



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

ANNEX

ANNEX

to the

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

**amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and
of the Council on cosmetic products**

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"> — purity \geq 99 %, — rutile form, or rutile 	<p>For face products containing Titanium Dioxide (nano) coated with the combination Alumina and Manganese Dioxide :</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"> — median particle size based on number size distribution ≥ 30 nm, — aspect ratio from 1 to 4,5, and volume specific surface area ≤ 460 m²/cm³, — coated with Silica, Hydrated Silica, Alumina, Aluminium Hydroxide, Aluminium Stearate, Stearic Acid, Trimethoxycaprylylsilane, Glycerin, Dimethicone, Hydrogen Dimethicone, Simethicone, <p>or coated with one of the following</p>	<p>Not to be used on the lips.</p>
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							combinations: <ul style="list-style-type: none">- 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 concentration of 0,7 % (not to be used in lip products),- Alumina at a maximum concentration of 3 % and	
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							<p>Triethoxycaprylylsilane at a maximum concentration of 9 %,</p> <p>— photocatalytic activity $\leq 10 \%$ 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.’