

I

(Acts whose publication is obligatory)

COMMISSION DIRECTIVE 2000/63/EC

of 5 October 2000

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 of the European Parliament and of the Council 94/34/EC⁽²⁾ and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee for Food,

Whereas:

(1) It is necessary to establish purity criteria for all additives other than colours and sweeteners mentioned in 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 98/72/EC⁽⁴⁾.

(2) Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners⁽⁵⁾, as amended by Directive 98/86/EC⁽⁶⁾ set out purity criteria for a number of food additives. This Directive should now be completed with purity criteria for the remaining food additives mentioned in Directive 95/2/EC.

(3) It is necessary, in the light of technical development, to amend the purity criteria set out in Directive 96/77/EC for butylated hydroxyanisole (BHA). It is consequently necessary to adapt that Directive.

(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) Food additives, if prepared by production methods or starting materials significantly different from those evaluated by the Scientific Committee for Food, or if different from those mentioned in this Directive, should be submitted for safety evaluation by the Scientific Committee for Food with emphasis on the purity criteria.

(6) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 96/77/EC shall be amended as follows:

1. In the Annex, the text concerning E 320 — butylated hydroxyanisole (BHA) shall be replaced by the text in Annex I to this Directive.
2. In the Annex, the text of Annex II to this Directive shall be added.

⁽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 295, 4.11.1998, p. 18.

⁽⁵⁾ OJ L 339, 30.12.1996, p. 1.

⁽⁶⁾ OJ L 334, 9.12.1998, p. 1.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 31 March 2001. They shall immediately inform the Commission thereof.

2. When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

3. Products put on the market or labelled before 31 March 2001 which do not comply with this Directive may be marketed until stocks are exhausted.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 5 October 2000.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

E 320 BUTYLATED HYDROXYANISOLE (BHA)

| | |
|--|---|
| Synonyms | BHA |
| Definition | |
| <i>Chemical names</i> | 3-Tertiary-butyl-4-hydroxyanisole A mixture of 2-tertiary-butyl-4-hydroxyanisole and 3-tertiary-butyl-4-hydroxyanisole |
| EINECS | 246-563-8 |
| <i>Chemical formula</i> | $C_{11}H_{16}O_2$ |
| <i>Formula weight</i> | 180,25 |
| <i>Assay</i> | Content not less than 98,5 % of $C_{11}H_{16}O_2$ and not less than 85 % of 3-tertiary-butyl-4-hydroxyanisole isomer |
| <i>Description</i> | White or slightly yellow crystals or waxy solid with a slight aromatic smell |
| Identification | |
| A. Solubility | Insoluble in water, freely soluble in ethanol |
| B. Melting range | Between 48 °C and 63 °C |
| C. Colour reaction | Passes test for phenol groups |
| Purity | |
| Sulphated ash | Not more than 0,05 % after calcination at 800 ± 25 °C |
| Phenolic impurities | Not more than 0,5 % |
| Specific absorption $E_{1\text{cm}}^{1\%}$ | $E_{1\text{cm}}^{1\%}$ (290 nm) not less than 190 and not more than 210 |
| Specific absorption $E_{1\text{cm}}^{1\%}$ | $E_{1\text{cm}}^{1\%}$ (228 nm) not less than 326 and not more than 345 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg' |

ANNEX II

POLYETHYLENEGLYCOL 6000**Synonyms**

PEG 6000
Macrogol 6000

Definition

Polyethylene glycol 6000 is a mixture of polymers with the general formula H-(OCH₂-CH)-OH corresponding to an average relative molecular mass of approximately 6 000

Chemical formula

(C₂H₄O)_n H₂O (n = number of ethylene oxide units corresponding to a molecular weight of 6000, about 140)

Molecular weight

5 600 - 7 000

Assay

Not less than 90,0 % and not more than 110,0 %

Description

A white or almost white solid with a waxy or paraffin-like appearance

Identification

A. Solubility

Very soluble in water and in methylene chloride
Practically insoluble in alcohol, in ether and in fatty and mineral oils

B. Melting range

Between 55 °C and 61 °C

Purity

Viscosity

Between 0,220 and 0,275 kgm⁻¹s⁻¹ at 20 °C

Hydroxyl value

Between 16 and 22

Sulphated ash

Not more than 0,2 %

Ethylene oxide

Not more than 1 mg/kg

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

E 296 MALIC ACID**Synonyms**

DL-Malic acid, pomalous acid

Definition*Chemical name*

DL-Malic acid, hydroxybutanedioic acid, hydroxysuccinic acid

EINECS

230-022-8

Chemical formula

C₄H₆O₅

Molecular weight

134,09

Assay

Content not less than 99,0 %

Description

White or nearly white crystalline powder or granules

Identification

- A. Melting range between 127 °C and 132 °C
- B. Positive test for malate
- C. Solutions of this substance are optically inactive in all concentrations

Purity

| | |
|---------------|-----------------------|
| Sulphated ash | Not more than 0,1 % |
| Fumaric acid | Not more than 1,0 % |
| Maleic acid | Not more than 0,05 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 297 FUMARIC ACID**Definition**

| | |
|-------------------------|--|
| <i>Chemical name</i> | Trans-butenedioic acid, trans-1,2-ethylene-dicarboxylic acid |
| EINECS | 203-743-0 |
| <i>Chemical formula</i> | C ₄ H ₄ O ₄ |
| <i>Molecular weight</i> | 116,07 |
| <i>Assay</i> | Content not less than 99,0 % on the anhydrous basis |
| <i>Description</i> | White crystalline powder or granules |

Identification

- A. Melting range
- B. Positive tests for double bonds and for 1,2-dicarboxylic acid
- C. pH of a 0,05 % solution at 25 °C

286 °C - 302 °C (closed capillary, rapid heating)

3,0 – 3,2

Purity

| | |
|----------------|----------------------------------|
| Loss on drying | Not more than 0,5 % (120 °C, 4h) |
| Sulphated ash | Not more than 0,1 % |
| Maleic acid | Not more than 0,1 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 343(i) MONOMAGNESIUM PHOSPHATE**Synonyms**

Magnesiumdihydrogenphosphate
Magnesiumphosphate, monobasic
Monomagnesium orthophosphate

Definition*Chemical name*

Monomagnesiumdihydrogenmonophosphate

EINECS

236-004-6

Chemical formula $Mg(H_2PO_4)_2 \cdot nH_2O$ (where n = 0 to 4)*Molecular weight*

218,30 (anhydrous)

Assay

Not less than 51,0 % after ignition

Description

White, odourless, crystalline powder, slightly soluble in water

Identification

A. Positive test for magnesium and for phosphate

B. MgO content

Not less than 21,5 % after ignition

Purity

Fluoride

Not more than 10 mg/kg (as fluorine)

Arsenic

Not more than 3 mg/kg

Lead

Not more than 4 mg/kg

Cadmium

Not more than 1 mg/kg

Mercury

Not more than 1 mg/kg

E 343(ii) DIMAGNESIUM PHOSPHATE**Synonyms**

Magnesiumhydrogenphosphate
Magnesiumphosphate, dibasic
Dimagnesium orthophosphate
Secondary magnesiumphosphate

Definition*Chemical name*

Dimagnesiummonohydrogenmonophosphate

EINECS

231-823-5

Chemical formula $MgHPO_4 \cdot nH_2O$ (where n = 0 - 3)*Molecular weight*

120,30 (anhydrous)

Assay

Not less than 96 % after ignition

Description

White, odourless, crystalline powder, slightly soluble in water

Identification

- A. Positive test for magnesium and for phosphate
- B. MgO content:

Not less than 33,0 % calculated on an anhydrous basis

Purity

Fluoride

Not more than 10 mg/kg (as fluorine)

Arsenic

Not more than 3 mg/kg

Lead

Not more than 4 mg/kg

Cadmium

Not more than 1 mg/kg

Mercury

Not more than 1 mg/kg

E 350 (i) SODIUM MALATE**Synonyms**

Sodium salt of malic acid

Definition

Chemical name

Disodium DL-malate, disodium salt of hydroxybutanedioic acid

Chemical formula

Hemihydrate: $C_4H_4Na_2O_5 \cdot \frac{1}{2} H_2O$

Trihydrate: $C_4H_4Na_2O_5 \cdot 3H_2O$

Molecular weight

Hemihydrate: 187,05

Trihydrate: 232,10

Assay

Content not less than 98,0 % on the anhydrous basis

Description

White crystalline powder or lumps

Identification

- A. Positive tests for 1,2-dicarboxylic acid and for sodium
- B. Azo dye formation
- C. Solubility

Positive

Freely soluble in water

Purity

Loss on drying

Not more than 7,0 % (130 °C, 4h) for the hemihydrate, or 20,5 % - 23,5 % (130 °C, 4h) for the trihydrate

Alkalinity

Not more than 0,2 % as Na_2CO_3

Fumaric acid

Not more than 1,0 %

Maleic acid

Not more than 0,05 %

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 350 (ii) SODIUM HYDROGEN MALATE**Synonyms**

Monosodium salt of DL-malic acid

Definition*Chemical name*

Monosodium DL-malate, monosodium 2-DL-hydroxy succinate

*Chemical formula*C₄H₅NaO₅*Molecular weight*

156,07

Assay

Content not less than 99,0 % on the anhydrous basis

Description

White powder

Identification

A. Positive tests for 1,2-dicarboxylic acid and for sodium

B. Azo dye formation

Positive

Purity

Loss on drying

Not more than 2,0 % (110 °C, 3h)

Maleic acid

Not more than 0,05 %

Fumaric acid

Not more than 1,0 %

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 351 POTASSIUM MALATE**Synonyms**

Potassium salt of malic acid

Definition*Chemical name*

Dipotassium DL-malate, dipotassium salt of hydroxybutanedioic acid

*Chemical formula*C₄H₄K₂O₅*Molecular weight*

210,27

Assay

Content not less than 59,5 %

Description

Colourless or almost colourless aqueous solution

Identification

A. Positive tests for 1,2-dicarboxylic acid and for potassium

B. Azo dye formation

Positive

Purity

| | |
|--------------|----------------------------------|
| Alkalinity | Not more than 0,2 % as K_2CO_3 |
| Fumaric acid | Not more than 1,0 % |
| Maleic acid | Not more than 0,05 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 352 (i) CALCIUM MALATE**Synonyms**

Calcium salt of malic acid

Definition

| | |
|-------------------------|---|
| <i>Chemical name</i> | Calcium DL-malate, calcium- α -hydroxysuccinate, calcium salt of hydroxybutanedioic acid |
| <i>Chemical formula</i> | $C_4H_5CaO_5$ |
| <i>Molecular weight</i> | 172,14 |
| <i>Assay</i> | Content not less than 97,5 % on the anhydrous basis |
| <i>Description</i> | White powder |

