# 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**

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|---|---|
| *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**

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|---|---|
| *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.<br>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-$\gamma$-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.<br>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**

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|---|---|
| *Chemical description* | Synthetic dl-$\delta$-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.<br>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**

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|---|---|
| *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.

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|---|---|
| *Content* | Not less than 99 % $C_{10}H_{12}O_5$ on a volatile matter-free basis. |
| *Melting range* | 146 to 150 °C after drying at 110 °C for four hours. |
| *Specific absorption E* $\frac{1\ \%}{1\ cm}$ *in ethanol* | Absorption at 275 nm: $E\ \frac{1\ \%}{1\ cm}$ (275 nm): not less than 485 and not more than 505. |
| *Volatile matter* | Not more than 1·0 % determined by drying at 110 °C for four hours. |
| *Sulphated ash* | Not more than 0·05 % of the volatile matter-free substances after calcination at 800 ± 25 °C. |
| *Free acids* | Not more than 0·5 % expressed as gallic acid (8·506 mg gallic acid corresponding to 1 ml 0·05 N sodium hydroxide). |
| *Chlorinated organic compounds* | Not more than 100 mg/kg expressed as chlorine. |

**E 311 — Octyl gallate**

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|---|---|
| *Chemical description* | Octyl gallate; n-octyl ester of 3,4,5-trihydroxybenzoic acid, $C_{15}H_{22}O_5$. |
| *Appearance* | White or very pale yellowish crystalline powder. |
| *Melting range* | 99 to 102·5 °C after drying at 90 °C for six hours. |
| *Content* | Not less than 98·5 % $C_{15}H_{22}O_5$ on a volatile matter-free basis. |
| *Specific absorption E* $\frac{1\ \%}{1\ cm}$ *in ethanol* | Absorption at 275 nm: $E\ \frac{1\ \%}{1\ cm}$ (275 nm): not less than 375 and not more than 390. |
| *Volatile matter* | Not more than 0·5 % determined by drying at 90 °C for six hours. |
| *Sulphated ash* | Not more than 0·05 % of the volatile matter-free substance after calcination at 800 ± 25 °C. |
| *Free acids* | Not more than 0·5 % expressed as gallic acid (8·506 mg gallic acid corresponding to 1 ml 0·05 N sodium hydroxide). |
| *Chlorinated organic compounds* | Not more than 100 mg/kg expressed as chlorine. |

**E 312 — Dodecyl gallate**

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|---|---|
| *Chemical description* | Dodecyl gallate; lauryl gallate; n-dodecyl ester of 3,4,5-trihydroxybenzoic acid; $C_{19}H_{30}O_5$. |
| *Appearance* | White or pale cream crystalline powder. |
| *Melting range* | 95 to 98 °C after drying at 90 °C for six hours. |
| *Content* | Not less than 98·5 % $C_{19}H_{30}O_5$ on a volatile matter-free basis. |

| | |
|---|---|
| *Specific absorption E* $\frac{1\ \%}{1\ cm}$ *in ethanol* | Absorption at 275 nm: E $\frac{1\ \%}{1\ cm}$ (275 nm): not less than 300 and not more than 325. |
| *Volatile matter* | Not more than 0·5 % determined by drying at 90 °C for six hours. |
| *Sulphated ash* | Not more than 0·05 % of the volatile matter-free substance after calcination at 800 ± 25 °C. |
| *Free acids* | Not more than 0·5 % expressed as gallic acid (8·506 mg gallic acid corresponding to 1 ml 0·05 N sodium hydroxide). |
| *Chlorinated organic compounds* | Not more than 100 mg/kg expressed as chlorine. |

