

CMRs



the forbidden / the exempted

EBOOK 2024



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Introduction

Article 15 of the Cosmetics Regulation 1223/2009 provides for a ban on the use in cosmetic products of substances classified as CMR (Carcinogenic, Mutagenic, toxic for Reproduction).

This harmonised classification is determined within the framework of the CLP Regulation on classification, labelling and packaging of chemical substances.

In the early days of the implementation of the Cosmetics Regulation, the prohibition of CMRs thus depended exclusively on other legislation, and applied “automatically”, once the ATPs (Adaptation to Technical and Scientific Progress) of the CLP were published... and without anything changing in the Annexes of the Regulation governing cosmetic products. This area of legal uncertainty posed major interpretation problems for the industry, especially since Article 15 of the Cosmetics Regulation also provides for the possibility of exemption from the automatic ban, in particular when the substances meet certain conditions (compliance with food safety requirements, absence of substitute substances, etc.) and have been deemed safe by the SCCS (Scientific Committee on Consumer Safety). This possibility is not taken into account in the CLP Regulation.

To put an end to this ambiguous situation, the European Commission decided to ensure the uniform implementation of the ban on CMR substances and to formally transpose the classifications into the annexes of the Cosmetics Regulation.

This took the form of annual so-called “Omnibus” Regulations, consolidated lists of newly classified CMR substances to be integrated into the different annexes of the Cosmetics Regulation.

The first of these was published in May 2019, there have been three more since then.

To date, a total of 337 substances have been banned and added to Annex II of the Cosmetics Regulation. 12 substances have been exempted from the ban and their conditions of use have been reviewed after the opinion of the SCCS and included in the other Annexes (III: restricted substances; IV: colorants; V: preservatives; VI: UV filters).

Even if the status of CMR substances is now clearly established, it is still difficult to be aware of the new regulations for each of them. The complete list is “split” into several regulatory texts and the annexes of the Cosmetics Regulation are not consolidated every day...

And it is all the more important today to be well informed on the subject as the competent authorities make tracking down substances banned from the market one of their recurrent control themes.

This Minibook has been designed to be clear and comprehensive. It first covers the main points of the five CMR Regulations published to date, and then provides a complete list of the substances that have been included in the various annexes of the Cosmetics Regulation.

A practical and essential tool to check the compliance of your formulas, update your portfolio of raw materials, proceed with any corrective measures that may be necessary, and wait for the inspectors of the competent authorities in complete serenity...

The CMRs Regulations

REGULATION 2019/831 OF 22 MAY 2019

- 227 substances classified as CMR are formally added to Annex II of Cosmetics Regulation 1223/2009 which lists the prohibited ingredients.
- Among them, preservatives (Quaternium-15, Formaldehyde, Paraformaldehyde, Chloroacetamide, Chlorofene), an antimicrobial agent (Methylene glycol) but also a solvent (Dichloromethane) and boron compounds, among others...
- Another preservative, Polyaminopropyl biguanide (PHMB), has its maximum permitted concentration increased from 0.3% to 0.1%, with the clarification that it should not be used in applications that could result in exposure of the end user's lungs by inhalation.
- Two ingredients, hitherto unregulated, are included in Annex III of the restricted substances:
 - > Trimethylbenzoyl diphenylphosphine oxide (TPO) is restricted to professional use in artificial nail preparations at a maximum concentration of 5%;
 - > Furfural is limited to a maximum concentration of 0.001%.
- **Date of entry into force:** June 2019

REGULATION 2019/1966 OF 27 NOVEMBER 2019

- An exemption from the prohibition is granted for salicylic acid and its salts, despite the classification in CMR 2, but its conditions of use are significantly restricted.
- As No other of the 12 substances classified as CMR by Regulation 2018/1480 have been requested for use, they are all added to Annex II (Prohibited Substances) of Cosmetics Regulation 1223/2009 if they are not already included.
- 19 CMR substances that had been forgotten in the first Omnibus Regulation are also added to Annex II of the Cosmetics Regulation.
- **Date of entry into force:** 1st October 2021

REGULATION 2021/850 OF 26 MAY 2021

- 12 substances are added to Annex II.
- An entry is added to Annex III (restricted substances) to the Cosmetics Regulation to specify new conditions of use for Titanium Dioxide.
- The wording of the conditions of use of Salicylic Acid, established by the previous CMR Regulation, is modified for more clarity.
- **Date of entry into force:** 1st October 2021

REGULATION 2021/1902 OF 29 OCTOBER 2021

- 23 substances are added to Annex II (prohibited substances) to the Cosmetics Regulation.
- Zinc Pyrithione is included in this list, despite a positive opinion from the SCCS, as it has not been established that there are no suitable alternative substances, including with anti-dandruff function.
- As expected, Butylphenyl Methylpropional (fragrance allergen) is also banned.
- On the other hand, Sodium Hydroxymethylglycinate, also added to Annex II, finally remains in Annex V

(preservatives) to the Regulation, but with a new condition of use: the theoretical maximum releasable concentration of formaldehyde from any source in the mixture as placed on the market must not exceed 0.1% w/w.

- **Date of entry into force:** 1st March 2022

REGULATION 2022/1531 OF 15 SEPTEMBER 2022

- 14 new entries are added to Annex II. Of these, only two have INCI names, Methylene Di-t-Butylcresol and MIBK.
- Methyl Salicylate (fragrance ingredient) is added to Annex III (restricted substances) to limit its maximum permitted concentrations in the different product categories.
- The entries for Sodium Hydroxymethylglycinate in Annexes II and V are amended to clarify the rules for this preservative.
- **Date of entry into force:** 17 December 2022.

REGULATION 2023/1490 OF 19 JULY 2023

- 30 new substances are added to Annex II.
- Seven have INCI names: Benzophenone, Theophylline, Melamine, Azadirachta Indica Seed Extract, Trimethylolpropane Triacrylate, Pentetic Acid, and Pentasodium Pentetate.
- This Regulation also extends the ban on 2-ethylhexanoic acid to its salts.
- **Date of entry into force:** 1 December 2023.

The CMRs in Annex II (Banned)