Identification

| | |
|---|---------------------------|
| A. Positive tests for malate, 1,2-dicarboxylic acid and for calcium | |
| B. Azo dye formation | Positive |
| C. Solubility | Slightly soluble in water |

Purity

| | |
|----------------|---------------------------------|
| Loss on drying | Not more than 2 % (100 °C, 3h) |
| Alkalinity | Not more than 0,2 % as $CaCO_3$ |
| Maleic acid | Not more than 0,05 % |
| Fumaric acid | Not more than 1,0 % |
| Fluoride | Not more than 30 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 352 (ii) CALCIUM HYDROGEN MALATE**Synonyms**

Monocalcium salt of DL-malic acid

Definition*Chemical name*

Monocalcium DL-malate, monocalcium 2-DL-hydroxysuccinate

Chemical formula $(C_4H_5O_5)_2Ca$ *Assay*

Content not less than 97,5 % on the anhydrous basis

Description

White powder

Identification

A. Positive tests for 1,2-dicarboxylic acid and for calcium

B. Azo dye formation

Positive

Purity

Loss on drying

Not more than 2,0 % (110 °C, 3h)

Maleic acid

Not more than 0,05 %

Fumaric acid

Not more than 1,0 %

Fluoride

Not more than 30 mg/kg

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 355 ADIPIC ACID**Definition***Chemical name*

Hexanedioic acid, 1,4-butanedicarboxylic acid

EINECS

204-673-3

Chemical formula $C_6H_{10}O_4$ *Molecular weight*

146,14

Assay

Content not less than 99,6 %

Description

White odourless crystals or crystalline powder

Identification

A. Melting range

151,5-154,0 °C

B. Solubility

Slightly soluble in water. Freely soluble in ethanol

Purity

| | |
|---------------|---|
| Water | Not more than 0,2 % (Karl Fischer method) |
| Sulphated ash | Not more than 20 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 363 SUCCINIC ACID**Definition**

| | |
|-------------------------|--|
| <i>Chemical name</i> | Butanedioic acid |
| EINECS | 203-740-4 |
| <i>Chemical formula</i> | C ₄ H ₆ O ₄ |
| <i>Molecular weight</i> | 118,09 |
| <i>Assay</i> | Content no less than 99,0 % |
| <i>Description</i> | Colourless or white, odourless crystals |

Identification

| | |
|------------------|-------------------------------|
| A. Melting range | Between 185,0 °C and 190,0 °C |
|------------------|-------------------------------|

Purity

| | |
|---------------------|--|
| Residue on ignition | Not more than 0,025 % (800 °C, 15 min) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 380 TRIAMMONIUM CITRATE**Synonyms**

Tribasic ammonium citrate

Definition

| | |
|-------------------------|--|
| <i>Chemical name</i> | Triammonium salt of 2-hydroxypropan-1,2,3-tricarboxylic acid |
| EINECS | 222-394-5 |
| <i>Chemical formula</i> | C ₆ H ₁₇ N ₃ O ₇ |
| <i>Molecular weight</i> | 243,22 |
| <i>Assay</i> | Content not less than 97,0 % |
| <i>Description</i> | White to off-white crystals or powder |

Identification

- A. Positive tests for ammonium and for citrate
 B. Solubility

Freely soluble in water

Purity

- Oxalate
 Arsenic
 Lead
 Mercury

Not more than 0,04 % (as oxalic acid)
 Not more than 3 mg/kg
 Not more than 5 mg/kg
 Not more than 1 mg/kg

E 452(iii) SODIUM CALCIUM POLYPHOSPHATE**Synonym**

Sodium calcium polyphosphate, glassy

Definition

Chemical name

Sodium calcium polyphosphate

EINECS

233-782-9

Chemical formula

$(\text{NaPO}_3)_n \text{CaO}$ where n is typically 5

Assay

Not less than 61 % and not more than 69 % as P_2O_5

Description

White glassy crystals, spheres

Identification

- A. pH of a 1 % m/m slurry
 B. CaO content

Approximately 5 to 7

7 %-15 % m/m

Purity

- Fluoride
 Arsenic
 Lead
 Cadmium
 Mercury

Not more than 10 mg/kg
 Not more than 3 mg/kg
 Not more than 4 mg/kg
 Not more than 1 mg/kg
 Not more than 1 mg/kg

E 459 BETA-CYCLODEXTRIN**Definition**

Beta-cyclodextrin is a non-reducing cyclic saccharide consisting of 7 α -1,4-linked D-glucopyranosyl units. The product is manufactured by the action of the enzyme cycloglycosyltransferase (CGTase) obtained from *Bacillus circulans* on partially hydrolysed starch

Chemical name

Cycloheptaamylose

EINECS

231-493-2

Chemical formula

$(\text{C}_6\text{H}_{10}\text{O}_5)_7$

| | |
|---|--|
| <i>Molecular weight</i> | 1135 |
| <i>Assay</i> | Content not less than 98,0 % of (C ₆ H ₁₀ O ₅) ₇ on an anhydrous basis |
| <i>Description</i> | Virtually odourless, white or almost white crystalline solid |
| Identification | |
| A. Solubility | Sparingly soluble in water; freely soluble in hot water; slightly soluble in ethanol |
| B. Specific rotation | [α] ²⁵ _D : + 160° to + 164° (1 % solution) |
| C. Infrared absorption | The infrared absorption spectrum of a potassium bromide dispersion of the test substance corresponds with that of a reference standard |
| Purity | |
| Water | Not more than 14 % (Karl Fischer method) |
| Other cyclodextrins | Not more than 2 % on an anhydrous basis |
| Residual solvents (toluene and trichloroethylene) | Not more than 1 mg/kg for each solvent |
| Reducing substances (as glucose) | Not more than 1 % |
| Sulphated ash | Not more than 0,1 % |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |

E 468 CROSS-LINKED SODIUM CARBOXYMETHYLCELLULOSE

| | |
|-------------------------|--|
| Synonyms | Cross-linked carboxymethyl cellulose Cross-linked CMC Cross-linked sodium CMC Cross-linked cellulose gum |
| Definition | Cross-linked sodium carboxymethyl cellulose is the sodium salt of thermally cross-linked partly O-carboxymethylated cellulose |
| <i>Chemical name</i> | Sodium salt of the cross-linked carboxymethyl ether cellulose |
| <i>Chemical formula</i> | The polymers containing substituted anhydroglucose units with the general formula: C ₆ H ₇ O ₂ (OR ₁)(OR ₂)(OR ₃) where R ₁ , R ₂ and R ₃ may be any of the following: — H — CH ₂ COONa — CH ₂ COOH |
| <i>Description</i> | Slightly hygroscopic, white to off white, odourless powder |

Identification

- A. Shake 1 g with 100 ml of a solution containing 4 mg/kg methylene blue and allow to settle. The substance to be examined absorbs the methylene blue and settles as a blue, fibrous mass
- B. Shake 1 g with 50 ml of water. Transfer 1 ml of the mixture to a test tube, add 1 ml water and 0,05 ml of freshly prepared 40 g/l solution of alpha-naphthol in methanol. Incline the test tube and add carefully 2 ml of sulphuric acid down the side so that it forms a lower layer. A reddish-violet colour develops at the interface
- C. It gives the reaction of sodium

Purity

| | |
|------------------------|--|
| Loss on drying | Not more than 6 % (105 °C, 3h) |
| Water solubles | Not more than 10 % |
| Degree of substitution | Not less than 0,2 and not more than 1,5 carboxymethyl groups per anhydroglucose unit |
| pH of 1 % | Not less than 5,0 and not more than 7,0 |
| Sodium content | Not more than 12,4 % on anhydrous basis |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 469 ENZYMATICALLY HYDROLYSED CARBOXYMETHYLCELLULOSE**Synonyms**

Sodium carboxymethyl cellulose, enzymatically hydrolysed

Definition

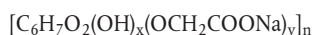
Enzymatically hydrolysed carboxymethylcellulose is obtained from carboxymethylcellulose by enzymatic digestion with a cellulase produced by *Trichoderma longibrachiatum* (formerly *T. reesei*)

Chemical name

Carboxymethyl cellulose, sodium, partially enzymatically hydrolysed

Chemical formula

Sodium salts of polymers containing substituted anhydroglucose units with the general formula:



where n is the degree of polymerisation

$$x = 1,50 \text{ to } 2,80$$

$$y = 0,2 \text{ to } 1,50$$

$$x + y = 3,0$$

(y = degree of substitution)

Formula weight

178,14 where y = 0,20

282,18 where y = 1,50

Macromolecules: Not less than 800 (n about 4)

| | |
|--------------------------------------|---|
| <i>Assay</i> | Not less than 99,5 %, including mono- and disaccharides, on the dried basis |
| <i>Description</i> | White or slightly yellowish or greyish, odourless, slightly hygroscopic granular or fibrous powder |
| Identification | |
| A. Solubility | Soluble in water, insoluble in ethanol |
| B. Foam test | Vigorously shake a 0,1 % solution of the sample. No layer of foam appears. This test distinguishes sodium carboxymethyl cellulose, whether hydrolysed or not, from other cellulose ethers and from alginates and natural gums |
| C. Precipitate formation | To 5 ml of a 0,5 % solution of the sample add 5 ml of a 5 % solution of copper or aluminium sulphate. A precipitate appears. This test distinguishes sodium carboxymethyl cellulose, whether hydrolysed or not, from other cellulose ethers and from gelatine, carob bean gum and tragacanth gum |
| D. Colour reaction | Add 0,5 g of the powdered sample to 50 ml of water, while stirring to produce a uniform dispersion. Continue the stirring until a clear solution is produced. Dilute 1 ml of the solution with 1 ml of water in a small test tube. Add 5 drops of 1-naphthol TS. Incline the tube, and carefully introduce down the side of the tube 2 ml of sulphuric acid so that it forms a lower layer. A red-purple colour develops at the interface |
| E. Viscosity (60 % solids) | Not less than 2,500 kgm ⁻¹ s ⁻¹ at 25 °C corresponding to an average molecule weight of 5 000 D |
| Purity | |
| Loss on drying | Not more than 12 % (105 °C to constant weight) |
| Degree of substitution | Not less than 0,2 and not more than 1,5 carboxymethyl groups per anhydroglucose unit on the dried basis |
| pH of a 1 % colloidal solution | Not less than 6,0 and not more than 8,5 |
| Sodium chloride and sodium glycolate | Not more than 0,5 % singly or in combination |
| Residual enzyme activity | Passes test. No change in viscosity of test solution occurs, which indicates hydrolysis of the sodium carboxymethyl cellulose |
| Lead | Not more than 3 mg/kg |

