COMMISSION OF THE EUROPEAN COMMUNITIES

COM(76) 573 final.

Brussels, 4 November 1976.

Proposal

for a Council Directive laying down the specific criteria of purity for antioxidants that may be used in foodstuffs intended for human consumption

(submitted to the Council by the Commission)

EXPLANATORY MEMORANDUM

1. Article 5 (1) of the Council Directive of 13 July 1970 (70/357/EEC) on the approximation of the laws of the Member States concerning the antioxidants authorised for use in foodstuffs intended for human consumption [1] states that the Council shall acting unanimously on a proposal from the Commission, lay down by directive the specific criteria of purity for the substances listed in Parts I to III and IV (4) to (7) of the Annex.

2. The purpose of this proposal is to lay down these criteria.

3. The Commission has established these criteria in close co-operation with Government experts and the economic and social interests concerned.

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[1] OJ N° L 157, 18/7/1970, p. 31

Proposal for a Council Directive laying down the specific criteria of purity for antioxidants that may be used in foodstuffs intended for human consumption

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to the Council Directive 70/357/EEC of 13 July 1970 on the approximation of the laws of the Member States concerning the antioxidents authorised for use in foodstuffs intended for human consumption (1), and in particular Article 5 (1) thereof,

Having regard to the proposal from the Commission,

Whereas pursuant to Article 5 thereof antioxidants must comply with the specific criteria of purity if any, laid down in accordance with Article 5 (1) thereof;

Whereas Directive 65/66/EEC of 26 January 65 (2), as last amended by Directive 76/463/EEC (3), laid down specific criteria of ourity for the preservatives authorized for use in foodstuffs intended for human consumption ;

Whereas specific criteria of purity should be laid down for all the antioxidants listed in Parts I to III and points 4 to 7 of part IV of the Annex to t Directive of 13 July 1970 excluding those for which specific criteria of purity have already been laid down in the Directive 65/66/EEC ;

Whereas meanwhile sorbitol and glycerol points 5 and 6 of part IV of the Annex to the Directive 70/357/EEC) have been included in the list of authorized substances in the Council Directive 74/329/EEC of 18 June 1974 on the approximation of the laws of the Member States relating to emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs (4) bearing the numbers E 420 and E 422 respectively ; whereas the specific criteria of purity for both these products will therefore be fixed in accordance with the Directive laying down the specific criteria of purity for emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs ,

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(1) OJ N° L 157, 18/7/1970, p. 30
(2) OJ N° 22, 9/2/1965, p. 373/65
(3) OJ N° L 126, 14/5/1976, p. 33
(4) OJ N° L 189, 12/7/1974, p. 1

H/S 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 hereto.

Article 2

Within eighteen months ofreceipt of notification of this Directive, Member States shall put into effect the regulations and administrative measures necessary to comply with the provisions of this Directive and shall inform the Commission thereof without delay.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, For the Council,

The President

ANNEX

Specific priority criteria

General comments

(a) Except where otherwise stated, the quantities and percentage values shall be calculated by weight for the anhydrous form of the substance.

(b) Where the substance in question does not exist from the outset in anhydrous form and where "volatile substances" are involved, the water of crystallization and water due to moisture shall be included in these substances.

(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 requires that certain technical data such as "vacuum" date be defined, the methods of analysis established pursuant to Article 5 § 2 of the Directive concerning substances having antioxidant activity shall be referred to.

(e) Where the concentration is mentioned, this shall be taken to mean, weight/volume, except where otherwise stated.

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

(g) For substances E 220 to E 224 inclusive, E 226 and E 270, the specific priority criteria have been established by the Directive establishing specific priority criteria for preserving agents.

