



EU ALLERGEN DECLARATION CERTIFICATE

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

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Product Identification

Parameter	Details
Product Name	Orange Blossom Absolute
Botanical Name	<i>Citrus aurantium</i> L. var. <i>amara</i>
Plant Part	Flowers
INCI Name	Citrus Aurantium Amara Flower Extract
CAS Number	8030-28-2
Country of Origin	Egypt
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 restricted fragrance allergens
- Commission Regulation (EU) 2023/1545 concerning expanded individual fragrance-allergen labelling

Under the EU cosmetics framework, listed fragrance allergens must generally be declared when their concentration exceeds:

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

Regulation (EU) 2023/1545 expanded the substances subject to individual fragrance-allergen labelling while retaining these concentration thresholds.

BOTANICAL EXTRACT STATUS

Orange Blossom Absolute is a natural complex extract with batch-variable composition.

The commercial name **Orange Blossom Absolute** is not itself a substitute for the INCI ingredient declaration. The finished cosmetic should identify the material according to the applicable INCI nomenclature and separately declare regulated fragrance allergens above their legal thresholds.

Assessment	Status
INCI Identity	Citrus Aurantium Amara Flower Extract
Natural Complex Substance	Yes
Quantitative Batch Allergen Report Supplied	No
Naturally occurring allergens possible	Yes
Finished-product calculation required	Yes
Automatic absence of allergens established	No

REPRESENTATIVE EU ALLERGEN PROFILE

Fragrance Allergen	CAS Number	Representative Raw-Material Status
Linalool	78-70-6	Typically present
Limonene	138-86-3 / 5989-27-5	May be present
Benzyl Alcohol	100-51-6	Typically present
Benzyl Benzoate	120-51-4	Typically present
Benzyl Salicylate	118-58-1	May be present
Farnesol	4602-84-0	May be present
Geraniol	106-24-1	May be present
Citral	5392-40-5	May be present
Citronellol	106-22-9	May be present
Eugenol	97-53-0	May be present
Isoeugenol	97-54-1	May be present
Alpha-Isomethyl Ionone	127-51-5	Not expected unless introduced
Coumarin	91-64-5	Not expected or trace
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
Anise Alcohol	105-13-5	Batch dependent

Methyl 2-Octynoate 111-12-6 Not expected

“May be present,” “not expected” and “typically present” are qualitative descriptions and do not represent measured batch results.

REPRESENTATIVE QUANTITATIVE DECLARATION

The following values are representative commercial estimates only and must not be used as certified batch results.

Allergen	Representative Estimated Range in Raw Material
Linalool	8.0–25.0%
Benzyl Alcohol	1.0–8.0%
Benzyl Benzoate	1.0–8.0%
Benzyl Salicylate	0.5–6.0%
Farnesol	0.2–3.0%
Limonene	0.1–3.0%
Geraniol	0.1–2.0%
Citronellol	Trace–1.0%
Citral	Trace–0.5%
Eugenol	Trace–0.5%
Isoeugenol	Trace–0.2%

EXPANDED EU ALLERGEN REQUIREMENTS

Regulation (EU) 2023/1545 expanded Annex III allergen-labelling requirements beyond the historical fragrance-allergen list.

A complete updated assessment should therefore be based on a batch-specific analytical declaration covering all applicable substances under the amended regulation, including relevant grouped names and oxidation products where required.

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

FINISHED-PRODUCT CALCULATION

Allergen in finished product (%) =

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

Example: Linalool

Where:

- Linalool in Orange Blossom Absolute = 15.0%
- Orange Blossom Absolute in finished product = 0.10%

Calculation:

$15.0 \times 0.10 \div 100 = 0.015\%$ Linalool

The resulting concentration would exceed both:

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

Therefore, Linalool would require declaration in both applications.

This example is illustrative only.

QUANTITATIVE STATUS

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

RESPONSIBILITY OF THE FINISHED-PRODUCT MANUFACTURER

The cosmetic manufacturer or EU Responsible Person must:

1. Obtain batch-specific quantitative allergen data.
2. Confirm the dosage of Orange Blossom Absolute.
3. Calculate the contribution of each allergen.
4. Add contributions from all other fragrance materials.

5. Apply the 0.001% leave-on threshold.
6. Apply the 0.01% rinse-off threshold.
7. Use the correct Annex III ingredient wording.
8. Update the Cosmetic Product Safety Report.
9. Retain supporting documents in the Product Information File.
10. Confirm compliance with all applicable transitional and market-placement requirements.

DECLARATION

Aromology Trading LLC declares that:

- Orange Blossom Absolute – Egypt is a natural floral extract.
- It may naturally contain multiple EU-regulated fragrance allergens.
- No regulated allergens are intentionally added separately, based on the stated product identity.
- Exact concentrations vary by harvest and production batch.
- No batch-specific quantitative allergen analysis was supplied.
- The representative profile must not be used as a final legal label calculation without confirmation.
- Final responsibility remains with the finished-product manufacturer or Responsible Person.

DISCLAIMER

This declaration is based on representative botanical and commercial information. It is not a substitute for:

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

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

AUTHORISED BY

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