

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2019/1857. (See end of Document for details)

ANNEX

Entry 27a of Annex VI to Regulation (EC) No 1223/2009 is replaced by the following entry:

Reference	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)	13463-67-2	236-675-6	015-288-023	1%-282-	Not to be used in application that may lead to exposure of the end-user's lungs by inhalation. Only nanomaterials having the following characteristics are allowed:	For face products containing Titanium Dioxide (nano) coated with the combination Alumina and Manganese Dioxide: Not to be used on the lips. purity \geq 99%, rutile form, or rutile with up to 5

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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								% 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 to 4,5, and volume specific surface area ≤ 460 m ² / cm ³ , coated with Silica, Hydrated Silica, Alumina, Aluminium
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							Hydroxide, Aluminium Stearate, Stearic Acid, Trimethoxycaprylsilane, Glycerin, Dimethicone, Hydrogen Dimethicone, Simethicone, or coated with one of the following combinations: — Silica at a maximum concentration of 16 % and Cetyl Phosphate at a maximum concentration of 6 %, — Alumina at a maximum concentration of 7 % and Manganese Dioxide at a maximum
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							concentration of 0,7 % (not to be used in lip products), Alumina at a maximum concentration of 3 % and Triethoxycaprylylsilane at a maximum concentration of 9 %, photocatalytic activity \leq 10 % compared to corresponding non-coated or non-doped reference, nanoparticles are photostable in the final formulation.
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