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(Acts whose publication is obligatory)

COMMISSION DIRECTIVE 2002/82/EC

of 15 October 2002

amending 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 ([1]), as amended by Directive 94/34/EC of the European Parliament and of the Council ([2]) and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee on Food,

Whereas:

(1) Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners ([3]), as last amended by Directive 2001/5/EC ([4]), lists those substances which may be used as additives other than colours and sweeteners in foodstuffs.

(2) Commission Directive 96/77/EC ([5]), as last amended by Directive 2001/30/EC ([6]) sets out the purity criteria for the additives other than colours and sweeteners mentioned in Directive 95/2/EC.

(3) It is necessary to adapt to technical progress existing purity criteria set out in Directive 96/77/EC and to establish new purity criteria for those food additives for which these were failing.

(4) 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).

(5) Directive 96/77/EC should therefore be amended accordingly.

(6) 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 as set out in the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 August 2003 at the latest. They shall forthwith inform the Commission thereof.

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

Article 3

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

([1]) OJ L 40, 11.2.1989, p. 27.
([2]) OJ L 237, 10.9.1994, p. 1.
([3]) OJ L 61, 18.3.1995, p. 1.
([4]) OJ L 55, 24.2.2001, p. 59.
([5]) OJ L 339, 30.12.1996, p. 1.
([6]) OJ L 146, 31.5.2001, p. 1.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 15 October 2002.

For the Commission
David BYRNE
Member of the Commission

ANNEX

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

(1) The text concerning E 338 Phosphoric acid, E 339 (i) Monosodium Phosphate, E 339 (ii) Disodium Phosphate, E 339 (iii) Trisodium Phosphate, E 340 (i) Monopotassium Phosphate, E 340 (ii) Dipotassium Phosphate, E 340 (iii) Tripotassium Phosphate, E 341 (i) Monocalcium Phosphate, E 341 (ii) Dicalcium Phosphate, E 341 (iii) Tricalcium Phosphate, E 450 (i) Disodium Diphosphate, E 450 (ii) Trisodium Diphosphate, E 450 (iii) Tetrasodium Diphosphate, E 450 (v) Tetrapotassium Diphosphate, E 450 (vi) Dicalcium Diphosphate, E 450 (vii) Calcium Dihydrogen Diphosphate, E 451 (i) Pentasodium Triphosphate and E 451 (ii) Pentapotassium Triphosphate, E 452 (i) Sodium Polyphosphate, E 452 (ii) Potassium Polyphosphate and E 452 (iv) Calcium Polyphosphate is replaced by the following:

'E 338 PHOSPHORIC ACID

Synonyms	Orthophosphoric acid Monophosphoric acid
Definition	
Chemical name	Phosphoric acid
EINECS	231-633-2
Chemical formula	H_3PO_4
Molecular weight	98,00
Assay	Phosphoric acid is commercially available as an aqueous solution at variable concentrations. Content not less than 67,0 % and not more than 85,7 %.
Description	Clear, colourless, viscous liquid
Identification	
A. Positive tests for acid and for phosphate	
Purity	
Volatile acids	Not more than 10 mg/kg (as acetic acid)
Chlorides	Not more than 200 mg/kg (expressed as chlorine)
Nitrates	Not more than 5 mg/kg (as $NaNO_3$)
Sulphates	Not more than 1 500 mg/kg (as $CaSO_4$)
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg
Note: This specification refers to a 75 % aqueous solution.	

