II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2018/1847

of 26 November 2018

amending Annex 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 Biphenyl-2-ol and its salts, which have been assigned the names o-phenylphenol, MEA o-phenylphenate, potassium o-phenylphenate and sodium o-phenylphenate under the International Nomenclature of Cosmetics Ingredients (INCI), are currently allowed as preservatives in cosmetic products with a maximum concentration of 0,2 % (as phenol) in ready for use preparation under entry 7 of Annex V to Regulation (EC) No 1223/2009.

(2) The Scientific Committee on Consumer Safety (SCCS) concluded in its opinion of 25 June 2015, revision of 15 December 2015, ([2]) as regards the use of o-phenylphenol as a preservative, that a maximum concentration of 0,2 % in leave-on cosmetic products is not safe, while a maximum concentration of 0,15 % in such products can be considered safe, and that a maximum concentration of 0,2 % in rinse-off cosmetic products is considered safe. The SCCS also concluded that there might be a potential of injury to the vision system attributable to o-phenylphenol.

(3) Following concerns raised by several Member States regarding the use of MEA o-phenylphenate, potassium o-phenylphenate and sodium o-phenylphenate, the SCCS indicated in an addendum to the above-mentioned opinion, adopted on 21-22 February 2018, ([3]) that the same conclusions on the safe use levels of o-phenylphenol cannot be applied as such to sodium o-phenylphenate, potassium o-phenylphenate or MEA o-phenylphenate. The SCCS stated that sodium o-phenylphenate, potassium o-phenylphenate and MEA o-phenylphenate may have potentially more potent toxic effects than o-phenylphenol due to greater skin penetration. The SCCS concluded that a potential risk to human health from the use of these substances as preservatives in cosmetic products cannot be excluded.

(4) In light of the above-mentioned SCCS opinions and in view of the potential risk to human health arising from the use of those substances, the use of o-phenylphenol as a preservative should be allowed with a maximum

([1]) OJ L 342, 22.12.2009, p. 59.
([2]) SCCS (Scientific Committee on Consumer Safety), Opinion on o-Phenylphenol, Sodium o-phenylphenate and Potassium o-phenylphenate, 25 June 2015, SCCS/1555/15, revision of 15 December 2015
([3]) SCCS (Scientific Committee on Consumer Safety), Addendum to the scientific opinion on the use as preservative of o-Phenylphenol, Sodium ophenylphenate and Potassium o-phenylphenate (SCCS/1555/15) Here: the use as preservative of Sodium o-phenylphenate, Potassium o-phenylphenate, MEA o-Phenylphenate 21-22/02/2018, SCCS/1597/18

concentration of 0,15 % in leave-on and 0,2 % in rinse-off cosmetic products. In addition, it should be indicated that contact with eyes should be avoided. The use of sodium o-phenylphenate, potassium o-phenylphenate and MEA o-phenylphenate as preservatives should not be allowed.

(5) Annex V to Regulation (EC) No 1223/2009 should therefore be amended accordingly.

(6) 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 those 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.

(7) 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

In Annex V to Regulation (EC) No 1223/2009, entry 7 is replaced by the text set out in the Annex to this Regulation.

Article 2

1. From 17 June 2019 cosmetic products containing Biphenyl-2-ol and not complying with the conditions laid down in this Regulation shall not be placed on the Union market.

From 17 September 2019 cosmetic products containing Biphenyl-2-ol and not complying with the conditions laid down in this Regulation shall not be made available on the Union market.

2. From 17 June 2019 cosmetic products containing Sodium 2-biphenylate, Potassium 2-biphenylate or 2-aminoethan-1-ol; 2-phenylphenol as preservatives shall not be placed on the Union market.

From 17 September 2019 cosmetic products containing Sodium 2-biphenylate, Potassium 2-biphenylate or 2-aminoethan-1-ol; 2-phenylphenol as preservatives 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*.

Article 1 shall apply from 17 June 2019.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 26 November 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Reference number	Substance Identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
‘7	Biphenyl-2-ol (*)	o-Phenylphenol	90-43-7	201-993-5	(a) Rinse-off Products (b) Leave-on products	(a) 0,2 % (as phenol) (b) 0,15 % (as phenol)		Avoid contact with eyes

(*) From 17 June 2019 cosmetic products containing Biphenyl-2-ol and not complying with those conditions shall not be placed on the Union market. From 17 September 2019 cosmetic products containing Biphenyl-2-ol and not complying with those conditions shall not be made available on the Union market.’