



PRODUCT INFORMATION DOSSIER (PI)

PRODUCT

Zenerity™ biotech ingredient

DATE

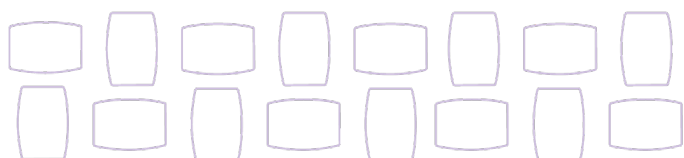
March 2024

VERSION

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PRODUCT INFORMATION

Trade Name & Code

Trade Name	Code
Zenerity™ biotech ingredient	BI150

Manufacturer

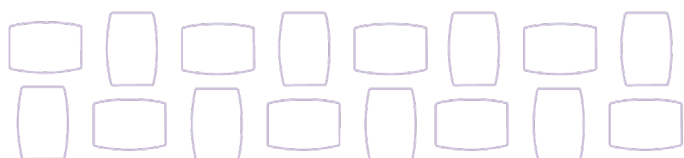
LIPOTEC S.A.U.

C/ ISAAC PERAL 17, POL. IND. CAMÍ RAL

08850 GAVÀ (BARCELONA) – SPAIN

Ingredients name

GLYCERIN, WATER (AQUA), BACILLUS FERMENT.



Composition

INGREDIENT	%*	CAS	EINECS
Glycerin	Up to 100	56-81-5	200-289-5
Water (Aqua)	17.5 – 21.5	7732-18-5	231-791-2
Bacillus Ferment	0.45 – 0.55	-	-

* 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
Glycerin	Solvent
Water (Aqua)	Solvent
Bacillus Ferment	Active ingredient

- vegetal origin: Glycerin.

INGREDIENT	PLANT (SPECIES)	PART OF PLANT	COUNTRY OF ORIGIN	CITES
Glycerin	<i>Brassica napus</i> <i>Brassica campestris</i> <i>Helianthus annuus</i>	Seed	Europe	N/A

- biosynthetic origin: Bacillus Ferment.

INGREDIENT	SPECIES	MANUFACTURING
Bacillus Ferment	<i>Bacillus sp.</i>	Fermentation

- animal origin: none.
- synthetic origin: none.
- mineral origin: Water (Aqua).

Naturality (according to ISO 16128)

CONTENT	%
Natural origin content	100



Specifications

Analytical Data

TEST	SPECIFICATION	METHOD
Physical appearance	Transparent solution	CC-10-01-B6
Colour	Light Yellow to Yellow	CC-10-01-B6
Specific gravity	1.16 – 1.26	CC-10-01-B3
pH	-	-
Viscosity (cPs)	-	-
Refractive index	1.423 – 1.463	CC-10-01-B48
Dry residue (%)	-	-

Microbiological Data

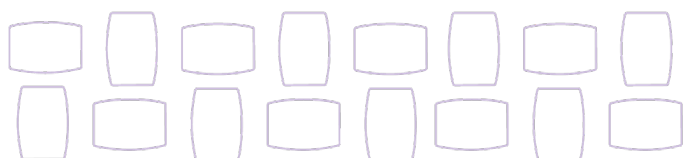
TEST	SPECIFICATION	METHOD
TOTAL AEROBIC MICROBIAL COUNT	< 1000 cfu/g	MI-10-01-D09
TOTAL YEAST AND MOULD COUNT	< 100 cfu/g	MI-10-01-D09
SPECIFIC MICROORGANISMS:		
<i>Escherichia coli</i>	ABSENCE/g	MI-10-01-D09
<i>Pseudomonas aeruginosa</i>	ABSENCE/g	MI-10-01-D09
<i>Staphylococcus aureus</i>	ABSENCE/g	MI-10-01-D09
<i>Candida albicans</i>	ABSENCE/g	MI-10-01-D09

Storage

Zenerity™ biotech ingredient should be stored in a clean, cool and dark place. Avoid extreme environmental conditions.

Shelf life

If stored as recommended, shelf life is 30 months.



