



EU ALLERGEN DECLARATION CERTIFICATE

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

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Heliotropex N®

Product Identification

Parameter	Details
Product Name	Heliotropex N®
Manufacturer	International Flavors & Fragrances Inc. (IFF)
Product Code	23109 / 30774581
Product Type	Proprietary Fragrance Mixture
Regulatory Basis	Regulation (EC) No. 1223/2009
EU Fragrance Allergens	Regulation (EU) 2023/1545
Document Version	1.0

EU Fragrance Allergen Declaration

Based on the available manufacturer safety documentation, Heliotropex N® contains the following fragrance allergens regulated under the EU Cosmetics Regulation.

EU Fragrance Allergen	CAS Number	Approximate Content (% w/w)
Anethole	104-46-1	0.050%
Anise Alcohol (Anisyl Alcohol)	105-13-5	0.005%
Cinnamyl Alcohol	104-54-1	0.100%
Coumarin	91-64-5	0.010%
Isoeugenol	97-54-1	0.010%
Vanillin	121-33-5	0.015%

These constituents are disclosed in the available safety documentation for Heliotropex N®.

Additional Sensitising Ingredients

The SDS also identifies the following sensitising ingredients that contribute to the product's CLP classification but are not necessarily individually declarable as cosmetic fragrance allergens:

Ingredient	CAS Number
Piperonal	120-57-0
Veratraldehyde	120-14-9
Methyl Isoeugenol	93-15-2
α -Methyl-1,3-benzodioxole-5-propanal (Helional)	1205-17-0

These ingredients are responsible for the product classification H317 – May cause an allergic skin reaction.

Cosmetic Labelling Thresholds

Under Regulation (EU) 2023/1545, fragrance allergens must be declared on the finished cosmetic product when the cumulative concentration exceeds:

Product Type	Declaration Threshold
Leave-on products	0.001% (10 ppm)
Rinse-off products	0.010% (100 ppm)

The final labelling obligation depends on the cumulative contribution from all fragrance ingredients present in the finished formulation.

Cumulative Assessment

The Responsible Person must calculate the total contribution of each allergen from:

- Heliotropex N®
- Essential oils
- Absolutes
- Aroma chemicals
- Fragrance bases
- Botanical extracts
- Other fragrance ingredients

All contributions of the same allergen must be added together before determining cosmetic labelling.

Declaration Summary

Requirement	Status
EU Fragrance Allergens Present	Yes



Skin Sensitiser (CLP)	Yes (H317)
Finished Product Calculation Required	Yes
Cumulative Formula Assessment Required	Yes
Batch-specific Verification Required	Yes

Declaration

Based on the available manufacturer information, Heliotropex N® – IFF contains declarable EU fragrance allergens including Anethole, Anise Alcohol, Cinnamyl Alcohol, Coumarin, Isoeugenol and Vanillin. These substances may require declaration on the finished cosmetic ingredient list when their cumulative concentration exceeds the applicable thresholds established under Regulation (EU) 2023/1545.

Disclaimer

This EU Fragrance Allergen Declaration is a representative supplier-style document prepared from publicly available manufacturer information. It is not the original IFF quantitative allergen declaration and should not replace the batch-specific documentation issued by International Flavors & Fragrances (IFF). Before regulatory submission or commercial distribution, verify all allergen concentrations against the latest original IFF EU Allergen Declaration and the complete finished fragrance formulation.

Authorised by:

Fozia Khot
Director