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# COMMISSION REGULATION (EU) No 231/2012

**of 9 March 2012**

**laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council**

**(Text with EEA relevance)**

(OJ L 83, 22.3.2012, p. 1)

Amended by:

| | | Official Journal | | |
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| | | No | page | date |
| ►M1 | Commission Regulation (EU) No 1050/2012 of 8 November 2012 | L 310 | 45 | 9.11.2012 |
| ►M2 | Commission Regulation (EU) No 25/2013 of 16 January 2013 | L 13 | 1 | 17.1.2013 |
| ►M3 | Commission Regulation (EU) No 497/2013 of 29 May 2013 | L 143 | 20 | 30.5.2013 |
| ►M4 | Commission Regulation (EU) No 724/2013 of 26 July 2013 | L 202 | 11 | 27.7.2013 |
| ►M5 | Commission Regulation (EU) No 739/2013 of 30 July 2013 | L 204 | 35 | 31.7.2013 |
| ►M6 | Commission Regulation (EU) No 816/2013 of 28 August 2013 | L 230 | 1 | 29.8.2013 |
| ►M7 | Commission Regulation (EU) No 817/2013 of 28 August 2013 | L 230 | 7 | 29.8.2013 |
| ►M8 | Commission Regulation (EU) No 1274/2013 of 6 December 2013 | L 328 | 79 | 7.12.2013 |
| ►M9 | Commission Regulation (EU) No 264/2014 of 14 March 2014 | L 76 | 22 | 15.3.2014 |
| ►M10 | Commission Regulation (EU) No 298/2014 of 21 March 2014 | L 89 | 36 | 25.3.2014 |
| ►M11 | Commission Regulation (EU) No 497/2014 of 14 May 2014 | L 143 | 6 | 15.5.2014 |
| ►M12 | Commission Regulation (EU) No 506/2014 of 15 May 2014 | L 145 | 35 | 16.5.2014 |
| ►M13 | Commission Regulation (EU) No 685/2014 of 20 June 2014 | L 182 | 23 | 21.6.2014 |
| ►M14 | Commission Regulation (EU) No 923/2014 of 25 August 2014 | L 252 | 11 | 26.8.2014 |
| ►M15 | Commission Regulation (EU) No 957/2014 of 10 September 2014 | L 270 | 1 | 11.9.2014 |
| ►M16 | Commission Regulation (EU) No 966/2014 of 12 September 2014 | L 272 | 1 | 13.9.2014 |
| ►M17 | Commission Regulation (EU) 2015/463 of 19 March 2015 | L 76 | 42 | 20.3.2015 |
| ►M18 | Commission Regulation (EU) 2015/649 of 24 April 2015 | L 107 | 17 | 25.4.2015 |
| ►M19 | Commission Regulation (EU) 2015/1725 of 28 September 2015 | L 252 | 12 | 29.9.2015 |
| ►M20 | Commission Regulation (EU) 2015/1739 of 28 September 2015 | L 253 | 3 | 30.9.2015 |
| ►M21 | Commission Regulation (EU) 2016/1814 of 13 October 2016 | L 278 | 37 | 14.10.2016 |
| ►M22 | Commission Regulation (EU) 2017/324 of 24 February 2017 | L 49 | 4 | 25.2.2017 |
| ►M23 | Commission Regulation (EU) 2017/1399 of 28 July 2017 | L 199 | 8 | 29.7.2017 |
| ►M24 | Commission Regulation (EU) 2018/75 of 17 January 2018 | L 13 | 24 | 18.1.2018 |

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| ►**M25** | Commission Regulation (EU) 2018/98 of 22 January 2018 | L 17 | 14 | 23.1.2018 |
| ►**M26** | Commission Regulation (EU) 2018/681 of 4 May 2018 | L 116 | 1 | 7.5.2018 |
| ►**M27** | Commission Regulation (EU) 2018/1461 of 28 September 2018 | L 245 | 1 | 1.10.2018 |
| ►**M28** | Commission Regulation (EU) 2018/1462 of 28 September 2018 | L 245 | 6 | 1.10.2018 |
| ►**M29** | Commission Regulation (EU) 2018/1472 of 28 September 2018 | L 247 | 1 | 3.10.2018 |
| ►**M30** | Commission Regulation (EU) 2018/1481 of 4 October 2018 | L 251 | 13 | 5.10.2018 |
| ►**M31** | Commission Regulation (EU) 2020/763 of 9 June 2020 | L 182 | 8 | 10.6.2020 |
| ►**M32** | Commission Regulation (EU) 2020/771 of 11 June 2020 | L 184 | 25 | 12.6.2020 |
| ►**M33** | Commission Regulation (EU) 2021/1156 of 13 July 2021 | L 249 | 87 | 14.7.2021 |
| ►**M34** | Commission Regulation (EU) 2022/650 of 20 April 2022 | L 119 | 65 | 21.4.2022 |
| ►**M35** | Commission Regulation (EU) 2022/1023 of 28 June 2022 | L 172 | 5 | 29.6.2022 |
| ►**M36** | Commission Regulation (EU) 2022/1037 of 29 June 2022 | L 173 | 52 | 30.6.2022 |
| ►**M37** | Commission Regulation (EU) 2022/1396 of 11 August 2022 | L 211 | 182 | 12.8.2022 |
| ►**M38** | Commission Regulation (EU) 2022/1922 of 10 October 2022 | L 264 | 1 | 11.10.2022 |
| ►**M39** | Commission Regulation (EU) 2023/440 of 28 February 2023 | L 64 | 4 | 1.3.2023 |
| ►**M40** | Commission Regulation (EU) 2023/447 of 1 March 2023 | L 65 | 16 | 2.3.2023 |
| ►**M41** | Commission Regulation (EU) 2023/1329 of 29 June 2023 | L 166 | 66 | 30.6.2023 |
| ►**M42** | Commission Regulation (EU) 2023/1428 of 7 July 2023 | L 175 | 6 | 10.7.2023 |

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# COMMISSION REGULATION (EU) No 231/2012

## of 9 March 2012

## laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council

**(Text with EEA relevance)**

*Article 1*

**Specifications for food additives**

Specifications for food additives including colours and sweeteners listed in Annex II and III to Regulation (EC) No 1333/2008 are laid down in the Annex to this Regulation.

*Article 2*

**Repeals**

Directives 2008/60/EC, 2008/84/EC and 2008/128/EC are repealed with effect from 1 December 2012.

*Article 3*

**Transitional measures**

Foodstuffs containing food additives that have been lawfully placed on the market before 1 December 2012, but do not comply with this Regulation, may continue to be marketed until stocks are exhausted.

*Article 4*

**Entry into force**

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 December 2012.

However, the specifications laid down in the Annex for additives steviol glycosides (E 960) and basic methacrylate copolymer (E 1205) shall apply from the date of entry into force of this Regulation.

This Regulation shall be binding in its entirety and directly applicable in the Member States.

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*ANNEX*

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Ethylene oxide may not be used for sterilising purposes in food additives.

No residue above 0,1 mg/kg, irrespective of its origin, of ethylene oxide (sum of ethylene oxide and 2-chloro-ethanol expressed as ethylene oxide [1]) shall be present in food additives listed in Annexes II and III to Regulation (EC) No 1333/2008, including mixtures of food additives.

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**Aluminium lakes for use in colours only where explicitly stated.**

| | |
|---|---|
| **Definition:** | Aluminium lakes are prepared by reacting colours complying with the purity criteria set out in the appropriate specification monograph with alumina under aqueous conditions. The alumina is usually freshly prepared undried material made by reacting aluminium sulphate or chloride with sodium or calcium carbonate or bicarbonate or ammonia. Following lake formation, the product is filtered, washed with water and dried. Unreacted alumina may also be present in the finished product. |
| HCl insoluble matter | Not more than 0,5 % |
| NaOH insoluble matter | Not more than 0,5 %, for E 127 erythrosine only |
| Ether extractable matter | Not more than 0,2 % (under neutral conditions) |
| | Specific purity criteria for the corresponding colours are applicable. |

**E 100 CURCUMIN**

| | |
|---|---|
| **Synonyms** | CI Natural Yellow 3; Turmeric Yellow; Diferoyl Methane |
| **Definition** | Curcumin is obtained by solvent extraction of turmeric i.e. the ground rhizomes of strains of *Curcuma longa* L. In order to obtain a concentrated curcumin powder, the extract is purified by crystallization. The product consists essentially of curcumins; i.e. the colouring principle (1,7-bis(4-hydroxy-3-methoxyphenyl)hepta-1,6-dien-3,5-dione) and its two desmethoxy derivatives in varying proportions. Minor amounts of oils and resins naturally occurring in turmeric may be present.<br>Curcumin is also used as the aluminium lake; the aluminium content is less than 30 %.<br>Only the following solvents may be used in the extraction: ethylacetate, acetone, carbon dioxide, dichloromethane, n-butanol, methanol, ethanol, hexane, propan-2-ol. |
| Colour Index No | 75300 |
| Einecs | 207-280-5 |
| Chemical name | I 1,7-Bis(4-hydroxy-3-methoxyphenyl)hepta-1,6-diene-3,5-dione<br>II 1-(4-Hydroxyphenyl)-7-(4-hydroxy-3-methoxy-phenyl-)hepta-1,6-diene-3,5-dione<br>III 1,7-Bis(4-hydroxyphenyl)hepta-1,6-diene-3,5-dione |
| Chemical formula | I $C_{21}H_{20}O_6$<br>II $C_{20}H_{18}O_5$<br>III $C_{19}H_{16}O_4$ |
| Molecular weight | I. 368,39 II. 338,39 III. 308,39 |
| Assay | Content not less than 90 % total colouring matters<br>$E^{1\%}_{1cm}$ 1 607 at ca. 426 nm in ethanol |

[1] i.e. ethylene oxide + 0,55* 2-chloroethanol.

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| **Description** | Orange-yellow crystalline powder |
| **Identification** | |
| Spectrometry | Maximum in ethanol at ca. 426 nm |
| Melting range | 179 °C-182 °C |
| **Purity** | |
| Solvent residues | Ethylacetate, Acetone, n-butanol, Methanol, Ethanol, Hexane, Propan-2-ol: Not more than 50 mg/kg, singly or in combination |
| | Dichloromethane: not more than 10 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 10 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

***Aluminium lakes of this colour may be used.***

**E 101 (i) RIBOFLAVIN**

| | |
|---|---|
| **Synonyms** | Lactoflavin; |
| **Definition** | |
| Colour Index No | |
| Einecs | 201-507-1 |
| Chemical name | 7,8-Dimethyl-10-(D-ribo-2,3,4,5-tetrahydroxy-pentyl)benzo(g)pteridine-2,4(3H,10H)-dione; 7,8-dimethyl-10-(1′-D-ribityl)isoalloxazine |
| Chemical formula | $C_{17}H_{20}N_4O_6$ |
| Molecular weight | 376,37 |
| Assay | Content not less than 98 % on the anhydrous basis |
| | $E^{1\%}_{1cm}$ 328 at ca. 444 nm in aqueous solution |
| **Description** | Yellow to orange-yellow crystalline powder, with slight odour |
| **Identification** | |
| Spectrometry | The ratio $A_{375}/A_{267}$ is between 0,31 and 0,33; The ratio $A_{444}/A_{267}$ is between 0,36 and 0,39: in aqueous solution |
| | Maximum in water at ca. 375 nm |
| Specific rotation | $[\alpha]_D^{20}$ between – 115° and – 140° in a 0,05 N sodium hydroxide solution |
| **Purity** | |
| Loss on drying | Not more than 1,5 % (105 °C, 4 hours) |

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| Sulphated ash | Not more than 0,1 % |
| Primary aromatic amines | Not more than 100 mg/kg (calculated as aniline) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

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***Aluminium lakes of this colour may be used.***

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**E 101 (ii) RIBOFLAVIN-5′-PHOSPHATE**

| | |
|---|---|
| **Synonyms** | Riboflavin-5′-phosphate sodium |
| **Definition** | These specifications apply to riboflavin 5′-phosphate together with minor amounts of free riboflavin and riboflavin diphosphate. |
| Colour Index No | |
| Einecs | 204-988-6 |
| Chemical name | Monosodium(2R,3R,4S)-5-(3′)10′-dihydro-7′,8′-dimethyl-2′,4′-dioxo-10′-benzo[γ]pteridinyl)-2,3,4-trihydroxypentyl phosphate; monosodium salt of 5′-monophosphate ester of riboflavin |
| Chemical formula | For the dihydrate form: $C_{17}H_{20}N_4NaO_9P \cdot 2H_2O$<br>For the anhydrous form: $C_{17}H_{20}N_4NaO_9P$ |
| Molecular weight | 514,36 |
| Assay | Content not less than 95 % total colouring matters calculated as $C_{17}H_{20}N_4NaO_9P.2H_2O$<br>$E^{1\%}_{1cm}$ 250 at ca. 375 nm in aqueous solution |
| **Description** | Yellow to orange crystalline hygroscopic powder, with slight odour |
| **Identification** | |
| Spectrometry | The ratio $A_{375}/A_{267}$ is between 0,30 and 0,34<br>The ratio $A_{444}/A_{267}$ is between 0,35 and 0,40<br>} in aqueous solution<br>Maximum in water at ca. 375 nm |
| Specific rotation | $[\alpha]_D^{20}$ between + 38° and + 42° in a 5 molar HCl solution |
| **Purity** | |
| Loss on drying | Not more than 8 % (100 °C, 5 hours in vacuum over $P_2O_5$) for the dihydrate form |
| Sulphated ash | Not more than 25 % |
| Inorganic phosphate | Not more than 1,0 % (calculated as $PO_4$ on the anhydrous basis) |
| Subsidiary colouring matters | Riboflavin (free): Not more than 6 %<br>Riboflavine diphosphate: Not more than 6 % |
| Primary aromatic amines | Not more than 70 mg/kg (calculated as aniline) |

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| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

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***Aluminium lakes of this colour may be used.***

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**E 102 TARTRAZINE**

| | |
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| **Synonyms** | CI Food Yellow 4 |
| **Definition** | Tartrazine is prepared from 4-amino-benzenesulphonic acid, which is diazotized using hydrochloric acid and sodium nitrite. The diazo compound is then coupled with 4,5-dihydro-5-oxo-1-(4sulphophenyl)-1H-pyrazole-3-carboxylic acid or with the methyl ester, the ethyl ester, or a salt of this carboxylic acid. The resulting dye is purified and isolated as the sodium salt. Tartrazine consists essentially of trisodium 5-hydroxy-1-(4-sulfonatophenyl)-4-(4-sulfonatophenylazo)-H-pyrazole-3-carboxylate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components.<br>Tartrazine is described as the sodium salt. The calcium and the potassium salt are also permitted. |
| Colour Index No | 19140 |
| Einecs | 217-699-5 |
| Chemical name | Trisodium-5-hydroxy-1-(4-sulfonatophenyl)-4-(4-sulfonatophenylazo)-H-pyrazole-3-carboxylate |
| Chemical formula | $C_{16}H_9N_4Na_3O_9S_2$ |
| Molecular weight | 534,37 |
| Assay | Content not less than 85 % total colouring matters calculated as the sodium salt<br>$E^{1\%}_{1cm}$ 530 at ca. 426 nm in aqueous solution |
| **Description** | Light orange powder or granules |
| Appearance of the aqueous solution | Yellow |
| **Identification** | |
| Spectrometry | Maximum in water at ca. 426 nm |
| **Purity** | |
| Water insoluble matter | Not more than 0,2 % |
| Subsidiary colouring matters | Not more than 1,0 % |
| Organic compounds other than colouring matters: | |
| 4-hydrazinobenzene sulfonic acid | Total not more than 0,5 % |
| 4-aminobenzene-1-sulfonic acid | |
| 5-oxo-1-(4-sulfophenyl)-2-pyrazoline-3-carboxylic acid | |
| 4,4′-diazoaminodi(benzene sulfonic acid) | |
| Tetrahydroxysuccinic acid | |

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|---|---|
| Unsulfonated primary aromatic amines | Not more than 0,01 % (calculated as aniline) |
| Ether extractable matter | Not more than 0,2 % under neutral conditions |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

***Aluminium lakes of this colour may be used.***

**E 104 QUINOLINE YELLOW**

| | |
|---|---|
| **Synonyms** | CI Food Yellow 13 |
| **Definition** | Quinoline Yellow is prepared by sulfonating 2-(2-quinolyl) indan-1,3-dione or a mixture containing about two thirds 2-(2-quinolyl)indane-1,3-dione and one third 2-(2-(6-methylquinolyl))indane-1,3-dione. Quinoline Yellow consists essentially of sodium salts of a mixture of disulfonates (principally), monosulfonates and trisulfonates of the above compound and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components.<br>Quinoline Yellow is described as the sodium salt. The calcium and the potassium salt are also permitted. |
| Colour Index No | 47005 |
| Einecs | 305-897-5 |
| Chemical name | The disodium salts of the disulfonates of 2-(2-quinolyl) indan-1,3-dione (principal component) |
| Chemical formula | $C_{18}H_9N\ Na_2O_8S_2$ (principal component) |
| Molecular weight | 477,38 (principal component) |
| Assay | Content not less than 70 % total colouring matters calculated as the sodium salt<br>Quinoline Yellow shall have the following composition:<br>Of the total colouring matters present:<br>— not less than 80 % shall be disodium 2-(2-quinolyl) indan-1,3-dione-disulfonates<br>— not more than 15 % shall be sodium 2-(2-quinolyl) indan-1,3-dione-monosulfonates<br>— not more than 7,0 % shall be trisodium 2-(2-quinolyl) indan-1,3-dione-trisulfonate<br>$E^{1\%}_{1cm}$ 865 (principal component) at ca. 411 nm in aqueous acetic acid solution |
| **Description** | Yellow powder or granules |
| Appearance of the aqueous solution | Yellow |
| **Identification** | |
| Spectrometry | Maximum in aqueous acetic acid solution of pH 5 at ca. 411 nm |

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| **Purity** | |
| Water insoluble matter | Not more than 0,2 % |
| Subsidiary colouring matters | Not more than 4,0 % |
| Organic compounds other than colouring matters: | |
| 2-methylquinoline | Total not more than 0,5 % |
| 2-methylquinoline-sulfonic acid | |
| Phthalic acid | |
| 2,6-dimethyl quinoline | |
| 2,6-dimethyl quinoline sulfonic acid | |
| 2-(2-quinolyl)indan-1,3-dione | Not more than 4 mg/kg |
| Unsulfonated primary aromatic amines | Not more than 0,01 % (calculated as aniline) |
| Ether extractable matter | Not more than 0,2 % under neutral conditions |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

***Aluminium lakes of this colour may be used.***

**E 110 SUNSET YELLOW FCF**

| | |
|---|---|
| **Synonyms** | CI Food Yellow 3; Orange Yellow S |
| **Definition** | Sunset Yellow FCF consists essentially of disodium 2-hydroxy-1-(4-sulfonatophenylazo) naphthalene-6-sulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Sunset Yellow FCF is manufactured by diazotizing 4-aminobenzenesulphonic acid using hydrochloric acid and sodium nitrite or sulphuric acid and sodium nitrite. The diazo compound is coupled with 6-hydroxy-2-naphthalene-sulphonic acid. The dye is isolated as the sodium salt and dried.<br>Sunset Yellow FCF is described as the sodium salt. The calcium and the potassium salt are also permitted. |
| Colour Index No | 15985 |
| Einecs | 220-491-7 |
| Chemical name | Disodium 2-hydroxy-1-(4-sulfonatophenylazo)naphthalene-6-sulfonate |
| Chemical formula | $C_{16}H_{10}N_2Na_2O_7S_2$ |
| Molecular weight | 452,37 |
| Assay | Content not less than 85 % total colouring matters calculated as the sodium salt<br>$E^{1\%}_{1cm}$ 555 at ca. 485 nm in aqueous solution at pH 7 |

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|---|---|
| **Description** | Orange-red powder or granules |
| Appearance of the aqueous solution | Orange |
| **Identification** | |
| Spectrometry | Maximum in water at ca. 485 nm at pH 7 |
| **Purity** | |
| Water insoluble matter | Not more than 0,2 % |
| Subsidiary colouring matters | Not more than 5,0 % |
| 1-(Phenylazo)-2-naphthalenol (Sudan I) | Not more than 0,5 mg/kg |
| Organic compounds other than colouring matters: | |
| 4-aminobenzene-1-sulfonic acid | Total not more than 0,5 % |
| 3-hydroxynaphthalene-2,7-disulfonic acid | |
| 6-hydroxynaphthalene-2-sulfonic acid | |
| 7-hydroxynaphthalene-1,3-disulfonic acid | |
| 4,4′-diazoaminodi(benzene sulfonic acid) | |
| 6,6′-oxydi(naphthalene-2-sulfonic acid) | |
| Unsulfonated primary aromatic amines | Not more than 0,01 % (calculated as aniline) |
| Ether extractable matter | Not more than 0,2 % under neutral conditions |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

***Aluminium lakes of this colour may be used.***

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**E 120 CARMINIC ACID, CARMINE**

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|---|---|
| **Synonyms** | CI Natural Red 4 |
| **Definition** | Carminic acid is obtained from aqueous, aqueous alcoholic or alcoholic extracts from Cochineal, which consists of the dried bodies of the female insect Dactylopius coccus Costa.<br>Carmines are aluminium lakes of carminic acid in which aluminium and carminic acid are thought to be present in the molar ratio 1:2.<br>The colouring principle is carminic acid. Minor amounts of its aminated form 4-aminocarminic acid may also be present.<br>In commercial products the colouring principle carminic acid may be present in association with ammonium, calcium, potassium or sodium cations, singly or in combination, and these cations may also be present in excess. Commercial products may also contain proteinaceous material derived from the source insect. |
| Colour Index No | 75470 |
| Einecs | Carminic acid: 215-023-3; carmines: 215-724-4 |
| Chemical name | 7-β-D-glucopyranosyl-3,5,6,8-tetrahydroxy-1-methyl-9,10-dioxoanthracene-2-carboxylic acid (carminic acid); carmine is the hydrated aluminium chelate of this acid |
| Chemical formula | $C_{22}H_{20}O_{13}$ (carminic acid) |
| Molecular weight | 492,39 (carminic acid) |

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| Assay | Content not less than 90 % carminic acid; not less than 50 % carminic acid in the chelates. | |
| **Description** | Red to dark red, friable, solid or powder | |
| **Identification** | | |
| Spectrometry | Carminic acid: | |
| | Maximum in aqueous ammonia solution at ca. 518 nm | |
| | Maximum in dilute hydrochloric solution at ca. 494 nm | |
| | E 1 %/1 cm 139 at peak around 494 nm in dilute hydrochloric acid | |
| | 4-aminocarminic acid: | |
| | Maximum in aqueous ammonia solution at 535 nm | |
| | Maximum in dilute hydrochloric solution at 530 nm | |
| | E 1 %/1 cm 260 at peak around 535 nm in aqueous ammonia solution, pH 9,5 | |
| | In commercial products carminic acid may be differentiated from its amine by HPLC | |
| **Purity** | | |
| Solvent residues | Ethanol: | Not more than 150 mg/kg |
| | Methanol: | Not more than 50 mg/kg |
| Total ash | Carminic acid: | Not more than 5 % |
| | Carmine: | Not more than 12 % |
| Protein (N × 6,25) | Carminic acid: | Not more than 2,2 % |
| | Carmine: | Not more than 25 % |
| 4-aminocarminic acid | Not more than 3 % relative to carminic acid | |
| Matter insoluble in dilute ammonia | Carmine: Not more than 1 % | |
| Arsenic | Not more than 1 mg/kg | |
| Lead | Not more than 1,5 mg/kg | |
| Mercury | Not more than 0,5 mg/kg | |
| Cadmium | Not more than 0,1 mg/kg | |
| **Microbiological criteria** | | |
| *Salmonella* spp. | Absent in 10 g | |

***Aluminium lakes of this colour may be used***.

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**E 122 AZORUBINE, CARMOISINE**

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|---|---|
| **Synonyms** | CI Food Red 3 |
| **Definition** | Azorubine consists essentially of disodium 4-hydroxy-3-(4-sulfonato-1-naphthylazo) naphthalene-1-sulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. |
| | Azorubine is described as the sodium salt. The calcium and the potassium salt are also permitted. |
| Colour Index No | 14720 |
| Einecs | 222-657-4 |
| Chemical name | Disodium 4-hydroxy-3-(4-sulfonato-1-naphthylazo) naphthalene-1-sulfonate |
| Chemical formula | $C_{20}H_{12}N_2Na_2O_7S_2$ |
| Molecular weight | 502,44 |
| Assay | Content not less than 85 % total colouring matters, calculated as the sodium salt |
| | $E^{1\%}_{1cm}$ 510 at ca. 516 nm in aqueous solution |

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|---|---|
| **Description** | Red to maroon powder or granules |
| Appearance of the aqueous solution | Red |
| **Identification** | |
| Spectrometry | Maximum in water at ca. 516 nm |
| **Purity** | |
| Water insoluble matter | Not more than 0,2 % |
| Subsidiary colouring matters | Not more than 1 % |
| Organic compounds other than colouring matters: | |
| 4-aminonaphthalene-1-sulfonic acid<br>4-hydroxynaphthalene-1-sulfonic acid | Total not more than 0,5 % |
| Unsulfonated primary aromatic amines | Not more than 0,01 % (calculated as aniline) |
| Ether extractable matter | Not more than 0,2 % under neutral conditions |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

***Aluminium lakes of this colour may be used.***

**E 123 AMARANTH**

| | |
|---|---|
| **Synonyms** | CI Food Red 9 |
| **Definition** | Amaranth consists essentially of trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-3,6-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Amaranth is manufactured by coupling 4-amino-1-naphthalenesulphonic acid with 3-hydroxy-2,7-naphthalenedisulphonic acid.<br>Amaranth is described as the sodium salt. The calcium and the potassium salt are also permitted. |
| Colour Index No | 16185 |
| Einecs | 213-022-2 |
| Chemical name | Trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-3,6-disulfonate |
| Chemical formula | $C_{20}H_{11}N_2Na_3O_{10}S_3$ |
| Molecular weight | 604,48 |
| Assay | Content not less than 85 % total colouring matters, calculated as the sodium salt<br>$E^{1\%}_{1cm}$ 440 at ca. 520 nm in aqueous solution |

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|---|---|
| **Description** | Reddish-brown powder or granules |
| Appearance of the aqueous solution | Red |
| **Identification** | |
| Spectrometry | Maximum in water at ca. 520 nm |
| **Purity** | |
| Water insoluble matter | Not more than 0,2 % |
| Subsidiary colouring matters | Not more than 3,0 % |
| Organic compounds other than colouring matters: | |
| 4-aminonaphthalene-1-sulfonic acid | Total not more than 0,5 % |
| 3-hydroxynaphthalene-2,7-disulfonic acid | |
| 6-hydroxynaphthalene-2-sulfonic acid | |
| 7-hydroxynaphthalene-1,3-disulfonic acid | |
| 7-hydroxynaphthalene-1,3-6-trisulfonic acid | |
| Unsulfonated primary aromatic amines | Not more than 0,01 % (calculated as aniline) |
| Ether extractable matter | Not more than 0,2 % under neutral conditions |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

***Aluminium lakes of this colour may be used.***

**E 124 PONCEAU 4R, COCHINEAL RED A**

| | |
|---|---|
| **Synonyms** | CI Food Red 7; New Coccine |
| **Definition** | Ponceau 4R consists essentially of trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-6,8-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Ponceau 4R is manufactured by coupling diazotized naphthionic acid to G acid (2-naphthol-6,8- disulphonic acid) and converting the coupling product to the trisodium salt.<br>Ponceau 4R is described as the sodium salt. The calcium and the potassium salt are also permitted. |
| Colour Index No | 16255 |
| Einecs | 220-036-2 |
| Chemical name | Trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-6,8-disulfonate |
| Chemical formula | $C_{20}H_{11}N_2Na_3O_{10}S_3$ |
| Molecular weight | 604,48 |

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|---|---|
| Assay | Content not less than 80 % total colouring matters, calculated as the sodium salt.<br>$E^{1\%}_{1cm}$ 430 at ca. 505 nm in aqueous solution |
| **Description** | Reddish powder or granules |
| Appearance of the aqueous solution | Red |
| **Identification** | |
| Spectrometry | Maximum in water at ca. 505 nm |
| **Purity** | |
| Water insoluble matter | Not more than 0,2 % |
| Subsidiary colouring matters | Not more than 1,0 % |
| Organic compounds other than colouring matters: | |
| 4-aminonaphthalene-1-sulfonic acid | Total not more than 0,5 % |
| 7-hydroxynaphthalene-1,3-disulfonic acid | |
| 3-hydroxynaphthalene-2,7-disulfonic acid | |
| 6-hydroxynaphthalene-2-sulfonic acid | |
| 7-hydroxynaphthalene-1,3-6-trisulfonic acid | |
| Unsulfonated primary aromatic amines | Not more than 0,01 % (calculated as aniline) |
| Ether extractable matter | Not more than 0,2 % under neutral conditions |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

***Aluminium lakes of this colour may be used.***

**E 127 ERYTHROSINE**

| | |
|---|---|
| **Synonyms** | CI Food Red 14 |
| **Definition** | Erythrosine consists essentially of disodium 2-(2,4,5,7-tetraiodo-3-oxido-6-oxoxanthen-9-yl) benzoate monohydrate and subsidiary colouring matters together with water, sodium chloride and/or sodium sulphate as the principal uncoloured components. Erythrosine is manufactured by iodination of fluorescein, the condensation product of resorcinol and phthalic anhydride<br>Erythrosine is described as the sodium salt. The calcium and the potassium salt are also permitted. |
| Colour Index No | 45430 |
| Einecs | 240-474-8 |
| Chemical name | Disodium 2-(2,4,5,7-tetraiodo-3-oxido-6-oxoxanthen-9-yl)benzoate monohydrate |
| Chemical formula | $C_{20}H_6I_4Na_2O_5\ H_2O$ |

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|---|---|
| Molecular weight | 897,88 |
| Assay | Content not less than 87 % total colouring matters, calculated as the anhydrous sodium salt<br>$E^{1\%}_{1cm}$ 1 100 at ca. 526 nm in aqueous solution at pH 7 |
| **Description** | Red powder or granules. |
| Appearance of the aqueous solution | Red |
| **Identification** | |
| Spectrometry | Maximum in water at ca. 526 nm at pH 7 |
| **Purity** | |
| Inorganic iodides | Not more than 0,1 % (calculated as sodium iodide) |
| Water insoluble matter | Not more than 0,2 % |
| Subsidiary colouring matters (except fluorescein) | Not more than 4,0 % |
| Fluorescein | Not more than 20 mg/kg |
| Organic compounds other than colouring matters: | |
| Tri-iodoresorcinol | Not more than 0,2 % |
| 2-(2,4-dihydroxy-3,5-diiodobenzoyl) benzoic acid | Not more than 0,2 % |
| Ether extractable matter | From a solution of pH from 7 through 8, not more than 0,2 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

***Aluminium Lakes of this colour may be used.***

**E 129 ALLURA RED AC**

| | |
|---|---|
| **Synonyms** | CI Food Red 17 |
| **Definition** | Allura Red AC consists essentially of disodium 2-hydroxy-1-(2-methoxy-5-methyl-4-sulfonato-phenylazo) naphthalene-6-sulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Allura Red AC is manufactured by coupling diazotized 5-amino-4-methoxy-2-toluenesulphonic acid with 6-hydroxy-2-naphthalene sulphonic acid<br>Allura Red AC is described as the sodium salt. The calcium and the potassium salt are also permitted. |
| Colour Index No | 16035 |
| Einecs | 247-368-0 |
| Chemical name | Disodium 2-hydroxy-1-(2-methoxy-5-methyl-4-sulfonatophenylazo) naphthalene-6-sulfonate |
| Chemical formula | $C_{18}H_{14}N_2Na_2O_8S_2$ |
| Molecular weight | 496,42 |

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|---|---|
| Assay | Content not less than 85 % total colouring matters, calculated as the sodium salt<br>$E^{1\%}_{1cm}$ 540 at ca. 504 nm in aqueous solution at pH 7 |
| **Description** | Dark red powder or granules |
| Appearance of the aqueous solution | Red |
| **Identification** | |
| Spectrometry | Maximum in water at ca. 504 nm |
| **Purity** | |
| Water insoluble matter | Not more than 0,2 % |
| Subsidiary colouring matters | Not more than 3,0 % |
| Organic compounds other than colouring matters: | |
| 6-hydroxy-2-naphthalene sulfonic acid, sodium salt | Not more than 0,3 % |
| 4-amino-5-methoxy-2-methyl-benezene sulfonic acid | Not more than 0,2 % |
| 6,6-oxybis (2-naphthalene sulfonic acid) disodium salt | Not more than 1,0 % |
| Unsulfonated primary aromatic amines | Not more than 0,01 % (calculated as aniline) |
| Ether extractable matter | From a solution of pH 7, not more than 0,2 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

***Aluminium lakes of this colour may be used.***

**E 131 PATENT BLUE V**

| | |
|---|---|
| **Synonyms** | CI Food Blue 5 |
| **Definition** | Patent Blue V consists essentially of the calcium or sodium compound of [4-(α-(4-diethylaminophenyl)-5-hydroxy-2,4-disulfophenyl-methylidene)-2,5-cyclohexadien-1-ylidene] diethylammonium hydroxide inner salt and subsidiary colouring matters together with sodium chloride and/or sodium sulphate and/or calcium sulphate as the principal uncoloured components.<br>The potassium salt is also permitted. |
| Colour Index No | 42051 |
| Einecs | 222-573-8 |
| Chemical name | The calcium or sodium compound of [4-(α-(4-diethylaminophenyl)-5-hydroxy-2,4-disulfophenyl-methylidene) 2,5-cyclohexadien-1-ylidene] diethyl-ammonium hydroxide inner salt |

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| Chemical formula | Calcium compound: $C_{27}H_{31}N_2O_7S_2Ca_{1/2}$<br>Sodium compound: $C_{27}H_{31}N_2O_7S_2Na$ |
| Molecular weight | Calcium compound: 579,72<br>Sodium compound: 582,67 |
| Assay | Content not less than 85 % total colouring matters, calculated as the sodium salt<br>$E^{1\%}_{1cm}$ 2 000 at ca. 638 nm in aqueous solution at pH 5 |
| **Description** | Dark blue powder or granules |
| Appearance of the aqueous solution | Blue |
| **Identification** | |
| Spectrometry | Maximum in water at 638 nm at pH 5 |
| **Purity** | |
| Water insoluble matter | Not more than 0,2 % |
| Subsidiary colouring matters | Not more than 2,0 % |
| Organic compounds other than colouring matters: | |
| 3-hydroxy benzaldehyde<br>3-hydroxy benzoic acid<br>3-hydroxy-4-sulfobenzoic acid<br>N,N-diethylamino benzene sulfonic acid | Total not more than 0,5 % |
| Leuco base | Not more than 4,0 % |
| Unsulfonated primary aromatic amines | Not more than 0,01 % (calculated as aniline) |
| Ether extractable matter | From a solution of pH 5 not more than 0,2 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

***Aluminium lakes of this colour may be used.***

**E 132 INDIGOTINE, INDIGO CARMINE**

| | |
|---|---|
| **Synonyms** | CI Food Blue 1 |
| **Definition** | Indigotine consists essentially of a mixture of disodium 3,3′dioxo-2,2′-bi-indolylidene-5,5′-disulfonate, and disodium 3,3′-dioxo-2,2′-bi-indolylidene-5,7′-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components.<br>Indigotine is described as the sodium salt. The calcium and the potassium salt are also permitted.<br>Indigo carmine is obtained by sulphonation of indigo. This is accomplished by heating indigo (or indigo paste) in the presence of sulphuric acid. The dye is isolated and subjected to purification procedures. |

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| Colour Index No | 73015 |
| Einecs | 212-728-8 |
| Chemical name | Disodium 3,3′-dioxo-2,2′-bi-indolylidene-5,5′-disulfonate |
| Chemical formula | $C_{16}H_8N_2Na_2O_8S_2$ |
| Molecular weight | 466,36 |
| Assay | Content not less than 85 % total colouring matters, calculated as the sodium salt;<br>disodium 3,3′-dioxo-2,2′-bi-indolylidene-5,7′-disulfonate: not more than 18 %<br>$E^{1\%}_{1cm}$ 480 at ca. 610 nm in aqueous solution |
| **Description** | Dark-blue powder or granules |
| Appearance of the aqueous solution | Blue |
| **Identification** | |
| Spectrometry | Maximum in water at ca. 610 nm |
| **Purity** | |
| Water insoluble matter | Not more than 0,2 % |
| Subsidiary colouring matters | Excluding disodium 3,3′-dioxo-2,2′-bi-indolylidene-5,7′-disulfonate: not more than 1,0 % |
| Organic compounds other than colouring matters: | |
| Isatin-5-sulfonic acid<br>5-sulfoanthranilic acid<br>Anthranilic acid | Total not more than 0,5 % |
| Unsulfonated primary aromatic amines | Not more than 0,01 % (calculated as aniline) |
| Ether extractable matter | Not more than 0,2 % under neutral conditions |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

***Aluminium lakes of this colour may be used.***

**E 133 BRILLIANT BLUE FCF**

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|---|---|
| **Synonyms** | CI Food Blue 2 |
| **Definition** | Brilliant Blue FCF consists essentially of disodium α-(4-(N-ethyl-3-sulfonatobenzylamino) phenyl)-α-(4-N-ethyl-3-sulfonatobenzylamino) cyclohexa-2,5-dienylidene) toluene-2-sulfonate and its isomers and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components.<br>Brilliant Blue FCF is described as the sodium salt. The calcium and the potassium salt are also permitted. |
| Colour Index No | 42090 |
| Einecs | 223-339-8 |

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|---|---|
| Chemical name | Disodium α-(4-(N-ethyl-3-sulfonatobenzylamino) phenyl)-α-(4-N-ethyl-3-sulfonatobenzylamino) cyclohexa-2,5-dienylidene) toluene-2-sulfonate |
| Chemical formula | $C_{37}H_{34}N_2Na_2O_9S_3$ |
| Molecular weight | 792,84 |
| Assay | Content not less than 85 % total colouring matters, calculated as the sodium salt<br>$E^{1\%}_{1cm}$ 1 630 at ca. 630 nm in aqueous solution |
| **Description** | Reddish-blue powder or granules |
| Appearance of the aqueous solution | Blue |
| **Identification** | |
| Spectrometry | Maximum in water at ca. 630 nm |
| **Purity** | |
| Water insoluble matter | Not more than 0,2 % |
| Subsidiary colouring matters | Not more than 6,0 % |
| Organic compounds other than colouring matters: | |
| Sum of 2-, 3- and 4-formyl benzene sulfonic acids | Not more than 1,5 % |
| 3-((ethyl)(4-sulfophenyl) amino) methyl benzene sulfonic acid | Not more than 0,3 % |
| Leuco base | Not more than 5,0 % |
| Unsulfonated primary aromatic amines | Not more than 0,01 % (calculated as aniline) |
| Ether extractable matter | Not more than 0,2 % at pH 7 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

***Aluminium lakes of this colour may be used.***

**E 140 (i) CHLOROPHYLLS**

| | |
|---|---|
| **Synonyms** | CI Natural Green 3; Magnesium Chlorophyll; Magnesium Phaeophytin |
| **Definition** | Chlorophylls are obtained by solvent extraction of strains of edible plant material, grass, lucerne and nettle. During the subsequent removal of solvent, the naturally present coordinated magnesium may be wholly or partly removed from the chlorophylls to give the corresponding phaeophytins. The principal colouring matters are the phaeophytins and magnesium chlorophylls. The extracted product, from which the solvent has been removed, contains other pigments such as carotenoids as well as oils, fats and waxes derived from the source material. Only the following solvents may be used for the extraction: acetone, methyl ethyl ketone, dichloromethane, carbon dioxide, methanol, ethanol, propan-2-ol and hexane. |