ANNEX

E 300 - L-Ascorbic acid (1)

APPEARENCE	White or pale yellow crystalline powder
MELTING POINT RANGE	189° - 193° with slight decomposition
CONTENT	Not less than 99 % $C_6H_8O_6$ after 24 h drying in a desiccator with sulphuric acid or phosphorus pentoxide
SPECIFIC OPTICAL ROTATORY POWER	$[\alpha]_D^{20}$ = + 20.5° to 21.5° (C = 10 % aqueous)
VOLATILE SUBSTANCES DETERMINED OVER A 24 H PERIOD IN A DESICCATOR WITH SULPHURIC ACID OR PHOSPHORUS PENTOXIDE	Not more than 0.4 %
SULPHATED ASH	Not more than 0.1 %
pH	2.4 to 2.8 in 2 % aqueous solution

(1) The substance concerned is L-(+)-Ascorbic acid

ANNEX

E 301 - Sodium L-ascorbate (1)
(Sodium salt of L-Ascorbic acid)

APPEARANCE	White or pale yellow crystalline powder
CONTENT	Not less than 99 % $C_6H_7O_6Na$ after 24 h drying in a desiccator with sulphuric acid or phosphorus pentoxide
SPECIFIC OPTICAL ROTATORY POWER	$[\alpha]_D^{20}$ = + 103° to + 106° (C = 5 % aqueous)
VOLATILE SUBSTANCES DETERMINED OVER 24 H PERIOD IN A DESICCATOR WITH SULPHURIC ACID OR PHOSPHORUS PENTOXIDE	Not more than 0.3 %
pH	6.8 to 8.0 in 10 % aqueous solution

(1) The substance concerned is a derivate of L-(+)-Ascorbic acid

ANNEX

E 302 - Calcium L-ascorbate (1)
(Calcium salt of L-Ascorbic acid)

APPEARANCE	White or very pale grey crystalline powder
CONTENT	Not less than 99 % Ca $(C_6H_7O_6)_2 \cdot 2H_2O$ after 24 h drying in a desiccator with sulphuric acid or phosphorus pentoxide
SPECIFIC OPTICAL ROTATORY POWER	$[\alpha]_D^{20}$ = + 95° + 97° (C = 5 % aqueous)
VOLATILE SUBSTANCES DETERMINED OVER A 24 H PERIOD IN A DESICCATOR WITH SULPHURIC ACID OR PHOSPHORUS PENTOXIDE	Not more than 0.3 % (2)
pH	6.0 to 7.5 in 10 % aqueous solution

(1) The substance concerned is a derivate of L-(+)-Ascorbic acid

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

ANNEX

E 303 - 5,6-Diacetyl-L-Ascorbic acid (1)
(Ascorbyl diacetate)

APPEARANCE	White or pale yellow crystalline powder
MELTING POINT RANGE	155° - 158°
CONTENT	Not less than 99 % $C_{10}H_{12}O_8$
SPECIFIC OPTICAL ROTATORY POWER	$[\alpha]_D^{20}$ = - 77° to - 79° (C = 2 % in methanol)
VOLATILE SUBSTANCES DETERMINED OVER A 24 H PERIOD IN A DESICCATOR WITH SULPHURIC ACID OR PHOSPHORUS PENTOXIDE	Not more than 1 %
SULPHATED ASH	Not more than 0.1 %

(1) The substance concerned is a derivate of L-(+)-Ascorbic acid

ANNEX

E 304 - 6-Palmityl-L-ascorbic acid (1)
(Ascorbyl palmitate)

APPEARANCE	Impalpable white or yellowish-white powder or yellowish-white crystals
MELTING POINT RANGE	111° - 113° (changes to viscous state without completely melting)
CONTENT	Not less than 98 % $C_{22}H_{38}O_7$
SPECIFIC OPTICAL ROTATORY POWER	$[\alpha]_D^{20}$ = + 21° to 24° (C = 5 % in methanol)
VOLATILE SUBSTANCES DETERMINED OVER A 24 H PERIOD IN A DESICCATOR WITH SULPHURIC ACID OR PHOSPHORUS PENTOXIDE	Not more than 1 %
SULPHATED ASH	Not more than 0.2 %

