

EU ALLERGEN DECLARATION CERTIFICATE

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

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NATURAL GAMMA OCTALACTONE

1. PRODUCT IDENTIFICATION

Parameter	Details
Product Name	Natural Gamma Octalactone
Chemical Name	Gamma-Octalactone
Alternative Names	γ -Octalactone; 4-Octanolide
INCI Name	Octalactone
CAS Number	104-50-7
EC Number	203-208-1
FEMA Number	2796

2. 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; and
- Commission Regulation (EU) 2023/1545 concerning the labelling of fragrance allergens in cosmetic products.

3. EU FRAGRANCE ALLERGEN STATUS

Gamma-Octalactone, CAS 104-50-7, is not individually listed as a declarable fragrance allergen under the current expanded EU Annex III fragrance-allergen requirements.

Substance	CAS Number	EU Annex III Allergen Status
Gamma-Octalactone	104-50-7	Not individually listed

4. DECLARATION OF LISTED ALLERGENS

Based on the identity and representative purity of the supplied material:

Declaration	Status
Gamma-Octalactone is an individually listed EU fragrance allergen	No
EU-listed fragrance allergens intentionally added	None
Perfume mixture added to the material	None
Essential oil or botanical extract added	None
Carrier or diluent added	None

5. REPRESENTATIVE ALLERGEN STATEMENT

The material is expected to contain:

EU-Listed Fragrance Allergen	Representative Concentration
Listed allergens intentionally added	Not present
Listed allergens expected from the principal substance	Not applicable

“Not present” means not intentionally added and not expected from the declared chemical identity. It does not constitute a guarantee of absolute analytical absence at every possible trace-detection limit.

6. COSMETIC LABELLING THRESHOLDS

For substances that are included in the EU Annex III fragrance-allergen list, individual labelling is generally required where the concentration in the finished cosmetic product exceeds:

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

These thresholds do not create a requirement to label gamma-octalactone by name because gamma-octalactone is not itself an individually listed Annex III fragrance allergen.

7. CUSTOMER RESPONSIBILITY

The manufacturer or responsible person for the finished cosmetic product must:

1. calculate allergens contributed by every raw material in the formulation;



2. consider analytical impurities and natural-complex substances where applicable;
3. apply the correct Annex III labelling names;
4. assess the total concentration in the finished product;
5. complete the Cosmetic Product Safety Report;
6. maintain an appropriate Product Information File; and
7. verify compliance with the laws applicable on the date the finished product is placed on the market.

8. CONCLUSION

Based on the declared identity and representative composition:

- Natural Gamma Octalactone (Fatty Coconut) is not individually listed as an EU declarable fragrance allergen.
- No EU-listed fragrance allergens are intentionally added to the material.
- The material does not require allergen declaration solely because it contains gamma-octalactone.
- Any listed allergens introduced by other ingredients in the finished formulation must still be calculated and declared where required.

9. DISCLAIMER

This declaration is based on the known chemical identity and representative commercial specification of the material. Batch-specific analytical testing should be used where confirmation at defined trace limits is required.

AUTHORISED BY

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Director

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