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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	15 September 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

Subject:	Commission Regulation (EU) .../... of XXX amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use in cosmetic products of certain substances classified as carcinogenic, mutagenic or toxic for reproduction
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EUROPEAN
COMMISSION

Brussels, XXX
[...] (2025) XXX draft

COMMISSION REGULATION (EU) .../...

of XXX

**amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council
as regards the use in cosmetic products of certain substances classified as carcinogenic,
mutagenic or toxic for reproduction**

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use in cosmetic products of certain substances classified as carcinogenic, mutagenic or toxic for reproduction

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products¹, and in particular Article 15(1), third sentence, and Article 15(2), fourth subparagraph, thereof,

Whereas:

- (1) Regulation (EC) No 1272/2008 of the European Parliament and of the Council² provides for a harmonised classification of substances as carcinogenic, mutagenic or toxic for reproduction (CMR) based on a scientific assessment by the Committee for Risk Assessment of the European Chemicals Agency. The substances are classified as CMR substances of category 1A, category 1B or category 2 depending on the weight of evidence of their CMR properties.
- (2) Article 15 of Regulation (EC) No 1223/2009 provides that substances which have been classified as CMR substances of category 1A, 1B or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 are to be prohibited from use in cosmetic products. Those CMR substances may however be used in cosmetic products where the conditions laid down in Article 15(1), second sentence, or Article 15(2), second subparagraph, of Regulation (EC) No 1223/2009 are fulfilled.
- (3) In order to uniformly implement the prohibition of CMR substances within the internal market, to ensure legal certainty in particular for economic operators and national competent authorities, and to ensure a high level of protection of human health, all CMR substances should be included in the list of prohibited substances in Annex II to Regulation (EC) No 1223/2009 and, where relevant, deleted from the lists of restricted or allowed substances in Annexes III to VI to that Regulation. However, where the conditions laid down in Article 15(1), second sentence, or Article 15(2), second subparagraph, of Regulation (EC) No 1223/2009 are fulfilled, the lists of restricted or allowed substances in Annexes III to VI to that Regulation should be amended accordingly.

¹ OJ L 342, 22.12.2009, p. 59, ELI: <http://data.europa.eu/eli/reg/2009/1223/oj>.

² Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/1272/oj>).

- (4) This Regulation concerns substances classified as CMR substances of categories 1A, 1B or 2 by Commission Delegated Regulation (EU) 2020/1182³ and by Commission Delegated Regulation (EU) 2024/2564⁴.
- (5) Perboric acid and its salts, which have been classified as CMR substances of category 1B, are listed in entries 1397, 1398 and 1399 of Annex II to Regulation (EC) No 1223/2009 and are, therefore, prohibited for use in cosmetic products. However, the substances listed in those entries are all perborate derivatives and are structurally related. They share a common borate core and release hydrogen peroxide upon dissolution in water, which accounts for their similar chemical properties and biological activity.
- (6) Due to their common mode of action and health risks, it is appropriate from a regulatory perspective to treat perboric acid and its salts as a group rather than individual substances. For reasons of clarity, legal certainty and simplification, the merging of entries 1397, 1398 and 1399 of Annex II to Regulation (EC) No 1223/2009 would simplify that Regulation and improve clarity for stakeholders. Therefore, entry 1397 should be amended to reflect the content of entries 1398 and 1399, while entries 1398 and 1399 should be deleted.
- (7) The substance ‘silver’ (CAS No. 7440-22-4) has been classified as a CMR substance of category 2 (toxic for reproduction) by Delegated Regulation (EU) 2024/2564, when its particle diameter is equal to or larger than 1 mm (silver massive), when its particle diameter is larger than 100 nm and smaller than 1 mm (silver powder) and when its particle diameter is larger than 1 nm and smaller than or equal to 100 nm (silver nano).
- (8) Silver is currently listed in entry 142 of Annex IV to Regulation (EC) No 1223/2009 as an authorised colorant (CI 77820), while its colloidal nanoform (1-100 nm) is prohibited in cosmetic products and listed as entry 1727 in Annex II to that Regulation.
- (9) In May 2023, a request for the application of Article 15(1), second sentence, of Regulation (EC) No 1223/2009 was submitted concerning only the use of micron-sized particulate silver in cosmetic products.
- (10) The Scientific Committee on Consumer Safety (SCCS) concluded in its opinion of 27 March 2024⁵ that micron-sized particulate silver can be considered safe under specific conditions of use in cosmetic products.
- (11) In light of the classification of silver massive, silver powder and silver nano as CMR substances of category 2, the specific exemption request relevant to only the micron-sized silver and the relevant SCCS opinion, entry 1727 of Annex II to Regulation (EC) No 1223/2009 should be amended to include silver massive and silver nano.

