Council of the
European Union

Brussels, 15 September 2020
(OR. en)

10771/20
ADD 1

DENLEG 56
FOOD 11
SAN 304

COVER NOTE

From:	European Commission
date of receipt:	10 September 2020
To:	General Secretariat of the Council
No. Cion doc.:	D066794/04 ANNEX
Subject:	ANNEX to the COMMISSION REGULATION (EU) …/… amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for titanium dioxide (E 171)

Delegations will find attached document D066794/04 ANNEX.

Encl.: D066794/04 ANNEX

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10116/2020 ANNEX
(POOL/E2/2020/10116/10116-EN
ANNEX.docx) D066794/04
[…](2020) XXX draft

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COMMISSION REGULATION (EU) …/…

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ANNEX

In the Annex to Regulation (EU) No 231/2012, the entry for E 171 titanium dioxide is replaced by the following:

'**E 171 TITANIUM DIOXIDE**

Synonyms	CI Pigment White 6
Definition	Titanium dioxide consists essentially of pure anatase and/or rutile titanium dioxide. It may contain small quantities (< 0.5%) of constituent particle growth and crystal phase control agents (alumina, sodium or potassium in combination with phosphate). It has no surface treatments or coatings. The anatase grades of pigmentary titanium dioxide can only be made by the sulphate process which creates a large amount of sulphuric acid as a by-product. The rutile grades of titanium dioxide may be made by the chloride or the sulphate process. Certain rutile grades of titanium dioxide are produced using mica (also known as potassium aluminium silicate) as a template to form the basic platelet structure. The surface of the mica is coated with titanium dioxide using a specialised patented process. Rutile titanium dioxide, platelet form is manufactured by subjecting titanium dioxide (rutile) coated mica nacreous pigment to an extractive dissolution in acid followed by an extractive dissolution in alkali. All of the mica is removed during this process and the resulting product is a platelet form of rutile titanium dioxide. Excluded from these specifications are potassium aluminium silicate-based pearlescent pigments.
Colour Index No	77891
Einecs	236-675-5
Chemical name	Titanium dioxide
Chemical formula	TiO_2
Molecular weight	79,88
Constituent particle size	Median minimum external dimension by particle number shall be higher than 100 nm, measured by electron microscopy. This means that in the measured sample less than 50% of constituent particles by number are particles

	with a minimum external dimension below 100 nm.
Assay	Content not less than 99 % on an alumina and silica-free basis
Description	White to slightly coloured powder
Identification	
Solubility	Insoluble in water and organic solvents. Dissolves slowly in hydrofluoric acid and in hot concentrated sulphuric acid
Purity	
Loss on drying	Not more than 0,5 % (105 °C, 3 hours)
Loss on ignition	Not more than 1,0 % on a volatile matter free basis (800 °C)
Alumina and silica	Total not more than 0.5%
Matter soluble in 0,5 N HCl	Not more than 0,5 % calculated as the sum of aluminium (as Al), sodium (as Na), potassium (as K) and phosphate (as P)
Water soluble matter	Not more than 0,5 %
Cadmium	Not more than 0,5 mg/kg after an extraction with 0,5 N HCl
Antimony	Not more than 1 mg/kg after an extraction with 0,5 N HCl
Arsenic	Not more than 1 mg/kg after an extraction with 0,5 N HCl
Lead	Not more than 5 mg/kg after an extraction with 0,5 N HCl
Mercury	Not more than 0,2 mg/kg after an extraction with 0,5 N HCl

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