

REGULATIONS

COMMISSION REGULATION (EU) 2016/1198

of 22 July 2016

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) Methylisothiazolinone is authorised as a preservative in cosmetic products at concentrations up to 0,01 % weight/weight (100 ppm) through entry 57 of Annex V to Regulation (EC) No 1223/2009.
- (2) The Scientific Committee on Consumer Safety (SCCS) adopted an opinion on the safety of methylisothiazolinone (sensitisation only) on 12 December 2013 ⁽²⁾.
- (3) The SCCS concluded that current clinical data indicate that the concentration of 100 ppm of methylisothiazolinone in cosmetic products is not safe for the consumer. For leave-on cosmetic products (including 'wet wipes'), no safe concentrations of methylisothiazolinone for induction of contact allergy or elicitation have been adequately demonstrated.
- (4) In light of the SCCS opinion mentioned above, it is important to address the increased incidence of allergies induced by methylisothiazolinone and this substance should therefore be banned in leave-on products.
- (5) Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (6) The application of the above-mentioned ban should be deferred to allow the industry to make the necessary adjustments to product formulations. In particular, undertakings should be granted six months to place on the market compliant products and to withdraw from the market non-compliant products after the entry into force of this Regulation.
- (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

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

⁽¹⁾ OJ L 342, 22.12.2009, p. 59.

⁽²⁾ SCCS/1521/13 Revision of 27 March 2014.

Article 2

From 12 February 2017 only cosmetic products which comply with this Regulation shall be placed and 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, 22 July 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Annex V to Regulation (EC) No 1223/2009, entry 57 is replaced by the following:

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
'57	2-Methyl-2H-isothiazol-3-one	Methylisothiazolinone ⁽¹⁾	2682-20-4	220-239-6	Rinse-off products	0,01 %		

⁽¹⁾ Methylisothiazolinone is also regulated in entry 39 of Annex V in a mixture with methylchloroisothiazolinone. The two entries are mutually exclusive: the use of the mixture of Methylchloroisothiazolinone (and) Methylisothiazolinone is incompatible with the use of Methylisothiazolinone alone in the same product.'