E 339 (i) MONOSODIUM PHOSPHATE

Synonyms	Monosodium monophosphate Acid monosodium monophosphate Monosodium orthophosphate Monobasic sodium phosphate Sodium dihydrogen monophosphate
Definition	
Chemical name	Sodium dihydrogen monophosphate
EINECS	231-449-2
Chemical formula	Anhydrous: NaH_2PO_4 Monohydrate: $NaH_2PO_4 \cdot H_2O$ Dihydrate: $NaH_2PO_4 \cdot 2H_2O$
Molecular weight	Anhydrous: 119,98 Monohydrate: 138,00 Dihydrate: 156,01
Assay	After drying at 60 °C for one hour and then at 105 °C for four hours, contains not less than 97 % of NaH_2PO_4
P_2O_5 content	Between 58,0 % and 60,0 % on the anhydrous basis
Description	A white odourless, slightly deliquescent powder, crystals or granules
Identification	
A. Positive tests for sodium and for phosphate	
B. Solubility	Freely soluble in water. Insoluble in ethanol or ether
C. pH of a 1 % solution	Between 4,1 and 5,0
Purity	
Loss on drying	The anhydrous salt loses not more than 2,0 %, the monohydrate not more than 15,0 %, and the dihydrate not more than 25 % when dried first at 60 °C for one hour, then at 105 °C for four hours
Water-insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 339 (ii) DISODIUM PHOSPHATE

Synonyms	Disodium monophosphate Secondary sodium phosphate Disodium orthophosphate Acid disodium phosphate
Definition	
Chemical name	Disodium hydrogen monophosphate Disodium hydrogen orthophosphate
EINECS	231-448-7
Chemical formula	Anhydrous: Na_2HPO_4 Hydrat: $Na_2HPO_4 \cdot nH_2O$ (n = 2, 7 or 12)
Molecular weight	141,98 (anhydrous)
Assay	After drying at 40 °C for three hours and subsequently at 105 °C for five hours, contains not less than 98 % of Na_2HPO_4
P_2O_5 content	Between 49 % and 51 % on the anhydrous basis
Description	Anhydrous disodium hydrogen phosphate is a white, hygroscopic, odourless powder. Hydrated forms available include the dihydrate: a white crystalline, odourless solid; the heptahydrate: white, odourless, efflorescent crystals or granular powder; and the dodecahydrate: white, efflorescent, odourless powder or crystals
Identification	
A. Positive tests for sodium and for phosphate	
B. Solubility	Freely soluble in water. Insoluble in ethanol
C. pH of a 1 % solution	Between 8,4 and 9,6
Purity	
Loss on drying	When dried at 40 °C for three hours and then at 105°C for five hours, the losses in weight are as follows: anhydrous not more than 5,0 %, dihydrate not more than 22,0 %, heptahydrate not more than 50,0 %, dodecahydrate not more than 61,0 %
Water-insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 339 (iii) TRISODIUM PHOSPHATE

Synonyms	Sodium phosphate Tribasic sodium phosphate Trisodium orthophosphate
Definition	Trisodium phosphate is obtained from aqueous solutions and crystallises in the anhydrous form and with 1/2, 1, 6, 8 or 12 H_2O. The dodecahydrate always crystallises from aqueous solutions with an excess of sodium hydroxide. It contains ¼ molecule of NaOH
Chemical name	Trisodium monophosphate Trisodium phosphate Trisodium orthophosphate
EINECS	231-509-8
Chemical formula	Anhydrous: Na_3PO_4 Hydrated: $Na_3PO_4 \cdot nH_2O$ (n = 1/2, 1, 6, 8, or 12)
Molecular weight	163,94 (anhydrous)
Assay	Sodium phosphate anhydrous and the hydrated forms, with the exception of the dodecahydrate, contain not less than 97,0 % of Na_3PO_4 calculated on the dried basis.Sodium phosphate dodecahydrate contains not less than 92,0 % of Na_3PO_4 calculated on the ignited basis
P_2O_5 content	Between 40,5 % and 43,5 % on the anhydrous basis
Description	White odourless crystals, granules or crystalline powder
Identification	
A. Positive tests for sodium and for phosphate	
B. Solubility	Freely soluble in water. Insoluble in ethanol
C. pH of a 1 % solution	Between 11,5 and 12,5
Purity	
Loss on ignition	When dried at 120 °C for two hours and then ignited at about 800 °C for 30 minutes, the losses in weight are as follows: anhydrous not more than 2,0 %, monohydrate not more than 11,0 %, dodecahydrate: between 45,0 % and 58,0 %
Water insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 340 (i) MONOPOTASSIUM PHOSPHATE

