Commission Regulation (EU) No 866/2014 of 8 August 2014 amending Annexes III, V and VI to Regulation (EC) No 1223/2009 of the European Parliament and the Council on cosmetic products (Text with EEA relevance)

COMMISSION REGULATION (EU) No 866/2014

of 8 August 2014

amending Annexes III, V and VI to Regulation (EC) No 1223/2009 of the European Parliament and 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(2) thereof,

Whereas:

(1) The substances identified by the denominations alkyl (C_{12-22}) trimethyl ammonium bromide and chloride are regulated as preservatives under entry 44 of Annex V to Regulation (EC) No 1223/2009 with a maximum concentration of 0,1 %.

(2) The Scientific Committee on Consumer Products ('SCCP'), subsequently replaced by the Scientific Committee on Consumer Safety ('SCCS') pursuant to Commission Decision 2008/721/EC[(2)], evaluated the safety of alkyl (C_{16}, C_{18}, C_{22}) trimethylammonium chloride (cetrimonium chloride, steartrimonium chloride and behentrimonium chloride) for other uses than as preservatives in 2005, 2007 and 2009.

(3) The SCCS concluded in its opinion of 8 December 2009[(3)] that, apart from the fact that quaternary ammonium derivative formulations have the potential to be skin irritants, especially when combinations of the concerned compounds are used, the use of cetrimonium chloride, steartrimonium chloride and behentrimonium chloride does not pose a risk to the health of the consumer in concentrations below certain limits, which are explicitly set out in the SCCS opinion.

(4) In order to take into account the skin irritation potential of the combinations of the quaternary ammonium derivatives mentioned above, the Commission considers that, while allowing the use of these substances for other uses than as preservatives at higher concentrations, the sums of these substances should be restricted to the maximum concentration indicated by the SCCS for the individual substances.

(5) The maximum concentrations indicated by the SCCS as safe for leave-on facial cream products should apply to all leave-on face products, as there is no reason to limit authorisation of those substances to leave-on face creams only.

(6) New entries in Annex III to Regulation (EC) No 1223/2009 should therefore be added to reflect the above-mentioned considerations, and entry 44 in Annex V should cross-refer to the new entries in Annex III, so that those Annexes are adapted to technical and scientific progress.

(7) The SCCS evaluated the safety of the mixture citric acid (and) silver citrate. In its opinion of 13 October 2009[(4)], it stated that, on the basis of the data submitted, the use of that mixture as a preservative in cosmetic products, at a concentration up to 0,2 % (corresponding to a silver concentration of 0,0024 %), does not pose a risk to the health of the consumer. The Committee specified that the substance was safe when used at the same maximum concentration in deodorants and anti-perspirants, as a preservative and/or an active ingredient. Its use in oral and eye products was, however, explicitly excluded given that only dermal exposure was assessed.

(8) A new entry in Annex V to Regulation (EC) No 1223/2009 should be added to reflect the above-mentioned considerations and to adapt it to technical and scientific progress.

(9) The SCCS assessed tris-biphenyl triazine, which is a UV-filter and a nanomaterial. In its opinion of 20 September 2011[(5)], it concluded that dermal exposure to formulations containing tris-biphenyl triazine with a mean particle size (median primary particle size) of 81 nm results in low absorption of that substance. Also after oral exposure, absorption of tris-biphenyl triazine is low. No systemic effects are observed after oral or dermal exposure up to 500 mg/kg bw/day. The data analysed by the SCCS leads to the conclusion that the use of 10 % tris-biphenyl triazine, including as nanomaterial, as a UV-filter in cosmetic products can be considered safe for dermal application.

(10) However, the SCCS clarified that, at the time of the risk assessment, there was too much uncertainty to conclude about safe use of 10 % tris-biphenyl triazine in spray applications, because of concerns over possible inhalation exposure. Therefore, the SCCS concluded that spray products containing tris-biphenyl triazine cannot be recommended until additional information on safety after repeated inhalation is provided.

(11) In light of the SCCS opinion and taking into account that the use of nanomaterials can improve the efficiency of UV-filters, Annex VI to Regulation (EC) No 1223/2009 should be amended for the purpose of adapting it to technical and scientific progress.

(12) 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

Annexes III, V and VI to Regulation (EC) No 1223/2009 are amended in accordance with the Annex to this Regulation.

Article 2

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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 866/2014. (See end of Document for details)*

[X1ANNEX

Editorial Information

X1 Substituted by Corrigendum to Commission Regulation (EU) No 866/2014 of 8 August 2014 amending Annexes III, V and VI to Regulation (EC) No 1223/2009 of the European Parliament and the Council on cosmetic products (Official Journal of the European Union L 238 of 9 August 2014).

Annexes III, V and VI to Regulation (EC) No 1223/2009 are amended as follows:

(1) In Annex III, the following entries 286 and 287 are added:

	Substance Identification				Conditions			
Reference number	**Chemical name/ INN**	**Name of Common Ingredients Glossary**	**CAS number**	**EC number**	**Product type, Body parts**	**Maximum concentration in ready for use preparation**	**Other**	**Wording of conditions of use and warnings**
a	**b**	**c**	**d**	**e**	**f**	**g**	**h**	**i**
‘286	C_{16}-alkyltrimethylammonium chloride	Cetrimonium chloride”	112-02-7	203-928-6	(a) rinse-off hair products	(a) 2,5 % for the individual concentrations or the sum of the individual concentrations of cetrimonium chloride and steartrimonium chloride	For purposes other than inhibiting the development of micro-organisms in the product. The purpose has to be apparent from the presentation of the product.	
	C_{18}-alkyltrimethylammonium chloride	Steartrimonium chloride”	112-03-8	203-929-1				
					(b) leave-on hair products	(b) 1,0 % for the individual concentrations or the sum of the individual concentrations of		

a For use as a preservative, see Annex V, entry No 44.’

						cetrimonium chloride and steartrimonium chloride		
					(c) on face products	(c) 0,5 % for the individual concentrations or the sum of the individual concentrations of cetrimonium chloride and steartrimonium chloride		
287	C_{22}-alkyltrimethylammonium chloride	Behentrimonium chloride	17301-53-0	241-327-0	(a) off hair products	(a) 5,0 % for the individual concentration of behentrimonium chloride or the sum of the individual concentrations of cetrimonium chloride, steartrimonium chloride and behentrimonium chloride, while at the same time respecting the relevant	For purposes other than inhibiting the development of micro-organisms in the product. The purpose has to be apparent from the presentation of the product.	

a For use as a preservative, see Annex V, entry No 44.'