Commission Regulation (EU) 2018/885 of 20 June 2018 amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2018/885

of 20 June 2018

amending Annex VI 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(2) thereof,

Whereas:

(1) 2,2′-Methylene-bis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethyl-butyl)phenol)/ Bisoctrizole with the International Nomenclature of Cosmetic Ingredients name Methylene Bis-Benzotriazolyl Tetramethylbutylphenol (MBBT) is authorised for use as a UV-filter in cosmetic products under entry 23 of Annex VI to Regulation (EC) No 1223/2009. The use of MBBT (nano) as a UV-filter in cosmetic products is currently not regulated.

(2) In its opinion of 25 March 2015[(2)], the Scientific Committee on Consumer Safety (SCCS) concluded that the use of MBBT (nano) as a UV-filter, with the characteristics as indicated in the opinion and at a concentration up to 10 % w/w in dermally applied cosmetic products does not pose a risk to human health after application on healthy, intact skin and also damaged skin. The characteristics indicated by the SCCS in that opinion relate to the physico-chemical properties of the material (such as purity, median particle size, number size distribution).

(3) The SCCS also considered that the conclusions of its opinion of 25 March 2015 do not apply to applications that might lead to the exposure of the end-user's lungs to MBBT (nano) by inhalation.

(4) In light of the SCCS opinion and in order to take into account technical and scientific progress, the use of MBBT (nano) as a UV-filter in cosmetic products, according to the SCCS's specifications, should be authorised at a maximum concentration of 10 % w/w, except in applications that may lead to the exposure of the end-user's lungs to MBBT (nano) by inhalation.

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

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/885. (See end of Document for details)*

(6) 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 VI to Regulation (EC) No 1223/2009 is 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.

Done at Brussels, 20 June 2018.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

Annex VI to Regulation (EC) No 1223/2009 is amended as follows:

(1) entry 23 is replaced by the following entry:

Reference Number	Substance identification				Conditions			Wording of conditions of use and warnings
	Chemical name/ INN/ XAN	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
‘23	2,2′-Methylenebis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol)/ Bisoctrizole	Methylene Bis-Benzotriazolyl Tetramethylbutylphenol	103597-45-1	403-800-1		10 %[a]		

a In case of combined use of Methylene Bis-Benzotriazolyl Tetramethylbutylphenol and Methylene Bis-Benzotriazolyl Tetramethylbutylphenol (nano), the sum shall not exceed the limit given in column g.’;

(2) entry 23a is inserted:

Reference Number	Substance identification				Conditions			Wording of conditions of use and warnings
	Chemical name/ INN/ XAN	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
‘23a	2,2′-Methylenebis-	Methylene Bis-	103597-45-1	403-800-1		10 %[a]	Not to be	

a In case of combined use of Methylene Bis-Benzotriazolyl Tetramethylbutylphenol and Methylene Bis-Benzotriazolyl Tetramethylbutylphenol (nano), the sum shall not exceed the limit given in column g.’.