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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.

⁽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.

(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*.

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

H₃PO₄

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 NaNO₃)

Sulphates

Not more than 1 500 mg/kg (as CaSO₄)

Fluoride

Not more than 10 mg/kg (expressed as fluoride)

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: $\text{NaH}_2\text{PO}_4 \cdot \text{H}_2\text{O}$ Dihydrate: $\text{NaH}_2\text{PO}_4 \cdot 2\text{H}_2\text{O}$ *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 *P₂O₅ 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: $\text{Na}_2\text{HPO}_4 \cdot n\text{H}_2\text{O}$ ($n = 2, 7$ 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

P₂O₅ 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 H₂O. 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: Na₃PO₄
 Hydrated: Na₃PO₄ · nH₂O (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 Na₃PO₄ calculated on the dried basis. Sodium phosphate dodecahydrate contains not less than 92,0 % of Na₃PO₄ calculated on the ignited basis

P₂O₅ 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
- C. pH of a 1 % solution

Freely soluble in water. Insoluble in ethanol
 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

P₂O₅ 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

P₂O₅ 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

P₂O₅ 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: $\text{Ca}(\text{H}_2\text{PO}_4)_2$ Monohydrate: $\text{Ca}(\text{H}_2\text{PO}_4)_2 \cdot \text{H}_2\text{O}$ *Molecular weight*

234,05 (anhydrous)

252,08 (monohydrate)

Assay

Content not less than 95 % on the dried basis

P₂O₅ 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: $\text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$

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

P₂O₅ 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 $10\text{CaO} \cdot 3\text{P}_2\text{O}_5 \cdot \text{H}_2\text{O}$

Chemical name

Pentacalcium hydroxy monophosphate
 Tricalcium monophosphate

EINECS

235-330-6 (*Pentacalcium hydroxy monophosphate*)
 231-840-8 (*Calcium orthophosphate*)

Chemical formula

$\text{Ca}_5(\text{PO}_4)_3 \cdot \text{OH}$ or $\text{Ca}_3(\text{PO}_4)_2$

Molecular weight

502 or 310

Assay

Content not less than 90 % calculated on the ignited basis

P₂O₅ 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 ethanol, soluble in dilute hydrochloric and nitric acid

Purity

Loss on ignition

Not more than 8 % after ignition at $800\text{ }^\circ\text{C} \pm 25\text{ }^\circ\text{C}$, 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*Na₂H₂P₂O₇*Molecular weight*

221,94

Assay

Content not less than 95 % of disodium diphosphate.

P₂O₅ 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: $\text{Na}_3\text{HP}_2\text{O}_7 \cdot \text{H}_2\text{O}$ Anhydrous: $\text{Na}_3\text{HP}_2\text{O}_7$ *Molecular weight*

Monohydrate: 261,95

Anhydrous: 243,93

Assay

Content not less than 95 % on the anhydrous basis

P₂O₅ 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: $\text{Na}_4\text{P}_2\text{O}_7$
Decahydrate: $\text{Na}_4\text{P}_2\text{O}_7 \cdot 10\text{H}_2\text{O}$

Molecular weight

Anhydrous: 265,94
Decahydrate: 446,09

*Assay*Content not less than 95 % of $\text{Na}_4\text{P}_2\text{O}_7$ on the ignited basis*P₂O₅ 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

P₂O₅ 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 $\text{Ca}_2\text{P}_2\text{O}_7$ *Molecular weight*

254,12

Assay

Content not less than 96 %

P₂O₅ 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

$\text{CaH}_2\text{P}_2\text{O}_7$

Molecular weight

215,97

Assay

Content not less than 90 % on the anhydrous basis

P₂O₅ 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 $\text{Na}_5\text{O}_{10}\text{P}_3 \cdot n\text{H}_2\text{O}$ (n = 0 or 6)*Molecular weight*

367,86

Assay

Content not less than 85,0 % (anhydrous) or 65,0 % (hexahydrate)

P₂O₅ 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

P₂O₅ 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, $(\text{NaPO}_3)_x$ where $x \geq 2$, terminated by Na_2PO_4 groups. These substances are usually identified by their $\text{Na}_2\text{O}/\text{P}_2\text{O}_5$ ratio or their P_2O_5 content. The $\text{Na}_2\text{O}/\text{P}_2\text{O}_5$ 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 $\text{H}_{(n+2)}\text{P}_n\text{O}_{(3n+1)}$ 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 $(\text{NaPO}_3)_x$ that spiral in opposite directions about a common axis. The $\text{Na}_2\text{O}/\text{P}_2\text{O}_5$ 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 $\text{H}_{(n+2)}\text{P}_n\text{O}_{(3n+1)}$ where 'n' is not less than 2

Molecular weight $(102)_n$ *P₂O₅ 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 $(\text{KPO}_3)_n$

Heterogenous mixtures of potassium salts of linear condensed polyphosphoric acids of general formula $\text{H}_{(n+2)}\text{P}_n\text{O}_{(3n+1)}$ where 'n' is not less than 2

Molecular weight $(118)_n$ *P₂O₅ 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 P₂O₅ 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 $(\text{CaP}_2\text{O}_6)_n$

Heterogenous mixtures of calcium salts of condensed polyphosphoric acids of general formula $\text{H}_{(n+2)}\text{P}_n\text{O}_{(n+1)}$ where 'n' is not less than 2

Molecular weight $(198)_n$ *P₂O₅ 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 P₂O₅ 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

$C_4H_6O_4 Zn \cdot 2H_2O$

Molecular weight

219,51

Assay

Content not less than 98 % and not more than 102 % of $C_4H_6O_4 Zn \cdot 2H_2O$

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 | |
| <i>Chemical name</i> | 2-methyl propane |
| <i>Chemical formula</i> | $(\text{CH}_3)_2\text{CH CH}_3$ |
| <i>Molecular weight</i> | 58,12 |
| <i>Assay</i> | Content not less than 94 % |
| <i>Description</i> | 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 | |
| <i>Chemical name</i> | Propane |
| <i>Chemical formula</i> | $\text{CH}_3\text{CH}_2\text{CH}_3$ |
| <i>Molecular weight</i> | 44,09 |
| <i>Assay</i> | Content not less than 95 % |
| <i>Description</i> | 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**

| | |
|-------------------------|---|
| <i>Chemical name</i> | Hydrogen |
| <i>EINECS</i> | 215-605-7 |
| <i>Chemical formula</i> | H ₂ |
| <i>Molecular weight</i> | 2 |
| <i>Assay</i> | Content not less than 99,9 % |
| <i>Description</i> | 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 POLYVINYLPIRROLIDONE**Synonyms**

Povidone
PVP
Soluble polyvinylpyrrolidone

Definition

| | |
|-------------------------|--|
| <i>Chemical name</i> | Polyvinylpyrrolidone, poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene] |
| <i>Chemical formula</i> | (C ₆ H ₉ NO) _n |
| <i>Molecular weight</i> | Not less than 25 000 |
| <i>Assay</i> | Content not less than 11,5 % and not more than 12,8 % of nitrogen (N) on the anhydrous basis |
| <i>Description</i> | 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 POLYVINYLPIRROLIDONE**Synonyms**

Crospovidone
Cross linked polyvidone
Insoluble polyvinylpyrrolidone

Definition

Polyvinylpyrrolidone 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'.