Synonyms	Monobasic potassium phosphate Monopotassium monophosphate Potassium orthophosphate
Definition	
Chemical name	Potassium dihydrogen phosphate Monopotassium dihydrogen orthophosphate Monopotassium dihydrogen monophosphate
EINECS	231-913-4
Chemical formula	KH_2PO_4
Molecular weight	136,09
Assay	Content not less than 98,0 % after drying at 105 °C for four hours
P_2O_5 content	Between 51,0 % and 53,0 % on the anhydrous basis
Description	Odourless, colourless crystals or white granular or crystalline powder, hygroscopic
Identification	
A. Positive tests for potassium and for phosphate	
B. Solubility	Freely soluble in water. Insoluble in ethanol
C. pH of a 1 % solution	Between 4,2 and 4,8
Purity	
Loss on drying	Not more than 2,0 % determined by drying at 105 °C for four hours
Water-insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 340 (ii) DIPOTASSIUM PHOSPHATE

Synonyms	Dipotassium monophosphate Secondary potassium phosphate Dipotassium acid phosphate Dipotassium orthophosphate Dibasic potassium phosphate
Definition	
Chemical name	Dipotassium hydrogen monophosphate Dipotassium hydrogen phosphate Dipotassium hydrogen orthophosphate
EINECS	231-834-5
Chemical formula	K_2HPO_4
Molecular weight	174,18
Assay	Content not less than 98 % after drying at 105°C for four hours
P_2O_5 content	Between 40,3 % and 41,5 % on the anhydrous basis
Description	Colourless or white granular powder, crystals or masses; deliquescent substance
Identification	
A. Positive tests for potassium and for phosphate	
B. Solubility	Freely soluble in water. Insoluble in ethanol
C. pH of a 1 % solution	Between 8,7 and 9,4
Purity	
Loss on drying	Not more than 2,0 % determined by drying at 105 °C for four hours
Water-insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 340 (iii) TRIPOTASSIUM PHOSPHATE

Synonyms	Potassium phosphate Tribasic potassium phosphate Tripotassium orthophosphate
Definition	
Chemical name	Tripotassium monophosphate Tripotassium phosphate Tripotassium orthophosphate
EINECS	231-907-1
Chemical formula	Anhydrous: K_3PO_4 Hydrated: $K_3PO_4 \cdot nH_2O$ (n = 1 or 3)
Molecular weight	212,27 (anhydrous)
Assay	Content not less than 97 % calculated on the ignited basis
P_2O_5 content	Between 30,5 % and 33,0 % on the ignited basis
Description	Colourless or white, odourless hygroscopic crystals or granules. Hydrated forms available include the monohydrate and trihydrate
Identification	
A. Positive tests for potassium and for phosphate	
B. Solubility	Freely soluble in water. Insoluble in ethanol
C. pH of a 1 % solution	Between 11,5 and 12,3
Purity	
Loss on ignition	Anhydrous: not more than 3,0 %; hydrated: not more than 23,0 %. Determined by drying at 105 °C for one hour and then ignite at about 800 °C ± 25 °C for 30 minutes
Water insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 341 (i) MONOCALCIUM PHOSPHATE

Synonyms	Monobasic calcium phosphate Monocalcium orthophosphate
Definition	
Chemical name	Calcium dihydrogen phosphate
EINECS	231-837-1
Chemical formula	Anhydrous: $Ca(H_2PO_4)_2$ Monohydrate: $Ca(H_2PO_4)_2 \cdot H_2O$
Molecular weight	234,05 (anhydrous) 252,08 (monohydrate)
Assay	Content not less than 95 % on the dried basis
P_2O_5 content	Between 55,5 % and 61,1 % on the anhydrous basis
Description	Granular powder or white, deliquescent crystals or granules
Identification	
A. Positive tests for calcium and for phosphate	
B. CaO content	Between 23,0 % and 27,5 % (anhydrous) Between 19,0 % and 24,8 % (monohydrate)
Purity	
Loss on drying	Not more than 14 % determined by drying at 105 °C for four hours (anhydrous) Not more than 17,5 % determined by drying at 60 °C for one hour, then at 105 °C for four hours (monohydrate)
Loss on ignition	Not more than 17,5 % after ignition at 800 °C ± 25 °C for 30 minutes (anhydrous) Not more than 25,0 % determined by drying at 105 °C for one hour, then ignite at 800 °C ± 25 °C for 30 minutes (monohydrate)
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 341 (ii) DICALCIUM PHOSPHATE

