

Commission Directive 2006/129/EC of 8 December 2006 amending and correcting Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners (Text with EEA relevance)

COMMISSION DIRECTIVE 2006/129/EC

of 8 December 2006

amending and correcting Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption<sup>(1)</sup>, and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee on Food and the European Food Safety Authority,

Whereas:

- (1) Commission Directive 96/77/EC<sup>(2)</sup> of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners sets out the purity criteria for the additives mentioned in Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners<sup>(3)</sup>.
- (2) It is appropriate to withdraw the purity criteria for E 216 propyl p-hydroxybenzoate and E 217 sodium propyl p-hydroxybenzoate which are no longer permitted for use as food additives.
- (3) A number of language versions of Directive 96/77/EC contain errors regarding the following substances: E 307 alpha-tocopherol, E 315 erythorbic acid, E 415 xanthan gum. Those errors need to be corrected. In addition it is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). In particular where appropriate, the specific purity criteria have been adapted to reflect the limits for individual heavy metals of interest. For reasons of clarity the whole text concerning those substances should be replaced.
- (4) The level of sulphated ash in the purity criteria for E 472c citric acid esters of mono- and diglycerides of fatty acids should be amended in order to cover partially or wholly neutralised products.
- (5) It is necessary to ensure that E 559 aluminium silicate is produced from raw kaolinitic clay which is free from unacceptable dioxin contamination. The presence of dioxin in the raw kaolinitic clay should therefore be restricted to the lowest possible level.

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- (6) It is necessary to adopt specifications for the new food additives authorised through Directive 2006/52/EC of the European Parliament and of the Council of 5 July 2006 amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs: E 319 tertiary-butylhydroquinone (TBHQ), E 426 soybean hemicellulose, E 462 ethyl cellulose, E 586 4-hexylresorcinol, E 1204 pullulan and E 1452 starch aluminium octenyl succinate.
- (7) Directive 96/77/EC should therefore be amended and corrected accordingly.
- (8) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

The Annex to Directive 96/77/EC is amended and corrected in accordance with the Annex to this Directive.

*Article 2*

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 15 February 2008 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 3*

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 8 December 2006.

*For the Commission*

Markos KYPRIANOU

*Member of the Commission*

## ANNEX

The Annex to Directive 96/77/EC is amended and corrected as follows:

- The texts concerning E 216 propyl p-hydroxybenzoate and E 217 sodium propyl p-hydroxybenzoate are deleted.
- The text concerning E 307 alpha-tocopherol is replaced by the following:

<b>E 307 ALPHA-TOCOPHEROL</b>	
<b>Synonyms</b>	DL- $\alpha$ -Tocopherol
<b>Definition</b>	
Chemical name	DL-5,7,8-Trimethyltolcol DL-2,5,7,8-Tetramethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol
Einecs	233-466-0
Chemical formula	C <sub>29</sub> H <sub>50</sub> O <sub>2</sub>
Molecular weight	430,71
Assay	Content not less than 96 %
<b>Description</b>	Slightly yellow to amber, nearly odourless, clear, viscous oil which oxidizes and darkens on exposure to air or light
<b>Identification</b>	
A. Solubility tests	Insoluble in water, freely soluble in ethanol, miscible in ether
B. Spectrophotometry	In absolute ethanol the maximum absorption is about 292 nm
<b>Purity</b>	
Refractive index	n <sub>D</sub> <sup>20</sup> 1,503 to 1,507
Specific absorption E <sup>1</sup> % <sub>1 cm</sub> in ethanol	E <sup>1</sup> % <sub>1 cm</sub> (292 nm) 72 to 76 (0,01 g in 200 ml of absolute ethanol)
Sulphated ash	Not more than 0,1 %
Specific rotation	[ $\alpha$ ] <sub>D</sub> <sup>25</sup> 0° ± 0,05° (1 in 10 solution in chloroform)
Lead	Not more than 2 mg/kg

