

EU ALLERGEN DECLARATION CERTIFICATE

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

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Product Information

Parameter	Details
Product Name	Rose Centifolia Oil
Botanical Name	<i>Rosa centifolia</i> L.
Common Name	May Rose Oil / Cabbage Rose Oil
INCI Name	<i>Rosa Centifolia Flower Oil</i>
CAS No.	8007-01-0
FEMA No.	2989
Botanical Family	Rosaceae
Country of Origin	Bulgaria
Plant Part Used	Fresh Flowers
Extraction Method	Steam Distillation
Product Type	Natural Essential Oil
Grade	Professional Perfumery and Cosmetic Grade

Regulatory Basis

This declaration has been prepared with reference to:

- Regulation (EC) No. 1223/2009 on cosmetic products
- Commission Regulation (EU) 2023/1545
- Annex III of the EU Cosmetics Regulation
- Applicable fragrance-allergen labelling requirements
- Representative compositional information for natural distilled rose oil

The consolidated EU Cosmetics Regulation distinguishes between rinse-off products, which are intended to be removed after application, and leave-on products, which remain in prolonged contact with the skin, hair or mucous membranes.

EU Fragrance Allergen Labelling Thresholds

Fragrance allergens must be individually identified in the finished cosmetic product ingredient list when their concentration exceeds:

Finished Product Type	Declaration Threshold
Leave-on Cosmetic Products	0.001% – 10 mg/kg or 10 ppm
Rinse-off Cosmetic Products	0.010% – 100 mg/kg or 100 ppm

These thresholds apply to the concentration of each individual allergen in the finished cosmetic product, not merely to its concentration in the fragrance ingredient.

The manufacturer or responsible person must consider the contribution of the allergen from all ingredients used in the finished formulation.

Traditional EU Fragrance Allergen Declaration

The following table covers the fragrance allergens historically subject to individual declaration under Annex III of the EU Cosmetics Regulation.

Fragrance Allergen	CAS No.	Representative Content in Raw Material (%)	Declaration Status
Alpha-Isomethyl Ionone	127-51-5	Not expected	Not Present
Amyl Cinnamal	122-40-7	Not expected	Not Present
Amylcinnamyl Alcohol	101-85-9	Not expected	Not Present
Anise Alcohol	105-13-5	Not expected	Not Present
Benzyl Alcohol	100-51-6	Trace-0.50	May Be Present
Benzyl Benzoate	120-51-4	Trace-0.10	May Be Present
Benzyl Cinnamate	103-41-3	Not expected	Not Present
Benzyl Salicylate	118-58-1	Trace	May Be Present
Cinnamal	104-55-2	Not expected	Not Present
Cinnamyl Alcohol	104-54-1	Not expected	Not Present
Citral	5392-40-5	Trace-0.20	May Be Present
Citronellol	106-22-9	20.00-40.00	Present
Coumarin	91-64-5	Not expected	Not Present
Eugenol	97-53-0	0.20-2.00	Present
Evernia Furfuracea Extract	90028-67-4	Not expected	Not Present
Evernia Prunastri Extract	90028-68-5	Not expected	Not Present
Farnesol	4602-84-0	Trace-2.00	Present
Geraniol	106-24-1	10.00-25.00	Present
Hexyl Cinnamal	101-86-0	Not expected	Not Present

Hydroxycitronellal	107-75-5	Not expected	Not Present
Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde	31906-04-4	Not expected	Not Present
Isoeugenol	97-54-1	Trace–0.20	May Be Present
Limonene	5989-27-5	Trace–1.00	Present / May Be Present
Linalool	78-70-6	Trace–2.00	Present
Methyl 2-Octynoate	111-12-6	Not expected	Not Present

Principal Declarable Allergens

Based on representative composition, the principal allergens expected in Rose Centifolia Oil – Bulgaria are:

Allergen	Representative Result (%)	Equivalent mg/kg	Status
Citronellol	32.40	324,000	Present
Geraniol	18.60	186,000	Present
Eugenol	1.10	11,000	Present
Farnesol	0.90	9,000	Present
Linalool	0.70	7,000	Present
Benzyl Alcohol	0.25	2,500	Present
Limonene	0.12	1,200	Present
Citral	0.08	800	Present
Isoeugenol	0.05	500	May Be Present
Benzyl Benzoate	0.04	400	May Be Present
Benzyl Salicylate	0.01	100	May Be Present

The values above are representative of a typical natural rose-oil profile and are not batch-specific laboratory results.

