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 (Text with EEA relevance)

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

(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), the fourth subparagraph of Article 15(2) and Article 31(1) 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. This Regulation implements Regulation (EC) No 1223/2009. Only the Court of Justice of the European Union is entitled to interpret Union law, including Article 15 of Regulation (EC) No 1223/2009.

(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) This Regulation covers the substances which have been 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.

(5) Concerning certain CMR substances for which a request for use in cosmetic products by way of exception has been submitted, it has not been established that all the conditions provided for in the second sentence of Article 15(1) or the second subparagraph of Article 15(2) of Regulation (EC) No 1223/2009 are fulfilled. This concerns Quaternium-15, Chloroacetamide, Dichloromethane, Formaldehyde, Perboric acid and Sodium perborate compounds

(6) The substance Methenamine 3-chloroallylochloride, with the International Nomenclature of Cosmetic Ingredients (INCI) name Quaternium-15, is currently listed in entry 31 of Annex V to Regulation (EC) No 1223/2009 as allowed in a concentration of up to 0,2 % in ready for use preparation. Quaternium-15 is a mixture of cis and trans isomers of which the cis-isomer has been classified as a CMR substance of category 2 by Commission Regulation (EC) No 790/2009[(4)]. The classification became applicable on 1 December 2010. In accordance with the second sentence of Article 15(1) of Regulation (EC) No 1223/2009, a substance classified in 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 cosmetic products. On 13 and 14 December 2011, the SCCS issued a scientific opinion on Quaternium-15 (cis-isomer)[(5)], which concluded that on the basis of the available data the safety of Quaternium-15 for use in cosmetic products cannot be established. In light of the classification of the cis-isomer present in Quaternium-15 as a CMR substance of category 2 and the opinion of the SCCS, Quaternium-15 should be deleted from the list of preservatives allowed in cosmetic products in Annex V to Regulation (EC) No 1223/2009 and added to the list of substances prohibited in cosmetic products in Annex II to that Regulation.

(7) The substance 2-Chloroacetamide, with the INCI name Chloroacetamide, is currently listed in entry 41 of Annex V to Regulation (EC) No 1223/2009 as allowed in a concentration of up to 0,3 % in ready for use preparation. Chloroacetamide has been classified as a CMR substance of category 2 under Regulation (EC) No 1272/2008. The classification became applicable before 1 December 2010, at which date Titles II, III and IV of Regulation (EC) No 1272/2008 became applicable in respect of substances. In accordance with the second sentence of Article 15(1) of Regulation (EC) No 1223/2009, a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in such products. On 22 March 2011, the SCCS issued a scientific opinion on Chloroacetamide[(6)] which concluded that, on the basis of the available data, the substance is not safe for consumers when used in a concentration of up to 0,3 % w/w in cosmetic products. In light of the classification as a CMR substance of category 2 and the opinion of the SCCS, Chloroacetamide should be deleted from the list of preservatives allowed in cosmetic products in Annex V to Regulation (EC) No 1223/2009 and added to the list of substances prohibited in cosmetic products in Annex II to that Regulation.

(8) The substance Dichloromethane is currently listed in entry 7 of Annex III to Regulation (EC) No 1223/2009 as allowed in cosmetic products in a concentration of up to 35 % in ready for use preparation. Dichloromethane has been classified as a CMR substance of category 2 under Regulation (EC) No 1272/2008. The classification became applicable before 1 December 2010. In accordance with the second sentence of Article 15(1) of Regulation (EC) No 1223/2009, a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in such products. On 11 December 2012, the SCCS issued a scientific opinion on Dichloromethane[(7)]. On 25 March 2015, the SCCS issued a new opinion[(8)] which was revised on 28 October 2015. In that revised opinion the SCCS concluded that the use of Dichloromethane in a concentration of up to 35 % in hair sprays and its use in spray formulations in general is not considered safe for the consumer. In light of the classification as a CMR substance of category 2 and the opinion of the SCCS, and since no other uses of Dichloromethane in cosmetic products are known and have been covered by the SCCS opinion, the substance should be deleted from the list of restricted substances in Annex III to Regulation (EC) No 1223/2009 and added to the list of substances prohibited in cosmetic products in Annex II to that Regulation.