E 500(i) SODIUM CARBONATE**Synonyms**

Soda ash

Definition*Chemical name*

Sodium carbonate

EINECS

207-838-8

*Chemical formula*Na₂CO₃ · nH₂O (n = 0, 1 or 10)*Molecular weight*

106,00 (anhydrous)

*Assay*Content not less than 99 % of Na₂CO₃ on the anhydrous basis*Description*Colourless crystals or white, granular or crystalline powder
The anhydrous form is hygroscopic, the decahydrate efflorescent

Identification

A. Positive tests for sodium and for carbonate

B. Solubility

Freely soluble in water. Insoluble in ethanol

Purity

Loss on drying

Not more than 2 % (anhydrous), 15 % (monohydrate) or 55 %-65 % (decahydrate) (70 °C raising gradually to 300 °C, to constant weight)

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 500(ii) SODIUM HYDROGEN CARBONATE**Synonyms**

Sodium bicarbonate, sodium acid carbonate, bicarbonate of soda, baking soda

Definition*Chemical name*

Sodium hydrogen carbonate

EINECS

205-633-8

*Chemical formula*NaHCO₃*Molecular weight*

84,01

Assay

Content not less than 99 % on the anhydrous basis

Description

Colourless or white crystalline masses or crystalline powder

Identification

A. Positive tests for sodium and for carbonate

B. pH of a 1 % solution

Between 8,0 and 8,6

C. Solubility

Soluble in water. Insoluble in ethanol

Purity

Loss on drying

Not more than 0,25 % (over silica gel, 4h)

Ammonium salts

No odour of ammonia detectable after heating

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 500(iii) SODIUM SESQUICARBONATE**Definition***Chemical name*

Sodium monohydrogen dicarbonate

EINECS

208-580-9

Chemical formula $\text{Na}_2(\text{CO}_3) \cdot \text{NaHCO}_3 \cdot 2\text{H}_2\text{O}$ *Molecular weight*

226,03

*Assay*Content between 35,0 % and 38,6 % of NaHCO_3 and between 46,4 % and 50,0 % of Na_2CO_3 *Description*

White flakes, crystals or crystalline powder

Identification

A. Positive tests for sodium and for carbonate

B. Solubility

Freely soluble in water

Purity

Sodium chloride

Not more than 0,5 %

Iron

Not more than 20 mg/kg

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 501(i) POTASSIUM CARBONATE**Definition***Chemical name*

Potassium carbonate

EINECS

209-529-3

Chemical formula $\text{K}_2\text{CO}_3 \cdot n\text{H}_2\text{O}$ (n = 0 or 1,5)*Molecular weight*

138,21 (anhydrous)

Assay

Content not less than 99,0 % on the anhydrous basis

*Description*White, very deliquescent powder.
The hydrate occurs as small, white, translucent crystals or granules**Identification**

A. Positive tests for potassium and for carbonate

B. Solubility

Very soluble in water. Insoluble in ethanol

Purity

| | |
|----------------|--|
| Loss on drying | Not more than 5 % (anhydrous) or 18 % (hydrate) (180 °C, 4h) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 501(ii) POTASSIUM HYDROGEN CARBONATE**Synonyms**

Potassium bicarbonate, acid potassium carbonate

Definition

| | |
|-------------------------|---|
| <i>Chemical name</i> | Potassium hydrogen carbonate |
| EINECS | 206-059-0 |
| <i>Chemical formula</i> | KHCO_3 |
| <i>Molecular weight</i> | 100,11 |
| <i>Assay</i> | Content not less than 99,0 % and not more than 101,0 % KHCO_3 on the anhydrous basis |
| <i>Description</i> | Colourless crystals or white powder or granules |

Identification

| | |
|---|---|
| A. Positive tests for potassium and for carbonate | |
| B. Solubility | Freely soluble in water. Insoluble in ethanol |

Purity

| | |
|----------------|--|
| Loss on drying | Not more than 0,25 % (over silica gel, 4h) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 503(i) AMMONIUM CARBONATE**Definition**

Ammonium carbonate consists of ammonium carbamate, ammonium carbonate and ammonium hydrogen carbonate in varying proportions

| | |
|-------------------------|---|
| <i>Chemical name</i> | Ammonium carbonate |
| EINECS | 233-786-0 |
| <i>Chemical formula</i> | $\text{CH}_6\text{N}_2\text{O}_2$, $\text{CH}_8\text{N}_2\text{O}_3$ and CH_5NO_3 |
| <i>Molecular weight</i> | Ammonium carbamate 78,06; ammonium carbonate 98,73; ammonium hydrogen carbonate 79,06 |
| <i>Assay</i> | Content not less than 30,0 % and not more than 34,0 % of NH_3 |
| <i>Description</i> | White powder or hard, white or translucent masses or crystals. Becomes opaque on exposure to air and is finally converted into white porous lumps or powder (of ammonium bicarbonate) due to loss of ammonia and carbon dioxide |

Identification

- A. Positive tests for ammonium and for carbonate
- B. pH of a 5 % solution about 8,6
- C. Solubility

Soluble in water

Purity

- Non-volatile matter
- Chlorides
- Sulphate
- Arsenic
- Lead
- Mercury

Not more than 500 mg/kg

Not more than 30 mg/kg

Not more than 30 mg/kg

Not more than 3 mg/kg

Not more than 5 mg/kg

Not more than 1 mg/kg

E 503(ii) AMMONIUM HYDROGEN CARBONATE**Synonyms**

Ammonium bicarbonate

Definition*Chemical name*

Ammonium hydrogen carbonate

EINECS

213-911-5

*Chemical formula*CH₅NO₃*Molecular weight*

79,06

Assay

Content not less than 99,0 %

Description

White crystals or crystalline powder

Identification

- A. Positive tests for ammonium and for carbonate
- B. pH of a 5 % solution about 8,0
- C. Solubility

Freely soluble in water. Insoluble in ethanol

Purity

- Non-volatile matter
- Chlorides
- Sulphate
- Arsenic
- Lead
- Mercury

Not more than 500 mg/kg

Not more than 30 mg/kg

Not more than 30 mg/kg

Not more than 3 mg/kg

Not more than 5 mg/kg

Not more than 1 mg/kg

E 507 HYDROCHLORIC ACID**Synonyms**

Hydrogen chloride, muriatic acid

Definition*Chemical name*

Hydrochloric acid

EINECS

231-595-7

Chemical formula

HCl

Molecular weight

36,46

Assay

Hydrochloric acid is commercially available in varying concentrations. Concentrated hydrochloric acid contains not less than 35,0 % HCl

Description

Clear, colourless or slightly yellowish, corrosive liquid having a pungent odour

Identification

A. Positive tests for acid and for chloride

B. Solubility

Soluble in water and in ethanol

Purity

Total organic compounds

Total organic compounds (non-fluorine containing): not more than 5 mg/kg
Benzene: not more than 0,05 mg/kg
Fluorinated compounds (total): not more than 25 mg/kg

Non-volatile matter

Not more than 0,5 %

Reducing substances

Not more than 70 mg/kg (as SO₂)

Oxidising substances

Not more than 30 mg/kg (as Cl₂)

Sulphate

Not more than 0,5 %

Iron

Not more than 5 mg/kg

Arsenic

Not more than 1 mg/kg

Lead

Not more than 1 mg/kg

Mercury

Not more than 1 mg/kg

E 509 CALCIUM CHLORIDE**Definition***Chemical name*

Calcium chloride

EINECS

233-140-8

*Chemical formula*CaCl₂ · nH₂O (n = 0,2 or 6)*Molecular weight*

110,99 (anhydrous), 147,02 (dihydrate), 219,08 (hexahydrate)

Assay

Content not less than 93,0 % on the anhydrous basis

Description

White, odourless, hygroscopic powder or deliquescent crystals

Identification

- A. Positive tests for calcium and for chloride
 B. Solubility

Anhydrous calcium chloride: freely soluble in water and ethanol
 Dihydrate: freely soluble in water, soluble in ethanol
 Hexahydrate: very soluble in water and ethanol

Purity

- Magnesium and alkali salts
 Fluoride
 Arsenic
 Lead
 Mercury

Not more than 5 % on the anhydrous basis
 Not more than 40 mg/kg
 Not more than 3 mg/kg
 Not more than 10 mg/kg
 Not more than 1 mg/kg

E 511 MAGNESIUM CHLORIDE**Definition**

Chemical name

Magnesium chloride

EINECS

232-094-6

Chemical formula

$\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$

Molecular weight

203,30

Assay

Content not less than 99,0 %

Description

Colourless, odourless, very deliquescent flakes or crystals

Identification

- A. Positive tests for magnesium and for chloride
 B. Solubility

Very soluble in water, freely soluble in ethanol

Purity

- Ammonium
 Arsenic
 Lead
 Mercury

Not more than 50 mg/kg
 Not more than 3 mg/kg
 Not more than 10 mg/kg
 Not more than 1 mg/kg

E 512 STANNOUS CHLORIDE**Synonyms**

Tin chloride, tin dichloride

Definition

Chemical name

Stannous chloride dihydrate

EINECS

231-868-0

Chemical formula

$\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$

| | |
|---|---|
| <i>Molecular weight</i> | 225,63 |
| <i>Assay</i> | Content not less than 98,0 % |
| <i>Description</i> | Colourless or white crystals May have a slight odour of hydrochloric acid |
| Identification | |
| A. Positive tests for tin (II) and for chloride | |
| B. Solubility | Water: soluble in less than its own weight of water, but it forms an insoluble basic salt with excess water Ethanol: soluble |
| Purity | |
| Sulphate | Not more than 30 mg/kg |
| Arsenic | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Lead | Not more than 5 mg/kg |

E 513 SULPHURIC ACID

| | |
|---|---|
| Synonyms | Oil of vitriol, dihydrogen sulphate |
| Definition | |
| <i>Chemical name</i> | Sulphuric acid |
| EINECS | 231-639-5 |
| <i>Chemical formula</i> | H ₂ SO ₄ |
| <i>Molecular weight</i> | 98,07 |
| <i>Assay</i> | Sulphuric acid is commercially available in varying concentrations. The concentrated form contains not less than 96,0 % |
| <i>Description</i> | Clear, colourless or slightly brown, very corrosive oily liquid |
| Identification | |
| A. Positive tests for acid and for sulphate | |
| B. Solubility | Miscible with water, with generation of much heat, also with ethanol |
| Purity | |
| Ash | Not more than 0,02 % |
| Reducing matter | Not more than 40 mg/kg (as SO ₂) |
| Nitrate | Not more than 10 mg/kg (on H ₂ SO ₄ basis) |

| | |
|----------|------------------------|
| Chloride | Not more than 50 mg/kg |
| Iron | Not more than 20 mg/kg |
| Selenium | Not more than 20 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 514(i) SODIUM SULPHATE**Definition**

| | |
|-------------------------|---|
| <i>Chemical name</i> | Sodium sulphate |
| <i>Chemical formula</i> | $\text{Na}_2\text{SO}_4 \cdot n\text{H}_2\text{O}$ (n = 0 or 10) |
| <i>Molecular weight</i> | 142,04 (anhydrous) 322,04 (decahydrate) |
| <i>Assay</i> | Content not less than 99,0 % on the anhydrous basis |
| <i>Description</i> | Colourless crystals or a fine, white, crystalline powder The decahydrate is efflorescent |

