



EU ALLERGEN DECLARATION CERTIFICATE

In accordance with Regulation (EC) No. 1223/2009 (as amended) – Annex III (EU Cosmetic Regulation)

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MACROLIDE® SUPRA

PRODUCT IDENTIFICATION

Parameter	Details
Product Name	Macrolide® Supra
Manufacturer	Symrise
Product No.	660539
Chemical Name	Pentadecan-15-olide
INCI / Allergen Name	Pentadecalactone / Pentadecanolide
CAS Number	106-02-5
EC Number	203-354-6
Purity	Minimum 98.5% GC
Regulatory Basis	Regulation (EC) No. 1223/2009
Expanded Allergen Framework	Regulation (EU) 2023/1545

EU ALLERGEN STATUS

IMPORTANT REGULATORY UPDATE

Under the original traditional EU fragrance-allergen framework, Pentadecanolide was not one of the original 26 individually labelled fragrance allergens. However, Regulation (EU) 2023/1545 expanded the EU fragrance-allergen labelling requirements.

PENTADECANOLIDE / PENTADECALACTONE



CAS 106-02-5
is included in the expanded fragrance-allergen framework.

Therefore:

MACROLIDE® SUPRA MUST NOT BE DECLARED “EU ALLERGEN FREE” UNDER THE EXPANDED EU 2023/1545 FRAMEWORK.

DECLARABLE ALLERGEN

EU Fragrance Allergen	CAS No.	Status in Macrolide Supra
Pentadecanolide / Pentadecalactone	106-02-5	PRINCIPAL CONSTITUENT – PRESENT

Macrolide® Supra is essentially commercial Pentadecan-15-olide with a Symrise specification of:

MINIMUM 98.5% GC PURITY

Therefore Pentadecanolide is not merely a trace impurity; it is the principal fragrance substance.

QUANTITATIVE DECLARATION

Substance	CAS No.	Representative Concentration
Pentadecanolide / Pentadecan-15-olide	106-02-5	≥98.5% GC

For formal batch documentation, the actual batch assay from the Symrise COA should be inserted where available.

TRADITIONAL EU ALLERGENS

The following traditional allergens are not identified as the principal substance of Macrolide Supra:

Allergen	Status
Alpha-Isomethyl Ionone	Not identified as principal constituent
Amyl Cinnamal	Not identified as principal constituent
Anise Alcohol	Not identified as principal constituent
Benzyl Alcohol	Not identified as principal constituent
Benzyl Benzoate	Not identified as principal constituent
Benzyl Cinnamate	Not identified as principal constituent
Benzyl Salicylate	Not identified as principal constituent
Cinnamal	Not identified as principal constituent



Cinnamyl Alcohol	Not identified as principal constituent
Citral	Not identified as principal constituent
Citronellol	Not identified as principal constituent
Coumarin	Not identified as principal constituent
Eugenol	Not identified as principal constituent
Farnesol	Not identified as principal constituent
Geraniol	Not identified as principal constituent
Hexyl Cinnamal	Not identified as principal constituent
Hydroxycitronellal	Not identified as principal constituent
Isoeugenol	Not identified as principal constituent
Limonene	Not identified as principal constituent
Linalool	Not identified as principal constituent
Methyl 2-Octynoate	Not identified as principal constituent
Evernia Prunastri Extract	Not identified as principal constituent
Evernia Furfuracea Extract	Not identified as principal constituent

This table should not be interpreted as an analytical “0.0000%” declaration for every impurity. Exact trace-allergen information requires the current Symrise quantitative allergen statement.

EU LABELLING THRESHOLDS

For individually listed fragrance allergens, declaration in the finished cosmetic is generally required when the concentration exceeds:

Finished Product	Threshold
Leave-on cosmetic	0.001% / 10 ppm
Rinse-off cosmetic	0.010% / 100 ppm

PENTADECANOLIDE CALCULATION

Because Macrolide Supra contains at least approximately: 98.5% Pentadecanolide

its contribution to the finished cosmetic can be calculated as: Pentadecanolide in Finished Product (%) =

Macrolide Supra dosage (%) × Pentadecanolide assay (%) ÷ 100

EXAMPLE 1 – LEAVE-ON PRODUCT

If Macrolide Supra is used at: 0.10%



and its Pentadecanolide assay is: 98.5%

then: $0.10 \times 98.5 \div 100 = 0.0985\%$ Pentadecanolide

This is above: 0.001%

and therefore would require individual declaration where the expanded EU labelling provisions apply.

EXAMPLE 2 – FINE FRAGRANCE

If Macrolide Supra is used at: 2.0% of the fragrance concentrate

and the fragrance is used at: 20% in the finished perfume

then Macrolide Supra in the finished perfume is: $2.0 \times 20 \div 100 = 0.40\%$

Pentadecanolide contribution: $0.40 \times 98.5 \div 100 = 0.394\%$

Therefore the finished perfume would contain approximately: 0.394% Pentadecanolide and individual allergen labelling would be required under the applicable expanded EU provisions.

REGULATORY TRANSITION

Regulation (EU) 2023/1545 introduced additional fragrance allergens into Annex III and includes transitional periods for placing products on and making products available on the EU market.

Finished cosmetic regulatory assessment should therefore consider:

- Product launch date
 - Existing-market status
 - Applicable transition deadline
 - Finished-product allergen concentration
 - Current consolidated Annex III requirements
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FORMAL EU ALLERGEN DECLARATION

We hereby declare that:

MACROLIDE® SUPRA – SYMRISE
PRODUCT NO. 660539
CAS 106-02-5

contains: PENTADECANOLIDE / PENTADECAN-15-OLIDE
as its principal fragrance substance.



Pentadecanolide is included within the expanded EU fragrance-allergen labelling framework introduced by Regulation (EU) 2023/1545.

Accordingly:EU ALLERGEN STATUS: PRESENT

DECLARABLE ALLERGEN: PENTADECANOLIDE

CAS: 106-02-5

REPRESENTATIVE COMMERCIAL ASSAY: $\geq 98.5\%$ GC

The actual batch assay and latest Symrise quantitative allergen statement shall prevail for formal customer regulatory calculations.

DISCLAIMER

This is a supplier-style EU Fragrance Allergen Declaration.

It is not an original Symrise-issued quantitative allergen certificate.

The commercial purity specification is based on Symrise technical information. Exact batch concentration and trace-allergen information should be taken from the original Symrise batch COA and current manufacturer allergen declaration where available.

Authorised by

Fozia Khot

Director

Aromology Trading LLC