(9) The substance Formaldehyde is currently listed in entry 13 of Annex III to Regulation (EC) No 1223/2009 as allowed in nail hardening products in a concentration of up to 5 % in ready for use preparation. It is also currently listed in entry 5 of Annex V to Regulation (EC) No 1223/2009 as allowed in oral products in a concentration of up to 0,1 % and in other products in a concentration of up to 0,2 %. Formaldehyde has been classified as a CMR substance of category 1B by Commission Regulation (EU) No 605/2014[(9)]. The classification became applicable on 1 January 2016. In accordance with the second subparagraph of Article 15(2) of Regulation (EC) No 1223/2009, substances classified as CMR substances of category 1A or 1B may be used in cosmetic products by way of exception where, subsequent to their classification as CMR substances, certain conditions are fulfilled, including the conditions that no suitable alternative substances are available, that an application is made for a particular use of the product category with a known exposure and that the substance has been evaluated and found safe by the SCCS. On 7 November 2014, the SCCS concluded in its opinion[(10)] that 'nail hardeners with a maximum concentration of about 2,2 % free formaldehyde can be used safely to harden or strengthen nails'. However, since it has not been established that there are no suitable alternative substances available for the purpose of hardening nails, Formaldehyde should be deleted from the list of restricted substances in Annex III to Regulation (EC) No 1223/2009. Since no application was made for other uses of Formaldehyde, the substance should be deleted from the list of preservatives allowed in cosmetic products in Annex V to that Regulation. Formaldehyde should also be added to the list of substances prohibited in cosmetic products in Annex II to Regulation (EC) No 1223/2009.

(10) Perboric acid and Sodium perborate compounds are covered by the hydrogen peroxide releasing substances currently listed in entry 12 of Annex III to Regulation (EC) No 1223/2009. They have been classified as CMR substances of category 1B by Regulation (EC) No 790/2009. The classification became applicable by 1 December 2010. A

request for the application of the second subparagraph of Article 15(2) of Regulation (EC) No 1223/2009 was submitted for the use of those substances in oxidative hair dye formulations. On 22 June 2010, the SCCS concluded in its opinion[11] that the 'general restrictions applicable to hydrogen peroxide releasing substances should apply to sodium perborate and perboric acid and that the use of sodium perborates as an ingredient in oxidative hair dye formulations with a maximum on-head concentration of 3 % will not pose a risk to the health of the consumer'. However, since it has not been established that there are no suitable alternative substances available for the purpose of oxidation of hair, Perboric acid and Sodium perborate compounds should be deleted from the list of restricted substances in Annex III to Regulation (EC) No 1223/2009 and added to the list of substances prohibited in cosmetic products in Annex II to that Regulation.

(11) Concerning certain substances which were classified as CMR substances under Regulation (EC) No 1272/2008 and for which a request for the application of the second sentence of Article 15(1) of Regulation (EC) No 1223/2009 has been submitted, it has been established that the condition provided for in that provision is fulfilled. This concerns Trimethylbenzoyl diphenylphosphine oxide, Furfural and Polyaminopropyl biguanide.

(12) The substance Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide, with the INCI name Trimethylbenzoyl diphenylphosphine oxide (TPO), is currently not included in the Annexes to Regulation (EC) No 1223/2009. TPO has been classified as a CMR substance of category 2 by Commission Regulation (EU) No 618/2012[12]. The classification became applicable on 1 December 2013. On 27 March 2014, the SCCS issued a scientific opinion[13] which concluded that TPO is safe when used as a nail modelling product in a concentration of up to 5,0 % but that it is however a moderate skin sensitizer. Considering the skin sensitising properties of TPO and the high risk of exposure through skin contact in case of self-application of nail products, the use of TPO should be restricted to professionals only. In light of those elements, TPO should be added to the list of restricted substances in Annex III to Regulation (EC) No 1223/2009 for professional use in artificial nail systems with a maximum concentration of 5 %.