(1) The substance concerned is a derivate of L-(+)-Ascorbic acid

ANNEX

E 306 - Tocopherol-rich extracts of natural origin

APPEARANCE	Clear, viscous, red to brownish-red oil
CONTENT	Not less than 34 % total tocopherols
SPECIFIC GRACITY d_4^{20}	Not less than 0.928 and not more than 0.951
FREE FATTY ACIDS	Neutralization of the free fatty acids in 10 g E 306 in the presence of phenolphthalein, must not require more than 10 ml 0.1 N sodium hydroxide or 0.1 N potassium hydroxide

ANNEX

E 307 - Synthetic Alpha-tocopherol (1)

APPEARANCE	Clear, viscous, yellowish oil which darkens on exposure to air or light
CONTENT	Not less than 96 % $C_{29}H_{50}O_2$
REFRACTIVE INDEX n_D^{20}	Not less than 1.503 and not more than 1.507
SPECIFIC GRAVITY d_4^{20}	Not less than 0.947 and not more than 0.958
SPECIFIC ABSORPTION $E_{1\ cm}^{1\ \%}$ IN ETHANOL	At the absorption maximum of 292 nm : $E_{1cm}^{1\ \%}$ (292 nm) : 72 - 76 At the absorption minimum of 255 nm : $E_{1\ cm}^{1\ \%}$(255 nm) : 6.0 - 8.0
SULPHATED ASH	Not more than 0.1 %

(1) The substance concerned in synthetic DL-Alpha-tocopherol

ANNEX

E 308 - Synthetic Gamma-tocopherol

APPEARANCE	Clear, viscous, pale yellow oil which darkens on exposure to air or light
CONTENT	Not less than 97 % $C_{28}H_{48}O_2$
REFRACTIVE INDEX n_D^{20}	Not less than 1.503 and not more than 1.507
SPECIFIC GRAVITY d_4^{20}	Not less than 0.948 and not more than 0.959
SPECIFIC ABSORPTION $E_{1\ cm}^{1\ \%}$ IN ETHANOL	At the absorption maximum of 298 nm : $E_{1cm}^{1\ \%}$ (298 nm) : 91 - 97 At the absorption minimum of 257 nm : $E_{1\ cm}^{1\ \%}$ (257 nm) : 5.0 - 8.0
SULPHATED ASH	Not more than 0.1 %

ANNEX

E 309 - Synthetic Delta-tocopherol

APPEARANCE	Clear, viscous pale yellowish or orange oil which darkens on exposure to air or light
CONTENT	Not less than 97 % $C_{27}H_{46}O_2$
REFRACTIVE INDEX n_D^{20}	Not less than 1.500 and not more than 1.504
SPECIFIC INDEX d_4^{20}	Not less than 0.952 and not more than 0.962
SPECIFIC ABSORPTION $E_{1\ cm}^{1\ \%}$ IN ETHANOL	At the absorption maximum of 297 nm - 298 nm $E_{1\ cm}^{1\ \%}$ (297 - 298 nm) : 89 - 95 At the absorption minimum of 257 nm : $E_{1\ cm}^{1\ \%}$ (257 nm) : 3.0 - 6.0
SULPHATED ASH	Not more than 0.1 %

ANNEX

E 311 - Octyl gallate

APPEARANCE	White or very pale yellowish crystalline powder
MELTING POINT RANGE	99 - 102.5° after 6 h drying at 90°
CONTENT	Not less than 98.5 % $C_{15}H_{22}O_5$ after 4 h drying at 60°
SPECIFIC ABSORPTION $E_{1\ cm}^{1\ \%}$ IN ETHANOL	At the absorption maximum of 275 nm : $E_{1\ cm}^{1\ \%}$ (275 nm) : 375 - 390 At the absorption minimum of 218 nm : $E_{1\ cm}^{1\ \%}$ (218 nm) : 935 - 960
VOLATILE SUBSTANCES DETERMINED OVER A 4 H PERIOD AT 60° IN A DESICCATOR	Not more than 0.5 %
SULPHATED ASH	Not more than 0.05 %
FREE ACIDS	Not more than 0.5 % expressed as gallic acid (9.407 mg gallic acid corresponding to 1 ml 0.05 N-sodium hydroxide).

