

Product Information Dossier (PI)



Product

**ES291**

**CHROMABRIGHT®** *synthetic molecule*

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Revision

**3**



Pol. Ind. Camí Ral C/ Isaac Peral, 17  
08850 Gavà Barcelona (Spain)  
Tel. +34 93 638 80 00  
[www.lipotec.com](http://www.lipotec.com)  
[commercial@lipotec.com](mailto:commercial@lipotec.com)

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## Product Information

### Trade Name & Code

TRADE NAME	CODE
CHROMABRIGHT® <i>synthetic molecule</i>	ES291

### Manufacturer

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

### INCI name

DIMETHYLMETHOXY CHROMANYL PALMITATE.

ES291

**CHROMABRIGHT®** *synthetic molecule*

## Composition

INGREDIENT	%	CAS	EINECS
Dimethylmethoxy Chromanyl Palmitate	100%	1105025-85-1	-

## Additional information on ingredients

INGREDIENT	FUNCTION
Dimethylmethoxy Chromanyl Palmitate	Active ingredient

- **vegetal origin:**  
(none)
- **biosynthetic origin:**  
(none)
- **animal origin:**  
(none)
- **synthetic origin:**  
Dimethylmethoxy Chromanyl Palmitate.
- **mineral origin:**  
(none)

## Specifications

### Analytical Data

TEST	SPECIFICATION	METHOD
Physical appearance	Powder	CC-10-01-B6
Colour	White to off white	CC-10-01-B6
Specific gravity	N.A.	
pH	N.A.	
Viscosity (cPs)	N.A.	
Particle size (mm)	N.A.	
Refractive index	N.A.	
Dry residue (%)	N.A.	
Melting Point (°C)	43 – 45	CC-10-01-B14
U.V. max. (in acetonitrile) (nm)	284 – 290	CC-10-01-B7
Chromabright® assay (%)	≥ 95	CC-10-01-B21
Identification (HPLC)	Similar retention time as in-house ref. standard.	CC-10-01-B21

### 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/30 mg	MI-10-01-D09
<i>Pseudomonas aeruginosa</i>	ABSENCE/30 mg	MI-10-01-D09
<i>Staphylococcus aureus</i>	ABSENCE/30 mg	MI-10-01-D09
<i>Candida albicans</i>	ABSENCE/30 mg	MI-10-01-D09

## Storage

CHROMABRIGHT® *synthetic molecule* should be stored in a clean, cool and dark place.

## Shelf life

If stored as recommended, shelf life is 30 months.

## Impurities

ANALYSIS	AVAILABLE	EXPECTED	RESULT/COMMENTS
Heavy metals	YES	-	Heavy Metals (as Pb) ≤ 10 ppm Arsenic ≤ 1 ppm
Diethylene Glycol	NO	NO	Not expected based on product knowledge
Other impurities	YES	-	Palmitic acid ≤ 0.5% Chloride (Cl) ≤ 0.1%

## Regulatory status

Information on the regulatory status of CHROMABRIGHT® *synthetic molecule* 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 <sup>1</sup> schedule Exception: Dimethylmethoxy Chromanyl Palmitate* No ingredients listed in SUSMP <sup>2</sup>
China	All ingredients listed in IECIC schedule
Canada	No ingredient listed in HOTLIST schedule

<sup>1</sup>AICS: Australian Inventory of Chemical Substances

<sup>2</sup>SUSMP: Standard for the Uniform Scheduling of Medicines and Poisons

\*The obligation to notify to NICNAS applies only to import volumes over 10 kg of substance/year

## REACH

INGREDIENT	STATUS	COMMENTS
Dimethylmethoxy Chromanyl Palmitate	Exempt (< 1 Tonne/year)	-