- The text concerning E 315 erythorbic acid is replaced by the following:

<b>E 315 ERYTHORBIC ACID</b>	
<b>Synonyms</b>	Isoascorbic acid D-Araboascorbic acid
<b>Definition</b>	
Chemical name	D-Erythro-hex-2-enoic acid $\gamma$ -lactone

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	Isoascorbic acid D-Isoascorbic acid
Einecs	201-928-0
Chemical formula	C <sub>6</sub> H <sub>8</sub> O <sub>6</sub>
Molecular weight	176,13
Assay	Content not less than 98 % on the anhydrous basis
<b>Description</b>	White to slightly yellow crystalline solid which darkens gradually on exposure to light
<b>Identification</b>	
A. Melting range	About 164 °C to 172 °C with decomposition
B. Positive test for ascorbic acid/ colour reaction	
<b>Purity</b>	
Loss on drying	Not more than 0,4 % after drying under reduced pressure on silica gel for 3 hours
Sulphated ash	Not more than 0,3 %
Specific rotation	[α] <sub>D</sub> <sup>25</sup> 10 % (w/v) aqueous solution between – 16,5° to – 18,0°
Oxalate	To a solution of 1 g in 10 ml of water add 2 drops of glacial acetic acid and 5 ml of 10 % calcium acetate solution. The solution should remain clear
Lead	Not more than 2 mg/kg

4. The following text concerning E 319 tertiary-butylhydroquinone (TBHQ) is inserted after E 316 sodium erythorbate:

#### **E 319 TERTIARY-BUTYLHYDROQUINONE (TBHQ)**

<b>Synonyms</b>	TBHQ
<b>Definition</b>	
Chemical names	Tert-butyl-1,4-benzenediol 2-(1,1-Dimethylethyl)-1,4-benzenediol
Einecs	217-752-2
Chemical formula	C <sub>10</sub> H <sub>14</sub> O <sub>2</sub>
Molecular weight	166,22
Assay	Content not less than 99 % of C <sub>10</sub> H <sub>14</sub> O <sub>2</sub>

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<b>Description</b>	White crystalline solid having a characteristic odour
<b>Identification</b>	
A. Solubility	Practically insoluble in water; soluble in ethanol
B. Melting point	Not less than 126,5 °C
C. Phenolics	Dissolve about 5 mg of the sample in 10 ml of methanol and add 10,5 ml of dimethylamine solution (1 in 4). A red to pink colour is produced
<b>Purity</b>	
Tertiary-Butyl- <i>p</i> -benzoquinone	Not more than 0,2 %
2,5-Di-tertiary-butyl hydroquinone	Not more than 0,2 %
Hydroxyquinone	Not more than 0,1 %
Toluene	Not more than 25 mg/kg
Lead	Not more than 2 mg/kg

5. The text concerning E 415 xanthan gum is replaced by the following:

#### E 415 XANTHAN GUM

<b>Definition</b>	Xanthan gum is a high molecular weight polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with natural strains of <i>Xanthomonas campestris</i> , purified by recovery with ethanol or propan-2-ol, dried and milled. It contains D-glucose and D-mannose as the dominant hexose units, along with D-glucuronic acid and pyruvic acid, and is prepared as the sodium, potassium or calcium salt. Its solutions are neutral
Molecular weight	Approximately 1 000 000
Einecs	234-394-2
Assay	Yields, on dried basis, not less than 4,2 % and not more than 5 % of CO <sub>2</sub> corresponding to between 91 % and 108 % of xanthan gum
<b>Description</b>	Cream-coloured powder
<b>Identification</b>	
A. Solubility	Soluble in water. Insoluble in ethanol
<b>Purity</b>	
Loss on drying	Not more than 15 % (105 °C, 2 <sup>1</sup> / <sub>2</sub> hours)