ANNEX

E 312 - Dodecyl gallate

APPEARANCE	White or pale cream crystalline powder
MELTING POINT RANGE	96° - 98° after 4 h drying at 60°
CONTENT	Not less than 98.5 % $C_{19}H_{30}O_5$ after 4 h drying at 60°
SPECIFIC ABSORPTION $E^{1\ \%}_{1\ cm}$ IN ETHANOL	At the absorption maximum of 275 nm : $E^{1\ \%}_{1\ cm}$ (275 nm) : 300 - 325
VOLATILE SUBSTANCES DETERMINED OVER A 4 H PERIOD AT 60° IN A DESICCATOR	Not more than 0.5 %
SULPHATED ASH	Not more than 0.05 %
FREE ACIDS	Not more than 0.5 % expressed as gallic acid (9.407 mg gallic acid corresponding to 1 ml 0.05 N-sodium hydroxide).

ANNEX

E 320 - Butylated hydroxyanisole (BHA) (1)

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-tert.-Butyl-4-hydroxy-anisole isomer
SPECIFIC ABSORPTION $E^{1\ \%}_{1\ cm}$ IN ETHANOL	At the absorption maximum of 290 nm : $E^{1\ \%}_{1\ cm}$ (290 nm) : 190 - 210 At the absorption minimum of 228 nm : $E^{1\ \%}_{1cm}$ (228 nm) : 326 - 345
4-HYDROXYANISOLE CONTENT	Not more than 0.5 %
SULPHATED ASH	Not more than 0.05 %

(1) All these criteria apply to the substance as it stands.

ANNEX

E 321 - Butylated hydroxytoluene (BHT)

APPEARANCE	White crystalline or powdery crystalline substance
CONTENT	Not less than 99 % $C_{15}H_{24}O$ (1)
MELTING POINT RANGE	69° - 70° (1)
SPECIFIC ABSORPTION $E^{1\,\%}_{1\ cm}$ IN ETHANOL	At the absorption maximum of 278 nm : $E^{1\,\%}_{1cm}$ (278 nm) : 81 - 88 (1)
SULPHATED ASH	Not more than 0.005 %

(1) The data here relate to the anhydrous substance (without anticoagulant)

ANNEX

E 322 - Lecithins

APPEARANCE	Brown liquid or viscous semi-liquid or powder
DESCRIPTION	Lecithins are mixtures of phosphatides obtained by means of physical procedure from animal or vegetable foodstuffs; this extraction my proceed as far as the stage of fractionation of the lecithin complex into its various components. The lecithins may be slightly bleached in aqueous medium by means of hydrogen peroxide. This oxidation must not chemically modify the lecithin phosphatides.
CONTENT	Not less than 60 % substance insoluble in acetone
VOLATILE SUBSTANCES DETERMINED BY 1 H DRYING AT 105° C	Not more than 2 %
SUBSTANCES INSOLUBLE IN BENZENE	Not more than 0.3 %
SUBSTANCES INSOLUBLE IN ACETONE	Not less than 50 %
ACID NUMBER EXPRESSED AS MILLIGRAMS POTASSIUM HYDROXIDE NEEDED TO NEUTRALIZE THE FREE ACIDS PRESENT IN A 1 G SAMPLE	Not more than 35
PEROXIDE NUMBER EXPRESSED AS MILLIEQUIVALENTS PER KG	Equal to or less than 10.