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|---|---|---|
| | Colour Index No | 75810 |
| | Einecs | Chlorophylls: 215-800-7, chlorophyll a: 207-536-6, Chlorophyll b: 208-272-4 |
| | Chemical name | The major colouring principles are:<br>Phytyl ($13^2$R,17S,18S)-3-(8-ethyl-$13^2$-methoxycarbonyl-2,7,12,18-tetramethyl-13′-oxo-3-vinyl-$13^1$-$13^2$-17,18-tetrahydrocyclopenta[at]-porphyrin-17-yl)propionate, (Phaeophytin a), or as the magnesium complex (Chlorophyll a)<br>Phytyl ($13^2$R,17S,18S)-3-(8-ethyl-7-formyl-$13^2$-methoxycarbonyl-2,12,18-trimethyl-13′-oxo-3-vinyl-$13^1$-$13^2$-17,18-tetrahydro-cyclopenta[at]-porphyrin-17-yl)propionate, (Pheophytin b), or as the magnesium complex (Chlorophyll b) |
| | Chemical formula | Chlorophyll a (magnesium complex): $C_{55}H_{72}MgN_4O_5$<br>Chlorophyll a: $C_{55}H_{74}N_4O_5$<br>Chlorophyll b (magnesium complex): $C_{55}H_{70}MgN_4O_6$<br>Chlorophyll b: $C_{55}H_{72}N_4O_6$ |
| | Molecular weight | Chlorophyll a (magnesium complex): 893,51<br>Chlorophyll a: 871,22<br>Chlorophyll b (magnesium complex): 907,49<br>Chlorophyll b: 885,20 |
| | Assay | Content of total combined Chlorophylls and their magnesium complexes is not less than 10 %<br>$E^{1\%}_{1cm}$ 700 at ca. 409 nm in chloroform |
| **Description** | | Waxy solid ranging in colour from olive green to dark green depending on the content of coordinated magnesium |
| **Identification** | | |
| | Spectrometry | Maximum in chloroform at ca. 409 nm |
| **Purity** | | |
| | Solvent residues | Acetone; Methyl Ethyl ketone; Methanol; Ethanol; Propan-2-ol; Hexane: Not more than 50 mg/kg, singly or in combination<br>Dichloromethane: 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 |
| | Cadmium | Not more than 1 mg/kg |

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**E 140 (ii) CHLOROPHYLLINS**

| | |
|---|---|
| **Synonyms** | CI Natural Green 5; Sodium Chlorophyllin; Potassium Chlorophyllin |
| **Definition** | The alkali salts of chlorophyllins are obtained by the saponification of a solvent extract of strains of edible plant material, grass, lucerne and nettle. The saponification removes the methyl and phytol ester groups and may partially cleave the cyclopentenyl ring. The acid groups are neutralised to form the salts of potassium and/or sodium.<br>Only the following solvents may be used for the extraction: acetone, methyl ethyl ketone, dichloromethane, carbon dioxide, methanol, ethanol, propan-2-ol and hexane. |
| Colour Index No | 75815 |
| Einecs | 287-483-3 |
| Chemical name | The major colouring principles in their acid forms are:<br>— 3-(10-carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-oxo-2-vinylphorbin-7-yl)propionate (chlorophyllin a)<br>and<br>— 3-(10-carboxylato-4-ethyl-3-formyl-1,5,8-trimethyl-9-oxo-2-vinylphorbin-7-yl)propionate (chlorophyllin b)<br>Depending on the degree of hydrolysis the cyclopentenyl ring may be cleaved with the resultant production of a third carboxyl function.<br>Magnesium complexes may also be present. |
| Chemical formula | Chlorophyllin a (acid form): $C_{34}H_{34}N_4O_5$<br>Chlorophyllin b (acid form): $C_{34}H_{32}N_4O_6$ |
| Molecular weight | Chlorophyllin a: 578,68<br>Chlorophyllin b: 592,66<br>Each may be increased by 18 daltons if the cyclopentenyl ring is cleaved. |
| Assay | Content of total chlorophyllins is not less than 95 % of the sample dried at ca. 100 °C for 1 hour.<br>$E^{1\%}_{1cm}$ 700 at ca. 405 nm in aqueous solution at pH 9<br>$E^{1\%}_{1cm}$ 140 at ca. 653 nm in aqueous solution at pH 9 |
| **Description** | Dark green to blue/black powder |
| **Identification** | |
| Spectrometry | Maximum in aqueous phosphate buffer at pH 9 at ca. 405 nm and at ca. 653 nm |
| **Purity** | |
| Solvent residues | Acetone, Methyl ethyl ketone, Methanol, Ethanol, Propan-2-ol, Hexane: Not more than 50 mg/kg, singly or in combination<br>Dichloromethane: not more than 10 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 10 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

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**E 141 (i) COPPER COMPLEXES OF CHLOROPHYLLS**

| | |
|---|---|
| **Synonyms** | CI Natural Green 3; Copper Chlorophyll; Copper Phaeophytin |
| **Definition** | Copper chlorophylls are obtained by addition of a salt of copper to the substance obtained by solvent extraction of strains of edible plant material, grass, lucerne, and nettle. The product, from which the solvent has been removed, contains other pigments such as carotenoids as well as fats and waxes derived from the source material. The principal colouring matters are the copper phaeophytins. Only the following solvents may be used for the extraction: acetone, methyl ethyl ketone, dichloromethane, carbon dioxide, methanol, ethanol, propan-2-ol and hexane. |
| Colour Index No | 75810 |
| Einecs | Copper chlorophyll a: 239-830-5; copper chlorophyll b: 246-020-5 |
| Chemical name | [Phytyl ($13^2$R,17S,18S)-3-(8-ethyl-$13^2$-methoxycarbonyl-2,7,12,18-tetramethyl-13′-oxo-3-vinyl-$13^1$-$13^2$-17,18-tetrahydrocyclopenta[at]-porphyrin-17-yl)propionate] copper (II) (Copper Chlorophyll a)<br>[Phytyl ($13^2$R,17S,18S)-3-(8-ethyl-7-formyl-$13^2$-methoxycarbonyl-2,12,18-trimethyl-13′-oxo-3-vinyl-$13^1$-$13^2$-17,18-tetrahydro-cyclopenta[at]-porphyrin-17-yl)propionate] copper (II) (Copper chlorophyll b) |
| Chemical formula | Copper chlorophyll a: $C_{55}H_{72}Cu\ N_4O_5$<br>Copper chlorophyll b: $C_{55}H_{70}Cu\ N_4O_6$ |
| Molecular weight | Copper chlorophyll a: 932,75<br>Copper chlorophyll b: 946,73 |
| Assay | Content of total copper chlorophylls is not less than 10 %.<br>$E^{1\%}_{1cm}$ 540 at ca. 422 nm in chloroform<br>$E^{1\%}_{1cm}$ 300 at ca. 652 nm in chloroform |
| **Description** | Waxy solid ranging in colour from blue green to dark green depending on the source material |
| **Identification** | |
| Spectrometry | Maximum in chloroform at ca. 422 nm and at ca. 652 nm |
| **Purity** | |
| Solvent residues | Acetone; Methyl ethyl ketone; Methanol; Ethanol; Propan-2-ol; Hexane: Not more than 50 mg/kg, singly or in combination<br>Dichloromethane: not more than 10 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

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|---|---|
| Copper ions | Not more than 200 mg/kg |
| Total copper | Not more than 8,0 % of the total copper phaeophytins |

***Aluminium lakes of this colour may be used.***

**E 141 (ii) COPPER COMPLEXES OF CHLOROPHYLLINS**

| | |
|---|---|
| **Synonyms** | Sodium Copper Chlorophyllin; Potassium Copper Chlorophyllin; CI Natural Green 5 |
| **Definition** | The alkali salts of copper chlorophyllins are obtained by the addition of copper to the product obtained by the saponification of a solvent extraction of strains of edible plant material, grass, lucerne, and nettle; the saponification removes the methyl and phytol ester groups and may partially cleave the cyclopentenyl ring. After addition of copper to the purified chlorophyllins, the acid groups are neutralised to form the salts of potassium and/or sodium.<br>Only the following solvents may be used for the extraction: acetone, methyl ethyl ketone, dichloromethane, carbon dioxide methanol, ethanol, propan-2-ol and hexane. |
| Colour Index No | 75815 |
| Einecs | |
| Chemical name | The major colouring principles in their acid forms are 3-(10-Carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-oxo-2-vinylphorbin-7-yl)propionate, copper complex (Copper chlorophyllin a) and 3-(10-Carboxylato-4-ethyl-3-formyl-1,5,8-trimethyl-9-oxo-2-vinylphorbin-7-yl) propionate, copper complex (Copper chlorophyllin b) |
| Chemical formula | Copper chlorophyllin a (acid form): $C_{34}H_{32}Cu\ N_4O_5$<br>Copper chlorophyllin b (acid form): $C_{34}H_{30}Cu\ N_4O_6$ |
| Molecular weight | Copper chlorophyllin a: 640,20<br>Copper chlorophyllin b: 654,18<br>Each may be increased by 18 daltons if the cyclopentenyl ring is cleaved. |
| Assay | Content of total copper chlorophyllins is not less than 95 % of the sample dried at 100 °C for 1 h.<br>$E^{1\%}_{1cm}$ 565 at ca. 405 nm in aqueous phosphate buffer at pH 7,5<br>$E^{1\%}_{1cm}$ 145 at ca. 630 nm in aqueous phosphate buffer at pH 7,5 |
| **Description** | Dark green to blue/black powder |
| **Identification** | |
| Spectrometry | Maximum in aqueous phosphate buffer at pH 7,5 at ca. 405 nm and at 630 nm |
| **Purity** | |
| Solvent residues | Acetone<br>Methyl ethyl ketone<br>Methanol<br>Ethanol<br>Propan-2-ol<br>Hexane<br>— Not more than 50 mg/kg, singly or in combination |

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|---|---|
| | Dichloromethane: 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 |
| Cadmium | Not more than 1 mg/kg |
| Copper ions | Not more than 200 mg/kg |
| Total copper | Not more than 8,0 % of the total copper chlorophyllins |

***Aluminium lakes of this colour may be used.***

**E 142 GREEN S**

| | |
|---|---|
| **Synonyms** | CI Food Green 4, Brilliant Green BS |
| **Definition** | Green S consists essentially of sodium N-[4-[[4-(dimethylamino)phenyl] 2-hydroxy-3,6-disulfo-1-naphthalenyl)methylene]-2,5-cyclohexadien-1-ylidene]-N-methylmethanaminium and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured compounds.<br>Green S is described as the sodium salt. The calcium and the potassium salt are also permitted. |
| Colour Index No | 44090 |
| Einecs | 221-409-2 |
| Chemical name | Sodium N-[4-[[4-(dimethylamino)phenyl](2-hydroxy-3,6-disulfo-1-naphthalenyl)-methylene]2,5-cyclohexadien-1-ylidene]-N-methylmethanaminium; Sodium 5-[4-dimethylamino-α-(4-dimethyliminocyclohexa-2,5-dienylidene) benzyl]-6-hydroxy-7-sulfonato-naphthalene-2-sulfonate (alternative chemical name). |
| Chemical formula | $C_{27}H_{25}N_2NaO_7S_2$ |
| Molecular weight | 576,63 |
| Assay | Content not less than 80 % total colouring matters calculated as the sodium salt<br>$E^{1\%}_{1cm}$ 1 720 at ca. 632 nm in aqueous solution |
| **Description** | Dark blue or dark green powder or granules |
| Appearance of the aqueous solution | Blue or green |
| **Identification** | |
| Spectrometry | Maximum in water at ca. 632 nm |
| **Purity** | |
| Water insoluble matter | Not more than 0,2 % |
| Subsidiary colouring matters | Not more than 1,0 % |
| Organic compounds other than colouring matters: | |
| 4,4′-bis(dimethylamino)-benzhydryl alcohol | Not more than 0,1 % |
| 4,4′-bis(dimethylamino)-benzophenone | Not more than 0,1 % |
| 3-hydroxynaphthalene-2,7-disulfonic acid | Not more than 0,2 % |

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| | |
|---|---|
| Leuco base | Not more than 5,0 % |
| Unsulfonated primary aromatic amines | Not more than 0,01 % (calculated as aniline) |
| Ether extractable matter | Not more than 0,2 % under neutral conditions |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

***Aluminium lakes of this colour may be used.***

**E 150a PLAIN CARAMEL**

| | |
|---|---|
| **Synonyms** | Caustic caramel |
| **Definition** | Plain caramel is prepared by the controlled heat treatment of carbohydrates (commercially available food grade nutritive sweeteners which are the monomers glucose and fructose and/or polymers thereof, e.g. glucose syrups, sucrose, and/or invert syrups, and dextrose). To promote caramelisation, acids, alkalis and salts may be employed, with the exception of ammonium compounds and sulphites. |
| Colour Index No | |
| Einecs | 232-435-9 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | Dark brown to black liquids or solids |
| **Identification** | |
| **Purity** | |
| Colour bound by DEAE cellulose | Not more than 50 % |
| Colour bound by phosphoryl cellulose | Not more than 50 % |
| Colour intensity ([1]) | 0,01-0,12 |
| Total nitrogen | Not more than 0,1 % |
| Total sulphur | Not more than 0,2 % |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

([1]) Colour intensity is defined as the absorbance of a 0,1 % (w/v) solution of caramel colour solids in water in a 1 cm cell at 610 nm.

▼B

**E 150b CAUSTIC SULPHITE CARAMEL**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Caustic sulphite caramel is prepared by the controlled heat treatment of carbohydrates (commercially available food grade nutritive sweeteners which are the monomers glucose and fructose and/or polymers thereof, e.g. glucose syrups, sucrose, and/or invert syrups, and dextrose) with or without acids or alkalis, in the presence of sulphite compounds (sulphurous acid, potassium sulphite, potassium bisulphite, sodium sulphite and sodium bisulphite); no ammonium compounds are used. |
| Colour Index No | |
| Einecs | 232-435-9 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | Dark brown to black liquids or solids |
| **Identification** | |
| **Purity** | |
| Colour bound by DEAE cellulose | More than 50 % |
| Colour intensity ([1]) | 0,05-0,13 |
| Total nitrogen | Not more than 0,3 % ([2]) |
| Sulphur dioxide | Not more than 0,2 % ([2]) |
| Total sulphur | 0,3-3,5 % ([2]) |
| Sulphur bound by DEAE cellulose | More than 40 % |
| Absorbance ratio of colour bound by DEAE cellulose | 19-34 |
| Absorbance ratio ($A_{280/560}$) | Greater than 50 |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 150c AMMONIA CARAMEL**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Ammonia caramel is prepared by the controlled heat treatment of carbohydrates (commercially available food grade nutritive sweeteners which are the monomers glucose and fructose and/or polymers thereof, e.g. glucose syrups, sucrose, and/or invert syrups, and dextrose) with or without acids or alkalis, in the presence of ammonium compounds (ammonium hydroxide, ammonium carbonate, ammonium hydrogen carbonate and ammonium phosphate); no sulphite compounds are used. |

([1]) Colour intensity is defined as the absorbance of a 0,1 % (w/v) solution of caramel colour solids in water in a 1 cm cell at 610 nm.
([2]) Expressed on equivalent colour basis i.e. is expressed in terms of a product having a colour intensity of 0,1 absorbance units.

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| | |
|---|---|
| Colour Index No | |
| Einecs | 232-435-9 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | Dark brown to black liquids or solids |
| **Identification** | |
| **Purity** | |
| Colour bound by DEAE cellulose | Not more than 50 % |
| Colour bound by phosphoryl cellulose | More than 50 % |
| Colour intensity ([1]) | 0,08-0,36 |
| Ammoniacal nitrogen | Not more than 0,3 % ([2]) |
| 4-methylimidazole | Not more than 200 mg/kg ([2]) |
| 2-acetyl-4-tetrahydroxy-butylimidazole | Not more than 10 mg/kg ([2]) |
| Total sulphur | Not more than 0,2 % ([2]) |
| Total nitrogen | 0,7-3,3 % ([2]) |
| Absorbance ratio of colour bound by phosphoryl cellulose | 13-35 |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 150d SULPHITE AMMONIA CARAMEL**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Sulphite ammonia caramel is prepared by the controlled heat treatment of carbohydrates (commercially available food grade nutritive sweeteners which are the monomers glucose and fructose and/or polymers thereof (e.g. glucose syrups, sucrose, and/or invert syrups, and dextrose) with or without acids or alkalis in the presence of both sulphite and ammonium compounds (sulphurous acid, potassium sulphite, potassium bisulphite, sodium sulphite, sodium bisulphite, ammonium hydroxide, ammonium carbonate, ammonium hydrogen carbonate, ammonium phosphate, ammonium sulphate, ammonium sulphite and ammonium hydrogen sulphite). |
| Colour Index No | |
| Einecs | 232-435-9 |
| Chemical name | |
| Chemical formula | |

([1]) Colour intensity is defined as the absorbance of a 0,1 % (w/v) solution of caramel colour solids in water in a 1 cm cell at 610 nm.
([2]) Expressed on equivalent colour basis i.e. is expressed in terms of a product having a colour intensity of 0,1 absorbance units.

▼B

| | |
|---|---|
| Molecular weight | |
| Assay | |
| **Description** | Dark brown to black liquids or solids |
| **Identification** | |
| **Purity** | |
| Colour bound by DEAE cellulose | More than 50 % |
| Colour intensity ([1]) | 0,10-0,60 |
| Ammoniacal nitrogen | Not more than 0,6 % ([2]) |
| Sulphur dioxide | Not more than 0,2 % ([2]) |
| 4-methylimidazole | Not more than 250 mg/kg ([2]) |
| Total nitrogen | 0,3-1,7 % ([2]) |
| Total sulphur | 0,8-2,5 % ([2]) |
| Nitrogen/sulphur ratio of alcohol precipitate | 0,7-2,7 |
| Absorbance ratio of alcohol precipitate ([3]) | 8-14 |
| Absorbance ratio ($A_{280/560}$) | Not more than 50 |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

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**E 151 BRILLIANT BLACK PN**

▼B

| | |
|---|---|
| **Synonyms** | CI Food Black 1 |

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| | |
|---|---|
| **Definition** | Brilliant Black PN consists essentially of tetrasodium-4-acetamido-5-hydroxy-6-[7-sulfonato-4-(4-sulfonatophenylazo)-1-naphthylazo] naphthalene-1,7-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components.<br>Brilliant Black PN is described as the sodium salt.<br>The calcium and the potassium salt are also permitted. |

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| | |
|---|---|
| Colour Index No | 28440 |
| Einecs | 219-746-5 |
| Chemical name | Tetrasodium 4-acetamido-5-hydroxy-6-[7-sulfonato-4-(4-sulfonatophenylazo)-1-naphthylazo] naphthalene-1,7-disulfonate |
| Chemical formula | $C_{28}H_{17}N_5Na_4O_{14}S_4$ |
| Molecular weight | 867,69 |

([1]) Colour intensity is defined as the absorbance of a 0,1 % (w/v) solution of caramel colour solids in water in a 1 cm cell at 610 nm.
([2]) Expressed on equivalent colour basis i.e. is expressed in terms of a product having a colour intensity of 0,1 absorbance units.
([3]) Absorbance ratio of alcohol precipitate is defined as the absorbance of the precipitate at 280 nm divided by the absorbance at 560 nm (1 cm cell).

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| | |
|---|---|
| Assay | Content not less than 80 % total colouring matters calculated as the sodium salt<br>$E^{1\%}_{1cm}$ 530 at ca. 570 nm in solution |
| **Description** | Black powder or granules |
| Appearance of the aqueous solution | Black-bluish |
| **Identification** | |
| Spectrometry | Maximum in water at ca. 570 nm |
| **Purity** | |
| Water insoluble matter | Not more than 0,2 % |
| Subsidiary colouring matters | Not more than 4 % (expressed on the dye content) |
| Organic compounds other than colouring matters: | |
| 4-acetamido-5-hydroxynaphthalene-1,7-disulfonic acid | Total not more than 0,8 % |
| 4-amino-5-hydroxynaphthalene-1,7-disulfonic acid | |
| 8-aminonaphthalene-2-sulfonic acid- | |
| 4,4′-diazoaminodi-(benzenesulfonic acid) | |
| Unsulfonated primary aromatic amines | Not more than 0,01 % (calculated as aniline) |
| Ether extractable matter | Not more than 0,2 % under neutral conditions |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

***Aluminium lakes of this colour may be used.***

**E 153 VEGETABLE CARBON**

| | |
|---|---|
| **Synonyms** | Vegetable black |
| **Definition** | Vegetable activated carbon is produced by the carbonisation of vegetable material such as wood, cellulose residues, peat and coconut and other shells. The activated carbon thus produced is milled by a roller mill and the resulting highly activated powdered carbon is treated by a cyclone. The fine fractio40800n from the cyclone is purified by hydrochloric acid washing, neutralised and then dried. The resulting product is what is known traditionally as vegetable black. Products with a higher colouring power are produced from the fine fraction by a further cyclone treatment or by extra milling, followed by acid washing, neutralising and drying. It consists essentially of finely divided carbon. It may contain minor amounts of nitrogen, hydrogen and oxygen. Some moisture may be absorbed on the product after manufacture. |

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| | |
|---|---|
| Colour Index No | 77266 |
| Einecs | 231-153-3 |
| Chemical name | Carbon |
| Chemical formula | C |
| Atomic weight | 12,01 |
| Assay | Content not less than 95 % of carbon calculated on an anhydrous and ash-free basis |
| Loss on drying | Not more than 12 % (120 °C 4 h) |
| **Description** | Black, odourless powder |
| **Identification** | |
| Solubility | Insoluble in water and organic solvents |
| Burning | When heated to redness it burns slowly without a flame |
| **Purity** | |
| Ash (Total) | Not more than 4,0 % (ignition temperature: 625 °C) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Polycyclic aromatic hydrocarbons | Benzo(a)pyrene less than 50 µg/kg in the extract obtained by extraction of 1 g of the product with 10 g pure cyclohexane in a continuous extraction. |
| Alkali soluble matter | The filtrate obtained by boiling 2 g of the sample with 20 ml N sodium hydroxide and filtering shall be colourless |

**E 155 BROWN HT**

| | |
|---|---|
| **Synonyms** | CI Food Brown 3 |
| **Definition** | Brown HT consists essentially of disodium 4,4′-(2,4-dihydroxy-5-hydroxymethyl-1,3-phenylene bisazo) di (naphthalene-1-sulfonate) and subsidiary colouring matters together with sodium chloride and/or sulphate as the principal uncoloured components.<br>Brown HT is described as the sodium salt. The calcium and potassium salt are also permitted. |
| Colour Index No | 20285 |
| Einecs | 224-924-0 |
| Chemical name | Disodium 4,4′-(2,4-dihydroxy-5-hydroxymethyl-1,3-phenylene bisazo)di (naphthalene-1-sulfonate) |
| Chemical formula | $C_{27}H_{18}N_4Na_2O_9S_2$ |
| Molecular weight | 652,57 |
| Assay | Content not less than 70 % total colouring matters calculated as the sodium salt.<br>$E^{1\%}_{1cm}$ 403 at ca. 460 nm in aqueous solution at pH 7 |
| **Description** | Reddish-brown powder or granules |
| Appearance of the aqueous solution | Brown |

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| | |
|---|---|
| **Identification** | |
| Spectrometry | Maximum in water of pH 7 at ca. 460 nm |
| **Purity** | |
| Water insoluble matter | Not more than 0,2 % |
| Subsidiary colouring matters | Not more than 10 % (TLC method) |
| Organic compounds other than colouring matters: | |
| 4-aminonaphthalene- 1-sulfonic acid | Not more than 0,7 % |
| Unsulfonated primary aromatic amines | Not more than 0,01 % (calculated as aniline) |
| Ether extractable matter | Not more than 0,2 % in a solution of pH 7 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

***Aluminium lakes of this colour may be used.***

**E 160 a (i) BETA-CAROTENE**

| | |
|---|---|
| **Synonyms** | CI Food Orange 5 |
| **Definition** | These specifications apply predominantly to all trans isomer of beta-carotene together with minor amounts of other carotenoids. Diluted and stabilised preparations may have different trans-cis isomer ratios. |
| Colour Index No | 40800 |
| Einecs | 230-636-6 |
| Chemical name | Beta-carotene; beta, beta-carotene |
| Chemical formula | $C_{40}H_{56}$ |
| Molecular weight | 536,88 |
| Assay | Not less than 96 % total colouring matters (expressed as beta-carotene)<br>$E^{1\%}_{1cm}$ 2 500 at approximately by 440 nm to 457 nm in cyclohexane |
| **Description** | Red to brownish-red crystals or crystalline powder |
| **Identification** | |
| Spectrometry | Maximum in cyclohexane at 453 nm to 456 nm |
| **Purity** | |
| Sulphated ash | Not more than 0,1 % |
| Subsidiary colouring matters | Carotenoids other than beta-carotene: not more than 3,0 % of total colouring matters |
| Lead | Not more than 2 mg/kg |

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**E 160 a (ii) PLANT CAROTENES**

| | | |
|---|---|---|
| **Synonyms** | CI Food Orange 5 | |
| **Definition** | Plant carotenes are obtained by solvent extraction of strains of edible plants, carrots, vegetable oils, grass, alfalfa (lucerne) and nettle.<br>The main colouring principle consists of carotenoids of which beta-carotene accounts for the major part. Alpha, gamma-carotene and other pigments may be present. Besides the colour pigments, this substance may contain oils, fats and waxes naturally occurring in the source material.<br>Only the following solvents may be used in the extraction: acetone, methyl ethyl ketone, methanol, ethanol, propan-2-ol, hexane (1), dichloromethane and carbon dioxide. | |
| Colour Index No | 75130 | |
| Einecs | 230-636-6 | |
| Chemical name | | |
| Chemical formula | Beta-carotene: $C_{40}H_{56}$ | |
| Molecular weight | Beta-carotene: 536,88 | |
| Assay | Content of carotenes (calculated as beta-carotene) is not less than 5 %. For products obtained by extraction of vegetables oils: not less than 0,2 % in edible fats<br>$E^{1\%}_{1cm}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane | |
| **Description** | | |
| **Identification** | | |
| Spectrometry | Maximum in cyclohexane at 440 nm to 457 nm and 470 nm to 486 nm | |
| **Purity** | | |
| Solvent residues | Acetone<br>Methyl ethyl ketone<br>Methanol<br>Propan-2-ol<br>Hexane<br>Ethanol | Not more than 50 mg/kg, singly or in combination |
| | Dichloromethane | Not more than 10 mg/kg |
| Lead | Not more than 2 mg/kg | |

**E 160 a (iii) BETA-CAROTENE FROM *Blakeslea trispora***

| | |
|---|---|
| **Synonyms** | CI Food Orange 5 |
| **Definition** | Obtained by a fermentation process using a mixed culture of the two sexual mating types (+) and (–) of strains of the fungus *Blakeslea trispora*. The beta-carotene is extracted from the biomass with ethyl acetate or isobutyl acetate followed by propan-2-ol and crystallised. The crystallised product consists mainly of trans beta-carotene. Because of the natural process approximately 3 % of the product consists of mixed carotenoids, which is specific for the product. |

(1) Benzene not more than 0,05 % v/v.

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| | |
|---|---|
| Colour Index No | 40800 |
| Einecs | 230-636-6 |
| Chemical name | Beta-carotene; beta, beta-carotene |
| Chemical formula | $C_{40}H_{56}$ |
| Molecular weight | 536,88 |
| Assay | Not less than 96 % total colouring matters (expressed as beta-carotene)<br>$E^{1\%}_{1cm}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane |
| **Description** | Red, brownish-red or purple-violet crystals or crystalline powder (colour varies according to extraction solvent used and conditions of crystallisation) |
| **Identification** | |
| Spectrometry | Maximum in cyclohexane at 453 nm to 456 nm |
| **Purity** | |
| Solvent residues | Ethyl acetate, Ethanol: Not more than 0,8 %, singly or in combination<br>Isobutyl acetate: Not more than 1,0 %<br>Propan-2-ol: Not more than 0,1 % |
| Sulphated ash | Not more than 0,2 % |
| Subsidiary colouring matters | Carotenoids other than beta-carotene: not more than 3,0 % of total colouring matters |
| Lead | Not more than 2 mg/kg |
| **Microbiological criteria** | |
| Moulds | Not more than 100 colonies per gram |
| Yeasts | Not more than 100 colonies per gram |
| *Salmonella* spp. | Absent in 25 g |
| *Escherichia coli* | Absent in 5 g |

**E 160 a (iv) ALGAL CAROTENES**

| | |
|---|---|
| **Synonyms** | CI Food Orange 5 |

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|---|---|
| **Definition** | Mixed carotenes may also be produced from strains of the algae *Dunaliella salina*. Beta-carotene is extracted using an essential oil. The preparation is a 20 to 30 % suspension in edible oil. The ratio of trans-cis isomers is in the range of 50/50 to 71/29.<br>The main colouring principle consists of carotenoids of which beta-carotene accounts for the major part. Alpha-carotene, lutein, zeaxanthin and beta-cryptoxanthin may be present. Besides the colour pigments, this substance may contain oils, fats and waxes naturally occurring in the source material. |

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| | |
|---|---|
| Colour Index No | 75130 |
| Einecs | |
| Chemical name | |
| Chemical formula | Beta-Carotene: $C_{40}H_{56}$ |
| Molecular weight | Beta-Carotene: 536,88 |

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| | |
|---|---|
| Assay | Content of carotenes (calculated as beta-carotene) is not less than 20 %<br>$E^{1\%}_{1cm}$ 2 500 at approximately by 440 nm to 457 nm in cyclohexane |
| **Description** | |
| **Identification** | |
| Spectrometry | Maximum in cyclohexane at 440 nm to 457 nm and 474 nm to 486 nm |
| **Purity** | |
| Natural tocopherols in edible oil | Not more than 0,3 % |
| Lead | Not more than 2 mg/kg |

▼M32

**E 160 b (i) ANNATTO BIXIN**

(I) SOLVENT-EXTRACTED BIXIN

| | |
|---|---|
| **Synonyms** | Annatto B, Orlean, Terre orellana, L. Orange, CI Natural Orange 4 |
| **Definition** | Solvent-extracted bixin is obtained by the extraction of the outer coating of the seeds of the annatto tree (*Bixa orellana* L.) with one or more of the following food grade solvents: acetone, methanol, hexane, ethanol, isopropyl alcohol, ethyl acetate, alkaline alcohol or supercritical carbon dioxide. The resulting preparation may be acidified, followed by the removal of the solvent, drying and milling.<br>Solvent-extracted bixin contains several coloured components; the major colouring principle is cis-bixin, a minor colouring principle is trans-bixin; thermal degradation products of bixin may also be present as a result of processing. |
| Colour Index No | 75120 |
| Einecs | 230-248-7 |
| Chemical name | cis-Bixin: Methyl (9-cis)-hydrogen-6,6'-diapo-Ψ,Ψ-carotenedioate |
| Chemical formula | cis-Bixin: $C_{25}H_{30}O_4$ |
| Molecular weight | 394,5 |
| Assay | Not less than 85 % colouring matter (expressed as bixin)<br>$E^{1\%}_{1cm}$ 3090 at ca. 487 nm in tetrahydrofuran and acetone |
| **Description** | Dark red-brown to red-purple powder |
| **Identification** | |
| Solubility | Insoluble in water, slightly soluble in ethanol |
| Spectrometry | The sample in acetone shows absorbance maxima at about 425, 457 and 487 nm |
| **Purity** | |
| Norbixin | Not more than 5 % of total colouring matters |
| Residual Solvents | Acetone: Not more than 30 mg/kg<br>Methanol: Not more than 50 mg/kg<br>Hexane: Not more than 25 mg/kg<br>Ethanol:<br>Isopropyl alcohol: not more than 50 mg/kg, singly or in combination<br>Ethyl acetate: |
| Arsenic | Not more than 2 mg/kg |

▼M32

| | |
|---|---|
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 0,5 mg/kg |

(II) AQUEOUS-PROCESSED BIXIN

| | |
|---|---|
| **Synonyms** | Annatto E, Orlean, Terre orellana, L. Orange, CI Natural Orange 4 |
| **Definition** | Aqueous-processed bixin is prepared by the extraction of the outer coating of the seeds of the annatto tree (*Bixa orellana* L.) by abrading the seeds in the presence of cold, mildly-alkaline water. The resultant preparation is acidified to precipitate bixin which is then filtered, dried and milled.<br>Aqueous-processed bixin contains several coloured components; the major colouring principle is cis-bixin, a minor colouring principle is trans-bixin; thermal degradation products of bixin may also be present as a result of processing. |
| Colour Index No | 75120 |
| Einecs | 230-248-7 |
| Chemical name | cis-Bixin: Methyl (9-cis)-hydrogen-6,6'-diapo-Ψ,Ψ-carotenedioate |
| Chemical formula | cis-Bixin: $C_{25}H_{30}O_4$ |
| Molecular weight | 394,5 |
| Assay | Not less than 25 % colouring matter (expressed as bixin)<br>$E^{1\ \%}_{1cm}$ 3090 at ca. 487 nm in tetrahydrofuran and acetone |
| **Description** | Dark red-brown to red-purple powder |
| **Identification** | |
| Solubility | Insoluble in water, slightly soluble in ethanol |
| Spectrometry | The sample in acetone shows absorbance maxima at about 425, 457 and 487 nm |
| **Purity** | |
| Norbixin | Not more than 7 % of total colouring matters |
| Arsenic | Not more than 2 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 0,5 mg/kg |

**E 160 b (ii) ANNATTO NORBIXIN**

(I) SOLVENT-EXTRACTED NORBIXIN

| | |
|---|---|
| **Synonyms** | Annatto C, Orlean, Terre orellana, L. Orange, CI Natural Orange 4 |
| **Definition** | Solvent-extracted norbixin is obtained from the outer coating of the seeds of the annatto tree (*Bixa orellana* L.) by washing with one or more of the following food grade solvents: acetone, methanol, hexane, ethanol, isopropyl alcohol, ethyl acetate, alkaline alcohol or supercritical carbon dioxide followed by solvent removal, crystallization and drying. Aqueous alkali is added to the resultant powder, which is then heated to hydrolyse the colouring matter and cooled. The aqueous solution is filtered, and acidified to precipitate the norbixin. The precipitate is filtered, washed, dried and milled, to give a granular powder. |

▼M32

| | |
|---|---|
| | Solvent-extracted norbixin contains several coloured components; the major colouring principle is *cis*-norbixin, a minor colouring principle is *trans*-norbixin; thermal degradation products of norbixin may also be present as a result of processing. |
| Colour Index No | 75120 |
| Einecs | 208-810-8 |
| Chemical name | cis-Norbixin: 6,6'-Diapo-Ψ,Ψ-carotenedioic acid<br>cis-Norbixin dipotassium salt: Dipotassium 6,6'-diapo-Ψ,Ψ-carotenedioate<br>cis-Norbixin disodium salt: Disodium 6,6'-diapo-Ψ,Ψ-carotenedioate |
| Chemical formula | *cis*-Norbixin: $C_{24}H_{28}O_4$<br>*cis*-Norbixin dipotassium salt: $C_{24}H_{26}K_2O_4$<br>*cis*-Norbixin disodium salt: $C_{24}H_{26}Na_2O_4$ |
| Molecular weight | 380,5 (acid), 456,7 (dipotassium salt), 424,5 (disodium salt) |
| Assay | Not less than 85 % colouring matter (expressed as norbixin)<br>$E^{1\ \%}_{1cm}$ 2870 at ca. 482 nm in 0,5 % potassium hydroxide solution |
| **Description** | Dark red-brown to red-purple powder |
| **Identification** | |
| Solubility | Soluble in alkaline water, slightly soluble in ethanol |
| Spectrometry | The sample in 0,5 % potassium hydroxide solution shows absorbance maxima at about 453 nm and 482 nm |
| **Purity** | |
| Residual Solvents | Acetone: Not more than 30 mg/kg<br>Methanol: Not more than 50 mg/kg<br>Hexane: Not more than 25 mg/kg<br>Ethanol:<br>Isopropyl alcohol:<br>Ethyl acetate: not more than 50 mg/kg, singly or in combination |
| Arsenic | Not more than 2 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 0,5 mg/kg |

(II) ALKALI-PROCESSED NORBIXIN, ACID-PRECIPITATED

| | |
|---|---|
| **Synonyms** | Annatto F, Orlean, Terre orellana, L. Orange, CI Natural Orange 4 |
| **Definition** | Alkali-processed norbixin (acid-precipitated) is prepared by the extraction of the outer coating of the seeds of the annatto tree (*Bixa orellana* L.) with aqueous alkali. The bixin is hydrolysed to norbixin in hot alkaline solution and is acidified to precipitate the norbixin. The precipitate is filtered, dried and milled to give a granular powder.<br>Alkali-processed norbixin contains several coloured components; the major colouring principle is *cis*-norbixin, a minor colouring principle is *trans*-norbixin; thermal degradation products of norbixin may also be present as a result of processing. |
| Colour Index No | 75120 |

▼M32

| | |
|---|---|
| Einecs | 208-810-8 |
| Chemical name | cis-Norbixin: 6,6'-Diapo-Ψ,Ψ-carotenedioic acid<br>cis-Norbixin dipotassium salt: Dipotassium 6,6'-diapo-Ψ,Ψ-carotenedioate<br>cis-Norbixin disodium salt: Disodium 6,6'-diapo-Ψ,Ψ-carotenedioate |
| Chemical formula | *cis*-Norbixin: $C_{24}H_{28}O_4$<br>*cis*-Norbixin dipotassium salt: $C_{24}H_{26}K_2O_4$<br>*cis*-Norbixin disodium salt: $C_{24}H_{26}Na_2O_4$ |
| Molecular weight | 380,5 (acid), 456,7 (dipotassium salt), 424,5 (disodium salt) |
| Assay | Not less than 35 % colouring matter (expressed as norbixin)<br>$E^{1\ \%}_{1cm}$ 2870 at ca. 482 nm in 0,5 % potassium hydroxide solution |
| **Description** | Dark red-brown to red-purple powder |
| **Identification** | |
| Solubility | Soluble in alkaline water, slightly soluble in ethanol |
| Spectrometry | The sample in 0,5 % potassium hydroxide solution shows absorbance maxima at about 453 nm and 482 nm |
| **Purity** | |
| Arsenic | Not more than 2 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 0,5 mg/kg |

(III) ALKALI-PROCESSED NORBIXIN, NOT ACID-PRECIPITATED

| | |
|---|---|
| **Synonyms** | Annatto G, Orlean, Terre orellana, L. Orange, CI Natural Orange 4 |
| **Definition** | Alkali-processed norbixin (not acid-precipitated) is prepared by the extraction of the outer coating of the seeds of the annatto tree (*Bixa orellana* L.) with aqueous alkali. The bixin is hydrolysed to norbixin in hot alkaline solution. The precipitate is filtered, dried and milled to give a granular powder. Extracts contain mainly the potassium or sodium salt of norbixin as the major colouring matter.<br>Alkali-processed norbixin (not acid-precipitated) contains several coloured components; the major colouring principle is *cis*-norbixin, a minor colouring principle is *trans*-norbixin; thermal degradation products of norbixin may also be present as a result of processing. |
| Colour Index No | 75120 |
| Einecs | 208-810-8 |
| Chemical name | cis-Norbixin: 6,6'-Diapo-Ψ,Ψ-carotenedioic acid<br>cis-Norbixin dipotassium salt: Dipotassium 6,6'-diapo-Ψ,Ψ-carotenedioate<br>cis-Norbixin disodium salt: Disodium 6,6'-diapo-Ψ,Ψ-carotenedioate |
| Chemical formula | *cis*-Norbixin: $C_{24}H_{28}O_4$<br>*cis*-Norbixin dipotassium salt: $C_{24}H_{26}K_2O_4$<br>*cis*-Norbixin disodium salt: $C_{24}H_{26}Na_2O_4$ |

▼M32

| | |
|---|---|
| Molecular weight | 380,5 (acid), 456,7 (dipotassium salt), 424,5 (disodium salt) |
| Assay | Not less than 15 % colouring matter (expressed as norbixin)<br>$E^{1\ \%}_{1cm}$ 2870 at ca. 482 nm in 0,5 % potassium hydroxide solution |
| **Description** | Dark red-brown to red-purple powder |
| **Identification** | |
| Solubility | Soluble in alkaline water, slightly soluble in ethanol |
| Spectrometry | The sample in 0,5 % potassium hydroxide solution shows absorbance maxima at about 453 nm and 482 nm |
| **Purity** | |
| Arsenic | Not more than 2 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 0,5 mg/kg |

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**E 160 c PAPRIKA EXTRACT, CAPSANTHIN, CAPSORUBIN**

| | |
|---|---|
| **Synonyms** | Paprika Oleoresin |
| **Definition** | Paprika extract is obtained by solvent extraction of the strains of paprika, which consists of the ground fruits pods, with or without seeds, of *Capsicum annuum* L., and contains the major colouring principles of this spice. The major colouring principles are capsanthin and capsorubin. A wide variety of other coloured compounds is known to be present.<br>Only the following solvents may be used in the extraction: methanol, ethanol, acetone, hexane, dichloromethane, ethyl acetate, propan-2-ol and carbon dioxide. |
| Colour Index No | |
| Einecs | Capsanthin: 207-364-1, capsorubin: 207-425-2 |
| Chemical name | Capsanthin: (3R, 3′S, 5′R)-3,3′-dihydroxy-β,κ-carotene-6-one<br>Capsorubin: (3S, 3′S, 5R, 5R′)-3,3′-dihydroxy-κ,κ-carotene-6,6′-dione |
| Chemical formula | Capsanthin: $C_{40}H_{56}O_3$<br>Capsorubin: $C_{40}H_{56}O_4$ |
| Molecular weight | Capsanthin: 584,85<br>Capsorubin: 600,85 |
| Assay | Paprika extract: content not less than 7,0 % carotenoids<br>Capsanthin/capsorubin: not less than 30 % of total carotenoids<br>$E^{1\%}_{1cm}$ 2 100 at ca. 462 nm in acetone |

