Commission Regulation (EU) 2016/1143 of 13 July 2016 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) 2016/1143

of 13 July 2016

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) Titanium dioxide is authorised both as a colorant under entry 143 of Annex IV to Regulation (EC) No 1223/2009 and as a UV-filter under entry 27 of Annex VI to that Regulation. In accordance with point (3) of the Preamble to Annexes II to VI to Regulation (EC) No 1223/2009, the substances listed in Annexes III to VI to that Regulation do not cover nanomaterials, except where specifically mentioned. Titanium dioxide (nano) is currently not regulated.

(2) According to the opinion of the Scientific Committee on Consumer Safety ('SCCS') of 22 July 2013, which was revised on 22 April 2014[(2)], the use of titanium dioxide (nano) as a UV-filter in sunscreens, with the characteristics as indicated in the opinion, and at a concentration up to 25 % w/w, can be considered to not pose any risk of adverse effects in humans after application on healthy, intact or sunburnt skin. In addition, considering the absence of a systemic exposure, the SCCS considers that the use of titanium dioxide (nano) in dermally applied cosmetic products should not pose any significant risk to the consumer.

(3) The characteristics indicated by the SCCS in its opinion concern the physico-chemical properties of the material (such as purity, structure and physical appearance, particle number size distribution, aspect ratio, volume specific surface area and photocatalytic activity) and whether it is uncoated or coated with specific chemicals. Therefore, these physico-chemical properties and requirements regarding coatings should be reflected in Regulation (EC) No 1223/2009.

(4) The SCCS also considered that, on the basis of available information, the use of titanium dioxide (nano) in spray products cannot be considered safe. In addition, the SCCS indicated, in a further opinion of 23 September 2014 for clarification of the meaning of the term 'sprayable applications/products' for the nano forms of carbon black CI 77266,

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titanium dioxide and zinc oxide[3], that its concern is limited to spray applications that might lead to exposure of the consumer's lungs to titanium dioxide (nano) by inhalation.

(5) In light of the SCCS opinions mentioned above, titanium dioxide (nano), according to the SCCS's specifications, should be authorised for use as a UV-filter in cosmetic products at a maximum concentration of 25 % w/w, except in applications that may lead to exposure of the end-user's lungs by inhalation.

(6) Annex VI to Regulation (EC) No 1223/2009 should be amended for the purpose of adapting it to technical and scientific progress.

(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 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, 13 July 2016.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

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

(1) entry 27 is replaced by the following entry:

	Substance Identification				Conditions			
Reference number	**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**	**Wording of conditions of use and warnings**
a	**b**	**c**	**d**	**e**	**f**	**g**	**h**	**i**
‘27	Titanium dioxide[a]	Titanium Dioxide	13463-67-7/ 1317-70-0/ 1317-80-2	236-675-5/ 215-280-1/ 215-282-2		25 %[b]		

a For use as a colorant, see Annex IV, No 143.

b In case of combined use of Titanium Dioxide and Titanium Dioxide (nano), the sum shall not exceed the limit given in column g.’;

(2) entry 27a is inserted:

	Substance Identification				Conditions			
Reference number	**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**	**Wording of conditions of use and warnings**
a	**b**	**c**	**d**	**e**	**f**	**g**	**h**	**i**
‘27a	Titanium dioxide[a]	Titanium Dioxide (nano)	13463-67-7/ 1317-70-0/ 1317-80-2	236-675-5/ 215-280-1/ 215-282-2		25 %[b]	Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation	

a For use as a colorant, see Annex IV, No 143.

b In case of combined use of Titanium Dioxide and Titanium Dioxide (nano), the sum shall not exceed the limit given in column g.’

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							Only nanomaterials having the following characteristics are allowed: — purity ≥ 99 %, — rutile form, or rutile with up to 5 % anatase, with crystalline structure and physical appearance as clusters of spherical, needle, or lanceolate shapes, — median particle size based on number size distribution ≥ 30 nm, — aspect ratio from 1	

a For use as a colorant, see Annex IV, No 143.

b In case of combined use of Titanium Dioxide and Titanium Dioxide (nano), the sum shall not exceed the limit given in column g.'