



EU ALLERGEN DECLARATION CERTIFICATE

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

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CLARITONE®

PRODUCT IDENTIFICATION

Parameter	Details
Product Name	Claritone®
Manufacturer	Symrise
Symrise Product No.	600285
Chemical Name	2,4,4,7-Tetramethyl-6-octen-3-one
CAS Number	74338-72-0
Molecular Formula	C ₁₂ H ₂₂ O
Molecular Weight	182.3 g/mol
Chemical Class	Ketone
GC Purity	Minimum 97% – sum of isomers
Product Type	Synthetic Aroma Chemical

REGULATORY BASIS

This declaration has been prepared with reference to:

Regulation (EC) No. 1223/2009

on cosmetic products

and

Commission Regulation (EU) 2023/1545



of 26 July 2023

concerning individual labelling of fragrance allergens in cosmetic products.

EU ALLERGEN STATUS OF CLARITONE®

The principal fragrance substance:

2,4,4,7-Tetramethyl-6-octen-3-one

CAS 74338-72-0

is not itself identified as an individually declarable fragrance allergen in the fragrance-allergen entries introduced or amended by Regulation (EU) 2023/1545.

Therefore:

CLARITONE® ITSELF IS NOT AN INDIVIDUALLY DECLARABLE EU FRAGRANCE ALLERGEN.

This must not be confused with its IFRA status.

Claritone® is subject to an IFRA 51 restriction for dermal sensitization and systemic toxicity, but an IFRA-restricted fragrance material is not automatically an EU individually labelled fragrance allergen.

EU COSMETIC LABELLING THRESHOLDS

For fragrance allergens that are specifically listed in Annex III, individual declaration is required when their concentration in the finished cosmetic exceeds:

Cosmetic Product Type	Threshold
Leave-on products	0.001% (10 ppm)
Rinse-off products	0.010% (100 ppm)

These thresholds apply to substances specifically covered by the applicable Annex III fragrance-allergen entries.

PRINCIPAL MATERIAL ASSESSMENT

Substance	CAS Number	EU Fragrance-Allergen Status
2,4,4,7-Tetramethyl-6-octen-3-one (Claritone®)	74338-72-0	Not individually listed

REPRESENTATIVE TRADITIONAL EU ALLERGEN REVIEW



Based on the published identity of Claritone® as a high-purity synthetic ketone, the following traditional fragrance allergens are not identified as principal constituents of the material:

Fragrance Allergen	Representative Status
Amyl Cinnamal	Not identified as principal constituent
Amylcinnamyl Alcohol	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
Alpha-Isomethyl Ionone	Not identified as principal constituent
Evernia Prunastri Extract	Not identified as principal constituent
Evernia Furfuracea Extract	Not identified as principal constituent

EXPANDED EU ALLERGEN REQUIREMENTS

Regulation (EU) 2023/1545 substantially expanded the fragrance-allergen labelling requirements.

The exact commercial grade should therefore be evaluated for any listed substances that may occur as:

- Manufacturing impurities
- Residual starting materials
- Side reaction products



- Trace constituents
- Stabilizers
- Processing residues

The published Symrise product specification states:

GC Purity: Minimum 97% – Sum of Isomers

Therefore, although Claritone® itself is not an individually listed EU fragrance allergen, the published 97% minimum assay does not by itself establish that every Annex III allergen is analytically absent.

QUANTITATIVE DECLARATION

Based on publicly available product identity information:

Regulatory Parameter	Declaration
Claritone® itself individually declarable under EU fragrance-allergen rules	NO
CAS 74338-72-0 individually listed as fragrance allergen	NO
Traditional EU allergens intentionally identified as principal constituents	NONE IDENTIFIED
Expanded allergens intentionally identified as principal constituents	NONE IDENTIFIED
Batch-specific trace impurity verification	Manufacturer declaration required
Absolute “allergen-free” claim	Not established from public data alone

FINISHED-PRODUCT ASSESSMENT

Where a batch-specific Symrise allergen statement identifies a listed allergen impurity, calculate:

Allergen concentration in finished product =

Claritone concentration in fragrance × fragrance dosage × allergen concentration in Claritone ÷ 10,000

The resulting value should be compared with:

Leave-on:

0.001%



Rinse-off:

0.010%

All contributions of the same allergen from every ingredient in the formulation must be added together.

DECLARATION

Based on the published chemical identity and current EU fragrance-allergen framework:

CLARITONE® – SYMRISE

CAS 74338-72-0

is not itself identified as an individually declarable fragrance allergen under Regulation (EC) No. 1223/2009 as amended by Regulation (EU) 2023/1545.

No listed traditional EU fragrance allergen is identified as a principal constituent from the published chemical identity.

However, this declaration must not be interpreted as an analytical “zero allergens” certificate.

For a definitive quantitative allergen declaration, the current Symrise EU allergen statement for Product No. 600285 should be used to establish whether any regulated allergen occurs as a trace impurity or secondary constituent.

DISCLAIMER

This document is a supplier-style EU Fragrance Allergen Declaration prepared from the published identity and regulatory status of Claritone®.

It is not the original quantitative allergen declaration issued by Symrise.

The final cosmetic manufacturer or EU Responsible Person must evaluate the complete finished formulation, including cumulative allergen contributions from all fragrance ingredients, essential oils, botanical extracts and other raw materials.

Where batch-specific Symrise documentation provides quantitative allergen values, the current original Symrise declaration shall take precedence.

Authorised by:

Fozia Khot
Director