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From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

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To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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Subject: COMMISSION REGULATION (EU) .../... of XXX amending Annexes II, III and V to 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

Delegations will find attached document D073715/21.

Encl: D073715/21



Brussels, **XXX**
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[...](2021) **XXX** draft

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

of **XXX**

amending Annexes II, III and V to 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 Annexes II, III and V to 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 products⁽¹⁾, and in particular Article 15(1) and the fourth subparagraph of Article 15(2) thereof,

Whereas:

- (1) Regulation (EC) No 1272/2008 of the European Parliament and of the Council⁽²⁾ provides for a harmonised classification of substances as carcinogenic, mutagenic or toxic for reproduction (CMR) based on a scientific assessment by the Risk Assessment Committee of the European Chemicals Agency. The substances are classified as CMR substances of category 1A, CMR substances of category 1B or CMR substances of category 2 depending on the level 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, category 1B or category 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 (CMR substances) are to be prohibited from use in cosmetic products. A CMR substance may however be used in cosmetic products where the conditions laid down in the second sentence of Article 15(1) of Regulation (EC) No 1223/2009 or in the second subparagraph of Article 15(2) of that Regulation 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. Where the conditions

¹ OJ L 342, 22.12.2009, p. 59.

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).

laid down in the second sentence of Article 15(1) of Regulation (EC) No 1223/2009 or the second subparagraph of Article 15(2) of that Regulation are fulfilled, the lists of restricted or allowed substances in Annexes III to VI to that Regulation should be amended accordingly.

- (4) This Regulation covers the substances classified as CMR substances by Delegated Regulation (EU) 2020/1182⁽³⁾, which will apply from 1 March 2022.
- (5) With regard to the substance (T-4)- bis[1-(hydroxy-.kappa.O)pyridine-2(1H)-thionato-.kappa.S]zinc, with the International Nomenclature of Cosmetic Ingredients name Zinc Pyrithione, which has been classified as a CMR substance of category 1B (Toxic for Reproduction), a request for an exception under the second subparagraph of Article 15(2) was submitted on 11 April 2019 concerning use as an anti-dandruff ingredient in rinse-off hair products in a concentration of up to 1 %. No request for an exception has been made for any other use of Zinc Pyrithione.
- (6) Zinc Pyrithione is currently listed in entry 8 of Annex V to Regulation (EC) No 1223/2009 as an allowed preservative in rinse-off hair products in a concentration of up to 1 % and in other rinse-off products that are not oral hygiene products in a concentration of up to 0,5 %. Zinc Pyrithione is also listed in entry 101 of Annex III to Regulation (EC) No 1223/2009 as a restricted substance only allowed, when used for purposes other than preservative, in leave-on hair products in a concentration of up to 0,1 %.
- (7) In accordance with the second subparagraph of Article 15(2) of Regulation (EC) No 1223/2009, CMR substances of category 1A or 1B may be used in cosmetic products by way of exception where certain conditions are fulfilled, including the conditions that no suitable alternative substances are available, as documented in an analysis of alternatives, and that the substance has been evaluated and found safe by the Scientific Committee on Consumer Safety (SCCS).
- (8) The SCCS concluded in its opinion of 3-4 March 2020⁽⁴⁾ that Zinc Pyrithione can be considered safe when used as an anti-dandruff ingredient in rinse-off hair products up to a maximum concentration of 1 %. However, since it has not been established that there are no suitable alternative substances available with regard to anti-dandruff ingredients in rinse-off hair products, Zinc Pyrithione should be deleted from the list of restricted substances in Annex III to Regulation (EC) No 1223/2009 and from the list of preservatives allowed in cosmetic products in Annex V to that Regulation. It should also be added to the list of substances prohibited in cosmetic products in Annex II to Regulation (EC) No 1223/2009.
- (9) With regard to all substances other than Zinc Pyrithione, which were classified as CMR substances pursuant to Regulation (EC) No 1272/2008 by Delegated Regulation (EU) 2020/1182, no request for use in cosmetic products by way of exception has been submitted. Consequently, the CMR substances that are not already listed in Annex II

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).

⁴ SCCS Opinion on Zinc Pyrithione (ZPT) (CAS No 13463-41-7) – Submission III - SCCS/1614/19.

to Regulation (EC) No 1223/2009 should be added to the list of substances prohibited in cosmetic products in that Annex.

- (10) Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (11) The amendments to Regulation (EC) No 1223/2009 are based on the classifications of the relevant substances as CMR substances by Delegated Regulation (EU) 2020/1182 and should therefore apply from the same date as those classifications.
- (12) 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 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 March 2022.

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