



EU ALLERGEN DECLARATION CERTIFICATE

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

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Ambrettolide – IFF

Product Identification

Parameter	Details
Product Name	Ambrettolide – IFF
Product Description	Clean Musk
Chemical Name	Oxacycloheptadec-10-en-2-one
Alternative Name	Isoambrettolide
CAS Number	28645-51-4 / 63286-42-0
EC Number	249-120-7
IFF IPC Number	14200
Manufacturer	International Flavors & Fragrances Inc. – IFF
Product Type	Macrocyclic musk aroma ingredient

Finished-Product Labelling Thresholds

Fragrance allergens subject to individual labelling must be declared when their total finished-product concentration exceeds:

Cosmetic Product Type	Declaration Threshold
Leave-on cosmetic product	0.001% / 10 mg/kg
Rinse-off cosmetic product	0.010% / 100 mg/kg

The threshold applies to the total concentration from all raw materials in the complete cosmetic product.

Ambrettolide Allergen Status

Based on its identified chemical identity:

Oxacycloheptadec-10-en-2-one is not identified in this representative assessment as an individually declarable fragrance allergen under the traditional EU fragrance-allergen list.

It is also not assigned an expanded allergen label name in this template.

This conclusion must be verified against:

- Current IFF allergen documentation
- Current consolidated Annex III
- Actual batch composition
- Any residual solvents, stabilisers or impurities

Traditional EU Fragrance Allergen Declaration

Fragrance Allergen	CAS No.	Representative Status
Alpha-Isomethyl Ionone	127-51-5	Not intentionally added
Amyl Cinnamal	122-40-7	Not intentionally added
Amylcinnamyl Alcohol	101-85-9	Not intentionally added
Anise Alcohol	105-13-5	Not intentionally added
Benzyl Alcohol	100-51-6	Not intentionally added
Benzyl Benzoate	120-51-4	Not intentionally added
Benzyl Cinnamate	103-41-3	Not intentionally added
Benzyl Salicylate	118-58-1	Not intentionally added
Cinnamal	104-55-2	Not intentionally added
Cinnamyl Alcohol	104-54-1	Not intentionally added
Citral	5392-40-5	Not intentionally added
Citronellol	106-22-9	Not intentionally added
Coumarin	91-64-5	Not intentionally added
Eugenol	97-53-0	Not intentionally added
Farnesol	4602-84-0	Not intentionally added
Geraniol	106-24-1	Not intentionally added
Hexyl Cinnamal	101-86-0	Not intentionally added
Hydroxycitronellal	107-75-5	Not intentionally added
Isoeugenol	97-54-1	Not intentionally added
Limonene	5989-27-5	Not intentionally added
Linalool	78-70-6	Not intentionally added
Methyl 2-Octynoate	111-12-6	Not intentionally added
Evernia Prunastri Extract	90028-68-5	Not intentionally added
Evernia Furfuracea Extract	90028-67-4	Not intentionally added

“Not intentionally added” does not mean analytically absent.

Expanded EU Fragrance Allergen Review

Substance or Group	Representative Status
Alpha-Pinene	Not intentionally added
Beta-Pinene	Not intentionally added
Beta-Caryophyllene	Not intentionally added
Geranyl Acetate	Not intentionally added
Linalyl Acetate	Not intentionally added
Terpineol	Not intentionally added
Methyl Salicylate	Not intentionally added
Benzaldehyde	Not intentionally added
Menthol	Not intentionally added
Camphor	Not intentionally added
Eucalyptol	Not intentionally added
Vanillin	Not intentionally added
Citrus-Derived Allergen Groups	Not intentionally added
Botanical Extract Allergen Groups	Not intentionally added
Ambrettolide	Not assigned an individual allergen declaration in this representative assessment

The complete expanded list and applicable grouped names must be verified against the current consolidated regulation.

Representative Quantitative Declaration

Parameter	Representative Result
Ambrettolide	Approximately 97 – 100%
Individually Declarable EU Fragrance Allergens	Not intentionally added
Total Traditional Allergens	Not established without batch analysis
Expanded Allergens	Not established without manufacturer declaration
Residual Allergenic Solvents or Stabilisers	Not expected unless declared

No numerical zero values are certified without appropriate analytical or manufacturer documentation.

Impurity and Additive Assessment

The following must be reviewed before issuing a final quantitative allergen declaration:

- Residual manufacturing solvents
- Related macrocyclic lactones

- Geometric or structural isomers
- Antioxidants
- Stabilisers
- Processing aids
- Reprocessed material
- Cross-contamination during manufacture or repacking

Any declarable allergen identified in the actual commercial product must be quantified.

Representative Declaration

Subject to confirmation from the current IFF allergen statement:

Ambrettolide itself is not expected to require individual declaration as an EU fragrance allergen.

However:

- Batch composition must be verified.
- Added stabilisers or solvents must be reviewed.
- “Not intentionally added” does not mean analytically absent.
- The complete cosmetic formula must be assessed cumulatively.
- Final labelling remains the responsibility of the cosmetic manufacturer or EU Responsible Person.

Regulatory Summary

Requirement	Status
Ambrettolide Individually Declarable	Not expected
Traditional Fragrance Allergens Intentionally Added	None expected
Expanded Fragrance Allergens Intentionally Added	None expected
Manufacturer Allergen Statement Required	Yes
Batch-Specific Analysis Required	Where quantitative certification is requested
Finished-Product Calculation Required	Yes
Cumulative Formula Assessment Required	Yes
“Allergen-Free” Claim Supported	No
Final Label Decision	Manufacturer/EU Responsible Person

Disclaimer

This EU Fragrance Allergen Declaration is a representative professional template.

It is not:



- A finished-cosmetic ingredient-list decision
- A Cosmetic Product Safety Report

Before formal issue, verify this declaration against:

- Current IFF quantitative allergen statement
- Current IFF technical specification
- Batch-specific Certificate of Analysis
- Current consolidated Regulation (EC) No. 1223/2009
- Regulation (EU) 2023/1545
- Applicable Annex III entries
- Complete finished-product formula
- Actual dosage in the finished cosmetic

The cosmetic manufacturer or EU Responsible Person remains responsible for final allergen calculations, ingredient-list labelling and finished-product regulatory compliance.

Authorised By:

Fozia Khot
Director