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

of **XXX**

amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of Benzyl Salicylate, Triphenyl Phosphate, Ammonium Silver Zinc Aluminium Silicate, Aluminium, water-soluble zinc salts, Acetylated Vetiver Oil, Citral, HC Blue No. 18, HC Red No. 18, HC Yellow No. 16, Hydroxypropyl p-phenylenediamine and its dihydrochloride salt, and DHHB in cosmetic products

(Text with EEA relevance)

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(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 31(1), thereof,

Whereas:

- (1) The substance ‘2-hydroxybenzoic acid phenylmethyl ester’ (CAS No. 118-58-1), which has been assigned the name ‘Benzyl Salicylate’ under the International Nomenclature Cosmetic Ingredients (INCI), is listed under entry 75 of Annex III to Regulation (EC) No 1223/2009. It is therefore allowed for use as a fragrance allergen in cosmetic products subject to a requirement to inform consumers about its presence when its concentration exceeds 0,001 % in leave-on and 0,01 % in rinse-off products.
- (2) The substance ‘triphenyl phosphate’ (CAS No. 115-86-6), which has been assigned the INCI name ‘Triphenyl Phosphate’, is not regulated under Regulation (EC) No 1223/2009 but is used in cosmetic products as a plasticiser to soften, or make supple, various synthetic polymers.
- (3) In light of concerns related to potential endocrine-disrupting properties of Benzyl Salicylate and Triphenyl Phosphate, the Commission launched a public call for data in 2019 and 2021, respectively. The cosmetics industry submitted scientific evidence to demonstrate the safety of those substances when used in cosmetic products. The Commission requested the Scientific Committee on Consumer Safety (SCCS) to carry out safety assessments of those substances in view of the information provided by industry.
- (4) The SCCS concluded in its opinion of 26 October 2023² that Benzyl Salicylate is safe for use in cosmetic products up to the maximum concentrations provided in the submissions by industry. Considering the SCCS opinion, it can be concluded that there is a potential risk to human health arising from the use of that substance in cosmetic products when the concentration of that substance exceeds certain levels. Therefore,

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

² SCCS (Scientific Committee on Consumer Safety), Opinion on Benzyl Salicylate (CAS No. 118-58-1, EC No. 204-262-9), preliminary version of 6-7 June 2023, final version of 26 October 2023, SCCS/1656/23

- the use of Benzyl Salicylate in cosmetic products should be restricted to the maximum concentrations proposed by the SCCS in Annex III to Regulation (EC) No. 1223/2009.
- (5) In its opinion of 25 July 2024³, the SCCS could not conclude on the safety of Triphenyl Phosphate because the information provided by industry was insufficient to fully evaluate it and exclude potential genotoxicity. Considering the SCCS opinion, it can be concluded that there is a potential risk to human health arising from the use of that substance in cosmetic products. That substance should therefore be added to the list of substances prohibited in cosmetic products in Annex II to Regulation (EC) No. 1223/2009.
 - (6) The substance ‘silver zinc zeolite’ (CAS No. 130328-20-0), which has been assigned the INCI name ‘Ammonium Silver Zinc Aluminium Silicate’, has been classified as ‘Toxic for Reproduction of Category 2’ by Commission Regulation (EU) 2017/776⁴.
 - (7) Pursuant to Article 15(1) of Regulation (EC) No 1223/2009, silver zinc zeolite is listed as a prohibited substance in cosmetic products (entry 1597 in Annex II to that Regulation⁵).
 - (8) In view of the diminishing number of available preservatives in cosmetic products, the industry submitted a dossier to defend the safe use of silver zinc zeolite as a preservative in cosmetic products. In its opinion of 21 December 2023⁶, the SCCS concluded that silver zinc zeolite is safe up to a maximum concentration of 1 % in spray deodorant and powder foundation, provided that the silver content in silver zinc zeolite does not exceed 2,5 %.
 - (9) Considering the SCCS opinion, silver zinc zeolite should be deleted from the list of prohibited substances in cosmetic products in Annex II to Regulation (EC) No 1223/2009 and should, therefore, be added to the list of preservatives allowed in cosmetic products in Annex V to that Regulation.
 - (10) Aluminium and aluminium-containing ingredients are used in a variety of cosmetic products with different functions. Currently, different aluminium-containing ingredients are listed in Regulation (EC) No. 1223/2009: entries 34, 50, 189, 190 and 192 of Annex III; in entries 117, 118, 119, 121, 131 and 150 of Annex IV, and entry 27a of Annex VI.
 - (11) In light of safety concerns related to the potentially significant contribution to the total systemic exposure to aluminium from cosmetics, the Commission requested the SCCS to carry out a safety assessment of aluminium-containing ingredients in view of the information provided by the industry.