**E 320 — Butylated hydroxyanisole (BHA)**

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|---|---|
| *Chemical description* | Mixture of 3- and 2-tertiarybutyl-4-hydroxyanisole; 2- and 3-tertiarybutyl-4-methoxy-phenol; $C_{11}H_{16}O_2$. |
| *Appearance* | White or pale yellowish powder or large crystals with waxy appearance and slight aromatic smell. |
| *Content* | Not less than 98·5 % $C_{11}H_{16}O_2$ and not less than 85 % of the 3-tertiary+butyl-4-hydroxyanisole isomer (1). |
| *Specific absorption E* $\frac{1\ \%}{1\ cm}$ *in ethanol* | Absorption at 290 nm: E $\frac{1\ \%}{1\ cm}$ (290 nm): not less than 190 and not more than 210.<br>Absorption at 228 nm: E $\frac{1\ \%}{1\ cm}$ (228 nm): not less than 326 and not more than 345. |
| *4-hydroxyanisole content* | Not more than 0·5 %. |
| *Sulphated ash* | Not more than 0·05 % after calcination at 800 ± 25 °C (1). |

**E 321 — Butylated hydroxy toluene (BHT)**

| | |
|---|---|
| *Chemical description* | 2,6-ditert-butyl-p-cresol; 4-methyl-2,6-ditert-butyl phenol; $C_{15}H_{24}O$. |
| *Appearance* | White crystalline or powdery crystalline substance. |
| *Content* | Not less than 99 % $C_{15}H_{24}O$. |
| *Melting range* | 69 to 70 °C. |
| *Specific absorption E* $\frac{1\ \%}{1\ cm}$ *in ethanol* | Absorption at 278 nm: E $\frac{1\ \%}{1\ cm}$ (278 nm): not less than 81 and not more than 88. |
| *Sulphated ash* | Not more than 0·005 % after calcination at 800 ± 25 °C (1). |

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

**E 322 — Lecithins**

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|---|---|
| *Description* | Lecithins are mixtures or fractions of phosphatides obtained by physical procedures from animal or vegetable foodstuffs. The lecithins may be slightly bleached in aqueous medium by means of hydrogen peroxide. This oxidation must not chemically modify the lecithin phosphatides. |
| *Appearance* | Brown liquid or viscous semi-liquid or powder. |
| *Content* | Not less than 60 % substances insoluble in acetone (1). |
| *Volatile matter* | Not more than 2 % determined by drying at 105 °C for one hour (1). |
| *Substances insoluble in toluene* | Not more than 0·3 % (1). |
| *Acid number* | Not more than 35 mg of potassium hydroxide per gram (1). |
| *Peroxide number* | Equal to or less than 10, expressed as milliequivalents per kilogram. |

**E 325 — Sodium lactate**

| | |
|---|---|
| *Chemical description* | Sodium salt of lactic acid; $C_3H_5O_3Na$. |
| *Appearance* | White hygroscopic mass. Solutions are practically colourless and odourless. |
| *Description* | The substance is usually available commercially in the form of an aqueous solution containing 50 to 80 % mass/mass of anhydrous sodium lactate. |
| *Content* | Not less than 98 % $C_3H_5O_3Na$ after drying. |
| *Acidity* | Not more than 0·5 % after drying expressed as lactic acid. |
| *Reducing substances* | No reduction of Fehling's solution. |

**E 326 — Potassium lactate**

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|---|---|
| *Chemical description* | Potassium salt of lactic acid; $C_3H_5O_3K$. |
| *Description* | The substance is usually available commercially in the form of an aqueous, slightly syrupy, clear, almost odourless solution containing about 60 % mass/mass of anhydrous potassium lactate. |
| *Content* | Not less than 98 % $C_3H_5O_3K$ after drying. |
| *Acidity* | Not more than 0·5 % after drying expressed as lactic acid. |
| *Reducing substances* | No reduction of Fehling's solution. |

