



## Testing and labelling allergenic fragrances

### Background

Regardless of whether they are of synthetic or natural origin, many fragrances used in cosmetics have allergenic properties. In some cases, they can cause serious adverse reactions in sensitised individuals. Annex III of the EC Regulation on cosmetic products (EC) No. 1223/2009 therefore defines substances that must be included in the list of ingredients if the concentration in the consumer product exceeds a certain level. Originally amounting to 26, the list of substances concerned was extended to include more than 80 substances in July 2023.

### Strategic assessment/need for action

According to Regulation (EC) No. 1223/2009, cosmetic products are required to undergo a safety assessment before being placed on the market. This includes an evaluation of all ingredients' allergenicity. Allergenic fragrances must be explicitly mentioned on the container and on the packaging of cosmetic products. Another 56 substances were added to the list of allergenic fragrances (Annex III) with Commission Regulation (EU) No. 2023/1545 of July 26, 2023, increasing the total to more than 80 substances. Without individual labelling, cosmetic products containing such substances in concentrations exceeding 0.001% in leave-on products (e.g. body lotions, creams, perfumes) or 0.01% in rinse-off products (e.g. shower gels, shampoos) may only be placed on the Union market until July 31, 2026, and made available on the Union market until July 31, 2028.

New additions to the list include numerous ingredients of natural essential oils, e.g., anethole, beta-caryophyllene, menthol, pinenes, or terpineol – often principal components of such essential oils – and many of the essential oils themselves, e.g., ylang-ylang, cinnamon oils, various citrus oils, or peppermint oils. Manufacturers/suppliers of the listed substances and essential oils or fragrance mixtures containing them and manufacturers of cosmetic products are therefore faced with the task of implementing the necessary changes to raw material specifications, formulations, and product labels in good time.

### Analysis of botanicals, extracts, essential oils

We determine the presence of allergenic fragrances by means of gas chromatography – mass spectrometry (GC-MS) in accordance with DIN EN 16274:2012-12 (Method for analysis of allergens – Quantification of an extended list of 57 suspected allergens in ready-to-inject fragrances). This procedure is suitable for fragrance solutions, essential oils, and – following oil distillation – for drugs. PhytoLab's validated proprietary extended procedure also offers a means of determining the presence of extracts, including those obtained by extracting fatty oils.

**We would be delighted to advise you.  
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#### Sources

<https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32023R1545>

<https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:02009R1223-20240404>