³ SCCS (Scientific Committee on Consumer Safety), Opinion on triphenyl phosphate (CAS No. 115-86-6, EC No. 204-112-2) preliminary version of 27 March 2024, final version of 25 July 2024, SCCS/1664/24.

⁴ Commission Regulation (EU) 2017/776 of 4 May 2017 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (Text with EEA relevance. (OJ L 116, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/776/oj>).

⁵ Commission Regulation (EU) 2019/831 of 22 May 2019 amending Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 137, 23.5.2019, p. 29, ELI: <http://data.europa.eu/eli/reg/2019/831/oj>).

⁶ SCCS (Scientific Committee on Consumer Safety), Opinion on silver zinc zeolite (CAS No. 130328-20-0, EC No. 603-404-0), preliminary version of 21 March 2023, final version of 21 December 2023, SCCS/1650/23.

- (12) On 27 March 2024, the SCCS adopted an opinion⁷, concluding that aluminium and aluminium-containing ingredients can be considered safe under specific conditions of use in various non-sprayable and sprayable cosmetic product categories.
- (13) Without prejudice to the restrictions and conditions already provided for in Annexes III, IV and VI to Regulation (EC) No. 1223/2009, the aluminium concentration limits indicated for non-spray and sprayable cosmetic product categories in the SCCS opinion should be reflected in Annex III to that Regulation.
- (14) Concerning ‘water-soluble zinc salts’, entry 24 of Annex III to Regulation (EC) No 1223/2009 restricts the use of zinc acetate, zinc chloride, zinc gluconate, and zinc glutamate up to a maximum concentration of 1 % (as zinc) in all cosmetic products.
- (15) In light of potential safety concerns related to the use of zinc salts in oral products such as toothpaste and mouthwash for specific age groups, the Commission requested the SCCS to carry out a safety assessment of those compounds in view of the information provided by the industry.
- (16) On 26 October 2023, the SCCS adopted an opinion⁸, concluding that water-soluble zinc salts covering zinc acetate (CAS No. 557-34-6), zinc chloride (CAS No. 7646-85-7), zinc gluconate (CAS No. 4468-02-4), zinc citrate (CAS No. 546-46-3), and zinc sulphate, zinc sulphate monohydrate, zinc sulphate heptahydrate (CAS No. 7733-02-0/7446-19-7/7446-20-0) can be considered safe when used in toothpaste in concentrations up to 1 % (as zinc) with the exception of children below 1 year of age where that concentration should not exceed 0,72 % (as zinc). In addition, the SCCS concluded that water-soluble zinc salts can be considered safe when used in mouthwash in concentrations up to 0,1 % (as zinc) across all age groups above 6 years.
- (17) In view of the SCCS opinion, it can be concluded that there is a potential risk to human health arising from the use of water-soluble zinc salts in oral products when the concentration of those substances exceeds certain levels. Therefore, the use of water-soluble zinc salts should be restricted to the maximum concentrations proposed by the SCCS.
- (18) The substance ‘acetylated vetiver oil’ (CAS No. 84082-84-8) is not regulated under Regulation (EC) No. 1223/2009 but is used as a fragrance in various types of cosmetic products.
- (19) In light of potential safety concerns related to the sensitisation potential of acetylated vetiver oil when used as a fragrance in cosmetic products, the Commission requested the SCCS to carry out a safety assessment in view of the information provided by the industry.
- (20) The SCCS concluded in its opinion of 20-21 June 2019⁹ that acetylated vetiver oil can be considered safe as a fragrance ingredient when used with 1 % alpha-tocopherol in cosmetic leave-on and rinse-off cosmetic products at the concentrations proposed by