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

**E 327 — Calcium lactate**

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|---|---|
| *Chemical description* | Calcium salt of lactic acid; calcium dilactate; $(C_3H_5O_2)_2Ca$; also available commercially in hydrated forms (one, three or four-and-a-half molecules of water). |
| *Appearance* | Almost odourless, white crystalline powder or granules. |
| *Content* | Not less than 98 % $(C_3H_5O_3)_2Ca$ on a volatile matter-free basis. |
| *Volatile matter* | Determined by drying at 120 °C for four hours:<br>— anhydrous: not more than 3 %,<br>— with one molecule of water: not more than 8 %,<br>— with three molecules of water: not more than 20 %,<br>— with four-and-a-half molecules of water: not more than 27 %. |
| *Acidity* | Not more than 0·5 % of the dry matter expressed as lactic acid. |
| *Fluorides* | Not more than 30 mg/kg expressed as fluorine. |
| *Reducing substances* | No reduction of Fehling's solution. |

**E 330 — Citric acid**

| | |
|---|---|
| *Chemical description* | 2-hydroxy-1,2,3-propane tricarboxylic acid; $C_6H_8O_7$; available commercially in anhydrous or monohydrate form. |
| *Appearance* | Colourless or translucent crystalline solid or white crystalline powder. |
| *Content* | Not less than 99·5 % $C_6H_8O_7$ after drying. |
| *Volatile matter* | Anhydrous: not more than 0·5 %.<br>Monohydrate: not more than 8·8 %. |
| *Oxalates* | Not more than 0·05 %, expressed as oxalic acid, after drying. |
| *Sulphated ash* | Not more than 0·05 % of the dry matter after calcination at 800 ± 25 °C. |
| *Sulphuric acid test* | 1 g sample dissolved in 10 ml 95 % sulphuric acid and heated for 60 minutes at 90° shall not show a darker colouration than a solution containing 0·5 part of a $CoCl_2 \cdot 6H_2O$ solution (59·5 mg/ml) and 4·5 parts of a $FeCl_3 \cdot 6H_2O$ solution (45·0 mg/ml). |

**E 331 — Sodium citrates**

(i) Monosodium citrate

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|---|---|
| *Chemical description* | Monosodium salt of citric acid; $C_6H_5O_7H_2Na$; in anhydrous form or as the monohydrate. |
| *Appearance* | Crystalline white powder or colourless crystals. |
| *Content* | Not less than 99 % $C_6H_5O_7H_2Na$ on a volatile matter-free basis. |

| | |
|---|---|
| *Volatile matter* | Determined by drying at 120 °C for two hours:<br>— anhydrous: not more than 1·0 %,<br>— monohydrate: not more than 8·8 %. |
| *Oxalates* | Not more than 0·05 % expressed as oxalic acid. |
| *pH* | Determined in a 1 % solution, not less than 3·5 and not more than 3·8. |

(ii) Disodium citrate

| | |
|---|---|
| *Chemical description* | Disodium salt of citric acid with one-and-a-half molecules of water; $C_6H_5O_7HNa_2$, 1·5 $H_2O$. |
| *Appearance* | Crystalline white powder or colourless crystals. |
| *Content* | Not less than 99 % $C_6H_5O_7HNa_2$ on a volatile matter-free basis. |
| *Volatile matter* | Determined by drying at 180 °C for two hours, not more than 13 %. |
| *Oxalates* | Not more than 0·05 % expressed as oxalic acid. |
| *pH* | Determined in a 1 % solution, not less than 4·9 and not more than 5·2. |

(iii) Trisodium citrate

| | |
|---|---|
| *Chemical description* | Trisodium salt of citric acid, in anhydrous, dihydrate or pentahydrate form; $C_6H_5O_7Na_3$. |
| *Appearance* | Crystalline white powder or colourless crystals. |
| *Content* | Not less than 99 % $C_6H_5O_7Na_3$ on a volatile matter-free basis. |
| *Volatile matter* | Determined by drying at 180 °C for two hours:<br>— anhydrous: not more than 1·0 %,<br>— dihydrate: not more than 13·5 %,<br>— pentahydrate: not more than 30·3 %. |
| *Oxalates* | Not more than 0·05 % expressed as oxalic acid. |
| *pH* | Determined in a 1 % solution, not less than 7·0 and not more than 9·0. |

**E 332 — Potassium citrates**

(i) Monopotassium citrate

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|---|---|
| *Chemical description* | Anhydrous monopotassium salt of citric acid; $C_6H_5O_7H_2K$. |