ANNEX

E 325 - Sodium lactate
(Sodium salt of lactic acid)

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 % of anhydrous sodium lactate.
CONTENT	Not less than 98 % Na $C_3H_5O_3$ after drying
ACIDITY	Neutralization of a 1 g sample after drying shall not require more than 0.5 ml 0.1 N sodium hydroxide solution in the presence of phenolphtalein.
REDUCING SUBSTANCES	No reduction of Fehling's solution

ANNEX

E 326 - Potassium lactate
(Potassium salt of lactic acid)

APPEARANCE	Slightly syrupy, almost odourless, clear liquid
DESCRIPTION	The substance is usually available commercially in the form of an aqueous solution containing 60 % anhydrous potassium lactate
CONTENT	Not less than 57 % K $C_3H_5O_3$
ACIDITY	Neutralization of a 1 g sample shall not require more than a 0.22 ml 0.1 N sodium hydroxide solution in the presence of phenolphtalein. The data given here refer to a 57 % aqueous solution. For other concentrated solutions, the values corresponding to their potassium lactate content must be calculated.
REDUCING SUBSTANCES	No reduction of Fehling's solution

ANNEX

E 327 - Calcium lactate (1)
(Calcium salt of lactic acid)

APPEARANCE	Almost odourless, white crystalline powder or granules
CONTENT	Not less than 98 % Ca $(C_3H_5O_3)_2$ after 4 h drying at 120°
VOLATILE SUBSTANCES DETERMINED BY 4 H DRYING AT 120°	Not more than 3 % The substance is available commercially in forms other than the anhydrous form, the most common being : - calcium lactate with one molecule of water of crystallization containing not more than 8 % volatile substances. - calcium lactate with three molecules of water of crystallization containing not more than 20 % volatile substances - calcium lactate with five molecules of water of crystallization containing not more than 30 % volatile substances.
ACIDITY	Neutralization of a 1 g sample shall not require more than 0.5 ml 0.1 N-sodium hydroxide solution in the presence of phenolphtalein. For aqueous solutions the values corresponding to their calcium lactate content must be calculated.
FLUORINE	Not more than 30 mg/kg
REDUCING SUBSTANCES	No reduction of Fehling's solution

(1) The data given here refer to the anhydrous substance.

ANNEX

E 330 - Citric acid

APPEARANCE	Colourless or translucent crystalline solid or white crystalline powder
CONTENT	Not less than 99.5 % $C_6H_8O_7$
VOLATILE SUBSTANCES	Not more than 0.5 % The substance may be obtained commercially in forms other than the anhydrous form. One of the most common of these is citric acid with one molecule of water of crystallization containing not more than 8.8 % volatile substances.
OXALATES	Not more than 0.05 % oxalic acid
SULPHATED ASH	Not more than 0.05 %
SULPHURIC ACID TEST	1 g sample dissolved in 10 ml 95 % sulphuric acid and heated for 60 min. at 90° shall not show a darker colouration than a solution containing 0.5 parts of a $CoCl_2.6H_2O$ solution (59.5 mg/ml) and 4.5 parts of a $FeCl_3.6H_2O$ solution (45.0 mg/ml)

ANNEX

E 331 - Sodium citrates
(Sodium salts of citric acid)

APPEARANCE	Crystalline white powder or colourless crystals.
CONTENT	Not less than 99 % sodium citrate expressed as trisodium citrate $Na_3\ C_6H_5O_7$ after drying at 180°
VOLATILE SUBSTANCES DETERMINED BY DRYING AT 180°	Not more than 1 % The substance is available commercially in forms other than the anhydrous form, the most common being : - sodium citrate with two molecules of water of crystallization containing not more than 13 % volatile substances - sodium citrate with 5.5 molecules of water of crystallization containing not more than 30 % volatile substances.
OXALATES	Not more than 0.05 % exalic acid

ANNEX

E 332 - Potassium citrates (1)

(Potassium salts of citric acid)

APPEARANCE	White, hygroscopic, granular powder or transparent crystals.
CONTENT	Not less than 99 % potassium citrate expressed as tripotassium citrate $C_6H_5O_7K_3$ after 4 h drying at 180°
VOLATILE SUBSTANCES DETERMINED BY 4 H DRYING AT 180°	Not more than 6 %
OXALATES	Not more than 0.05 % oxalic acid

(1) The substance is available commercially in the form of potassium citrate with one molecule of water of crystallization. The data here refer to the substance with one molecule of water of crystallization.

