



EU ALLERGEN DECLARATION CERTIFICATE

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

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Heliotropine Diethyl Acetal

Product Identification

Item	Details
Product Name	Heliotropine Diethyl Acetal
Alternative Name	Heliotropyl Diethyl Acetal
Synonym	Piperonyl Diethyl Acetal
Chemical Name	5-(Diethoxymethyl)-1,3-benzodioxole
CAS Number	40527-42-2
EC / EINECS Number	254-956-0
Molecular Formula	C ₁₂ H ₁₆ O ₄
Molecular Weight	224.25 g/mol
Product Type	Synthetic Aroma Chemical

EU Fragrance Allergen Status

Based on the chemical identity of Heliotropine Diethyl Acetal, CAS 40527-42-2, the substance itself is not identified as an individually declarable fragrance allergen under the fragrance-allergen labelling provisions of Annex III of Regulation (EC) No. 1223/2009, including the expanded allergen requirements introduced by Regulation (EU) 2023/1545.

Accordingly:

Heliotropine Diethyl Acetal itself is not an EU declarable fragrance allergen.

This assessment applies to the identified high-purity synthetic aroma chemical and does not automatically certify the absence of trace allergens in every commercial batch.

Representative Allergen Assessment

EU Declarable Fragrance Allergen	Expected Status
Alpha-Isomethyl Ionone	Not expected
Amyl Cinnamal	Not expected
Amyl Salicylate	Not expected
Amylcinnamyl Alcohol	Not expected
Anethole	Not expected
Anise Alcohol	Not expected
Benzaldehyde	Not expected
Benzyl Alcohol	Not expected
Benzyl Benzoate	Not expected
Benzyl Cinnamate	Not expected
Benzyl Salicylate	Not expected
Camphor	Not expected
Cinnamal	Not expected
Cinnamyl Alcohol	Not expected
Citral	Not expected
Citronellol	Not expected
Coumarin	Not expected
Eugenol	Not expected
Farnesol	Not expected
Geraniol	Not expected
Hexyl Cinnamal	Not expected
Hydroxycitronellal	Not expected
Isoeugenol	Not expected
Limonene	Not expected
Linalool	Not expected
Menthol	Not expected
Methyl 2-Octynoate	Not expected
Evernia prunastri Extract	Not expected
Evernia furfuracea Extract	Not expected

Expanded EU Allergen Requirements

Commission Regulation (EU) 2023/1545 expanded the list of fragrance allergens requiring individual labelling in cosmetic products.

Based on the identity of the raw material:



Heliotropine Diethyl Acetal – CAS 40527-42-2

is not itself identified as one of these individually labelled fragrance allergens.

However, a batch-specific manufacturer allergen statement should be used to determine whether any regulated fragrance allergens occur as:

- Manufacturing impurities
- Residual starting materials
- Stabilising components
- Added solvents
- Added antioxidants
- Other intentionally or unintentionally present constituents

Raw Material Declaration

Parameter	Declaration
Heliotropine Diethyl Acetal	Principal Component
CAS 40527-42-2	Confirmed
Typical Assay	>95% GC
Synthetic Aroma Chemical	Yes
Natural Essential Oil	No
Botanical Extract	No
EU Declarable Allergen Itself	No
Intentionally Added EU Fragrance Allergens	None declared
Quantitative Batch Allergen Analysis	Manufacturer declaration required

Important Regulatory Qualification

The terms “Not Expected” and “None Declared” should not be interpreted as analytical confirmation of 0.0000%.

For formal regulatory documentation, the current manufacturer declaration should be consulted for:

- Exact quantitative allergen concentrations
 - Analytical detection limits
 - Trace impurities
 - Stabiliser information
 - Manufacturing changes
 - Batch-specific composition
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Finished Cosmetic Declaration Thresholds

Where an individually declarable fragrance allergen is present from this or any other raw material, it must be declared in the finished cosmetic ingredient list when its concentration exceeds the applicable threshold:

Product Type	Declaration Threshold
Leave-on cosmetic products	0.001%
Rinse-off cosmetic products	0.01%

The cumulative contribution of each allergen from **all fragrance ingredients** must be considered.

Finished Product Assessment

When Heliotropine Diethyl Acetal is incorporated into a perfume or cosmetic fragrance, the responsible manufacturer must evaluate:

- Complete fragrance composition
 - Essential oils
 - Absolutes
 - Natural extracts
 - Aroma chemicals
 - Bases and accords
 - Solvents
 - Carriers
 - Antioxidants
 - Preservatives
 - Trace impurities
 - Cumulative allergen contribution
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Declaration

Based on the available chemical and regulatory information:

- Heliotropine Diethyl Acetal is 5-(Diethoxymethyl)-1,3-benzodioxole.
- CAS Number: 40527-42-2.
- EC Number: 254-956-0.
- It is a synthetic aroma chemical.
- Heliotropine Diethyl Acetal itself is not identified as an individually declarable EU fragrance allergen.
- No intentionally added EU fragrance allergens are declared in this representative assessment.



- A blanket “allergen-free” claim is not made.
- The original manufacturer quantitative allergen declaration should take precedence for formal customer submissions.
- Finished cosmetic labelling must be calculated using the complete formulation.
- The cosmetic manufacturer or EU Responsible Person remains responsible for final compliance.

This declaration applies only to the identified raw material and does not certify a finished perfume or cosmetic product.

Authorised by

Fozia Khot

Director

Aromology Trading LLC