Synonyms	Dibasic calcium phosphate Dicalcium orthophosphate
Definition	
Chemical name	Calcium monohydrogen phosphate Calcium hydrogen orthophosphate Secondary calcium phosphate
EINECS	231-826-1
Chemical formula	Anhydrous: $CaHPO_4$ Dihydrate: $CaHPO_4 \cdot 2H_2O$
Molecular weight	136,06 (anhydrous) 172,09 (dihydrate)
Assay	Dicalcium phosphate, after drying at 200 °C for three hours, contains not less than 98 % and not more than the equivalent of 102 % of $CaHPO_4$
P_2O_5 content	Between 50,0 % and 52,5 % on the anhydrous basis
Description	White crystals or granules, granular powder or powder
Identification	
A. Positive tests for calcium and for phosphate	
B. Solubility tests	Sparingly soluble in water. Insoluble in ethanol
Purity	
Loss on ignition	Not more than 8,5 % (anhydrous), or 26,5 % (dihydrate) after ignition at 800 °C ± 25 °C for 30 minutes
Fluoride	Not more than 50 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 341 (iii) TRICALCIUM PHOSPHATE

Synonyms	Calcium phosphate, tribasic Calcium orthophosphate Pentacalcium hydroxy monophosphate Calcium hydroxyapatite
Definition	Tricalcium phosphate consists of a variable mixture of calcium phosphates obtained from neutralisation of phosphoric acid with calcium hydroxide and having the approximate composition of $10CaO \cdot 3P_2O_5 \cdot H_2O$
Chemical name	Pentacalcium hydroxy monophosphate Tricalcium monophosphate
EINECS	235-330-6 *(Pentacalcium hydroxy monophosphate)* 231-840-8 *(Calcium orthophosphate)*
Chemical formula	$Ca_5(PO_4)_3 \cdot OH$ or $Ca_3(PO_4)_2$
Molecular weight	502 or 310
Assay	Content not less than 90 % calculated on the ignited basis
P_2O_5 content	Between 38,5 % and 48,0 % on the anhydrous basis
Description	A white, odourless powder which is stable in air
Identification	
A. Positive tests for calcium and for phosphate	
B. Solubility	Practically insoluble in water; insoluble in etanol, soluble in dilute hydrochloric and nitric acid
Purity	
Loss on ignition	Not more than 8 % after ignition at 800 °C ± 25 °C, to constant weight
Fluoride	Not more than 50 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 450 (i) DISODIUM DIPHOSPHATE

Synonyms	Disodium dihydrogen diphosphate Disodium dihydrogen pyrophosphate Sodium acid pyrophosphate Disodium pyrophosphate
Definition	
Chemical name	Disodium dihydrogen diphosphate
EINECS	231-835-0
Chemical formula	$Na_2H_2P_2O_7$
Molecular weight	221,94
Assay	Content not less than 95 % of disodium diphosphate.
P_2O_5 Content	Not less than 63,0 % and not more than 64,5 %
Description	White powder or grains
Identification	
A. Positive tests for sodium and for phosphate	
B. Solubility	Soluble in water
C. pH of a 1 % solution	Between 3,7 and 5,0
Purity	
Loss on drying	Not more than 0,5 % (105 °C, four hours)
Water-insoluble matter	Not more than 1 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 450 (ii) TRISODIUM DIPHOSPHATE

Synonyms	Acid trisodium pyrophosphate Trisodium monohydrogen diphosphate
Definition	
EINECS	238-735-6
Chemical formula	Monohydrate: $Na_3HP_2O_7 \cdot H_2O$ Anhydrous: $Na_3HP_2O_7$
Molecular weight	Monohydrate: 261,95 Anhydrous: 243,93
Assay	Content not less than 95 % on the anhydrous basis
P_2O_5 content	Not less than 57 % and not more than 59 %
Description	White powder or grains, occurs anhydrous or as a monohydrate
Identification	
A. Positive tests for sodium and for phosphate	
B. Soluble in water	
C. pH of a 1 % solution	Between 6,7 and 7,5
Purity	
Loss on ignition	Not more than 4,5 % on the anhydrous compound Not more than 11,5 % on the monohydrous basis
Loss on drying	Not more than 0,5 % (105 °C, four hours)
Water-insoluble matter	Not more than 0,2 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 450 (iii) TETRASODIUM DIPHOSPHATE

