



EU ALLERGEN DECLARATION CERTIFICATE

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

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Galaxolide™ Undiluted

Product Identification

Parameter	Details
Product Name	Galaxolide™ Undiluted
Alternative Name	Galaxolide Pure
Manufacturer	International Flavors & Fragrances Inc. – IFF
IFF Product Code	00070290
IFF IPC Number	70290
INCI / Allergen Name	Hexamethylindanopyran
Common Abbreviation	HHCB
CAS Number	1222-05-5
EC Number	214-946-9
Regulatory Basis	Regulation (EC) No. 1223/2009
Expanded Allergen Regulation	Regulation (EU) 2023/1545

EU Regulatory Status

Regulation (EU) 2023/1545 added:
Hexamethylindanopyran
to the substances requiring individual declaration in cosmetic ingredient lists.

Regulatory Identification	Details
Annex III Name	Hexamethylindanopyran
CAS Number	1222-05-5
EC Number	214-946-9
Leave-on Declaration Threshold	0.001%
Rinse-off Declaration Threshold	0.010%

The official regulation identifies Hexamethylindanopyran, CAS 1222-05-5, as declarable above these thresholds.

Quantitative Allergen Declaration

Galaxolide Undiluted is principally Hexamethylindanopyran.

Fragrance Allergen	CAS Number	Representative Raw-Material Content
Hexamethylindanopyran	1222-05-5	Approximately 100% technical material

The exact assay is based on the technical stereoisomer and GC profile rather than a single-isomer purity figure.

For regulatory calculations, the raw material should conservatively be treated as:

100% Hexamethylindanopyran

unless the current quantitative IFF declaration provides a different certified value.

Traditional EU Fragrance Allergens

The principal Galaxolide substance is not one of the historical 24 fragrance allergens, but is now included under the expanded EU framework.

Other traditional fragrance allergens are not intentionally expected from the stated product identity.

Traditional Allergen Group	Representative Status
Limonene	Not intentionally added
Linalool	Not intentionally added
Citral	Not intentionally added
Geraniol	Not intentionally added
Citronellol	Not intentionally added
Eugenol	Not intentionally added
Isoeugenol	Not intentionally added
Coumarin	Not intentionally added
Benzyl Alcohol	Not intentionally added
Benzyl Benzoate	Not intentionally added
Hydroxycitronellal	Not intentionally added
Hexyl Cinnamal	Not intentionally added
Alpha-Isomethyl Ionone	Not intentionally added
Oakmoss / Treemoss Extracts	Not intentionally added

“Not intentionally added” does not establish analytical absence.

Finished-Product Calculation

Direct Addition

Where Galaxolide Undiluted is added directly:

Hexamethylindanopyran in finished product (%) = Galaxolide use level (%)

Examples:

Galaxolide Use Level	Hexamethylindanopyran in Finished Product	EU Labelling Result
0.0005%	0.0005%	Below both thresholds
0.001%	0.001%	At leave-on threshold
0.010%	0.010%	At rinse-off threshold
0.10%	0.10%	Declarable in leave-on and rinse-off
1.00%	1.00%	Declarable in leave-on and rinse-off

Approximate Trigger Levels

Since Galaxolide Undiluted is treated as approximately 100% Hexamethylindanopyran:

Product Type	Galaxolide Level Triggering Declaration
Leave-on product	Above 0.001%
Rinse-off product	Above 0.010%

At normal perfumery concentrations, individual declaration will generally be required in EU cosmetics.

Cumulative Assessment

The finished-product calculation must include Hexamethylindanopyran from:

- Galaxolide Undiluted
- Galaxolide 50% DPG
- Galaxolide 50% DEP
- Galaxolide 50% IPM
- Galaxolide 50% BB
- Fragrance compounds containing HHCB
- Musk bases
- Other raw materials containing Galaxolide

All contributions must be combined.

Diluted Galaxolide Grades

Where another Galaxolide grade is used, calculate according to its active concentration.

Commercial Grade	Representative HHCB Content
Galaxolide Undiluted	Approximately 100%
Galaxolide 50% DPG	Approximately 50%
Galaxolide 50% DEP	Approximately 50%
Galaxolide 50% IPM	Approximately 50%
Galaxolide 50% BB	Approximately 50%, plus carrier assessment

The carrier may introduce additional declarable allergens. For example, a benzyl-benzoate grade must also be assessed for Benzyl Benzoate.

Regulation Implementation

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

The Responsible Person must confirm:

- Applicable market-placement date
- Whether reformulation or relabelling is required
- Current consolidated Annex III text
- Final ingredient-list wording
- Transitional provisions applicable to the product

Declaration Summary

Requirement	Status
Hexamethylindanopyran present	Yes
Representative concentration	Approximately 100%
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 ingredient-list decision	Cosmetic manufacturer / EU Responsible Person

Declaration

Based on the identified composition:

Galaxolide™ Undiluted contains Hexamethylindanopyran, CAS 1222-05-5, as its principal fragrance substance.

It must be declared in the finished cosmetic ingredient list when its cumulative concentration exceeds:

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

For conservative calculation, Galaxolide Undiluted should be treated as 100% Hexamethylindanopyran unless the current IFF quantitative allergen statement specifies otherwise.

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
- A finished-product ingredient-list approval
- A Cosmetic Product Safety Report

Before formal issue, verify against:

- Current IFF quantitative allergen declaration
- Original IFF batch Certificate of Analysis
- Current commercial grade and active concentration
- Regulation (EC) No. 1223/2009
- Regulation (EU) 2023/1545
- Current consolidated Annex III
- Complete finished-product formula
- Contributions from all other raw materials

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

Authorised by:

Fozia Khot
Director