

ALLERGEN DECLARATION CERTIFICATE

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

Nutmeg Absolute

PRODUCT IDENTIFICATION

Parameter	Details
Product Name	Nutmeg Absolute
Botanical Name	<i>Myristica fragrans</i> Houtt.
INCI Name	Myristica Fragrans Kernel Extract
Plant Part	Dried Kernels / Seeds
Extraction Method	Solvent Extraction
Material Type	Natural Complex Substance

Myristica Fragrans Kernel Extract is identified as an extract prepared from nutmeg kernels.

REGULATORY BASIS

This declaration has been prepared with reference to:

- Regulation (EC) No. 1223/2009 on cosmetic products
- Annex III of Regulation (EC) No. 1223/2009
- Commission Regulation (EU) 2023/1545 concerning fragrance-allergen labelling
- Applicable restrictions for specific naturally occurring fragrance constituents

DECLARATION

Nutmeg Absolute is a natural complex botanical extract.

It may naturally contain substances that are subject to:

- Individual fragrance-allergen labelling
- Annex III concentration restrictions
- Finished-product safety assessment
- Quantitative calculation from all ingredient sources

No batch-specific quantitative allergen or GC/MS report was supplied for this declaration. Exact percentages therefore cannot be certified.

REPRESENTATIVE FRAGRANCE-ALLERGEN PROFILE

EU Fragrance Allergen	CAS Number	Representative Status
Limonene	5989-27-5 / 138-86-3	May be naturally present
Linalool	78-70-6	May be naturally present
Eugenol	97-53-0	May be naturally present
Isoeugenol	97-54-1	May be naturally present
Geraniol	106-24-1	May be naturally present
Citral	5392-40-5	May be naturally present
Citronellol	106-22-9	May be naturally present
Coumarin	91-64-5	May be naturally present
Benzyl Alcohol	100-51-6	May be naturally present
Benzyl Benzoate	120-51-4	May be naturally present
Farnesol	4602-84-0	Not normally expected at significant level
Cinnamal	104-55-2	Not normally expected
Cinnamyl Alcohol	104-54-1	Not normally expected
Anisyl Alcohol	105-13-5	Not normally expected
Alpha-Isomethyl Ionone	127-51-5	Not intentionally added
Amyl Cinnamal	122-40-7	Not intentionally added
Hexyl Cinnamal	101-86-0	Not intentionally added
Hydroxycitronellal	107-75-5	Not intentionally added
Methyl 2-Octynoate	111-12-6	Not intentionally added
Oakmoss Extract	90028-68-5	Not intentionally added
Treemoss Extract	90028-67-4	Not intentionally added

“May be naturally present” does not confirm a specific concentration.

OTHER REGULATED NATURAL CONSTITUENTS

The following substances are not treated solely as conventional fragrance-allergen declarations but may be subject to separate Annex III restrictions or safety controls:

Constituent	Representative Status	Regulatory Consideration
Safrole	May be naturally present	Quantitative restriction and safety assessment required
Methyl Eugenol	May be naturally present	Quantitative restriction applies according to product type
Estragole	May be naturally present	Safety and constituent assessment required
Myristicin	Characteristic nutmeg constituent	Toxicological assessment required
Elemicin	May be naturally present	Toxicological assessment required

Their presence must be determined from the actual batch analysis.

QUANTITATIVE STATUS

Assessment	Status
Batch-specific GC/MS supplied	No
Quantitative EU allergen analysis supplied	No
Listed allergens intentionally added separately	None declared

Naturally occurring allergens	Possible
Exact allergen concentrations	Not determined
Safrole concentration	Not determined
Methyl Eugenol concentration	Not determined
Suitable for precise final-label calculation without analysis	No

EU COSMETIC LABELLING THRESHOLDS

An individually listed fragrance allergen must be declared in the finished cosmetic product ingredient list when its concentration exceeds:

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

The threshold applies to each allergen in the final consumer product, not to its percentage in Nutmeg Absolute.

CALCULATION METHOD

For each confirmed allergen:

Allergen in finished product (%) =

Allergen concentration in Nutmeg Absolute (%) × Nutmeg Absolute dosage in finished product (%) ÷ 100

The contribution of the same allergen from every other raw material must then be added.

ILLUSTRATIVE CALCULATION

Where the batch contains:

- Eugenol: 0.40%
- Nutmeg Absolute used in finished product: 0.50%

The eugenol concentration in the finished product would be:

$$0.40 \times 0.50 \div 100 = 0.002\%$$

This would exceed the 0.001% leave-on threshold and would require declaration in a leave-on cosmetic product.

This example is illustrative only and is not a certified batch result.

RESPONSIBILITY OF THE FINISHED-PRODUCT MANUFACTURER

The manufacturer or Responsible Person must:

1. Obtain the actual batch-specific allergen and restricted-constituent analysis.

2. Calculate each allergen's total concentration from all ingredients.
 3. Assess safrole, methyl eugenol and other restricted constituents separately.
 4. Apply the correct Annex III ingredient names.
 5. Declare allergens exceeding the applicable finished-product thresholds.
 6. Complete the Cosmetic Product Safety Report.
 7. Maintain the Product Information File.
 8. Ensure compliance with all destination-market requirements.
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CONCLUSION

Based on the information available:

- No declarable fragrance allergens are intentionally added separately.
 - Nutmeg Absolute may naturally contain limonene, linalool, eugenol, isoeugenol, citral, geraniol and other fragrance allergens.
 - It may also contain restricted constituents including safrole and methyl eugenol.
 - Exact concentrations cannot be certified without batch-specific quantitative analysis.
 - This declaration must not be used as the sole basis for final cosmetic ingredient labelling.
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