Synonyms	Tetrasodium pyrophosphate Sodium pyrophosphate
Definition	
Chemical name	Tetrasodium diphosphate
EINECS	231-767-1
Chemical formula	Anhydrous: $Na_4P_2O_7$ Decahydrate: $Na_4P_2O_7 \cdot 10H_2O$
Molecular weight	Anhydrous: 265,94 Decahydrate: 446,09
Assay	Content not less than 95 % of $Na_4P_2O_7$ on the ignited basis
P_2O_5 content	Not less than 52,5 % and not more than 54,0 %
Description	Colourless or white crystals, or a white crystalline or granular powder. The decahydrate effloresces slightly in dry air
Identification	
A. Positive tests for sodium and for phosphate	
B. Solubility	Soluble in water. Insoluble in ethanol
C. pH of a 1 % solution	Between 9,8 and 10,8
Purity	
Loss on ignition	Not more than 0,5 % for the anhydrous salt, not less than 38 % and not more than 42 % for the decahydrate, in both cases determined after drying at 105 °C for four hours, followed by ignition at 550 °C for 30 minutes
Water-insoluble matter	Not more than 0,2 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 450 (v) TETRAPOTASSIUM DIPHOSPHATE

Synonyms	Potassium pyrophosphate Tetrapotassium pyrophosphate
Definition	
Chemical name	Tetrapotassium diphosphate
EINECS	230-785-7
Chemical formula	$K_4P_2O_7$
Molecular weight	330,34 (anhydrous)
Assay	Content not less than 95 % on the ignited basis
P_2O_5 content	Not less than 42,0 % and not more than 43,7 % on the anhydrous basis
Description	Colourless crystals or white, very hygroscopic powder
Identification	
A. Positive tests for potassium and for phosphate	
B. Solubility	Soluble in water, insoluble in ethanol
C. pH of a 1 % solution	Between 10,0 and 10,8
Purity	
Loss on ignition	Not more than 2 % after drying at 105 °C for four hours and then ignition at 550 °C for 30 minutes
Water-insoluble substances	Not more than 0,2 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 450 (vi) DICALCIUM DIPHOSPHATE

Synonyms	Calcium pyrophosphate
Definition	
Chemical name	Dicalcium diphosphate Dicalcium pyrophosphate
EINECS	232-221-5
Chemical formula	$Ca_2P_2O_7$
Molecular weight	254,12
Assay	Content not less than 96 %
P_2O_5 content	Not less than 55 % and not more than 56 %
Description	A fine, white, odourless powder
Identification	
A. Positive tests for calcium and for phosphate	
B. Solubility	Insoluble in water. Soluble in dilute hydrochloric and nitric acids
C. pH of a 10 % suspension in water	Between 5,5 and 7,0
Purity	
Loss on ignition	Not more than 1,5 % at 800 °C ± 25 °C for 30 minutes
Fluoride	Not more than 50 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 450 (vii) CALCIUM DIHYDROGEN DIPHOSPHATE

Synonyms	Acid calcium pyrophosphate Monocalcium dihydrogen pyrophosphate
Definition	
Chemical name	Calcium dihydrogen diphosphate
EINECS	238-933-2
Chemical formula	$CaH_2P_2O_7$
Molecular weight	215,97
Assay	Content not less than 90 % on the anhydrous basis
P_2O_5 content	Not less than 61 % and not more than 64 %
Description	White crystals or powder
Identification	
A. Positive tests for calcium and for phosphate	
Purity	
Acid-insoluble matter	Not more than 0,4 %
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 451 (i) PENTASODIUM TRIPHOSPHATE