ANNEX

E 333 - Calcium citrates (1)
(Calcium salts of citric acid)

APPEARANCE	Fine white powder
CONTENT	Not less than 97.5 % calcium citrate expressed as tricalcium citrate $Ca_3 (C_6H_5O_7)_2$ after drying at 180°
VOLATILE SUBSTANCES DETERMINED BY DRYING AT 180°	Not more than 13 %
CARBONATES	Dissolving of 1 g calcium citrate in 10 ml dilute hydrochloric acid (2) must not liberate more than a few isolated bubbles.
OXALATES	Not more than 0.05 % oxalic acid
FLUORINE	Not more than 30 mg/kg

(1) The substance is available commercially in the form of calcium citrate with four molecules of water of crystallization containing not more than 13 % volatile substances.

(2) Mix 260 ml hydrochloric acid (25 % w/v HCl) and a little water, then make up to 1 000 ml (approximately 2 N).

ANNEX

E 334 - Tartaric acid (1)

APPEARANCE	Colourless or translucent crystalline solid, or white crystalline powder
CONTENT	Not less than 99.5 % $C_4H_6O_6$ after drying at 105°
VOLATILE SUBSTANCES DETERMINED AFTER DRYING AT 105°	Not more than 0.5 %
SULPHATED ASH	Not more than 0.1 %
OXALATES	Not more than 0.05 % oxalic acid

(1) The substance concerned is L-(+)-Tartaric acid

ANNEX

E 335 - Sodium tartrates (1)
(Sodium salts of tartaric acid)

APPEARANCE	Transparent, colourless crystals
CONTENT	Not less than 99 % $Na_2\ C_4H_4O_6$ after 3 h drying at 150°
VOLATILE SUBSTANCES DETERMINED BY 3 H DRYING AT 150°	Not more than 17 %
OXALATES	Not more than 0.05 % oxalic acid

(1) The substances concerned are derivates of L-(+)-Tartaric acid. This substance is available commercially in the form of sodium tartrate with two molecules of water of crystallization containing not less than 14 % and not more than 17 % of volatile substances.

ANNEX

E 336 - Potassium tartrates (1)
(Potassium salts of tartaric acid)

APPEARANCE	White crystalline or granulated powder
CONTENT	Not less than 99 % $K_2C_4H_4O_6$ after drying at 160°
VOLATILE SUBSTANCES DETERMINED BY DRYING AT 160°	Not less than 4 %
OXALATES	Not more than 0.05 % oxalic acid

(1) The substance concerned is a derivate of L-(+)-Tartaric acid.
The substance is available commercially in the form of potassium tartrate with half a molecule of water of crystallization containing not more than 4 % volatile substances.

ANNEX

E 337 - Sodium potassium tartrate (1)

APPEARANCE	Colourless crystals or white crystalline powder
CONTENT	Not less than 99 % Na K $C_4H_4O_6$ after 3 h drying at 150°
VOLATILE SUBSTANCES DETERMINED BY 3 H DRYING AT 150°	Not more than 26 %
OXALATES	Not more than 0.05 % oxalic acid.

(1) The substance concerned is a derivate of L-(+)-Tartaric acid. The substance is available commercially in the form of sodium potassium tartrate with four molecules of water of crystallization containing not less than 21 % and not more than 26 % volatile substances.

