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

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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 silver

Delegations will find attached document D(2026) 117877.

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[...] (2026) 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 silver**

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 silver

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 31(1), thereof,

Whereas:

- (1) The substance ‘silver’ (CAS No. 7440-22-4) has been classified as a CMR (carcinogenic, mutagenic, or toxic for reproduction) substance of category 2 (toxic for reproduction) by Commission Delegated Regulation (EU) 2024/2564², 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 nanoparticles).
- (2) Following this classification the Commission adopted Commission Regulation (EU) 2026/78³, which amended entry 1727 of Annex II to Regulation (EC) No 1223/2009 to include silver nano [$1\text{ nm} < \text{particle diameter} \leq 100\text{ nm}$] and silver massive [$\text{particle diameter} \geq 1\text{ mm}$]. Furthermore, Regulation (EU) 2026/78 added micron-sized silver to the list of substances restricted in cosmetic products in Annex III to Regulation (EC) No 1223/2009 and amended entry 142 of Annex IV to that Regulation to allow the use of micron-sized silver (silver powder) [$100\text{ nm} < \text{particle diameter} < 1\text{ mm}$] as a colorant only at certain conditions considered safe by the Scientific Committee on Consumer Safety (SCCS).
- (3) Following the submission of data from the industry in August 2025 demonstrating the safety of micron-sized silver (powder) in specific cosmetic products, the SCCS published a scientific opinion on silver on 24 April 2026⁴, which provides a comprehensive assessment of its safety, taking into account additional exposure scenarios and refined toxicological data.

¹ OJ L 342, 22.12.2009, p. 59.

² 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).

³ Commission Regulation (EU) 2026/78 of 12 January 2026 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 (OJ L, 2026/78, 13.1.2026, ELI: <http://data.europa.eu/eli/reg/2026/78/oj>).

⁴ SCCS (Scientific Committee on Consumer Safety), scientific advice on Silver (CAS/EC No. 7440-22-4/231-131-3) used in cosmetic products, preliminary version of 17 December 2025, final version of 26 March 2026, SCCS/1687/25.

- (4) In that opinion, the SCCS concluded that the use of silver under certain conditions is safe for consumers, including conditions of use that go beyond those laid down in Regulation (EU) 2026/78. In particular, the SCCS concluded that, since micron-sized particulate silver [$100\text{ nm} < \text{particle diameter} < 1\text{ mm}$] does not penetrate the skin, it is safe when used up to a maximum concentration of 0.2% in rinse-off cosmetic products, 0.3% in leave-on cosmetic products, 0.2% in oral exposure products and 0.3% in nail products. In cosmetic products intended for children, micron-sized particulate silver is also safe at the same concentrations as above, with the exception of oral products, where it is safe in a concentration of up to 0.05% in mouthwash products.
- (5) In light of that scientific development, it is appropriate to amend entries 379 and 142 in Annex III and Annex IV, respectively, to Regulation (EC) No 1223/2009 in order to reflect the latest scientific knowledge and ensure a high level of protection of human health while avoiding unnecessary restrictions on safe uses.
- (6) Given that the amendments to the restrictions adopted by Regulation (EU) 2026/78 on the use of silver (powder), provided in entries 379 and 142 in Annex III and Annex IV, respectively, to Regulation (EC) No 1223/2009, apply from 1 May 2026 and that the conditions laid down therein do not fully reflect the most recent scientific assessment of the SCCS, it is necessary to amend those two entries without delay.
- (7) In order to ensure the smooth functioning of the internal market and to avoid unnecessary withdrawals or restrictions on cosmetic products containing micron-sized silver (silver powder) [$100\text{ nm} < \text{particle diameter} < 1\text{ mm}$] that are considered safe in light of the latest scientific assessment of the SCCS, and in view of its objective of aligning the regulatory framework with the most recent scientific evidence and alleviating certain restrictions, this Regulation should enter into force as a matter of urgency and should apply from 1 May 2026.
- (8) Given that Regulation (EU) 2026/78 applies from 1 May 2026 and in order to ensure a seamless application of this Regulation, the latter should enter into force on the day of its publication and apply from 1 May 2026. 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 III and IV 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 day 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*