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Total ash	Not more than 16 % on the anhydrous basis determined at 650 °C after drying at 105 °C for four hours
Pyruvic acid	Not less than 1,5 %
Nitrogen	Not more than 1,5 %
Ethanol and propan-2-ol	Not more than 500 mg/kg singly or in combination
Lead	Not more than 2 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and mould	Not more than 300 colonies per gram
<i>E. coli</i>	Absent in 5 g
<i>Salmonella</i> spp.	Absent in 10 g
<i>Xanthomonas campestris</i>	Viable cells absent in 1 g

6. The following text concerning E 426 soybean hemicellulose is inserted after E 425(ii) konjac glucomannan:

<b>E 426 SOYBEAN HEMICELLULOSE</b>	
<b>Synonyms</b>	
<b>Definition</b>	Soybean hemicellulose is a refined water-soluble polysaccharide obtained from natural strain soybean fibre by hot water extraction
Chemical names	Water soluble soybean polysaccharides Water soluble soybean fibre
Assay	Not less than 74 % carbohydrate
<b>Description</b>	Free flowing spray-dried white powder
<b>Identification</b>	
A. Solubility	Soluble in hot and cold water without gel formation
pH of 1 % solution	5,5 ± 1,5
B. Viscosity of 10 % solution	Not more than 200 mPa.s
<b>Purity</b>	
Loss on drying	Not more than 7 % (105 °C, 4 h)
Protein	Not more than 14 %
Total ash	Not more than 9,5 % (600 °C, 4 h)
Arsenic	Not more than 2 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

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Cadmium	Not more than 1 mg/kg
Standard plate count	Not more than 3 000 colonies per gram
Yeast and mould	Not more than 100 colonies per gram
<i>E. Coli</i>	Negative in 10 g

7. The following text concerning E 462 ethyl cellulose is inserted after E 461 methyl cellulose:

<b>E 462 ETHYL CELLULOSE</b>	
<b>Synonyms</b>	Cellulose ethyl ether
<b>Definition</b>	Ethyl cellulose is cellulose obtained directly from fibrous plant material and partially etherified with ethyl groups
Chemical names	Ethyl ether of cellulose
Chemical formula	The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)$ where $R_1$ and $R_2$ may be any of the following: —        H — $CH_2CH_3$
Assay	Content not less than 44 % and not more than 50 % of ethoxyl groups (-OC <sub>2</sub> H <sub>5</sub> ) on the dried basis (equivalent to not more than 2,6 ethoxyl groups per anhydroglucose unit)
<b>Description</b>	Slightly hygroscopic, white to off white, odourless and tasteless powder
<b>Identification</b>	
A.        Solubility	Practically insoluble in water, in glycerol and in propane-1,2-diol but soluble in varying proportions in certain organic solvents depending upon the ethoxyl content. Ethyl cellulose containing less than 46 to 48 % of ethoxyl groups is freely soluble in tetrahydrofuran, in methyl acetate, in chloroform and in aromatic hydrocarbon ethanol mixtures. Ethyl cellulose containing 46 to 48 % or more of ethoxyl groups is freely soluble in ethanol, in methanol, in toluene, in chloroform and in ethyl acetate
B.        Film forming test	Dissolve 5 g of the sample in 95 g of an 80:20 (w/w) mixture of toluene ethanol. A clear, stable, slightly yellow

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solution is formed. Pour a few ml of the solution onto a glass plate and allow the solvent to evaporate. A thick, tough, continuous, clear film remains. The film is flammable

**Purity**

Loss on drying	Not more than 3 % (105 °C, 2 h)
Sulphated ash	Not more than 0,4 %
pH of a 1 % colloidal solution	Neutral to litmus
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