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|---|---|
| *Appearance* | White, hygroscopic, granular powder or transparent crystals. |
| *Content* | Not less than 99 % $C_6H_5O_7H_2K$ on a volatile matter-free basis. |
| *Volatile matter* | Not more than 1 % determined by drying at 120 °C for four hours. |
| *Oxalates* | Not more than 0·05 % expressed as oxalic acid. |
| *pH* | Determined in a 1 % solution, not less than 3·5 and not more than 3·8. |

(ii) Tripotassium citrate

| | |
|---|---|
| *Chemical description* | Monohydrated tripotassium salt of citric acid; $C_6H_5O_7K_3$, 1 $H_2O$. |
| *Appearance* | White hygroscopic granular powder or transparent crystals. |
| *Content* | Not less than 99 % $C_6H_5O_7K_3$ on a volatile matter-free basis. |
| *Volatile matter* | Not more than 6 % determined by drying at 180 °C for four hours. |
| *Oxalates* | Not more than 0·05 % expressed as oxalic acid. |
| *pH* | Determined in a 1 % solution, not less than 7·0 and not more than 9·0. |

**E 333 — Calcium citrates**

(i) Monocalcium citrate

| | |
|---|---|
| *Chemical description* | Monohydrate monocalcium salt of citric acid; $(C_6H_5O_7)_2$ $H_4Ca$, 1 $H_2O$. |
| *Appearance* | Fine white powder. |
| *Content* | Not less than 97·5 % $(C_6H_5O_7)_2$ $H_4Ca$ on a volatile matter-free basis. |
| *Volatile matter* | Not more than 7 % determined by drying at 120 °C for four hours. |
| *Carbonates* | Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles. |
| *Oxalates* | Not more than 0·05 % expressed as oxalic acid. |
| *Fluorides* | Not more than 30 mg/kg expressed as fluorine. |

(ii) Dicalcium citrate

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|---|---|
| *Chemical description* | Trihydrated dicalcium salt of citric acid; $(C_6H_5O_7)_2$ $H_2Ca_2$, 3 $H_2O$. |

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|---|---|
| *Appearance* | Fine white powder. |
| *Content* | Not less than 97·5 % $(C_6H_5O_7)_2\ H_2Ca_2$ on a volatile matter-free basis. |
| *Volatile matter* | Not more than 20 % determined by drying at 120 °C for four hours. |
| *Carbonates* | Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles. |
| *Oxalates* | Not more than 0·05 % expressed as oxalic acid. |
| *Fluorides* | Not more than 30 mg/kg expressed as fluorine. |

(iii) Tricalcium citrate

| | |
|---|---|
| *Chemical description* | Tetrahydrated tricalcium salt of citric acid; $(C_6H_5O_7)_2\ Ca_3,\ 4\ H_2O$. |
| *Appearance* | Fine white powder. |
| *Content* | Not less than 97·5 % $(C_6H_5O_7)_2\ Ca_3$ on a volatile matter-free basis. |
| *Volatile matter* | Not more than 14 % determined by drying at 150 °C for four hours. |
| *Carbonates* | Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles. |
| *Oxalates* | Not more than 0·05 % expressed as oxalic acid. |
| *Fluorides* | Not more than 30 mg/kg expressed as fluorine. |

**E 334 — Tartaric acid**

| | |
|---|---|
| *Chemical description* | L-(+)-tartaric acid; 2,3-dihydroxysuccinic acid; $C_4H_6O_6$. |
| *Appearance* | Colourless or translucent crystalline solid or white crystalline powder. |
| *Content* | Not less than 99·5 % $C_4H_6O_6$. |
| *Volatile matter* | Not more than 0·5 %. |
| *Sulphated ash* | Not more than 0·1 % of the dry matter after calcination at 800 ± 25 °C. |
| *Oxalates* | Not more than 0·05 % expressed as oxalic acid. |
| *Melting range* | 168 to 170 °C. |
| *Specific optical rotatory power* | $[\alpha]\ \frac{20}{D}$ from + 11·5 to + 13·5° (C = 20 % aqueous). |

