Commission Regulation (EU) 2019/1966 of 27 November 2019 amending and correcting Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2019/1966

of 27 November 2019

amending and correcting Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

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

(4) All substances which were classified as CMR substances pursuant to Regulation (EC) No 1272/2008 as at 1 December 2018, when Commission Regulation (EU) 2017/776[(3)]

became applicable, were intended to be covered by Commission Regulation (EU) 2019/831[(4)]. This Regulation covers the substances classified as CMR substances by Commission Regulation (EU) 2018/1480[(5)], which will apply from 1 May 2020.

(5) With regard to the substance 2-hydroxy-benzoic acid, with the International Nomenclature of Cosmetic Ingredients (INCI) name Salicylic acid, which has been classified as a CMR substance of category 2, a request for the application of the second sentence of Article 15(1) of Regulation (EC) No 1223/2009 has been submitted and it has been established that the condition provided for in that provision is fulfilled.

(6) Salicylic acid and its salts are currently listed in entry 3 of Annex V to Regulation (EC) No 1223/2009 as preservatives allowed in cosmetic products in a concentration of up to 0,5 % (acid).

(7) Salicylic acid is also listed in entry 98 of Annex III to Regulation (EC) No 1223/2009 as a restricted substance only allowed, when used for purposes other than preservative, in rinse-off hair products in a concentration of up to 3,0 % and in other products in a concentration of up to 2,0 %.

(8) In accordance with the second sentence of Article 15(1) of Regulation (EC) No 1223/2009, a substance classified as a CMR substance of category 2 may be used in cosmetic products where the substance has been evaluated by the Scientific Committee on Consumer Safety (SCCS) and found safe for use in such products.

(9) On 21 December 2018, the SCCS issued a scientific opinion on Salicylic acid[(6)] ('the SCCS opinion') which concluded that, on the basis of the available data, the substance is safe for consumers when used as a preservative in cosmetic products in a concentration of up to 0,5 % (acid) considering its current restrictions in place. The SCCS opinion is not applicable to any oral products, nor to sprayable products that could lead to exposure of the consumer's lungs by inhalation.

(10) The SCCS also concluded that Salicylic acid is safe when used for purposes other than preservative in a concentration of up to 3,0 % for rinse-off hair products and up to 2,0 % for other products, considering its current restrictions in place, except for body lotion, eye shadow, mascara, eyeliner, lipstick and roll-on deodorant applications. The SCCS opinion is not applicable to any oral products, nor to sprayable products that could lead to exposure of the consumer's lungs by inhalation.

(11) Finally, the SCCS concluded that Salicylic acid is an eye irritant with the potential to cause serious damage to the eyes and pointed out that specific tests are currently on-going to assess whether salicylic acid has endocrine disrupting properties and that depending the outcome of these tests, the potential endocrine disrupting properties of salicylic acid in cosmetics may need to be considered.

(12) In light of the classification of Salicylic acid as a CMR substance of category 2 and as an eye irritant which may cause serious eye damage and of the SCCS opinion, the substance should be authorised as a preservative in cosmetic products in a concentration of up to 0,5 % (acid), considering its current restrictions, except for oral products and for applications that may lead to exposure of the end-user's lungs by inhalation. It should also be authorised, with regard to non-preservative use, in rinse-off hair products in a

concentration of up to 3,0 % and in other products except for body lotion, eye shadow, mascara, eyeliner, lipstick and roll-on deodorant applications, in a concentration of up to 2,0 %. It should not, in any case, be authorised in applications that may lead to exposure of the end-user's lungs by inhalation. Considering the conclusion of the SCCS that Salicylic acid is an eye irritant, the current restriction and condition stating that the substance is not to be used in products for children under 3 years of age, except for shampoos, should be modified so that they cover all products for children under 3 years of age. The restrictions set out in Annex III to Regulation (EC) No 1223/2009 and the conditions set out in Annex V to that Regulation should be adapted accordingly.

(13) With regard to all other substances than Salicylic acid which were classified as CMR substances pursuant to Regulation (EC) No 1272/2008 by Regulation (EU) 2018/1480, no request for use in cosmetic products by way of exception has been submitted. None of those substances are currently restricted or authorised in Annexes III or V to Regulation (EC) No 1223/2009. Four of those substances are currently listed in Annex II to that Regulation. The 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.