Identification

- A. Positive tests for sodium and for sulphate
- B. Acidity of a 5 % solution: neutral or slightly alkaline to litmus paper

Purity

| | |
|----------------|---|
| Loss on drying | Not more than 1,0 % (anhydrous) or not more than 57 % (decahydrate) at 130 °C |
| Selenium | Not more than 30 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 514(ii) SODIUM HYDROGEN SULPHATE**Synonyms**

Acid sodium sulphate, sodium bisulphate, nitre cake

Definition

| | |
|-------------------------|---------------------------------------|
| <i>Chemical name</i> | Sodium hydrogen sulphate |
| <i>Chemical formula</i> | NaHSO_4 |
| <i>Molecular weight</i> | 120,06 |
| <i>Assay</i> | Content not less than 95,2 % |
| <i>Description</i> | White, odourless crystals or granules |

Identification

- A. Positive tests for sodium and for sulphate
- B. Solutions are strongly acidic

Purity

| | |
|-----------------|------------------------|
| Loss on drying | Not more than 0,8 % |
| Water insoluble | Not more than 0,05 % |
| Selenium | Not more than 30 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 515(i) POTASSIUM SULPHATE**Definition**

| | |
|-------------------------|--|
| <i>Chemical name</i> | Potassium sulphate |
| <i>Chemical formula</i> | K_2SO_4 |
| <i>Molecular weight</i> | 174,25 |
| <i>Assay</i> | Content not less than 99,0 % |
| <i>Description</i> | Colourless or white crystals or crystalline powder |

Identification

- A. Positive tests for potassium and for sulphate
- B. pH of a 5 % solution
- C. Solubility

Purity

| | |
|----------|------------------------|
| Selenium | Not more than 30 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 515(ii) POTASSIUM HYDROGEN SULPHATE**Definition****Synonyms**

| | |
|----------------------|---|
| <i>Chemical name</i> | Potassium bisulphate, potassium acid sulphate |
| | Potassium hydrogen sulphate |

| | |
|--|---|
| <i>Chemical formula</i> | KHSO ₄ |
| <i>Molecular weight</i> | 136,17 |
| <i>Assay</i> | Content not less than 99 % |
| <i>Melting point</i> | 197 °C |
| <i>Description</i> | White deliquescent crystals, pieces or granules |
| Identification | |
| A. Positive test for potassium | |
| B. Solubility | Freely soluble in water, insoluble in ethanol |
| Purity | |
| Selenium | Not more than 30 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| | |
| E 516 CALCIUM SULPHATE | |
| Synonyms | Gypsum, selenite, anhydrite |
| Definition | |
| <i>Chemical name</i> | Calcium sulphate |
| EINECS | 231-900-3 |
| <i>Chemical formula</i> | CaSO ₄ · nH ₂ O (n = 0 or 2) |
| <i>Molecular weight</i> | 136,14 (anhydrous), 172,18 (dihydrate) |
| <i>Assay</i> | Content not less than 99,0 % on the anhydrous basis |
| <i>Description</i> | Fine, white to slightly yellowish-white odourless powder |
| Identification | |
| A. Positive tests for calcium and for sulphate | |
| B. Solubility | Slightly soluble in water, insoluble in ethanol |
| Purity | |
| Loss on drying | Anhydrous: not more than 1,5 % (250 °C, constant weight) Dihydrate: not more than 23 % (ibid.) |
| Fluoride | Not more than 30 mg/kg |
| Selenium | Not more than 30 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 517 AMMONIUM SULPHATE**Definition***Chemical name*

Ammonium sulphate

EINECS

231-984-1

Chemical formula $(\text{NH}_4)_2\text{SO}_4$ *Molecular weight*

132,14

Assay

Content not less than 99,0 % and not more than 100,5 %

Description

White powder, shining plates or crystalline fragments

Identification

A. Positive tests for ammonium and for sulphate

B. Solubility

Freely soluble in water, insoluble in ethanol

Purity

Loss on ignition

Not more than 0,25 %

Selenium

Not more than 30 mg/kg

Lead

Not more than 5 mg/kg

E 520 ALUMINIUM SULPHATE**Synonyms**

Alum

Definition*Chemical name*

Aluminium sulphate

EINECS

233-135-0

Chemical formula $\text{Al}_2(\text{SO}_4)_3$ *Molecular weight*

342,13

Assay

Content not less than 99,5 % on the ignited basis

Description

White powder, shining plates or crystalline fragments

Identification

A. Positive tests for aluminium and for sulphate

B. pH of a 5 % solution 2,9 or above

C. Solubility

Freely soluble in water, insoluble in ethanol

Purity

| | |
|------------------------------|--------------------------------|
| Loss on ignition | Not more than 5 % (500 °C, 3h) |
| Alkalies and alkaline earths | Not more than 0,4 % |
| Selenium | Not more than 30 mg/kg |
| Fluoride | Not more than 30 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 10 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 521 ALUMINIUM SODIUM SULPHATE**Synonyms**

Soda alum, sodium alum

Definition

Chemical name Aluminium sodium sulphate

EINECS 233-277-3

Chemical formula $\text{AlNa}(\text{SO}_4)_2 \cdot n\text{H}_2\text{O}$ (n = 0 or 12)

Molecular weight 242,09 (anhydrous)

Assay Content on the anhydrous basis not less than 96,5 % (anhydrous) and 99,5 % (dodecahydrate)

Description Transparent crystals or white crystalline powder

Identification

A. Positive tests for aluminium, for sodium and for sulphate

B. Solubility

Dodecahydrate is freely soluble in water. The anhydrous form is slowly soluble in water. Both forms are insoluble in ethanol

Purity

| | |
|----------------|--|
| Loss on drying | Anhydrous form: not more than 10,0 % (220 °C, 16h) Dodecahydrate: not more than 47,2 % (50 °C-55 °C, 1h then 200 °C, 16h) |
| Ammonium salts | No odour of ammonia detectable after heating |
| Selenium | Not more than 30 mg/kg |
| Fluoride | Not more than 30 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 522 ALUMINIUM POTASSIUM SULPHATE**Synonyms**

Potassium alum, potash alum

Definition*Chemical name*

Aluminium potassium sulphate dodecahydrate

EINECS

233-141-3

Chemical formula $\text{AlK}(\text{SO}_4)_2 \cdot 12 \text{H}_2\text{O}$ *Molecular weight*

474,38

Assay

Content not less than 99,5 %

Description

Large, transparent crystals or white crystalline powder

Identification

A. Positive tests for aluminium, for potassium and for sulphate

B. pH of a 10 % solution between 3,0 and 4,0

C. Solubility

Freely soluble in water, insoluble in ethanol

Purity

Ammonium salts

No odour of ammonia detectable after heating

Selenium

Not more than 30 mg/kg

Fluoride

Not more than 30 mg/kg

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 523 ALUMINIUM AMMONIUM SULPHATE**Synonyms**

Ammonium alum

Definition*Chemical name*

Aluminium ammonium sulphate

EINECS

232-055-3

Chemical formula $\text{AlNH}_4(\text{SO}_4)_2 \cdot 12 \text{H}_2\text{O}$ *Molecular weight*

453,32

Assay

Content not less than 99,5 %

Description

Large, colourless crystals or white powder

Identification

A. Positive tests for aluminium, for ammonium and for sulphate

B. Solubility

Freely soluble in water, soluble in ethanol

Purity

Alkali metals and alkaline earths

Not more than 0,5 %

Selenium

Not more than 30 mg/kg

Fluoride

Not more than 30 mg/kg

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 524 SODIUM HYDROXIDE**Synonyms**

Caustic soda, lye

Definition

Chemical name

Sodium hydroxide

EINECS

215-185-5

Chemical formula

NaOH

Molecular weight

40,0

Assay

Content of solid forms not less than 98,0 % of total alkali (as NaOH). Content of solutions accordingly, based on the stated or labelled percentage of NaOH

Description

White or nearly white pellets, flakes, sticks, fused masses or other forms. Solutions are clear or slightly turbid, colourless or slightly coloured, strongly caustic and hygroscopic and when exposed to the air they absorb carbon dioxide, forming sodium carbonate

Identification

A. Positive tests for sodium

B. A 1 % solution is strongly alkaline

C. Solubility

Very soluble in water. Freely soluble in ethanol

Purity

Water insoluble and organic matter

A 5 % solution is completely clear and colourless to slightly coloured

Carbonate

Not more than 0,5 % (as Na₂CO₃)

Arsenic

Not more than 3 mg/kg

Lead

Not more than 0,5 mg/kg

Mercury

Not more than 1 mg/kg

E 525 POTASSIUM HYDROXIDE**Synonyms**

Caustic potash

Definition*Chemical name*

Potassium hydroxide

EINECS

215-181-3

Chemical formula

KOH

Molecular weight

56,11

Assay

Content not less than 85,0 % of alkali calculated as KOH

Description

White or nearly white pellets, flakes, sticks, fused masses or other forms

Identification

A. Positive tests for potassium

B. A 1 % solution is strongly alkaline

C. Solubility

Very soluble in water. Freely soluble in ethanol

Purity

Water insoluble matter

A 5 % solution is completely clear and colourless

Carbonate

Not more than 3,5 % (as K_2CO_3)

Arsenic

Not more than 3 mg/kg

Lead

Not more than 10 mg/kg

Mercury

Not more than 1 mg/kg

E 526 CALCIUM HYDROXIDE**Synonyms**

Slaked lime, hydrated lime

Definition*Chemical name*

Calcium hydroxide

EINECS

215-137-3

Chemical formula $Ca(OH)_2$ *Molecular weight*

74,09

Assay

Content not less than 92,0 %

Description

White powder

Identification

A. Positive tests for alkali and for calcium

B. Solubility

Slightly soluble in water. Insoluble in ethanol. Soluble in glycerol

Purity

Acid insoluble ash

Not more than 1,0 %

Magnesium and alkali salts

Not more than 1,0 %

Barium

Not more than 300 mg/kg

Fluoride

Not more than 50 mg/kg

Arsenic

Not more than 3 mg/kg

Lead

Not more than 10 mg/kg

E 527 AMMONIUM HYDROXIDE**Synonyms**

Aqua ammonia, strong ammonia solution

Definition*Chemical name*

Ammonium hydroxide

*Chemical formula*NH₄OH*Molecular weight*

35,05

*Assay*Content not less than 27 % of NH₃*Description*

Clear, colourless solution, having an exceedingly pungent, characteristic odour

Identification

A. Positive tests for ammonia

Purity

Non-volatile matter

Not more than 0,02 %

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

E 528 MAGNESIUM HYDROXIDE**Definition***Chemical name*

Magnesium hydroxide

EINECS

215-170-3

*Chemical formula*Mg(OH)₂

| | |
|---|---|
| <i>Molecular weight</i> | 58,32 |
| <i>Assay</i> | Content not less than 95,0 % on the anhydrous basis |
| <i>Description</i> | Odourless, white bulky powder |
| Identification | |
| A. Positive test for magnesium and for alkali | |
| B. Solubility | Practically insoluble in water and in ethanol |
| Purity | |
| Loss on drying | Not more than 2,0 % (105 °C, 2h) |
| Loss on ignition | Not more than 33 % (800 °C to constant weight) |
| Calcium oxide | Not more than 1,5 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 10 mg/kg |