Impurities

ANALYSIS	AVAILABLE	EXPECTED	RESULT/COMMENTS
Heavy metals	YES*	-	Mercury < 1 ppm Lead < 10 ppm Arsenic < 2 ppm Cadmium < 3 ppm Antimony < 5 ppm
Diethylene Glycol	YES	NO	Glycerin complies with the relevant safety limit for Diethylene Glycol (DEG), according to USP and Ph. Eur. Monographs (maximum 0.1%).
Other impurities	NO	-	Not analyzed

*Data based on the results of the analysis of one representative batch of Zenerity™ biotech ingredient

Regulatory status

Information on the regulatory status of Zenerity™ biotech 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.
USA	No ingredients restricted by applicable cosmetic regulations. No ingredients listed in California's Proposition 65.
Japan	No ingredient restrictions known on the Standards for Cosmetics, Notification No.331/2000, as amended in April 2016.
Brazil	In accordance with article 11 from Resolution RDC No.7 of February 10, 2015.
Australia	All ingredients listed in AIIC ¹ schedule. Exception : Bacillus Ferment* No ingredients listed in SUSMP ² .
China	All ingredients listed in IECIC schedule.
Canada	No ingredient listed in HOTLIST schedule Exception: Glycerin [†]

¹AIIC: Australian Inventory of Industrial Chemicals.

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

*Chemicals not listed on the AIIC must be categorized by the importer before importation into Australia.

[†]The raw material used is within the specifications of an accepted pharmacopoeia with respect to diethylene glycol (DEG) impurities.



REACH

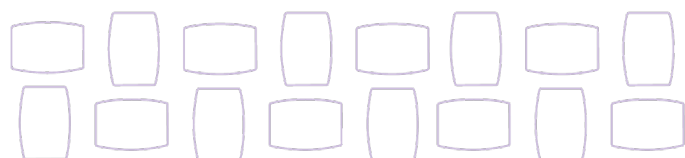
INGREDIENT	STATUS	COMMENTS
Glycerin	Exempt (Annex V)	-
Water (Aqua)	Exempt (Annex IV)	-
Bacillus Ferment	Exempt (<1 Tonne/year)	-

Statements

STATEMENT	YES/NO	COMMENTS
Does the product contain any genetically modified ingredient?	NO	-
Does the product contain as an ingredient any of the 81 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	-

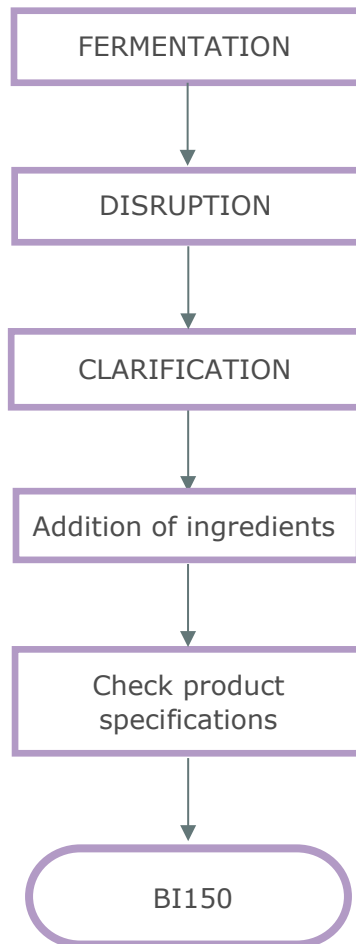


Does the product contain any ingredient that, according to the information provided by our suppliers, falls under the definition of Volatile Organic Compound (VOC) as described in Directive 2004/42/CE?	NO	-
Does the product contain any substance listed as a Substance of Very High Concern (SVHC) above a concentration of 0.1% weight by weight?	NO	-
Is there risk of contamination with Bovine Spongiform Encephalopathy (BSE) or Transmissible Spongiform Encephalopathy (TSE) through the use of this product?	NO	-
Is the product expected to contain, as an ingredient, 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 Zenerity™ biotech ingredient is manufactured according to the manufacturing standard protocol:



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