(14) The substance 8-hydroxyquinoline; quinolin-8-ol, with the INCI name Oxyquinoline, has been classified as a CMR substance of category 1B by Regulation (EU) 2017/776 while its sulphate form, the substance Bis(8-hydroxyquinolinium) sulphate, with the INCI name Oxyquinoline sulphate, has not been classified as a CMR substance. Both substances were listed in entry 395 of Annex II to Regulation (EC) No 1223/2009 at the time when the classification of Oxyquinoline as a CMR substance started to apply and were prohibited for use in cosmetic products except under the conditions laid down in entry 51 of Annex III to that Regulation. Having being classified as a CMR substance, Oxyquinoline should have been removed from entry 51 of Annex III to Regulation (EC) No 1223/2009. By Regulation (EU) 2019/831, entry 51 was however erroneously deleted in its entirety, including the reference to that entry in entry 395 of Annex II to Regulation (EC) No 1223/2009. In order to correctly reflect the prohibition of Oxyquinoline in cosmetic products on the basis of its classification as a CMR substance, entry 51 should be re-introduced for Oxyquinoline sulphate in Annex III to Regulation (EC) No 1223/2009 and entry 395 in Annex II to that Regulation should be adapted accordingly.

(15) The substance methyl-phenylene diamine, with the INCI name Diaminotoluene, has been added to the list of prohibited substances in Annex II to Regulation (EC) No 1223/2009 by Regulation (EU) 2019/831 as entry 1507. However, that entry does not correspond to a specific substance but to a group of substances among which only 4-methyl-m-phenylene diamine and 2-methyl-m-phenylene diamine, the mixture and the reaction mass of those two substances have been classified as CMR substances under Regulation (EC) No 1272/2008. Among those CMR substances, 4-methyl-m-phenylenediamine, 2-methyl-m-phenylenediamine and mixture of those two substances are already listed as entries 364, 413 and 1144 in Annex II to Regulation (EC) No 1223/2009 while the substance reaction mass of 4-methyl-m-phenylenediamine and 2-methyl-m-phenylenediamine has not yet been banned for use in cosmetics. Therefore,

entry 1507 in Annex II to Regulation (EC) No 1223/2009 should be amended and cover only that substance. Since the CMR substances 4-methyl-m-phenylenediamine and 2-methyl-m-phenylenediamine as well as the mixture and the reaction mass of those substances are also part of the wider group of restricted substances listed as entry 9 of Annex III to Regulation (EC) No 1223/2009, the corresponding entries in Annex II, including entry 1507 as amended, should have been excluded from entry 9. Therefore, entry 9 of Annex III to Regulation (EC) No 1223/2009 should be adapted accordingly.

(16) Moreover, 19 substances or groups of substances classified as CMR substances by Commission Regulation (EU) 2016/1179[7], which became applicable on 1 March 2018, have by error not been included in Regulation (EU) 2019/831, despite the fact that no request for use in cosmetic products has been submitted for those substances or groups of substances. None of those substances or groups of substances are currently restricted or authorised in Annexes III or V to Regulation (EC) No 1223/2009. 18 of those substances or groups of substances are currently not listed in Annex II to Regulation (EC) No 1223/2009 and should therefore be included in the list of substances prohibited in cosmetic products in that Annex II. One of the substances, i.e. disodium octaborate anhydrous, belongs to the group of substances already listed as entry 1396 in Annex II to Regulation (EC) No 1223/2009 and should be included in that entry. Entry 1396 should therefore be adapted accordingly.

(17) Regulation (EC) No 1223/2009 should therefore be amended and corrected accordingly.

(18) The amendments to Regulation (EC) No 1223/2009 are based on the classifications of the relevant substances as CMR substances by Regulation (EU) 2018/1480 and should therefore apply from the same date as those classifications.

(19) In order to avoid any discontinuity and legal uncertainty for economic operators, the correction of the error introduced by Regulation (EU) 2019/831 with regard to the substance Oxyquinoline sulphate should apply retroactively from the date of entry into force of that Regulation.

(20) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS REGULATION:

(**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).

(**3**) 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 (OJ L 116, 5.5.2017, p. 1).

(**4**) 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).

(**5**) Commission Regulation (EU) 2018/1480 of 4 October 2018 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 and correcting Commission Regulation (EU) 2017/776 (OJ L 251, 5.10.2018, p. 1).

(**6**) SCCS/1601/18, http://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_223.pdf

(**7**) Commission Regulation (EU) 2016/1179 of 19 July 2016 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 (OJ L 195, 20.7.2016, p. 11).

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) 2019/1966, Introductory Text.