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| | | |
|---|---|---|
| **Description** | Dark-red viscous liquid | |
| **Identification** | | |
| Spectrometry | Maximum in acetone at ca. 462 nm | |
| Colour reaction | A deep blue colour is produced by adding one drop of sulphuric acid to one drop of sample in 2-3 drops of chloroform | |
| **Purity** | | |
| Solvent residues | Ethyl acetate<br>Methanol<br>Ethanol<br>Acetone<br>Hexane<br>Propan-2-ol | Not more than 50 mg/kg, singly or in combination |
| | Dichloromethane: | not more than 10 mg/kg |
| Capsaicin | Not more than 250 mg/kg | |
| Arsenic | Not more than 3 mg/kg | |
| Lead | Not more than 2 mg/kg | |
| Mercury | Not more than 1 mg/kg | |
| Cadmium | Not more than 1 mg/kg | |

**E 160 d LYCOPENE**

(i) SYNTHETIC LYCOPENE

| | |
|---|---|
| **Synonyms** | Lycopene from chemical synthesis |
| **Definition** | Synthetic lycopene is a mixture of geometric isomeres of lycopenes and is produced by the Wittig condensation of synthetic intermediates commonly used in the production of other carotenoids used in food. Synthetic lycopene consists predominantly of all-*trans*-lycopene together with 5-*cis*-lycopene and minor quantities of other isomers. Commercial lycopene preparations intended for use in food are formulated as suspensions in edible oils or water-dispersible or water-soluble powder. |
| Colour Index No | 75125 |
| Einecs | 207-949-1 |
| Chemical name | ψ,ψ-carotene, all-*trans*-lycopene, (all-E)-lycopene, (all-E)-2,6,10,14,19,23,27,31-octamethyl-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriacontatridecaene |
| Chemical formula | $C_{40}H_{56}$ |
| Molecular weight | 536,85 |
| Assay | Not less than 96 % total lycopenes (not less than 70 % all-*trans*-lycopene)<br>$E^{1\%}_{1cm}$ at 465-475 nm in hexane (for 100 % pure all-*trans*-lycopene) is 3 450 |
| **Description** | Red crystalline powder |

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| | |
|---|---|
| **Identification** | |
| Spectrophotometry | A solution in hexane shows an absorption maximum at approximately 470 nm |
| Test for carotenoids | The colour of the solution of the sample in acetone disappears after successive additions of a 5 % solution of sodium nitrite and 1N sulphuric acid |
| Solubility | Insoluble in water, freely soluble in chloroform |
| Properties of 1 % solution in chloroform | Is clear and has intensive red-orange colour |
| **Purity** | |
| Loss on drying | Not more than 0,5 % (40 °C, 4 h at 20 mm Hg) |
| Apo-12'-lycopenal | Not more than 0,15 % |
| Triphenyl phosphine oxide | Not more than 0,01 % |
| Solvent residues | Methanol not more than 200 mg/kg,<br>Hexane, Propan-2-ol: Not more than 10 mg/kg each.<br>Dichloromethane: Not more than 10 mg/kg (in commercial preparations only) |
| Lead | Not more than 1 mg/kg |

(ii) LYCOPENE FROM RED TOMATOES

| | |
|---|---|
| **Synonyms** | Natural Yellow 27 |
| **Definition** | Lycopene is obtained by solvent extraction of red tomatoes (*Lycopersicon esculentum* L.) with subsequent removal of the solvent. Only the following solvent may be used: carbon dioxide, ethyl acetate, acetone, propan-2-ol, methanol, ethanol and hexane. The major colouring principle of tomatoes is lycopene; minor amounts of other carotenoid pigments may be present. Besides the colour pigments the product may contain oil, fats, waxes and flavour components naturally occurring in tomatoes. |
| Colour Index No | 75125 |
| Einecs | 207-949-1 |
| Chemical name | Ψ,Ψ-carotene, all-*trans*-lycopene, (all-E)-lycopene, (all-E)-2,6,10,14,19,23,27,31-octamethyl-2,6,8,10,12,14,16,18,2 0,22,24,26,30-dotriacontatridecaene |
| Chemical formula | $C_{40}H_{56}$ |
| Molecular weight | 536,85 |
| Assay | $E^{1\%}_{1cm}$ at 465-475 nm in hexane (for 100 % pure all-*trans*-lycopene) is 3 450.<br>Content not less than 5 % total colouring matters |
| **Description** | Dark red viscous liquid |
| **Identification** | |
| Spectrophotometry | Maximum in hexane at ca. 472 nm |

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| | | |
|---|---|---|
| **Purity** | | |
| Solvent residues | Propan-2-ol<br>Hexane<br>Acetone<br>Ethanol<br>Methanol<br>Ethylacetate | Not more than 50 mg/kg, singly or in combination |
| Sulphated ash | Not more than 1 % | |
| Mercury | Not more than 1 mg/kg | |
| Cadmium | Not more than 1 mg/kg | |
| Arsenic | Not more than 3 mg/kg | |
| Lead | Not more than 2 mg/kg | |

(iii) LYCOPENE FROM *BLAKESLEA TRISPORA*

| | |
|---|---|
| **Synonyms** | Natural Yellow 27 |
| **Definition** | Lycopene from *Blakeslea trispora* is extracted from the fungal biomass and purified by crystallisation and filtration. It consists predominantly of all-*trans*-lycopene. It also contains minor quantities of other carotenoids. Propan-2-ol and isobutyl acetate are the only solvents used in the manufacture. Commercial lycopene preparations intended for use in food are formulated as suspensions in edible oils or water-dispersible or water-soluble powder. |
| Colour Index No | 75125 |
| Einecs | 207-949-1 |
| Chemical name | Ψ,Ψ-carotene, all-*trans*-lycopene, (all-E)-lycopene, ((all-E)-2,6,10,14,19,23,27,31-octamethyl-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriacontatridecaene |
| Chemical formula | $C_{40}H_{56}$ |
| Molecular weight | 536,85 |
| Assay | Not less than 95 % total lycopenes and not less than 90 % all-*trans*-lycopene of all colouring matters<br>$E^{1\%}_{1cm}$ at 465-475 nm in hexane (for 100 % pure all-*trans*-lycopene) is 3 450 |
| **Description** | Red crystalline powder |
| **Identification** | |
| Spectrophotometry | A solution in hexane shows an absorption maximum at approximately 470 nm |
| Test of carotenoids | The colour of the solution of the sample in acetone disappears after successive additions of a 5 % solution of sodium nitrite and 1N sulphuric acid |
| Solubility | Insoluble in water, freely soluble in chloroform |
| Properties of 1 % solution in chloroform | Is clear and has intensive red-orange colour |

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| | |
|---|---|
| **Purity** | |
| Loss on drying | Not more than 0,5 % (40 °C, 4 h at 20 mm Hg) |
| Other carotenoids | Not more than 5 % |
| Solvent residues | Propan-2-ol: not more than 0,1 %<br>Isobutyl acetate: not more than 1,0 %<br>Dichloromethane: not more than 10 mg/kg (in commercial preparations only) |
| Sulphated ash | Not more than 0,3 % |
| Lead | Not more than 1 mg/kg |

**E 160 e BETA-APO-8′-CAROTENAL (C30)**

| | |
|---|---|
| **Synonyms** | CI Food Orange 6 |
| **Definition** | These specifications apply predominantly to the all-*trans* isomer of β-apo-8′-carotenal together with minor amounts of other carotenoids. Diluted and stabilised forms are prepared from β-apo-8′-carotenal meeting these specifications and include solutions or suspensions of ß-apo-8′carotenal in edible fats or oils, emulsions and water dispersible powders. These preparations may have different cis/trans isomer ratios. |
| Colour Index No | 40820 |
| Einecs | 214-171-6 |
| Chemical name | β-Apo-8′-carotenal; *trans*-β-Apo-8′carotene-aldehyde |
| Chemical formula | $C_{30}H_{40}O$ |
| Molecular weight | 416,65 |
| Assay | Not less than 96 % of total colouring matters<br>$E^{1\%}_{1cm}$ 2 640 at 460-462 nm in cyclohexane |
| **Description** | Dark violet crystals with metallic lustre or crystalline powder |
| **Identification** | |
| Spectrometry | Maximum in cyclohexane at 460-462 nm |
| **Purity** | |
| Sulphated ash | Not more than 0,1 % |
| Subsidiary colouring matters | Carotenoids other than β-apo-8′-carotenal:<br>not more than 3,0 % of total colouring matters |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 161 b LUTEIN**

| | |
|---|---|
| **Synonyms** | Mixed Carotenoids; Xanthophylls |
| **Definition** | Lutein is obtained by solvent extraction of the strains of edible fruits and plants, grass, lucerne (alfalfa) and *Tagetes erecta*. The main colouring principle consists of carotenoids of which lutein |

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|---|---|---|
| | and its fatty acid esters account for the major part. Variable amounts of carotenes will also be present. Lutein may contain fats, oils and waxes naturally occurring in the plant material.<br>Only the following solvents may be used for the extraction: methanol, ethanol, propan-2-ol, hexane, acetone, methyl ethyl ketone and carbon dioxide | |
| Colour Index No | | |
| Einecs | 204-840-0 | |
| Chemical name | 3,3′-dihydroxy-d-carotene | |
| Chemical formula | $C_{40}H_{56}O_2$ | |
| Molecular weight | 568,88 | |
| Assay | Content of total colouring matter not less than 4 % calculated as lutein<br>$E^{1\%}_{1cm}$ 2 550 at ca. 445 nm in chloroform/ethanol (10 + 90) or in hexane/ethanol/acetone (80 + 10 + 10) | |
| **Description** | Dark, yellowish brown liquid | |
| **Identification** | | |
| Spectrometry | Maximum in chloroform/ethanol (1:9) at ca. 445 nm | |
| **Purity** | | |
| Solvent residues | Acetone<br>Methyl ethyl ketone<br>Methanol<br>Ethanol<br>Propan-2-ol<br>Hexane | Not more than 50 mg/kg, singly or in combination |
| Arsenic | Not more than 3 mg/kg | |
| Lead | Not more than 3 mg/kg | |
| Mercury | Not more than 1 mg/kg | |
| Cadmium | Not more than 1 mg/kg | |

**E 161g CANTHAXANTHIN**

| | |
|---|---|
| **Synonyms** | CI Food Orange 8 |
| **Definition** | These specifications apply to predominantly all-*trans* isomers of canthaxanthin together with minor amounts of other carotenoids. Diluted and stabilised forms are prepared from canthaxanthin meeting these specifications and include solutions or suspensions of canthaxanthin in edible fats or oils, emulsions and water dispersible powders. These preparations may have different cis/trans isomer ratios. |
| Colour Index No | 40850 |

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| | |
|---|---|
| Einecs | 208-187-2 |
| Chemical name | β-Carotene-4,4′-dione; canthaxanthin; 4,4′-dioxo-β-carotene |
| Chemical formula | $C_{40}H_{52}O_2$ |
| Molecular weight | 564,86 |
| Assay | Not less than 96 % of total colouring matters (expressed as canthaxanthin) |
| | $E^{1\%}_{1cm}$ 2 200 at ca. 485 nm in chloroform; at 468-472 nm in cyclohexane; at 464-467 nm in petroleum ether |
| **Description** | Deep violet crystals or crystalline powder |
| **Identification** | |
| Spectrometry | Maximum in chloroform at ca. 485 nm<br>Maximum in cyclohexane at 468-472 nm<br>Maximum in petroleum ether at 464-467 nm |
| **Purity** | |
| Sulphated ash | Not more than 0,1 % |
| Subsidiary colouring matters | Carotenoids other than canthaxanthin: not more than 5,0 % of total colouring matters |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 162 BEETROOT RED, BETANIN**

| | |
|---|---|
| **Synonyms** | Beet Red |
| **Definition** | Beet red is obtained from the roots of strains of red beets (*Beta vulgaris* L. var. *rubra*) by pressing crushed beet as press juice or by aqueous extraction of shredded beet roots and subsequent enrichment in the active principle. The colour is composed of different pigments all belonging to the class betalaine. The main colouring principle consists of betacyanins (red) of which betanin accounts for 75-95 %. Minor amounts of betaxanthin (yellow) and degradation products of betalaines (light brown) may be present.<br>Besides the colour pigments the juice or extract consists of sugars, salts, and/or proteins naturally occurring in red beets. The solution may be concentrated and some products may be refined in order to remove most of the sugars, salts and proteins. |
| Colour Index No | |
| Einecs | 231-628-5 |
| Chemical name | (S-(R′,R′)-4-(2-(2-Carboxy-5(β-D-glucopyranosyloxy)-2,3-dihydro-6-hydroxy-1H-indol-1-yl)ethenyl)-2,3-dihydro-2,6-pyridine-dicarboxylic acid; 1-(2-(2,6-dicarboxy-1,2,3,4-tetrahydro-4-pyridylidene)ethylidene)-5-β-D-glucopyranosyloxy)-6-hydroxyindolium-2-carboxylate |

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|---|---|
| Chemical formula | Betanin: $C_{24}H_{26}N_2O_{13}$ |
| Molecular weight | 550,48 |
| Assay | Content of red colour (expressed as betanine) is not less than 0,4 %<br>$E^{1\%}_{1cm}$ 1 120 at ca. 535 nm in aqueous solution at pH 5 |
| **Description** | Red or dark red liquid, paste, powder or solid |
| **Identification** | |
| Spectrometry | Maximum in water of pH 5 at ca. 535 nm |
| **Purity** | |
| Nitrate | Not more than 2 g nitrate anion/g of red colour (as calculated from assay). |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 163 ANTHOCYANINS**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Anthocyanins are obtained by maceration or extraction with sulphited water, acidified water, carbon dioxide, methanol or ethanol from the strains of vegetables and edible fruits, with subsequent concentration and/or purification if necessary. The resulting product can be transformed into powder by an industrial drying process. Anthocyanins contain common components of the source material, namely anthocyanine, organic acids, tannins, sugars, minerals etc., but not necessarily in the same proportions as found in the source material. Ethanol may naturally be present as a result of the maceration process. The colouring principle is anthocyanin. Products are marketed according to their colour strength as determined by the assay. Colour content is not expressed using quantitative units. |
| Colour Index No | |
| Einecs | 208-438-6 (cyanidin); 205-125-6 (peonidin); 208-437-0 (delphinidin); 211-403-8 (malvidin); 205-127-7 (pelargonidin); 215-849-4 (petunidin) |
| Chemical name | 3,3′,4′,5,7-Pentahydroxy-flavylium chloride (cyanidin)<br>3,4′,5,7-Tetrahydroxy-3′-methoxyflavylium chloride (peonidin)<br>3,4′,5,7-Tetrahydroxy-3′,5′-dimethoxyflavylium chloride (malvidin)<br>3,5,7-Trihydroxy-2-(3,4,5,trihydroxyphenyl)-1-benzopyrylium chloride (delphinidin)<br>3,3′4′,5,7-Pentahydroxy-5′-methoxyflavylium chloride (petunidin)<br>3,5,7-Trihydroxy-2-(4-hydroxyphenyl)-1-benzopyrilium chloride (pelargonidin) |

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|---|---|
| Chemical formula | Cyanidin: $C_{15}H_{11}O_6Cl$<br>Peonidin: $C_{16}H_{13}O_6Cl$<br>Malvidin: $C_{17}H_{15}O_7Cl$<br>Delphinidin: $C_{15}H_{11}O_7Cl$<br>Petunidin: $C_{16}H_{13}O_7Cl$<br>Pelargonidin: $C_{15}H_{11}O_5Cl$ |
| Molecular weight | Cyanidin: 322,6<br>Peonidin: 336,7<br>Malvidin: 366,7<br>Delphinidin: 340,6<br>Petunidin: 352,7<br>Pelargonidin: 306,7 |
| Assay | $E^{1\%}_{1cm}$ 300 for the pure pigment at 515-535 nm at pH 3,0 |
| **Description** | Purplish-red liquid, powder or paste, having a slight characteristic odour |
| **Identification** | |
| Spectrometry | Maximum in methanol with 0,01 % conc. HCl<br>Cyanidin: 535 nm<br>Peonidin: 532 nm<br>Malvidin: 542 nm<br>Delphinidin: 546 nm<br>Petunidin: 543 nm<br>Pelargonidin: 530 nm |
| **Purity** | |
| Solvent residues | Methanol: Not more than 50 mg/kg<br>Ethanol: Not more than 200 mg/kg |
| Sulfur dioxide | Not more than 1 000 mg/kg per percent pigment |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

***Aluminium lakes of this colour may be used.***

**E 170 CALCIUM CARBONATE**

| | |
|---|---|
| **Synonyms** | CI Pigment White 18; Chalk |
| **Definition** | Calcium carbonate is the product obtained from ground limestone or by the precipitation of calcium ions with carbonate ions. |
| Colour Index No | 77220 |
| Einecs | Calcium carbonate: 207-439-9<br>Limestone: 215-279-6 |
| Chemical name | Calcium carbonate |
| Chemical formula | $CaCO_3$ |

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| | |
|---|---|
| Molecular weight | 100,1 |
| Assay | Content not less than 98 % on the anhydrous basis |
| **Description** | White crystalline or amorphous, odourless and tasteless powder |
| **Identification** | |
| Solubility | Practically insoluble in water and in alcohol. Dissolves with effervescence in diluted acetic acid, in diluted hydrochloric acid and in diluted nitric acid, and the resulting solutions, after boiling, give positive tests for calcium. |
| **Purity** | |
| Loss on drying | Not more than 2,0 % (200 °C, 4 hours) |
| Acid-insoluble substances | Not more than 0,2 % |
| Magnesium and alkali salts | Not more than 1 % |
| Fluoride | Not more than 50 mg/kg |
| Antimony (as Sb) | Not more than 100 mg/kg, singly or in combination |
| Copper (as Cu) | |
| Chromium (as Cr) | |
| Zinc (as Zn) | |
| Barium (as Ba) | |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 3 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 171 TITANIUM DIOXIDE**

| | |
|---|---|
| **Synonyms** | CI Pigment White 6 |
| **Definition** | Titanium dioxide consists essentially of pure anatase and/or rutile titanium dioxide which may be coated with small amounts of alumina and/or silica to improve the technological properties of the product.<br>The anatase grades of pigmentary titanium dioxide can only be made by the sulphate process which creates a large amount of sulphuric acid as a by-product. The rutile grades of titanium dioxide are typically made by the chloride process.<br>Certain rutile grades of titanium dioxide are produced using mica (also known as potassium aluminum silicate) as a template to form the basic platelet structure. The surface of the mica is coated with titanium dioxide using a specialised patented process.<br>Rutile titanium dioxide, platelet form is manufactured by subjecting titanium dioxide (rutile) coated mica nacreous pigment to an extractive dissolution in acid followed by an extractive dissolution in alkali. All of the mica is removed during this process and the resulting product is a platelet form of rutile titanium dioxide. |
| Colour Index No | 77891 |
| Einecs | 236-675-5 |

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| | |
|---|---|
| Chemical name | Titanium dioxide |
| Chemical formula | $TiO_2$ |
| Molecular weight | 79,88 |
| Assay | Content not less than 99 % on an alumina and silica-free basis |
| **Description** | White to slightly coloured powder |
| **Identification** | |
| Solubility | Insoluble in water and organic solvents. Dissolves slowly in hydrofluoric acid and in hot concentrated sulphuric acid. |
| **Purity** | |
| Loss on drying | Not more than 0,5 % (105 °C, 3 hours) |
| Loss on ignition | Not more than 1,0 % on a volatile matter free basis (800 °C) |
| Aluminium oxide and/or silicon dioxide | Total not more than 2,0 % |
| Matter soluble in 0,5 N HCl | Not more than 0,5 % on an alumina and silica-free basis and, in addition, for products containing alumina and/or silica, not more than 1,5 % on the basis of the product as sold. |
| Water soluble matter | Not more than 0,5 % |
| Cadmium | Not more than 1 mg/kg after an extraction with 0,5 N HCl. |
| Antimony | Not more than 2 mg/kg after an extraction with 0,5 N HCl. |
| Arsenic | Not more than 1 mg/kg after an extraction with 0,5 N HCl. |
| Lead | Not more than 10 mg/kg after an extraction with 0,5 N HCl. |
| Mercury | Not more than 1 mg/kg after an extraction with 0,5 N HCl. |

**E 172 IRON OXIDES AND IRON HYDROXIDES**

| | | |
|---|---|---|
| **Synonyms** | Iron Oxide Yellow: CI Pigment Yellow 42 and 43 | |
| | Iron Oxide Red: CI Pigment Red 101 and 102 | |
| | Iron Oxide Black: CI Pigment Black 11 | |
| **Definition** | Iron oxides and iron hydroxides are produced synthetically and consist essentially of anhydrous and/or hydrated iron oxides. The range of hues includes yellows, reds, browns and blacks. Food quality iron oxides are primarily distinguished from technical grades by the comparatively low levels of contamination by other metals. This is achieved by the selection and control of the source of the iron and/or by the extent of chemical purification during the manufacturing process. | |
| Colour Index No | Iron Oxide Yellow: | 77492 |
| | Iron Oxide Red: | 77491 |
| | Iron Oxide Black: | 77499 |

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|---|---|---|---|
| Einecs | Iron Oxide Yellow: | 257-098-5 | |
| | Iron Oxide Red: | 215-168-2 | |
| | Iron Oxide Black: | 235-442-5 | |
| Chemical name | Iron Oxide Yellow: hydrated ferric oxide, hydrated iron (III) oxide | | |
| | Iron Oxide Red: anhydrous ferric oxide, anhydrous iron (III) oxide | | |
| | Iron Oxide Black: ferroso ferric oxide, iron (II, III) oxide | | |
| Chemical formula | Iron Oxide Yellow: | $FeO(OH) \cdot H_2O$ | |
| | Iron Oxide Red: | $Fe_2O_3$ | |
| | Iron Oxide Black: | $FeO.Fe_2O_3$ | |
| Molecular weight | 88,85: | FeO(OH) | |
| | 159,70: | $Fe_2O_3$ | |
| | 231,55: | $FeO.Fe_2O_3$ | |
| Assay | Yellow not less than 60 %, red and black not less than 68 % total iron, expressed as iron | | |
| **Description** | Powder; yellow, red, brown or black in hue | | |
| **Identification** | | | |
| Solubility | Insoluble in water and in organic solvents<br>Soluble in concentrated mineral acids | | |
| **Purity** | | | |
| Water soluble matter | Not more than 1,0 % | | |
| Arsenic | Not more than 3 mg/kg | | |
| Cadmium | Not more than 1 mg/kg | | |
| Chromium | Not more than 100 mg/kg | | |
| Copper | Not more than 50 mg/kg | By total dissolution | |
| Lead | Not more than 10 mg/kg | | |
| Mercury | Not more than 1 mg/kg | | |
| Nickel | Not more than 200 mg/kg | | |
| Zinc | Not more than 100 mg/kg | | |

**E 173 ALUMINIUM**

| | |
|---|---|
| **Synonyms** | CI Pigment Metal |
| **Definition** | Aluminium powder is composed of finely divided particles of aluminium. The grinding may or may not be carried out in the presence of edible vegetable oils and/or food additive quality fatty acids. It is free from admixture with substances other than edible vegetable oils and/or food additive quality fatty acids. |

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|---|---|
| Colour Index No | 77000 |
| Einecs | 231-072-3 |
| Chemical name | Aluminium |
| Chemical formula | Al |
| Atomic weight | 26,98 |
| Assay | Not less than 99 % calculated as Al on an oil-free basis |
| **Description** | A silvery-grey powder or tiny sheets |
| **Identification** | |
| Solubility | Insoluble in water and in organic solvents. Soluble in dilute hydrochloric acid. |
| Test for aluminium | A sample dissolved in dilute hydrochloric acid passes test |
| **Purity** | |
| Loss on drying | Not more than 0,5 % (105 °C, to constant weight) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 10 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 174 SILVER**

| | |
|---|---|
| **Synonyms** | Argentum |
| **Definition** | |
| Colour Index No | 77820 |
| Einecs | 231-131-3 |
| Chemical name | Silver |
| Chemical formula | Ag |
| Atomic weight | 107,87 |
| Assay | Content not less than 99,5 % Ag |
| **Description** | Silver-coloured powder or tiny sheets |
| **Identification** | |
| **Purity** | |

**E 175 GOLD**

| | |
|---|---|
| **Synonyms** | Pigment Metal 3; Aurum |
| **Definition** | |
| Colour Index No | 77480 |
| Einecs | 231-165-9 |
| Chemical name | Gold |

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| | | |
|---|---|---|
| Chemical formula | Au | |
| Atomic weight | 197,0 | |
| Assay | Content not less than 90 % Au | |
| **Description** | Gold-coloured powder or tiny sheets | |
| **Identification** | | |
| **Purity** | | |
| Silver | Not more than 7 % | After complete dissolution |
| Copper | Not more than 4 % | |

**E 180 LITHOLRUBINE BK**

| | |
|---|---|
| **Synonyms** | CI Pigment Red 57; Rubinpigment; Carmine 6B |
| **Definition** | Lithol Rubine BK consists essentially of calcium 3-hydroxy-4-(4-methyl-2-sulfonatophenylazo)-2-naphthalenecarboxylate and subsidiary colouring matters together with water, calcium chloride and/or calcium sulphate as the principal uncoloured components. |
| Colour Index No | 15850:1 |
| Einecs | 226-109-5 |
| Chemical name | Calcium 3-hydroxy-4-(4-methyl-2-sulfonatophenylazo)-2-naphthalenecarboxylate |
| Chemical formula | $C_{18}H_{12}CaN_2O_6S$ |
| Molecular weight | 424,45 |
| Assay | Content not less than 90 % total colouring matters<br>$E^{1\%}_{1cm}$ 200 at ca. 442 nm in dimethylformamide |
| **Description** | Red powder |
| **Identification** | |
| Spectrometry | Maximum in dimethylformamide at ca. 442 nm |
| **Purity** | |
| Subsidiary colouring matters | Not more than 0,5 % |
| Organic compounds other than colouring matters: | |
| 2-Amino-5-methylbenzenesulfonic acid, calcium salt | Not more than 0,2 % |
| 3-hydroxy-2-naphthalenecarboxylic acid, calcium salt | Not more than 0,4 % |
| Unsulfonated primary aromatic amines | Not more than 0,01 % (expressed as aniline) |

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| Ether extractable matter | From a solution of pH 7, not more than 0,2 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

***Aluminium lakes of this colour may be used.***

**E 200 SORBIC ACID**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 203-768-7 |
| Chemical name | Sorbic acid; *trans*, *trans*-2,4-Hexadienoic acid |
| Chemical formula | $C_6H_8O_2$ |
| Molecular weight | 112,12 |
| Assay | Content not less than 99 % on the anhydrous basis |
| **Description** | Colourless needles or white free flowing powder, having a slight characteristic odour and showing no change in colour after heating for 90 minutes at 105 °C |
| **Identification** | |
| Melting range | Between 133 °C and 135 °C, after vacuum drying for four hours in a sulphuric acid desiccator |
| Spectrometry | A propan-2-ol solution (1 in 4 000 000) shows absorbance maximum at 254 ± 2 nm |
| Test for double bonds | Passes test |
| Solubility | Slightly soluble in water, soluble in ethanol. |
| **Purity** | |
| Water content | Not more than 0,5 % (Karl Fischer method) |
| Sulphated ash | Not more than 0,2 % |
| Aldehydes | Not more than 0,1 % (as formaldehyde) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

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**E 202 POTASSIUM SORBATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 246-376-1 |
| Chemical name | Potassium sorbate; Potassium (E,E)-2,4-hexadienoate; Potassium salt of *trans*, *trans* 2,4-hexadienoic acid |
| Chemical formula | $C_6H_7O_2K$ |
| Molecular weight | 150,22 |
| Assay | Content not less than 99 % on the dried basis |
| **Description** | White crystalline powder showing no change in colour after heating for 90 minutes at 105 °C |
| **Identification** | |
| Melting range for sorbic acid | Melting range of sorbic acid isolated by acidification and not recrystallised 133 °C to 135 °C after vacuum drying in a sulphuric acid desiccator |
| Test for potassium | Passes test |
| Test for double bonds | Passes test |
| **Purity** | |
| Loss on drying | Not more than 1,0 % (105 °C, 3 hours) |
| Acidity or alkalinity | Not more than about 1,0 % (as sorbic acid or $K_2CO_3$) |
| Aldehydes | Not more than 0,1 %, calculated as formaldehyde |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

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**E 210 BENZOIC ACID**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 200-618-2 |
| Chemical name | Benzoic acid; Benzenecarboxylic acid; Phenylcarboxylic acid |
| Chemical formula | $C_7H_6O_2$ |
| Molecular weight | 122,12 |
| Assay | Content not less than 99,5 % on the anhydrous basis |

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| | |
|---|---|
| **Description** | White crystalline powder |
| **Identification** | |
| Melting range | 121,5 °C -123,5 °C |
| Sublimation test | Passes test |
| Test for benzoate | Passes test |
| pH | About 4 (solution in water) |
| **Purity** | |
| Loss on drying | Not more than 0,5 % (3 hours, over sulphuric acid) |
| Sulphated ash | Not more than 0,05 % |
| Chlorinated organic compounds | Not more than 0,07 % expressed as chloride corresponding to 0,3 % expressed as monochlorobenzoic acid |
| Readily oxidisable substances | Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N $KMnO_4$ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N $KMnO_4$ to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required |
| Readily carbonisable substances | A cold solution of 0,5 g of benzoic acid in 5 ml of 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC ([1]), 0,3 ml of ferric chloride TSC ([2]), 0,1 ml of copper sulphate TSC ([3]) and 4,4 ml of water |
| Polycyclic acids | On fractional acidification of a neutralised solution of benzoic acid, the first precipitate must not have a different melting point from that of the benzoic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

([1]) Cobalt chloride TSC: dissolve approximately 65 g of cobalt chloride $CoCl_2 \cdot 6H_2O$ in a sufficient quantity of a mixture of 25 ml hydrochloric acid and 975 ml of water to give a total volume of 1 litre. Place exactly 5 ml of this solution in a round-bottomed flask containing 250 ml of iodine solution, add 5 ml of 3 % hydrogen peroxide, then 15 ml of a 20 % solution of sodium hydroxide. Boil for 10 minutes, allow to cool, add 2 g of potassium iodide and 20 ml of 25 % sulphuric acid. After the precipitate is completely dissolved, titrate the liberated iodine with sodium thiosulphate (0,1 N) in the presence of starch TS. 1 ml of sodium thiosulphate (0,1 N) corresponds to 23,80 mg of $CoCl_2 \cdot 6H_2O$. Adjust final volume of solution by the addition of a sufficient quantity of the hydrochloric acid/water mixture to give a solution containing 59,5 mg of $CoCl_2 \cdot 6H_2O$ per ml.

([2]) Ferric chloride TSC: dissolve approximately 55 g of ferric chloride in a sufficient quantity of a mixture of 25 ml of hydrochloric acid and 975 ml of water to give a total volume of 1 litre. Place 10 ml of this solution in a round-bottomed flask containing 250 ml of iodine solution, add 15 ml of water and 3 g of potassium iodide; leave the mixture to stand for 15 minutes. Dilute with 100 ml of water then titrate the liberated iodine with sodium thiosulphate (0,1 N) in the presence of starch TS. 1 ml of sodium thiosulphate (0,1 N) corresponds to 27,03 mg of $FeCl_3 \cdot 6H_2O$. Adjust final volume of solution by the addition of a sufficient quantity of the hydrochloric acid/water to give a solution containing 45,0 mg of $FeCl_3 \cdot 6H_2O$ per ml.

([3]) Copper sulphate TSC: dissolve approximate by 65 g of copper sulphate $CuSO_4 \cdot 5H_2O$ in a sufficient quantity of a mixture of 25 ml of hydrochloric acid and 975 ml of water to give a total volume of 1 litre. Place 10 ml of this solution in a round-bottomed flask containing 250 ml of iodine solution, add 40 ml of water, 4 ml of acetic acid and 3 g of potassium iodide. Titrate the liberated iodine with sodium thiosulphate (0,1 N) in the presence of starch TS (*). 1 ml of sodium thiosulphate (0,1 N) corresponds to 24,97 mg of $CuSO_4 \cdot 5H_2O$. Adjust final volume of solution by the addition of a sufficient quantity of the hydrochloric acid/water mixture to give a solution containing 62,4 mg of $CuSO_4 \cdot 5H_2O$ per ml.

(*) Starch TS: triturate 0,5 g starch (potato starch, maize starch or soluable starch) with 5 ml of water; to the resulting paste add a sufficient quantity of water to give a total volume of 100 ml, stirring all the time. Boil for a few minutes, allow to cool, filter. The starch must be freshly prepared.

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**E 211 SODIUM BENZOATE**

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|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 208-534-8 |
| Chemical name | Sodium benzoate; Sodium salt of benzenecarboxylic acid; Sodium salt of phenylcarboxylic acid |
| Chemical formula | $C_7H_5O_2Na$ |
| Molecular weight | 144,11 |
| Assay | Not less than 99 % of $C_7H_5O_2Na$, after drying at 105 °C for four hours |
| **Description** | A white, almost odourless, crystalline powder or granules |
| **Identification** | |
| Solubility | Freely soluble in water, sparingly soluble in ethanol |
| Melting range for benzoic acid | Melting range of benzoic acid isolated by acidification and not recrystallised 121,5 °C to 123,5 °C, after drying in a sulphuric acid desiccator |
| Test for benzoate | Passes test |
| Test for sodium | Passes test |
| **Purity** | |
| Loss on drying | Not more than 1,5 % (105 °C, 4 hours) |
| Readily oxidisable substances | Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N $KMnO_4$ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N $KMnO_4$ to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required |
| Polycyclic acids | On fractional acidification of a (neutralised) solution of sodium benzoate, the first precipitate must not have a different melting range from that of benzoic acid |
| Chlorinated organic compounds | Not more than 0,06 % expressed as chloride, corresponding to 0,25 % expressed as monochlorobenzoic acid |
| Acidity or alkalinity | Neutralisation of 1 g of sodium benzoate, in the presence of phenolphthalein, must not require more than 0,25 ml of 0,1 N NaOH or 0,1 N HCl |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 212 POTASSIUM BENZOATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 209-481-3 |
| Chemical name | Potassium benzoate; Potassium salt of benzenecarboxylic acid; Potassium salt of phenylcarboxylic acid |

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| | |
|---|---|
| Chemical formula | $C_7H_5KO_2 \cdot 3H_2O$ |
| Molecular weight | 214,27 |
| Assay | Content not less than 99 % $C_7H_5KO_2$ after drying at 105 °C to constant weight |
| **Description** | White crystalline powder |
| **Identification** | |
| Melting range for benzoic acid | Melting range of benzoic acid isolated by acidification and not recrystallised 121,5 °C to 123,5 °C, after vacuum drying in a sulphuric acid desiccator |
| Test for benzoate | Passes test |
| Test for potassium | Passes test |
| **Purity** | |
| Loss on drying | Not more than 26,5 % (105 °C, 4 hours) |
| Chlorinated organic compounds | Not more than 0,06 % expressed as chloride, corresponding to 0,25 % expressed as monochlorobenzoic acid |
| Readily oxidisable substances | Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N $KMnO_4$ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N $KMnO_4$ to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required |
| Readily carbonisable substances | A cold solution of 0,5 g of benzoic acid in 5 ml 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC, 0,3 ml of ferric chloride TSC, 0,1 ml of copper sulphate TSC and 4,4 ml of water |
| Polycyclic acids | On fractional acidification of a (neutralised) solution of potassium benzoate, the first precipitate must not have a different melting range from that of benzoic acid |
| Acidity or alkalinity | Neutralisation of 1 g of potassium benzoate, in the presence of phenolphthalein, must not require more than 0,25 ml of 0,1 N NaOH or 0,1 N HCl |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 213 CALCIUM BENZOATE**

| | | |
|---|---|---|
| **Synonyms** | Monocalcium benzoate | |
| **Definition** | | |
| Einecs | 218-235-4 | |
| Chemical name | Calcium benzoate; Calcium dibenzoate | |
| Chemical formula | Anhydrous: | $C_{14}H_{10}O_4Ca$ |
| | Monohydrate: | $C_{14}H_{10}O_4Ca \cdot H_2O$ |
| | Trihydrate: | $C_{14}H_{10}O_4Ca \cdot 3H_2O$ |

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|---|---|---|
| Molecular weight | Anhydrous: | 282,31 |
| | Monohydrate: | 300,32 |
| | Trihydrate: | 336,36 |
| Assay | Content not less than 99 % after drying at 105 °C | |
| **Description** | White or colourless crystals, or white powder | |
| **Identification** | | |
| Melting range for benzoic acid | Melting range of benzoic acid isolated by acidification and not recrystallised 121,5 °C to 123,5 °C, after vacuum drying in a sulphuric acid desiccator | |
| Test for benzoate | Passes test | |
| Test for calcium | Passes test | |
| **Purity** | | |
| Loss on drying | Not more than 17,5 % (105 °C, to constant weight) | |
| Water insoluble matter | Not more than 0,3 % | |
| Chlorinated organic compounds | Not more than 0,06 % expressed as chloride, corresponding to 0,25 % expressed as monochlorobenzoic acid | |
| Readily oxidisable substances | Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N $KMnO_4$ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N $KMnO_4$ to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required | |
| Readily carbonisable substances | Cold solution of 0,5 g of benzoic acid in 5 ml of 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC, 0,3 ml of ferric chloride TSC, 0,1 ml of copper sulphate TSC and 4,4 ml of water | |
| Polycyclic acids | On fractional acidification of a (neutralised) solution of calcium benzoate, the first precipitate must not be a different melting range from that of benzoic acid | |
| Acidity or alkalinity | Neutralisation of 1 g of calcium benzoate, in the presence of phenolphthalein, must not require more than 0,25 ml of 0,1 N NaOH or 0,1 N HCl | |
| Fluoride | Not more than 10 mg/kg | |
| Arsenic | Not more than 3 mg/kg | |
| Lead | Not more than 2 mg/kg | |
| Mercury | Not more than 1 mg/kg | |

**E 214 ETHYL p-HYDROXYBENZOATE**

| | |
|---|---|
| **Synonyms** | Ethylparaben; Ethyl *p*-oxybenzoate |
| **Definition** | |
| Einecs | 204-399-4 |
| Chemical name | Ethyl-*p*-hydroxybenzoate; Ethyl ester of *p*-hydroxybenzoic acid |

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|---|---|
| Chemical formula | $C_9H_{10}O_3$ |
| Molecular weight | 166,8 |
| Assay | Content not less than 99,5 % after drying for two hours at 80 °C |
| **Description** | Almost odourless, small, colourless crystals or a white, crystalline powder |
| **Identification** | |
| Melting range | 115-118 °C |
| Test for *p*-hydroxybenzoate | Melting range of *p*-hydroxybenzoic acid isolated by acidification and not recrystallised: 213 °C to 217 °C, after vacuum drying in a sulphuric acid desiccator |
| Test for alcohol | Passes test |
| **Purity** | |
| Loss on drying | Not more than 0,5 % (80 °C, 2 hours) |
| Sulphated ash | Not more than 0,05 % |
| *p*-Hydroxybenzoic acid and salicylic acid | Not more than 0,35 % expressed as *p*-hydroxybenzoic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 215 SODIUM ETHYL p-HYDROXYBENZOATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 252-487-6 |
| Chemical name | Sodium ethyl *p*-hydroxybenzoate; Sodium compound of the ethyl ester of *p*-hydroxybenzoic acid |
| Chemical formula | $C_9H_9O_3Na$ |
| Molecular weight | 188,8 |
| Assay | Content of ethylester of *p*-hydroxybenzoic acid not less than 83 % on the anhydrous basis |
| **Description** | White, crystalline hygroscopic powder |
| **Identification** | |
| Melting range | 115 °C to 118 °C, after vacuum drying in a sulphuric acid desiccator |
| Test for *p*-hydroxybenzoate | Melting range of *p*-hydroxybenzoic acid derived from the sample is 213 °C to 217 °C |
| Test for sodium | Passes test |
| pH | 9,9-10,3 (0,1 % aqueous solution) |
| **Purity** | |
| Loss on drying | Not more than 5 %, (by vacuum drying in a sulphuric acid desiccator) |
| Sulphated ash | 37 to 39 % |

