
Saccharide Isomerate	Exempt (< 1 Tonne/year)	-
Sodium Phosphate	Exempt (< 1 Tonne/year)	-
Glyceryl Caprylate	Pre-registered by our suppliers	-

Statements

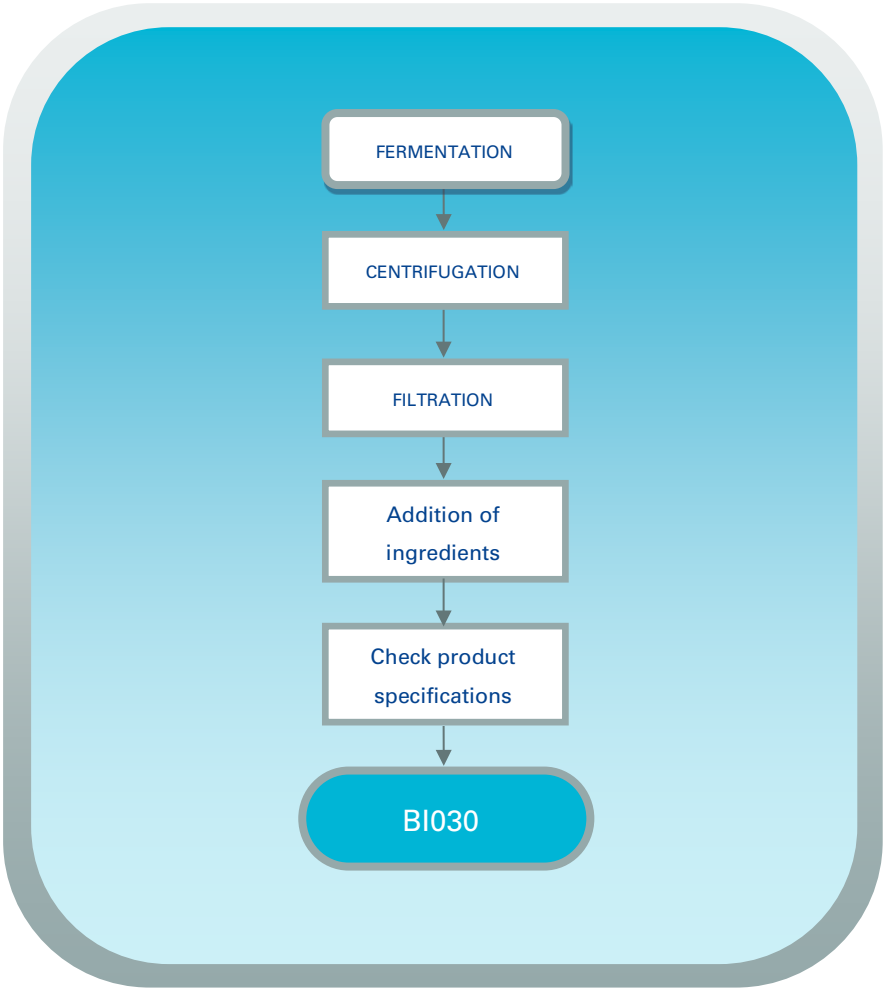
STATEMENT	YES/NO	COMMENTS
Does the product contain any genetically modified ingredient?	NO	-
Does the product contain as an ingredient any of the 26 substances listed in Annex III of Cosmetics Regulation (EC) 1223/2009 and identified by the SCCNFP as likely to cause allergenic reactions?	NO	-
Has the 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?	*	-
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 ingredients fall under the definition of "Volatile Organic Compound (VOC)" as described in Directive 2004/42/CE: Propanediol. Please, note that this ingredient is not listed in Annex I of the Swiss Ordinance 814.018.

Manufacturing flowchart

The product HYANIFY™ *marine ingredient* is manufactured according to the manufacturing standard protocol:



Safety

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

IN VITRO TESTS

Cytotoxicity test on human epidermal keratinocytes

The results showed low cytotoxic effects on human epidermal keratinocyte cell cultures, only at the highest tested concentration tested, showing an IC_{50} = n.d. (> 5 mg/ml), which equals a dosage higher than 65x the recommended HYANIFY™ *marine ingredient* dosage.

Cytotoxicity test on 3T3 fibroblasts

The results showed no cytotoxic effects on 3T3 fibroblast cell cultures at the tested concentrations.

Ocular Irritation (HET-CAM test)

The results showed no signs of ocular irritation at the tested concentration.

NRU Phototoxicity test

The results presented no signs of phototoxicity on 3T3 fibroblast cell cultures at the tested concentrations.

Bacterial reverse mutation test (Ames test)

The product did not induce gene mutations by base pair changes or frameshifts in the genome of any of the strains used.

IN VIVO TEST

Skin sensitisation and cutaneous compatibility test

A HRIPT (Human Repeated Insult Patch Test) was performed on 108 volunteers aged 18 to 70. At 1%, el producto showed very good skin compatibility. No allergic reaction was detected; thus, the product may be considered hypoallergenic.

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	