Synonyms	Pentasodium tripolyphosphate Sodium tripolyphosphate
Definition	
Chemical name	Pentasodium triphosphate
EINECS	231-838-7
Chemical formula	$Na_5O_{10}P_3 \cdot nH_2O$ (n = 0 or 6)
Molecular weight	367,86
Assay	Content not less than 85,0 % (anhydrous) or 65,0 % (hexahydrate)
P_2O_5 content	Not less than 56 % and not more than 59 % (anhydrous) or not less than 43 % and not more than 45 % (hexahydrate)
Description	White, slightly hygroscopic granules or powder
Identification	
A. Solubility	Freely soluble in water. Insoluble in ethanol
B. Positive tests for sodium and for phosphate	
C. pH of a 1 % solution	Between 9,1 and 10,2
Purity	
Loss on drying	Anhydrous: Not more than 0,7 % (105 °C, one hour) Hexahydrate: Not more than 23,5 % (60 °C, one hour, followed by drying at 105 °C, four hours)
Water-insoluble substances	Not more than 0,1 %
Higher polyphosphates	Not more than 1 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 451 (ii) PENTAPOTASSIUM TRIPHOSPHATE

Synonyms	Pentapotassium tripolyphosphate Potassium triphosphate Potassium tripolyphosphate
Definition	
Chemical name	Pentapotassium triphosphate Pentapotassium tripolyphosphate
EINECS	237-574-9
Chemical formula	$K_5O_{10}P_3$
Molecular weight	448,42
Assay	Content not less than 85 % on the anhydrous basis
P_2O_5 content	Not less than 46,5 % and not more than 48 %
Description	White, very hygroscopic powder or granules
Identification	
A. Solubility	Very soluble in water
B. Positive tests for potassium and for phosphate	
C. pH of a 1 % solution	Between 9,2 and 10,5
Purity	
Loss on ignition	Not more than 0,4 % (after drying at 105 °C, four hours, followed by ignition at 550 °C, 30 minutes)
Water-insoluble matter	Not more than 2 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 452 (i) SODIUM POLYPHOSPHATE

1. SOLUBLE POLYPHOSPHATE

Synonyms	Sodium hexametaphosphate Sodium tetrapolyphosphate Graham's salt Sodium polyphosphates, glassy Sodium polymetaphosphate Sodium metaphosphate
Definition	Soluble sodium polyphosphates are obtained by fusion and subsequent chilling of sodium orthophosphates. These compounds are a class consisting of several amorphous, water-soluble polyphosphates composed of linear chains of metaphosphate units, $(NaPO_3)x$ where $x \geq 2$, terminated by Na_2PO_4 groups. These substances are usually identified by their Na_2O/P_2O_5 ratio or their P_2O_5 content. The Na_2O/P_2O_5 ratios vary from about 1,3 for sodium tetrapolyphosphate, where x = approximately 4; to about 1,1 for Graham's salt, commonly called sodium hexametaphosphate, where x = 13 to 18; and to about 1,0 for the higher molecular weight sodium polyphosphates, where x = 20 to 100 or more. The pH of their solutions varies from 3,0 to 9,0
Chemical name	Sodium polyphosphate
EINECS	272-808-3
Chemical formula	Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula $H_{(n+2)}P_nO_{(3n+1)}$ where 'n' is not less than 2
Molecular weight	$(102)_n$
Assay *P_2O_5 content*	Not less than 60 % and not more than 71 % on the ignited basis
Description	Colourless or white, transparent platelets, granules, or powders
Identification	
A. Solubility	Very soluble in water
B. Positive tests for sodium and for phosphate	
C. pH of a 1 % solution	Between 3,0 and 9,0
Purity	
Loss on ignition	Not more than 1 %
Water-insoluble matter	Not more than 0,1 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

2. INSOLUBLE POLYPHOSPHATE

Synonyms	Insoluble sodium metaphosphate Maddrell's salt Insoluble sodium polyphosphate, IMP
Definition	Insoluble sodium metaphosphate is a high molecular weight sodium polyphosphate composed of two long metaphosphate chains $(NaPO_3)_x$ that spiral in opposite directions about a common axis. The Na_2O/P_2O_5 ratio is about 1,0. The pH of 1 in 3 suspension in water is about 6,5
Chemical name	Sodium polyphosphate
EINECS	272-808-3
Chemical formula	Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula $H_{(n+2)}P_nO_{(3n+1)}$ where 'n' is not less than 2
Molecular weight	$(102)_n$
P_2O_5 content	Not less than 68,7 % and not more than 70,0 %
Description	White crystalline powder
Identification	
A. Solubility	Insoluble in water, soluble in mineral acids and in solutions of potassium and ammonium (but not sodium) chlorides
B. Positive tests for sodium and for phosphate	
C. pH of 1 in 3 suspension in water	About 6,5
Purity	
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 452 (ii) POTASSIUM POLYPHOSPHATE