Additional Allergens Introduced by Regulation (EU) 2023/1545

Commission Regulation (EU) 2023/1545 expanded the number of fragrance substances and botanical derivatives that may require individual declaration in cosmetic products.

The following expanded-list substances may be naturally present in distilled rose oil.

Additional Fragrance Allergen or Group	CAS No.	Representative Status
Beta-Caryophyllene	87-44-5	May Be Present

Geranyl Acetate	105-87-3	Present / May Be Present
Neryl Acetate	141-12-8	May Be Present
Alpha-Pinene	80-56-8	May Be Present
Beta-Pinene	127-91-3	May Be Present
Terpineol	8000-41-7	May Be Present
Alpha-Terpinene	99-86-5	Trace / May Be Present
Gamma-Terpinene	99-85-4	Trace / May Be Present
Terpinolene	586-62-9	Trace / May Be Present
Linalyl Acetate	115-95-7	Trace / May Be Present
Methyl Salicylate	119-36-8	Trace / May Be Present
Benzaldehyde	100-52-7	Trace / May Be Present
Camphor	76-22-2	Not Expected or Trace
Menthol	1490-04-6	Not Expected
Carvone	99-49-0	Not Expected or Trace
Vanillin	121-33-5	Not Expected or Trace
Cananga Odorata Oil / Extract	Various	Not Present
Cinnamomum Cassia Leaf Oil	8007-80-5	Not Present
Citrus Aurantium Peel Oil	Various	Not Present
Eucalyptus Globulus Leaf Oil	8000-48-4	Not Present
Jasmine Oil / Extract	Various	Not Present
Lavender Oil / Extract	Various	Not Present
Rose Flower Oil / Extract Group	Various	Present as the Product Identity

The exact legal naming of expanded allergens in the finished ingredient list must follow the applicable Annex III entry and current INCI terminology.

Representative Expanded-Allergen Profile

Constituent	Representative Concentration (%)	Status
Geranyl Acetate	0.60	Present
Beta-Caryophyllene	0.15	May Be Present
Neryl Acetate	0.12	May Be Present
Alpha-Pinene	0.08	May Be Present
Beta-Pinene	0.05	May Be Present
Terpineol	0.04	May Be Present
Benzaldehyde	0.02	May Be Present
Methyl Salicylate	0.01	May Be Present
Other Expanded Allergens Below analytical reporting limit or not expected Review Batch Data		

Finished Product Allergen Calculation

The concentration of an allergen in a finished product is calculated using the following formula:

Finished Product Allergen Concentration (%) = Raw Material Use Level (%) × Allergen Content in Raw Material (%) ÷ 100

Calculation Example 1 – Citronellol

Rose Centifolia Oil used in a finished perfume at:

1.00%

Representative citronellol content in the oil:

32.40%

Calculation:

$1.00 \times 32.40 \div 100 = 0.324\%$ citronellol in the finished product

Conclusion

The finished concentration of 0.324% exceeds:

- The leave-on threshold of 0.001%
- The rinse-off threshold of 0.010%

Therefore, Citronellol must be declared on the finished cosmetic product ingredient list.

Calculation Example 2 – Eugenol

Rose Centifolia Oil used at:

0.50%

Representative eugenol content:

1.10%

Calculation:

$0.50 \times 1.10 \div 100 = 0.0055\%$ eugenol

Conclusion

- In a leave-on cosmetic, Eugenol must be declared, because 0.0055% exceeds 0.001%.
- In a rinse-off cosmetic, declaration would not be triggered by this ingredient alone because 0.0055% is below 0.010%.

The contribution from all other ingredients must still be added before the final decision is made.

Maximum Raw Material Use Before Allergen Declaration

The following values illustrate the approximate concentration of Rose Centifolia Oil that may be used before the specified allergen reaches an EU declaration threshold.

Allergen	Representative Content in Oil (%)	Approximate Maximum Oil Level in Leave-on Product Before 0.001% Threshold	Approximate Maximum Oil Level in Rinse-off Product Before 0.010% Threshold
Citronellol	32.40	0.0031%	0.0309%
Geraniol	18.60	0.0054%	0.0538%
Eugenol	1.10	0.0909%	0.9091%
Farnesol	0.90	0.1111%	1.1111%
Linalool	0.70	0.1429%	1.4286%
Benzyl Alcohol	0.25	0.4000%	4.0000%
Limonene	0.12	0.8333%	8.3333%
Citral	0.08	1.2500%	12.5000%

These calculations are illustrative and must not replace calculations based on the actual batch allergen certificate.