E 529 CALCIUM OXIDE

| | |
|--|--|
| Synonyms | Burnt lime |
| Definition | |
| <i>Chemical name</i> | Calcium oxide |
| EINECS | 215-138-9 |
| <i>Chemical formula</i> | CaO |
| <i>Molecular weight</i> | 56,08 |
| <i>Assay</i> | Content not less than 95,0 % on the ignited basis |
| <i>Description</i> | Odourless, hard, white or greyish white masses of granules, or white to greyish powder |
| Identification | |
| A. Positive test for alkali and for calcium | |
| B. Heat is generated on moistening the sample with water | |
| C. Solubility | Slightly soluble in water. Insoluble in ethanol. Soluble in glycerol |

Purity

| | |
|----------------------------|---|
| Loss on ignition | Not more than 10,0 % (ca 800 °C to constant weight) |
| Acid insoluble matter | Not more than 1,0 % |
| Barium | Not more than 300 mg/kg |
| Magnesium and alkali salts | Not more than 1,5 % |
| Fluoride | Not more than 50 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 10 mg/kg |

E 530 MAGNESIUM OXIDE**Definition**

| | |
|-------------------------|--|
| <i>Chemical name</i> | Magnesium oxide |
| EINECS | 215-171-9 |
| <i>Chemical formula</i> | MgO |
| <i>Molecular weight</i> | 40,31 |
| <i>Assay</i> | Content not less than 98,0 % on the ignited basis |
| <i>Description</i> | A very bulky, white powder known as light magnesium oxide or a relative dense, white powder known as heavy magnesium oxide. 5 g of light magnesium oxide occupy a volume of 40 to 50 ml, while 5 g of heavy magnesium oxide occupy a volume of 10 to 20 ml |

Identification

| | |
|---|--|
| A. Positive test for alkali and for magnesium | |
| B. Solubility | Practically insoluble in water. Insoluble in ethanol |

Purity

| | |
|------------------|--|
| Loss on ignition | Not more than 5,0 % (ca 800 °C to constant weight) |
| Calcium oxide | Not more than 1,5 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 10 mg/kg |

E 535 SODIUM FERROCYANIDE**Synonyms**

Yellow prussiate of soda, sodium hexacyanoferrate

Definition*Chemical name*

Sodium ferrocyanide

EINECS

237-081-9

Chemical formula $\text{Na}_4\text{Fe}(\text{CN})_6 \cdot 10 \text{H}_2\text{O}$ *Molecular weight*

484,1

Assay

Content not less than 99,0 %

Description

Yellow crystals or crystalline powder

Identification

A. Positive test for sodium and for ferrocyanide

Purity

Free moisture

Not more than 1,0 %

Water insoluble matter

Not more than 0,03 %

Chloride

Not more than 0,2 %

Sulphate

Not more than 0,1 %

Free cyanide

Not detectable

Ferricyanide

Not detectable

Lead

Not more than 5 mg/kg

E 536 POTASSIUM FERROCYANIDE**Synonyms**

Yellow prussiate of potash, potassium hexacyanoferrate

Definition*Chemical name*

Potassium ferrocyanide

EINECS

237-722-2

Chemical formula $\text{K}_4\text{Fe}(\text{CN})_6 \cdot 3 \text{H}_2\text{O}$ *Molecular weight*

422,4

Assay

Content not less than 99,0 %

Description

Lemon yellow crystals

Identification

A. Positive test for potassium and for ferrocyanide

Purity

| | |
|------------------------|-----------------------|
| Free moisture | Not more than 1,0 % |
| Water insoluble matter | Not more than 0,03 % |
| Chloride | Not more than 0,2 % |
| Sulphate | Not more than 0,1 % |
| Free cyanide | Not detectable |
| Ferricyanide | Not detectable |
| Lead | Not more than 5 mg/kg |

E 538 CALCIUM FERROCYANIDE**Synonyms**

Yellow prussiate of lime, calcium hexacyanoferrate

Definition

Chemical name Calcium ferrocyanide

EINECS 215-476-7

Chemical formula $\text{Ca}_2\text{Fe}(\text{CN})_6 \cdot 12\text{H}_2\text{O}$

Molecular weight 508,3

Assay Content not less than 99,0 %

Description Yellow crystals or crystalline powder

Identification

A. Positive test for calcium and for ferrocyanide

Purity

| | |
|------------------------|-----------------------|
| Free moisture | Not more than 1,0 % |
| Water insoluble matter | Not more than 0,03 % |
| Chloride | Not more than 0,2 % |
| Sulphate | Not more than 0,1 % |
| Free cyanide | Not detectable |
| Ferricyanide | Not detectable |
| Lead | Not more than 5 mg/kg |

E 541 SODIUM ALUMINIUM PHOSPHATE, ACIDIC

| | |
|--|---|
| Synonyms | SALP |
| Definition | |
| <i>Chemical name</i> | Sodium trialuminium tetradecahydrogen octaphosphate tetrahydrate (A) or Trisodium dialuminium pentadecahydrogen octaphosphate (B) |
| EINECS | 232-090-4 |
| <i>Chemical formula</i> | $\text{NaAl}_3\text{H}_{14}(\text{PO}_4)_8 \cdot 4\text{H}_2\text{O}$ (A) $\text{Na}_3\text{Al}_2\text{H}_{15}(\text{PO}_4)_8$ (B) |
| <i>Molecular weight</i> | 949,88 (A) 897,82 (B) |
| <i>Assay</i> | Content not less than 95,0 % (both forms) |
| <i>Description</i> | White odourless powder |
| Identification | |
| A. Positive test for sodium, for aluminium and for phosphate | |
| B. pH | Acid to litmus |
| C. Solubility | Insoluble in water. Soluble in hydrochloric acid |
| Purity | |
| Loss on ignition | 19,5 % - 21,0 % (A) } (750 °C - 800 °C, 2h) 15 % - 16 % (B) } (750 °C - 800 °C, 2h) |
| Fluoride | Not more than 25 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 4 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 551 SILICON DIOXIDE

| | |
|----------------------|--|
| Synonyms | Silica, silicium dioxide |
| Definition | Silicon dioxide is an amorphous substance, which is produced synthetically by either a vapour-phase hydrolysis process, yielding fumed silica, or by a wet process, yielding precipitated silica, silica gel, or hydrous silica. Fumed silica is produced in essentially an anhydrous state, whereas the wet-process products are obtained as hydrates or contain surface absorbed water |
| <i>Chemical name</i> | Silicon dioxide |

| | |
|---|---|
| EINECS | 231-545-4 |
| <i>Chemical formula</i> | (SiO ₂) _n |
| <i>Molecular weight</i> | 60,08 (SiO ₂) |
| <i>Assay</i> | Content after ignition not less than 99,0 % (fumed silica) or 94,0 % (hydrated forms) |
| <i>Description</i> | White, fluffy powder or granules Hygroscopic |
| Identification | |
| A. Positive test for silica | |
| Purity | |
| Loss on drying | Not more than 2,5 % (fumed silica, 105 °C, 2h) Not more than 8,0 % (precipitated silica and silica gel, 105 °C, 2h) Not more than 70 % (hydrous silica, 105 °C, 2h) |
| Loss on ignition | Not more than 2,5 % after drying (1 000 °C, fumed silica) Not more than 8,5 % after drying (1 000 °C, hydrated forms) |
| Soluble ionisable salts | Not more than 5,0 % (as Na ₂ SO ₄) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| E 552 CALCIUM SILICATE | |
| Definition | Calcium silicate is a hydrous or anhydrous silicate with varying proportions of CaO and SiO ₂ |
| <i>Chemical name</i> | Calcium silicate |
| EINECS | 215-710-8 |
| <i>Assay</i> | Content on the anhydrous basis: — as SiO ₂ not less than 50 % and not more than 95 % — as CaO not less than 3 % and not more than 35 % |
| <i>Description</i> | White to off-white free-flowing powder that remains so after absorbing relatively large amounts of water or other liquids |
| Identification | |
| A. Positive test for silicate and for calcium | |
| B. Forms a gel with mineral acids | |

Purity

| | |
|------------------|--|
| Loss on drying | Not more than 10 % (105 °C, 2h) |
| Loss on ignition | Not less than 5 % and not more than 14 % (1 000 °C, constant weight) |
| Sodium | Not more than 3 % |
| Fluoride | Not more than 50 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 553a(i) MAGNESIUM SILICATE**Definition**

Magnesium silicate is a synthetic compound of which the molar ratio of magnesium oxide to silicon dioxide is approximately 2:5

Assay

Content not less than 15 % of MgO and not less than 67 % of SiO₂ on the ignited basis

Description

Very fine, white, odourless powder, free from grittiness

Identification

- A. Positive test for magnesium and for silicate
 B. pH of a 10 % slurry

Between 7,0 and 10,8

Purity

| | |
|---------------------|--|
| Loss on drying | Not more than 15 % (105 °C, 2h) |
| Loss on ignition | Not more than 15 % after drying (1 000 °C, 20 min) |
| Water soluble salts | Not more than 3 % |
| Free alkali | Not more than 1 % (as NaOH) |
| Fluoride | Not more than 10 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 553a(ii) MAGNESIUM TRISILICATE**Definition***Chemical name*

Magnesium trisilicate

Chemical formula

Mg₂Si₃O₈ · xH₂O (approximate composition)

EINECS

239-076-7

Assay

Content not less than 29,0 % of MgO and not less than 65,0 % of SiO₂ both on the ignited basis

Description

Fine, white powder, free from grittiness

Identification

A. Positive test for magnesium and for silicate

B. pH of a 5 % slurry

Between 6,3 and 9,5

Purity

Loss on ignition

Not less than 17 % and not more than 34 % (1 000 °C)

Water soluble salts

Not more than 2 %

Free alkali

Not more than 1 % (as NaOH)