ANNEX

E 338 - Orthophosphoric acid (1)

APPEARANCE	Clear, colourless, viscous liquid
CONTENT	Not less than 85 % H_3PO_4
CHLORIDES	Not more than 0.02 % expressed as chlorine
NITRATES	Not more than 0.0005 % expressed at $NaNO_3$
SULPHATES	Not more than 0.15 % expressed as $CaSO_4$
FLUORINE	Not more than 10 mg/kg expressed as fluorine
VOLATILE ACIDS	Not more than 0.001 % expressed as acetic acid

(1) All the data here refer to a substance composed of not less than 85 % H_3PO_4 and not more than 15 % water.

ANNEX

E 339 A - Monosodium orthophosphate (1)

(Sodium salts of orthophosphoric acid)

APPEARANCE	Slightly deliquescent, white powder, crystals or granules
CONTENT	Not less than 97 % NaH_2PO_4 after 1 h drying at 60° and then 4 h drying at 105°
VOLATILE SUBSTANCES DETERMINED BY 1 H DRYING AT 60° THEN 4 H DRYING AT 105°	Not more than 2 %
WATER INSOLUBLE SUBSTANCES	Not more than 0.2 %
FLUORINE	Not more than 10 mg/kg expressed as fluorine.

(1) The forms of the substance available commercially other than the anhydrous form are :

Monosodium orthophosphate with one molecule of water of crystallization containing not more than 15 %

Monosodium orthophosphate with two molecules of water of crystallization containing not more than 25 %.

ANNEX

E 339 B - Disodium orthophosphate (1)

(Sodium salts of orthophosphoric acid)

APPEARANCE	Anhydrous form : white hygroscopic powder With two molecules water : white crystalline solid With seven molecules water : white granular powder of effluorescent crystals With twelve molecules water : white powder or effluorescent crystals
CONTENT	Not less than 98 % $Na_2 H PO_4$ after 1 h drying at 60° and then 4 h drying at 105°
VOLATILE SUBSTANCES DETERMINED BY 1 H DRYING AT 60° AND 4 H DRYING AT 105°	Not less than 5 %
WATER INSOLUBLE SUBSTANCES	Not more than 0.2 %
FLUORINE	Not more than 10 mg/kg expressed as fluorine

(1) The product is available commercially in forms other than the anhydrous form such as :

- Disodium orthophosphate with two molecules of water of crystallization containing not more than 21 % of volatile substances
- Disodium orthophosphate with seven molecules of water of crystallization containing not more than 50 % of volatile substances
- Disodium orthophosphate with twelve molecules of water crystallization containing not more than 61 % of volatile substances.

ANNEX

E 339 C - Trisodium orthophosphate (1)

(Sodium salts of orthophosphoric acid)

APPEARANCE	White powder, crystals or granules
CONTENT	Not less than 97 % $Na_3 PO_4$ after 30 min calcining at 800°
VOLATILE SUBSTANCES DETERMINED BY 30 MIN CALCINATION AT 800°	Not more than 2 %
WATER INSOLUBLE SUBSTANCES	Not more than 0.2 %
FLUORINE	Not more than 10 mg/kg expressed as fluorine.

(1) The substance is available commercially in the following forms other than the anhydrous form :

- Trisodium orthophosphate with one molecule of water of crystallization containing not more than 9 % of volatile substances
- Trisodium orthophosphate with twelve molecules of water of crystallization containing not more than 55 % of volatile substances.

ANNEX

E 340 A - Monopotassium orthophosphate
(Potassium salts of orthophosphoric acid)

APPEARANCE	Colourless crystals or white granular or crystalline powder
CONTENT	Not less than 98 % KH_2PO_4 after 4 h drying at 105°
VOLATILE SUBSTANCES DETERMINED BY 4 H DRYING AT 105°	Not more than 2 %
WATER INSOLUBLE SUBSTANCES	Not more than 0.2 %
FLUORINE	Not more than 10 mg/kg expressed as fluorine.

