



EU ALLERGEN DECLARATION CERTIFICATE

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

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Vertofix® Coeur – IFF

Product Identification

Parameter	Details
Product Name	Vertofix® Coeur
Manufacturer	International Flavors & Fragrances Inc. – IFF
IFF IPC Number	220700
Chemical Name	1-Cedr-8-en-9-ylethanone
Common Chemical Name	Methyl Cedryl Ketone
EU Allergen / INCI Name	Acetyl Cedrene
CAS Number	32388-55-9
EC Number	251-020-3
Molecular Formula	C ₁₇ H ₂₆ O
Molecular Weight	Approximately 246.4 g/mol
Product Type	Natural-derived aroma chemical
Regulatory Basis	Regulation (EC) No. 1223/2009
Expanded Allergen Regulation	Regulation (EU) 2023/1545

Regulatory Allergen Status

Vertofix® Coeur consists principally of:

Acetyl Cedrene

Acetyl Cedrene is included among the fragrance allergens requiring individual declaration under Annex III of Regulation (EC) No. 1223/2009, as amended by Regulation (EU) 2023/1545.

Regulatory Parameter	Details
EU Allergen Name	Acetyl Cedrene
CAS Number	32388-55-9



EC Number	251-020-3
Individually Declarable	Yes
Leave-on Threshold	0.001%
Rinse-off Threshold	0.010%

Quantitative Allergen Declaration

EU Fragrance Allergen	CAS Number	Representative Content in Raw Material
Acetyl Cedrene	32388-55-9	100.00%

For conservative EU cosmetic-allergen calculations, Vertofix® Coeur should be treated as:

100% Acetyl Cedrene

unless the current original IFF quantitative allergen statement provides a different batch-specific value.

Traditional EU Fragrance Allergens

Based on the known principal chemical identity, the following traditional fragrance allergens are not intentionally expected as separate constituents:

Traditional Fragrance Allergen Representative Status

Alpha-Isomethyl Ionone	Not intentionally added
Amyl Cinnamal	Not intentionally added
Anise Alcohol	Not intentionally added
Benzyl Alcohol	Not intentionally added
Benzyl Benzoate	Not intentionally added
Benzyl Cinnamate	Not intentionally added
Benzyl Salicylate	Not intentionally added
Cinnamal	Not intentionally added
Cinnamyl Alcohol	Not intentionally added
Citral	Not intentionally added
Citronellol	Not intentionally added
Coumarin	Not intentionally added
Eugenol	Not intentionally added
Farnesol	Not intentionally added
Geraniol	Not intentionally added
Hexyl Cinnamal	Not intentionally added
Hydroxycitronellal	Not intentionally added
Isoeugenol	Not intentionally added
Limonene	Not intentionally added



Linalool	Not intentionally added
Methyl 2-Octynoate	Not intentionally added
Evernia Prunastri Extract	Not intentionally added
Evernia Furfuracea Extract	Not intentionally added

“Not intentionally added” does not establish absolute analytical absence.

Finished-Product Labelling Thresholds

Acetyl Cedrene must be individually declared in the finished cosmetic ingredient list when its cumulative concentration exceeds:

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

The thresholds apply to the complete finished cosmetic product.

Maximum Fragrance-Concentrate Level Before Declaration

The maximum amount of Vertofix® Coeur in the fragrance concentrate before reaching the declaration threshold depends on the fragrance dosage.

Formula

Maximum Vertofix® Coeur in fragrance (%) =

Declaration threshold (%) × 100 ÷ fragrance dosage (%)

Leave-On Examples

Fragrance Dosage in Finished Product Approximate Vertofix® Coeur Level Reaching 0.001%

0.50%	0.20% of fragrance
1.00%	0.10% of fragrance
5.00%	0.02% of fragrance
10.00%	0.01% of fragrance
20.00%	0.005% of fragrance

Rinse-Off Examples

Fragrance Dosage in Finished Product Approximate Vertofix® Coeur Level Reaching 0.010%

0.50%	2.00% of fragrance
1.00%	1.00% of fragrance
2.00%	0.50% of fragrance



5.00%	0.20% of fragrance
10.00%	0.10% of fragrance

Cumulative Allergen Assessment

The cosmetic manufacturer must calculate Acetyl Cedrene from all sources, including:

- Vertofix® Coeur
- Methyl Cedryl Ketone
- Acetyl Cedrene supplied under other trade names
- Cedryl-derived fragrance bases
- Cedarwood-inspired fragrance compounds
- Woody and amber bases
- Proprietary perfume compounds
- Other aroma chemicals containing Acetyl Cedrene
- Natural-derived materials containing measurable Acetyl Cedrene

All contributions must be added cumulatively before determining the ingredient-list declaration.

Trade-Name and INCI Distinction

The commercial trade name:

Vertofix® Coeur

is not the name normally used for EU allergen labelling.

The declarable allergen name is:

ACETYL CEDRENE

The finished cosmetic ingredient list should use the applicable Annex III ingredient name, subject to confirmation by the EU Responsible Person.

Skin Sensitisation and EU Allergen Labelling

Vertofix® Coeur may also be classified as a skin sensitizer under its Safety Data Sheet.

The following assessments must remain separate:

1. GHS/CLP hazard classification
2. IFRA conformity
3. EU Annex III allergen labelling
4. Cosmetic Product Safety Report
5. Finished-product consumer exposure assessment

EU allergen declaration does not replace the requirement to conduct a complete cosmetic safety assessment.

Regulation Implementation

Regulation (EU) 2023/1545 introduced transitional periods for products placed and made available on the EU market.

The EU Responsible Person must confirm:

- Applicable product-placement date
 - Applicable sell-through provisions
 - Current consolidated Annex III
 - Whether label modification is required
 - Final ingredient-list terminology
 - Contributions from the complete fragrance formula
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Declaration Summary

Requirement	Status
Acetyl Cedrene present	Yes
CAS Number	32388-55-9
Representative raw-material concentration	100.00%
Individually declarable under EU 2023/1545	Yes
Leave-on threshold	0.001%
Rinse-off threshold	0.010%
Allergen-free claim supported	No
Finished-product calculation required	Yes
Cumulative formula calculation required	Yes
Final label decision	Cosmetic manufacturer / EU Responsible Person

Formal Declaration

Based on the identified composition:

Vertofix® Coeur – IFF contains Acetyl Cedrene, CAS 32388-55-9, as its principal fragrance substance.

For conservative regulatory calculation, the product should be treated as:

100% Acetyl Cedrene

Acetyl Cedrene must be individually declared in the finished cosmetic ingredient list when its cumulative concentration exceeds:

- 0.001% in leave-on cosmetic products
- 0.010% in rinse-off cosmetic products

Disclaimer

This EU Fragrance Allergen Declaration is a representative supplier-style document.

It is not:

- The original IFF quantitative allergen certificate
- A batch-specific laboratory-analysis report
- A finished-cosmetic ingredient-list approval
- A Cosmetic Product Safety Report
- A substitute for regulatory assessment by the EU Responsible Person

Before formal commercial or regulatory issue, verify this document against:

- Current original IFF quantitative allergen declaration
- Exact IFF product code and grade
- Original batch Certificate of Analysis
- Current IFF Safety Data Sheet
- Regulation (EC) No. 1223/2009
- Regulation (EU) 2023/1545
- Current consolidated Annex III
- Complete fragrance composition
- Complete finished-product formula

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

Authorised by:

Fozia Khot
Director