⁷ SCCS (Scientific Committee on Consumer Safety), Opinion on the safety of aluminium in cosmetic products - Submission IV, preliminary version of 14 December 2023, final version of 27 March 2024, SCCS/1662/23.

⁸ SCCS (Scientific Committee on Consumer Safety), Opinion on water soluble zinc salts used in oral hygiene products - Submission II, preliminary version of 3 July 2023, final version of 26 October 2023, SCCS/1657/23.

⁹ SCCS (Scientific Committee on Consumer Safety), Opinion on fragrance ingredient Acetylated Vetiver Oil (AVO) - Submission III, SCCS/1599/18, preliminary version of 21-22 June 2018, final version of 26 February 2019, Corrigendum 20-21 June 2019.

the industry. In addition, in its opinion of 25 October 2024¹⁰, the SCCS concluded that acetylated vetiver oil can also be considered safe when used in sprayable products that may lead to inhalation exposure.

- (21) In view of the SCCS opinions, it can be concluded that there is a potential risk to human health arising from the use of acetylated vetiver oil in cosmetic products when the concentration of that substance exceeds certain levels. Therefore, the use of acetylated vetiver oil in cosmetic products should be restricted to the maximum concentrations proposed by the SCCS.
- (22) The substance ‘3,7-Dimethyl-2,6octadienal’ (CAS No. 5392-40-5), which has been assigned the INCI name ‘Citral’, is listed under entry 70 of Annex III to Regulation (EC) No 1223/2009. It is therefore allowed for use as a fragrance allergen in cosmetic products subject to a requirement to inform consumers about its presence when its concentration exceeds 0,001 % in leave-on and 0,01 % in rinse-off products.
- (23) In light of potential safety concerns related to the sensitisation potential of Citral when used as a fragrance in cosmetic products, the Commission requested the SCCS to assess its upper safe levels using the quantitative risk assessment 2 (QRA2) methodology for the sensitisation endpoint based on the information provided by the industry.
- (24) On 29 July 2024, the SCCS adopted an opinion¹¹, concluding that Citral can be considered safe in relation to the induction of sensitisation at the concentrations proposed by the industry.
- (25) In view of the SCCS opinion, it can be concluded that there is a potential risk to human health arising from the use of Citral in cosmetic products when the concentration of that substance exceeds certain levels. Therefore, the use of that substance in cosmetic products should be restricted to the maximum concentrations proposed by the SCCS.
- (26) The substance ‘3-[(E)-(3-chloro-4-hydroxyphenyl)diazanyl]-2,1-benzisothiazole-5-sulfonamide’ (CAS No. 1166834-57-6/852356-91-3), which has been assigned the INCI name ‘HC Blue No. 18’, is currently not regulated under Regulation (EC) No 1223/2009, and is used as a substance in oxidative and non-oxidative hair dye products.
- (27) Based on safety data provided by the industry on the use of HC Blue No. 18 in oxidative and non-oxidative hair dye products, the SCCS concluded in their scientific advice of 27 April 2023¹² that that substance 18 is safe when used in such products at on-head concentrations of up to 0,35 %.
- (28) In light of the SCCS scientific advice, it can be concluded that there is a potential risk to human health arising from the use of HC Blue No. 18 in oxidative and non-oxidative hair dye products when the concentration of that substance exceeds a certain level. Therefore, the use of that substance in those products should be restricted to a maximum concentration of 0,35 %.