ANNEX

E 340 B - Dipotassium orthophosphate
(Potassium salts of orthophosphoric acid)

APPEARANCE	Colourless or white granular deliquescent substance
CONTENT	Not less than 98 % $K_2 H PO_4$ after 4 h drying at 105°
WOLATILE SUBSTANCES DETERMINED BY 4 H DRYING AT 105°	Not more than 2 %
WATER INSOLUBLE SUBSTANCES	Not more than 0.2 %
FLUORINE	Not more than 10 mg/kg expressed as fluorine.

ANNEX

E 340 C - Tripotassium orthophosphate (1)

(Potassium salts of orthophosphoric acid)

APPEARANCE	White hygroscopic crystals or granules
CONTENT	Not less than 97 % $K_3 PO_4$ after 30 min calcination at 800°
VOLATILE SUBSTANCES DETERMINED BY 30 MIN CALCINATION AT 300°	Not more than 3 %
WATER INSOLUBLE SUBSTANCES	Not more than 0.2 %
FLUORINE	Not more than 10 mg/kg expressed as fluorine.

(1) The substance is available commercially in forms other than the anhydrous form, the most common being :

Tripotassium orthophosphate with one molecule of water of crystallization containing not more than 20 % of volatile substances.

ANNEX

E 341 A - Monocalcium orthophosphate
(Calcium salts of orthophosphoric acid)

APPEARANCE	White, deliquescent granular powder, crystals or granules
CALCIUM CONTENT	Anhydrous form : not less than 23 % and not more than 25 % expressed as CaO With one molecule of water : not less than 22.2 % and not more than 24.7 % expressed as CaO.
VOLATILE SUBSTANCES	Anhydrous form : not less than 14 % and not more than 15.5 % determined by less during 30 min heating at 800° With one molecule of water : not more than 0.6 % (1), determined by 3 h drying at 60°
FLUORINE	Not more than 30 mg/kg expressed as fluorine.

(1) 0.6 % does not refer to water of crystallization but at moisture lost under these conditions.

ANNEX

E 341 B - Dicalcium orthophosphate
(Calcium salts of orthophosphoric acid)

APPEARANCE	Impalpable white powder
CALCIUM CONTENT	Anhydrous form : not less than 39 % and not more than 42 % expressed as CaO With two molecules of water : not less than 31.9 % and not more than 33.5 % expressed as CaO
VOLATILE SUBSTANCES DETERMINED BY CALCINATION BETWEEN 800 AND 825° TO CONSTANT WEIGHT	Anhydrous form : not less than 7 % and not more than 8.5 % With two molecules of water : not less than 24.5 % and not more than 26.5 %
FLUORINE	Not more than 50 mg/kg expressed as fluorine.

ANNEX

E 341 C - Tricalcium orthophosphate
(Calcium salts of orthophosphoric acid)

APPEARANCE	Impalpable white powder
CALCIUM CONTENT	Not less than 90 % $Ca_3 (PO_4)_2$ after calcination between 800 and 825° to constant weight
VOLATILE SUBSTANCES DETERMINED BY CALCINATION BETWEEN 800 AND 825° TO CONSTANT WEIGHT	Not more than 10 %
FLUORINE	Not more than 50 mg/kg expressed as fluorine.

ANNEX

Propylene glycol (1,2-propanediol)

APPEARANCE	Clear, colourless, odourless, viscous, hygroscopic liquid with a slightly sharp flavour
CONTENT	Not less than 97,5 % by weight 1,2 propanediol and not more than 0.2 % water; the remaining 0.8 % being composed of a polypropyleneglycol compound which, in the case of the substance containing no water, may reach 1 %
DISTILLATION RANGE	Not less than 185° and not more than 189°
SPECIFIC GRAVITY d_4^{20}	Not less than 1.035 and not more than 1.037
REFRACTIVE INDEX n_D^{20}	Not less than 1.431 and not more than 1.433
CALCINATION RESIDUES	Not more than 0,07 %