



Council of the  
European Union

072233/EU XXVI. GP  
Eingelangt am 19/07/19

Brussels, 19 July 2019  
(OR. en)

11367/19  
ADD 1

MI 587  
ENT 177  
CONSUM 219  
ECO 86  
ENV 704  
CHIMIE 101

#### COVER NOTE

---

From:	European Commission
date of receipt:	18 July 2019
To:	General Secretariat of the Council
No. Cion doc.:	D062619/01
Subject:	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

---

Delegations will find attached document D062619/01.

---

Encl.: D062619/01



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**

D062619/01

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 % (**)	Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.  Only nanomaterials having the following characteristics are allowed:	<b>For face products containing Titanium Dioxide (nano) coated with the combination Alumina and Manganese</b>

							<ul style="list-style-type: none"> <li>— purity <math>\geq 99</math> %,</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 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,</li> </ul>	<p><b>Dioxide :</b></p> <p><b>Not to be used on the lips.</b></p>
--	--	--	--	--	--	--	---	---

							<p>Simethicone, <b>or coated with one of the following combinations:</b></p> <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></ul>	
--	--	--	--	--	--	--	--	--

							<ul style="list-style-type: none"> <li>- <b>Alumina at a maximum concentration of 3 % and Triethoxycaprylylsilane at a maximum concentration of 9 %,</b></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>	
--	--	--	--	--	--	--	---	--

(\*) 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.’