Synonyms	Potassium metaphosphate Potassium polymetaphosphate Kurrol salt
Definition	
Chemical name	Potassium polyphosphate
EINECS	232-212-6
Chemical formula	$(KPO_3)n$ Heterogenous mixtures of potassium salts of linear condensed polyphosphoric acids of general formula $H_{(n+2)}P_nO_{(3n+1)}$where 'n' is not less than 2
Molecular weight	$(118)_n$
P_2O_5 content	Not less than 53,5 % and not more than 61,5 % on the ignited basis
Description	Fine white powder or crystals or colourless glassy platelets
Identification	
A. Solubility	1 g dissolves in 100 ml of a 1 in 25 solution of sodium acetate
B. Positive tests for potassium and for phosphate	
C. pH of a 1 % suspension	Not more than 7,8
Purity	
Loss on ignition	Not more than 2 % (105 °C, four hours followed by ignition at 550 °C, 30 minutes)
Cyclic phosphate	Not more than 8 % on P_2O_5 content
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 452 (iv) CALCIUM POLYPHOSPHATE

Synonyms	Calcium metaphosphate Calcium polymetaphosphate
Definition	
Chemical name	Calcium polyphosphate
EINECS	236-769-6
Chemical formula	$(CaP_2O_6)n$ Heterogenous mixtures of calcium salts of condensed polyphosphoric acids of general formula $H_{(n + 2)}P_nO_{(n + 1)}$ where 'n' is not less than 2
Molecular weight	$(198)_n$
P_2O_5 content	Not less than 71 % and not more than 73 % on the ignited basis
Description	Odourless, colourless crystals or white powder
Identification	
A. Solubility	Usually sparingly soluble in water. Soluble in acid medium
B. Positive tests for calcium and for phosphate	
C. CaO content	27 to 29,5 %
Purity	
Loss on ignition	Not more than 2 % (105 °C, four hours followed by ignition at 550 °C, 30 minutes)
Cyclic phosphate	Not more than 8 % on P_2O_5 content
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg'

(2) The following text relating to E 650 Zinc acetate, E 943a Butane, E 943b Isobutane, E 944 Propane, E 949 Hydrogen, E 1201 Polyvinylpyrrolidone and E 1202 Polyvinylpolypyrrolidone is added:

'E 650 ZINC ACETATE

Synonyms	Acetic acid, zinc salt, dihydrate
Definition	
Chemical name	Zinc acetate dihydrate
Chemical formula	$C_4H_6O_4$ Zn · $2H_2O$
Molecular weight	219,51
Assay	Content not less than 98 % and not more than 102 % of $C_4H_6O_4$ Zn · $2H_2O$
Description	Colourless crystals or fine, off-white powder
Identification	
A. Positive tests for acetate and for zinc	
B. pH of a 5 % solution	Between 6,0 and 8,0
Purity	
Insoluble matter	Not more than 0,005 %
Chlorides	Not more than 50 mg/kg
Sulphates	Not more than 100 mg/kg
Alkalines and alkaline earths	Not more than 0,2 %
Organic volatile impurities	Passes test
Iron	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 20 mg/kg
Cadmium	Not more than 5 mg/kg

E 943a BUTANE

Synonyms	n-Butane
Definition	
Chemical name	Butane
Chemical formula	$CH_3CH_2CH_2CH_3$
Molecular weight	58,12
Assay	Content not less than 96 %
Description	Colourless gas or liquid with mild, characteristic odour
Identification	
A. Vapour pressure	108,935 kPa at 20 °C
Purity	
Methane	Not more than 0,15 % v/v
Ethane	Not more than 0,5 % v/v
Propane	Not more than 1,5 % v/v

