

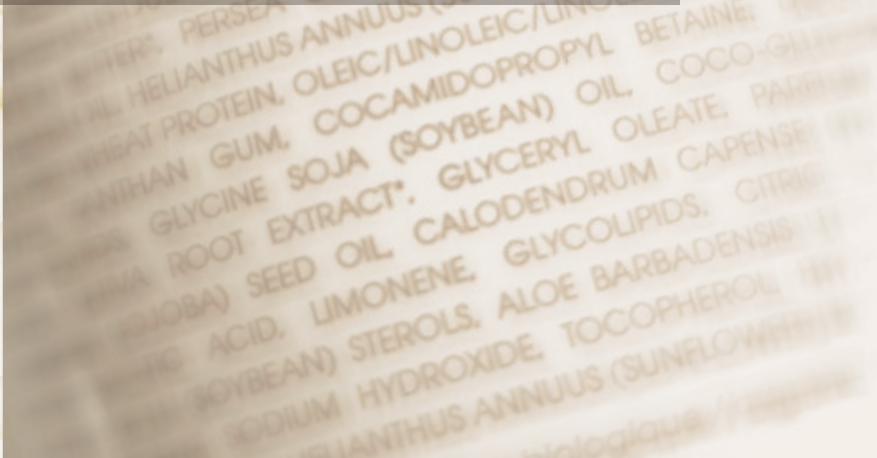
THE INGREDIENTS COLLECTION



# FRAGRANCE ALLERGENS

- "HISTORICAL" AND "NEW" ALLERGENS
- RESTRICTIONS AND LABELLING REQUIREMENTS
- REGULATIONS IN EUROPE AND 16 INTERNATIONAL COUNTRIES
- 80 INGREDIENT SHEETS (IDENTIFICATION, REGULATIONS, IFRA STANDARDS, ETC.)

2024



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# Introduction

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The story of fragrance allergens in cosmetics is a long one... but this time it seems to be coming to an end.

It took more than 10 years for the SCCS (Scientific Committee on Consumer Safety) Opinion of 26 and 27 June 2012 to finally be translated into regulations.

The stakes were high, and the implications for the industry particularly far-reaching. The Opinion recommended nothing less than a ban on substances that had previously been permitted, restrictions on the use of certain others, and above all, compulsory labelling for around 80 of them!

Although the industry protested and disputed the relevance of such a measure, in the end it was consumer information that prevailed.

In 2023, after 10 years of discussions, consultations, impact studies, counter-proposals, analyses and assessments, the “Allergens” Regulation was finally published.

It finally made it compulsory to label 80 fragrance ingredients and substances on the packaging (but with a possible window of opportunity for digital information at a later stage), as soon as they are present in at more than 0.01% in rinse-off products and more than 0.001% in leave-on products.

It brings with it new INCI names where none existed before, with some of them grouping together several related substances that already had INCI names, CAS numbers added for several of them, and also the regulatory obligation for manufacturers to measure these “new” allergens in their products, to know whether or not they need to be labelled.

Not to mention the regulatory obligation to review all product ingredient lists to bring them up to date, and to change their packaging to include them...

What are these “new” allergens? How are they regulated? How should they be labelled? And how will this new labelling be accepted (or not) internationally?

This ebook sets out to answer all these questions, starting with a reminder of the historical background to this upheaval, followed by details of the new Regulation and practical solutions for implementing it.

It also includes the technical and regulatory data sheets for the 80 substances involved, with their European regulations (cosmetics and CLP), their IFRA standards and the rules that apply to them in 16 crucial export destinations.

It is true that the “Allergens” Regulation sets deadlines for compliance: three years for products placed on the market, five years for products made available on the market.

Given the scale of the task, it's not too early to start preparing: this ebook has been designed as the best tool for doing just that.



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# A bit of history...

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# ALLERGENS: MORE SUBSTANCES, MORE LIMITATIONS

**It was due at the end of 2011. The public consultation once finished, the SCCS Opinion on allergens, approved during the 26 and 27 June plenary meeting, has been released. At stake, a new regulation is ahead, not only for the 26 substances that shall already be labelled, but also for complementary 30 chemical substances and 26 natural extracts.**

The SCCS worked on two approaches:

- The overall prevention of allergies, to avoid (by a ban to use) or to lower (by defining maximum concentrations considered as safe) the contacts of the public with the allergenic substances
- The individual prevention, through the mandatory declaration of allergenic substances, so that every consumer may avoid the substances able to trigger allergenic reactions

To do this, the experts have made an exhaustive review of all the available data on sensitizing substances, mainly published since 1999, when the first list of 26 to-be-labelled allergenic substances was issued on the European level. They have drawn conclusions that may be the core of a future new regulation.