¹⁰ SCCS (Scientific Committee on Consumer Safety), Opinion on the inhalation toxicity of the fragrance ingredient Acetylated Vetiver Oil – AVO (CAS No 84082-84-8, EC No 282-031-1) in sprayable cosmetic products - Submission IV, preliminary version of 28 February 2024, final version of 25 October 2024, SCCS/1663/24.

¹¹ SCCS (Scientific Committee on Consumer Safety), Opinion on Citral (CAS No. 5392-40-5, EC No. 226-394-6) - sensitisation endpoint, preliminary version of 27 March 2024, final version of 29 July 2024, SCCS/1666/24.

¹² SCCS (Scientific Committee on Consumer Safety), Scientific advice on HC Blue 18 (Colipa No. B122) - submission II, 27 April 2023, SCCS/1653/23.

- (29) The substance ‘3-(2,5-diaminophenyl)propan-1-ol and 3-(2,5-diaminophenyl) propan-1-ol dihydrochloride salt’ (CAS No. 73793-79-0 and 1928659-47-5 6), which has been assigned the INCI name ‘Hydroxypropyl-p-phenylenediamine and Hydroxypropyl-p-phenylenediamine 2HCl’, is currently not regulated under Regulation (EC) No. 1223/2009, and is used as a substance in oxidative hair dye products.
- (30) Based on safety data provided by the industry on the use of Hydroxypropyl-p-phenylenediamine and Hydroxypropyl-p-phenylenediamine 2HCl in oxidative hair dye products, the SCCS concluded in its opinion of 28 February 2024¹³ that those substances are safe when used in such products at on-head concentrations of up to 2 %.
- (31) In light of the SCCS opinion, it can be concluded that there is a potential risk to human health arising from the use of Hydroxypropyl-p-phenylenediamine and Hydroxypropyl-p-phenylenediamine 2HCl in oxidative hair dye products when the concentration of that substance exceeds a certain level. Therefore, the use of those substances in those products should be restricted to a maximum concentration of 2 %.
- (32) The substance ‘2-chloro-4-[(1E)-(1-methyl-1H-pyrazol-5-yl)diazenyl]-phenol’ (CAS No 1184721-10-5), which has been assigned the INCI name ‘HC Yellow No. 16’, is currently not regulated under Regulation (EC) No 1223/2009, and is used as a substance in oxidative and non-oxidative hair dye products.
- (33) Based on safety data provided by the industry on the use of HC Yellow No. 16 in oxidative and non-oxidative hair dye products, the SCCS concluded in their scientific advice of 25 October 2024¹⁴ that that substance is safe when used in such products at on-head concentrations of up to 1 % in oxidative and up to 1,5 % in non-oxidative hair dye products.
- (34) In light of the SCCS scientific advice, it can be concluded that there is a potential risk to human health arising from the use of HC Yellow No. 16 in oxidative and non-oxidative hair dye products when the concentration of that substance exceeds a certain level. Therefore, the use of that substance in non-oxidative and oxidative hair dye products should be restricted to a maximum concentration of 1,5 % and 1 % respectively.
- (35) The substance ‘2-chloro-4-[(E)-[3-(methylthio)-1,2,4-thiadiazol-5-yl]diazenyl]phenol’ (CAS No. 1444596-49-9), which has been assigned the INCI name ‘HC Red No. 18’, is currently not regulated under Regulation (EC) No 1223/2009, and is used as a substance in oxidative and non-oxidative hair dye products.
- (36) Based on safety data provided by the industry on the use of HC Red No. 18 in oxidative and non-oxidative hair dye products, the SCCS concluded in their scientific advice of 22 January 2025¹⁵ that that substance is safe when used in such products at

¹³ SCCS (Scientific Committee on Consumer Safety), Opinion on Hydroxypropyl p-phenylenediamine and its dihydrochloride salt (A165) (CAS/EC No. 73793-79-0/827-723-1 and 1928659-47-5/-), preliminary version of 26 October 2023, final version of 28 February 2024, SCCS/1659/23.