**E 335 — Sodium tartrates**

(i) Monosodium tartrate

| | |
|---|---|
| *Chemical description* | Monohydrated monosodium salt of L-(+)-tartaric acid; $C_4H_4O_6$ H Na, $H_2O$. |
| *Description* | Transparent, colourless crystals. |
| *Content* | Not less than 99 % $C_4H_4O_6$ H Na on a volatile matter-free basis. |
| *Volatile matter* | Not more than 10 % determined by drying at 105 °C for four hours. |
| *Oxalates* | Not more than 0·05 % expressed as oxalic acid. |

(ii) Disodium tartrate

| | |
|---|---|
| *Chemical description* | Dihydrated disodium salt of L-(+)-tartaric acid, $C_4H_4O_6$ $Na_2$, 2 $H_2O$. |
| *Description* | Transparent, colourless crystals. |
| *Content* | Not less than 99 % $C_4H_4O_6$ $Na_2$ on a volatile matter-free basis. |
| *Volatile matter* | Not more than 17 % determined by drying at 150 °C for four hours. |
| *Oxalates* | Not more than 0·05 % expressed as oxalic acid. |

**E 336 — Potassium tartrates**

(i) Monopotassium tartrate

| | |
|---|---|
| *Chemical description* | Anhydrous monopotassium salt of L-(+)-tartaric acid; $C_4H_4O_6$ HK. |
| *Description* | White crystalline or granulated powder. |
| *Content* | Not less than 98 % $C_4H_4O_6$ HK on a volatile matter-free basis. |
| *Volatile matter* | Not more than 1 % determined by drying at 105 °C for four hours. |
| *Oxalates* | Not more than 0·05 % expressed as oxalic acid. |

(ii) Dipotassium tartrate

| | |
|---|---|
| *Chemical description* | Dipotassium salt with half a molecule of water of L-(+)-tartaric acid; $C_4H_4O_6$ $K_2$, $^1/_2$ $H_2O$. |
| *Description* | White crystalline or granulated powder. |

| | |
|---|---|
| *Content* | Not less than 99 % $C_4H_4O_6K_2$ on a volatile matter-free basis. |
| *Volatile matter* | Not more than 4 % determined by drying at 150 °C for four hours. |
| *Oxalates* | Not more than 0·05 % expressed as oxalic acid. |

**E 337 — Potassium sodium tartrate**

| | |
|---|---|
| *Chemical description* | Derivate of L-(+)-tartaric acid; potassium sodium L (+) tartrate; Available commercially in the form of potassium sodium tartrate with four molecules of water of crystallization; $C_4H_4O_6K$ Na, 4 $H_2O$. |
| *Description* | Colourless crystals or white crystalline powder. |
| *Content* | Not less than 99 % $C_4H_4O_6K$ Na on a volatile matter-free basis. |
| *Volatile matter* | Not more than 21 % determined by drying at 150 °C for three hours. |
| *Oxalates* | Not more than 0·05 % expressed as oxalic acid. |

**E 338 — Orthophosphoric acid**

| | |
|---|---|
| *Chemical description* | Orthophosphoric acid $H_3PO_4$ in concentrated aqueous solution. |
| *Appearance* | Clear, colourless, viscous liquid. |
| *Content* | Not less than 85 % $H_3PO_4$ (1). |
| *Chlorides* | Not more than 200 mg/kg expressed as chlorine (1). |
| *Nitrates* | Not more than 5 mg/kg expressed as $NaNO_3$ (1). |
| *Sulphates* | Not more than 1 500 mg/kg expressed as $CaSO_4$ (1). |
| *Fluorides* | Not more than 10 mg/kg expressed as fluorine (1). |
| *Volatile acids* | Not more than 10 mg/kg expressed as acetic acid (1). |

