Commission Regulation (EU) 2019/698 of 30 April 2019 amending Annexes 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) 2019/698

of 30 April 2019

amending Annexes 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 31(1) thereof,

Whereas:

(1) The substance 1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one, which has been assigned the name Climbazole under the International Nomenclature of Cosmetic Ingredients (INCI), is currently allowed as a preservative in cosmetic products at a maximum concentration of 0,5 % in ready for use preparation. It is listed in entry 32 of Annex V to Regulation (EC) No 1223/2009. In accordance with Article 14(1)(d)(ii) of Regulation (EC) No 1223/2009, Climbazole may also be contained in cosmetic products for an intended use other than as preservative, only within the concentration limit laid down in entry 32 of Annex V.

(2) The Scientific Committee on Consumer Safety (SCCS) concluded at its plenary meeting on 21-22 June 2018, in an addendum to its earlier opinions on Climbazole[(2)], that, under an aggregate exposure scenario, Climbazole is safe when used as a preservative in face cream, hair lotion and foot care products at a maximum concentration of 0,2 % and when used as a preservative in rinse-off shampoo at a maximum concentration of 0,5 %.

(3) The SCCS also concluded that, under an aggregate exposure scenario, Climbazole is safe when used as an anti-dandruff agent in rinse-off shampoo at a maximum concentration of 2 %.

(4) In light of the addendum, there is a potential risk to human health arising from the use of Climbazole as a preservative or as a non-preservative at the currently allowed maximum concentration of 0,5 % in all cosmetic products. The use of Climbazole as a preservative should therefore only be allowed in face cream, hair lotion, foot care products and rinse-off shampoo. The maximum concentration should be 0,2 % for face cream, hair lotion and foot care products and 0,5 % for rinse-off shampoo.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2019/698. (See end of Document for details)*

(5) The use of Climbazole as a non-preservative should be restricted to rinse-off shampoo, when the substance is used as an anti-dandruff agent. For such use, the maximum concentration should be 2 %.

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

(7) The industry should be allowed a reasonable period of time to adapt to the new requirements by making the necessary adjustments to product formulations to ensure that only products complying with the new requirements are placed on the market. The industry should also be allowed a reasonable period of time to withdraw products which do not comply with the new requirements from the market.

(8) 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 III to Regulation (EC) No 1223/2009 is amended in accordance with Annex I to this Regulation.

Article 2

In Annex V to Regulation (EC) No 1223/2009, entry 32 is replaced by the text set out in Annex II to this Regulation.

Article 3

1 From 27 November 2019 cosmetic products containing 1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one for other than preservation purposes and not complying with the restrictions laid down in this Regulation shall not be placed on the Union market.

From 27 February 2020 cosmetic products containing 1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one for other than preservation purposes and not complying with the restrictions laid down in this Regulation shall not be made available on the Union market.

2 From 27 November 2019 cosmetic products containing 1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one for preservation purposes and not complying with the conditions laid down in this Regulation shall not be placed on the Union market.

From 27 February 2020 cosmetic products containing 1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one for preservation purposes and not complying with the conditions laid down in this Regulation shall not be made available on the Union market.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 2 shall apply from 27 November 2019.

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