8. The text concerning E 472c citric acid esters of mono- and diglycerides of fatty acids is replaced by the following:

**E 472c CITRIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS**

<b>Synonyms</b>	Citrem Citric acid esters of mono- and diglycerides Citroglycerides Mono- and diglycerides of fatty acids esterified with citric acid
<b>Definition</b>	Esters of glycerol with citric acid and fatty acids occurring in food oils and fats. They may contain small amounts of free glycerol, free fatty acids, free citric acid and free glycerides. They may be partially or wholly neutralised with sodium hydroxide or with potassium hydroxide
<b>Description</b>	Yellowish or light brown liquids to waxy solids or semi-solids
<b>Identification</b>	
A. Positive test for glycerol, for fatty acids and for citric acid	
B. Solubility	Insoluble in cold water Dispersible in hot water Soluble in oils and fats In soluble in cold ethanol
<b>Purity</b>	
Acids other than citric and fatty acids	Not detectable



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Free glycerol	Not more than 2 %
Total glycerol	Not less than 8 % and not more than 33 %
Total citric acid	Not less than 13 % and not more than 50 %
Sulphated ash (determined at 800 ± 25 °C)	Non-neutralised products: not more than 0,5 % Partially or wholly neutralised products: not more than 10 %
Lead	Not more than 2 mg/kg
Free fatty acids	Not more than 3 % estimated as oleic acid

*Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however, these substances may be present up to a maximum level of 6 % (expressed as sodium oleate).*

9. The text concerning E 559 aluminium silicate (kaolin) is replaced by the following:

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#### **E 559 ALUMINIUM SILICATE (KAOLIN)**

<b>Synonyms</b>	Kaolin, light or heavy
<b>Definition</b>	Aluminium silicate hydrous (kaolin) is a purified white plastic clay composed of kaolinite, potassium aluminium silicate, feldspar and quartz. Processing should not include calcination. The raw kaolinitic clay used in the production of aluminium silicate shall have a level of dioxin which does not make it injurious to health or unfit for human consumption
Einecs	215-286-4 (kaolinite)
Chemical formula	Al <sub>2</sub> Si <sub>2</sub> O <sub>5</sub> (OH) <sub>4</sub> (kaolinite)
Molecular weight	264
Assay	Content not less than 90 % (sum of silica and alumina, after ignition) Silica (SiO <sub>2</sub> ) Between 45 % and 55 % Alumina (Al <sub>2</sub> O <sub>3</sub> ) Between 30 % and 39 %
<b>Description</b>	Fine, white or greyish white, unctuous powder. Kaolin is made up of loose aggregations of randomly oriented stacks of kaolinite flakes or of individual hexagonal flakes.
<b>Identification</b>	

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A.	Positive test for alumina and for silicate	
B.	X-ray diffraction	Characteristic peaks at 7,18/3,58/2,38/1,78 Å
C.	IR absorption	Peaks at 3 700 and 3 620 cm <sup>-1</sup>
<b>Purity</b>		
	Loss on ignition	Between 10 and 14 % (1 000 °C, constant weight)
	Water soluble matter	Not more than 0,3 %
	Acid soluble matter	Not more than 2 %
	Iron	Not more than 5 %
	Potassium oxide (K <sub>2</sub> O)	Not more than 5 %
	Carbon	Not more than 0,5 %
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 5 mg/kg
	Mercury	Not more than 1 mg/kg

10. The following text concerning E 586 4-hexylresorcinol is inserted after E 578 calcium gluconate:

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**E 586 4-HEXYLRESORCINOL**

<b>Synonyms</b>	4-Hexyl-1,3-benzenediol Hexylresorcinol	
<b>Definition</b>		
Chemical names	4-Hexylresorcinol	
Einecs	205-257-4	
Chemical formula	C <sub>12</sub> H <sub>18</sub> O <sub>2</sub>	
Molecular weight	197,24	
Assay	Not less than 98,0 % on the dried basis	
<b>Description</b>	White powder	
<b>Identification</b>		
A.	Solubility	Freely soluble in ether and acetone; very slightly soluble in water
B.	Nitric acid test	To 1 ml of a saturated solution of the sample, add 1 ml of nitric acid. A light red colour appears
C.	Bromine test	To 1 ml of saturated solution of the sample, add 1 ml of bromine TS. A

