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R Dear customers and partners,

our new newsletter inci-news 04-23 offers an overview of current legal changes through VO 2023/1545. We are very pleased about your interest, your inquiries, suggestions and the professional exchange

your inci experts



New Regulation on the labelling of allergenic fragrances

VO 2023/1545 has been published on 26.07.2023

As already announced in **inci-news 05-22**, the EU Commission is now getting serious. Regulation 2023/1545 EU

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

will come into force on 15.08.2023. With the publication of 26.07.2023, probably the most extensive change in the area of fragrance allergens will be implemented.

This concerns in particular **a variety of natural essential oils and their components**, especially *citrus oils* such as *bergamot* and *orange oil*, *ylang ylang oil* and *lavender oils* as well as *jasmine* and *rose extracts*.

These are mainly found in formulations of natural cosmetic products.

After a review of existing formulations, it can be seen that ingredients are also listed which are particularly common in cosmetic formulations, such as *beta-caryophyllenes*, *linalyl acetates*, *pinenes*, *rose ketones* and *vanillin*, among others. In addition, fragrances such as *prehaptenses* and *prohaptenses*, which can be converted into known contact allergens by oxidation or bioactivation, are placed on an equal footing with fragrance allergens, so that the same restrictions and requirements apply to them.



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For all substances mentioned in the regulation, the already existing declaration obligation is provided for from an application concentration of $\geq 0.001\%$ for leave-on products and $\geq 0.01\%$ for rinse-off products. In some cases, **additional restrictions for certain** product groups or maximum concentrations in the ready-to-use preparation as well as purity requirements are linked to individual ingredients.

The regulation enters into force on **15 August 2023**. After **31 July 2026**, you may only place cosmetic products on the European market that comply with the requirements of this Regulation. After **31 July 2028**, you may only **make** products available on the European market that comply with the said Regulation. If you still have products with the old labelling on the market after this date, you may be obliged by the supervisory authorities to recall the goods.

The following measures are derived from this for you as the distributor:

1. Ask your perfume oil and/or essential oil suppliers for the updated allergen lists.
2. Adapt your internal documentation and update your databases. If necessary, make recipe changes to exclude unwanted allergens or non-conformities.
3. Plan ranges of available raw materials and finished goods. Start the raw material/recipe changeover in good time.
4. The change in the list of allergens can have an extensive impact on the layout of packaging and labels.
5. Similarly, the documentation elements of safety report, product information file, CPNP notification and marketability change.

For all cosmetic companies, this means an enormous challenge both for the existing products and for the product innovations that are being newly developed.

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We would be happy to support you with our expertise in mastering this task – get in touch with us.