Isobutane	Not more than 3,0 % v/v
1,3-butadiene	Not more than 0,1 % v/v
Moisture	Not more than 0,005 %

E 943b ISOBUTANE

Synonyms	2-methyl propane
Definition	
Chemical name	2-methyl propane
Chemical formula	$(CH_3)_2CH\ CH_3$
Molecular weight	58,12
Assay	Content not less than 94 %
Description	Colourless gas or liquid with mild, characteristic odour
Identification	
A. Vapour pressure	205,465 kPa at 20 °C
Purity	
Methane	Not more than 0,15 % v/v
Ethane	Not more than 0,5 % v/v
Propane	Not more than 2,0 % v/v
n-Butane	Not more than 4,0 % v/v
1,3-butadiene	Not more than 0,1 % v/v
Moisture	Not more than 0,005 %

E 944 PROPANE

Definition	
Chemical name	Propane
Chemical formula	$CH_3CH_2CH_3$
Molecular weight	44,09
Assay	Content not less than 95 %
Description	Colourless gas or liquid with mild, characteristic odour
Identification	
A. Vapour pressure	732,910 kPa at 20 °C
Purity	
Methane	Not more than 0,15 % v/v
Ethane	Not more than 1,5 % v/v
Isobutane	Not more than 2,0 % v/v
n-Butane	Not more than 1,0 % v/v
1,3-butadiene	Not more than 0,1 % v/v
Moisture	Not more than 0,005 %

E 949 HYDROGEN

Definition	
Chemical name	Hydrogen
EINECS	215-605-7
Chemical formula	H_2
Molecular weight	2
Assay	Content not less than 99,9 %
Description	Colourless, odourless, highly flammable gas
Purity	
Water	Not more than 0,005 % v/v
Oxygen	Not more than 0,001 % v/v
Nitrogen	Not more than 0,75 % v/v

E 1201 POLYVINYLPYRROLIDONE

Synonyms	Povidone PVP Soluble polyvinylpyrrolidone
Definition	
Chemical name	Polyvinylpyrrolidone, poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene]
Chemical formula	$(C_6H_9NO)_n$
Molecular weight	Not less than 25 000
Assay	Content not less than 11,5 % and not more than 12,8 % of nitrogen (N) on the anhydrous basis
Description	White or nearly white powder
Identification	
A. Solubility	Soluble in water and in ethanol. Insoluble in ether
B. pH of a 5 % solution	Between 3,0 and 7,0
Purity	
Water	Not more than 5 % (Karl Fischer)
Total ash	Not more than 0,1 %
Aldehyde	Not more than 500 mg/kg (as acetaldehyde)
Free-N-vinylpyrrolidone	Not more than 10 mg/kg
Hydrazine	Not more than 1 mg/kg
Lead	Not more than 5 mg/kg

E 1202 POLYVINYLPOLYPYRROLIDONE

Synonyms	Crospovidone Cross linked polyvidone Insoluble polyvinylpyrrolidone
Definition	Polyvinylpolypyrrolidone is a poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene], cross linked in a random fashion. It is produced by the polymerisation of N-vinyl-2-pyrrolidone in the presence of either caustic catalyst or N, N'-divinyl-imidazolidone. Due to its insolubility in all common solvents the molecular weight range is not amenable to analytical determination
Chemical name	Polyvinylpyrrolidone, poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene]
Chemical formula	$(C_6H_9NO)_n$
Assay	Content not less than 11 % and not more than 12,8 % nitrogen (N) on the anhydrous basis
Description	A white hygroscopic powder with a faint, non-objectionable odour
Identification	
A. Solubility	Insoluble in water, ethanol and ether
B. pH of a 1 % suspension in water	Between 5,0 and 8,0
Purity	
Water	Not more than 6 % (Karl Fischer)
Sulphated ash	Not more than 0,4 %
Water-soluble matter	Not more than 1 %
Free-N-vinylpyrrolidone	Not more than 10 mg/kg
Free-N,N'-divinyl-imidazolidone	Not more than 2 mg/kg
Lead	Not more than 5 mg/kg'.