## **From 26 to 82... as a minimum**

The first lesson of this Opinion: the list of 26 fragrance substances is still valid. However, on the one hand, it is completed, and, on the other hand, it now includes other substances, chemicals, or natural such as plants extracts and essential oils. It comprises also substances that, due to an oxidation or an enzymatic process, may produce allergens.

Therefore, the SCCS has issued four lists(See below for details):

1. Established contact allergen in humans
2. Established contact allergen in animals, which may be also in humans
3. Likely contact allergen (if human, animal and other evidence is considered too small for listing them in list 1)
4. Possible contact allergen (if human, animal and other evidence is considered insufficient, despite doubts on their effect).

For the SCCS, the substances comprised in the three first lists are ingredients, the presence of which in the cosmetic products, the consumer should be warned against. More clearly: mandatory declaration for any ingredient from these three lists.

## **Limits for use**

Among the 82 entries of the first list, 13 chemicals and eight natural extracts are considered as “of special concern”.

For them, the SCCS recommends defining upper limits for use, when, until now, allergens had only to be listed.

Two options, then:

- When data are many enough, it should be established specific maximum limits for every substance of concern
- When data are insufficient, a general upper limit would be applicable, set at 0.01% (100 ppm) by the SCCS. It would be applicable also when the allergen is in a plant extract

## **Bans**

As already announced, the committee of experts has renewed its adverse opinions on three substances: Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde, on the one hand, Chloroatranol and Atranol, the main allergenic substances of the Evernia Prunastri and Evernia Furfuracea moss, on the other hand.

The SCCS is of the opinion that the number of reported allergies due to these substances, even after considering the efforts to limit their concentrations in products, makes it necessary to classify them in the “not safe for use” substances category. This should make them banned within some time.

## Activated allergens

Another new point: for the SCCS, the substances that become active after an abiotic (not biological) or metabolic activation, especially through oxidation, leading then to allergens more powerful than the parent-substance, should be considered as the equivalent of these allergens. This leads to the same restrictions for use and the same obligations for labelling.

Among these substances, the experts quote Limonene, Linalool, Linalyl Acetate, Geraniol, Geranial, alpha-Terpinene, Eugenol, Isoeugenol and Cinnamyl Alcohol.

This document will now be submitted to the European Commission, which will have to transpose it in regulation.

## For further information

- See the [full text of the Opinion on fragrance allergens in cosmetic products](#) (SCCS, 2012)

## 1. Established contact allergens in humans

*Allergens of special concern are substances where between 100 and 1,000 cases (+++) and more than 1,000 (++++) have been 23 published. These are set in bold.*

*Fragrance substances identified as allergens in the 1999 opinion 24 of SCCNFP are marked with an asterisk.*

*“ox” = oxidised; “non-ox.” = non-oxidised*

### Individual chemicals

- Acetylcedrene, CAS 32388-55-9 : +
- Amyl Cinnamal\*, CAS 122-40-7 : ++
- Amyl Cinnamyl alcohol\*, CAS 101-85-9 : ++
- Amyl Salicylate, CAS 2050-08-0 : +
- trans-Anethole, CAS 4180-23-8 : +
- Anise Alcohol\*, CAS 105-13-5 : +
- Benzaldehyde, CAS 100-52-7 : +
- Benzyl Alcohol\*, CAS 100-51-6 : ++
- Benzyl Benzoate\*, CAS 120-51-4 : ++
- Benzyl Cinnamate\*, CAS 103-41-3 : ++
- Benzyl Salicylate\*, CAS 118-58-1 : ++
- Butylphenyl Methylpropional\*, CAS 80-54-6 : ++
- Camphor, CAS 76-22-2 / 464-49-3 : +
- beta-Caryophyllene (ox.), CAS 87-44-5 : + (non-ox.); + (ox.)
- Carvone, CAS 99-49-0 / 6485-40-1 / 2244-16-8 : +
- **Cinnamal\***, CAS 104-55-2 : +++
- **Cinnamyl Alcohol\***, CAS 104-54-1 : +++
- **Citral\***, CAS 5392-40-5 : +++
- Citronellol\*, CAS 106-22-9 / 1117-61-9 / 7540-51-4 : ++
- **Coumarin\***, CAS 91-64-5 : +++