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	yellow, flocculent precipitate dissolves producing a yellow solution
D. Melting range	62 to 67 °C
<b>Purity</b>	
Acidity	Not more than 0,05 %
Sulphated ash	Not more than 0,1 %
Resorcinol and other phenols	Shake about 1 g of the sample with 50 ml of water for a few minutes, filter, and to the filtrate add 3 drops of ferric chloride TS. No red or blue colour is produced
Nickel	Not more than 2 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 3 mg/kg

11. The following text concerning E 1204 pullulan is inserted after E 1200 polydextrose:

<b>E 1204 PULLULAN</b>	
<b>Definition</b>	Linear, neutral glucan consisting mainly of maltotriose units connected by -1,6 glycosidic bonds. It is produced by fermentation from a food grade hydrolysed starch using a non-toxin producing strain of <i>Aureobasidium pullulans</i> . After completion of the fermentation, the fungal cells are removed by microfiltration, the filtrate is heat-sterilised and pigments and other impurities are removed by adsorption and ion exchange chromatography
Einecs	232-945-1
Chemical formula	(C <sub>6</sub> H <sub>10</sub> O <sub>5</sub> ) <sub>x</sub>
Assay	Not less than 90 % of glucan on the dried basis
<b>Description</b>	White to off-white odourless powder
<b>Identification</b>	
A. Solubility	Soluble in water, practically insoluble in ethanol.
B. pH of 10 % solution	5,0 to 7,0
C. Precipitation with polyethylene glycol 600	Add 2 ml of polyethylene glycol 600 to 10 ml of a 2 % aqueous solution of pullulan. A white precipitate is formed

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D. Depolymerisation with pullulanase	Prepare two test tubes each with 10 ml of a 10 % pullulan solution. Add 0,1 ml pullulanase solution having activity 10 units/g to one test tube, and 0,1 ml water to the other. After incubation at about 25 °C for 20 min, the viscosity of the pullulanase-treated solution is visibly lower than that of the untreated solution
<b>Purity</b>	
Loss on drying	Not more than 6 % (90 °C, pressure not more than 50 mm Hg, 6 h)
Mono-, di- and oligosaccharides	Not more than 10 % expressed as glucose
Viscosity	100 to 180 mm <sup>2</sup> /s (10 % w/w aqueous solution at 30 °C)
Lead	Not more than 1 mg/kg
Yeast and moulds	Not more than 100 colonies per gram
Coliforms	Absent in 25 g
Salmonella	Absent in 25 g

12. The following text concerning E 1452 starch aluminium octenyl succinate is inserted after E 1451 acetylated oxidised starch:

#### **E 1452 STARCH ALUMINIUM OCTENYL SUCCINATE**

<b>Synonyms</b>	SAOS
<b>Definition</b>	Starch aluminium octenyl succinate is starch esterified with octenylsuccinic anhydride and treated with aluminium sulphate
<b>Description</b>	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
<b>Identification</b>	
A. If not pregelatinised: by microscopic observation	
B. Iodine staining positive (dark blue to light red colour)	
<b>Purity</b>	
(all values expressed on an anhydrous basis except for loss on drying)	
Loss on drying	Not more than 21 %
Octenylsuccinyl groups	Not more than 3 %

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Octenylsuccinic acid residue	Not more than 0,3 %
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches Not more than 10 mg/kg for the other modified starches unless otherwise specified
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 0,1 mg/kg
Aluminium	Not more than 0,3 %

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- (1) [OJ L 40, 11.2.1989, p. 27](#). Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council ([OJ L 284, 31.10.2003, p. 1](#)).
- (2) [OJ L 339, 30.12.1996, p. 1](#). Directive as last amended by Directive 2004/45/EC ([OJ L 113, 20.4.2004, p. 19](#)).
- (3) [OJ L 61, 18.3.1995, p. 1](#). Directive as last amended by Directive 2006/52/EC ([OJ L 204, 26.7.2006, p. 10](#)).