

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2016/1143. (See end of Document for details)

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				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
'27	Titanium dioxide ^a	Titanium Dioxide	13463-67236-675-5/ 1317-70-015-280-1/ 1317-80-215-282-2			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:

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 ^a	Titanium Dioxide (nano)	13463-67236-675-5/ 1317-70-015-280-1/ 1317-80-215-282-2			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

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									to 4,5, and volume specific surface area ≤ 460 $\text{m}^2/$ cm^3 , coated with Silica, Hydrated Silica, Alumina, Aluminium Hydroxide, Aluminium Stearate, Stearic Acid, Trimethoxycaprylylsilane, Glycerin, Dimethicone, Hydrogen Dimethicone, Simethicone; photocatalytic activity ≤ 10 % compared to corresponding non- coated or non- doped reference, nanoparticles are photostable in the final formulation.
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