



EU ALLERGEN DECLARATION CERTIFICATE

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

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Levulinate Ethyl

Product Identification

Item	Details
Product Name	Ethyl Levulinate
Manufacturer	Synarome
Chemical Name	Ethyl 4-oxopentanoate
CAS Number	539-88-8
EC Number	208-728-2
FEMA Number	2442
Molecular Formula	C ₇ H ₁₂ O ₃
Molecular Weight	144.17 g/mol
Product Type	Synthetic Aroma Chemical
Chemical Family	Keto Ester
Odour Profile	Fruity, berry, grape, apple, sweet, green

2. EU Fragrance Allergen Status

Based on the chemical identity:

Ethyl Levulinate – CAS 539-88-8

Ethyl Levulinate itself is not identified as an individually declarable fragrance allergen under the EU cosmetic fragrance-allergen labelling provisions.

Accordingly:



ETHYL LEVULINATE ITSELF IS NOT AN EU DECLARABLE FRAGRANCE ALLERGEN

The material is a synthetic single aroma chemical and not an essential oil, absolute or other natural complex substance.

Representative EU 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

“Not expected” does not constitute analytical confirmation of absolute zero concentration.



Expanded EU Fragrance Allergens

Commission Regulation (EU) 2023/1545 expanded the number of fragrance allergens subject to individual cosmetic labelling.

Based on the identity of Ethyl Levulinate:

CAS 539-88-8

Ethyl Levulinate itself is not one of the individually declarable fragrance allergens introduced by the expanded EU requirements.

A commercial batch should nevertheless be assessed for any relevant:

- Process impurities
- Residual starting materials
- Added stabilisers
- Solvents
- Carriers
- Other intentionally added components

using the current manufacturer documentation.

Raw Material Allergen Declaration

Parameter	Declaration
Ethyl Levulinate	Principal Component
CAS 539-88-8	Confirmed
EC 208-728-2	Confirmed
Synthetic Aroma Chemical	Yes
Natural Essential Oil	No
Botanical Extract	No
EU Declarable Allergen Itself	No
Naturally Occurring Allergens Expected	No
Intentionally Added Fragrance Allergens	None declared in this representative assessment
Quantitative Batch Confirmation	Manufacturer documentation should take precedence

EU Allergen-Free Consideration



The chemical identity of Ethyl Levulinate does not correspond to a regulated EU fragrance allergen.

Independent fragrance/food-grade specifications also identify Ethyl Levulinate as having no known food allergens.

However, for regulatory precision, this declaration does not use “0.0000%” for every fragrance allergen unless supported by a batch-specific Synarome quantitative declaration.

Therefore the appropriate regulatory statement is:

No EU declarable fragrance allergens are expected from the chemical identity of Ethyl Levulinate.

Finished Cosmetic Declaration Thresholds

If any declarable fragrance allergen is contributed by another component of the complete fragrance, individual declaration is required when the concentration in the finished cosmetic exceeds:

Finished Cosmetic Product	Threshold
Leave-on Products	0.001%
Rinse-off Products	0.01%

Finished Product Assessment

The finished fragrance or cosmetic manufacturer must evaluate the complete formulation, including:

- Ethyl Levulinate
- Other synthetic aroma chemicals
- Essential oils
- Absolutes
- CO₂ extracts
- Fragrance bases
- Solvents and carriers
- Antioxidants
- Preservatives
- Manufacturing impurities

The concentration of each declarable fragrance allergen must be calculated cumulatively from all sources.



Declaration

Based on the available chemical and regulatory information:

- Ethyl Levulinate is Ethyl 4-oxopentanoate.
- CAS Number: 539-88-8.
- EC Number: 208-728-2.
- FEMA Number: 2442.
- Molecular Formula: $C_7H_{12}O_3$.
- Molecular Weight: 144.17 g/mol.
- It is a synthetic aroma chemical.
- Ethyl Levulinate itself is not identified as an individually declarable EU fragrance allergen.
- No naturally occurring fragrance allergens are expected from the chemical identity of this single synthetic material.
- A blanket analytical claim of “0.0000% for all allergens” is not made without the current Synarome quantitative declaration.
- Finished cosmetic labelling must be determined from the complete fragrance formulation.
- The cosmetic manufacturer or EU Responsible Person remains responsible for final regulatory compliance.

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

Authorised by:

Fozia Khot
Director