

EU ALLERGEN DECLARATION CERTIFICATE

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

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PRODUCT INFORMATION

Item	Details
Product Name	Lylal Schiff Base
Chemical Name	Methyl Anthranilate/Lylal Schiff Base
CAS Number	67634-12-2
EC Number	266-816-6
Molecular Formula	$C_{21}H_{29}NO_3$
Product Type	Synthetic Schiff Base Fragrance Material

The substance identity and molecular formula are recorded under PubChem CID 106740.

REGULATORY BASIS

This declaration is prepared with reference to:

- Regulation (EC) No. 1223/2009 on cosmetic products.
- Applicable amendments to Annex II and Annex III.
- Regulation (EU) 2023/1545 concerning fragrance-allergen labelling.
- The IFRA Standards, 51st Amendment.

IMPORTANT EU REGULATORY STATUS

Lylal Schiff Base is manufactured using HMPCC/Lylal.

A Schiff base may contain:

- Residual unreacted HMPCC.
- Chemically bound HMPCC-derived material.
- HMPCC that may be released through hydrolysis under certain conditions.

Conversion into a Schiff base must not be assumed to remove the regulatory relevance of the HMPCC precursor.

Therefore, this material should not be represented as suitable for EU cosmetic use without a manufacturer-issued legal assessment and quantitative analytical evidence.

EU FRAGRANCE ALLERGEN PROFILE

Substance	CAS Number	Representative Status
Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde — HMPCC/Lyral	31906-04-4	Residual or releasable content must be quantified
HMPCC-related isomer	51414-25-6	May be associated with the precursor
Methyl Anthranilate	134-20-3	Residual precursor may be present
Lyral Schiff Base	67634-12-2	Main reaction product
Other EU fragrance allergens	—	Not established from representative data

QUANTITATIVE ALLERGEN DECLARATION

Parameter	Declaration
Residual free HMPCC/Lyral	Not determined
HMPCC equivalent bound in Schiff base	Requires manufacturer calculation
Potential hydrolytically released HMPCC	Not determined
Residual Methyl Anthranilate	Batch dependent
Other regulated fragrance allergens	No authenticated quantitative data available
Suitable for EU cosmetic use	Not confirmed

No allergen percentages have been assigned because validated batch-specific analytical documentation was not supplied.

EU COSMETIC LABELLING THRESHOLDS

For fragrance allergens that are legally permitted and subject to declaration, the general finished-product thresholds are:

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

These labelling thresholds do not override a prohibition or other restriction. A prohibited substance cannot be made compliant merely by declaring it on the ingredient list.

DECLARATION

Based on the available information:

- Lyrall Schiff Base cannot be declared free from HMPCC.
- It cannot be declared free from EU-regulated fragrance allergens.
- It cannot be certified as suitable for EU cosmetics.
- A generic “allergens not detected” statement would be unsupported.
- Final regulatory status must be established from manufacturer-issued analytical and legal documentation.

REQUIRED MANUFACTURER DOCUMENTS

Before use in any cosmetic product, obtain:

1. Batch-specific Certificate of Analysis.
 2. Quantitative residual-HMPCC analysis.
 3. Schiff-base purity or assay.
 4. Hydrolysis or release assessment, where applicable.
 5. Current IFRA certificate.
 6. EU regulatory-compliance declaration.
 7. Quantitative EU allergen declaration.
 8. Confirmation of any carrier or solvent.
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CONCLUSION

Lyrall Schiff Base is not certified as EU cosmetic compliant by this declaration.

Residual and potentially releasable HMPCC must be quantitatively established. No EU allergen concentrations are declared without batch-specific manufacturer data.

The original manufacturer's regulatory and allergen documentation shall always take precedence.

Authorised by:

Fozia Khot
Director