

Product Information Dossier (PI)



Product

BI060

ACTIGYM™ *marine
ingredient*

Date

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Revision

5



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Product Information

Trade Name & Code

TRADE NAME	CODE
ACTIGYM™ <i>marine ingredient</i>	BI060

Manufacturer

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

INCI name

GLYCERIN, WATER (AQUA), BACILLUS/SOYBEAN FERMENT EXTRACT

Composition

INGREDIENT	%	CAS	EINECS
Glycerin	Up to 100%	56-81-5	200-289-5
Water (Aqua)	4.437 – 5.423%	7732-18-5	231-791-2
Bacillus/Soybean Ferment Extract	0.063 - 0.077%	-	-

Additional information on ingredients

INGREDIENT	FUNCTION
Glycerin	Solvent
Water (Aqua)	Solvent
Bacillus/Soybean Ferment Extract	Active ingredient

- **vegetal origin:**

INCI	PLANT (SPECIES)	PART OF THE PLANT	COUNTRY OF ORIGIN	CITES
Glycerin	<i>Brassica campestris</i>	Seed	EU*	N/A
	<i>Helianthus annuus</i>	Seed	EU*	N/A

*according to information provided by supplier

- **biosynthetic origin:**
Bacillus/Soybean Ferment Extract;
- **animal origin:**
(none)
- **synthetic origin:**
(none)
- **mineral origin:**
Water (Aqua)

Specifications

Analytical Data

TEST	SPECIFICATION	METHOD
Physical appearance	Transparent solution	CC-10-01-B6
Colour	Colourless to Yellow	CC-10-01-B6
Specific gravity (g/mL)	1.20 – 1.30	CC-10-01-B3
pH	N.A.	
Viscosity (cPs)	N.A.	
Particle size (mm)	N.A.	
Refractive index	1.440 – 1.480	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:		
<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

ACTIGYM™ *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 ACTIGYM™ *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 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 Exception: Glycerin [†]

¹AICS: Australian Inventory of Chemical Substances

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

[†]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 II/V)	-
Water (Aqua)	Exempt (Annex IV)	-
Bacillus/soybean ferment extract	Exempt (< 1 Tonne/year)	-

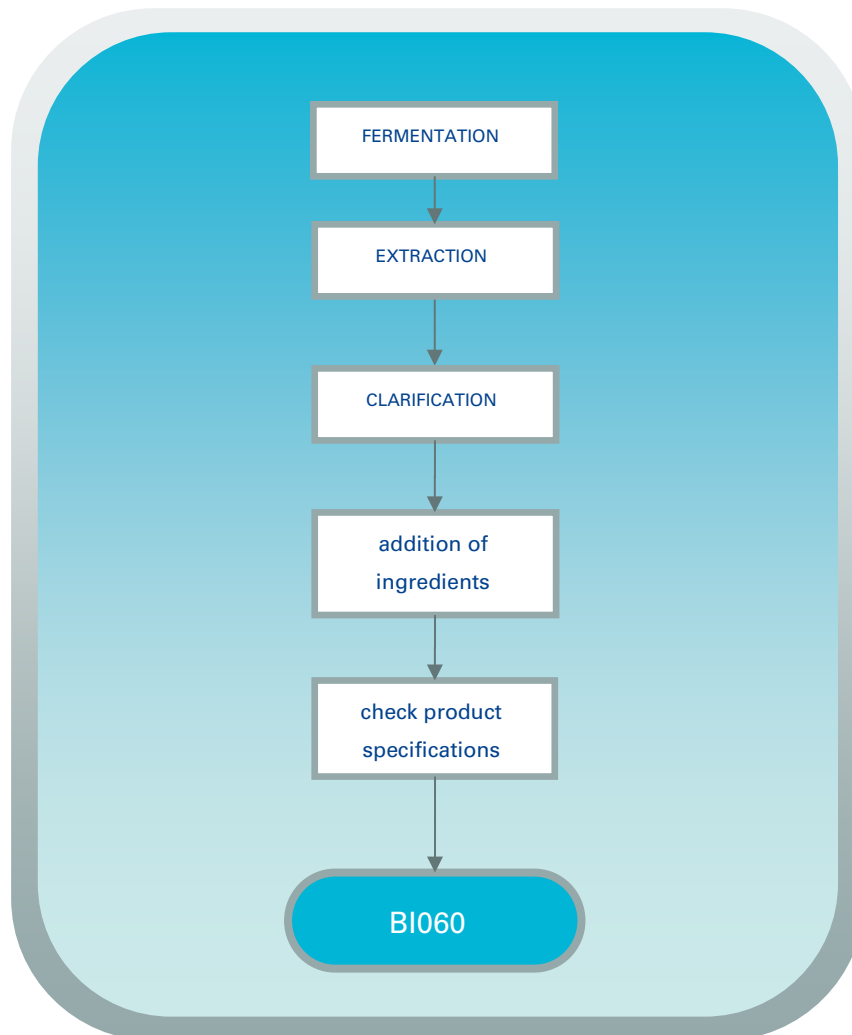
Statements

STATEMENT	YES/NO	COMMENTS
Does the product contain any genetically modified ingredient?	NO	-
Does the product contain as an ingredient any of the 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 ACTIGYM™ *marine ingredient* is manufactured according to the manufacturing standard protocol:



Safety

IN VITRO TESTS

The toxicological profile of the ingredient Bacillus/Soybean Ferment Extract for cosmetic purposes was assessed *in vitro*. All tests were performed using solutions of Bacillus/Soybean Ferment Extract at the desired concentrations.

Cytotoxicity test on human epidermal keratinocytes

Moderate cytotoxic effects on human epidermal keratinocyte cell cultures were observed, showing an $IC_{50} > 0.1015\%$; this concentration is approximately equivalent to that in 145% ACTIGYM™ *marine ingredient* (29x the recommended ACTIGYM™ *marine ingredient* dosage).

Cytotoxicity test on 3T3 fibroblasts

Low cytotoxic effects were observed on 3T3 fibroblast cell cultures, showing an $IC_{50} = n.d$ (0.5-1%); this concentration is approximately equivalent to that in 7 to 14x ACTIGYM™ *marine ingredient* (in the range of 142 to 285x the recommended ACTIGYM™ *marine ingredient* dosage).

Ocular irritation (HET-CAM test)

The results showed slight ocular irritation at concentration 1%, approximately equivalent to that in 14x ACTIGYM™ *marine ingredient* (more than 285x the recommended ACTIGYM™ *marine ingredient* dosage).

Phototoxicity (NRU test).

The results showed no phototoxicity on 3T3 fibroblast cell cultures, showing a PIF (Photo-Irritation Factor) value = -n.d. and a MPE (Mean Photo Effect) value = 0.037.

Bacterial reverse mutation test (Ames test)

No mutagenic effects were observed in the experimental conditions tested.

IN VIVO TESTS

Skin sensitisation

The product ACTIGYM™ *marine ingredient* can be considered non-irritating and non-sensitising at concentration 10%.

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	
Stability Report	X	
Material Safety Data Sheet	X	
Safety Dossier	X	

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