Fluoride

Not more than 10 mg/kg

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 570 FATTY ACIDS**Definition**Linear fatty acids, caprylic acid (C₈), capric acid (C₁₀), lauric acid (C₁₂), myristic acid (C₁₄), palmitic acid (C₁₆), stearic acid (C₁₈), oleic acid (C_{18:1})*Chemical name*octanoic acid (C₈), decanoic acid (C₁₀), dodecanoic acid (C₁₂), tetradecanoic acid (C₁₄), hexadecanoic acid (C₁₆), octadecanoic acid (C₁₈), 9-octadecenoic acid (C_{18:1})*Assay*

Not less than 98 % by chromatography

Description

A colourless liquid or white solid obtained from oils and fats

Identification

A. Individual fatty acids can be identified by acid value, iodine value, gas chromatography and molecular weight

Purity

Residue on ignition

Not more than 0,1 %

Unsaponifiable matter

Not more than 1,5 %

Water

Not more than 0,2 % (Karl Fischer method)

Arsenic

Not more than 3 mg/kg

Lead

Not more than 1 mg/kg

Mercury

Not more than 1 mg/kg

E 574 GLUCONIC ACID**Synonyms**

D-gluconic acid, dextronic acid

Definition

Gluconic acid is an aqueous solution of gluconic acid and glucono-delta-lactone

Chemical name

Gluconic acid

*Chemical formula*C₆H₁₂O₇ (gluconic acid)*Molecular weight*

196,2

Assay

Content not less than 50,0 % (as gluconic acid)

Description

Colourless to light yellow, clear syrupy liquid

Identification

A. Formation of phenylhydrazine derivative positive

Compound formed melts between 196 °C and 202 °C with decomposition

Purity

Residue on ignition

Not more than 1,0 %

Reducing matter

Not more than 0,75 % (as D-glucose)

Chloride

Not more than 350 mg/kg

Sulphate

Not more than 240 mg/kg

Sulphite

Not more than 20 mg/kg

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 575 GLUCONO-DELTA-LACTONE**Synonyms**

Gluconolactone, GDL, D-gluconic acid delta-lactone, delta-gluconolactone

Definition

Glucono-delta-lactone is the cyclic 1,5-intramolecular ester of D-gluconic acid. In aqueous media it is hydrolysed to an equilibrium mixture of D-gluconic acid (55 %-66 %) and the delta- and gamma-lactones

Chemical name

D-Glucono-1,5-lactone

EINECS

202-016-5

*Chemical formula*C₆H₁₀O₆*Molecular weight*

178,14

Assay

Content not less than 99,0 % on the anhydrous basis

Description

Fine, white, nearly odourless, crystalline powder

Identification

- | | |
|--|--|
| A. Formation of phenylhydrazine derivative of gluconic acid positive | Compound formed melts between 196 °C and 202 °C with decomposition |
| B. Solubility | Freely soluble in water. Sparingly soluble in ethanol |
| C. Melting point | 152 °C ± 2 °C |

Purity

- | | |
|---------------------|---|
| Water | Not more than 1,0 % (Karl Fischer method) |
| Reducing substances | Not more than 0,75 % (as D-glucose) |
| Lead | Not more than 2 mg/kg |

E 576 SODIUM GLUCONATE**Synonyms**

Sodium salt of D-gluconic acid

Definition*Chemical name*

Sodium D-gluconate

EINECS

208-407-7

*Chemical formula*C₆H₁₁NaO₇ (anhydrous)*Molecular weight*

218,14

Assay

Content not less than 98,0 %

Description

White to tan, granular to fine, crystalline powder

Identification

- | | |
|---|---|
| A. Positive test for sodium and for gluconate | |
| B. Solubility | Very soluble in water. Sparingly soluble in ethanol |
| C. pH of a 10 % solution | Between 6,5 and 7,5 |

Purity

- | | |
|-----------------|------------------------------------|
| Reducing matter | Not more than 1,0 % (as D-glucose) |
| Lead | Not more than 2 mg/kg |

E 577 POTASSIUM GLUCONATE**Synonyms**

Potassium salt of D-gluconic acid

Definition*Chemical name*

Potassium D-gluconate

| | |
|--|---|
| EINECS | 206-074-2 |
| <i>Chemical formula</i> | C ₆ H ₁₁ KO ₇ (anhydrous) C ₆ H ₁₁ KO ₇ · H ₂ O (monohydrate) |
| <i>Molecular weight</i> | 234,25 (anhydrous) 252,26 (monohydrate) |
| <i>Assay</i> | Content not less than 97,0 % and not more than 103,0 % on dried basis |
| <i>Description</i> | Odourless, free flowing white to yellowish white, crystalline powder or granules |
| Identification | |
| A. Positive test for potassium and for gluconate | |
| B. pH of a 10 % solution | Between 7,0 and 8,3 |
| Purity | |
| Loss on drying | Anhydrous: not more than 3,0 % (105 °C, 4h, vacuum) Monohydrate: not less than 6 % and not more than 7,5 % (105 °C, 4h, vacuum) |
| Reducing substances | Not more than 1,0 % (as D-glucose) |
| Lead | Not more than 2 mg/kg |
| E 578 CALCIUM GLUCONATE | |
| Synonyms | Calcium salt of D-gluconic acid |
| Definition | |
| <i>Chemical name</i> | Calcium di-D-gluconate |
| EINECS | 206-075-8 |
| <i>Chemical formula</i> | C ₁₂ H ₂₂ CaO ₁₄ (anhydrous) C ₁₂ H ₂₂ CaO ₁₄ · H ₂ O (monohydrate) |
| <i>Molecular weight</i> | 430,38 (anhydrous form) 448,39 (monohydrate) |
| <i>Assay</i> | Content not less than 98,0 % and not more than 102 % on the anhydrous and monohydrate basis |
| <i>Description</i> | Odourless, white crystalline granules or powder, stable in air |
| Identification | |
| A. Positive test for calcium and for gluconate | |
| B. Solubility | Soluble in water, insoluble in ethanol |
| C. pH of a 5 % solution | Between 6,0 and 8,0 |

Purity

| | |
|---------------------|--|
| Loss on drying | Not more than 3,0 % (105 °C, 16h) (anhydrous) Not more than 2,0 % (105 °C, 16h) (monohydrate) |
| Reducing substances | Not more than 1,0 % (as D-glucose) |
| Lead | Not more than 2 mg/kg |

E 640 GLYCINE AND ITS SODIUM SALT**Synonyms (gly)**

Aminoacetic acid, glycocoll

(Na salt)

Sodium glycinate

Definition

| | |
|-------------------------------|---|
| <i>Chemical name (gly)</i> | Aminoacetic acid |
| <i>(Na salt)</i> | Sodium glycinate |
| <i>Chemical formula (gly)</i> | $C_2H_5NO_2$ |
| <i>(Na salt)</i> | $C_2H_5NO_2 Na$ |
| EINECS (gly) | 200-272-2 |
| <i>(Na salt)</i> | 227-842-3 |
| <i>Molecular weight (gly)</i> | 75,07 |
| <i>(Na salt)</i> | 98 |
| <i>Assay</i> | Content not less than 98,5 % on the anhydrous basis |
| <i>Description</i> | White crystals or crystalline powder |

Identification

- A. Positive test for aminoacid (gly and Na salt)
- B. Positive test for sodium (Na salt)

Purity

| | |
|---------------------------|----------------------------------|
| Loss on drying (gly) | Not more than 0,2 % (105 °C, 3h) |
| (Na salt) | Not more than 0,2 % (105 °C, 3h) |
| Residue on ignition (gly) | Not more than 0,1 % |
| (Na salt) | Not more than 0,1 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 900 DIMETHYL POLYSILOXANE**Synonyms**

Polydimethyl siloxane, silicone fluid, silicone oil, dimethyl silicone

DefinitionDimethylpolysiloxane is a mixture of fully methylated linear siloxane polymers containing repeating units of the formula $(\text{CH}_3)_2\text{SiO}$ and stabilised with trimethylsiloxy end-blocking units of the formula $(\text{CH}_3)_3\text{SiO}$ *Chemical name*

Siloxanes and silicones, di-methyl

Chemical formula $(\text{CH}_3)_3\text{-Si-[O-Si(CH}_3)_2]_n\text{-O-Si(CH}_3)_3$ *Assay*

Content of total silicon not less than 37,3 % and not more than 38,5 %

Description

Clear, colourless, viscous liquid

Identification

A. Specific gravity (25°/25 °C)

Between 0,964 and 0,977

B. Refractive index $[n]_D^{25}$

Between 1,400 and 1,405

C. Infrared spectrum characteristic of the compound

Purity

Loss on drying

Not more than 0,5 % (150 °C, 4h)

Viscosity

Not less than $1,00 \cdot 10^{-4} \text{ m}^2\text{s}^{-1}$ at 25 °C

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 901 BEESWAX**Synonyms**

White wax, yellow wax

DefinitionYellow bees wax is the wax obtained by melting the walls of the honeycomb made by the honey bee, *Apis mellifera* L., with hot water and removing foreign matter

White beeswax is obtained by bleaching yellow beeswax

EINECS

232-383-7 (beeswax)

Description

Yellowish white (white form) or yellowish to greyish brown (yellow form) pieces or plates with a fine-grained and non-crystalline fracture, having an agreeable, honey-like odour

Identification

A. Melting range

Between 62 °C and 65 °C

B. Specific gravity

About 0,96

C. Solubility

Insoluble in water

Sparingly soluble in alcohol

Very soluble in chloroform and ether

Purity

| | |
|--|---------------------------------------|
| Acid value | Not less than 17 and not more than 24 |
| Saponification value | 87-104 |
| Peroxide value | Not more than 5 |
| Glycerol and other polyols | Not more than 0,5 % (as glycerol) |
| Ceresin, paraffins and certain other waxes | Absent |
| Fats, Japan wax, rosin and soaps | Absent |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 902 CANDELILLA WAX**Definition**

Candelilla wax is a purified wax obtained from the leaves of the candelilla plant, *Euphorbia antisyphilitica*

EINECS

232-347-0

Description

Hard, yellowish brown, opaque to translucent wax

Identification

| | |
|---------------------|---|
| A. Specific gravity | About 0,983 |
| B. Melting range | Between 68,5 °C and 72,5 °C |
| C. Solubility | Insoluble in water Soluble in chloroform and toluene |

Purity

| | |
|--|---------------------------------------|
| Acid value | Not less than 12 and not more than 22 |
| Saponification value | Not less than 43 and not more than 65 |
| Glycerol and other polyols | Not more than 0,5 % (as glycerol) |
| Ceresin, paraffins and certain other waxes | Absent |
| Fats, Japan wax, rosin and soaps | Absent |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 903 CARNAUBA WAX**Definition**