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|---|---|
| *p*-Hydroxybenzoic acid and salicylic acid | Not more than 0,35 % expressed as *p*-hydroxybenzoic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 218 METHYL p-HYDROXYBENZOATE**

| | |
|---|---|
| **Synonyms** | Methylparaben; Methyl-*p*-oxybenzoate |
| **Definition** | |
| Einecs | 243-171-5 |
| Chemical name | Methyl *p*-hydroxybenzoate; Methyl ester of *p*-hydroxybenzoic acid |
| Chemical formula | $C_8H_8O_3$ |
| Molecular weight | 152,15 |
| Assay | Content not less than 99 % after drying for two hours at 80 °C |
| **Description** | Almost odourless, small colourless crystals or white crystalline powder |
| **Identification** | |
| Melting range | 125 °C - 128 °C |
| Test for *p*-hydroxybenzoate | Melting range of *p*-hydroxybenzoic acid derived from the sample is 213 °C to 217 °C after drying for two hours at 80 °C |
| **Purity** | |
| Loss on drying | Not more than 0,5 % (80 °C, 2 hours) |
| Sulphated ash | Not more than 0,05 % |
| *p*-Hydroxybenzoic acid and salicylic acid | Not more than 0,35 % expressed as *p*-hydroxybenzoic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 219 SODIUM METHYL p-HYDROXYBENZOATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | |
| Chemical name | Sodium methyl *p*-hydroxybenzoate; Sodium compound of the methylester of *p*-hydroxybenzoic acid |
| Chemical formula | $C_8H_7O_3Na$ |
| Molecular weight | 174,15 |
| Assay | Content not less than 99,5 % on the anhydrous basis |
| **Description** | White, hygroscopic powder |

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|---|---|
| **Identification** | |
| Melting range | The white precipitate formed by acidifying with hydrochloric acid a 10 % (w/v) aqueous solution of the sodium derivative of methyl *p*-hydroxybenzoate (using litmus paper as indicator) shall, when washed with water and dried at 80 °C for two hours, have a melting range of 125 °C to 128 °C |
| Test for sodium | Passes test |
| pH | 9,7-10,3 (0,1 % solution in carbon dioxide free water) |
| **Purity** | |
| Water content | Not more than 5 % (Karl Fischer method) |
| Sulphated ash | 40 % to 44,5 % on the anhydrous basis |
| *p*-Hydroxybenzoic acid and salicylic acid | Not more than 0,35 % expressed as *p*-hydroxybenzoic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 220 SULPHUR DIOXIDE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 231-195-2 |
| Chemical name | Sulphur dioxide; Sulphurous acid anhydride |
| Chemical formula | $SO_2$ |
| Molecular weight | 64,07 |
| Assay | Content not less than 99 % |
| **Description** | Colourless, non-flammable gas with strong pungent suffocating odour |
| **Identification** | |
| Test for sulphurous substances | Passes test |
| **Purity** | |
| Water content | Not more than 0,05 % (Karl Fischer method) |
| Non-volatile residue | Not more than 0,01 % |
| Sulphur trioxide | Not more than 0,1 % |
| Selenium | Not more than 10 mg/kg |
| Other gases not normally present in the air | No trace |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

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**E 221 SODIUM SULPHITE**

| | | | |
|---|---|---|---|
| **Synonyms** | | | |
| **Definition** | | | |
| | Einecs | 231-821-4 | |
| | Chemical name | Sodium sulphite (anhydrous or heptahydrate) | |
| | Chemical formula | Anhydrous: | $Na_2SO_3$ |
| | | Heptahydrate: | $Na_2SO_3 7H_2O$ |
| | Molecular weight | Anhydrous: | 126,04 |
| | | Heptahydrate: | 252,16 |
| | Assay | Anhydrous: | Not less than 95 % of $Na_2SO_3$ and not less than 48 % of $SO_2$ |
| | | Heptahydrate: | Not less than 48 % of $Na_2SO_3$ and not less than 24 % of $SO_2$ |
| **Description** | | White crystalline powder or colourless crystals | |
| **Identification** | | | |
| | Test for sulphite | Passes test | |
| | Test for sodium | Passes test | |
| | pH | 8,5-11,5 (anhydrous: 10 % solution; heptahydrate: 20 % solution) | |
| **Purity** | | | |
| | Thiosulphate | Not more than 0,1 % based on the $SO_2$ content | |
| | Iron | Not more than 10 mg/kg based on the $SO_2$ content | |
| | Selenium | Not more than 5 mg/kg based on the $SO_2$ content | |
| | Arsenic | Not more than 3 mg/kg | |
| | Lead | Not more than 2 mg/kg | |
| | Mercury | Not more than 1 mg/kg | |

▼M3

**E 222 SODIUM HYDROGEN SULPHITE**

▼B

| | | |
|---|---|---|
| **Synonyms** | | |
| **Definition** | | |
| | Einecs | 231-921-4 |
| | Chemical name | Sodium bisulphite; Sodium hydrogen sulphite |
| | Chemical formula | $NaHSO_3$ in aqueous solution |
| | Molecular weight | 104,06 |
| | Assay | Content not less than 32 % w/w $NaHSO_3$ |
| **Description** | | A clear, colourless to yellow solution |
| **Identification** | | |
| | Test for sulphite | Passes test |

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| | |
|---|---|
| Test for sodium | Passes test |
| pH | 2,5-5,5 (10 % aqueous solution) |
| **Purity** | |

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| | |
|---|---|
| Iron | Not more than 10 mg/kg based on the $SO_2$ content |

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| | |
|---|---|
| Selenium | Not more than 5 mg/kg based on the $SO_2$ content |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 223 SODIUM METABISULPHITE**

| | |
|---|---|
| **Synonyms** | Pyrosulphite; Sodium pyrosulphite |
| **Definition** | |
| Einecs | 231-673-0 |
| Chemical name | Sodium disulphite; Disodium pentaoxodisulphate |
| Chemical formula | $Na_2S_2O_5$ |
| Molecular weight | 190,11 |
| Assay | Content not less than 95 % $Na_2S_2O_5$ and not less than 64 % of $SO_2$ |
| **Description** | White crystals or crystalline powder |
| **Identification** | |
| Test for sulphite | Passes test |
| Test for sodium | Passes test |
| pH | 4,0-5,5 (10 % aqueous solution) |
| **Purity** | |
| Thiosulphate | Not more than 0,1 % based on the $SO_2$ content |
| Iron | Not more than 10 mg/kg based on the $SO_2$ content |
| Selenium | Not more than 5 mg/kg based on the $SO_2$ content |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 224 POTASSIUM METABISULPHITE**

| | |
|---|---|
| **Synonyms** | Potassium pyrosulphite |
| **Definition** | |
| Einecs | 240-795-3 |
| Chemical name | Potassium disulphite; Potassium pentaoxo disulphate |
| Chemical formula | $K_2S_2O_5$ |
| Molecular weight | 222,33 |

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| | |
|---|---|
| Assay | Content not less than 90 % $K_2S_2O_5$ and not less than 51,8 % of $SO_2$, the remainder being composed almost entirely of potassium sulphate |
| **Description** | Colourless crystals or white crystalline powder |
| **Identification** | |
| Test for sulphite | Passes test |
| Test for potassium | Passes test |
| **Purity** | |
| Thiosulphate | Not more than 0,1 % based on the $SO_2$ content |
| Iron | Not more than 10 mg/kg based on the $SO_2$ content |
| Selenium | Not more than 5 mg/kg based on the $SO_2$ content |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 226 CALCIUM SULPHITE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 218-235-4 |
| Chemical name | Calcium sulphite |
| Chemical formula | $CaSO_3 \cdot 2H_2O$ |
| Molecular weight | 156,17 |
| Assay | Content not less than 95 % of $CaSO_3 \cdot 2H_2O$ and not less than 39 % of $SO_2$ |
| **Description** | White crystals or white crystalline powder |
| **Identification** | |
| Test for sulphite | Passes test |
| Test for calcium | Passes test |
| **Purity** | |
| Iron | Not more than 10 mg/kg based on the $SO_2$ content |
| Selenium | Not more than 5 mg/kg based on the $SO_2$ content |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

▼M8

**E 227 CALCIUM HYDROGEN SULPHITE**

▼B

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 237-423-7 |

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| | |
|---|---|
| Chemical name | Calcium bisulphite; Calcium hydrogen sulphite |
| Chemical formula | $Ca(HSO_3)_2$ |
| Molecular weight | 202,22 |
| Assay | 6 to 8 % (w/v) of sulphur dioxide and 2,5 to 3,5 % (w/v) of calcium dioxide corresponding to 10 to 14 % (w/v) of calcium bisulphite [$Ca(HSO_3)_2$] |
| **Description** | Clear greenish-yellow aqueous solution having a distinct odour of sulphur dioxide |
| **Identification** | |
| Test for sulphite | Passes test |
| Test for calcium | Passes test |
| **Purity** | |
| Iron | Not more than 10 mg/kg based on the $SO_2$ content |
| Selenium | Not more than 5 mg/kg based on the $SO_2$ content |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

▼M8

**E 228 POTASSIUM HYDROGEN SULPHITE**

▼B

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 231-870-1 |
| Chemical name | Potassium bisulphite; Potassium hydrogen sulphite |
| Chemical formula | $KHSO_3$ in aqueous solution |
| Molecular weight | 120,17 |
| Assay | Content not less than 280 g $KHSO_3$ per litre (or 150 g $SO_2$ per litre) |
| **Description** | Clear colourless aqueous solution |
| **Identification** | |
| Test for sulphite | Passes test |
| Test for potassium | Passes test |
| **Purity** | |
| Iron | Not more than 10 mg/kg based on the $SO_2$ content |
| Selenium | Not more than 5 mg/kg based on the $SO_2$ content |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

▼B

**E 234 NISIN**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Nisin consists of several closely related polypeptides produced by strains of *Lactococcus lactis* subsp. *lactis* |
| Einecs | 215-807-5 |
| Chemical name | |
| Chemical formula | $C_{143}H_{230}N_{42}O_{37}S_7$ |
| Molecular weight | 3 354,12 |
| Assay | Nisin concentrate contains not less than 900 units per mg in a mixture of non-fat milk solids and a minimum sodium chloride content of 50 % |
| **Description** | White powder |
| **Identification** | |
| **Purity** | |
| Loss on drying | Not more than 3 % (102 °C to 103 °C, to constant weight) |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 235 NATAMYCIN**

| | |
|---|---|
| **Synonyms** | Pimaricin |
| **Definition** | Natamycin is a fungicide of the polyene macrolide group, and is produced by strains of *Streptomyces natalensis* and other relevant species |
| Einecs | 231-683-5 |
| Chemical name | A stereoisomer of 22-(3-Amino-3,6-dideoxy-β-D- mannopyranosyloxy)-1,3,26-trihydroxy-12-methyl-10-oxo-6,11,28-trioxatricyclo[22.3.1.$0^{5,7}$]octacosa-8,14,16,18,20-pentaene-25-carboxylic acid. |
| Chemical formula | $C_{33}H_{47}O_{13}N$ |
| Molecular weight | 665,74 |
| Assay | Content not less than 95 % on the dried basis |
| **Description** | White to creamy-white crystalline powder |
| **Identification** | |
| Colour reactions | On adding a few crystals of natamycin on a spot plate, to a drop of:<br>concentrated hydrochloric acid, a blue colour develops,<br>concentrated phosphoric acid, a green colour develops,which changes into pale red after a few minutes |
| Spectrometry | A 0,0005 % w/v solution in 1 % methanolic acetic acid solution has absorption maxima at about 290 nm, 303 nm and 318 nm, a shoulder at about 280 nm and exhibits minima at about 250 nm, 295,5 nm and 311 nm |

▼B

| | |
|---|---|
| pH | 5,5-7,5 (1 % w/v solution in previously neutralised mixture of 20 parts dimethylformamide and 80 parts of water) |
| Specific rotation | $[\alpha]_D^{20}$ + 250° to + 295° (a 1 % w/v solution in glacial acetic acid, at 20 °C and calculated with reference to the dried material) |
| **Purity** | |
| Loss on drying | Not more than 8 % (over $P_2O_5$, in vacuum at 60 °C to constant weight) |
| Sulphated ash | Not more than 0,5 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| **Microbiological criteria** | |
| Total plate count | Not more than 100 colonies per gram |

**E 239 HEXAMETHYLENE TETRAMINE**

| | |
|---|---|
| **Synonyms** | Hexamine; Methenamine |
| **Definition** | |
| Einecs | 202-905-8 |
| Chemical name | 1,3,5,7-Tetraazatricyclo [3.3.1.$1^{3,7}$]-decane, hexamethylenetetramine |
| Chemical formula | $C_6H_{12}N_4$ |
| Molecular weight | 140,19 |
| Assay | Content not less than 99 % on the anhydrous basis |
| **Description** | Colourless or white crystalline powder |
| **Identification** | |
| Test for formaldehyde | Passes test |
| Test for ammonia | Passes test |
| Sublimation point: | Approximately 260 °C |
| **Purity** | |
| Loss on drying | Not more than 0,5 % (at 105 °C in vacuum over $P_2O_5$ for 2 hours) |
| Sulphated ash | Not more than 0,05 % |
| Sulphates | Not more than 0,005 % expressed as $SO_4$ |
| Chlorides | Not more than 0,005 % expressed as Cl |
| Ammonium salts | Not detectable |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

▼B

**E 242 DIMETHYL DICARBONATE**

| | |
|---|---|
| **Synonyms** | DMDC; Dimethyl pyrocarbonate |
| **Definition** | |
| Einecs | 224-859-8 |
| Chemical name | Dimethyl dicarbonate; Pyrocarbonic acid dimethyl ester |
| Chemical formula | $C_4H_6O_5$ |
| Molecular weight | 134,09 |
| Assay | Content not less than 99,8 % |
| **Description** | Colourless liquid, decomposes in aqueous solution. It is corrosive to skin and eyes and toxic by inhalation and ingestion |
| **Identification** | |
| Decomposition | After dilution positive tests for $CO_2$ and methanol |
| Melting point | 17 °C |
| Boiling point | 172 °C with decomposition |
| Density 20 °C | Approximately 1,25 $g/cm^3$ |
| Infrared absorption spectrum | Maxima at 1 156 and 1 832 $cm^{-1}$ |
| **Purity** | |
| Dimethyl carbonate | Not more than 0,2 % |
| Chlorine, total | Not more than 3 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

▼M12

**E 243 ETHYL LAUROYL ARGINATE**

| | |
|---|---|
| **Synonyms** | Lauric arginate ethyl ester; lauramide arginine ethyl ester; ethyl-Nα-lauroyl-L-arginate·HCl; LAE; |

▼M19

| | |
|---|---|
| **Definition** | Ethyl lauroyl arginate is synthesized by esterifying arginine with ethanol, followed by reacting the ester with lauroyl chloride, in aqueous media at a controlled temperature between 10 and 15 °C and at a pH between 6,7 and 6,9. The resultant ethyl lauroyl arginate is recovered as the hydrochloride salt, which is filtered and dried. |

▼M12

| | |
|---|---|
| ELINCS | 434-630-6 |
| Chemical name | Ethyl-Nα-dodecanoyl-L-arginate·HCl |
| Chemical formula | C20H41N4O3Cl |
| Molecular Weight | 421,02 |
| Assay | Not less than 85 % and not more than 95 % |
| **Description** | White powder |

▼M12

| | |
|---|---|
| **Identification** | |
| Solubility | Freely soluble in water, ethanol, propylene glycol and glycerol |
| **Purity** | |
| Nα-Lauroyl-L-arginine | Not more than 3 % |
| Lauric acid | Not more than 5 % |
| Ethyl laurate | Not more than 3 % |
| L-Arginine·HCl | Not more than 1 % |
| Ethyl arginate·2HCl | Not more than 1 % |
| Lead | Not more than 1 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

▼M36

**E 246 GLYCOLIPIDS**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | The naturally occurring glycolipids are obtained by a fermentation process using the wild type strain MUCL 53181 of the fungus *Dacryopinax spathularia* (edible sweet osmanthus ear mushroom). Glucose is used as a carbon source. The solvent-free downstream process includes filtration and microfiltration to remove microbial cells, precipitation and washing with buffered water to purify. The product is pasteurized and spray-dried. The production process does not chemically modify the glycolipids or change their innate composition. |
| CAS number | 2205009-17-0 |
| Chemical name | Glycolipids from *Dacryopinax spathularia* |
| Assay | Not less than 93 % total glycolipid content on the dried basis. |
| **Description** | Beige to light brown powder, weak characteristic odour |
| **Identification** | |
| Solubility | Complies (10 g/l in water) |
| pH | Between 5,0 and 7,0 (10 g/l in water) |
| Turbidity | Not more than 28 NTU (10 g/l in water) |

▼M36

| | |
|---|---|
| **Purity** | |
| Water content | Not more than 5 % (Karl Fischer Method) |
| Protein | Not more than 3 % (factor N x 6,25) |
| Fat | Not more than 2 % (gravimetric) |
| Sodium | Not more than 3,3 % |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 0,7 mg/kg |
| Cadmium | Not more than 0,1 mg/kg |
| Mercury | Not more than 0,1 mg/kg |
| Nickel | Not more than 2 mg/kg |
| **Microbiological criteria** | |
| Total aerobic count | Not more than 100 colonies per gram |
| Yeast and moulds | Not more than 10 colonies per gram |
| Coliforms | Not more than 3 MPN per gram |
| *Salmonella* spp. | Absent in 25 g’ |

▼B

**E 249 POTASSIUM NITRITE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 231-832-4 |
| Chemical name | Potassium nitrite |
| Chemical formula | $KNO_2$ |
| Molecular weight | 85,11 |
| Assay | Content not less than 95 % on the anhydrous basis ([1]) |
| **Description** | White or slightly yellow, deliquescent granules |
| **Identification** | |
| Test for nitrite | Passes test |
| Test for potassium | Passes test |
| pH | 6,0-9,0 (5 % solution) |

([1]) May only be sold in a mixture with salt or a salt substitute.

▼B

| | |
|---|---|
| **Purity** | |
| Loss on drying | Not more than 3 % (4 hours, over silica gel) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 250 SODIUM NITRITE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 231-555-9 |
| Chemical name | Sodium nitrite |
| Chemical formula | $NaNO_2$ |
| Molecular weight | 69,00 |
| Assay | Content not less than 97 % on the anhydrous basis ([1]) |
| **Description** | White crystalline powder or yellowish lumps |
| **Identification** | |
| Test for nitrite | Passes test |
| Test for sodium | Passes test |
| **Purity** | |
| Loss on drying | Not more than 0,25 % (4 hours, over silica gel) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 251 SODIUM NITRATE**

(i) SOLID SODIUM NITRATE

| | |
|---|---|
| **Synonyms** | Chile saltpetre; Cubic or soda nitre |
| **Definition** | |
| Einecs | 231-554-3 |
| Chemical name | Sodium nitrate |
| Chemical formula | $NaNO_3$ |
| Molecular weight | 85,00 |
| Assay | Content not less than 99 % on the anhydrous basis |
| **Description** | White crystalline, slightly hygroscopic powder |

([1]) May only be sold in a mixture with salt or a salt substitute.

▼B

| | |
|---|---|
| **Identification** | |
| Test for nitrate | Passes test |
| Test for sodium | Passes test |
| pH | 5,5-8,3 (5 % solution) |
| **Purity** | |
| Loss on drying | Not more than 2 % (105 °C, 4 hours) |
| Nitrites | Not more than 30 mg/kg expressed as $NaNO_2$ |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

(ii) LIQUID SODIUM NITRATE

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Liquid sodium nitrate is an aqueous solution of sodium nitrate as the direct result of the chemical reaction between sodium hydroxide and nitric acid in stoechiometric amounts, without subsequent crystallisation. Standardised forms prepared from liquid sodium nitrate meeting these specifications may contain nitric acid in excessive amounts, if clearly stated or labelled. |
| Einecs | 231-554-3 |
| Chemical name | Sodium nitrate |
| Chemical formula | $NaNO_3$ |
| Molecular weight | 85,00 |
| Assay | Content between 33,5 % and 40,0 % of $NaNO_3$ |
| **Description** | Clear colourless liquid |
| **Identification** | |
| Test for nitrate | Passes test |
| Test for sodium | Passes test |
| pH | 1,5-3,5 |
| **Purity** | |
| Free nitric acid | Not more than 0,01 % |
| Nitrites | Not more than 10 mg/kg expressed as $NaNO_2$ |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 0,3 mg/kg |

***This specification refers to a 35 % aqueous solution.***

**E 252 POTASSIUM NITRATE**

| | |
|---|---|
| **Synonyms** | Chile saltpetre; Cubic or soda nitre |
| **Definition** | |
| Einecs | 231-818-8 |

▼B

| | |
|---|---|
| Chemical name | Potassium nitrate |
| Chemical formula | $KNO_3$ |
| Molecular weight | 101,11 |
| Assay | Content not less than 99 % on the anhydrous basis |
| **Description** | White crystalline powder or transparent prisms having a cooling, saline, pungent taste |
| **Identification** | |
| Test for nitrate | Passes test |
| Test for potassium | Passes test |
| pH | 4,5-8,5 (5 % solution) |
| **Purity** | |
| Loss on drying | Not more than 1 % (105 °C, 4 hours) |
| Nitrites | Not more than 20 mg/kg expressed as $KNO_2$ |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 260 ACETIC ACID**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 200-580-7 |
| Chemical name | Acetic acid; Ethanoic acid |
| Chemical formula | $C_2H_4O_2$ |
| Molecular weight | 60,05 |
| Assay | Content not less than 99,8 % |
| **Description** | Clear, colourless liquid having a pungent, characteristic odour |
| **Identification** | |
| Boiling point | 118 °C at 760 mm pressure (of mercury) |
| Specific gravity | About 1,049 |
| Test for acetate | A one in three solution gives positive tests for acetate |
| Solidification point | Not lower than 14,5 °C |
| **Purity** | |
| Non-volatile residue | Not more than 100 mg/kg |
| Formic acid, formates and other oxidisable substances | Not more than 1 000 mg/kg expressed as formic acid |
| Readily oxidisable substances | Dilute 2 ml of the sample in a glass-stoppered container with 10 ml of water and add 0,1 ml of 0,1 N potassium permanganate. The pink colour does not change to brown within 30 minutes |

▼B

| | |
|---|---|
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 0,5 mg/kg |
| Mercury | Not more than 1 mg/kg |

▼M2

**E 261 (i) POTASSIUM ACETATE**

▼B

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 204-822-2 |
| Chemical name | Potassium acetate |
| Chemical formula | $C_2H_3O_2K$ |
| Molecular weight | 98,14 |
| Assay | Content not less than 99 % on the anhydrous basis |
| **Description** | Colourless, deliquescent crystals or a white crystalline powder, odourless or with a faint acetic odour |
| **Identification** | |
| pH | 7,5-9,0 (5 % aqueous solution) |
| Test for acetate | Passes test |
| Test for potassium | Passes test |
| **Purity** | |
| Loss on drying | Not more than 8 % (150 °C, 2 hours) |
| Formic acid, formates and other oxidisable substances | Not more than 1 000 mg/kg expressed as formic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

▼M2

**E 261 (ii) POTASSIUM DIACETATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Potassium diacetate is a molecular compound of potassium acetate and acetic acid |
| Einecs | 224-217-7 |
| Chemical name | Potassium hydrogen diacetate |
| Chemical formula | $C_4H_7KO_4$ |

▼M2

| | |
|---|---|
| Molecular weight | 158,2 |
| Assay | Content 36 to 38 % of free acetic acid and 61 to 64 % of potassium acetate |
| **Description** | White crystals |
| **Identification** | |
| pH | 4,5-5 (10 % aqueous solution) |
| Test for acetate | Passes test |
| Test for potassium | Passes test |
| **Purity** | |
| Water content | Not more than 1 % (Karl Fischer method) |
| Formic acid, formates and other oxidisable substances | Not more than 1 000 mg/kg expressed as formic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

▼B

**E 262 (i) SODIUM ACETATE**

| | | |
|---|---|---|
| **Synonyms** | | |
| **Definition** | | |
| Einecs | 204-823-8 | |
| Chemical name | Sodium acetate | |
| Chemical formula | $C_2H_3NaO_2 \cdot nH_2O$ (n = 0 or 3) | |
| Molecular weight | Anhydrous: | 82,03 |
| | Trihydrate: | 136,08 |
| Assay | Content (for both of anhydrous and trihydrate form) not less than 98,5 % on the anhydrous basis | |
| **Description** | Anhydrous: | White, odourless, granular, hygroscopic powder |
| | Trihydrate: | Colourless, transparent crystals or a granular crystalline powder, odourless or with a faint, acetic odour. Effloresces in warm, dry air |

▼B

| | | |
|---|---|---|
| **Identification** | | |
| pH | 8,0-9,5 (1 % aqueous solution) | |
| Test for acetate | Passes test | |
| Test for sodium | Passes test | |
| **Purity** | | |
| Loss on drying | Anhydrous: | Not more than 2 % (120 °C, 4 hours) |
| | Trihydrate: | Between 36 and 42 % (120 °C, 4 hours) |
| Formic acid, formates and other oxidisable substances | Not more than 1 000 mg/kg expressed as formic acid | |
| Arsenic | Not more than 3 mg/kg | |
| Lead | Not more than 2 mg/kg | |
| Mercury | Not more than 1 mg/kg | |

**E 262 (ii) SODIUM DIACETATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Sodium diacetate is a molecular compound of sodium acetate and acetic acid |
| Einecs | 204-814-9 |
| Chemical name | Sodium hydrogen diacetate |
| Chemical formula | $C_4H_7NaO_4 \cdot nH_2O$ (n = 0 or 3) |
| Molecular weight | 142,09 (anhydrous) |

▼M34

| | |
|---|---|
| Assay | Content 39 to 43 % of free acetic acid and 57 to 60 % of sodium acetate |

▼B

| | |
|---|---|
| **Description** | White, hygroscopic crystalline solid with an acetic odour |
| **Identification** | |
| pH | 4,5-5,0 (10 % aqueous solution) |
| Test for acetate | Passes test |
| Test for sodium | Passes test |
| **Purity** | |
| Water content | Not more than 2 % (Karl Fischer method) |
| Formic acid, formates and other oxidisable substances | Not more than 1 000 mg/kg expressed as formic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 263 CALCIUM ACETATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 200-540-9 |

▼B

| | | |
|---|---|---|
| Chemical name | Calcium acetate | |
| Chemical formula | Anhydrous: | $C_4H_6O_4Ca$ |
| | Monohydrate: | $C_4H_6O_4Ca \cdot H_2O$ |
| Molecular weight | Anhydrous: | 158,17 |
| | Monohydrate: | 176,18 |
| Assay | Content not less than 98 % on the anhydrous basis | |
| **Description** | Anhydrous calcium acetate is a white, hygroscopic, bulky, crystalline solid with a slightly bitter taste. A slight odour of acetic acid may be present. The monohydrate may be needles, granules or powder | |
| **Identification** | | |
| pH | 6,0-9,0 (10 % aqueous solution) | |
| Test for acetate | Passes test | |
| Test for calcium | Passes test | |
| **Purity** | | |
| Loss on drying | Not more than 11 % (155 °C to constant weight, for the monohydrate) | |
| Water insoluble matter | Not more than 0,3 % | |
| Formic acid, formates and other oxidisable substances | Not more than 1 000 mg/kg expressed as formic acid | |
| Arsenic | Not more than 3 mg/kg | |
| Lead | Not more than 2 mg/kg | |
| Mercury | Not more than 1 mg/kg | |

**E 270 LACTIC ACID**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Consists of a mixture of lactic acid ($C_3H_6O_3$) and lactic acid lactate ($C_6H_{10}O_5$). It is obtained by the lactic fermentation of sugars or is prepared synthetically.<br>Lactic acid is hygroscopic and when concentrated by boiling, it condenses to form lactic acid lactate, which on dilution and heating hydrolyses to lactic acid. |
| Einecs | 200-018-0 |
| Chemical name | Lactic acid; 2-Hydroxypropionic acid; 1-Hydroxyethane-1-carboxylic acid |
| Chemical formula | $C_3H_6O_3$ |
| Molecular weight | 90,08 |
| Assay | Content not less than 76 % |
| **Description** | Colourless or yellowish, nearly odourless, syrupy liquid to solid |
| **Identification** | |
| Test for lactate | Passes test |

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|---|---|
| **Purity** | |
| Sulphated ash | Not more than 0,1 % |
| Chloride | Not more than 0,2 % |
| Sulphate | Not more than 0,25 % |
| Iron | Not more than 10 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

*Note:* This specification refers to a 80 % aqueous solution; for weaker aqueous solutions, calculate values corresponding to their lactic acid content

**E 280 PROPIONIC ACID**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 201-176-3 |
| Chemical name | Propionic acid; Propanoic acid |
| Chemical formula | $C_3H_6O_2$ |
| Molecular weight | 74,08 |
| Assay | Content not less than 99,5 % |
| **Description** | Colourless or slightly yellowish, oily liquid with a slightly pungent odour |
| **Identification** | |
| Melting point | – 22 °C |
| Distillation range | 138,5 °C to 142,5 °C |
| **Purity** | |
| Non-volatile residue | Not more than 0,01 % when dried at 140 °C to constant weight |
| Aldehydes | Not more than 0,1 % expressed as formaldehyde |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 281 SODIUM PROPIONATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 205-290-4 |
| Chemical name | Sodium propionate; Sodium propanoate |
| Chemical formula | $C_3H_5O_2Na$ |
| Molecular weight | 96,06 |
| Assay | Content not less than 99 % after drying for two hours at 105 °C |

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|---|---|
| **Description** | White crystalline hygroscopic powder, or a fine white powder |
| **Identification** | |
| Test for propionate | Passes test |
| Test for sodium | Passes test |
| pH | 7,5-10,5 (10 % aqueous solution) |
| **Purity** | |
| Loss on drying | Not more than 4 % (105 °C, 2 hours) |
| Water insoluble matter | Not more than 0,1 % |
| Iron | 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 282 CALCIUM PROPIONATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 223-795-8 |
| Chemical name | Calcium propionate |
| Chemical formula | $C_6H_{10}O_4Ca$ |
| Molecular weight | 186,22 |
| Assay | Content not less than 99 %, after drying for two hours at 105 °C |
| **Description** | White crystalline powder |
| **Identification** | |
| Test for propionate | Passes test |
| Test for calcium | Passes test |
| pH | 6,0-9,0 (10 % aqueous solution) |
| **Purity** | |
| Loss on drying | Not more than 4 % (105 °C, 2 hours) |
| Water insoluble matter | Not more than 0,3 % |
| Iron | Not more than 50 mg/kg |

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|---|---|
| Fluoride | Not more than 20 mg/kg |

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

**E 283 POTASSIUM PROPIONATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 206-323-5 |

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|---|---|
| Chemical name | Potassium propionate; Potassium propanoate |
| Chemical formula | $C_3H_5KO_2$ |
| Molecular weight | 112,17 |
| Assay | Content not less than 99 % after drying for two hours at 105 °C |
| **Description** | White crystalline powder |
| **Identification** | |
| Test for propionate | Passes test |
| Test for potassium | Passes test |
| **Purity** | |
| Loss on drying | Not more than 4 % (105 °C, 2 hours) |
| Water insoluble matter | Not more than 0,1 % |
| Iron | Not more than 30 mg/kg |
| 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 284 BORIC ACID**

| | |
|---|---|
| **Synonyms** | Boracic acid; Orthoboric acid; Borofax |
| **Definition** | |
| Einecs | 233-139-2 |
| Chemical name | |
| Chemical formula | $H_3BO_3$ |
| Molecular weight | 61,84 |
| Assay | Content not less than 99,5 % |
| **Description** | Colourless, odourless, transparent crystals or white granules or powder; slightly unctuous to the touch; occurs in nature as the mineral sassolite |
| **Identification** | |
| Melting point | At approximately 171 °C |
| Burning test | Burns with a nice green flame |
| pH | 3,8-4,8 (3,3 % aqueous solution) |
| **Purity** | |
| Peroxides | No colour develops with added KI-solution |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

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**E 285 SODIUM TETRABORATE (BORAX)**

| | |
|---|---|
| **Synonyms** | Sodium borate |
| **Definition** | |
| Einecs | 215-540-4 |
| Chemical name | Sodium tetraborate; Sodium biborate; Sodium pyroborate; Anhydrous tetraborate |
| Chemical formula | $Na_2B_4O_7$<br>$Na_2B_4O_7 \cdot 10H_2O$ |
| Molecular weight | 201,27 |
| Assay | |
| **Description** | Powder or glass-like plates becoming opaque on exposure to air; slowly soluble in water |
| **Identification** | |
| Melting range | Between 171 °C and 175 °C with decomposition |
| **Purity** | |
| Peroxides | No colour develops with added KI-solution |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 290 CARBON DIOXIDE**

| | |
|---|---|
| **Synonyms** | Carbonic acid gas; Dry ice (solid form); Carbonic anhydride |
| **Definition** | |
| Einecs | 204-696-9 |
| Chemical name | Carbon dioxide |
| Chemical formula | $CO_2$ |
| Molecular weight | 44,01 |
| Assay | Content not less than 99 % v/v on the gaseous basis |
| **Description** | A colourless gas under normal environmental conditions with a slight pungent odour. Commercial carbon dioxide is shipped and handled as a liquid in pressurised cylinders or bulk storage systems, or in compressed solid blocks of ‘dry ice’. Solid (dry ice) forms usually contain added substances, such as propylene glycol or mineral oil, as binders |
| **Identification** | |
| Precipitate formation | When a stream of the sample is passed through a solution of barium hydroxide, a white precipitate is produced which dissolves with effervescence in dilute acetic acid |
| **Purity** | |
| Acidity | 915 ml of gas bubbled through 50 ml of freshly boiled water must not render the latter more acid to methylorange than is 50 ml freshly boiled water to which has been added 1 ml of hydrochloric acid (0,01 N) |

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|---|---|
| Reducing substances, hydrogen phosphide and sulphide | 915 ml of gas bubbled through 25 ml of ammoniacal silver nitrate reagent to which has been added 3 ml of ammonia must not cause clouding or blackening of this solution |
| Carbon monoxide | Not more than 10 µl/l |
| Oil content | Not more than 5 mg/kg |

**E 296 MALIC ACID**

| | |
|---|---|
| **Synonyms** | Pomalous acid |
| **Definition** | |
| Einecs | 230-022-8, 210-514-9, 202-601-5 |
| Chemical name | hydroxybutanedioic acid; hydroxysuccinic acid |
| Chemical formula | $C_4H_6O_5$ |
| Molecular weight | 134,09 |
| Assay | Content not less than 99,0 % |
| **Description** | White or nearly white crystalline powder or granules |
| **Identification** | |
| Melting range | 127-132 °C |
| Test for malate | Passes test |
| **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 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 297 FUMARIC ACID**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 203-743-0 |
| Chemical name | *trans*-Butenedioic acid; *trans*-1,2-Ethylene-dicarboxylic acid |
| Chemical formula | $C_4H_4O_4$ |
| Molecular weight | 116,07 |
| Assay | Content not less than 99,0 % on the anhydrous basis |
| **Description** | White crystalline powder or granules |
| **Identification** | |
| Melting range | 286-302 °C (closed capillary, rapid heating) |
| Test for double bonds | Passes test |
| Test for 1,2-dicarboxylic acid | Passes test |
| pH | 3,0-3,2 (0,05 % solution at 25 °C) |

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|---|---|
| **Purity** | |
| Loss on drying | Not more than 0,5 % (120 °C, 4 hours) |
| 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 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 300 ASCORBIC ACID, L-ASCORBIC ACID**

| | |
|---|---|
| **Synonyms** | L-xylo-Ascorbic acid; L(+)- Ascorbic acid |
| **Definition** | |
| Einecs | 200-066-2 |
| Chemical name | L-ascorbic acid; Ascorbic acid; 2,3-Didehydro-L-threo-hexono-1,4-lactone; 3-Keto-L-gulofuranolactone |
| Chemical formula | $C_6H_8O_6$ |
| Molecular weight | 176,13 |
| Assay | contains not less than 99 % of $C_6H_8O_6$ after drying in a vacuum desiccator over sulphuric acid for 24 hours, |
| **Description** | White to pale yellow, odourless crystalline powder |
| Melting range | Between 189 °C and 193 °C with decomposition |
| **Identification** | |
| Test for ascorbic acid | Passes test |
| pH | Between 2,4 and 2,8 (2 % aqueous solution) |
| Specific rotation | $[\alpha]_D^{20}$ between + 20,5° and + 21,5° (10 % w/v aqueous solution) |
| **Purity** | |
| Loss on drying | Not more than 0,4 % (in vacuum over sulphuric acid, 24 hours) |
| Sulphated ash | Not more than 0,1 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 301 SODIUM ASCORBATE**

| | |
|---|---|
| **Synonyms** | Sodium L-ascorbate; L-Ascorbic acid monosodium salt |
| **Definition** | |
| Einecs | 205-126-1 |
| Chemical name | Sodium ascorbate; Sodium L-ascorbate; 2,3-Didehydro-L-threo-hexono-1,4-lactone sodium enolate; 3-Keto-L-gulofurano-lactone sodium enolate |
| Chemical formula | $C_6H_7O_6Na$ |

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| | |
|---|---|
| Molecular weight | 198,11 |
| Assay | Sodium ascorbate, after drying in a vacuum desiccator over sulphuric acid for 24 hours, contains not less than 99 % of $C_6H_7O_6Na$ |
| **Description** | White or almost white, odourless crystalline powder which darkens on exposure to light |
| **Identification** | |
| Test for ascorbate | Passes test |
| Test for sodium | Passes test |
| pH | Between 6,5 and 8,0 (10 % aqueous solution) |
| Specific rotation | $[\alpha]_D^{20}$ between + 103° and + 106° (10 % w/v aqueous solution) |
| **Purity** | |
| Loss on drying | Not more than 0,25 % (in vacuum over sulphuric acid, 24 hours) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 302 CALCIUM ASCORBATE**

| | |
|---|---|
| **Synonyms** | Calcium ascorbate dihydrate |
| **Definition** | |
| Einecs | 227-261-5 |
| Chemical name | Calcium ascorbate dihydrate; Calcium salt of 2,3-didehydro-L-threo-hexono-1,4-lactone dihydrate |
| Chemical formula | $C_{12}H_{14}O_{12}Ca \cdot 2H_2O$ |
| Molecular weight | 426,35 |
| Assay | Content not less than 98 % on a volatile matter-free basis |
| **Description** | White to slightly pale greyish-yellow odourless crystalline powder |
| **Identification** | |
| Test for ascorbate | Passes test |
| Test for calcium | Passes test |
| pH | Between 6,0 and 7,5 (10 % aqueous solution) |
| Specific rotation | $[\alpha]_D^{20}$ between + 95° and + 97° (5 % w/v aqueous solution) |
| **Purity** | |
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |
| Volatile matter | Not more than 0,3 % determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

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**E 304 (i) ASCORBYL PALMITATE**

| | |
|---|---|
| **Synonyms** | L-ascorbyl palmitate |
| **Definition** | |
| Einecs | 205-305-4 |
| Chemical name | Ascorbyl palmitate; L-ascorbyl palmitate; 2,3-didehydro-L-threo-hexono-1,4-lactone-6-palmitate; 6-palmitoyl-3-keto-L-gulofuranol-actone |
| Chemical formula | $C_{22}H_{38}O_7$ |
| Molecular weight | 414,55 |
| Assay | Content not less than 98 % on the dried basis |
| **Description** | White or yellowish-white powder with a citrus-like odour |
| **Identification** | |
| Melting range | Between 107 °C and 117 °C |
| Specific rotation | $[\alpha]_D^{20}$ between + 21° and + 24° (5 % w/v in methanol solution) |
| **Purity** | |
| Loss on drying | Not more than 2,0 % (vacuum oven, 56-60 °C, 1 hour) |
| Sulphated ash | Not more than 0,1 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 304 (ii) ASCORBYL STEARATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 246-944-9 |
| Chemical name | Ascorbyl stearate; L-ascorbyl stearate; 2,3-didehydro-L-threo-hexono-1,4-lactone-6-stearate; 6-stearoyl-3-keto-L-gulofuranolactone |
| Chemical formula | $C_{24}H_{42}O_7$ |
| Molecular weight | 442,6 |
| Assay | Content not less than 98 % |
| **Description** | White or yellowish, white powder with a citrus-like odour |
| **Identification** | |
| Melting point | About 116 °C |
| **Purity** | |
| Loss on drying | Not more than 2,0 % (vacuum oven, 56-60 °C, 1 hour) |
| Sulphated ash | Not more than 0,1 % |
| Arsenic | Not more than 3 mg/kg |