(13) The substance 2-Furaldehyde, with the INCI name Furfural, is used as a fragrance or flavour ingredient in cosmetic products and is currently not included in the Annexes to Regulation (EC) No 1223/2009. It has been classified as a CMR substance of category 2 under Regulation (EC) No 1272/2008. The classification became applicable before 1 December 2010. On 27 March 2012, the SCCS concluded in its opinion[14] that the use of Furfural in a concentration of up to 10 ppm (0,001 %) in ready for use preparation, including oral products, does not pose any risk to the health of the consumer. In light of the classification of Furfural as a CMR substance of category 2 and the opinion of the SCCS, Furfural should be added to the list of restricted substances in Annex III to Regulation (EC) No 1223/2009 with a maximum concentration of 0,001 %.

(14) The substance Polyhexamethylene biguanide hydrochloride (PHMB), with the INCI name Polyaminopropyl Biguanide, is currently listed as a preservative in entry 28 of Annex V to Regulation (EC) No 1223/2009 with a maximum concentration of 0,3 %.

It has been classified as a CMR substance of category 2 by Commission Regulation (EU) No 944/2013[15]. The classification became applicable on 1 January 2015. On 18 June 2014, the SCCS adopted an opinion[16] which concluded that on the basis of the data available, PHMB is not safe for consumers when used as a preservative in all cosmetic products at a maximum concentration of 0,3 %. However, the SCCS opinion also concluded that the safe use could be based on a lower use concentration and/or restrictions with regard to cosmetic products' categories and that dermal absorption studies on additional representative cosmetic formulations are needed. On 7 April 2017, the SCCS adopted a new opinion[17] which concluded that, based on the data provided, the use of PHMB as a preservative in all cosmetic products up to 0,1 % is safe but that its use in sprayable formulations is not advised. In light of the classification of PHMB as a CMR substance of category 2 and of the new SCCS opinion, PHMB should be authorised as a preservative in all cosmetic products, except in applications that may lead to exposure of the end-user's lungs by inhalation, with a maximum concentration of 0,1 %. The conditions set out in Annex V to Regulation (EC) No 1223/2009 should be adapted accordingly.

(15) Concerning a large group of substances which were classified as CMR substances under Regulation (EC) No 1272/2008, no request for use in cosmetic products by way of exception has been submitted. Those 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. This concerns, inter alia, some boron compounds currently listed in entries 1a and 1b of Annex III to Regulation (EC) No 1223/2009.

(16) Some boron compounds currently listed in entries 1a and 1b of Annex III to Regulation (EC) No 1223/2009 and Dibutyltin hydrogen borate have been classified as CMR substances of category 1B by Regulation (EC) No 790/2009. The classification became applicable by 1 December 2010. In accordance with the second subparagraph of Article 15(2) of Regulation (EC) No 1223/2009, substances classified as CMR substances of category 1A or 1B may be used in cosmetic products by way of exception where, subsequent to their classification as CMR substances, certain conditions are fulfilled. On 22 June 2010, the SCCS issued an opinion[18] which concluded that some of the boron compounds currently listed in entries 1a and 1b of Annex III to that Regulation are safe for use in cosmetics under certain conditions. However, since no application for a particular use was made and since it has not been established that there are no suitable alternative substances available for the purpose of the relevant uses listed in Annex III to Regulation (EC) No 1223/2009, those boron compounds should be deleted from the list of restricted substances in Annex III to that Regulation and added to the list of substances prohibited in cosmetic products in Annex II to Regulation (EC) No 1223/2009. As regards Dibutyltin hydrogen borate, no application for a particular use was made and it has not been found safe by the SCCS. That substance should therefore be added to the list of substances prohibited in cosmetic products in Annex II to Regulation (EC) No 1223/2009.

