



Brussels, **XXX**  
[...] (2015) **XXX** draft

ANNEX 1

**ANNEX**

**to the**

**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**

**ANNEX**

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

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

Reference number	Substance Identification				Restrictions			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
27	Titanium dioxide <sup>(2)</sup>	Titanium Dioxide	13463-67-7/ 1317-70-0/ 1317-80-2	236-675-5/ 205-280-1 / 215-282-2		25 % (x)		

<sup>(2)</sup> For use as a colorant, see Annex IV, No. 143.

(2) entry 27a is inserted:

Reference number	Substance Identification				Restrictions			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
'27a	Titanium dioxide (2)	Titanium Dioxide (nano)	13463-67-7/ 1317-70-0/ 1317-80-2	236-675-5/ 205-280-1/ 215-282-2		25 % (x)	<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 with up to 5 % anatase, with crystalline structure and physical appearance as clusters of spherical, needle, or lanceolate shapes;</li> <li>- Median particle size based</li> </ul>	

						<p>on number size distribution <math>\geq 30</math> nm;</p> <ul style="list-style-type: none"> <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, stearate, stearic acid, trimethoxycaprylylsilane, glycerin, dimethicone, dimethicone/methicone copolymer, simethicone;</li> <li>- Photocatalytic activity <math>\leq 10</math> % compared to corresponding non-coated or non-doped reference;</li> <li>- Nanoparticles are photostable in the final formulation.'</li> </ul>	
--	--	--	--	--	--	--	--

<sup>(2)</sup> For use as a colorant, see Annex IV, No. 143.

<sup>(x)</sup> In case of combined use of Titanium Dioxide and Titanium Dioxide (nano), the sum shall not exceed the limit given in column g.