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

**E 306 TOCOPHEROL-RICH EXTRACT**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Product obtained by the vacuum steam distillation of edible vegetable oil products, comprising concentrated tocopherols and tocotrienols<br>Contains tocopherols such as d-α-, d-β-, d-γ- and d-δ-tocopherols |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | 430,71 (d-α-tocopherol) |
| Assay | Content not less than 34 % of total tocopherols |
| **Description** | Brownish red to red, clear, viscous oil having a mild, characteristic odour and taste. May show a slight separation of wax-like constituents in microcrystalline form |
| **Identification** | |
| By suitable gas liquid chromatographic method | |
| Specific rotation | $[\alpha]_D^{20}$ not less than + 20° |
| Solubility | Insoluble in water. Soluble in ethanol. Miscible in ether |
| **Purity** | |
| Sulphated ash | Not more than 0,1 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 307 ALPHA-TOCOPHEROL**

| | |
|---|---|
| **Synonyms** | dl-α-Tocopherol; (all rac)-α-Tocopherol |
| **Definition** | |
| Einecs | 233-466-0 |
| Chemical name | DL-5,7,8-Trimethyltocol; DL-2,5,7,8-tetramethyl-2-(4′,8′,12′-trimethyltridecyl)-6-chromanol |
| Chemical formula | $C_{29}H_{50}O_2$ |
| Molecular weight | 430,71 |
| Assay | Content not less than 96 % |
| **Description** | Slightly yellow to amber, nearly odourless, clear, viscous oil which oxidises and darkens on exposure to air or light |
| **Identification** | |
| Solubility | Insoluble in water, freely soluble in ethanol, miscible in ether |

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| Spectrophotometry | In absolute ethanol the maximum absorption is about 292 nm |
| Specific rotation | $[\alpha]_D^{25}$ 0° ± 0,05° (1 in 10 solution in chloroform) |
| **Purity** | |
| Refractive index | $[n]_D^{20}$ 1,503-1,507 |
| Specific absorption in ethanol | $E_{1cm}^{1\%}$ (292 nm) 71-76<br>(0,01 g in 200 ml of absolute ethanol) |
| Sulphated ash | Not more than 0,1 % |
| Lead | Not more than 2 mg/kg |

**E 308 GAMMA-TOCOPHEROL**

| | |
|---|---|
| **Synonyms** | dl-γ-Tocopherol |
| **Definition** | |
| Einecs | 231-523-4 |
| Chemical name | 2,7,8-trimethyl-2-(4′,8′,12′-trimethyltridecyl)-6-chromanol |
| Chemical formula | $C_{28}H_{48}O_2$ |
| Molecular weight | 416,69 |
| Assay | Content not less than 97 % |
| **Description** | Clear, viscous, pale yellow oil which oxidises and darkens on exposure to air or light |
| **Identification** | |
| Spectrometry | Maximum absorptions in absolute ethanol at about 298 nm and 257 nm |
| **Purity** | |
| Specific absorption in ethanol | $E_{1cm}^{1\%}$ (298 nm) between 91 and 97<br>$E_{1cm}^{1\%}$ (257 nm) between 5,0 and 8,0 |
| Refractive index | $[n]_D^{20}$ 1,503-1,507 |
| Sulphated ash | Not more than 0,1 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 309 DELTA-TOCOPHEROL**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 204-299-0 |
| Chemical name | 2,8-dimethyl-2-(4′,8′,12′-trimethyltridecyl)-6-chromanol |
| Chemical formula | $C_{27}H_{46}O_2$ |
| Molecular weight | 402,7 |
| Assay | Content not less than 97 % |
| **Description** | Clear, viscous, pale yellowish or orange oil which oxidises and darkens on exposure to air or light |

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|---|---|
| **Identification** | |
| Spectrometry | Maximum absorptions in absolute ethanol at about 298 nm and 257 nm |
| **Purity** | |
| Specific absorption $E^{1\%}_{1cm}$ in ethanol | $E^{1\%}_{1cm}$ (298 nm) between 89 and 95<br>$E^{1\%}_{1cm}$ (257 nm) between 3,0 and 6,0 |
| Refractive index | $[n]_D^{20}$ 1,500-1,504 |
| Sulphated ash | Not more than 0,1 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 310 PROPYL GALLATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 204-498-2 |
| Chemical name | Propyl gallate; Propyl ester of gallic acid; n-propyl ester of 3,4,5-trihydroxybenzoic acid |
| Chemical formula | $C_{10}H_{12}O_5$ |
| Molecular weight | 212,20 |
| Assay | Content not less than 98 % on the anhydrous basis |
| **Description** | White to creamy-white, crystalline, odourless solid |
| **Identification** | |
| Solubility | Slightly soluble in water, freely soluble in ethanol, ether and propane-1,2-diol |
| Melting range | Between 146 °C and 150 °C after drying at 110 °C for four hours |
| **Purity** | |
| Loss on drying | Not more than 0,5 % (110 °C, 4 hours) |
| Sulphated ash | Not more than 0,1 % |
| Free acid | Not more than 0,5 % (as gallic acid) |
| Chlorinated organic compound | Not more than 100 mg/kg (as C1) |
| Specific absorption in ethanol | $E^{1\%}_{1cm}$ (275 nm) not less than 485 and not more than 520 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

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**E 315 ERYTHORBIC ACID**

| | |
|---|---|
| **Synonyms** | Isoascorbic acid; D-Araboascorbic acid |
| **Definition** | |
| Einecs | 201-928-0 |
| Chemical name | D-Erythro-hex-2-enoic acid γ-lactone; Isoascorbic acid; D-Isoascorbic acid |
| Chemical formula | $C_6H_8O_6$ |
| Molecular weight | 176,13 |
| Assay | Content not less than 98 % on the anhydrous basis |
| **Description** | White to slightly yellow crystalline solid which darkens gradually on exposure to light |
| **Identification** | |
| Melting range | About 164 °C to 172 °C with decomposition |
| Test for ascorbic acid/colour reaction | Passes test |
| Specific rotation | $[\alpha]_D^{25}$ 10 % (w/v) aqueous solution between – 16,5° to – 18,0° |
| **Purity** | |
| Loss on drying | Not more than 0,4 % after drying under (reduced pressure on silica gel, 3 hours) |
| Sulphated ash | Not more than 0,3 % |
| Oxalate | To a solution of 1 g in 10 ml of water add 2 drops of glacial acetic acid and 5 ml of 10 % calcium acetate solution. The solution should remain clear |
| Lead | Not more than 2 mg/kg |

**E 316 SODIUM ERYTHORBATE**

| | |
|---|---|
| **Synonyms** | Sodium isoascorbate |
| **Definition** | |
| Einecs | 228-973-9 |
| Chemical name | Sodium isoascorbate; Sodium D-isoascorbic acid; Sodium salt of 2,3-didehydro-D-erythro-hexono-1,4-lactone; 3-keto-D-gulofurano-lactone sodium enolate monohydrate |
| Chemical formula | $C_6H_7O_6Na \cdot H_2O$ |
| Molecular weight | 216,13 |
| Assay | Content not less than 98 % after drying in a vacuum desiccator over sulphuric acid for 24 hours expressed on the monohydrate basis |

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| | |
|---|---|
| **Description** | White crystalline solid |
| **Identification** | |
| Solubility | Freely soluble in water, very slightly soluble in ethanol |
| Test for ascorbic acid/colour reaction | Passes test |
| Test for sodium | Passes test |
| pH | 5,5 to 8,0 (10 % aqueous solution) |
| Specific rotation | $[\alpha]_D^{25}$ 10 % (w/v) aqueous solution between + 95° and + 98° |
| **Purity** | |
| Loss on drying | Not more than 0,25 % after drying (in vacuum over sulphuric acid, 24 hours) |
| Oxalate | To a solution of 1 g in 10 ml of water add 2 drops of glacial acetic acid and 5 ml of 10 % calcium acetate solution. The solution should remain clear. |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 319 TERTIARY-BUTYLHYDROQUINONE (TBHQ)**

| | |
|---|---|
| **Synonyms** | TBHQ |
| **Definition** | |
| Einecs | 217-752-2 |
| Chemical name | Tert-butyl-1,4-benzenediol; 2-(1,1-Dimethylethyl)-1,4-benzenediol |
| Chemical formula | $C_{10}H_{14}O_2$ |
| Molecular weight | 166,22 |
| Assay | Content not less than 99 % of $C_{10}H_{14}O_2$ |
| **Description** | White crystalline solid having a characteristic odour |
| **Identification** | |
| Solubility | Practically insoluble in water; soluble in ethanol |
| Melting point | Not less than 126,5 °C |
| Phenolics | Dissolve about 5 mg of the sample in 10 ml of methanol and add 10,5 ml of dimethylamine solution (1 in 4). A red to pink colour is produced |
| **Purity** | |
| Tertiary-Butyl-*p*-benzoquinone | Not more than 0,2 % |
| 2,5-Di-tertiary-butyl hydroquinone | Not more than 0,2 % |
| Hydroxyquinone | Not more than 0,1 % |
| Toluene | Not more than 25 mg/kg |
| Lead | Not more than 2 mg/kg |

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**E 320 BUTYLATED HYDROXYANISOLE (BHA)**

| | |
|---|---|
| **Synonyms** | BHA |
| **Definition** | |
| Einecs | 246-563-8 |
| Chemical name | 3-Tertiary-butyl-4-hydroxyanisole; A mixture of 2-tertiary-butyl-4-hydroxyanisole and 3-tertiary-butyl-4-hydroxyanisole |
| Chemical formula | $C_{11}H_{16}O_2$ |
| Molecular weight | 180,25 |
| Assay | 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 |
| **Description** | White or slightly yellow flakes or waxy solid with a slight aromatic smell |
| **Identification** | |
| Solubility | Insoluble in water, freely soluble in ethanol |
| Melting range | Between 48 °C and 63 °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 | $E^{1\%}_{1cm}$ (290 nm) not less than 190 and not more than 210<br>$E^{1\%}_{1cm}$ (228 nm) not less than 326 and not more than 345 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 321 BUTYLATED HYDROXYTOLUENE (BHT)**

| | |
|---|---|
| **Synonyms** | BHT |
| **Definition** | |
| Einecs | 204-881-4 |
| Chemical name | 2,6-Ditertiary-butyl-*p*-cresol; 4-Methyl-2,6-ditertiarybutylphenol |
| Chemical formula | $C_{15}H_{24}O$ |
| Molecular weight | 220,36 |
| Assay | Content not less than 99 % |
| **Description** | White, crystalline or flaked solid, odourless or having a characteristic faint aromatic odour |
| **Identification** | |
| Solubility | Insoluble in water and propane- 1,2-diol<br>Freely soluble in ethanol |
| Melting point | At 70 °C |

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|---|---|
| Spectrometry | The absorption in the range 230 to 320 nm of a 2 cm layer of a 1 in 100 000 solution in dehydrated ethanol exhibits a maximum only at 278 nm |
| **Purity** | |
| Sulphated ash | Not more than 0,005 % |
| Phenolic impurities | Not more than 0,5 % |
| Specific absorption in ethanol | $E^{1\%}_{1cm}$ (278 nm) not less than 81 and not more than 88 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 322 LECITHINS**

| | |
|---|---|
| **Synonyms** | Phosphatides; Phospholipids |
| **Definition** | Lecithins are mixtures or fractions of phosphatides obtained by physical procedures from animal or vegetable foodstuffs; they also include hydrolysed products obtained through the use of harmless and appropriate enzymes. The final product must not show any signs of residual enzyme activity<br>The lecithins may be slightly bleached in aqueous medium by means of hydrogen peroxide. This oxidation must not chemically modify the lecithin phosphatides |
| Einecs | 232-307-2 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Lecithins: not less than 60,0 % of substances insoluble in acetone<br>Hydrolysed lecithins: not less than 56,0 % of substances insoluble in acetone |
| **Description** | Lecithins: brown liquid or viscous semi-liquid or powder<br>Hydrolysed lecithins: light brown to brown viscous liquid or paste |
| **Identification** | |
| Test for choline | Passes test |
| Test for phosphorus | Passes test |
| Test for fatty acids | Passes test |
| Test for hydrolysed lecithin | To a 800 ml beaker add 500 ml of water (30-35 °C). Then slowly add 50 ml of the sample with constant stirring. Hydrolysed lecithin will form a homogeneous emulsion. Non-hydrolysed lecithin will form a distinct mass of about 50 g |
| **Purity** | |
| Loss on drying | Not more than 2,0 % (105 °C, 1 hour) |
| Toluene-insoluble matter | Not more than 0,3 % |

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| | |
|---|---|
| Acid value | Lecithins: not more than 35 mg of potassium hydroxide per gram<br>Hydrolysed lecithins: not more than 45 mg of potassium hydroxide per gram |
| Peroxide value | Equal to or less than 10 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

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**E 322a OAT LECITHIN**

| | |
|---|---|
| **Synonyms** | Fractionated oat oil |
| **Definition** | Oat lecithin is a fractionated oat oil rich in polar lipids, mainly galactolipids. Oat lecithin is produced from food grade oat kernels that are sieved and extracted using ethanol at an elevated temperature to produce a crude lipid extract. This crude extract undergoes multistage evaporation and filtration, yielding crude oat oil, which is separated, evaporated and filtered to produce oat lecithin.<br>Only ethanol may be used in the extraction as extraction solvent. |
| Einecs | 281-672-4 |
| Assay | Not less than 30 % of polar lipids insoluble in acetone |
| **Description** | Yellowish-brown viscous liquid |
| **Identification** | |
| Choline | Not more than 2 g/100 g |
| Phosphorous | Not less than 0,5 % |
| Polar lipids | Not less than 35 % w/w |
| Neutral lipids | 55–65 % w/w |
| Saturated | 17–20 % w/w |
| Monounsaturated | 38–42 % w/w |
| Polyunsaturated | 38–42 % w/w |
| **Purity** | |
| Loss of drying | Not more than 2 % |
| Toluene-insoluble matter | Not more than 1 % w/w |
| Acid value | Not more than 30 mg KOH/g |
| Peroxide value | less than 10 meq O2/kg fat |
| Solvent residues | Ethanol: not more than 300 mg/kg |
| Arsenic | Not more than 0,1 mg/kg |
| Lead | Not more than 0,05 mg/kg |
| Mercury | Not more than 0,02 mg/kg |
| Cadmium | Not more than 0,05 mg/kg |

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| | |
|---|---|
| **Microbiological criteria** | |
| Aerobic plate count | Not more than 1 000 CFU/g |
| Yeast | Not more than 100 CFU/g |
| Moulds | Not more than 100 CFU/g |
| Enterobacteriaceae | Not more than 10 CFU/g |
| Aerobic spores | Not more than 1 CFU/g |
| **Other** | |
| Gluten | Not more than 20 mg/kg |

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**E 325 SODIUM LACTATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 200-772-0 |
| Chemical name | Sodium lactate; Sodium 2-hydroxypropanoate |
| Chemical formula | $C_3H_5NaO_3$ |
| Molecular weight | 112,06 (anhydrous) |
| Assay | Content not less than 57 % and not more than 66 % |
| **Description** | Colourless, transparent, liquid. Odourless, or with a slight, characteristic odour |
| **Identification** | |
| Test for lactate | Passes test |

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|---|---|
| Test for sodium | Passes test |

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| | |
|---|---|
| pH | 6,5 to 7,5 (20 % aqueous solution) |
| **Purity** | |
| Acidity | Not more than 0,5 % after drying expressed as lactic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Reducing substances | No reduction of Fehling's solution |

*Note:* This specification refers to a 60 % aqueous solution

**E 326 POTASSIUM LACTATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 213-631-3 |
| Cheminal name | Potassium lactate; Potassium 2-hydroxypropanoate |
| Chemical formula | $C_3H_5O_3K$ |
| Molecular weight | 128,17 (anhydrous) |
| Assay | Content not less than 57 % and not more than 66 % |

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|---|---|
| **Description** | Slightly viscous, almost odourless clear liquid. Odourless, or with a slight, characteristic odour |
| **Identification** | |
| Ignition | Ignite potassium lactate solution to an ash. The ash is alkaline, and an effervescence occurs when acid is added |
| Colour reaction | Overlay 2 ml of potassium lactate solution on 5 ml of a 1 in 100 solution of catechol in sulphuric acid. A deep red colour is produced at the zone of contact |
| Test for potassium | Passes test |
| Test for lactate | Passes test |
| **Purity** | |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Acidity | Dissolve 1 g of potassium lactate solution in 20 ml of water, add 3 drops of phenolphthalein TS and titrate with 0,1 N sodium hydroxide. Not more than 0,2 ml should be required |
| Reducing substances | No reduction of Fehling's solution |

*Note:* This specification refers to a 60 % aqueous solution

**E 327 CALCIUM LACTATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 212-406-7 |
| Chemical name | Calcium dilactate; Calcium dilactate hydrate; 2-Hydroxypropanoic acid calcium salt |
| Chemical formula | $(C_3H_5O_2)_2$ Ca·n$H_2O$ (n = 0 - 5) |
| Molecular weight | 218,22 (anhydrous) |
| Assay | Content not less than 98 % on the anhydrous basis |
| **Description** | Almost odourless, white crystalline powder or granules |
| **Identification** | |
| Test for lactate | Passes test |
| Test for calcium | Passes test |
| Solubility | Soluble in water and practically insoluble in ethanol |
| pH | Between 6,0 and 8,0 (5 % solution) |
| **Purity** | |
| Loss on drying | anhydrous: not more than 3,0 % (120 °C, 4 hours)<br>with 1 molecule of water: not more than 8,0 % (120 °C, 4 hours)<br>with 3 molecules of water: not more than 20,0 % (120 °C, 4 hours)<br>with 4,5 molecules of water: not more than 27,0 % (120 °C, 4 hours) |
| Acidity | Not more than 0,5 % of the dry matter expressed as lactic acid |

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| | |
|---|---|
| Fluoride | Not more than 30 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Reducing substances | No reduction of Fehling's solution |

**E 330 CITRIC ACID**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Citric acid is produced from lemon or pineapple juice, by fermentation of carbohydrate solutions or other suitable media using *Candida* spp. or non-toxicogenic strains of *Aspergillus niger* |
| Einecs | 201-069-1 |
| Chemical name | Citric acid; 2-Hydroxy-1,2,3-propanetricarboxylic acid; β-Hydroxytricarballylic acid |
| Chemical formula | (a) $C_6H_8O_7$ (anhydrous)<br>(b) $C_6H_8O_7$·H2O (monohydrate) |
| Molecular weight | (a) 192,13 (anhydrous)<br>(b) 210,15 (monohydrate) |
| Assay | Citric acid may be anhydrous or it may contain 1 molecule of water. Citric acid contains not less than 99,5 % of $C_6H_8O_7$, calculated on the anhydrous basis |
| **Description** | Citric acid is a white or colourless, odourless, crystalline solid, having a strongly acid taste. The monohydrate effloresces in dry air |
| **Identification** | |
| Solubility | Very soluble in water; freely soluble in ethanol; soluble in ether |
| **Purity** | |
| Water content | Anhydrous citric acid contains not more than 0,5 % water; citric acid monohydrate contains not more than 8,8 % water (Karl Fischer method) |
| Sulphated ash | Not more than 0,05 % after calcination at 800 ± 25 °C |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 0,5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Oxalates | Not more than 100 mg/kg, expressed as oxalic acid, after drying |
| Readily carbonisable substances | Heat 1 g of powdered sample with 10 ml of 98 % minimum sulphuric acid in a water bath at 90 °C in the dark for one hour. Not more than a pale brown colour should be produced (Matching Fluid K) |

▼B

**E 331 (i) MONOSODIUM CITRATE**

| | |
|---|---|
| **Synonyms** | Monobasic sodium citrate |
| **Definition** | |
| Einecs | 242-734-6 |
| Chemical name | Monosodium citrate; Monosodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid |
| Chemical formula | (a) $C_6H_7O_7Na$ (anhydrous)<br>(b) $C_6H_7O_7Na \cdot H_2O$ (monohydrate) |
| Molecular weight | (a) 214,11 (anhydrous)<br>(b) 232,23 (monohydrate) |
| Assay | Content not less than 99 % on the anhydrous basis |
| **Description** | Crystalline white powder or colourless crystals |
| **Identification** | |
| Test for citrate | Passes test |
| Test for sodium | Passes test |
| pH | Between 3,5 and 3,8 (1 % aqueous solution) |
| **Purity** | |
| Loss on drying | anhydrous: not more than 1,0 % (140 °C, 0,5 hour)<br>monohydrate: not more than 8,8 % (180 °C, 4 hours) |
| Oxalates | Not more than 100 mg/kg expressed as oxalic acid, after drying |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 331 (ii) DISODIUM CITRATE**

| | |
|---|---|
| **Synonyms** | Dibasic sodium citrate |
| **Definition** | |
| Einecs | 205-623-3 |
| Chemical name | Disodium citrate; Disodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid; Disodium salt of citric acid with 1,5 molecules of water |
| Chemical formula | $C_6H_6O_7Na_2 \cdot 1{,}5H_2O$ |
| Molecular weight | 263,11 |
| Assay | Content not less than 99 % on the anhydrous basis |
| **Description** | Crystalline white powder or colourless crystals |
| **Identification** | |
| Test for citrate | Passes test |
| Test for sodium | Passes test |
| pH | Between 4,9 and 5,2 (1 % aqueous solution) |

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| | |
|---|---|
| **Purity** | |
| Loss on drying | Not more than 13,0 % (180 °C, 4 hours) |
| Oxalates | Not more than 100 mg/kg expressed as oxalic acid, after drying |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 331 (iii) TRISODIUM CITRATE**

| | |
|---|---|
| **Synonyms** | Tribasic sodium citrate |
| **Definition** | |
| Einecs | 200-675-3 |
| Chemical name | Trisodium citrate; Trisodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid; Trisodium salt of citric acid, in anhydrous, dihydrate or pentahydrate form |
| Chemical formula | Anhydrous: $C_6H_5O_7Na_3$<br>Hydrated: $C_6H_5O_7Na_3 \cdot nH_2O$ (n = 2 or 5) |
| Molecular weight | 258,07 (anhydrous)<br>294,10 (hydrated n = 2)<br>348,16 (hydrated n = 5) |
| Assay | Not less than 99 % on the anhydrous basis |
| **Description** | Crystalline white powder or colourless crystals |
| **Identification** | |
| Test for citrate | Passes test |
| Test for sodium | Passes test |
| pH | Between 7,5 and 9,0 (5 % aqueous solution) |
| **Purity** | |
| Loss of drying | Anhydrous: not more than 1,0 % (180 °C, 18 hours)<br>Dihydrate: 10,0 to 13,0 % (180 °C, 18 hours)<br>Pentahydrate: not more than 30,3 % (180 °C, 4 hours) |
| Oxalates | Not more than 100 mg/kg expressed as oxalic acid, after drying |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 332 (i) MONOPOTASSIUM CITRATE**

| | |
|---|---|
| **Synonyms** | Monobasic potassium citrate |
| **Definition** | |
| Einecs | 212-753-4 |
| Chemical name | Monopotassium citrate; Monopotassium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid; Anhydrous monopotassium salt of citric acid |

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| | |
|---|---|
| Chemical formula | $C_6H_7O_7K$ |
| Molecular weight | 230,21 |
| Assay | Content not less than 99 % on the anhydrous basis |
| **Description** | White, hygroscopic, granular powder or transparent crystals |
| **Identification** | |
| Test for citrate | Passes test |
| Test for potassium | Passes test |
| pH | Between 3,5 and 3,8 (1 % aqueous solution) |
| **Purity** | |
| Loss on drying | Not more than 1,0 % (180 °C, 4 hours) |
| Oxalates | Not more than 100 mg/kg expressed as oxalic acid, after drying |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 332 (ii) TRIPOTASSIUM CITRATE**

| | |
|---|---|
| **Synonyms** | Tribasic potassium citrate |
| **Definition** | |
| Einecs | 212-755-5 |
| Chemical name | Tripotassium citrate; Tripotassium salt of 2-hydroxy-1,2,3-propane-tricarboxylic acid; Monohydrated tripotassium salt of citric acid |
| Chemical formula | $C_6H_5O_7K_3 \cdot H_2O$ |
| Molecular weight | 324,42 |
| Assay | Content not less than 99 % on the anhydrous basis |
| **Description** | White, hygroscopic, granular powder or transparent crystals |
| **Identification** | |
| Test for citrate | Passes test |
| Test for potassium | Passes test |
| pH | Between 7,5 and 9,0 (5 % aqueous solution) |
| **Purity** | |
| Loss on drying | Not more than 6,0 % (180 °C, 4 hours) |
| Oxalates | Not more than 100 mg/kg (expressed as oxalic acid, after drying) |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

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**E 333 (i) MONOCALCIUM CITRATE**

| | |
|---|---|
| **Synonyms** | Monobasic calcium citrate |
| **Definition** | |
| Einecs | |
| Chemical name | Monocalcium citrate; Monocalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid; Monohydrate monocalcium salt of citric acid |
| Chemical formula | $(C_6H_7O_7)_2Ca \cdot H_2O$ |
| Molecular weight | 440,32 |
| Assay | Content not less than 97,5 % on the anhydrous basis |
| **Description** | Fine white powder |
| **Identification** | |
| Test for citrate | Passes test |
| Test for calcium | Passes test |
| pH | Between 3,2 and 3,5 (1 % aqueous solution) |
| **Purity** | |
| Loss on drying | Not more than 7,0 % (180 °C, 4 hours) |
| Oxalates | Not more than 100 mg/kg (expressed as oxalic acid, after drying) |
| Fluoride | Not more than 30 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Aluminium | Not more than 30 mg/kg (only if added to food for infants and young children)<br>Not more than 200 mg/kg (for all uses except food for infants and young children) |
| Carbonates | Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles |

**E 333 (ii) DICALCIUM CITRATE**

| | |
|---|---|
| **Synonyms** | Dibasic calcium citrate |
| **Definition** | |
| Einecs | |
| Chemical name | Dicalcium citrate; Dicalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid; Trihydrated dicalcium salt of citric acid |
| Chemical formula | $(C_6H_7O_7)_2Ca_2 \cdot 3H_2O$ |
| Molecular weight | 530,42 |
| Assay | Not less than 97,5 % on the anhydrous basis |
| **Description** | Fine white powder |

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| | |
|---|---|
| **Identification** | |
| Test for citrate | Passes test |
| Test for calcium | Passes test |
| **Purity** | |
| Loss on drying | Not more than 20,0 % (180 °C, 4 hours) |
| Oxalates | Not more than 100 mg/kg (expressed as oxalic acid, after drying) |
| Fluoride | Not more than 30 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Aluminium | Not more than 30 mg/kg (only if added to food for infants and young children)<br>Not more than 200 mg/kg (for all uses except food for infants and young children) |
| Carbonates | Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles |

**E 333 (iii) TRICALCIUM CITRATE**

| | |
|---|---|
| **Synonyms** | Tribasic calcium citrate |
| **Definition** | |
| Einecs | 212-391-7 |
| Chemical name | Tricalcium citrate; Tricalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid; Tetrahydrated tricalcium salt of citric acid |
| Chemical formula | $(C_6H_6O_7)_2Ca_3 \cdot 4H_2O$ |
| Molecular weight | 570,51 |
| Assay | Not less than 97,5 % on the anhydrous basis |
| **Description** | Fine white powder |
| **Identification** | |
| Test for citrate | Passes test |
| Test for calcium | Passes test |
| **Purity** | |
| Loss on drying | Not more than 14,0 % (180 °C, 4 hours) |
| Oxalates | Not more than 100 mg/kg (expressed as oxalic acid, after drying) |
| Fluoride | Not more than 30 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

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| | |
|---|---|
| Aluminium | Not more than 30 mg/kg (only if added to food for infants and young children)<br>Not more than 200 mg/kg (for all uses except food for infants and young children) |
| Carbonates | Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles |

**E 334 L(+)-TARTARIC ACID, TARTARIC ACID**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 201-766-0 |
| Chemical name | L-tartaric acid; L-2,3-dihydroxybutanedioic acid; d-α,β-dihydroxy-succinic acid |
| Chemical formula | $C_4H_6O_6$ |
| Molecular weight | 150,09 |
| Assay | Content not less than 99,5 % on the anhydrous basis |
| **Description** | Colourless or translucent crystalline solid or white crystalline powder |
| **Identification** | |
| Melting range | Between 168 °C and 170 °C |
| Test for tartrate | Passes test |
| Specific rotation | $[\alpha]_D^{20}$ between + 11,5° and + 13,5° (20 % w/v aqueous solution) |
| **Purity** | |
| Loss on drying | Not more than 0,5 % (over $P_2O_5$, 3 hours) |
| Sulphated ash | Not more than 1 000 mg/kg (after calcination at 800 ± 25 °C) |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Oxalates | Not more than 100 mg/kg expressed as oxalic acid, after drying |

**E 335 (i) MONOSODIUM TARTRATE**

| | |
|---|---|
| **Synonyms** | Monosodium salt of L-(+)-tartaric acid |
| **Definition** | |
| Einecs | |
| Chemical name | Monosodium salt of L-2,3-dihydroxybutanedioic acid; Monohydrated monosodium salt of L-(+)-tartaric acid |
| Chemical formula | $C_4H_5O_6Na{\cdot}H_2O$ |
| Molecular weight | 194,05 |
| Assay | Content not less than 99 % on the anhydrous basis |
| **Description** | Transparent colourless crystals |

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| | |
|---|---|
| **Identification** | |
| Test for tartrate | Passes test |
| Test for sodium | Passes test |
| **Purity** | |
| Loss on drying | Not more than 10,0 % (105 °C, 4 hours) |
| Oxalates | Not more than 100 mg/kg (expressed as oxalic acid, after drying) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 335 (ii) DISODIUM TARTRATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 212-773-3 |
| Chemical name | Disodium L-tartrate; Disodium (+)-tartrate; Disodium salt of (+)-2,3-dihydroxybutanedioic acid; Dihydrated disodium salt of L-(+)-tartaric acid |
| Chemical formula | $C_4H_4O_6Na_2 \cdot 2H_2O$ |
| Molecular weight | 230,8 |
| Assay | Content not less than 99 % on the anhydrous basis |
| **Description** | Transparent, colourless crystals |
| **Identification** | |
| Test for tartrate | Passes test |
| Test for sodium | Passes test |
| Solubility | 1 gram is insoluble in 3 ml of water. Insoluble in ethanol |
| pH | Between 7,0 and 7,5 (1 % aqueous solution) |
| **Purity** | |
| Loss on drying | Not more than 17,0 % (150 °C, 4 hours) |
| Oxalates | Not more than 100 mg/kg (expressed as oxalic acid, after drying) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 336 (i) MONOPOTASSIUM TARTRATE**

| | |
|---|---|
| **Synonyms** | Monobasic potassium tartrate |
| **Definition** | |
| Einecs | |
| Chemical name | Anhydrous monopotassium salt of L-(+)-tartaric acid; Monopotassium salt of L-2,3-dihydroxybutanedioic acid |

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| | |
|---|---|
| Chemical formula | $C_4H_5O_6K$ |
| Molecular weight | 188,16 |
| Assay | Content not less than 98 % on the anhydrous basis |
| **Description** | White crystalline or granulated powder |
| **Identification** | |
| Test for tartrate | Passes test |
| Test for potassium | Passes test |
| Melting point | 230 °C |
| pH | 3,4 (1 % aqueous solution) |
| **Purity** | |
| Loss on drying | Not more than 1,0 % (105 °C, 4 hours) |
| Oxalates | Not more than 100 mg/kg (expressed as oxalic acid, after drying) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 336 (ii) DIPOTASSIUM TARTRATE**

| | |
|---|---|
| **Synonyms** | Dibasic potassium tartrate |
| **Definition** | |
| Einecs | 213-067-8 |
| Chemical name | Dipotassium salt of L-2,3-dihydroxybutanedioic acid; Dipotassium salt with half a molecule of water of L-(+)-tartaric acid |
| Chemical formula | $C_4H_4O_6K_2 \cdot ½H_2O$ |
| Molecular weight | 235,2 |
| Assay | Content not less than 99 % on the anhydrous basis |
| **Description** | White crystalline or granulated powder |
| **Identification** | |
| Test for tartrate | Passes test |
| Test for potassium | Passes test |
| pH | Between 7,0 and 9,0 (1 % aqueous solution) |
| **Purity** | |
| Loss on drying | Not more than 4,0 % (150 °C, 4 hours) |
| Oxalates | Not more than 100 mg/kg (expressed as oxalic acid, after drying) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

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**E 337 POTASSIUM SODIUM TARTRATE**

| | |
|---|---|
| **Synonyms** | Potassium sodium L-(+)-tartrate; Rochelle salt; Seignette salt |
| **Definition** | |
| Einecs | 206-156-8 |
| Chemical name | Potassium sodium salt of L-2,3-dihydroxybutanedioic acid; Potassium sodium L-(+)-tartrate |
| Chemical formula | $C_4H_4O_6KNa{\cdot}4H_2O$ |
| Molecular weight | 282,23 |
| Assay | Content not less than 99 % on the anhydrous basis |
| **Description** | Colourless crystals or white crystalline powder |
| **Identification** | |
| Test for tartrate | Passes test |
| Test for potassium | Passes test |
| Test for sodium | Passes test |
| Solubility | 1 gram is soluble in 1 ml of water, insoluble in ethanol |
| Melting range | 70-80 °C |
| pH | Between 6,5 and 8,5 (1 % aqueous solution) |
| **Purity** | |
| Loss on drying | Not more than 26,0 % and not less than 21,0 % (150 °C, 3 hours) |
| Oxalates | Not more than 100 mg/kg (expressed as oxalic acid, after drying) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 338 PHOSPHORIC ACID**

| | |
|---|---|
| **Synonyms** | Orthophosphoric acid; Monophosphoric acid |
| **Definition** | |
| Einecs | 231-633-2 |
| Chemical name | Phosphoric acid |
| Chemical formula | $H_3PO_4$ |
| Molecular weight | 98,00 |
| Assay | Content not less than 67,0 % and not more than 85,7 %. Phosphoric acid is commercially available as an aqueous solution at variable concentrations. |
| **Description** | Clear, colourless, viscous liquid |
| **Identification** | |
| Test for acid | Passes test |
| Test for phosphate | Passes test |

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|---|---|
| **Purity** | |
| Volatile acids | Not more than 10 mg/kg (as acetic acid) |
| Chlorides | Not more than 200 mg/kg (expressed as chlorine) |
| Nitrates | Not more than 5 mg/kg (as $NaNO_3$) |
| Sulphates | Not more than 1 500 mg/kg (as $CaSO_4$) |
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1 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** | |
| Einecs | 231-449-2 |
| Chemical name | Sodium dihydrogen monophosphate |
| Chemical formula | Anhydrous: $NaH_2PO_4$<br>Monohydrate: $NaH_2PO_4 \cdot H_2O$<br>Dihydrate: $NaH_2PO_4 \cdot 2H_2O$ |
| Molecular weight | Anhydrous: 119,98<br>Monohydrate: 138,00<br>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 $NaH_2PO_4$<br>$P_2O_5$ content between 58,0 % and 60,0 % on the anhydrous basis |
| **Description** | A white odourless, slightly deliquescent powder, crystals or granules |
| **Identification** | |
| Test for sodium | Passes test |
| Test for phosphate | Passes test |
| Solubility | Freely soluble in water. Insoluble in ethanol or ether |
| pH | Between 4,1 and 5,0 (1 % solution) |
| **Purity** | |
| Loss on drying | The anhydrous salt loses not more than 2,0 %, the monohydrate not more than 15,0 %, the dihydrate not more than 25 % (60 °C, 1 hour then 105 °C, 4 hours) |
| Water insoluble matter | Not more than 0,2 % on the anhydrous basis |
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |

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

**E 339 (ii) DISODIUM PHOSPHATE**

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

**E 339 (iii) TRISODIUM PHOSPHATE**

| | |
|---|---|
| **Synonyms** | Sodium phosphate; Tribasic sodium phosphate; Trisodium orthophosphate |

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| | |
|---|---|
| **Definition** | Trisodium phosphate is obtained from aqueous solutions and crystallises in the anhydrous form and with 1/2, 1, 6, 8 or 12 $H_2O$. The dodecahydrate always crystallises from aqueous solutions with an excess of sodium hydroxide. It contains ¼ molecule of NaOH |
| Einecs | 231-509-8 |
| Chemical name | Trisodium monophosphate; Trisodium phosphate; Trisodium orthophosphate |
| Chemical formula | Anhydrous: $Na_3PO_4$<br>Hydrated: $Na_3PO_4$ $nH_2O$ (n = 1/2, 1, 6, 8, or 12) |
| Molecular weight | 163,94 (anhydrous) |
| Assay | Sodium phosphate anhydrous and the hydrated forms, with the exception of the dodecahydrate, contain not less than 97,0 % of $Na_3PO_4$ calculated on the dried basis. Sodium phosphate dodecahydrate contains not less than 92,0 % of $Na_3PO_4$ calculated on the ignited basis<br>$P_2O_5$ content between 40,5 % and 43,5 % on the anhydrous basis |
| **Description** | White odourless crystals, granules or crystalline powder |
| **Identification** | |
| Test for sodium | Passes test |
| Test for phosphate | Passes test |
| Solubility | Freely soluble in water. Insoluble in ethanol |
| pH | Between 11,5 and 12,5 (1 % solution) |
| **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 matter | Not more than 0,2 % on the anhydrous basis |
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 340 (i) MONOPOTASSIUM PHOSPHATE**

| | |
|---|---|
| **Synonyms** | Monobasic potassium phosphate; Monopotassium monophosphate; Mono potassium orthophosphate |
| **Definition** | |
| Einecs | 231-913-4 |
| Chemical name | Potassium dihydrogen phosphate; Monopotassium dihydrogen orthophosphate; Monopotassium dihydrogen monophosphate |
| Chemical formula | $KH_2PO_4$ |
| Molecular weight | 136,09 |

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| | |
|---|---|
| Assay | Content not less than 98,0 % after drying at 105 °C for four hours<br>$P_2O_5$ content between 51,0 % and 53,0 % on the anhydrous basis |
| **Description** | Odourless, colourless crystals or white granular or crystalline powder |
| **Identification** | |
| Test for potassium | Passes test |
| Test for phosphate | Passes test |
| Solubility | Freely soluble in water. Insoluble in ethanol |
| pH | Between 4,2 and 4,8 (1 % solution) |
| **Purity** | |
| Loss on drying | Not more than 2,0 % (105 °C, 4 hours) |
| Water insoluble matter | Not more than 0,2 % on the anhydrous basis |
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 340 (ii) DIPOTASSIUM PHOSPHATE**

| | |
|---|---|
| **Synonyms** | Dipotassium monophosphate; Secondary potassium phosphate; Dipotassium orthophosphate; Dibasic potassium phosphate |
| **Definition** | |
| Einecs | 231-834-5 |
| Chemical name | Dipotassium hydrogen monophosphate; Dipotassium hydrogen phosphate; Dipotassium hydrogen orthophosphate |
| Chemical formula | $K_2HPO_4$ |
| Molecular weight | 174,18 |
| Assay | Content not less than 98 % after drying at 105 °C for four hours<br>$P_2O_5$ content between 40,3 % and 41,5 % on the anhydrous basis |
| **Description** | Colourless or white granular powder, crystals or masses; deliquescent substance, hygroscopic |
| **Identification** | |
| Test for potassium | Passes test |
| Test for phosphate | Passes test |
| Solubility | Freely soluble in water. Insoluble in ethanol |
| pH | Between 8,7 and 9,4 (1 % solution) |
| **Purity** | |
| Loss on drying | Not more than 2,0 % (105 °C, 4 hours) |

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| | |
|---|---|
| Water insoluble matter | Not more than 0,2 % (on the anhydrous basis) |
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 340 (iii) TRIPOTASSIUM PHOSPHATE**

| | |
|---|---|
| **Synonyms** | Tribasic potassium phosphate; Tripotassium orthophosphate |
| **Definition** | |
| Einecs | 231-907-1 |
| Chemical name | Tripotassium monophosphate; Tripotassium phosphate; Tripotassium orthophosphate |
| Chemical formula | Anhydrous: $K_3PO_4$<br>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<br>$P_2O_5$ content between 30,5 % and 34,0 % on the ignited basis |
| **Description** | Colourless or white, odourless hygroscopic crystals or granules. Hydrated forms available include the monohydrate and trihydrate |
| **Identification** | |
| Test for potassium | Passes test |
| Test for phosphate | Passes test |
| Solubility | Freely soluble in water. Insoluble in ethanol |
| pH | Between 11,5 and 12,3 (1 % solution) |
| **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 matter | Not more than 0,2 % (on the anhydrous basis) |
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 341 (i) MONOCALCIUM PHOSPHATE**

| | |
|---|---|
| **Synonyms** | Monobasic calcium phosphate; Monocalcium orthophosphate |
| **Definition** | |
| Einecs | 231-837-1 |

