

Product Information Dossier (PI)



Product

BI080

NOCTURSHAPE™ *blue*
ingredient

Date

January 2016

Revision

5



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Product Information

Trade Name & Code

TRADE NAME	CODE
NOCTURSHAPE™ <i>blue ingredient</i>	BI080

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 to 100%	7732-18-5	231-791-2
Propanediol	22.05 – 26.95 %	504-63-2	207-997-3
Disodium Phosphate	1.314 – 1.606 %	7558-79-4	231-44-87
Xanthan Gum	0.9 – 1.1 %	11138-66-2	234-394-2
Saccharide Isomerate	0.45 – 0.55 %	-	-
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
Xanthan Gum	Viscosity Controlling
Saccharide Isomerate	Active ingredient
Sodium Phosphate	Buffering
Glyceryl Caprylate	Emollient

- **vegetal origin:**
Glyceryl Caprylate;

INCI	PLANT (SPECIES)	PART USED	GEOGRAPHIC ORIGIN	CITES
Glyceryl Caprylate	<i>Elaeis guineensis</i> , <i>Cocos nucifera</i>	Kernel	South-East Asia	N/A

- **biosynthetic origin:**
Propanediol, Xanthan Gum, Saccharide Isomerate;
- **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	Grey to Yellow	CC-10-01-B6
Specific gravity	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:		
<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

NOCTURSHAPE™ *blue 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	YES	-	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 NOCTURSHAPE™ *blue 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

¹AICS: Australian Inventory of Chemical Substances

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

REACH

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

Statements

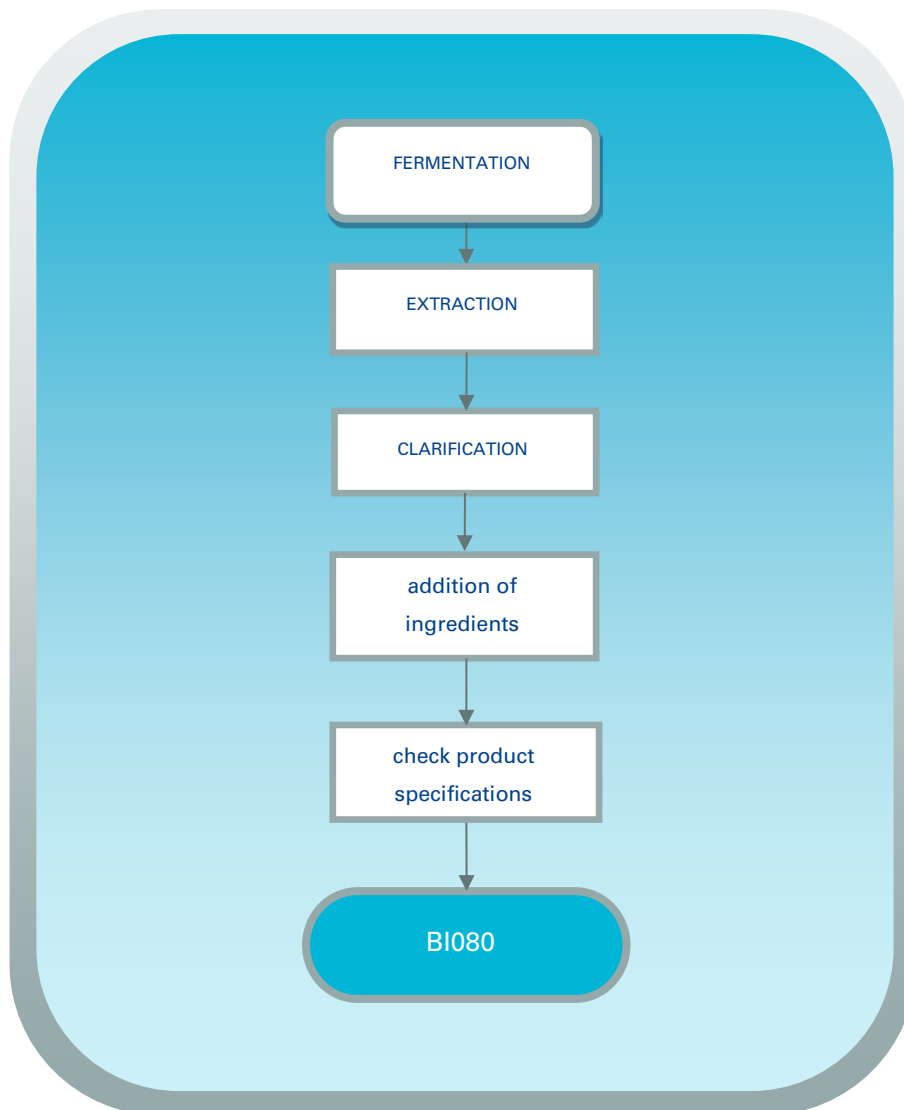
STATEMENT	YES/NO	COMMENTS
Does the product contain any genetically modified ingredient?	NO	-
Does the product contain as an ingredient any of the 26 substances listed in Annex III of Cosmetics Regulation (EC) 1223/2009 and identified by the SCCNFP as likely to cause allergenic reactions?	NO	-
Has the 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 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?	*	-
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 these ingredients are not listed in Annex I of the Swiss Ordinance 814.018.

Manufacturing flowchart

The product NOCTURSHAPE™ *blue ingredient* is manufactured according to the manufacturing standard protocol:



Safety

IN VITRO TESTS

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

Cytotoxicity test on human epidermal keratinocytes

The product showed no significant cytotoxic effects on human epidermal keratinocyte cell cultures at the tested concentrations.

Cytotoxicity test on 3T3 Fibroblasts

The product proved not to have significant cytotoxic effects on 3T3 fibroblast cell cultures at the tested concentrations.

Ocular irritation (HET-CAM test)

Slight ocular irritation was observed at the tested concentration (1%), equivalent to 50 to 100x the concentration of Saccharide Isomerate in NOCTURSHAPE™ *blue ingredient* at the recommended dose range.

NRU Phototoxicity test

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

Bacterial reverse mutation test (Ames test)

The results showed no mutagenicity at the concentrations assayed.

IN VIVO TESTS

Skin sensitisation and cutaneous compatibility test

NOCTURSHAPE™ *blue ingredient* can be considered non-irritating and non-sensitizing under the experimental conditions.

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	
Safety Dossier	X	

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