¹⁴ SCCS (Scientific Committee on Consumer Safety), scientific advice on hair dye HC Yellow No. 16 (Colipa No B123) (CAS No. 1184721-10-5) - Submission II, preliminary version of 31 July 2024, final version of 25 October 2024, SCCS/1670/24.

¹⁵ SCCS (Scientific Committee on Consumer Safety), scientific advice on HC Red No. 18 (B124) (CAS 1444596-49-9) - submission II, preliminary version of 6 December 2024, final version of 22 January 2025, SCCS/1673/24.

- on-head concentrations of up to 1,5 % in oxidative and up to 0,5 % in non-oxidative hair dye products.
- (37) In light of the SCCS scientific advice, it can be concluded that there is a potential risk to human health arising from the use of HC Red No. 18 in oxidative and non-oxidative hair dye products when the concentration of that substance exceeds a certain level. Therefore, the use of that substance in oxidative and non-oxidative hair dye products should be restricted to a maximum concentration of 1,5 % and 0,5 % respectively.
- (38) The substance ‘benzoic acid, 2-[4-(diethylamino)-2- 8 hydroxybenzoyl]-, hexylester’ (CAS/EC No. 302776-68-7/443-860- 7 6), which has been assigned the INCI name ‘Diethylamino Hydroxybenzoyl Hexyl Benzoate (DHHB)’, is listed in entry 28 of Annex VI to Regulation (EC) No 1223/2009 and is therefore allowed for use as a UV filter in cosmetic products.
- (39) Considering recent concerns over the presence of di-n-hexyl phthalate (DnHexP) as a contaminant in the production of DHHB, and in view of technical and scientific progress and, in particular, the various health concerns, the SCCS concluded in their scientific advice of 14 February 2025¹⁶ that the trace level of 260 ppm is safe as an unavoidable trace impurity in DHHB. The SCCS has also noted in its scientific advice the available information showing that the levels of DnHexP in DHHB can be lowered to 1 ppm. Therefore, the SCCS is of the opinion that this trace level of 1 ppm should be the target for the maximal level of DnHexP as an unavoidable trace impurity in DHHB.
- (40) Given the increased cost of production of DHHB with a trace level of 1 ppm of DnHexP, in particular for small and medium-sized companies, and consequently the higher cost of sunscreens products containing DHHB for consumers, the Commission and Member States have agreed that the level of 10 ppm can be accepted as safe for DnHexP in DHHB.
- (41) In light of the SCCS scientific advice, it can be concluded that there is a potential risk to human health arising from the contaminant DnHexP in the UV filter DHHB when the concentration of that contaminant exceeds a certain level. Therefore, the maximal level of DnHexP as an unavoidable trace impurity in DHHB should be restricted to 10 ppm, taking into account the economic impact on manufacturers of sunscreen products.
- (42) Regulation (EC) No 1223/2009 should therefore be amended and corrected accordingly.
- (43) To enable the cosmetics industry to use hair dyes and preservatives in cosmetic products, the relevant amendments to Annexes III and V should apply without delay. It is appropriate however, to provide for a reasonable period of time in order to allow for the industry to adapt to the new requirements on the use of other substances restricted in this Regulation and to phase out the placing, and making available, on the market of cosmetic products which do not comply with those requirements or conditions.
- (44) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

¹⁶ SCCS (Scientific Committee on Consumer Safety), scientific advice on the safety of Diethylamino Hydroxybenzoyl Hexyl Benzoate – DHHB -S83 (CAS/EC No. 302776-68-7/443-860-6) from cosmetic products, preliminary version of 14 February 2025, final version of 26 June 2025, SCCS/1678/25.

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II, III, V and VI 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*.

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*