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| | |
|---|---|
| Chemical name | Calcium dihydrogen phosphate |
| Chemical formula | Anhydrous: $Ca(H_2PO_4)_2$<br>Monohydrate: $Ca(H_2PO_4)_2 \cdot H_2O$ |
| Molecular weight | 234,05 (anhydrous)<br>252,08 (monohydrate) |
| Assay | Content not less than 95 % on the dried basis<br>$P_2O_5$ content between 55,5 % and 61,1 % on the anhydrous basis |
| **Description** | Granular powder or white, deliquescent crystals or granules |
| **Identification** | |
| Test for calcium | Passes test |
| Test for phosphate | Passes test |
| CaO content | Between 23,0 % and 27,5 % (anhydrous)<br>Between 19,0 % and 24,8 % (monohydrate) |
| **Purity** | |
| Loss on drying | Anhydrous: not more than 14 % (105 °C, 4 hours)<br>Monohydrate: not more than 17,5 % (105 °C, 4 hours) |
| Loss on ignition | Anhydrous: not more than 17,5 % (after ignition at 800 °C ± 25 °C for 30 minutes)<br>Monohydrate: not more than 25,0 % (determined by drying at 105 °C for one hour, then ignite at 800 °C ± 25 °C for 30 minutes) |
| Fluoride | Not more than 30 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Aluminium | Not more than 70 mg/kg (only if added to food for infants and young children)<br>Not more than 200 mg/kg (for all uses except food for infants and young children) |

**E 341 (ii) DICALCIUM PHOSPHATE**

| | |
|---|---|
| **Synonyms** | Dibasic calcium phosphate; Dicalcium orthophosphate |
| **Definition** | |
| Einecs | 231-826-1 |
| Chemical name | Calcium monohydrogen phosphate; Calcium hydrogen orthophosphate; Secondary calcium phosphate |
| Chemical formula | Anhydrous: $CaHPO_4$<br>Dihydrate: $CaHPO_4 \cdot 2H_2O$ |
| Molecular weight | 136,06 (anhydrous)<br>172,09 (dihydrate) |

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|---|---|
| Assay | Dicalcium phosphate, after drying at 200 °C for three hours, contains not less than 98 % and not more than the equivalent of 102 % of $CaHPO_4$ |
| | $P_2O_5$ content between 50,0 % and 52,5 % on the anhydrous basis |
| **Description** | White crystals or granules, granular powder or powder |
| **Identification** | |
| Test for calcium | Passes test |
| Test for phosphate | Passes test |
| Solubility | 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 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Aluminium | Not more than 100 mg/kg for the anhydrous form and not more than 80 mg/kg for the dihydrated form (only if added to food for infants and young children) |
| | Not more than 600 mg/kg for the anhydrous form and not more than 500 mg/kg for the dihydrated form (for all uses except food for infants and young children). This applies until 31 March 2015. |
| | Not more than 200 mg/kg for the anhydrous form and the dihydrated form (for all uses except food for infants and young children). This applies from 1 April 2015. |

**E 341 (iii) TRICALCIUM PHOSPHATE**

| | |
|---|---|
| **Synonyms** | Calcium phosphate, tribasic; Calcium orthophosphate; Pentacalcium hydroxy monophosphate; Calcium hydroxyapatite |

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| | |
|---|---|
| **Definition** | Tricalcium phosphate consists of a variable mixture of calcium phosphates obtained from neutralisation of phosphoric acid with calcium hydroxide or calcium carbonate and having the approximate composition of $10CaO{\cdot}3P_2O_5{\cdot}H_2O$ |

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| | |
|---|---|
| Einecs | 235-330-6 (Pentacalcium hydroxy monophosphate) |
| | 231-840-8 (Calcium orthophosphate) |
| Chemical name | Pentacalcium hydroxy monophosphate; Tricalcium monophosphate |
| Chemical formula | $Ca_5(PO_4)_3 \cdot OH$ or $Ca_3(PO_4)_2$ |
| Molecular weight | 502 or 310 |
| Assay | Content not less than 90 % calculated on the ignited basis |
| | $P_2O_5$ content between 38,5 % and 48,0 % on the anhydrous basis |
| **Description** | A white, odourless powder which is stable in air |

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| | |
|---|---|
| **Identification** | |
| Test for calcium | Passes test |
| Test for phosphate | Passes test |
| 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 °C ± 25 °C for 0,5 hour |
| Fluoride | Not more than 50 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Aluminium | Not more than 150 mg/kg (only if added to food for infants and young children)<br>Not more than 500 mg/kg (for all uses except food for infants and young children). This applies until 31 March 2015<br>Not more than 200 mg/kg (for all uses except food for infants and young children). This applies from 1 April 2015. |

**E 343 (i) MONOMAGNESIUM PHOSPHATE**

| | |
|---|---|
| **Synonyms** | Magnesiumdihydrogenphosphate; Magnesiumphosphate, monobasic; Monomagnesium orthophosphate |
| **Definition** | |
| Einecs | 236-004-6 |
| Chemical name | Monomagnesiumdihydrogenmonophosphate |
| Chemical formula | $Mg(H_2PO_4)_2\ nH_2O$ (where n = 0 to 4) |
| Molecular weight | 218,30 (anhydrous) |
| Assay | Not less than 51,0 % after ignition calculated as P2O5 at the ignited basis (800 °C ± 25 °C for 30 minutes) |
| **Description** | White, odourless, crystalline powder, slightly soluble in water |
| **Identification** | |
| Test for magnesium | Passes test |
| Test for phosphate | Passes test |
| MgO content | Not less than 21,5 % after ignition or at an anhydrous basis (105 °C, 4 hours) |
| **Purity** | |
| Fluoride | Not more than 10 mg/kg (as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

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**E 343 (ii) DIMAGNESIUM PHOSPHATE**

| | |
|---|---|
| **Synonyms** | Magnesiumhydrogenphosphate; Magnesiumphosphate, dibasic; Dimagnesium orthophosphate; Secondary magnesiumphosphate |
| **Definition** | |
| Einecs | 231-823-5 |
| Chemical name | Dimagnesiummonohydrogenmonophosphate |
| Chemical formula | $MgHPO_4 \cdot nH_2O$ (where n = 0-3) |
| Molecular weight | 120,30 (anhydrous) |
| Assay | Not less than 96 % after ignition (800 °C ± 25 °C for 30 minutes) |
| **Description** | White, odourless, crystalline powder, slightly soluble in water |
| **Identification** | |
| Test for magnesium | Passes test |
| Test for phosphate | Passes test |
| MgO content | Not less than 33,0 % calculated on the anhydrous basis (105 °C, 4 hours) |
| **Purity** | |
| Fluoride | Not more than 10 mg/kg (as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 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** | |
| Einecs | |
| Chemical name | Disodium DL-malate; disodium salt of hydroxybutanedioic acid |
| Chemical formula | Hemihydrate: $C_4H_4Na_2O_5$ ½ $H_2O$<br>Trihydrate: $C_4H_4Na_2O_5$ $3H_2O$ |
| Molecular weight | Hemihydrate: 187,05<br>Trihydrate: 232,10 |
| Assay | Content not less than 98,0 % on the anhydrous basis |
| **Description** | White crystalline powder or lumps |
| **Identification** | |
| Test for 1,2-dicarboxylic acid | Passes test |
| Test for sodium | Passes test |
| Azo dye formation | Positive |
| Solubility | Freely soluble in water |

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| | |
|---|---|
| **Purity** | |
| Loss on drying | Hemihydrate: Not more than 7,0 % (130 °C, 4 hours)<br>Trihydrate: 20,5-23,5 % (130 °C, 4 hours) |
| 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 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

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

| | |
|---|---|
| **Synonyms** | Monosodium salt of DL-malic acid |
| **Definition** | |
| Einecs | |
| Chemical name | Monosodium DL-malate; monosodium 2-DL-hydroxy succinate |
| Chemical formula | $C_4H_5NaO_5$ |
| Molecular weight | 156,07 |
| Assay | Content not less than 99,0 % on the anhydrous basis |
| **Description** | White powder |
| **Identification** | |
| Test for 1,2-dicarboxylic acid | Passes test |
| Test for sodium | Passes test |
| Azo dye formation | Positive |
| **Purity** | |
| Loss on drying | Not more than 2,0 % (110 °C, 3 hours) |
| 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 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 351 POTASSIUM MALATE**

| | |
|---|---|
| **Synonyms** | Potassium salt of malic acid |
| **Definition** | |
| Einecs | |
| Chemical name | Dipotassium DL-malate; dipotassium salt of hydroxybutanedioic acid |
| Chemical formula | $C_4H_4K_2O_5$ |
| Molecular weight | 210,27 |

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| | |
|---|---|
| Assay | Content not less than 59,5 % |
| **Description** | Colourless or almost colourless aqueous solution |
| **Identification** | |
| Test for 1,2-dicarboxylic acid | Passes test |
| Test for potassium | Passes test |
| 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 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 352 (i) CALCIUM MALATE**

| | |
|---|---|
| **Synonyms** | Calcium salt of malic acid |
| **Definition** | |
| Einecs | |
| Chemical name | Calcium DL-malate; calcium-α-hydroxysuccinate; calcium salt of hydroxybutanedioic acid |
| Chemical formula | $C_4H_5CaO_5$ |
| Molecular weight | 172,14 |
| Assay | Content not less than 97,5 % on the anhydrous basis |
| **Description** | White powder |
| **Identification** | |
| Test for malate | Passes test |
| Test 1,2-dicarboxylic acid | Passes test |
| Test for calcium | Passes test |
| Azo dye formation | Positive |
| Solubility | Slightly soluble in water |
| **Purity** | |
| Loss on drying | Not more than 2 % (100 °C, 3 hours) |
| 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 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

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

| | |
|---|---|
| **Synonyms** | Monocalcium salt of DL-malic acid |
| **Definition** | |
| Einecs | |
| Chemical name | Monocalcium DL-malate; monocalcium 2-DL-hydroxysuccinate |
| Chemical formula | $(C_4H_5O_5)_2Ca$ |
| Molecular weight | |
| Assay | Content not less than 97,5 % on the anhydrous basis |
| **Description** | White powder |
| **Identification** | |
| Test for 1,2-dicarboxylic acid | Passes test |
| Test for calcium | Passes test |
| Azo dye formation | Positive |
| **Purity** | |
| Loss on drying | Not more than 2,0 % (110 °C, 3 hours) |
| 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 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 353 METATARTARIC ACID**

| | |
|---|---|
| **Synonyms** | Ditartaric acid |
| **Definition** | |
| Einecs | |
| Chemical name | Metatartaric acid |
| Chemical formula | $C_4H_6O_6$ |
| Molecular weight | |
| Assay | Not less than 99,5 % |
| **Description** | Crystalline or powder form with a white or yellowish colour. Very deliquescent with a faint odour of caramel |
| **Identification** | |
| Solubility | Very soluble in water and ethanol |
| Identification test | Place a sample of 1 to 10 mg of this substance in a test tube with 2 ml of concentrated sulphuric acid and 2 drops of sulpho-resorcinol reagent. When heated to 150 °C, an intense violet coloration appears |
| **Purity** | |
| Arsenic | Not more than 3 mg/kg |

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

**E 354 CALCIUM TARTRATE**

| | |
|---|---|
| **Synonyms** | L-Calcium tartrate |
| **Definition** | |
| Einecs | |
| Chemical name | Calcium L(+)-2,3-dihydroxybutanedioate di-hydrate |
| Chemical formula | $C_4H_4CaO_6 \cdot 2H_2O$ |
| Molecular weight | 224,18 |
| Assay | Not less than 98,0 % |
| **Description** | Fine crystalline powder with a white or off-white colour |
| **Identification** | |
| Solubility | Slightly soluble in water. Solubility approximately 0,01 g/100 ml water (20 °C). Sparingly soluble in ethanol. Slightly soluble in diethyl ether. Soluble in acids |
| Specific rotation | $[\alpha]_D^{20}$ + 7,0° to + 7,4° (0,1 % in a 1N HCl solution) |
| pH | Between 6,0 and 9,0 (5 % slurry) |
| **Purity** | |
| Sulphates | Not more than 1 g/kg (as $H_2SO_4$) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 355 ADIPIC ACID**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 204-673-3 |
| Chemical name | Hexanedioic acid; 1,4-butanedicarboxylic acid |
| 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** | |
| Melting range | 151,5-154,0 °C |
| 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 |

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

**E 356 SODIUM ADIPATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 231-293-5 |
| Chemical name | Sodium adipate |
| Chemical formula | $C_6H_8Na_2O_4$ |
| Molecular weight | 190,11 |
| Assay | Content not less than 99,0 % (on anhydrous basis) |
| **Description** | White odourless crystals or crystalline powder |
| **Identification** | |
| Melting range | 151-152 °C (for adipic acid) |
| Solubility | Approximately 50 g/100 ml water (20 °C) |
| Test for sodium | Passes test |
| **Purity** | |
| Water content | Not more than 3 % (Karl Fischer) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 357 POTASSIUM ADIPATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 242-838-1 |
| Chemical name | Potassium adipate |
| Chemical formula | $C_6H_8K_2O_4$ |
| Molecular weight | 222,32 |
| Assay | Content not less than 99,0 % (on anhydrous basis) |
| **Description** | White odourless crystals or crystalline powder |
| **Identification** | |
| Melting range | 151-152 °C (for adipic acid) |
| Solubility | Approximately 60 g/100 ml water (20 °C) |
| Test for potassium | Passes test |
| **Purity** | |
| Water | Not more than 3 % (Karl Fischer) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

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**E 363 SUCCINIC ACID**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 203-740-4 |
| Chemical name | Butanedioic acid |
| Chemical formula | $C_4H_6O_4$ |
| Molecular weight | 118,09 |
| Assay | Content no less than 99,0 % |
| **Description** | Colourless or white, odourless crystals |
| **Identification** | |
| Melting range | 185,0-190,0 °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 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 380 TRIAMMONIUM CITRATE**

| | |
|---|---|
| **Synonyms** | Tribasic ammonium citrate |
| **Definition** | |
| Einecs | 222-394-5 |
| Chemical name | Triammonium salt of 2-hydroxypropan-1,2,3-tricarboxylic acid |
| Chemical formula | $C_6H_{17}N_3O_7$ |
| Molecular weight | 243,22 |
| Assay | Content not less than 97,0 % |
| **Description** | White to off-white crystals or powder |
| **Identification** | |
| Test for ammonium | Passes test |
| Test for citrate | Passes test |
| Solubility | Freely soluble in water |
| **Purity** | |
| Oxalate | Not more than 0,04 % (as oxalic acid) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

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**E 385 CALCIUM DISODIUM ETHYLENEDIAMINETETRAACETATE**

| | |
|---|---|
| **Synonyms** | Calcium disodium EDTA; Calcium disodium edetate |
| **Definition** | |
| Einecs | 200-529-9 |
| Chemical name | N,N′-1,2-Ethanediylbis [N-(carboxymethyl)-glycinate] [(4-)-O,O′,$O^N$,$O^N$]calciate(2)-disodium; Calcium disodium ethylenediaminetetra acetate; Calcium disodium (ethylenedinitrilo)tetra acetate |
| Chemical formula | $C_{10}H_{12}O_8CaN_2Na_2 \cdot 2H_2O$ |
| Molecular weight | 410,31 |
| Assay | Content not less than 97 % on the anhydrous basis |
| **Description** | White, odourless crystalline granules or white to nearly white powder, slightly hygroscopic |
| **Identification** | |
| Test for sodium | Passes test |
| Test for calcium | Passes test |
| Chelating activity to metal ions | Positive |
| pH | Between 6,5 and 7,5 (1 % solution) |
| **Purity** | |
| Water content | 5 to 13 % (Karl Fischer method) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 392 EXTRACTS OF ROSEMARY**

| | |
|---|---|
| **Synonyms** | Extract of rosemary leaf (antioxidant) |
| **Definition** | Extracts of rosemary contain several components, which have been proven to exert antioxidative functions. These components belong mainly to the classes of phenolic acids, flavonoids, diterpenoids. Besides the antioxidant compounds, the extracts can also contain triterpenes and organic solvent extractable material specifically defined in the following specification. |
| Einecs | 283-291-9 |
| Chemical name | Rosemary extract (*Rosmarinus officinalis*) |
| **Description** | Rosemary leaf extract antioxidant is prepared by extraction of the leaves of *Rosmarinus officinalis* using a food approved solvent system. Extracts may then be deodorised and decolourised. Extracts may be standardised. |
| **Identification** | |
| Reference antioxidative compounds: phenolic diterpenes | Carnosic acid ($C_{20}H_{28}O_4$) and Carnosol ($C_{20}H_{26}O_4$)<br>(which comprise not less than 90 % of the total phenolic diterpenes) |

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|---|---|
| Reference key volatiles | Borneol, Bornyl Acetate, Camphor, 1,8-Cineol, Verbenone |
| Density | > 0,25 g/ml |
| Solubility | Insoluble in water |
| **Purity** | |
| Loss of drying | < 5 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |

**1 — Extracts of rosemary produced from dried rosemary leaves by acetone extraction.**

| | |
|---|---|
| **Description** | Extracts of rosemary are produced from dried rosemary leaves by acetone extraction, filtration, purification and solvent evaporation, followed by drying and sieving to obtain a fine powder or a liquid. |
| **Identification** | |
| Content of reference antioxidative compounds | ≥ 10 % w/w, expressed as the total of carnosic acid and carnosol |
| Antioxidant/Volatiles — Ratio | (Total % w/w of carnosic acid and carnosol) ≥ 15<br>(% w/w of reference key volatiles)*<br>(* as a percentage of total volatiles in the extract, measured by Gas Chromatography — Mass Spectrometry Detection, 'GC-MSD') |
| **Purity** | |
| Residual solvents | Acetone: Not more than 500 mg/kg |

**2 — Extracts of rosemary prepared by extraction of dried rosemary leaves by means of supercritical carbon dioxide.**

| | |
|---|---|
| **Description** | Extracts of rosemary produced from dried rosemary leaves extracted by means of supercritical carbon dioxide with a small amount of ethanol as entrainer. |
| **Identification** | |
| Content of reference antioxidative compounds | ≥ 13 % w/w, expressed as the total of carnosic acid and carnosol |
| Antioxidant/Volatiles – Ratio | (Total % w/w of carnosic acid and carnosol) ≥ 15<br>(% w/w of reference key volatiles)*<br>(* as a percentage of total volatiles in the extract, measured by Gas Chromatography — Mass Spectrometry Detection, 'GC-MSD') |
| **Purity** | |
| Residual solvents | Ethanol: not more than 2 % |

**3 — Extracts of rosemary prepared from a deodorised ethanolic extract of rosemary.**

| | |
|---|---|
| **Description** | Extracts of rosemary which are prepared from a deodorised ethanolic extract of rosemary. The extracts may be further purified, for example by treatment with active carbon and/or molecular distillation. The extracts may be suspended in suitable and approved carriers or spray dried. |

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| | |
|---|---|
| **Identification** | |
| Content of reference antioxidative compounds | ≥ 5 % w/w, expressed as the total of carnosic acid and carnosol |
| Antioxidant/Volatiles – Ratio | (Total % w/w of carnosic acid and carnosol) ≥ 15<br>(% w/w of reference key volatiles)*<br>(* as a percentage of total volatiles in the extract, measured by Gas Chromatography – Mass Spectrometry Detection, 'GC-MSD') |
| **Purity** | |
| Residual solvents | Ethanol: not more than 500 mg/kg |

**4 — Extracts of rosemary decolourised and deodorised, obtained by a two-step extraction using hexane and ethanol.**

| | |
|---|---|
| **Description** | Extracts of rosemary which are prepared from a deodorised ethanolic extract of rosemary, undergone a hexane extraction. The extract may be further purified, for example by treatment with active carbon and/or molecular distillation. They may be suspended in suitable and approved carriers or spray dried. |
| **Identification** | |
| Content of reference antioxidative compounds | ≥ 5 % w/w, expressed as the total of carnosic acid and carnosol |
| Antioxidant/Volatiles – Ratio | (Total % w/w of carnosic acid and carnosol) ≥ 15<br>(% w/w of reference key volatiles)*<br>(* as a percentage of total volatiles in the extract, measured by Gas Chromatography – Mass Spectrometry Detection, 'GC-MSD') |
| **Purity** | |
| Residual solvents | Hexane: not more than 25 mg/kg<br>Ethanol: not more than 500 mg/kg |

**E 400 ALGINIC ACID**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Linear glycuronoglycan consisting mainly of β-(1-4) linked D-mannuronic and α-(1-4) linked L-guluronic acid units in pyranose ring form. Hydrophilic colloidal carbohydrate extracted by the use of dilute alkali from strains of various species of brown seaweeds (*Phaeophyceae*) |
| Einecs | 232-680-1 |
| Chemical name | |
| Chemical formula | $(C_6H_8O_6)_n$ |
| Molecular weight | 10 000-600 000 (typical average) |
| Assay | Alginic acid yields, on the anhydrous basis, not less than 20 % and not more than 23 % of carbon dioxide ($CO_2$), equivalent to not less than 91 % and not more than 104,5 % of alginic acid $(C_6H_8O_6)_n$ (calculted on equivalent weight basis of 200) |
| **Description** | Alginic acid occurs in filamentous, grainy, granular and powdered forms. It is a white to yellowish brown and nearly odourless |

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|---|---|
| **Identification** | |
| Solubility | Insoluble in water and organic solvents, slowly soluble in solutions of sodium carbonate, sodium hydroxide and trisodium phosphate |
| Calcium chloride precipitation test | To a 0,5 % solution of the sample in 1 M sodium hydroxide solution add one fifth of its volume of a 2,5 % solution of calcium chloride. A voluminous, gelatinous precipitate is formed. This test distinguishes alginic acid from acacia gum, sodium carboxymethyl cellulose, carboxymethyl starch, carrageenan, gelatin, gum ghatti, karaya gum, locust bean gum, methyl cellulose and tragacanth gum. |
| Ammonium sulphate precipitation test | To a 0,5 % solution of the sample in 1 M sodium hydroxide solution add one half of its volume of a saturated solution of ammonium sulphate. No precipitate is formed. This test distinguishes alginic acid from agar, sodium carboxymethyl cellulose, carrageenan, de-esterified pectin, gelatin, locust bean gum, methyl cellulose and starch. |
| Colour reaction | Dissolve as completely as possible 0,01 g of the sample by shaking with 0,15 ml of 0,1 N sodium hydroxide and add 1 ml of acid ferric sulphate solution. Within 5 minutes a cherry-red colour develops that finally becomes deep purple. |
| pH | Between 2,0 and 3,5 (3 % suspension) |
| **Purity** | |
| Loss on drying | Not more than 15 % (105 °C, 4 hours) |
| Sulphated ash | Not more than 8 % on the anhydrous basis |
| Sodium hydroxide (1 M solution) insoluble matter | Not more than 2 % on the anhydrous basis |
| Formaldehyde | 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 |
| Cadmium | Not more than 1 mg/kg |
| **Microbiological criteria** | |
| Total plate count | Not more than 5 000 colonies per gram |
| Yeast and moulds | Not more than 500 colonies per gram |
| *Escherichia coli* | Absent in 5 g |
| *Salmonella* spp. | Absent in 10 g |

**E 401 SODIUM ALGINATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | |
| Chemical name | Sodium salt of alginic acid |
| Chemical formula | $(C_6H_7NaO_6)_n$ |
| Molecular weight | 10 000-600 000 (typical average) |

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|---|---|
| Assay | Yields, on the anhydrous basis, not less than 18 % and not more than 21 % of carbon dioxide corresponding to not less than 90,8 % and not more than 106,0 % of sodium alginate (calculated on equivalent weight basis of 222) |
| **Description** | Nearly odourless, white to yellowish fibrous or granular powder |
| **Identification** | |
| Test for sodium | Passes test |
| Test for alginic acid | Passes test |
| **Purity** | |
| Loss on drying | Not more than 15 % (105 °C, 4 hours) |
| Water insoluble matter | Not more than 2 % on the anhydrous basis |
| Formaldehyde | 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 |
| Cadmium | Not more than 1 mg/kg |
| **Microbiological criteria** | |
| Total plate count | Not more than 5 000 colonies per gram |
| Yeast and moulds | Not more than 500 colonies per gram |
| *Escherichia coli* | Absent in 5 g |
| *Salmonella* spp. | Absent in 10 g |

**E 402 POTASSIUM ALGINATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | |
| Chemical name | Potassium salt of alginic acid |
| Chemical formula | $(C_6H_7KO_6)_n$ |
| Molecular weight | 10 000-600 000 (typical average) |
| Assay | Yields, on the anhydrous basis, not less than 16,5 % and not more than 19,5 % of carbon dioxide corresponding to not less than 89,2 % and not more than 105,5 % of potassium alginate (calculated on an equivalent weight basis of 238) |
| **Description** | Nearly odourless, white to yellowish fibrous or granular powder |
| **Identification** | |
| Test for potassium | Passes test |
| Test for alginic acid | Passes test |
| **Purity** | |
| Loss on drying | Not more than 15 % (105 °C, 4 hours) |
| Water insoluble matter | Not more than 2 % on the anhydrous basis |
| Formaldehyde | Not more than 50 mg/kg |

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| | |
|---|---|
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| **Microbiological criteria** | |
| Total plate count | Not more than 5 000 colonies per gram |
| Yeast and moulds | Not more than 500 colonies per gram |
| *Escherichia coli* | Absent in 5 g |
| *Salmonella* spp. | Absent in 10 g |

**E 403 AMMONIUM ALGINATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | |
| Chemical name | Ammonium salt of alginic acid |
| Chemical formula | $(C_6H_{11}NO_6)_n$ |
| Molecular weight | 10 000-600 000 (typical average) |
| Assay | Yields, on the anhydrous basis, not less than 18 % and not more than 21 % of carbon dioxide corresponding to not less than 88,7 % and not more than 103,6 % ammonium alginate (calculated on an equivalent weight basis of 217) |
| **Description** | White to yellowish fibrous or granular powder |
| **Identification** | |
| Test for ammonium | Passes test |
| Test for alginic acid | Passes test |
| **Purity** | |
| Loss on drying | Not more than 15 % (105 °C, 4 hours) |
| Sulphated ash | Not more than 7 % on the dried basis |
| Water insoluble matter | Not more than 2 % on the anhydrous basis |
| Formaldehyde | Not more than 50 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| **Microbiological criteria** | |
| Total plate count | Not more than 5 000 colonies per gram |
| Yeast and moulds | Not more than 500 colonies per gram |
| *Escherichia coli* | Absent in 5 g |
| *Salmonella* spp. | Absent in 10 g |

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**E 404 CALCIUM ALGINATE**

| | |
|---|---|
| **Synonyms** | Calcium salt of alginate |
| **Definition** | |
| Einecs | |
| Chemical name | Calcium salt of alginic acid |
| Chemical formula | $(C_6H_7Ca_{1/2}O_6)_n$ |
| Molecular weight | 10 000-600 000 (typical average) |
| Assay | Yields, on the anhydrous basis, not less than 18 % and not more than 21 % carbon dioxide corresponding to not less than 89,6 % and not more than 104,5 % of calcium alginate (calculated on an equivalent weight basis of 219) |
| **Description** | Nearly odourless, white to yellowish fibrous or granular powder |
| **Identification** | |
| Test for calcium | Passes test |
| Test for alginic acid | Passes test |
| **Purity** | |
| Loss on drying | Not more than 15,0 % (105 °C, 4 hours) |
| Formaldehyde | 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 |
| Cadmium | Not more than 1 mg/kg |
| **Microbiological criteria** | |
| Total plate count | Not more than 5 000 colonies per gram |
| Yeast and moulds | Not more than 500 colonies per gram |
| *Escherichia coli* | Absent in 5 g |
| *Salmonella* spp. | Absent in 10 g |

**E 405 PROPANE-1,2-DIOL ALGINATE**

| | |
|---|---|
| **Synonyms** | Hydroxypropyl alginate; 1,2-Propanediol ester of alginic acid; Propylene glycol alginate |
| **Definition** | |
| Einecs | |
| Chemical name | 1,2-Propanediol ester of alginic acid; varies in composition according to its degree of esterification and the percentage of free and neutralised carboxyl groups in the molecule |
| Chemical formula | $(C_9H_{14}O_7)_n$ (esterified) |
| Molecular weight | 10 000-600 000 (typical average) |
| Assay | Yields, on the anhydrous basis, not less than 16 % and not more than 20 % of carbon dioxide ($CO_2$) |
| **Description** | Nearly odourless, white to yellowish brown fibrous or granular powder |

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|---|---|
| **Identification** | |
| Test for 1,2-propanediol | Passes test (after hydrolysis) |
| Test for alginic acid | Passes test (after hydrolysis) |
| **Purity** | |
| Loss on drying | Not more than 20 % (105 °C, 4 hours) |
| Total propane-1,2-diol content | Not less than 15 % and not more than 45 % |
| Free propane-1,2-diol content | Not more than 15 % |
| Water insoluble matter | Not more than 2 % on the anhydrous basis |
| Formaldehyde | 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 |
| Cadmium | Not more than 1 mg/kg |
| **Microbiological criteria** | |
| Total plate count | Not more than 5 000 colonies per gram |
| Yeast and moulds | Not more than 500 colonies per gram |
| *Escherichia coli* | Absent in 5 g |
| *Salmonella* spp. | Absent in 10 g |

**E 406 AGAR**

| | |
|---|---|
| **Synonyms** | Gelose; Kanten, Bengal, Ceylon, Chinese or Japanese isinglass; Layor Carang |
| **Definition** | Agar is a hydrophilic colloidal polysaccharide consisting mainly of galactose units with a regular alternation of L and D isomeric forms. These hexoses are alternately linked with alpha-1,3 and beta-1,4 bonds in the copolymer. On about every tenth D-galactopyranose unit one of the hydroxyl groups is esterified with sulphuric acid which is neutralised by calcium, magnesium, potassium or sodium. It is extracted from certain strains of marine algae of the families *Gelidiaceae* and *Gracilariaceae* and relevant red algae of the class *Rhodophyceae* |
| Einecs | 232-658-1 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | The threshold gel concentration should not be higher than 0,25 % |
| **Description** | Agar is odourless or has a slight characteristic odour. Unground agar usually occurs in bundles consisting of thin, membranous, agglutinated strips, or in cut, flaked or granulated forms. It may be light yellowish-orange, yellowish-grey to pale yellow, or colourless. It is tough when damp, brittle when dry. Powdered agar is white to yellowish-white or pale yellow. When examined in water under a microscope, agar powder appears more transparent. In chloral hydrate solution, the powdered agar appears more transparent than in water, more or less granular, striated, angular and occasionally contains frustules of diatoms. Gel strength may be standardised by the addition of dextrose and maltodextrines or sucrose |

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|---|---|
| **Identification** | |
| Solubility | Insoluble in cold water; soluble in boiling water |
| **Purity** | |
| Loss on drying | Not more than 22 % (105 °C, 5 hours) |
| Ash | Not more than 6,5 % on the anhydrous basis determined at 550 °C |
| Acid-insoluble ash (insoluble in approximately 3N Hydrochloric acid) | Not more than 0,5 % determined at 550 °C on the anhydrous basis |
| Insoluble matter (after stirring for 10 minutes in hot water) | Not more than 1,0 % |
| Starch | Not detectable by the following method: to a 1 in 10 solution of the sample add a few drops of iodine solution. No blue colour is produced |
| Gelatin and other proteins | Dissolve about 1 g of agar in 100 ml of boiling water and allow to cool of about 50 °C. To 5 ml of the solution add 5 ml of trinitrophenol solution (1 g of anhydrous trinitrophenol/100 ml of hot water). No turbidity appears within 10 minutes |
| Water absorption | Place 5 g to agar in a 100 ml graduated cylinder, fill to the mark with water, mix and allow to stand at about 25 °C for 24 hours. Pour the contents of the cylinder through moistened glass wool, allowing the water to drain into a second 100 ml graduated cylinder. Not more than 75 ml of water is obtained |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| **Microbiological criteria** | |
| Total plate count | Not more than 5 000 colonies per gram |
| Yeast and moulds | Not more than 300 colonies per gram |
| *Escherichia coli* | Absent in 5 g |
| *Salmonella* spp. | Absent in 5 g |

**E 407 CARRAGEENAN**

| | |
|---|---|
| **Synonyms** | Products of commerce are sold under different names such as:<br>Irish moss gelose; Eucheuman (from *Eucheuma* spp.); Iridophycan (from *Iridaea* spp.); Hypnean (from *Hypnea* spp.); Furcellaran or Danish agar (from *Furcellaria fastigiata*); Carrageenan (from *Chondrus* and *Gigartina* spp.) |
| **Definition** | Carrageenan is obtained by extraction with water or dilute aqueous alkali of strains of seaweeds of *Gigartinaceae*, *Solieriaceae*, *Hypneaceae* and *Furcellariaceae*, families of the class *Rhodophyceae* (red seaweeds).<br>Carrageenan consists chiefly of the potassium, sodium, magnesium and calcium sulphate esters of galactose and 3,6-anhydrogalactose polysacharide. These hexoses are alternately linked α-1,3 and β-1,4 in the copolymer. |

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| | The prevalent polysaccharides in carrageenan are designated as kappa, iota, lambda depending on the number of sulphate by repeating unit (i.e. 1,2,3 sulphate). Between kappa and iota there is a continuum of intermediate compositions differing in number of sulphates per repeat units between 1 and 2.<br>During the process, no organic precipitant shall be used other than methanol, ethanol and propan-2-ol.<br>The wording carrageenan is reserved for the non hydrolysed or otherwise chemically degraded polymer.<br>Formaldehyde may be present as an adventitious impurity up to a maximum of 5 mg/kg. |
| Einecs | 232-524-2 |
| Chemical name | Sulphate esters of polygalactose |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | Yellowish to colourless, coarse to fine powder which is practically odourless |
| **Identification** | |
| Test for galactose | Passes test |
| Test for anhydrogalactose | Passes test |
| Test for sulphate | Passes test |
| Solubility | Soluble in hot water; insoluble in alcohol for a 1,5 % dilution |
| **Purity** | |
| Solvent residues | Not more than 0,1 % of methanol, ethanol, propan-2-ol, singly or in combination |
| Viscosity | Not less than 5 mPa.s (1,5 % solution at 75 °C) |
| Loss on drying | Not more than 12 % (105 °C, 4 hours) |
| Sulphates | Not less than 15 % and not more than 40 % on the dried basis (as $SO_4$) |
| Ash | Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C |
| Acid-insoluble ash | Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid) |
| Acid-insoluble matter | Not more than 2 % on the dried basis (insoluble in 1 % v/v sulphuric acid) |
| Low molecular weight carrageenan (Molecular weight fraction below 50 kDa) | Not more than 5 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 2 mg/kg |
| **Microbiological criteria** | |
| Total plate count | Not more than 5 000 colonies per gram |

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|---|---|
| Yeast and moulds | Not more than 300 colonies per gram |
| *Escherichia coli* | Absent in 5 g |
| *Salmonella* spp. | Absent in 10 g |

**E 407a PROCESSED EUCHEUMA SEAWEED**

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|---|---|
| **Synonyms** | PES (acronym for processed eucheuma seaweed). The PES obtained from *Euchema cottonii* is generally called kappa PES and the PES from *Euchema spinosum* iota PES. |
| **Definition** | Processed eucheuma seaweed is obtained by aqueous alkaline (KOH) treatment at high temperature of the strains of seaweeds *Eucheuma cottonii* and *Eucheuma spinosum*, of the class *Rhodophyceae* (red seaweeds) followed by fresh water washing to remove impurities and drying to obtain the product. Further purification may be achieved by washing with an alcohol. The alcohols authorised are restricted to methanol, ethanol or propan-2-ol. The product consists chiefly of the potassium, sodium, magnesium and calcium sulphate esters of galactose and 3,6-anhydrogalactose polysaccharide. Up to 15 % algal cellulose is also present in the product. The wording processed eucheuma seaweed is reserved to the non hydrolysed or otherwise chemically degraded polymer. Formaldehyde may be present up to a maximum of 5 mg/kg. |
| **Description** | Tan to yellowish, coarse to fine powder which is practically odourless |
| **Identification** | |
| Test for galactose | Passes test |
| Test for anhydrogalactose | Passes test |
| Test for sulphate | Passes test |
| Solubility | Forms cloudy viscous suspensions in water. Insoluble in ethanol for a 1,5 % solution. |
| **Purity** | |
| Solvent residues | Not more than 0,1 % of methanol, ethanol, propan-2-ol, singly or in combination |
| Viscosity | Not less than 5 mPa.s (1,5 % solution at 75 °C) |
| Loss on drying | Not more than 12 % (105 °C, 4 hours) |
| Sulphate | Not less than 15 % and not more than 40 % on the dried basis (as $SO_4$) |
| Ash | Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C |
| Acid-insoluble ash | Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid) |
| Acid-insoluble matter | Not less than 8 % and not more than 15 % on the dried basis (insoluble in 1 % v/v sulphuric acid) |
| Low molecular weight carrageenan (Molecular weight fraction below 50 kDa) | Not more than 5 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

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|---|---|
| Cadmium | Not more than 2 mg/kg |
| **Microbiological criteria** | |
| Total plate count | Not more than 5 000 colonies per gram |
| Yeast and moulds | Not more than 300 colonies per gram |
| *Escherichia coli* | Absent in 5 g |
| *Salmonella* spp. | Absent in 10 g |

**E 410 LOCUST BEAN GUM**

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|---|---|
| **Synonyms** | Carob bean gum; Algaroba gum |
| **Definition** | Locust bean gum is the ground endosperm of the seeds of the strains of carob tree, *Ceratonia siliqua* (L.) Taub. (family *Leguminosae*). Consists mainly of a high molecular weight hydrocolloidal polysaccharide, composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as galactomannan |
| Einecs | 232-541-5 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | 50 000-3 000 000 |
| Assay | Galactomannan content not less than 75 % |
| **Description** | White to yellowish-white, nearly odourless powder |
| **Identification** | |
| Test for galactose | Passes test |
| Test for mannose | Passes test |
| Microscopic examination | Place some ground sample in an aqueous solution containing 0,5 % iodine and 1 % potassium iodide on a glass slide and examine under microscope. Locust bean gum contains long stretched tubiform cells, separated or slightly interspaced. Their brown contents are much less regularly formed than in guar gum. Guar gum shows close groups of round to pear shaped cells. Their contents are yellow to brown |
| Solubility | Soluble in hot water, insoluble in ethanol |
| **Purity** | |
| Loss on drying | Not more than 15 % (105 °C, 5 hours) |
| Ash | Not more than 1,2 % determined at 800 °C |
| Protein (N × 6,25) | Not more than 7 % |
| Acid-insoluble matter | Not more than 4 % |
| Starch | Not detectable by the following method: to a 1 in 10 solution of the sample add a few drops of iodine solution. No blue colour is produced |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

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|---|---|
| Cadmium | Not more than 1 mg/kg |
| Ethanol and propan-2-ol | Not more than 1 %, single or in combination |

**E 412 GUAR GUM**

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|---|---|
| **Synonyms** | Gum cyamopsis; Guar flour |
| **Definition** | Guar gum is the ground endosperm of the seeds of strains of the guar plant, *Cyamopsis tetragonolobus* (L.) Taub. (family *Leguminosae*). Consists mainly of a high molecular weight hydrocolloidal polysaccharide composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as galactomannan. The gum may be partially hydrolysed by either heat treatment, mild acid or alcaline oxidative treatment for viscosity adjustment. |
| Einecs | 232-536-0 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | 50 000-8 000 000 |
| Assay | Galactomannan content not less than 75 % |
| **Description** | A white to yellowish-white, nearly odourless powder |
| **Identification** | |
| Test for galactose | Passes test |
| Test for mannose | Passes test |
| Solubility | Soluble in cold water |
| **Purity** | |
| Loss on drying | Not more than 15 % (105 °C, 5 hours) |
| Ash | Not more than 5,5 % determined at 800 °C |
| Acid-insoluble matter | Not more than 7 % |
| Protein | Not more than 10 % (factor N x 6,25) |
| Starch | Not detectable by the following method: to a 1 in 10 solution of the sample add a few drops of iodine solution. (No blue colour is produced) |
| Organic peroxides | Not more than 0,7 meq active oxygen/kg sample |
| Furfural | Not more than 1 mg/kg |
| Pentachlorophenol | Not more than 0,01 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 413 TRAGACANTH**

| | |
|---|---|
| **Synonyms** | Tragacanth gum; Tragant |
| **Definition** | Tragacanth is a dried exudation obtained from the stems and branches of strains of *Astragalus gummifer* Labillardiere and other Asiatic species of *Astragalus* (family *Leguminosae*). It consists mainly of high molecular weight polysaccharides (galactoarabans and acidic polysaccharides) which, on hydrolysis, yield galacturonic acid, galactose, arabinose, xylose and fucose. Small amounts of rhamnose and of glucose (derived from traces of starch and/or cellulose) may also be present |