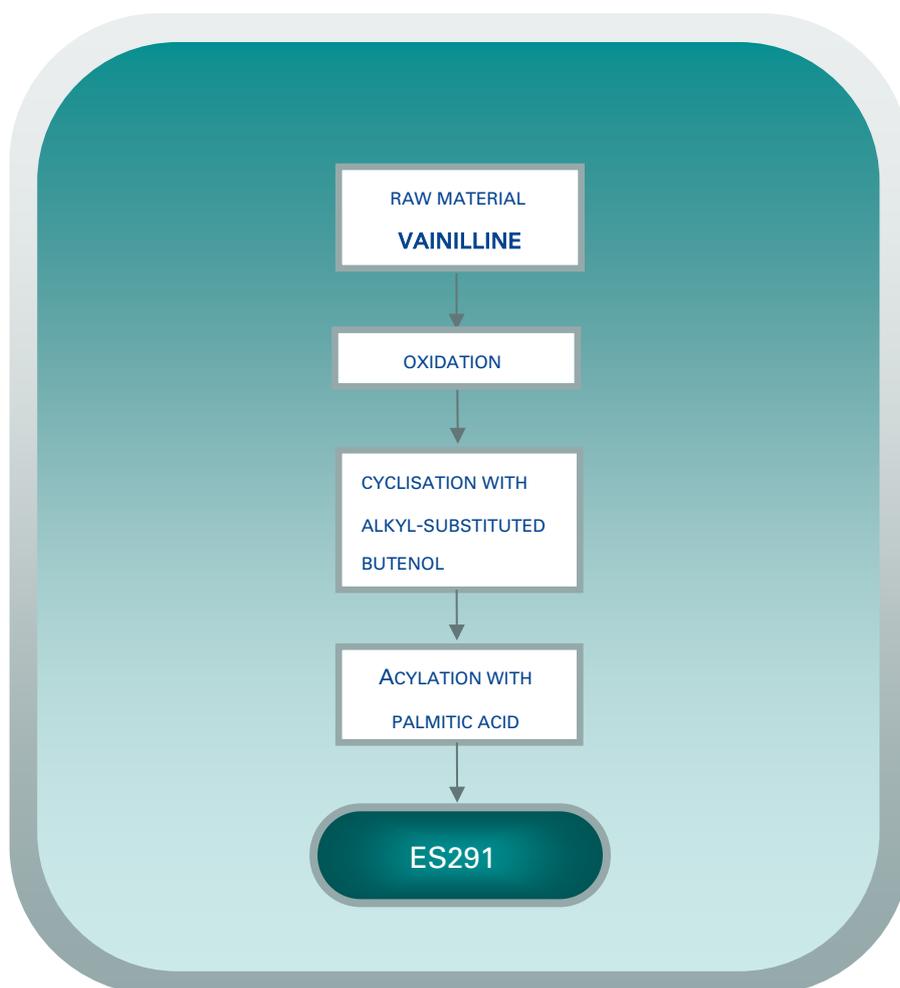
## Statements

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 allergenic reactions?	NO	-
Has the product undergone animal tests sponsored by Lipotec S.A.U.?	YES	The active ingredient with INCI name Dimethylmethoxy Chromanyl Palmitate, contained in our product CHROMABRIGHT® <i>synthetic molecule</i> has undergone animal tests for safety purposes. The last test was performed in 2007.
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 CHROMABRIGHT® *synthetic molecule* is manufactured according to the manufacturing standard protocol:



## Safety

The toxicological profile of CHROMABRIGHT® *synthetic molecule* for cosmetic purposes was assessed *in vitro* and *in vivo*.

### IN VITRO TESTS

#### **Cytotoxicity test on human epidermal keratinocytes**

CHROMABRIGHT® *synthetic molecule* showed no significant signs of cytotoxicity at the concentrations assayed.

#### **Cytotoxicity test on 3T3 fibroblasts**

CHROMABRIGHT® *synthetic molecule* proved not to have significant cytotoxic effects.

#### **Ocular Irritation (HET-CAM test)**

According to the results of the HET-CAM test, CHROMABRIGHT® *synthetic molecule* showed no ocular irritation at the tested concentrations.

#### **NRU Phototoxicity test**

CHROMABRIGHT® *synthetic molecule* showed no signs of phototoxicity at the concentrations assayed.

#### **Bacterial reverse mutation test (Ames test)**

CHROMABRIGHT® *synthetic molecule* produced no mutagenic activity in any of the bacterial strains tested.

### IN VIVO TESTS

#### **Skin sensitisation and cutaneous compatibility test**

A HRIPT (Human Repeated Insult Patch Test) was performed on 100 volunteers aged 18 to 70. 2% CHROMABRIGHT® *synthetic molecule* induced neither irritation nor any sensitising reaction.

*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	
Tox Summary	X	
Efficacy Reports	X	
Safety Data Sheet	X	

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