(17) Article 31(1) of Regulation (EC) No 1223/2009 provides that where there is a potential risk to human health, arising from the use of substances in cosmetic products,

which needs to be addressed on a Community-wide basis, the Commission may, after consulting the SCCS, amend Annexes II to VI to that Regulation accordingly. The Commission has consulted the SCCS on the safety of certain substances which are similar from a chemical perspective to substances classified as CMR substances of categories 1A, 1B or 2. This concerns certain boron compounds as well as Paraformaldehyde and Methylene Glycol.

(18) Certain boron compounds currently listed in entries 1a and 1b of Annex III to Regulation (EC) No 1223/2009, other than those referred to in Recital 16, have not been classified as CMR substances. On 12 December 2013, the SCCS issued an opinion on borates, tetraborates and octaborates[(19)], where it concluded that those substances, as well as other boric acid salts or esters, such as MEA-borate, MIPA-borate, potassium borate, trioctyldodecyl borate and zinc borate, form boric acid in aqueous solutions and that therefore the general restrictions applicable to boric acid should apply to the whole group of borates, tetraborates and octaborates. Boric acid has been classified as a CMR substance of category 1B by Regulation (EC) No 790/2009. The classification became applicable by 1 December 2010. In light of the opinion of the SCCS, the whole group of borates, tetraborates and octaborates, except the substances in that group that have been classified as CMR substances, as well as other boric acid salts or esters, should be deleted from the list of restricted substances in Annex III to Regulation (EC) No 1223/2009 and added to the list of substances prohibited in cosmetic products in Annex II to that Regulation.

(19) The substance Paraformaldehyde is currently listed in entry 5 of Annex V to Regulation (EC) No 1223/2009 but, contrary to Formaldehyde, it has not been classified as a CMR substance. The substance Methylene Glycol is currently not included in the Annexes to Regulation (EC) No 1223/2009. On 26–27 June 2012, the SCCS adopted an opinion on Methylene Glycol[(20)] which established that Methylene Glycol is rapidly reversible under a variety of conditions to form Formaldehyde in aqueous solutions and that Paraformaldehyde can depolymerise to form Formaldehyde by heating or drying. In light of the opinion of the SCCS, there is a potential risk to human health arising from the use of those substances in cosmetic products. Paraformaldehyde should therefore be deleted from the list of preservatives allowed in cosmetic products in Annex V to Regulation (EC) No 1223/2009 and Paraformaldehyde and Methylene Glycol should be added to the list of substances prohibited in cosmetic products in Annex II to that Regulation.

(20) Regulation (EC) No 1223/2009 should therefore be amended accordingly.

(21) 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 (EC) No 790/2009 of 10 August 2009 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 235, 5.9.2009, p. 1).

(**5**) SCCS/1344/10, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_077.pdf.

(**6**) SCCS/1360/10, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_053.pdf.

(**7**) SCCS/1408/11, https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_118.pdf

(**8**) SCCS/1547/15, https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_170.pdf

(**9**) Commission Regulation (EU) No 605/2014 of 5 June 2014 amending, for the purposes of introducing hazard and precautionary statements in the Croatian language and 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 167, 6.6.2014, p. 36).

(**10**) SCCS/1538/14, https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_164.pdf

(**11**) SCCS/1345/10, https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_031.pdf

(**12**) Commission Regulation (EU) No 618/2012 of 10 July 2012 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 179, 11.7.2012, p. 3).

(**13**) SCCS/1528/14, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_149.pdf

(**14**) SCCS/1461/12, https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_083.pdf

(**15**) Commission Regulation (EU) No 944/2013 of 2 October 2013 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 261, 3.10.2013, p. 5).

(**16**) SCCS/1535/14, https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_157.pdf

(**17**) SCCS/1581/16, https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_204.pdf

(**18**) SCCS/1249/09, https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_027.pdf

(**19**) SCCS/1523/13, https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_146.pdf

(**20**) SCCS/1483/12, https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_097.pdf

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) 2019/831, Introductory Text.