Carnauba wax is a purified wax obtained from the leaf buds and leaves of the Brazilian Mart wax palm, *Copernicia cereferia*

EINECS

232-399-4

Description

Light brown to pale yellow powder or flakes or hard and brittle solid with a resinous fracture

Identification

A. Specific gravity

About 0,997

B. Melting range

Between 82 °C and 86 °C

C. Solubility

Insoluble in water
Partly soluble in boiling ethanol
Soluble in chloroform and diethyl ether

Purity

Sulphated ash

Not more than 0,25 %

Acid value

Not less than 2 and not more than 7

Ester value

Not less than 71 and not more than 88

Unsaponifiable matter

Not less than 50 % and not more than 55 %

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 904 SHELLAC**Synonyms**

Bleached shellac, white shellac

Definition

Shellac is the purified and bleached lac, the resinous secretion of the insect *Laccifer (Tachardia) lacca* Kerr (Fam. *Coccidae*)

EINECS

232-549-9

Description

Bleached shellac — off-white, amorphous, granular resin
Wax-free bleached shellac — light yellow, amorphous, granular resin

Identification

A. Solubility

Insoluble in water; freely (though very slowly) soluble in alcohol; slightly soluble in acetone

B. Acid value

Between 60 and 89

Purity

| | |
|----------------|---|
| Loss on drying | Not more than 6,0 % (40 °C, over silica gel, 15h) |
| Rosin | Absent |
| Wax | Bleached shellac: not more than 5,5 % Wax-free bleached shellac: not more than 0,2 % |
| Lead | Not more than 2 mg/kg |

E 920 L-CYSTEINE**Definition**

L-cysteine hydrochloride or hydrochloride monohydrate. Human hair may not be used as a source for this substance

EINECS

200-157-7 (anhydrous)

Chemical formula

$C_3H_7NO_2S \cdot HCl \cdot n H_2O$ (where n = 0 or 1)

Molecular weight

157,62 (anhydrous)

Assay

Content not less than 98,0 % and not more than 101,5 % on the anhydrous basis

Description

White powder or colourless crystals

Identification

A. Solubility

Freely soluble in water and in ethanol

B. Melting range

Anhydrous form melts at about 175 °C

C. Specific rotation

$[\alpha]^{20}_D$: between + 5,0° and + 8,0° or

$[\alpha]^{25}_D$: between + 4,9° and 7,9°

Purity

| | |
|---------------------|--|
| Loss on drying | Between 8,0 % and 12,0 % Not more than 2,0 % (anhydrous form) |
| Residue on ignition | Not more than 0,1 % |
| Ammonium-ion | Not more than 200 mg/kg |
| Arsenic | Not more than 1,5 mg/kg |
| Lead | Not more than 5 mg/kg |

E 927b CARBAMIDE**Synonyms**

Urea

Definition**EINECS**

200-315-5

Chemical formula

CH_4N_2O

| | |
|-----------------------------------|--|
| <i>Molecular weight</i> | 60,06 |
| <i>Assay</i> | Content not less than 99,0 % on the anhydrous basis |
| <i>Description</i> | Colourless to white, prismatic, crystalline powder or small, white pellets |
| Identification | |
| A. Solubility | Very soluble in water Soluble in ethanol |
| B. Precipitation with nitric acid | To pass the test a white, crystalline precipitate is formed |
| C. Colour reaction | To pass the test a reddish-violet colour is produced |
| D. Melting range | 132 °C to 135 °C |
| Purity | |
| Loss on drying | Not more than 1,0 % (105 °C, 1h) |
| Sulphated ash | Not more than 0,1 % |
| Ethanol-insoluble matter | Not more than 0,04 % |
| Alkalinity | Passes test |
| Ammonium-ion | Not more than 500 mg/kg |
| Biuret | Not more than 0,1 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |

E 938 ARGON**Definition**

| | |
|--|--|
| <i>Chemical name</i> | Argon |
| EINECS | 231-147-0 |
| <i>Chemical formula</i> | Ar |
| <i>Molecular weight</i> | 40 |
| <i>Assay</i> | Not less than 99 % |
| <i>Description</i> | Colourless, odourless, non-flammable gas |
| Purity | |
| Water | Not more than 0,05 % |
| Methane and other hydrocarbons calculated as methane | Not more than 100 µl/l |

E 939 HELIUM**Definition**

| | |
|-------------------------|--|
| <i>Chemical name</i> | Helium |
| EINECS | 231-168-5 |
| <i>Chemical formula</i> | He |
| <i>Molecular weight</i> | 4 |
| <i>Assay</i> | Not less than 99 % |
| <i>Description</i> | Colourless, odourless, non-flammable gas |

Purity

| | |
|--|------------------------|
| Water | Not more than 0,05 % |
| Methane and other hydrocarbons calculated as methane | Not more than 100 µl/l |

E 941 NITROGEN**Definition**

| | |
|-------------------------|--|
| <i>Chemical name</i> | Nitrogen |
| EINECS | 231-783-9 |
| <i>Chemical formula</i> | N ₂ |
| <i>Molecular weight</i> | 28 |
| <i>Assay</i> | Not less than 99 % |
| <i>Description</i> | Colourless, odourless, non-flammable gas |

Purity

| | |
|--|------------------------|
| Water | Not more than 0,05 % |
| Carbon monoxide | Not more than 10 µl/l |
| Methane and other hydrocarbons calculated as methane | Not more than 100 µl/l |
| Nitrogen dioxide and nitrogen oxide | Not more than 10 µl/l |
| Oxygen | Not more than 1 % |

E 942 NITROUS OXIDE**Definition**

| | |
|-------------------------|------------------|
| <i>Chemical name</i> | Nitrous oxide |
| EINECS | 233-032-0 |
| <i>Chemical formula</i> | N ₂ O |

| | |
|-------------------------------------|---|
| Molecular weight | 44 |
| Assay | Not less than 99 % |
| Description | Colourless, non-flammable gas, sweetish odour |
| Purity | |
| Water | Not more than 0,05 % |
| Carbon monoxide | Not more than 30 µl/l |
| Nitrogen dioxide and nitrogen oxide | Not more than 10 µl/l |

E 948 OXYGEN**Definition**

| | |
|------------------|--|
| Chemical name | Oxygen |
| EINECS | 231-956-9 |
| Chemical formula | O ₂ |
| Molecular weight | 32 |
| Assay | Not less than 99 % |
| Description | Colourless, odourless, non-flammable gas |

Purity

| | |
|--|------------------------|
| Water | Not more than 0,05 % |
| Methane and other hydrocarbons calculated as methane | Not more than 100 µl/l |

E 999 QUILLAIA EXTRACT**Synonyms**

Soapbark extract, Quillay bark extract, Panama bark extract, Quillai extract, Murillo bark extract, China bark extract

Definition

Quillaia extract is obtained by aqueous extraction of *Quillai saponaria Molina*, or other *Quillaia* species, trees of the family *Rosaceae*. It contains a number of triterpenoid saponins consisting of glycosides of quillaic acid. Some sugars including glucose, galactose, arabinose, xylose, and rhamnose are also present, along with tannin, calcium oxalate and other minor components

| | |
|-------------|---|
| Description | Quillaia extract in the powder form is light brown with a pink tinge. It is also available as an aqueous solution |
|-------------|---|

Identification

| | |
|---------------------------|---------------------|
| A. pH of a 2,5 % solution | Between 4,5 and 5,5 |
|---------------------------|---------------------|

Purity

| | |
|-------|--|
| Water | Not more than 6,0 % (Karl Fischer method) (powder form only) |
|-------|--|

| | |
|---------|-----------------------|
| Arsenic | Not more than 2 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

E 1103 INVERTASE**Definition**

Invertase is produced from *Saccharomyces cerevisiae*

Systematic name

β -D-Fructofuranoside fructohydrolase

Enzyme Commission No

EC 3.2.1.26

EINECS

232-615-7

Purity

| | |
|------------------------|-------------------------|
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Cadmium | Not more than 0,5 mg/kg |
| Total bacterial count | Not more than 50 000/g |
| <i>Salmonella</i> spp. | Absent by test in 25 g |
| Coliforms | Not more than 30/g |
| <i>E. coli</i> | Absent by test in 25 g |

E 1200 POLYDEXTROSE**Synonyms**

Modified polydextroses

Definition

Randomly bonded glucose polymers with some sorbitol end-groups, and with citric acid or phosphoric acid residues attached to the polymers by mono or diester bonds. They are obtained by melting and condensation of the ingredients and consist of approximately 90 parts D-glucose, 10 parts sorbitol and 1 part citric acid or 0,1 part phosphoric acid. The 1,6-glucosidic linkage predominates in the polymers but other linkages are present. The products contain small quantities of free glucose, sorbitol, levoglucosan (1,6-anhydro-D-glucose) and citric acid and may be neutralised with any food grade base and/or decolorised and deionised for further purification. The products may also be partially hydrogenated with Raney nickel catalyst to reduce residual glucose. Polydextrose-N is neutralised polydextrose

Assay

Content not less than 90 % of polymer on the ash free and anhydrous basis

Description

White to light tan-coloured solid. Polydextroses dissolve in water to give a clear, colourless to straw coloured solution

Identification

- A. Positive tests for sugar and for reducing sugar
- B. pH of a 10 % solution

Between 2,5 and 7,0 for polydextrose
Between 5,0 and 6,0 for polydextrose-N

Purity

| | |
|-------------------------|--|
| Water | Not more than 4,0 % (Karl Fischer method) |
| Sulphated ash | Not more than 0,3 % (polydextrose) Not more than 2,0 % (polydextrose N) |
| Nickel | Not more than 2 mg/kg for hydrogenated polydextroses |
| 1,6-Anhydro-D-glucose | Not more than 4,0 % on the ash-free and the dried basis |
| Glucose and sorbitol | Not more than 6,0 % combined on the ash-free and the dried basis; glucose and sorbitol are determined separately |
| Molecular weight limit | Negative test for polymers of molecular weight greater than 22,000 |
| 5-Hydroxymethylfurfural | Not more than 0,1 % (polydextrose) Not more than 0,05 % (polydextrose-N) |
| Lead | Not more than 0,5 mg/kg |

E 1404 OXIDISED STARCH**Definition**

Oxidised starch is starch treated with sodium hypochlorite

Description

White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

Identification

- A. If not pregelatinised: by microscopic observation
- B. Iodine staining positive (dark blue to light red colour)

Purity (all values expressed on an anhydrous basis except for loss on drying)

| | |
|-----------------|---|
| Loss on drying | Not more than 15,0 % for cereal starch Not more than 21,0 % for potato starch Not more than 18,0 % for other starches |
| Carboxyl groups | Not more than 1,1 % |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches Not more than 10 mg/kg for other modified starches, unless otherwise specified |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 0,1 mg/kg |