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|---|---|
| Einecs | 232-252-5 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | Approximately 800 000 |
| Assay | |
| **Description** | Unground Tragacanth gum occurs as flattened, lamellated, straight or curved fragments or as spirally twisted pieces 0,5-2,5 mm thick and up to 3 cm in length. It is white to pale yellow in colour but some pieces may have a red tinge. The pieces are horny in texture, with a short fracture. It is odourless and solutions have an insipid mucilaginous taste. Powdered tragacanth is white to pale yellow or pinkish brown (pale tan) in colour |
| **Identification** | |
| Solubility | 1 g of the sample in 50 ml of water swells to form a smooth, stiff, opalescent mucilage; insoluble in ethanol and does not swell in 60 % (w/v) aqueous ethanol |
| **Purity** | |
| Test for Karaya gum | Negative. Boil 1 g with 20 ml of water until a mucilage is formed. Add 5 ml of hydrochloric acid and again boil the mixture for five minutes. No permanent pink or red colour develops |
| Loss on drying | Not more than 16 % (105 °C, 5 hours) |
| Total ash | Not more than 4 % |
| Acid insoluble ash | Not more than 0,5 % |
| Acid insoluble matter | Not more than 2 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| **Microbiological criteria** | |
| *Salmonella* spp. | Absent in 10 g |
| *Escherichia coli* | Absent in 5 g |

**E 414 ACACIA GUM**

| | |
|---|---|
| **Synonyms** | Gum arabic |
| **Definition** | Acacia gum is a dried exudation obtained from the stems and branches of strains of *Acacia senegal* (L) Willdenow or closely related species of Acacia (family *Leguminosae*). It consists mainly of high molecular weight polysaccharides and their calcium, magnesium and potassium salts, which on hydrolysis yield arabinose, galactose, rhamnose and glucuronic acid |
| Einecs | 232-519-5 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | Approximately 350 000 |
| Assay | |

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|---|---|
| **Description** | Unground acacia gum occurs as white or yellowish-white spheroidal tears of varying sizes or as angular fragments and is sometimes mixed with darker fragments. It is also available in the form of white to yellowish-white flakes, granules, powder or spray-dried material. |
| **Identification** | |
| Solubility | 1 g dissolves in 2 ml of cold water forming a solution which flows readily and is acid to litmus, insoluble in ethanol |
| **Purity** | |
| Loss on drying | Not more than 17 % (105 °C, 5 hours) for granular and not more than 10 % (105 °C, 4 hours) for spray-dried material |
| Total ash | Not more than 4 % |
| Acid insoluble ash | Not more than 0,5 % |
| Acid insoluble matter | Not more than 1 % |
| Starch or dextrin | Boil a 1 in 50 solution of the gum and cool. To 5 ml add 1 drop of iodine solution. No bluish or reddish colours are produced |
| Tannin | To 10 ml of a 1 in 50 solution add about 0,1 ml of ferric chloride solution (9 g $FeCl_3.6H_2O$ made up to 100 ml with water). No blackish colouration or blackish precipitate is formed |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Hydrolysis products | Mannose, xylose and galacturonic acid are absent (determined by chromatography) |
| **Microbiological criteria** | |
| *Salmonella* spp. | Absent in 10 g |
| *Escherichia coli* | Absent in 5 g |

**E 415 XANTHAN GUM**

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|---|---|
| **Synonyms** | |
| **Definition** | Xanthan gum is a high molecular weight polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with strains of *Xanthomonas campestris*, purified by recovery with ethanol or propan-2-ol, dried and milled. It contains D-glucose and D-mannose as the dominant hexose units, along with D-glucuronic acid and pyruvic acid, and is prepared as the sodium, potassium or calcium salt. Its solutions are neutral |
| Einecs | 234-394-2 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | Approximately 1 000 000 |
| Assay | Yields, on dried basis, not less than 4,2 % and not more than 5 % of $CO_2$ corresponding to between 91 % and 108 % of xanthan gum |

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|---|---|
| **Description** | Cream-coloured powder |
| **Identification** | |
| Solubility | Soluble in water. Insoluble in ethanol |
| **Purity** | |
| Loss on drying | Not more than 15 % (105 °C, 2,5 hours) |
| Total ash | Not more than 16 % on the anhydrous basis determined at 650 °C after drying at 105 °C for four hours |
| Pyruvic acid | Not less than 1,5 % |
| Nitrogen | Not more than 1,5 % |
| Ethanol and propan-2-ol | Not more than 500 mg/kg singly or in combination |
| Lead | Not more than 2 mg/kg |
| **Microbiological criteria** | |
| Total plate count | Not more than 5 000 colonies per gram |
| Yeast and moulds | Not more than 300 colonies per gram |
| *Escherichia coli* | Absent in 5 g |
| *Salmonella* spp. | Absent in 10 g |
| *Xanthomonas campestris* | Viable cells absent in 1 g |

**E 416 KARAYA-GUM**

| | |
|---|---|
| **Synonyms** | Katilo; Kadaya; Gum *sterculia*; *Sterculia*; Karaya, gum karaya; Kullo; Kuterra |
| **Definition** | Karaya gum is a dried exudation from the stems and branches of strains of: *Sterculia urens* Roxburgh and other species of *Sterculia* (family *Sterculiaceae*) or from *Cochlospermum gossypium* A.P. De Candolle or other species of *Cochlospermum* (family *Bixaceae*). It consists mainly of high molecular weight acetylated polysaccharides, which on hydrolysis yield galactose, rhamnose, and galacturonic acid, together with minor amounts of glucuronic acid |
| Einecs | 232-539-4 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | Karaya gum occurs in tears of variable size and in broken irregular pieces having a characteristic semi-crystalline appearance. It is pale yellow to pinkish brown in colour, translucent and horny. Powdered karaya gum is a pale grey to pinkish brown. The gum has a distinctive odour of acetic acid |
| **Identification** | |
| Solubility | Insoluble in ethanol |
| Swelling in ethanol solution | Karaya gum swells in 60 % ethanol distinguishing it from other gums |
| **Purity** | |
| Loss on drying | Not more than 20 % (105 °C, 5 hours) |

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|---|---|
| Total ash | Not more than 8 % |
| Acid insoluble ash | Not more than 1 % |
| Acid insoluble matter | Not more than 3 % |
| Volatile acid | Not less than 10 % (as acetic acid) |
| Starch | Not detectable |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| **Microbiological criteria** | |
| *Salmonella* spp. | Absent in 10 g |
| *Escherichia coli* | Absent in 5 g |

**E 417 TARA GUM**

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|---|---|
| **Definition** | Tara gum is obtained by grinding the endosperm of the seeds of strains of *Caesalpinia spinosa* (family *Leguminosae*). It consists chiefly of polysaccharides of high molecular weight composed mainly of galactomannans. The principal component consists of a linear chain of (1-4)-β-D-mannopyranose units with α-D-galactopyranose units attached by (1-6) linkages. The ratio of mannose to galactose in tara gum is 3:1. (In locust bean gum this ratio is 4:1 and in guar gum 2:1) |
| Einecs | 254-409-6 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | A white to white-yellow odourless powder |
| **Identification** | |
| Solubility | Soluble in water, insoluble in ethanol |
| Gel formation | To an aqueous solution of the sample add small amounts of sodium borate. A gel is formed |
| **Purity** | |
| Loss on drying | Not more than 15 % |
| Ash | Not more than 1,5 % |
| Acid insoluble matter | Not more than 2 % |
| Protein | Not more than 3,5 % (factor N x 5,7) |
| Starch | Not detectable |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

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**E 418 GELLAN GUM**

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|---|---|
| **Synonyms** | |
| **Definition** | Gellan gum is a high molecular weight polysaccharide gum produced by a pure culture fermentation of a carbohydrate by strains of *Pseudomonas elodea*, purified by recovery with propan-2-ol or ethanol, dried, and milled. The high molecular weight polysaccharide is principally composed of a tetrasaccharide repeating unit of one rhamnose, one glucuronic acid, and two glucoses, and substituted with acyl (glyceryl and acetyl) groups as the O-glycosidically linked esters. The glucuronic acid is neutralised to a mixed potassium, sodium, calcium, and magnesium salt |
| Einecs | 275-117-5 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | Approximately 500 000 |
| Assay | Yields, on the dried basis, not less than 3,3 % and not more than 6,8 % of $CO_2$ |
| **Description** | An off-white powder |
| **Identification** | |
| Solubility | Soluble in water, forming a viscous solution.<br>Insoluble in ethanol |
| **Purity** | |
| Loss on drying | Not more than 15 % after drying (105 °C, 2,5 hours) |
| Nitrogen | Not more than 3 % |
| Propan-2-ol | Not more than 750 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| **Microbiological criteria** | |
| Total plate count | Not more than 10 000 colonies per gram |
| Yeast and moulds | Not more than 400 colonies per gram |
| *Escherichia coli* | Negative in 5 g |
| *Salmonella* spp. | Negative in 10 g |

**E 420 (i) SORBITOL**

| | |
|---|---|
| **Synonyms** | D-glucitol; D-sorbitol |
| **Definition** | Sorbitol is obtained by hydrogenation of D-glucose. It is mainly composed of D-sorbitol. According to the level of D-glucose, the part of the products which is not D-sorbitol is composed of related substances such as mannitol, iditol, maltitol. |
| Einecs | 200-061-5 |
| Chemical name | D-glucitol |
| Chemical formula | $C_6H_{14}O_6$ |

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|---|---|
| Molecular weight | 182,2 |
| Assay | Content not less than 97 % of total glycitols and not less than 91 % of D-sorbitol on dry weight basis (glycitols are compounds with the structural formula $CH_2OH$-$(CHOH)_n$-$CH_2OH$, where '*n*' is an integer). |
| **Description** | White hygroscopic powder, crystalline powder, flakes or granules. |
| Appearance of the aqueous solution: | The solution is clear. |
| **Identification** | |
| Solubility | Very soluble in water, slightly soluble in ethanol |
| Melting range | 88 to 102 °C |
| Sorbitol monobenzylidene derivative | To 5 g of the sample add 7 ml of methanol, 1 ml of benzaldehyde and 1 ml of hydrochloric acid. Mix and shake in a mechanical shaker until crystals appear. Filter with the aid of suction, dissolve the crystals in 20 ml of boiling water containing 1 g of sodium bicarbonate, filter while hot, cool the filtrate, filter with suction, wash with 5 ml of methanol-water mixture (1 in 2) and dry in air. The crystals so obtained melt between 173 and 179 °C |

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|---|---|
| **Purity** | |
| Water content | Not more than 1,5 % (Karl Fischer Method) |
| Conductivity | Not more than 20 µS/cm (on 20 % dry solids solution) at temperature 20 °C |
| Reducing sugars | Not more than 0,3 % (expressed as glucose on dry weight basis) |
| Total sugars | Not more than 1 % (expressed as glucose on dry weight basis) |
| Nickel | Not more than 2 mg/kg (expressed on dry weight basis) |
| Arsenic | Not more than 3 mg/kg (expressed on dry weight basis) |
| Lead | Not more than 1 mg/kg (expressed on dry weight basis) |

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**E 420 (ii) SORBITOL SYRUP**

| | |
|---|---|
| **Synonyms** | D-glucitol syrup |
| **Definition** | Sorbitol syrup formed by hydrogenation of glucose syrup is composed of D-sorbitol, D-mannitol and hydrogenated saccharides.<br>The part of the product which is not D-sorbitol is composed mainly of hydrogenated oligosaccharides formed by the hydrogenation of glucose syrup used as raw material (in which case the syrup is non-crystallising) or mannitol. Minor quantities of glycitols where $n \leq 4$ may be present (glycitols are compounds with the structural formula $CH_2OH$-$(CHOH)_n$-$CH_2OH$, where '*n*' is an integer) |
| Einecs | 270-337-8 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content not less than 69 % total solids and not less than 50 % of D-sorbitol on the anhydrous basis |

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|---|---|
| **Description** | Clear and colourless aqueous solution |
| **Identification** | |
| Solubility | Miscible with water, with glycerol, and with propane-1,2-diol |
| Sorbitol monobenzylidene derivative | To 5 g of the sample add 7 ml of methanol, 1 ml of benzaldehyde and 1 ml of hydrochloric acid. Mix and shake in a mechanical shaker until crystals appear. Filter with the aid of suction, dissolve the crystals in 20 ml of boiling water containing 1 g of sodium bicarbonate, filter while hot. Cool the filtrate filter with suction, wash with 5 ml of methanol-water mixture (1 in 2) and dry in air. The crystals so obtained melt between 173 and 179 °C |

▼M4

| | |
|---|---|
| **Purity** | |
| Water content | Not more than 31 % (Karl Fischer Method) |
| Conductivity | Not more than 10 µS/cm (on the product as such) at temperature 20 °C |
| Reducing sugars | Not more than 0,3 % (expressed as glucose on dry weight basis) |
| Nickel | Not more than 2 mg/kg (expressed on dry weight basis) |
| Arsenic | Not more than 3 mg/kg (expressed on dry weight basis) |
| Lead | Not more than 1 mg/kg (expressed on dry weight basis) |

**E 421 (i) MANNITOL BY HYDROGENATION**

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(i) MANNITOL

| | |
|---|---|
| **Synonyms** | D-mannitol |

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|---|---|
| **Definition** | Manufactured by catalytic hydrogenation of carbohydrate solutions containing glucose and/or fructose.<br>The product contains min. 96 % mannitol. The part of the product which is not mannitol is mainly composed of sorbitol (2 % max), maltitol (2 % max) and isomalt (1,1 GPM (1-O-alpha-D-Glucopyranosyl-D-mannitol dehydrate): 2 % max and 1,6 GPS (6-O-alpha-D- Glucopyranosyl-D-Sorbitol): 2 % max). Unspecified impurities shall not represent more than 0,1 % of each. |

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|---|---|
| Einecs | 200-711-8 |
| Chemical name | D-mannitol |
| Chemical formula | $C_6H_{14}O_6$ |
| Molecular weight | 182,2 |
| Assay | Content not less than 96,0 % D-mannitol and not more than 102 % on the dried basis |
| **Description** | White, odourless, crystalline powder |
| **Identification** | |
| Solubility | Soluble in water, very slightly soluble in ethanol, practically insoluble in ether |
| Melting range | Between 164 and 169 °C |
| Infrared absorption spectrometry | Comparison with a reference standard e.g. EP or USP |
| Specific rotation | $[\alpha]_D^{20}$ + 23° to + 25° (borate solution) |

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| pH | Between 5 and 8. Add 0,5 ml of a saturated solution of potassium chloride to 10 ml of a 10 % w/v solution of the sample, then measure the pH |

▼M4

**Purity**

| | |
|---|---|
| Water content | Not more than 0,5 % (Karl Fischer Method) |
| Conductivity | Not more than 20 µS/cm (on 20 % dry solids solution) at temperature 20 °C |
| Reducing sugars | Not more than 0,3 % (expressed as glucose) |
| Total sugars | Not more than 1 % (expressed as glucose) |
| Nickel | Not more than 2 mg/kg |
| Lead | Not more than 1 mg/kg |

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(ii) MANNITOL MANUFACTURED BY FERMENTATION

| | |
|---|---|
| **Synonyms** | D-mannitol |
| **Definition** | Manufactured by discontinuous fermentation under aerobic conditions using a conventional strain of the yeast *Zygosaccharomyces rouxii.* The part of the product which is not mannitol is mainly composed of sorbitol, maltitol and isomalt. |
| Einecs | 200-711-8 |
| Chemical name | D-mannitol |
| Chemical formula | $C_6H_{14}O_6$ |
| Molecular weight | 182,2 |
| Assay | Not less than 99 % on the dried basis |
| **Description** | White, odourless crystalline powder |
| **Identification** | |
| Solubility | Soluble in water, very slightly soluble in ethanol, practically insoluble in ether |
| Melting range | Between 164 and 169 °C |
| Infrared absorption spectrometry | Comparison with a reference standard e.g. EP or USP |
| Specific rotation | $[\alpha]_D^{20}$ + 23° to + 25° (borate solution) |
| pH | Between 5 and 8<br>Add 0,5 ml of a saturated solution of potassium chloride to 10 ml of a 10 % w/v solution of the sample, then measure the pH |

▼M4

**Purity**

| | |
|---|---|
| Arabitol | Not more than 0,3 % |
| Water content | Not more than 0,5 % (Karl Fischer Method) |
| Conductivity | Not more than 20 µS/cm (on 20 % dry solids solution) at temperature 20 °C |
| Reducing sugars | Not more than 0,3 % (expressed as glucose) |
| Total sugars | Not more than 1 % (expressed as glucose) |
| Lead | Not more than 1 mg/kg |

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| | |
|---|---|
| **Microbiological criteria** | |
| Aerobic mesophilic bacteria | Not more than 1 000 colonies per gram |
| Coliforms | Absent in 10 g |
| *Salmonella* spp. | Absent in 25 g |
| *Escherichia coli* | Absent in 10 g |
| *Staphylococcus aureus* | Absent in 10 g |
| *Pseudomonas aeruginosa* | Absent in 10 g |
| Moulds | Not more than 100 colonies per gram |
| Yeasts | Not more than 100 colonies per gram |

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**E 422 GLYCEROL**

| | |
|---|---|
| **Synonyms** | Glycerin; Glycerine |
| **Definition** | Glycerol is obtained only from vegetable oils and fats, either directly or from the crude glycerol obtained as a by-product of biodiesel production and undergoes purification processes that involve distillation, and other clean up steps to obtain refined glycerol. |
| Einecs | 200-289-5 |
| Chemical name | 1,2,3-propanetriol; Glycerol; Trihydroxypropane |
| Chemical formula | $C_3H_8O_3$ |
| Molecular weight | 92,10 |
| Assay | Content not less than 98 % of glycerol on the anhydrous basis |
| **Description** | Clear, colourless hygroscopic syrupy liquid with not more than a slight characteristic odour, which is neither harsh nor disagreeable |
| **Identification** | |
| Specific gravity (25 °C/25 °C) | Not less than 1,257 |
| Refractive index | $[n]_D^{20}$ between 1,471 and 1,474 |
| **Purity** | |
| Water content | Not more than 5 % (Karl Fischer method) |
| Sulphated ash | Not more than 0,01 % determined at 800 ± 25 °C |
| Butanetriols | Not more than 0,2 % |
| Acrolein | Not more than 3 mg/kg |
| Fatty acids and esters | Not more than 0,1 % calculated as butyric acid |
| Chlorinated compounds | Not more than 30 mg/kg (as chlorine) |
| 3-Monochloropropane-1,2-diol (3- MCPD) | Not more than 0,1 mg/kg |
| Arsenic | Not more than 0,1 mg/kg |
| Lead | Not more than 0,1 mg/kg |
| Mercury | Not more than 0,1 mg/kg |
| Cadmium | Not more than 0,1 mg/kg |

▼M7

**E 423 OCTENYL SUCCINIC ACID MODIFIED GUM ARABIC**

| | |
|---|---|
| **Synonyms** | Gum arabic hydrogen octenylbutandioate; Gum arabic hydrogen octenylsuccinate; OSA modified gum arabic; OSA modified gum acacia |
| **Definition** | Octenyl succinic acid modified gum arabic is produced by esterifying gum arabic (*Acacia seyal*), or gum arabic (*Acacia senegal*) in aqueous solution with not more than 3 % of octenyl succinic acid anhydride. It is subsequently spray dried. |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Weight Average Molecular Weight | Fraction (i): 3,105 g/mol<br>Fraction (ii) 1,106 g/mol |
| Assay | |
| **Description** | Off-white to light tan, free flowing powder |
| **Identification** | |
| Viscosity of a 5 % solution at 25 °C | Not more than 30 mPa.s. |
| Precipitation reaction | Forms flocculent precipitate in lead sub-acetate solution (TS) |
| Solubility | Freely soluble in water; insoluble in ethanol |
| pH for a 5 % aqueous solution | 3,5 to 6,5 |
| **Purity** | |
| Loss on drying | Not more than 15 % (105 °C, 5 h) |
| Degree of esterification | Not more than 0,6 % |
| Total ash | Not more than 10 % (530 °C) |
| Acid-insoluble ash | Not more than 0,5 % |
| Water insoluble matter | Not more than 1,0 % |
| Test for starch or dextrine | Boil a 1 in 50 aqueous solution of the sample, add about 0,1 ml iodine TS. No bluish or reddish colour should be produced. |
| Test for tannin-bearing gums | To 10 ml of a 1 in 50 aqueous solution of the sample add about 0,1 ml ferric chloride TS. No blackish coloration or blackish precipitate should be formed. |
| Residual octenyl succinic acid | Not more than 0,3 % |
| Lead | Not more than 2 mg/kg |
| **Microbiological criteria** | |
| *Salmonella* sp. | Absent in 25 g |
| *Escherichia coli* | Absent in 1 g |

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**E 425 (i) KONJAC GUM**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Konjac gum is a water-soluble hydrocolloid obtained from the Konjac flour by aqueous extraction. Konjac flour is the unpurified raw product from the root of the perennial plant *Amorphophallus konjac.* The main component of Konjac gum is the water-soluble high-molecular-weight polysaccharide glucomannan, which consists of D-mannose and D-glucose units at a molar ratio of 1,6:1,0, connected by β(1-4)-glycosidic bonds. Shorter side chains are attached through β(1-3)-glycosidic bonds, and acetyl groups occur at random at a ratio of about 1 group per 9 to 19 sugar units |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | The main component, glucomannan, has an average molecular weight of 200 000 to 2 000 000 |
| Assay | Not less than 75 % carbohydrate |
| **Description** | A white to cream to light tan powder |
| **Identification** | |
| Solubility | Dispersible in hot or cold water forming a highly viscous solution with a pH between 4,0 and 7,0 |
| Gel formation | Add 5 ml of a 4 % sodium borate solution to a 1 % solution of the sample in a test tube, and shake vigorously. A gel forms |
| Formation of heat-stable gel | Prepare a 2 % solution of the sample by heating it in a boiling water bath for 30 min, with continuous agitation and then cooling the solution to room temperature. For each g of the sample used to prepare 30 g of the 2 % solution, add 1 ml of 10 % potassium carbonate solution to the fully hydrated sample at ambient temperature. Heat the mixture in a water bath to 85 °C, and maintain for 2 h without agitation. Under these conditions a thermally stable gel is formed |
| **Purity** | |
| Loss on drying | Not more than 12 % (105 °C, 5 hours) |
| Starch | Not more than 3 % |
| Protein | Not more than 3 % (factor N × 5,7) |
| Viscosity (1 % solution) | Not less than 3 $kgm^{-1}s^{-1}$ at 25 °C |
| Ether-soluble material | Not more than 0,1 % |
| Total ash | Not more than 5,0 % (800 °C, 3 to 4 hours) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| **Microbiological criteria** | |
| *Salmonella* spp. | Absent in 12,5 g |
| *Escherichia coli* | Absent in 5 g |

**E 425 (ii) KONJAC GLUCOMANNAN**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Konjac glucomannan is a water-soluble hydrocolloid obtained from Konjac flour by washing with water-containing ethanol. Konjac flour is the unpurified raw product from the tuber of the perennial plant *Amorphophallus konjac*. The main component is the water-soluble high-molecular-weight polysaccharide glucomannan, which consists of D-mannose and D-glucose units at a molar ratio of 1,6:1,0, connected by β(1-4)-glycosidic bonds with a branch at about each 50th or 60th unit. About each 19th sugar residue is acetylated |

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|---|---|
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | 500 000 to 2 000 000 |
| Assay | Total dietary fibre: not less than 95 % on a dry weight basis |
| **Description** | White to slightly brownish fine particle size, free flowing and odourless powder |
| **Identification** | |
| Solubility | Dispersible in hot or cold water forming a highly viscous solution with a pH between 5,0 and 7,0. Solubility is increased by heat and mechanical agitation |
| Formation of heat-stable gel | Prepare a 2 % solution of the sample by heating it in a boiling water bath for 30 min, with continuous agitation and then cooling the solution to room temperature. For each g of the sample used to prepare 30 g of the 2 % solution, add 1 ml of 10 % potassium carbonate solution to the fully hydrated sample at ambient temperature. Heat the mixture in a water bath to 85 °C, and maintain for 2 h without agitation. Under these conditions a thermally stable gel is formed |
| **Purity** | |
| Loss on drying | Not more than 8 % (105 °C, 3 hours) |
| Starch | Not more than 1 % |
| Viscosity (1 % solution) | Not less than 20 $kgm^{-1}s^{-1}$ at 25 °C |
| Protein | Not more than 1,5 % (N × 5,7)<br>Determine nitrogen by Kjeldahl method. The percentage of nitrogen in the sample multiplied by 5,7 gives the percent of protein in the sample |
| Ether-soluble material | Not more than 0,5 % |
| Sulphite (as $SO_2$) | Not more than 4 mg/kg |
| Chloride | Not more than 0,02 % |
| 50 % Alcohol-soluble material | Not more than 2,0 % |
| Total ash | Not more than 2,0 % (800 °C, 3 to 4 hours) |
| Lead | Not more than 1 mg/kg |
| **Microbiological criteria** | |
| *Salmonella* spp. | Absent in 12,5 g |
| *Escherichia coli* | Absent in 5 g |

**E 426 SOYBEAN HEMICELLULOSE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Soybean Hemicellulose is a refined water-soluble polysaccharide obtained from strain soybean fibre by hot water extraction. No organic precipitant shall be used other than ethanol |
| Einecs | |
| Chemical name | Water soluble soybean polysaccharides; Water soluble soybean fibre |
| Chemical formula | |
| Molecular weight | |
| Assay | Not less than 74 % carbohydrate |

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|---|---|
| **Description** | Free flowing white or yellowish white powder |
| **Identification** | |
| Solubility | Soluble in hot and cold water without gel formation |
| pH | 5,5 ± 1,5 (1 % solution) |
| **Purity** | |
| Loss on drying | Not more than 7 % (105 °C, 4 hours) |
| Protein | Not more than 14 % |
| Viscosity | Not more than 200 mPa.s (10 % solution) |
| Total ash | Not more than 9,5 % (600 °C, 4 hours) |
| Arsenic | Not more than 2 mg/kg |
| Ethanol | Not more than 2 % |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| **Microbiological criteria** | |
| Total plate count | Not more than 3 000 colonies per gram |
| Yeast and moulds | Not more than 100 colonies per gram |
| *Escherichia coli* | Absent in 10 g |

**E 427 CASSIA GUM**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Cassia gum is the ground purified endosperm of the seeds of *Cassia tora* and *Cassia obtusifoli* (*Leguminosae*) containing less than 0,05 % of *Cassia occidentalis*. It consists mainly of high molecular weight polysaccharides composed primarily of a linear chain of 1,4-β-D-mannopyranose units linked with 1,6-α-D-galactopyranose units. The ratio of mannose to galactose is about 5:1.<br>In the manufacture the seeds are dehusked and degermed by thermal mechanical treatment followed by milling and screening of the endosperm. The ground endosperm is further purified by extraction with propan-2-ol. |
| Assay | Not less than 75 % of Galactomannan |
| **Description** | Pale yellow to off-white, odourless powder |
| **Identification** | |
| Solubility | Insoluble in ethanol. Disperses well in cold water forming a colloidal solution. |
| Gel formation with borate | To an aqueous dispersion of the sample add sufficient sodium borate test solution (TS) to raise the pH to above 9; a gel is formed. |
| Gel formation with xanthan gum | Weigh 1,5 g of the sample and 1,5 g of xanthan gum and blend them. Add this blend (with rapid stirring) into 300 ml water at 80 °C in a 400 ml beaker. Stir until the mixture is dissolved and continue stirring for an extra 30 min after dissolution (maintain the temperature above 60 °C during the stirring process). Discontinue stirring and allow the mixture to cool at room temperature for at least 2 h. |

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| | A firm, viscoelastic gel forms after the temperature drops below 40 °C, but no such gel forms in a 1 % control solution of cassia gum or xanthan gum alone prepared in a similar manner. |
| Viscosity | Less than 500 mPa.s (25 °C, 2h, 1 % solution) corresponding to an average molecular weight of 200 000-300 000 Da |
| **Purity** | |
| Acid insoluble matter | Not more than 2,0 % |
| pH | 5,5-8 (1 % aqueous solution) |
| Crude fat | Not more than 1 % |
| Protein | Not more than 7 % |
| Total ash | Not more than 1,2 % |
| Loss on drying | Not more than 12 % (5h, 105 °C) |
| Total anthraquinones | Not more than 0,5 mg/kg(detection limit) |
| Solvent residues | Not more than 750 mg/kg Propan-2-ol |
| Lead | Not more than 1 mg/kg |
| **Microbiological criteria** | |
| Total plate count | Not more than 5 000 colony forming units per gram |
| Yeast and moulds | Not more than 100 colony forming units per gram |
| *Salmonella* spp. | Absent in 25 g |
| *Escherichia coli* | Absent in 1 g |

**E 431 POLYOXYETHYLENE (40) STEARATE**

| | |
|---|---|
| **Synonyms** | Polyoxyl (40) stearate; Polyoxyethylene (40) monostearate |
| **Definition** | A mixture of the mono- and diesters of edible commercial stearic acid and mixed polyoxyethylene diols (having an average polymer length of about 40 oxyethylene units) together with free polyol |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content not less than 97,5 % on the anhydrous basis |
| **Description** | Cream-coloured flakes or waxy solid at 25 °C with a faint odour |
| **Identification** | |
| Solubility | Soluble in water, ethanol, methanol and ethyl acetate. Insoluble in mineral oil |
| Congealing range | 39-44 °C |
| Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyoxyethylated polyol |
| **Purity** | |
| Water content | Not more than 3 % (Karl Fischer method) |
| Acid value | Not more than 1 |
| Saponification value | Not less than 25 and not more than 35 |
| Hydroxyl value | Not less than 27 and not more than 40 |
| 1,4-Dioxane | Not more than 5 mg/kg |

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|---|---|
| Ethylene glycols (mono- and di-) | Not more than 0,25 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 432 POLYOXYETHYLENE SORBITAN MONOLAURATE (POLYSORBATE 20)**

| | |
|---|---|
| **Synonyms** | Polysorbate 20; Polyoxyethylene (20) sorbitan monolaurate |
| **Definition** | A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial lauric acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content not less than 70 % of oxyethylene groups, equivalent to not less than 97,3 % of polyoxyethylene (20) sorbitan monolaurate on the anhydrous basis |
| **Description** | A lemon to amber-coloured oily liquid at 25 °C with a faint characteristic odour |
| **Identification** | |
| Solubility | Soluble in water, ethanol, methanol, ethyl acetate and dioxane. Insoluble in mineral oil and petroleum ether |
| Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyoxyethylated polyol |
| **Purity** | |
| Water content | Not more than 3 % (Karl Fischer method) |
| Acid value | Not more than 2 |
| Saponification value | Not less than 40 and not more than 50 |
| Hydroxyl value | Not less than 96 and not more than 108 |
| 1,4-dioxane | Not more than 5 mg/kg |

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|---|---|
| Ethylene glycols (mono- and di-) | Not more than 0,25 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 433 POLYOXYETHYLENE SORBITAN MONOOLEATE (POLYSORBATE 80)**

| | |
|---|---|
| **Synonyms** | Polysorbate 80; Polyoxyethylene (20) sorbitan monooleate |
| **Definition** | A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial oleic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides |

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|---|---|
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content not less than 65 % of oxyethylene groups, equivalent to not less than 96,5 % of polyoxyethylene (20) sorbitan monooleate on the anhydrous basis |
| **Description** | A lemon to amber-coloured oily liquid at 25 °C with a faint characteristic odour |
| **Identification** | |
| Solubility | Soluble in water, ethanol, methanol, ethyl acetate and toluene. Insoluble in mineral oil and petroleum ether |
| Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyoxyethylated polyol |
| **Purity** | |
| Water content | Not more than 3 % (Karl Fischer method) |
| Acid value | Not more than 2 |
| Saponification value | Not less than 45 and not more than 55 |
| Hydroxyl value | Not less than 65 and not more than 80 |
| 1,4-dioxane | Not more than 5 mg/kg |

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|---|---|
| Ethylene glycols (mono- and di-) | Not more than 0,25 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 434 POLYOXYETHYLENE SORBITAN MONOPALMITATE (POLYSORBATE 40)**

| | |
|---|---|
| **Synonyms** | Polysorbate 40; Polyoxyethylene (20) sorbitan monopalmitate |
| **Definition** | A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial palmitic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content not less than 66 % of oxyethylene groups, equivalent to not less than 97 % of polyoxyethylene (20) sorbitan monopalmitate on the anhydrous basis |
| **Description** | A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour |
| **Identification** | |
| Solubility | Soluble in water, ethanol, methanol, ethyl acetate and acetone. Insoluble in mineral oil |

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| Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyoxyethylated polyol |
| **Purity** | |
| Water content | Not more than 3 % (Karl Fischer method) |
| Acid value | Not more than 2 |
| Saponification value | Not less than 41 and not more than 52 |
| Hydroxyl value | Not less than 90 and not more than 107 |
| 1,4-dioxane | Not more than 5 mg/kg |

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|---|---|
| Ethylene glycols (mono- and di-) | Not more than 0,25 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 435 POLYOXYETHYLENE SORBITAN MONOSTEARATE (POLYSORBATE 60)**

| | |
|---|---|
| **Synonyms** | Polysorbate 60; Polyoxyethylene (20) sorbitan monostearate |
| **Definition** | A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial stearic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content not less than 65 % of oxyethylene groups, equivalent to not less than 97 % of polyoxyethylene (20) sorbitan monostearate on the anhydrous basis |
| **Description** | A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour |
| **Identification** | |
| Solubility | Soluble in water, ethyl acetate and toluene. Insoluble in mineral oil and vegetable oils |
| Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyoxyethylated polyol |
| **Purity** | |
| Water content | Not more than 3 % (Karl Fischer method) |
| Acid value | Not more than 2 |
| Saponification value | Not less than 45 and not more than 55 |
| Hydroxyl value | Not less than 81 and not more than 96 |
| 1,4-dioxane | Not more than 5 mg/kg |

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|---|---|
| Ethylene glycols (mono- and di-) | Not more than 0,25 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 436 POLYOXYETHYLENE SORBITAN TRISTEARATE (POLYSORBATE 65)**

| | |
|---|---|
| **Synonyms** | Polysorbate 65; Polyoxyethylene (20) sorbitan tristearate |
| **Definition** | A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial stearic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content not less than 46 % of oxyethylene groups, equivalent to not less than 96 % of polyoxyethylene (20) sorbitan tristearate on the anhydrous basis |
| **Description** | A tan-coloured, waxy solid at 25 °C with a faint characteristic odour |
| **Identification** | |
| Solubility | Dispersible in water. Soluble in mineral oil, vegetal oils, petroleum ether, acetone, ether, dioxane, ethanol and methanol |
| Congealing range | 29-33 °C |
| Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyoxyethylated polyol |
| **Purity** | |
| Water content | Not more than 3 % (Karl Fischer method) |
| Acid value | Not more than 2 |
| Saponification value | Not less than 88 and not more than 98 |
| Hydroxyl value | Not less than 40 and not more than 60 |
| 1,4-dioxane | Not more than 5 mg/kg |

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|---|---|
| Ethylene glycols (mono- and di-) | Not more than 0,25 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

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**E 440 (i) PECTIN**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Pectin consists mainly of the partial methyl esters of polygalacturonic acid and their ammonium, sodium, potassium and calcium salts. It is obtained by extraction in an aqueous medium of strains of appropriate edible plant material, usually citrus fruits or apples. No organic precipitant shall be used other than methanol, ethanol and propan-2-ol |
| Einecs | 232-553-0 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content not less than 65 % of galacturonic acid on the ash-free and anhydrous basis after washing with acid and alcohol |
| **Description** | White, light yellow, light grey or light brown powder |
| **Identification** | |
| Solubility | Soluble in water forming a colloidal, opalescent solution. Insoluble in ethanol |
| **Purity** | |
| Loss on drying | Not more than 12 % (105 °C, 2 hours) |
| Acid insoluble ash | Not more than 1 % (insoluble in approximately 3N hydrochloric acid) |
| Sulphur dioxide | Not more than 50 mg/kg on the anhydrous basis |
| Nitrogen content | Not more than 1,0 % after washing with acid and ethanol |
| Total insolubles | Not more than 3 % |
| Solvent residues | Not more than 1 % of free methanol, ethanol and propan-2-ol, singly or in combination, on the volatile matter-free basis |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 440 (ii) AMIDATED PECTIN**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Amidated pectin consists mainly of the partial methyl esters and amides of polygalacturonic acid and their ammonium, sodium, potassium and calcium salts. It is obtained by extraction in an aqueous medium of appropriate strains of edible plant material, usually citrus fruits or apples and treatment with ammonia under alkaline conditions. No organic precipitant shall be used other than methanol, ethanol and propan-2-ol |
| Einecs | |
| Chemical name | |

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| | |
|---|---|
| Chemical formula | |
| Molecular weight | |
| Assay | Content not less than 65 % of galacturonic acid on the ash-free and anhydrous basis after washing with acid and alcohol |
| **Description** | White, light yellow, light greyish or light brownish powder |
| **Identification** | |
| Solubility | Soluble in water forming a colloidal, opalescent solution. Insoluble in ethanol |
| **Purity** | |
| Loss on drying | Not more than 12 % (105 °C, 2 hours) |
| Acid-insoluble ash | Not more than 1 % (insoluble in approximately 3N hydrochloric acid) |
| Degree of amidation | Not more than 25 % of total carboxyl groups |
| Sulphur dioxide residue | Not more than 50 mg/kg on the anhydrous basis |
| Nitrogen content | Not more than 2,5 % after washing with acid and ethanol |
| Total insolubles: | Not more than 3 % |
| Solvent residues | Not more than 1 % of methanol, ethanol and propan-2-ol, singly or in combination, on a volatile matter-free basis |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 442 AMMONIUM PHOSPHATIDES**

| | |
|---|---|
| **Synonyms** | Ammonium salts of phosphatidic acid; Mixed ammonium salts of phoshorylated glycerides |
| **Definition** | A mixture of the ammonium compounds of phosphatidic acids derived from edible fat and oil. One or two or three glyceride moieties may be attached to phosphorus. Moreover, two phosphorus esters may be linked together as phosphatidyl phosphatides |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | The phosphorus content is not less than 3 % and not more than 3,4 % by weight; the ammonium content is not less than 1,2 % and not more than 1,5 % (calculated as N) |

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| **Description** | Unctuous semi-solid to oily liquid |

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| **Identification** | |
| Solubility | Soluble in fats. Insoluble in water. Partially soluble in ethanol and in acetone |
| Test for glycerol | Passes test |
| Test fatty acids | Passes test |

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|---|---|
| Test for phosphate | Passes test |
| **Purity** | |
| Petroleum ether insoluble matter | Not more than 2,5 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 444 SUCROSE ACETATE ISOBUTYRATE**

| | |
|---|---|
| **Synonyms** | SAIB |
| **Definition** | Sucrose acetate isobutyrate is a mixture of the reaction products formed by the esterification of food grade sucrose with acetic acid anhydride and isobutyric anhydride, followed by distillation. The mixture contains all possible combinations of esters in which the molar ratio of acetate to butyrate is about 2:6 |
| Einecs | 204-771-6 |
| Chemical name | Sucrose diacetate hexaisobutyrate |
| Chemical formula | $C_{40}H_{62}O_{19}$ |
| Molecular weight | 832-856 (approximate), $C_{40}H_{62}O_{19}$: 846,9 |
| Assay | Content not less than 98,8 % and not more than 101,9 % of $C_{40}H_{62}O_{19}$ |
| **Description** | A pale straw-coloured liquid, clear and free of sediment and having a bland odour |
| **Identification** | |
| Solubility | Insoluble in water. Soluble in most organic solvents |
| Refractive index | $[n]_D^{40}$: 1,4492-1,4504 |
| Specific gravity | $[d]^{25}{}_D$: 1,141-1,151 |
| **Purity** | |
| Triacetin | Not more than 0,1 % |
| Acid value | Not more than 0,2 |
| Saponification value | Not less than 524 and not more than 540 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 445 GLYCEROL ESTERS OF WOOD ROSIN**

| | |
|---|---|
| **Synonyms** | Ester gum |
| **Definition** | A complex mixture of tri- and diglycerol esters of resin acids from wood rosin. The rosin is obtained by the solvent extraction of aged pine stumps followed by a liquid-liquid solvent refining process. Excluded from these specifications are substances derived from gum rosin, and exudate of living pine trees, and substances derived from tall oil rosin, a by-product of kraft (paper) |

