

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	Manuka Oil
Botanical Name	<i>Leptospermum scoparium</i>
INCI Name	Leptospermum Scoparium Branch/Leaf Oil
CAS Number	23749-44-8
Country of Origin	New Zealand
Product Type	Natural Essential Oil / Natural Complex Substance

REGULATORY BASIS

This declaration has been prepared with reference to:

- Regulation (EC) No. 1223/2009 on cosmetic products.
- Annex III of Regulation (EC) No. 1223/2009.
- Regulation (EU) 2023/1545 concerning expanded fragrance-allergen labelling.

REPRESENTATIVE DECLARED ALLERGENS

A published commercial allergen declaration for Manuka Oil reported the following values:

EU Fragrance Allergen	CAS Number	Representative Concentration
Linalool	78-70-6	0.20%
Limonene	138-86-3 / 5989-27-5	0.05%

These values are derived from one commercial declaration and are representative only. They must not be treated as guaranteed concentrations for every New Zealand Manuka Oil batch.

OTHER ANNEX III FRAGRANCE ALLERGENS

Fragrance Allergen	Representative Status
Citral	Not quantified
Citronellol	Not quantified
Geraniol	Not quantified
Eugenol	Not quantified
Isoeugenol	Not quantified
Farnesol	Not quantified
Benzyl Alcohol	Not quantified
Benzyl Benzoate	Not quantified
Benzyl Salicylate	Not quantified
Coumarin	Not quantified
Cinnamal	Not quantified
Cinnamyl Alcohol	Not quantified
Additional allergens under Regulation (EU) 2023/1545	Batch-specific analysis required

A separate supplier allergen certificate exists for organic New Zealand Manuka Oil under the EU cosmetic framework, confirming that allergen assessment must be based on the individual commercial material.

EU COSMETIC LABELLING THRESHOLDS

Fragrance allergens must be declared in the finished cosmetic product ingredient list when their final concentration exceeds:

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

EXAMPLE CALCULATION

Where Manuka Oil containing 0.20% linalool is used at 1.00% in a finished product:

Linalool contribution:

$0.20\% \times 1.00\% = 0.002\%$ in the finished product

This would exceed the 0.001% leave-on threshold, but remain below the 0.01% rinse-off threshold, before considering linalool contributed by any other ingredients.

The complete formulation must always be assessed.

DECLARATION

Manuka Oil is a natural botanical material and its fragrance-allergen profile may vary by:

- Harvest location.
- Botanical chemotype.
- Season.
- Distillation conditions.
- Storage and oxidation.
- Individual production batch.

Final cosmetic labelling must therefore be established using:

- The manufacturer's batch-specific allergen declaration.
- Current GC-MS analytical data.
- The concentration used in the finished cosmetic product.
- Contributions from every other formulation ingredient.
- Current applicable EU legislation.

CONCLUSION

Based on representative commercial documentation, Manuka Oil may contain:

- Linalool
- Limonene

No statement of "allergens absent" or "allergens not detected" is made for constituents without batch-specific analytical evidence.

The original manufacturer's current quantitative EU Allergen Declaration shall always take precedence.

Authorised by:

Fozia Khot
Director