E 1410 MONOSTARCH PHOSPHATE**Definition**

Monostarch phosphate is starch esterified with ortho-phosphoric acid, or sodium or potassium ortho-phosphate or sodium triphosphate

Description

White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

Identification

- A. If not pregelatinised: by microscopic observation
- B. Iodine staining positive (dark blue to light red colour)

Purity (all values expressed on an anhydrous basis except for loss on drying)

Loss on drying

Not more than 15,0 % for cereal starch
 Not more than 21,0 % for potato starch
 Not more than 18,0 % for other starches

Residual phosphate

Not more than 0,5 % (as P) for wheat or potato starch
 Not more than 0,4 % (as P) for other starches

Sulphur dioxide

Not more than 50 mg/kg for modified cereal starches
 Not more than 10 mg/kg for other modified starches, unless otherwise specified

Arsenic

Not more than 1 mg/kg

Lead

Not more than 2 mg/kg

Mercury

Not more than 0,1 mg/kg

E 1412 DISTARCH PHOSPHATE**Definition**

Distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride

Description

White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

Identification

- A. If not pregelatinised: by microscopic observation
- B. Iodine staining positive (dark blue to light red colour)

Purity (all values expressed on an anhydrous basis except for loss on drying)

Loss on drying

Not more than 15,0 % for cereal starch
 Not more than 21,0 % for potato starch
 Not more than 18,0 % for other starches

| | |
|--------------------|---|
| Residual phosphate | Not more than 0,5 % (as P) for wheat or potato starch Not more than 0,4 % (as P) for other starches |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches Not more than 10 mg/kg for other modified starches, unless otherwise specified |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 0,1 mg/kg |

E 1413 PHOSPHATED DISTARCH PHOSPHATE**Definition**

Phosphated distarch phosphate is starch having undergone a combination of treatments as described for monostarch phosphate and for distarch phosphate

Description

White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

Identification

- A. If not pregelatinised: by microscopic observation
- B. Iodine staining positive (dark blue to light red colour)

Purity (all values expressed on an anhydrous basis except for loss on drying)

| | |
|--------------------|---|
| Loss on drying | Not more than 15,0 % for cereal starch Not more than 21,0 % for potato starch Not more than 18,0 % for other starches |
| Residual phosphate | Not more than 0,5 % (as P) for wheat or potato starch Not more than 0,4 % (as P) for other starches |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches Not more than 10 mg/kg for other modified starches, unless otherwise specified |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 0,1 mg/kg |

E 1414 ACETYLATED DISTARCH PHOSPHATE**Definition**

Acetylated distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride and esterified by acetic anhydride or vinyl acetate

Description

White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

Identification

- A. If not pregelatinised: by microscopic observation
- B. Iodine staining positive (dark blue to light red colour)

Purity (all values expressed on an anhydrous basis except for loss on drying)

Loss on drying

Not more than 15,0 % for cereal starch
 Not more than 21,0 % for potato starch
 Not more than 18,0 % for other starches

Acetyl groups

Not more than 2,5 %

Residual phosphate

Not more than 0,14 % (as P) for wheat or potato starch
 Not more than 0,04 % (as P) for other starches

Vinyl acetate

Not more than 0,1 mg/kg

Sulphur dioxide

Not more than 50 mg/kg for modified cereal starches
 Not more than 10 mg/kg for other modified starches, unless otherwise specified

Arsenic

Not more than 1 mg/kg

Lead

Not more than 2 mg/kg

Mercury

Not more than 0,1 mg/kg

E 1420 ACETYLATED STARCH**Synonyms**

Starch acetate

Definition

Acetylated starch is starch esterified with acetic anhydride or vinyl acetate

Description

White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

Identification

- A. If not pregelatinised: by microscopic observation
- B. Iodine staining positive (dark blue to light red colour)

Purity (all values expressed on an anhydrous basis except for loss on drying)

Loss on drying

Not more than 15,0 % for cereal starch
 Not more than 21,0 % for potato starch
 Not more than 18,0 % for other starches

Acetyl groups

Not more than 2,5 %

| | |
|-----------------|---|
| Vinyl acetate | Not more than 0,1 mg/kg |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches Not more than 10 mg/kg for other modified starches, unless otherwise specified |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 0,1 mg/kg |

E 1422 ACETYLATED DISTARCH ADIPATE**Definition**

Acetylated distarch adipate is starch cross-linked with adipic anhydride and esterified with acetic anhydride

Description

White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

Identification

- A. If not pregelatinised: by microscopic observation
- B. Iodine staining positive (dark blue to light red colour)

Purity (all values expressed on an anhydrous basis except for loss on drying)

Loss on drying

Not more than 15,0 % for cereal starch
Not more than 21,0 % for potato starch
Not more than 18,0 % for other starches

Acetyl groups

Not more than 2,5 %

Adipate groups

Not more than 0,135 %

Sulphur dioxide

Not more than 50 mg/kg for modified cereal starches
Not more than 10 mg/kg for other modified starches, unless otherwise specified

Arsenic

Not more than 1 mg/kg

Lead

Not more than 2 mg/kg

Mercury

Not more than 0,1 mg/kg

E 1440 HYDROXYPROPYL STARCH**Definition**

Hydroxypropyl starch is starch etherified with propylene oxide

Description

White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

Identification

- A. If not pregelatinised: by microscopic observation
- B. Iodine staining positive (dark blue to light red colour)

Purity (all values expressed on an anhydrous basis except for loss on drying)

| | |
|------------------------|---|
| Loss on drying | Not more than 15,0 % for cereal starch Not more than 21,0 % for potato starch Not more than 18,0 % for other starches |
| Hydroxypropyl groups | Not more than 7,0 % |
| Propylene chlorohydrin | Not more than 1 mg/kg |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches Not more than 10 mg/kg for other modified starches, unless otherwise specified |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 0,1 mg/kg |

E 1442 HYDROXYPROPYL DISTARCH PHOSPHATE**Definition**

Hydroxypropyl distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride and etherified with propylene oxide

Description

White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

Identification

- A. If not pregelatinised: by microscopic observation
- B. Iodine staining positive (dark blue to light red colour)

Purity (all values expressed on an anhydrous basis except for loss on drying)

| | |
|------------------------|---|
| Loss on drying | Not more than 15,0 % for cereal starch Not more than 21,0 % for potato starch Not more than 18,0 % for other starches |
| Hydroxypropyl groups | Not more than 7,0 % |
| Residual phosphate | Not more than 0,14 % (as P) for wheat or potato starch Not more than 0,04 (as P) for other starches |
| Propylene chlorohydrin | Not more than 1 mg/kg |

| | |
|-----------------|---|
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches Not more than 10 mg/kg for other modified starches, unless otherwise specified |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 0,1 mg/kg |

E 1450 STARCH SODIUM OCTENYL SUCCINATE

| | |
|--|---|
| Synonyms | SSOS |
| Definition | Starch sodium octenyl succinate is starch esterified with octenylsuccinic anhydride |
| <i>Description</i> | White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles |
| Identification | |
| A. If not pregelatinised: by microscopic observation | |
| B. Iodine staining positive (dark blue to light red colour) | |
| Purity (all values expressed on an anhydrous basis except for loss on drying) | |
| Loss on drying | Not more than 15,0 % for cereal starch Not more than 21,0 % for potato starch Not more than 18,0 % for other starches |
| Octenylsuccinyl groups | Not more than 3 % |
| Octenylsuccinic acid residue | Not more than 0,3 % |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches Not more than 10 mg/kg for other modified starches, unless otherwise specified |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 0,1 mg/kg |

E 1451 ACETYLATED OXIDISED STARCH

| | |
|--------------------|--|
| Definition | Acetylated oxidised starch is starch treated with sodium hypochlorite followed by esterification with acetic anhydride |
| <i>Description</i> | White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles |

Identification

- A. If not pregelatinised: by microscopic observation
- B. Iodine staining positive (dark blue to light red colour)

Purity (all values expressed on an anhydrous basis except for loss on drying)

| | |
|-----------------|---|
| Loss on drying | Not more than 15,0 % for cereal starch Not more than 21,0 % for potato starch Not more than 18,0 % for other starches |
| Carboxyl groups | Not more than 1,3 % |
| Acetyl groups | Not more than 2,5 % |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches Not more than 10 mg/kg for other modified starches, unless otherwise specified |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 0,1 mg/kg |

E 1505 TRIETHYL CITRATE**Synonyms**

Ethyl citrate

Definition

| | |
|-------------------------|--|
| <i>Chemical name</i> | Triethyl-2-hydroxypropan-1,2,3-tricarboxylate |
| EINECS | 201-070-7 |
| <i>Chemical formula</i> | $C_{12}H_{20}O_7$ |
| <i>Molecular weight</i> | 276,29 |
| <i>Assay</i> | Content not less than 99,0 % |
| <i>Description</i> | Odourless, practically colourless, oily liquid |

Identification

- A. Specific gravity d_{25}^{25} : 1,135-1,139
- B. Refractive index $[n]_D^{20}$: 1,439-1,441

Purity

| | |
|---------|--|
| Water | Not more than 0,25 % (Karl Fischer method) |
| Acidity | Not more than 0,02 % (as citric acid) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |

E 1518 GLYCERYL TRIACETATE**Synonyms**

Triacetin

Definition*Chemical name*

Glyceryl triacetate

EINECS

203-051-9

*Chemical formula*C₉H₁₄O₆*Molecular weight*

218,21

Assay

Content not less than 98,0 %

Description

Colourless, somewhat oily liquid having a slightly fatty odour

Identification

A. Positive tests for acetate and for glycerol

B. Refractive index

Between 1,429 and 1,431 at 25 °C

C. Specific gravity (25 °C/25 °C)

Between 1,154 and 1,158

D. Boiling range

Between 258° and 270 °C

Purity

Water

Not more than 0,2 % (Karl Fischer method)

Sulphated ash

Not more than 0,02 % (as citric acid)

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

E 1520 PROPANE-1,2-DIOL**Synonyms**

Propylene glycol

Definition*Chemical names*

1,2-dihydroxypropane

EINECS

200-338-0

*Chemical formula*C₃H₈O₂*Molecular weight*

76,10

Assay

Content not less than 99,5 % on the anhydrous basis

Description

Clear, colourless, hygroscopic, viscous liquid

Identification

- A. Solubility
- B. Specific gravity
- C. Refractive index

Soluble in water, ethanol and acetone

d_{20}^{20} : 1,035-1,040

$[n]^{20}_D$: 1,431-1,433

Purity

Distillation range

99 % v/v distils between 185 °C-189 °C

Sulphated ash

Not more than 0,07 %

Water

Not more than 1,0 % (Karl Fischer method)

Lead

Not more than 5 mg/kg'