³ Commission Delegated Regulation (EU) 2020/1182 of 19 May 2020 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 261, 11.8.2020, p. 2, ELI: http://data.europa.eu/eli/reg_del/2020/1182/oj).

⁴ Commission Delegated Regulation (EU) 2024/2564 of 19 June 2024 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council as regards the harmonised classification and labelling of certain substances (OJ L 2024/2564, 30.9.2024, ELI: http://data.europa.eu/eli/reg_del/2024/2564/oj).

⁵ SCCS (Scientific Committee on Consumer Safety), Opinion on the safety of Silver (CAS/EC No. 7440-22-4/231-131-3) used in cosmetic products, preliminary version of 27 March 2024, final version of 20 June, SCCS/1665/24.

Furthermore, entry 142 of Annex IV to Regulation (EC) No 1223/2009 should be amended to allow the use of micron-sized silver (silver powder) as a colorant only at certain conditions considered safe by the SCCS, while micron-sized silver should also be added to the list of substances restricted in cosmetic products in Annex III to that Regulation.

- (12) The substance 'hexyl 2-hydroxybenzoate' (CAS No. 6259-76-3) has been classified as a CMR substance of category 2 (toxic for reproduction) by Delegated Regulation (EU) 2024/2564.
- (13) Hexyl 2-hydroxybenzoate, with INCI name 'Hexyl Salicylate', is currently not regulated under Regulation (EC) No 1223/2009.
- (14) In December 2022, a request for the application of Article 15(1), second sentence, of Regulation (EC) No 1223/2009 was submitted concerning the use of Hexyl Salicylate in cosmetic products.
- (15) The SCCS concluded in its opinion of 25 October 2024⁶ that Hexyl Salicylate can be considered safe under specific conditions of use in cosmetic products.
- (16) In light of the classification of Hexyl Salicylate as a CMR substance of category 2 and the final opinion of SCCS, Hexyl Salicylate should be added to the list of substances restricted in cosmetic products in Annex III to Regulation (EC) 1223/2009.
- (17) The substance 'biphenyl-2-ol' (CAS No. 90-43-7), has been classified as a CMR substance of category 2 (carcinogen of category 2), by Delegated Regulation (EU) 2024/2564.
- (18) Biphenyl-2-ol, with INCI name 'o-Phenylphenol', is currently listed in entry 7 of Annex V to Regulation (EC) No 1223/2009 as an allowed preservative in rinse-off and leave-on products with a maximum allowed concentration of 0,2 % and 0,15 % (as phenol), respectively.
- (19) In December 2023, a request for the application of Article 15(1), second sentence, of Regulation (EC) No 1223/2009 was submitted concerning the use of o-Phenylphenol as a preservative in cosmetic products. In addition, the request included the safety of 'Sodium o-Phenylphenate' (CAS No. 132-27-4), which is the sodium salt of o-Phenylphenol and which is currently not listed in the Annexes to Regulation (EC) No 1223/2009.
- (20) The SCCS concluded in its opinion of 25 October 2024⁷ that o-Phenylphenol and Sodium o-Phenylphenate can be considered safe under specific conditions of use in cosmetic products.
- (21) In light of the classification of o-Phenylphenol as a CMR substance of category 2 and the final SCCS opinion on both o-Phenylphenol and Sodium o-Phenylphenate, entry 7 of Annex V to Regulation (EC) No 1223/2009 should be amended to add the

⁶ SCCS (Scientific Committee on Consumer Safety), Addendum to the Scientific Opinion on Hexyl Salicylate SCCS/1658/23 (CAS/EC No. 6259-76-3/228-408-6) – children exposure 0-3 y.o., SCCS/1668/24, preliminary version of 26 July 2024, final version of 25 October 2024, corrigendum of 18 December 2024.

⁷ SCCS (Scientific Committee on Consumer Safety), Opinion on the safety of 'Biphenyl-2-ol' and 'Sodium 2-biphenylolate' (CAS/EC No. 90-43-7/201-993-5 and 132-27-4/205-055-6) used in cosmetic products, preliminary version of 31 July 2024, final version of 25 October 2024, SCCS/1669/24.

substance Sodium o-Phenylphenate to the list of preservatives allowed in cosmetic products.

- (22) With regard to all substances other than silver, hexyl 2-hydroxybenzoate and biphenyl-2-ol, which were classified as CMR substances by Delegated Regulation (EU) 2024/2564, no request for use in cosmetic products has been submitted. Consequently, the CMR substances that are not already listed in Annex II to Regulation (EC) No 1223/2009 should be added to the list of substances prohibited in cosmetic products in that Annex.
- (23) Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (24) The amendments to Regulation (EC) No 1223/2009 that are based on the classifications of the relevant substances as CMR substances by Delegated Regulation (EU) 2024/2564 should apply from the same date as those classifications.
- (25) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II, III, IV and V to Regulation (EC) No 1223/2009 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 May 2026.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula von der Leyen