



Brussels, **XXX**  
[...] (2019) **XXX** draft

**COMMISSION REGULATION (EU) .../...**

**of **XXX****

**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) .../...

of **XXX**

## 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<sup>1</sup>, and in particular Article 31(2) thereof,

Whereas:

- (1) Titanium dioxide is currently allowed as a UV-filter in cosmetic products, including in the form of nanomaterial. Titanium dioxide (nano) is listed in entry 27a of Annex VI to Regulation (EC) No 1223/2009. It is allowed at a maximum concentration of 25 % in ready for use preparation, except in applications that may lead to exposure of the end user's lungs by inhalation and subject to the characteristics listed in the entry.
- (2) The characteristics listed in entry 27a of Annex VI concern the allowed physico-chemical properties of titanium dioxide (nano) and the substances with which it can be coated.
- (3) The Scientific Committee on Consumer Safety (SCCS) concluded in an opinion of 7 March 2017, corrected on 22 June 2018<sup>2</sup>, that the use of the three forms of titanium dioxide (nano) under assessment, coated with either silica and cetyl phosphate (up to 16 % and 6 %, respectively), alumina and manganese dioxide (up to 7 % and 0,7 %, respectively), or alumina and triethoxycaprylylsilane (up to 3 % and 9 %, respectively), can be considered safe for use in cosmetic products intended for application on healthy, intact or sunburnt skin. The SCCS added that this conclusion, however, does not apply to applications that might lead to exposure of the consumer's lungs to the titanium dioxide nanoparticles through the inhalation route (such as powders or sprayable products).
- (4) The SCCS also concluded that the ingredients used in some type of products (e.g. in lipsticks) may be incidentally ingested. The potential harmful effects of manganese dioxide should therefore be taken into account if the manganese dioxide-coated nanomaterials are to be used for applications that could lead to oral ingestion.
- (5) In light of the SCCS opinion and in order to take into account technical and scientific progress, the three combinations of coatings at their respective concentration limits as assessed by the SCCS should be allowed for use with titanium dioxide (nano) as a

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<sup>1</sup> OJ L 342, 22.12.2009, p. 59.

<sup>2</sup> SCCS/1580/16, final version of 7 March 2017, corrigendum of 22 June 2018.

UV-filter, subject to the other conditions listed in entry 27a of Annex VI to Regulation (EC) No 1223/2009.

- (6) However, there is a potential risk to human health arising from the ingestion of manganese dioxide. Therefore, the combination of coatings alumina and manganese dioxide should not be allowed for use in lip products, as they are ingested to some extent. Moreover, consumers may also apply some face products, such as sunscreens intended for application on the face, on the lips under reasonably foreseeable conditions of use. The application of face products on the lips leads to ingestion of the product to some extent. Therefore, face products containing the combination of coatings alumina and manganese dioxide should bear a warning against the use of these products on the lips.
- (7) Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (8) 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,

*For the Commission  
The President  
Jean-Claude Juncker*



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ANNEX

**ANNEX**

**to the**

**Commission Regulation (EU) .../...**

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**ANNEX**

Entry 27a of Annex VI to Regulation (EC) No 1223/2009 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
'27a	Titanium dioxide (*)	Titanium Dioxide (nano)	13463-67-7/ 1317-70-0/ 1317-80-2	236-675-5/ 215-280-1/ 215-282-2		25 % (**)	<p>Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.</p> <p>Only nanomaterials having the following characteristics are allowed:</p> <ul style="list-style-type: none"> <li>— purity <math>\geq</math> 99 %,</li> <li>— rutile form, or rutile</li> </ul>	<p><b>For face products containing Titanium Dioxide (nano) coated with the combination Alumina and Manganese Dioxide :</b></p>

						<p>with up to 5 % anatase, with crystalline structure and physical appearance as clusters of spherical, needle, or lanceolate shapes,</p> <ul style="list-style-type: none"> <li>— median particle size based on number size distribution <math>\geq 30</math> nm,</li> <li>— aspect ratio from 1 to 4,5, and volume specific surface area <math>\leq 460</math> m<sup>2</sup>/cm<sup>3</sup>,</li> <li>— coated with Silica, Hydrated Silica, Alumina, Aluminium Hydroxide, Aluminium Stearate, Stearic Acid, Trimethoxycaprylylsilane, Glycerin, Dimethicone, Hydrogen Dimethicone, Simethicone,</li> </ul> <p><b>or coated with one of the following</b></p>	<p><b>Not to be used on the lips.</b></p>
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							<b>combinations:</b> <ul style="list-style-type: none"><li>- <b>Silica at a maximum concentration of 16 % and Cetyl Phosphate at a maximum concentration of 6%,</b></li><li>- <b>Alumina at a maximum concentration of 7 % and Manganese Dioxide at a maximum concentration of 0,7 % (not to be used in lip products),</b></li><li>- <b>Alumina at a maximum concentration of 3 % and</b></li></ul>	
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							<p><b>Triethoxycaprylylsilane at a maximum concentration of 9 %,</b></p> <p>— photocatalytic activity <math>\leq 10 \%</math> compared to corresponding non-coated or non-doped reference,</p> <p>— nanoparticles are photostable in the final formulation.</p>	
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(\* ) For use as a colorant, see Annex IV, No 143.

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