**E 339 — Sodium orthophosphates**

(i) Monosodium orthophosphate

| | |
|---|---|
| *Chemical description* | Monosodium monophosphate; acid monosodium monophosphate; monosodium orthophosphate; monobasic sodium phosphate; Na $H_2PO_4$.<br>The substance is available commercially in anhydrous or hydrated form with one or two molecules of water. |
| *Appearance* | Slightly deliquescent white powder, crystals or granules. |
| *Content* | Not less than 97 % Na $H_2PO_4$ on a volatile matter-free basis. |

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

| | |
|---|---|
| *Volatile matter* | Determined by drying at 60 °C for one hour and then at 105 °C for four hours:<br>— anhydrous: not more than 2 %,<br>— with one molecule of water: not more than 15 %,<br>— with two molecules of water: not more than 25 %. |
| *Water insoluble substances* | Not more than 0·2 % of the volatile matter-free substance. |
| *Fluorides* | Not more than 10 mg/kg expressed as fluorine. |

(ii) Disodium orthophosphate

| | |
|---|---|
| *Chemical description* | Disodium monophosphate; secondary sodium phosphate; disodium orthophosphate; acid disodium phosphate; $Na_2H\ PO_4$.<br>The substance is available commercially in anhydrous form or as a hydrate with two, seven or 12 molecules of water. |
| *Appearance* | Anhydrous: white hygroscopic powder.<br>With two molecules of water: white crystalline solid.<br>With seven molecules of water: granular powder or white efflorescent crystals.<br>With 12 molecules of water: white efflorescent powder or crystals. |
| *Content* | Not less than 98 % $Na_2H\ PO_4$ on a volatile matter-free basis. |
| *Volatile matter* | Determined by drying at 60 °C for one hour and at 105 °C for four hours:<br>— anhydrous: not more than 5 %,<br>— with one molecule of water: not more than 21 %,<br>— with seven molecules of water: not more than 50 %,<br>— with 12 molecules of water: not more than 61 %. |
| *Water insoluble substances* | Not more than 0·2 % of the volatile matter-free substance. |
| *Fluorides* | Not more than 10 mg/kg expressed as fluorine. |

(iii) Trisodium orthophosphates

| | |
|---|---|
| *Chemical description* | Trisodium monophosphate; trisodium orthophosphate; $Na_3PO_4$.<br>The substance is available commercially in anhydrous form or as a hydrate with one or 12 molecules of water. |
| *Appearance* | White powder, crystals or granules. |
| *Content* | Not less than 97 % $Na_3PO_4$ on a volatile matter-free basis. |
| *Volatile matter* | Determined by drying at 105 °C for one hour, followed by calcination at 800 ± 25 °C for 30 minutes:<br>— anhydrous: not more than 2 %,<br>— with one molecule of water: not more than 9 %,<br>— with 12 molecules of water: not more than 55 %. |

| | |
|---|---|
| *Water insoluble substances* | Not more than 0·2 % of the volatile matter-free substance. |
| *Fluorides* | Not more than 10 mg/kg expressed as fluorine. |

**E 340 — Potassium orthophosphates**

(i) Monopotassium orthophosphate

| | |
|---|---|
| *Chemical description* | Monopotassium monophosphate; acid monopotassium monophosphate; $KH_2PO_4$. |
| *Appearance* | Colourless crystals or white granular or crystalline powder, hygroscopic. |
| *Content* | Not less than 98 % $KH_2PO_4$ on a volatile matter-free basis. |
| *Volatile matter* | Not more than 2 % determined by drying at 105 °C for four hours. |
| *Water insoluble substances* | Not more than 0·2 % of the volatile matter-free substance. |
| *Fluorides* | Not more than 10 mg/kg expressed as fluorine. |

(ii) Dipotassium orthophosphate

| | |
|---|---|
| *Chemical description* | Dipotassium monophosphate; secondary potassium phosphate; acid dipotassium orthophosphate; dipotassium phosphate; $K_2H\ PO_4$. |
| *Appearance* | Colourless or white granular deliquescent substance. |
| *Content* | Not less than 98 % $K_2H\ PO_4$ on a volatile matter-free basis. |
| *Volatile matter* | Not more than 2 % determined by drying at 105 °C for four hours. |
| *Water insoluble substances* | Not more than 0·2 % of the volatile matter-free substance. |
| *Fluorides* | Not more than 10 mg/kg expressed as fluorine. |

