COUNCIL DIRECTIVE

of 25 July 1978

laying down specific criteria of purity for antioxidants which may be used in foodstuffs intended for human consumption

(78/664/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 70/357/EEC of 13 July 1970 on the approximation of the laws of the Member States concerning the antioxidants authorized for use in foodstuffs intended for human consumption (1), as last amended by Directive 78/143/EEC (2), and in particular Article 5 (1) thereof,

Having regard to the proposal from the Commission,

Whereas, pursuant to Article 4 of Directive 70/357/EEC, antioxidants must comply with specific criteria of purity laid down in accordance with Article 5 (1) thereof;

Whereas specific criteria of purity should be laid down for the antioxidants listed in Parts I to III and points 4 to 7 of Part IV of the Annex to Directive 70/357/EEC, on the understanding that certain of these criteria have already been laid down in Directive 65/66/EEC (3), as last amended by Directive 76/463/EEC (4), and in Directive 78/663/EEC (5);

Whereas this Directive lays down no specific criteria of purity for ethyl alcohol covered by point 4 of Part IV of the Annex to Directive 70/357/EEC, and this substance will be considered in greater detail when rules of a general nature governing solvents are drawn up in the future;

Whereas for economic and technological reasons in certain Member States, provision should be made for the Member States to retain their existing national arrangements concerning specific criteria of purity concerning DL-tartaric acid and salts thereof, hydrolysed lecithins, and the aldehyde content of propylene glycol,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The specific criteria of purity referred to in Article 5 (1) of Directive 70/357/EEC are set out in the Annex to this Directive.

Article 2

1. This Directive does not affect national measures in existence at the time of its notification under which specific criteria of purity are set for:

(a) DL-tartaric acid and salts thereof;

(b) hydrolysed lecithins;

(c) the aldehyde content of propylene glycol.

2. The Council, acting unanimously on a proposal from the Commission, shall decide before 1 January 1982 on the criteria of purity referred to in paragraph 1 (a) and (b).

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 18 months after notification of this Directive. They shall forthwith inform the Commission thereof.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 25 July 1978.

For the Council

The President

J. ERTL

(1) OJ No L 157, 18. 7. 1970, p. 31.
(2) OJ No L 44, 15. 2. 1978, p. 18.
(3) OJ No 22, 9. 2. 1965, p. 373/65.
(4) OJ No L 126, 14. 5. 1976, p. 33.
(5) See page 4 of this Official Journal.

ANNEX

SPECIFIC CRITERIA OF PURITY FOR ANTIOXIDANTS WHICH MAY BE USED IN FOODSTUFFS INTENDED FOR HUMAN CONSUMPTION

General remarks

(a) Except where otherwise stated, the quantities and percentages shall be calculated by mass on the basis of the anhydrous form of the substance.

(b) Where the substance in question is not anhydrous at the outset and where 'volatile matter' is involved, the latter shall include all moisture, including water of crystallization.

(c) Where the drying temperature and time are not stated, the latter shall be understood to mean 'to constant weight' and the former shall be 105 °C.

(d) Where the interpretation of the criteria set out below require that certain technical data such as 'vacuum' data be defined, the methods of analysis established pursuant to Article 5 (2) of the Directive concerning antioxidants shall be referred to.

(e) Where the concentration of a solution is given, this shall be taken to mean mass/volume except where otherwise stated.

(f) Temperatures shall always be stated in degrees centigrade (Celsius).

(g) The specific criteria of purity applicable to substances E 220 to E 224, E 226 and E 270 are laid down by Directive 65/66/EEC.

(h) The specific criteria of purity applicable to sorbitol, glycerol and to substance E 472 (c) are laid down by Council Directive 78/663/EEC.

E 300 — L-ascorbic acid

Chemical description	(+)-L-ascorbic acid; 3-oxo-L-gulofuranolactone; $C_6H_8O_6$.
Appearance	White or pale yellow crystalline powder.
Melting range	189 to 193 °C with slight decomposition.
Content	Not less than 99 % $C_6H_8O_6$ on a volatile matter-free basis.
Specific optical rotatory power	$[\alpha]_D^{20}$ = + 20·5 to + 21·5° (C = 10 % aqueous).
Volatile matter	Not more than 0·4 % determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide.
Sulphated ash	Not more than 0·1 % on a volatile matter-free basis determined by calcination at 800 ± 25 °C.
pH	2·4 to 2·8 in 2 % aqueous solution.

E 301 — Sodium L-ascorbate

Chemical description	Sodium salt of (+)-L-ascorbic acid; 3-oxo-L-gulofuranolactone; sodium enolate; $C_6H_7O_6Na$.

Appearance	White or pale yellow crystalline powder.
Content	Not less than 99 % $C_6H_7O_6Na$ on a volatile matter-free basis.
Specific optical rotatory power	$[\alpha]_D^{20}$ = + 103 to + 106° (C = 5 % aqueous).
Volatile matter	Not more than 0·3 % determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide.
pH	6·0 to 8·0 in 10 % aqueous solution.

E 302 — Calcium L-ascorbate

Chemical description	Calcium salt of (+)-L-ascorbic acid; $(C_6H_7O_6)_2Ca \cdot 2H_2O$.
Appearance	White or very pale grey crystalline powder.
Content	Not less than 99 % $(C_6H_7O_6)_2Ca \cdot 2H_2O$ on a volatile matter-free basis.
Specific optical rotatory power	$[\alpha]_D^{20}$ = + 95 to + 97° (C = 5 % aqueous).
Volatile matter	Not more than 0·3 % (1) determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide.
pH	6·0 to 7·5 in 10 % aqueous solution.

