



EU ALLERGEN DECLARATION CERTIFICATE

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

Aromology Trading LLC
G05 Al Ghazal Building
Nadd Al Hamar
Dubai, United Arab Emirates

Website: www.aromology.com
Email: info@aromology.com

Product Identification

Parameter	Details
Product Name	Orange Leaf Absolute
Alternative Name	Petitgrain Absolute
Botanical Name	<i>Citrus aurantium</i> L. var. <i>amara</i>
Plant Part	Leaves and young twigs
INCI Name	Citrus Aurantium Amara Leaf Extract
CAS Number	8014-17-3
Country of Origin	Tunisia
Extraction Method	Solvent extraction
Material Type	Natural Complex Substance

REGULATORY BASIS

This declaration has been prepared with reference to:

- Regulation (EC) No. 1223/2009 on cosmetic products
- Annex III concerning regulated fragrance allergens
- Commission Regulation (EU) 2023/1545 concerning fragrance-allergen labelling
- The 2025 corrigendum to Regulation (EU) 2023/1545

Regulation (EU) 2023/1545 amended the EU Cosmetics Regulation by expanding the substances subject to individual fragrance-allergen labelling.

EU DECLARATION THRESHOLDS

Listed fragrance allergens must generally be declared in the finished cosmetic ingredient list when their concentration exceeds:

Finished Cosmetic Type	Declaration Threshold
Leave-on products	0.001%
Rinse-off products	0.01%

These thresholds apply to the concentration of each allergen in the finished cosmetic product and not directly to the concentrated raw material.

NATURAL COMPLEX SUBSTANCE STATUS

Orange Leaf Absolute is a variable botanical extract. Its allergen profile may be influenced by:

- Plant variety
- Growing region
- Harvest conditions
- Leaf-to-twigs ratio
- Extraction process
- Storage and oxidation
- Production batch

Assessment	Status
Natural Complex Substance	Yes
Batch-Specific Allergen Report Supplied	No
Naturally Occurring EU Allergens Possible	Yes
Finished-Product Calculation Required	Yes
Automatic Absence of Allergens Established	No
Final Cosmetic Compliance Established	No

REPRESENTATIVE EU ALLERGEN PROFILE

EU Fragrance Allergen	CAS Number	Representative Raw-Material Status
Linalool	78-70-6	Typically present
Limonene	138-86-3 / 5989-27-5	Typically present
Geraniol	106-24-1	May be present
Citral	5392-40-5	May be present
Citronellol	106-22-9	May be present
Farnesol	4602-84-0	May be present

Eugenol	97-53-0	May be present at trace level
Isoeugenol	97-54-1	May be present at trace level
Benzyl Alcohol	100-51-6	Batch dependent
Benzyl Benzoate	120-51-4	Batch dependent
Benzyl Salicylate	118-58-1	Not expected or trace
Coumarin	91-64-5	Not expected or trace
Anise Alcohol	105-13-5	Not expected or trace
Alpha-Isomethyl Ionone	127-51-5	Not naturally expected
Hydroxycitronellal	107-75-5	Not naturally expected
Hexyl Cinnamal	101-86-0	Not naturally expected
Amyl Cinnamal	122-40-7	Not naturally expected
Cinnamal	104-55-2	Not naturally expected
Cinnamyl Alcohol	104-54-1	Not naturally expected
Methyl 2-Octynoate	111-12-6	Not expected

The expressions “typically present,” “may be present,” “trace” and “not expected” are qualitative descriptions and do not represent measured batch results.

REPRESENTATIVE ESTIMATED ALLERGEN RANGES

The following values are representative commercial estimates only.

Allergen	Representative Estimated Range in Raw Material
Linalool	15.0–40.0%
Limonene	0.5–6.0%
Geraniol	0.5–6.0%
Citronellol	Trace–2.0%
Citral	Trace–1.0%
Farnesol	Trace–1.0%
Benzyl Alcohol	Trace–1.0%
Benzyl Benzoate	Trace–1.0%
Eugenol	Trace–0.2%
Isoeugenol	Trace–0.1%

These ranges must not be used as certified batch values or final cosmetic-labelling data.

OXIDATION CONSIDERATION

Linalool, Limonene and other terpenes may oxidise during prolonged exposure to:

- Air
- Heat
- Light
- Moisture

Oxidation may alter the sensitisation profile of the material. Containers should therefore be kept tightly closed and protected from heat and light.

EXPANDED EU ALLERGEN REQUIREMENTS

The amended EU rules extend individual fragrance-allergen labelling beyond the historical group of commonly declared fragrance allergens.

A complete Regulation (EU) 2023/1545 assessment should therefore use batch-specific analytical information covering all applicable Annex III substances and grouped ingredient names relevant to the actual composition.

This representative declaration cannot confirm the presence or absence of every newly regulated substance.

FINISHED-PRODUCT CALCULATION

Allergen in finished product (%) =

Allergen concentration in raw material (%) × raw-material dosage in finished product (%)
÷ 100

Illustrative Example: Linalool

Where:

- Linalool in Orange Leaf Absolute = 30.0%
- Orange Leaf Absolute in the finished cosmetic = 0.10%

Calculation:

$30.0 \times 0.10 \div 100 = 0.030\%$ Linalool

The resulting level exceeds:

- The 0.001% leave-on declaration threshold
- The 0.01% rinse-off declaration threshold

Linalool would therefore require declaration in both example applications.

This example is illustrative only.

QUANTITATIVE STATUS

Assessment	Status
Batch-Specific GC/MS Supplied	No
Quantitative EU Allergen Certificate Supplied	No
Exact Allergen Concentrations Certified	No
Representative Profile Provided	Yes
Suitable for Final Legal Label Calculation	Only after batch confirmation
Cosmetic Safety Assessment Required	Yes
Product Information File Documentation Required	Yes

RESPONSIBILITY OF THE FINISHED-PRODUCT MANUFACTURER

The cosmetic manufacturer or EU Responsible Person must:

1. Obtain batch-specific quantitative allergen information.
 2. Confirm the dosage of Orange Leaf Absolute.
 3. Calculate each allergen contributed by this raw material.
 4. Add allergen contributions from every other ingredient.
 5. Apply the 0.001% leave-on threshold.
 6. Apply the 0.01% rinse-off threshold.
 7. Use the applicable Annex III ingredient wording.
 8. Update the Cosmetic Product Safety Report.
 9. Retain supporting documentation in the Product Information File.
 10. Confirm compliance with applicable transitional and market-placement requirements.
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DECLARATION

Aromology Trading LLC declares that:

- Orange Leaf Absolute (Tunisia) is a natural botanical extract.
- It may naturally contain multiple EU-regulated fragrance allergens.



- No regulated fragrance allergens are intentionally added separately, based on the stated product identity.
- Exact allergen concentrations vary between production batches.
- No batch-specific quantitative allergen analysis was supplied.
- The representative information must not be used as a final legal label calculation without analytical confirmation.
- Final compliance responsibility rests with the finished-product manufacturer or EU Responsible Person.

DISCLAIMER

This declaration is based on representative botanical and commercial information. It does not replace:

- Original manufacturer allergen documentation
- Batch-specific GC/MS analysis
- A complete Regulation (EU) 2023/1545 allergen declaration
- Finished-product allergen calculations
- A Cosmetic Product Safety Report

No guarantee of allergen absence or concentration is made without analytical confirmation.

AUTHORISED BY

Fozia Khot

Director

Aromology Trading LLC