(iii) Tripotassium orthophosphate

| | |
|---|---|
| *Chemical description* | Tripotassium monophosphate; tripotassium orthophosphate; $K_3PO_4$.<br>The substance is available commercially in anhydrous form or hydrated form, the most common being that with one molecule of water of crystallization. |
| *Appearance* | White hygroscopic crystals or granules. |
| *Content* | Not less than 97 % $K_3PO_4$ on a volatile matter-free basis. |
| *Volatile matter* | Determined by drying at 105 °C for one hour followed by calcination at 800 ± 25 °C for 30 minutes:<br>— anhydrous: not more than 3 %,<br>— with one molecule of water: not more than 20 %. |

| | |
|---|---|
| *Water insoluble substances* | Not more than 0·2 % of the volatile matter-free substance. |
| *Fluorides* | Not more than 10 mg/kg expressed as fluorine. |

**E 341 -- Calcium orthophosphates**

(i) Monocalcium orthophosphate

| | |
|---|---|
| *Chemical description* | Monocalcium phosphate; $CaH_4(PO_4)_2$. Available commercially in anhydrous form or as the monohydrate. |
| *Appearance* | Granular powder or white, deliquescent crystals or granules. |
| *Calcium content* | Anhydrous: not less than 23 % and not more than 25 % expressed as CaO (1).<br>With one molecule of water: not less than 22·2 % and not more than 24·7 % expressed as CaO (1). |
| *Volatile matter* | Anhydrous: not less than 14 % and not more than 15·5 % determined after calcination at 800 ± 25 °C for 30 minutes.<br>With one molecule of water: not more than 0·6 % determined by drying at 60 °C for three hours. |
| *Fluorides* | Not more than 30 mg/kg expressed as fluorine. |

(ii) Dicalcium orthophosphate

| | |
|---|---|
| *Chemical description* | Dibasic calcium phosphate; dicalcium phosphate; Ca H $PO_4$. Available commercially in anhydrous and dihydrate form. |
| *Appearance* | Impalpable white powder. |
| *Calcium content* | Anhydrous: not less than 39 % and not more than 42 % expressed as CaO (1).<br>With two molecules of water: not less than 31·9 % and not more than 33·5 % expressed as CaO (1). |
| *Volatile matter* | Determined by calcination at 800 ± 25 °C to constant weight.<br>Anhydrous: not less than 7 % and not more than 8·5 %.<br>Dihydrate: not less than 24·5 % and not more than 26·5 %. |
| *Fluorides* | Not more than 50 mg/kg expressed as fluorine. |

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

**Propylene glycol (1,2-propanediol)**

| | |
|---|---|
| *Chemical description* | Propane-1,2-diol; 1,2-dihydroxypropane; methyl glycol; $C_3H_8O_2$. |
| *Appearance* | Clear, colourless, almost odourless, viscous, hygroscopic liquid with a slightly bitter-sweet flavour. |
| *Content* | Not less than 98·5 % by weight propane-1,2-diol (1). |
| *Distillation range* | Not less than 185 °C and not more than 189 °C. |
| *Relative density* $d\ {}^{20}_{4}$ | Not less than 1·035 and not more than 1·037. |
| *Refractive index* $n\ {}^{20}_{D}$ | Not less than 1·431 and not more than 1·433. |
| *Sulphated ash* | Not more than 0·07 % of the dry matter after calcination at 800 ± 25 °C (1). |
| *Total content of dimer, trimer and higher polymers of propane-1,2-diol* | Not more than 0·1 % (1). |
| *Propane-1,3-diol content* | Not more than 100 mg/kg (1). |
| *Chlorinated organic compounds* | Not more than 1 mg/kg expressed as chlorine (1). |

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