E 303 — 5,6-Diacetyl-L-ascorbic acid

Chemical description	Ascorbyl diacetate, derivative of (+)-L-ascorbic acid; $C_{10}H_{12}O_8$.
Appearance	White or pale yellow crystalline powder.
Melting range	155 to 158 °C.
Content	Not less than 99 % $C_{10}H_{12}O_8$ on a volatile matter-free basis.
Specific optical rotatory power	$[\alpha]_D^{20}$ = − 77 to − 79° (C = 2 % in methanol).
Volatile matter	Not more than 1 % determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide.
Sulphated ash	Not more than 0·1 % of the volatile matter-free substance determined by calcination at 800 ± 25 °C.

E 304 — 6-Palmitoyl-L-ascorbic acid

Chemical description	Ascorbyl palmitate; derivative of (+)-L-ascorbic acid; L-ascorbyl palmitate; 6-0-palmitoyl-3-oxo-L-gulofuranolactone.

(1) This percentage value does not relate to the water of crystallization but to the atmospheric water vapour (moisture in the substance) determined under these conditions.

Appearance	Impalpable white or yellowish-white powder or yellowish-white crystals.
Content	Not less than 98 % $C_{22}H_{38}O_7$ on a volatile matter-free basis.
Melting range	111 to 113 °C (changes to viscous state without completely melting).
Specific optical rotatory power	$[\alpha]_D^{20}$ = + 21 to +24° (C = 5 % in methanol).
Volatile matter	Not more than 1 % determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide.
Sulphated ash	Not more than 0·2 % of the volatile matter-free substance after calcination at 800 ± 25 °C.

E 306 — Tocopherol-rich extracts of natural origin

Chemical description	Mixed tocopherols concentrate obtained from edible vegetable oils or their derivatives.
Appearance	Clear, viscous, red to brownish-red oil.
Content	Not less than 34 % total tocopherols (1).
Relative density d_4^{20}	Not less than 0·928 and not more than 0·951 (1).
Free fatty acids	Not more than 3 % expressed in terms of oleic acid (1).

E 307 — Synthetic alpha-tocopherol

Chemical description	Synthetic dl-α-tocopherol; 2,5,7,8-tetramethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol; $C_{29}H_{50}O_2$.
Appearance	Clear, viscous, yellowish oil which darkens on exposure to air or light.
Content	Not less than 96 % $C_{29}H_{50}O_2$ (1).
Refractive index n_D^{20}	Not less than 1·503 and not more than 1·507 (1).
Relative density d_4^{20}	Not less than 0·947 and not more than 0·958 (1).
Specific absorption $E_{1\,cm}^{1\,\%}$ *in ethanol*	Absorption at 292 nm: $E_{1\,cm}^{1\,\%}$ (292 nm): not less than 72 and not more than 76. Absorption at 255 nm: $E_{1\,cm}^{1\,\%}$ (255 nm): not less than 6·0 and not more than 8·0.
Sulphated ash	Not more than 0·1 % after calcination at 800 ± 25 °C (1).

(1) These criteria apply to the product as it is.

E 308 — Synthetic gamma-tocopherol

Chemical description	Synthetic dl-γ-tocopherol, 2,7,8-trimethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol; $C_{28}H_{48}O_2$.
Appearance	Clear, viscous, pale yellow oil which darkens on exposure to air or light.
Content	Not less than 97 % $C_{28}H_{48}O_2$ (1).
Refractive index n_D^{20}	Not less than 1·503 and not more than 1·507 (1).
Relative density d_4^{20}	Not less than 0·948 and not more than 0·959 (1).
Specific absorption $E_{1\,cm}^{1\,\%}$ *in ethanol*	Absorption at 298 nm: $E_{1\,cm}^{1\,\%}$ (298 nm): not less than 91 and not more than 97. Absorption at 257 nm: $E_{1\,cm}^{1\,\%}$ (257 nm): not less than 5·0 and not more than 8·0.
Sulphated ash	Not more than 0·1 % after calcination at 800 ± 25 °C (1).

E 309 — Synthetic delta-tocopherol

Chemical description	Synthetic dl-δ-tocopherol; 2,8-dimethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol; $C_{28}H_{48}O_2$.
Appearance	Clear, viscous, pale yellowish or orange oil which darkens on exposure to air or light.
Content	Not less than 97 % $C_{27}H_{46}O_2$ (1).
Refractive index n_D^{20}	Not less 1·500 and not more than 1·504 (1).
Relative density d_4^{20}	Not less than 0·952 and not more than 0·962 (1).
Specific absorption $E_{1\,cm}^{1\,\%}$ *in ethanol*	Absorption at 298 nm: $E_{1\,cm}^{1\,\%}$ (298 nm): not less than 89 and not more than 95. Absorption at 257 nm: $E_{1\,cm}^{1\,\%}$ (257 nm): not less than 3·0 and not more than 6·0.
Sulphated ash	Not more than 0·1 % after calcination at 800 ± 25 °C (1).

E 310 — Propyl gallate

Chemical description	Propyl gallate; n-propyl ester of 3,4,5-trihydroxybenzoic acid; $C_{10}H_{12}O_5$.
Appearance	White or pale cream crystalline powder.

(1) These criteria apply to the product as it is.