Declaration Summary

Requirement	Status
Natural Botanical Essential Oil	Yes
Contains EU-Declarable Fragrance Allergens	Yes
Citronellol	Present
Geraniol	Present
Eugenol	Present
Farnesol	Present
Linalool	Present
Limonene	Present / May Be Present

Citral	Present / May Be Present
Benzyl Alcohol	Present / May Be Present
Benzyl Benzoate	May Be Present
Benzyl Salicylate	May Be Present
Isoeugenol	May Be Present
Expanded Regulation Allergens	Present or Potentially Present
Batch-Specific GC-MS Review	Required
Finished Product Allergen Calculation	Required

Substances Not Intentionally Added

Based on the stated natural production method, the following fragrance allergens are not intentionally added:

- Alpha-Isomethyl Ionone
- Amyl Cinnamal
- Amylcinnamyl Alcohol
- Cinnamal
- Cinnamyl Alcohol
- Coumarin
- Hexyl Cinnamal
- Hydroxycitronellal
- Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde
- Methyl 2-Octynoate
- Oakmoss Extract
- Treemoss Extract
- Synthetic fragrance allergens
- Synthetic rose bases

The absence of intentional addition does not exclude trace natural presence, cross-contamination or analytical detection below the applicable reporting limit.

Natural Variation Statement

Rose Centifolia Oil is a natural botanical product. Its composition may vary according to:

- Botanical species
- Cultivar
- Geographical region
- Soil and climatic conditions
- Harvest period
- Flower maturity
- Time between harvesting and distillation

- Distillation temperature and duration
- Fractionation practices
- Storage conditions
- Oxidation history

Consequently, fragrance-allergen levels may differ from one production batch to another.

Botanical Identity Notice

Commercial Bulgarian rose oil is predominantly produced from *Rosa damascena* Mill., whereas the product identity supplied for this declaration is *Rosa centifolia* L.

Before this declaration is formally issued, the following should be verified against the original producer's documentation:

- Botanical species
- INCI name
- CAS number
- Country of cultivation
- Extraction method
- GC-MS composition
- Allergen profile
- IFRA certificate
- Certificate of Analysis

Where the actual botanical species is confirmed as *Rosa damascena*, the product name and INCI identity should be corrected throughout the regulatory documentation.

Certification Statement

Based on representative compositional information for natural distilled rose oil, Rose Centifolia Oil – Bulgaria contains naturally occurring fragrance allergens that may require individual declaration under Regulation (EC) No. 1223/2009, as amended by Commission Regulation (EU) 2023/1545.

The principal declarable allergens are expected to include:

- Citronellol
- Geraniol
- Eugenol
- Farnesol
- Linalool
- Limonene
- Citral



- Benzyl Alcohol

Additional allergens included under the expanded EU requirements may also be present in trace or measurable quantities.

Final labelling must be based on:

- Actual batch-specific allergen data
- The raw material concentration in the finished product
- Contributions from all other formulation ingredients
- Applicable EU transition dates
- The current version of Annex III
- The finished-product safety assessment

Disclaimer

This EU Fragrance Allergen Declaration is a professional representative template prepared using typical compositional information for natural distilled rose oil.

The quantitative concentrations stated in this declaration are not evidence of laboratory testing of a specific batch. They must be replaced or verified using:

- The original producer's allergen declaration
- Batch-specific GC-MS analysis
- Quantitative allergen analysis
- The applicable analytical reporting limits

This declaration applies only to the raw material identified herein. It does not certify the regulatory compliance of any finished perfume, cosmetic, personal-care or household product.

The finished-product manufacturer, importer, distributor or EU Responsible Person remains responsible for:

- Confirming the identity and composition of the supplied raw material
- Calculating cumulative allergen concentrations from all ingredients
- Applying the correct INCI declaration
- Preparing the Cosmetic Product Safety Report
- Maintaining the Product Information File
- Ensuring compliance with Regulation (EC) No. 1223/2009
- Ensuring compliance with Commission Regulation (EU) 2023/1545
- Confirming compliance with any subsequent amendments
- Ensuring that the final product label is accurate and legally compliant.

Authorised by

Fozia Khot

Director

Aromology Trading LLC