Commission Regulation (EU) 2019/681 of 30 April 2019 amending Annex II to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2019/681

of 30 April 2019

amending Annex II 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 31(1) thereof,

Whereas:

(1) The substance 2-Chloro-p-Phenylenediamine, including its sulfate and dihydrochloride salts, is used in formulations for colouring eyebrows and eyelashes in a maximum concentration of 4,6 %. The Scientific Committee on Consumer Safety (SCCS) stated in its opinion of 19 September 2013[(2)] ('the SCCS opinion') that no sufficient margin of safety could be deduced for the use of 2-Chloro-p-Phenylenediamine in oxidative hair dye formulations for eyebrows and eyelashes in a concentration of maximum 4,6 %. The SCCS further stated that it was not possible to give a conclusion on the genotoxic potential of 2-Chloro-p-Phenylenediamine based on the available data and the lack of a proper in vivo test for gene mutation induction. Therefore, the SCCS did not consider the use of 2-Chloro-p-Phenylenediamine safe for the consumer. The SCCS has subsequently clarified that it is of the opinion that sulfate and dihydrochloride salts of 2-Chloro-p-Phenylenediamine should be handled with the same caution as 2-Chloro-p-Phenylenediamine until proven to be safe, because they have the same core structure, including genotoxic potential, as 2-Chloro-p-Phenylenediamine. Moreover, the SCCS has clarified that the scope of the SCCS opinion and its conclusion can be extended to the hair on the head[(3)].

(2) In light of the SCCS opinion, and the subsequent clarification by SCCS, there is a potential risk to human health arising from the use of 2-Chloro-p-Phenylenediamine, its sulfate and dihydrochloride salts in products for colouring eyebrows and eyelashes. With regard to products for colouring the hair on the head, the exposure to the substance is even higher, since those products are applied to a larger surface of the body. On that basis, and in light of the clarification by SCCS, there is also a potential risk to human health arising from the use of 2-Chloro-p-Phenylenediamine, its sulfate and dihydrochloride salts in products for colouring the hair of the head. Therefore, 2-Chloro-p-Phenylenediamine, its sulfate and dihydrochloride salts should be prohibited

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2019/681. (See end of Document for details)*

in hair dye products, including eyebrow dye products, and in eyelash dye products and added in the list of prohibited substances in Annex II to Regulation (EC) No 1223/2009.

(3) It is appropriate to provide for reasonable periods of time in order for the industry to adapt to the new prohibition. When determining the length of those periods, the interest of the economic operators should be balanced against the specific health risk factors identified.

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

(5) 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

Annex II to Regulation (EC) No 1223/2009 is amended in accordance with the Annex to this Regulation.

Article 2

From 22 November 2019 hair dye products, including eyebrow dye products, and eyelash dye products containing the substances prohibited by this Regulation shall not be placed on the Union market.

From 22 February 2020 hair dye products, including eyebrow dye products, and eyelash dye products containing the substances prohibited by this Regulation shall not be made available on the Union market.

Article 3

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, 30 April 2019.

For the Commission

The President

Jean-Claude JUNCKER