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|---|---|
| | pulp processing. The final product is composed of approximately 90 % resin acids and 10 % neutrals (non-acidic compounds). The resin acid fraction is a complex mixture of isomeric diterpenoid monocarboxylic acids having the empirical molecular formula of $C_{20}H_{30}O_2$, chiefly abietic acid. The substance is purified by steam stripping or by countercurrent steam distillation |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | Hard, yellow to pale amber-coloured solid |
| **Identification** | |
| Solubility | Insoluble in water, soluble in acetone |
| Infrared absorption spectrum | Characteristic of the compound |
| **Purity** | |
| Specific gravity of solution | $[d]^{20}_{25}$ not less than 0,935 when determined in a 50 % solution in d-limonene (97 %, boiling point 175,5-176 °C, $d^{20}_4$: 0,84) |
| Ring and ball softening range | Between 82 °C and 90 °C |
| Acid value | Not less than 3 and not more than 9 |
| Hydroxyl value | Not less than 15 and not more than 45 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Test for absence of tall oil rosin (sulphur test) | When sulphur-containing organic compounds are heated in the presence of sodium formate, the sulphur is converted to hydrogen sulphide which can readily be detected by the use of lead acetate paper. A positive test indicates the use of tall oil rosin instead of wood rosin |

**E 450 (i) DISODIUM DIPHOSPHATE**

| | |
|---|---|
| **Synonyms** | Disodium dihydrogen diphosphate; Disodium dihydrogen pyrophosphate; Sodium acid pyrophosphate; Disodium pyrophosphate |
| **Definition** | |
| Einecs | 231-835-0 |
| Chemical name | Disodium dihydrogen diphosphate |
| Chemical formula | $Na_2H_2P_2O_7$ |
| Molecular weight | 221,94 |
| Assay | Content not less than 95 % of disodium diphosphate<br>$P_2O_5$ content not less than 63,0 % and not more than 64,5 % |

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| | |
|---|---|
| **Description** | White powder or grains |
| **Identification** | |
| Test for sodium | Passes test |
| Test for phosphate | Passes test |
| Solubility | Soluble in water |
| pH | Between 3,7 and 5,0 (1 % solution) |
| **Purity** | |
| Loss on drying | Not more than 0,5 % (105 °C, 4 hours) |
| Water insoluble matter | Not more than 1 % |
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Aluminium | Not more than 200 mg/kg |

**E 450 (ii) TRISODIUM DIPHOSPHATE**

| | |
|---|---|
| **Synonyms** | Trisodium pyrophosphate; Trisodium monohydrogen diphosphate; Trisodium monohydrogen pyrophosphate; Trisodium diphosphate |
| **Definition** | |
| Einecs | 238-735-6 |
| Chemical name | |
| Chemical formula | Monohydrate: $Na_3HP_2O_7 \cdot H_2O$<br>Anhydrous: $Na_3HP_2O_7$ |
| Molecular weight | Monohydrate: 261,95<br>Anhydrous: 243,93 |
| Assay | Content not less than 95 % on the dried basis<br>$P_2O_5$ content not less than 57 % and not more than 59 % |
| **Description** | White powder or grains, occurs anhydrous or as a monohydrate |
| **Identification** | |
| Test for sodium | Passes test |
| Test for phosphate | Passes test |
| Solubility | Soluble in water |
| pH | Between 6,7 and 7,5 (1 % solution) |
| **Purity** | |
| Loss on ignition | Not more than 4,5 % on the anhydrous compound (450-550 °C).<br>Not more than 11,5 % on the monohydrate basis |
| Loss on drying | Not more than 0,5 % (105 °C, 4 hours) for anhydrous<br>Not more than 1,0 % (105 °C, 4 hours) for monohdyrate |

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|---|---|
| Water insoluble matter | Not more than 0,2 % |
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 450 (iii) TETRASODIUM DIPHOSPHATE**

| | |
|---|---|
| **Synonyms** | Tetrasodium pyrophosphate; Tetrasodium disphosphate; Tetrasodium phosphate |
| **Definition** | |
| Einecs | 231-767-1 |
| Chemical name | Tetrasodium diphosphate |
| Chemical formula | Anhydrous: $Na_4P_2O_7$<br>Decahydrate: $Na_4P_2O_7 \cdot 10H_2O$ |
| Molecular weight | Anhydrous: 265,94<br>Decahydrate: 446,09 |
| Assay | Content not less than 95 % of $Na_4P_2O_7$ on the ignited basis<br>$P_2O_5$ content not less than 52,5 % and not more than 54,0 % |
| **Description** | Colourless or white crystals, or a white crystalline or granular powder. The decahydrate effloresces slightly in dry air |
| **Identification** | |
| Test for sodium | Passes test |
| Test for phosphate | Passes test |
| Solubility | Soluble in water. Insoluble in ethanol |
| pH | Between 9,8 and 10,8 (1 % solution) |
| **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 (105 °C, 4 hours then 550 °C, 30 minutes) |
| Water insoluble matter | Not more than 0,2 % |
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 450 (v) TETRAPOTASSIUM DIPHOSPHATE**

| | |
|---|---|
| **Synonyms** | Tetrapotassium pyrophosphate |
| **Definition** | |
| Einecs | 230-785-7 |
| Chemical name | Tetrapotassium diphosphate |

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| | |
|---|---|
| Chemical formula | $K_4P_2O_7$ |
| Molecular weight | 330,34 (anhydrous) |
| Assay | Content not less than 95 % (800 °C for 0,5 hours)<br>$P_2O_5$ content not less than 42,0 % and not more than 43,7 % on the anhydrous basis |
| **Description** | Colourless crystals or white, very hygroscopic powder |
| **Identification** | |
| Test for potassium | Passes test |
| Test for phosphate | Passes test |
| Solubility | Soluble in water, insoluble in ethanol |
| pH | Between 10,0 and 10,8 (1 % solution) |
| **Purity** | |
| Loss on ignition | Not more than 2 % (105 °C, 4 hours then 550 °C, 30 minutes) |
| Water insoluble matter | Not more than 0,2 % |
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 450 (vi) DICALCIUM DIPHOSPHATE**

| | |
|---|---|
| **Synonyms** | Calcium pyrophosphate |
| **Definition** | |
| Einecs | 232-221-5 |
| Chemical name | Dicalcium diphosphate<br>Dicalcium pyrophosphate |
| Chemical formula | $Ca_2P_2O_7$ |
| Molecular weight | 254,12 |
| Assay | Content not less than 96 %<br>$P_2O_5$ content not less than 55 % and not more than 56 % |
| **Description** | A fine, white, odourless powder |
| **Identification** | |
| Test for calcium | Passes test |
| Test for phosphate | Passes test |
| Solubility | Insoluble in water. Soluble in dilute hydrochloric and nitric acids |
| pH | Between 5,5 and 7,0 (10 % suspension in water) |
| **Purity** | |
| Loss on ignition | Not more than 1,5 % (800 °C ± 25 °C, 30 minutes |
| Fluoride | Not more than 50 mg/kg (expressed as fluorine) |

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

**E 450 (vii) CALCIUM DIHYDROGEN DIPHOSPHATE**

| | |
|---|---|
| **Synonyms** | Acid calcium pyrophosphate; Monocalcium dihydrogen pyrophosphate |
| **Definition** | |
| Einecs | 238-933-2 |
| Chemical name | Calcium dihydrogen diphosphate |
| Chemical formula | $CaH_2P_2O_7$ |
| Molecular weight | 215,97 |
| Assay | Content not less than 90 % on the anhydrous basis<br>$P_2O_5$ content not less than 61 % and not more than 66 % |
| **Description** | White crystals or powder |
| **Identification** | |
| Test for calcium | Passes test |
| Test for phosphate | Passes test |
| **Purity** | |
| Acid-insoluble matter | Not more than 0,4 % |
| Fluoride | Not more than 30 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Aluminium | Not more than 800 mg/kg. This applies until 31 March 2015.<br>Not more than 200 mg/kg. This applies from 1 April 2015. |

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**E 450 (ix) MAGNESIUM DIHYDROGEN DIPHOSPHATE**

| | |
|---|---|
| **Synonyms** | Acid magnesium pyrophosphate, monomagnesium dihydrogen pyrophosphate; magnesium diphosphate, magnesium pyrophosphate |
| **Definition** | Magnesium dihydrogen diphosphate is the acidic magnesium salt of diphosphoric acid. It is manufactured by adding an aqueous dispersion of magnesium hydroxide slowly to phosphoric acid, until a molar ratio about 1:2 between Mg and P is reached. The temperature is held under 60 °C during the reaction. About 0,1 % hydrogen peroxide is added to the reaction mixture and the slurry is then heated and milled. |

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|---|---|
| EINECS | 244-016-8 |
| Chemical name | Mono magnesium dihydrogen diphosphate |
| Chemical formula | $MgH_2P_2O_7$ |
| Molecular Weight | 200,25 |
| Assay | $P_2O_5$ content not less than 68,0 % and not more than 70,5 % expressed as $P_2O_5$<br>MgO content not less than 18,0 % and not more than 20,5 % expressed as MgO |
| **Description** | White crystals or powder |
| **Identification** | |
| Solubility | Slightly soluble in water, practically insoluble in ethanol |
| Particle size: | The average particle size will deviate between 10 and 50 μm |
| **Purity** | |
| Loss on ignition | Not more than 12 % (800 °C, 0,5 hours) |
| Fluoride | Not more than 20 mg/kg (expressed as fluorine) |
| Aluminium | Not more than 50 mg/kg |
| Arsenic | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg. |
| Lead | Not more than 1 mg/kg |

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**E 451 (i) PENTASODIUM TRIPHOSPHATE**

| | |
|---|---|
| **Synonyms** | Pentasodium tripolyphosphate; Sodium tripolyphosphate |
| **Definition** | |
| Einecs | 231-838-7 |
| Chemical name | Pentasodium triphosphate |
| Chemical formula | $Na_5O_{10}P_3 \cdot nH_2O$ (n = 0 or 6) |
| Molecular weight | 367,86 |
| Assay | Content not less than 85,0 % (anhydrous) or 65,0 % (hexahydrate)<br>$P_2O_5$ content not less than 56 % and not more than 59 % (anhydrous) or not less than 43 % and not more than 45 % (hexahydrate) |

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| | |
|---|---|
| **Description** | White, slightly hygroscopic granules or powder |
| **Identification** | |
| Solubility | Freely soluble in water. Insoluble in ethanol |
| Test for sodium | Passes test |
| Test for phosphate | Passes test |
| pH | Between 9,1 and 10,2 (1 % solution) |
| **Purity** | |
| Loss on drying | Anhydrous: Not more than 0,7 % (105 °C, 1 hour)<br>Hexahydrate: Not more than 23,5 % (60 °C, 1 hour, then 105 °C, 4 hours) |
| Water insoluble matter | 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 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 451 (ii) PENTAPOTASSIUM TRIPHOSPHATE**

| | |
|---|---|
| **Synonyms** | Pentapotassium tripolyphosphate; Potassium triphosphate; Potassium tripolyphosphate |
| **Definition** | |
| Einecs | 237-574-9 |
| Chemical name | Pentapotassium triphosphate; Pentapotassium tripolyphosphate |
| Chemical formula | $K_5O_{10}P_3$ |
| Molecular weight | 448,42 |
| Assay | Content not less than 85 % on the anhydrous basis<br>$P_2O_5$ content not less than 46,5 % and not more than 48 % |
| **Description** | White, very hygroscopic powder or granules |
| **Identification** | |
| Solubility | Very soluble in water |
| Test for potassium | Passes test |
| Test for phosphate | Passes test |
| pH | Between 9,2 and 10,5 (1 % solution) |
| **Purity** | |
| Loss on ignition | Not more than 0,4 % (105 °C, 4 hours, then 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 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |

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| | |
|---|---|
| Mercury | Not more than 1 mg/kg |

**E 452 (i) SODIUM POLYPHOSPHATE**

I. SOLUBLE POLYPHOSPHATE

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

II. INSOLUBLE POLYPHOSPHATE

| | |
|---|---|
| **Synonyms** | Insoluble sodium metaphosphate; Maddrell's salt; Insoluble sodium polyphosphate; IMP |
| **Definition** | Insoluble sodium metaphosphate is a high molecular weight sodium polyphosphate composed of two long metaphosphate chains $(NaPO_3)_x$ that spiral in opposite directions about a common axis. The $Na_2O/P_2O_5$ ratio is about 1,0. The pH of 1 in 3 suspension in water is about 6,5 |
| Einecs | 272-808-3 |

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| | |
|---|---|
| Chemical name | Sodium polyphosphate |
| Chemical formula | Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula $H_{(n+2)}P_nO_{(3n+1)}$ where 'n' is not less than 2 |
| Molecular weight | $(102)_n$ |
| Assay | $P_2O_5$ content not less than 68,7 % and not more than 70,0 % |
| **Description** | White crystalline powder |
| **Identification** | |
| Solubility | Insoluble in water, soluble in mineral acids and in solutions of potassium and ammonium (but not sodium) chlorides |
| Test for sodium | Passes test |
| Test for phosphate | Passes test |
| pH | About 6,5 (1 in 3 suspension in water) |
| **Purity** | |
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 452 (ii) POTASSIUM POLYPHOSPHATE**

| | |
|---|---|
| **Synonyms** | Potassium metaphosphate; Potassium polymetaphosphate; Kurrol salt |
| **Definition** | |
| Einecs | 232-212-6 |
| Chemical name | Potassium polyphosphate |
| Chemical formula | $(KPO_3)n$<br>Heterogenous mixtures of potassium salts of linear condensed polyphosphoric acids of general formula $H_{(n+2)}P_nO_{(3n+1)}$ where 'n' is not less than 2 |
| Molecular weight | $(118)_n$ |
| Assay | $P_2O_5$ content not less than 53,5 % and not more than 61,5 % on the ignited basis |
| **Description** | Fine white powder or crystals or colourless glassy platelets |
| **Identification** | |
| Solubility | 1 g dissolves in 100 ml of a 1 in 25 solution of sodium acetate |
| Test for potassium | Passes test |
| Test for phosphate | Passes test |
| pH | Not more than 7,8 (1 % suspension) |
| **Purity** | |
| Loss on ignition | Not more than 2 % (105 °C, 4 hours then 550 °C, 30 minutes) |
| Cyclic phosphate | Not more than 8 % on $P_2O_5$ content |

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| | |
|---|---|
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

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

| | |
|---|---|
| **Synonyms** | Sodium calcium polyphosphate, glassy |
| **Definition** | |
| Einecs | 233-782-9 |
| Chemical name | Sodium calcium polyphosphate |
| Chemical formula | $(NaPO_3)_n$ CaO where n is typically 5 |
| Molecular weight | |
| Assay | $P_2O_5$ content not less than 61 % and not more than 69 % on the ignited basis |
| **Description** | White glassy crystals, spheres |
| **Identification** | |
| pH | Approximately 5 to 7 (1 % m/m slurry) |
| CaO content | 7 % - 15 % m/m |
| **Purity** | |
| Fluoride | Not more than 10 mg/kg |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 452 (iv) CALCIUM POLYPHOSPHATE**

| | |
|---|---|
| **Synonyms** | Calcium metaphosphate; Calcium polymetaphosphate |
| **Definition** | |
| Einecs | 236-769-6 |
| Chemical name | Calcium polyphosphate |
| Chemical formula | $(CaP_2O_6)n$<br>Heterogenous mixtures of calcium salts of condensed polyphosphoric acids of general formula $H_{(n+2)}P_nO_{(n+1)}$ where ‘n’ is not less than 2 |
| Molecular weight | $(198)_n$ |
| Assay | $P_2O_5$ content not less than 71 % and not more than 73 % on the ignited basis |
| **Description** | Odourless, colourless crystals or white powder |
| **Identification** | |
| Solubility | Usually sparingly soluble in water. Soluble in acid medium |
| Test for calcium | Passes test |

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|---|---|
| Test for phosphate | Passes test |
| CaO content | 27 to 29,5 % |
| **Purity** | |
| Loss on ignition | Not more than 2 % (105 °C, 4 hours then 550 °C, 30 minutes) |
| Cyclic phosphate | Not more than 8 % (on $P_2O_5$ content) |
| Fluoride | Not more than 30 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

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**E 456 POTASSIUM POLYASPARTATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Potassium polyaspartate is the potassium salt of polyaspartic acid, produced from L-aspartic acid and potassium hydroxide. The thermic process transforms the aspartic acid in polysuccinimide that is insoluble. Polysuccinimide is treated with potassium hydroxide allowing the opening of the ring and polymerisation of the units. The last step is the spray drying phase, which results in a light tan powder |
| CAS number | 64723-18-8 |
| Chemical name | L-aspartic acid, homopolymer, potassium salt |
| Chemical formula | $[C_4H_4NO_3K]_n$ |
| Weight average molecular weight | Approximately 5 300 g/mol |
| Assay | Not less than 98 % on dry weight basis |
| Particle size | Not less than 45 μm (not more than 1 % in weight of particles of less than 45 μm) |
| **Description** | A light brown odourless powder |
| **Identification** | |
| Solubility | Very soluble in water and slightly soluble in organic solvents |
| pH | 7,5-8,5 (40 % aqueous solution) |
| **Purity** | |
| Degree of substitutions | Not less than 91,5 % on dry weight basis |
| Loss on drying | Not more than 11 % (105 °C,12 hours) |
| Potassium hydroxide | Not more than 2 % |
| Aspartic acid | Not more than 1 % |
| Other impurities | Not more than 0,1 % |
| Arsenic | Not more than 2,5 mg/kg |

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| | |
|---|---|
| Lead | Not more than 1,5 mg/kg |
| Mercury | Not more than 0,5 mg/kg |
| Cadmium | Not more than 0,1 mg/kg |

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**E 459 BETA-CYCLODEXTRIN**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Beta-cyclodextrin is a non-reducing cyclic saccharide consisting of seven α-1,4-linked D-glucopyranosyl units. The product is manufactured by the action of the enzyme cycloglycosyltransferase (CGTase) obtained from *Bacillus circulans, Paenibacillus macerans* or recombinant *Bacillus licheniformis* strain SJ1608 on partially hydrolysed starch |
| Einecs | 231-493-2 |
| Chemical name | Cycloheptaamylose |
| Chemical formula | $(C_6H_{10}O_5)_7$ |
| Molecular weight | 1 135 |
| Assay | Content not less than 98,0 % of $(C_6H_{10}O_5)_7$ on an anhydrous basis |
| **Description** | Virtually odourless white or almost white crystalline solid |
| Appearance of the aqueous solution | Clear and colourless |
| **Identification** | |
| Solubility | Sparingly soluble in water; freely soluble in hot water; slightly soluble in ethanol |
| Specific rotation | $[\alpha]_D^{25}$ + 160° to + 164° (1 % solution) |
| pH value: | 5,0-8,0 (1 % solution) |
| **Purity** | |
| Water content | Not more than 14 % (Karl Fischer method) |
| Other cyclodextrins | Not more than 2 % on an anhydrous basis |
| Solvent residues | Not more than 1 mg/kg of each of toluene and trichloroethylene |
| Sulphated ash | Not more than 0,1 % |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |

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**E 460 (i) MICROCRYSTALLINE CELLULOSE, CELLULOSE GEL**

| | |
|---|---|
| **Synonyms** | |

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|---|---|
| **Definition** | Microcrystalline cellulose is purified, partially depolymerised cellulose prepared by treating alpha-cellulose, obtained as a pulp from strains of fibrous plant material, with mineral acids. The degree of polymerisation is typically less than 400 |
| Einecs | 232-674-9 |

▼B

| | |
|---|---|
| Chemical name | Cellulose |
| Chemical formula | $(C_6H_{10}O_5)_n$ |
| Molecular weight | About 36 000 |
| Assay | Not less than 97 % calculated as cellulose on the anhydrous basis |
| Particle size | Not less than 5 $\mu$m (not more than 10 % of particles of less than 5 $\mu$m) |
| **Description** | A fine white or almost white odourless powder |
| **Identification** | |

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|---|---|
| Solubility | Insoluble in water, ethanol, ether and dilute mineral acids. Practically insoluble or insoluble in sodium hydroxide solution (concentration: 50 g NaOH/L) |

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|---|---|
| Colour reaction | To 1 mg of the sample, add 1 ml of phosphoric acid and heat on a water bath for 30 minutes. Add 4 ml of a 1 in 4 solution of pyrocatechol in phosphoric acid and heat for 30 minutes. A red colour is produced |
| Infrared absorption spectroscopy | To be identified |
| Suspension test | Mix 30 g of the sample with 270 ml of water in a high-speed (12 000 rpm) power blender for 5 minutes. The resultant mixture will be either a free-following suspension or a heavy, lumpy suspension which flows poorly, if at all, settles only slightly and contains many trapped air bubbles. If a free-flowing suspension is obtained, transfer 100 ml into a 100-ml graduated cylinder and allow to stand for 1 hour. The solids settles and a supernatant liquid appears |
| pH | The pH of the supernatant liquid is between 5,0 and 7,5 (10 % suspension in water) |
| **Purity** | |
| Loss on drying | Not more than 7 % (105 °C, 3 hours) |
| Water soluble matter | Not more than 0,24 % |
| Sulphated ash | Not more than 0,5 % (800 ± 25 °C) |
| Starch | Not detectable<br>To 20 ml of the dispersion obtained in Identification, suspension test, add a few drops of iodine solution and mix. No purplish to blue or blue colour should be produced |
| Carboxyl groups | Not more than 1 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 460 (ii) POWDERED CELLULOSE**

| | |
|---|---|
| **Definition** | Purified, mechanically disintegrated cellulose prepared by processing alpha-cellulose obtained as a pulp from strains of fibrous plant materials |
| Einecs | 232-674-9 |
| Chemical name | Cellulose; Linear polymer of 1:4 linked glucose residues |
| Chemical formula | $(C_6H_{10}O_5)_n$ |
| Molecular weight | $(162)_n$ (n is predominantly 1 000 and greater) |
| Assay | Content not less than 92 % |

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| | |
|---|---|
| Particle size | Not less than 5 $\mu$m (not more than 10 % of particles of less than 5 $\mu$m) |
| **Description** | A white, odourless powder |
| **Identification** | |
| Solubility | Insoluble in water, ethanol, ether and dilute mineral acids. Slightly soluble in sodium hydroxide solution |
| Suspension test | Mix 30 g of the sample with 270 ml of water in a high-speed (12 000 rpm) power blender for 5 minutes. The resultant mixture will be either a free-flowing suspension or a heavy, lumpy suspension which flows poorly, if at all, settles only slightly and contains many trapped air bubbles. If a free-flowing suspension is obtained, transfer 100 ml into a 100-ml graduated cylinder and allow to stand for 1 hour. The solids settles and a supernatant liquid appears |
| pH | The pH of the supernatant liquid is between 5,0 and 7,5 (10 % suspension in water) |
| **Purity** | |
| Loss on drying | Not more than 7 % (105 °C, 3 hours) |
| Water soluble matter | Not more than 1,0 % |
| Sulphated ash | Not more than 0,3 % (800 ± 25 °C) |
| Starch | Not detectable<br>To 20 ml of the dispersion obtained in Identification, suspension test, add a few drops of iodine solution and mix. No purplish to blue or blue colour should be produced |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 461 METHYL CELLULOSE**

| | |
|---|---|
| **Synonyms** | Cellulose methyl ether |
| **Definition** | Methyl cellulose is cellulose obtained directly from strains of fibrous plant material and partially etherified with methyl groups |
| Einecs | |
| Chemical name | Methyl ether of cellulose |
| Chemical formula | The polymers contain substituted anhydroglucose units with the following general formula:<br>$C_6H_7O_2(OR_1)(OR_2)(OR_3)$ where $R_1$, $R_2$, $R_3$ each may be one of the following:<br>— H<br>— $CH_3$ or<br>— $CH_2CH_3$ |
| Molecular weight | From about 20 000 to 380 000 |
| Assay | Content not less than 25 % and not more than 33 % of methoxyl groups ($-OCH_3$) and not more than 5 % of hydroxyethoxyl groups ($-OCH_2CH_2OH$) |

▼B

| | |
|---|---|
| **Description** | Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder |
| **Identification** | |
| Solubility | Swelling in water, producing a clear to opalescent, viscous, colloidal solution.<br>Insoluble in ethanol, ether and chloroform.<br>Soluble in glacial acetic acid |
| pH | Not less than 5,0 and not more than 8,0 (1 % colloidal solution) |
| **Purity** | |
| Loss on drying | Not more than 10 % (105 °C, 3 hours) |
| Sulphated ash | Not more than 1,5 % (800 ± 25 °C) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 462 ETHYL CELLULOSE**

| | |
|---|---|
| **Synonyms** | Cellulose ethyl ether |
| **Definition** | Ethyl cellulose is cellulose obtained directly from fibrous plant material and partially etherified with ethyl groups |
| Einecs | |
| Chemical name | Ethyl ether of cellulose |
| Chemical formula | The polymers contain substituted anhydroglucose units with the following general formula:<br>$C_6H_7O_2(OR_1)(OR_2)$ where $R_1$ and $R_2$ may be any of the following:<br>— H<br>— $CH_2CH_3$ |
| Molecular weight | |
| Assay | Content not less than 44 % and not more than 50 % of ethoxyl groups ($-OC_2H_5$) on the dried basis (equivalent to not more than 2,6 ethoxyl groups per anhydroglucose unit) |
| **Description** | Slightly hygroscopic white to off-white, odourless and tasteless powder |
| **Identification** | |
| Solubility | Practically insoluble in water, in glycerol and in propane-1,2-diol but soluble in varying proportions in certain organic solvents depending upon the ethoxyl content. Ethyl cellulose containing less than 46 to 48 % of ethoxyl groups is freely soluble in tetrahydrofuran, in methyl acetate, in chloroform and in aromatic hydrocarbon ethanol mixtures. Ethyl cellulose containing 46 to 48 % or more of ethoxyl groups is freely soluble in ethanol, in methanol, in toluene, in chloroform and in ethyl acetate |
| Film forming test | Dissolve 5 g of the sample in 95 g of an 80:20 (w/w) mixture of toluene ethanol. A clear, stable, slightly yellow solution is formed. Pour a few ml of the solution onto a glass plate and allow the solvent to evaporate. A thick, tough, continuous, clear film remains. The film is flammable |

▼B

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|---|---|
| pH | Neutral to litmus (1 % colloidal solution) |
| **Purity** | |
| Loss on drying | Not more than 3 % (105 °C, 2 hours) |
| Sulphated ash | Not more than 0,4 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 463 HYDROXYPROPYL CELLULOSE**

| | |
|---|---|
| **Synonyms** | Cellulose hydroxypropyl ether |
| **Definition** | Hydroxypropylcellulose is cellulose obtained directly from strains of fibrous plant material and partially etherified with hydroxypropyl groups |
| Einecs | |
| Chemical name | Hydroxypropyl ether of cellulose |
| Chemical formula | The polymers contain substituted anhydroglucose units with the following general formula:<br>$C_6H_7O_2(OR_1)(OR_2)(OR_3)$, where $R_1$, $R_2$, $R_3$ each may be one of the following:<br>— H<br>— $CH_2CHOHCH_3$<br>— $CH_2CHO(CH_2CHOHCH_3)CH_3$<br>— $CH_2CHO[CH_2CHO(CH_2CHOHCH_3)CH_3]CH_3$ |
| Molecular weight | From about 30 000 to 1 000 000 |
| Assay | Content not more than 80,5 % of hydroxypropoxyl groups ($-OCH_2CHOHCH_3$) equivalent to not more than 4,6 hydroxypropyl groups per anhydroglucose unit on the anhydrous basis |
| **Description** | Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder |
| **Identification** | |
| Solubility | Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Soluble in ethanol. Insoluble in ether |
| Gas chromatography | Determine the substituents by gas chromotography |
| pH | Not less than 5,0 and not more than 8,0 (1 % colloidal solution) |
| **Purity** | |
| Loss on drying | Not more than 10 % (105 °C, 3 hours) |
| Sulphated ash | Not more than 0,5 % determined at 800 ± 25 °C |
| Propylene chlorohydrins | Not more than 0,1 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

▼M27

**E 463a LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE (L-HPC)**

| | |
|---|---|
| **Synonyms** | Cellulose hydroxypropyl ether, low substituted |
| **Definition** | L-HPC is a low-substituted poly (hydroxypropyl) ether of cellulose.<br>L-HPC is manufactured by partial etherification of the anhydroglucose units of pure cellulose (wood pulp) with propylene oxide/hydroxypropyl groups. The resulting product is then purified, dried and milled to yield low-substituted hydroxypropyl cellulose.<br>L-HPC contains not less than 5,0 % and not more than 16,0 % of hydroxypropoxy groups, calculated on the dried basis.<br>L-HPC differs from hydroxypropyl cellulose (E 463) with respect to the degree of molar substitution with hydroxypropoxy groups of the glucose ring unit (0,2 for L-HPC vs 3,5 for E 463) of the cellulose backbone. |
| IUPAC name | Cellulose, 2-hydroxypropyl ether (low substituted) |
| CAS number | 9004-64-2 |
| Einecs number | |
| Chemical name | Hydroxypropyl ether of cellulose, low-substituted |
| Chemical formula | The polymers contain substituted anhydroglucose units with the following general formula:<br>$C_6H_7O_2(OR_1)(OR_2)(OR_3)$<br>where $R_1$, $R_2$, $R_3$ each may be one of the following:<br>— H<br>— $CH_2CHOHCH_3$<br>— $CH_2CHO(CH_2CHOHCH_3)CH_3$<br>— $CH_2CHO[CH_2CHO(CH_2CHOHCH_3)CH_3]CH_3$ |
| Molecular weight | From about 30 000 to 150 000 g/mol |
| Assay | The average number of hydroxypropoxy groups<br>($–OCH_2CHOHCH_3$) corresponds to 0,2 hydroxypropyl groups per anhydroglucose unit on the anhydrous basis |
| Particle size | by laser diffraction method — Not less than 45 μm (not more than 1 % in weight of particles of less than 45 μm) and not more than 65 μm<br>by size-exclusion chromatography (SEC) — Average (D50) particle size between 47,3 μm and 50,3 μm; D90 value (90 % below given value) between 126,2 μm and 138 μm |
| **Description** | Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder |
| **Identification** | Passes test |
| Solubility | Insoluble in water; swelling in water. It dissolves in a solution of 10 % sodium hydroxide producing a viscous solution. |
| Assay | Determination of the degree of molar substitution by gas chromatography |
| pH | Not less than 5,0 and not more than 7,5 (1 % colloidal suspension) |
| **Purity** | |
| Loss on drying | Not more than 5,0 % (105 °C, 1 hour) |
| Residue on ignition | Not more than 0,8 % determined at 800 °C ± 25 °C |
| Propylene chlorohydrins | Not more than 0,1 mg/kg (on an anhydrous basis) (gas chromatography–mass spectrometry (GC–MS)) |
| Arsenic | Not more than 2 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 0,5 mg/kg |
| Cadmium | Not more than 0,15 mg/kg |

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**E 464 HYDROXYPROPYL METHYL CELLULOSE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Hydroxypropyl methyl cellulose is cellulose obtained directly from strains of fibrous plant material and partially etherified with methyl groups and containing a small degree of hydroxypropyl substitution |
| Einecs | |
| Chemical name | 2-Hydroxypropyl ether of methylcellulose |
| Chemical formula | The polymers contain substituted anhydroglucose units with the following general formula:<br>$C_6H_7O_2(OR_1)(OR_2)(OR_3)$, where $R_1$, $R_2$, $R_3$ each may be one of the following:<br>— H<br>— $CH_3$<br>— $CH_2CHOHCH_3$<br>— $CH_2CHO$ ($CH_2CHOHCH_3$) $CH_3$<br>— $CH_2CHO[CH_2CHO$ ($CH_2CHOHCH_3$) $CH_3]CH_3$ |
| Molecular weight | From about 13 000 to 200 000 |
| Assay | Content not less than 19 % and not more than 30 % methoxyl groups ($-OCH_3$) and not less than 3 % and not more than 12 % hydroxypropoxyl groups ($-OCH_2CHOHCH_3$), on the anhydrous basis |
| **Description** | Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder |
| **Identification** | |
| Solubility | Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol |
| Gas chromatography | Determine the substituents by gas chromatography |
| pH | Not less than 5,0 and not more than 8,0 (1 % colloidal solution) |
| **Purity** | |
| Loss on drying | Not more than 10 % (105 °C, 3 hours) |
| Sulphated ash | Not more than 1,5 % for products with viscosities of 50 mPa.s or above<br>Not more than 3 % for products with viscosities below 50 mPa.s |
| Propylene chlorohydrins | Not more than 0,1 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 465 ETHYL METHYL CELLULOSE**

| | |
|---|---|
| **Synonyms** | Methylethylcellulose |
| **Definition** | Ethyl methyl cellulose is cellulose obtained directly from strains of fibrous plant material and partially etherified with methyl and ethyl groups |
| Einecs | |
| Chemical name | Ethyl methyl ether of cellulose |

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|---|---|
| Chemical formula | The polymers contain substituted anhydroglucose units with the following general formula:<br>$C_6H_7O_2(OR_1)(OR_2)(OR_3)$, where $R_1$, $R_2$, $R_3$ each may be one of the following:<br>— H<br>— $CH_3$<br>— $CH_2CH_3$ |
| Molecular weight | From about 30 000 to 40 000 |
| Assay | Content on the anhydrous basis not less than 3,5 % and not more than 6,5 % of methoxyl groups ($-OCH_3$) and not less than 14,5 % and not more than 19 % of ethoxyl groups ($-OCH_2CH_3$), and not less than 13,2 % and not more than 19,6 % of total alkoxyl groups, calculated as methoxyl |
| **Description** | Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder |
| **Identification** | |
| Solubility | Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Soluble in ethanol. Insoluble in ether |
| pH | Not less than 5,0 and not more than 8,0 (1 % colloidal solution) |
| **Purity** | |
| Loss on drying | Not more than 15 % for the fibrous form, and not more than 10 % for the powdered form (105 °C to constant weight) |
| Sulphated ash | Not more than 0,6 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

▼M8

**E 466 SODIUM CARBOXY METHYL CELLULOSE, CELLULOSE GUM**

| | |
|---|---|
| **Synonyms** | NaCMC; Sodium CMC |
| **Definition** | Sodium carboxy methyl cellulose is the partial sodium salt of a carboxymethyl ether of cellulose, the cellulose being obtained directly from strains of fibrous plant material |

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|---|---|
| Einecs | |
| Chemical name | Sodium salt of the carboxymethyl ether of cellulose |
| Chemical formula | The polymers contain substituted anhydroglucose units with the following general formula:<br>$C_6H_7O_2(OR_1)(OR_2)(OR_3)$, where $R_1$, $R_2$, $R_3$ each may be one of the following:<br>— H<br>— $CH_2COONa$<br>— $CH_2COOH$ |
| Molecular weight | Higher than approximately 17 000 (degree of polymerisation approximately 100) |
| Assay | Content on the anhydrous basis not less than 99,5 % |
| **Description** | Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder |

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|---|---|
| **Identification** | |
| Solubility | Yields a viscous colloidal solution with water. Insoluble in ethanol |
| Foam test | A 0,1 % solution of the sample is shaken vigorously. No layer of foam appears. (This test permits the distinction of sodium carboxymethyl cellulose from other cellulose ethers) |
| Precipitate formation | To 5 ml of a 0,5 % solution of the sample, add 5 ml of 5 % solution of copper sulphate or of aluminium sulphate. A precipitate appears. (This test permits the distinction of sodium carboxymethyl cellulose from other cellulose ethers and from gelatine, locust bean gum and tragacanth) |
| Colour reaction | Add 0,5 g powdered carboxy methyl cellulose sodium to 50 ml of water, while stirring to produce an uniform dispersion. Continue the stirring until a clear solution is produced, and use the solution for the following test:<br>To 1 mg of the sample, diluted with an equal volume of water, in a small test tube, add 5 drops of 1-naphthol solution. Incline the test 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 |
| pH | Not less than 5,0 and not more than 8,5 (1 % colloidal solution) |
| **Purity** | |
| Degree of substitution | Not less than 0,2 and not more than 1,5 carboxymethyl groups (-$CH_2COOH$) per anhydroglucose unit |
| Loss on drying | Not more than 12 % (105 °C to constant weight) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Total glycolate | Not more than 0,4 %, calculated as sodium glycolate on the anhydrous basis |
| Sodium | Not more than 12,4 % on the anhydrous basis |

**E 468 CROSS-LINKED SODIUM CARBOXYMETHYLCELLULOSE, CROSS-LINKED CELLULOSE GUM**

| | |
|---|---|
| **Synonyms** | Cross-linked carboxymethyl cellulose; Cross-linked CMC; Cross-linked sodium CMC; |
| **Definition** | Cross-linked sodium carboxymethyl cellulose is the sodium salt of thermally cross-linked partly O-carboxymethylated cellulose |
| Einecs | |
| Chemical name | Sodium salt of the cross-linked carboxymethyl ether cellulose |
| Chemical formula | The polymers containing substituted anhydroglucose units with the general formula:<br>$C_6H_7O_2(OR_1)(OR_2)(OR_3)$ where $R_1$, $R_2$ and $R_3$ may be any of the following:<br>— H<br>— $CH_2COONa$<br>— $CH_2COOH$ |
| Molecular weight | |
| Assay | |

▼B

| | |
|---|---|
| **Description** | Slightly hygroscopic, white to off white, odourless powder |
| **Identification** | |
| Precipitate formation | 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 |
| Colour reaction | 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 |
| Test for sodium | Passes test |
| pH | Not less than 5,0 and not more than 7,0 (1 % solution) |
| **Purity** | |
| Loss on drying | Not more than 6 % (105 °C, 3 hours) |
| Water soluble matter | Not more than 10 % |
| Degree of substitution | Not less than 0,2 and not more than 1,5 carboxymethyl groups per anhydroglucose unit |
| Sodium content | Not more than 12,4 % on anhydrous basis |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 469 ENZYMATICALLY HYDROLYSED CARBOXYMETHYLCELLULOSE, ENZYMATICALLY HYDROLISED CELLULOSE GUM**

| | |
|---|---|
| **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*) |
| Einecs | |
| Chemical name | Carboxymethyl cellulose, sodium, partially enzymatically hydrolysed |
| Chemical formula | Sodium salts of polymers containing substituted anhydroglucose units with the general formula:<br>$[C_6H_7O_2(OH)_x(OCH_2COONa)_y]_n$<br>where n is the degree of polymerisation<br>x = 1,50 to 2,80<br>y = 0,2 to 1,50<br>x + y = 3,0<br>(y = degree of substitution) |
| Molecular weight | 178,14 where y = 0,20<br>282,18 where y = 1,50<br>Macromolecules: Not less than 800 (n about 4) |
| Assay | Not less than 99,5 %, including mono- and disaccharides, on the dried basis |

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|---|---|
| **Description** | White or slightly yellowish or greyish, odourless, slightly hygroscopic granular or fibrous powder |
| **Identification** | |
| Solubility | Soluble in water, insoluble in ethanol |
| 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 |
| 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 |
| 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 |
| Viscosity (60 % solids) | Not less than 2 500 $kgm^{-1}s^{-1}$ at 25 °C corresponding to an average molecule weight of 5 000 Da |
| pH | Not less than 6,0 and not more than 8,5 (1 % colloidal solution) |
| **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 |
| 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 470a SODIUM, POTASSIUM AND CALCIUM SALTS OF FATTY ACIDS**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Sodium, potassium and calcium salts of fatty acids occurring in food oils and fats, these salts being obtained either from edible fats and oils or from distilled food fatty acids. |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content on the anhydrous basis not less than 95 % (105 °C till a constant weight) |
| **Description** | White or creamy white light powders, flakes or semi-solids |

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|---|---|
| **Identification** | |
| Solubility | Sodium and potassium salts: soluble in water and ethanol. Calcium salts: insoluble in water, ethanol and ether |
| Test for cations | Passes test |
| Test for fatty acids | Passes test |
| **Purity** | |
| Sodium | Not less than 9 % and not more than 14 % expressed as $Na_2O$ |
| Potassium | Not less than 13 % and not more than 21,5 % expressed as $K_2O$ |
| Calcium | Not less than 8,5 % and not more than 13 % expressed as CaO |
| Unsaponifiable matter | Not more than 2 % |
| Free fatty acids | Not more than 3 % estimated as oleic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Free alkali | Not more than 0,1 % expressed as NaOH |
| Matter insoluble in alcohol | Not more than 0,2 % (sodium and potassium salts only) |

**E 470b MAGNESIUM SALTS OF FATTY ACIDS**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Magnesium salts of fatty acids occurring in foods oils and fats, these salts being obtained either from edible fats and oils or from distilled food fatty acids |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content on the anhydrous basis not less than 95 % (105 °C till a constant weight) |
| **Description** | White or creamy-white light powders, flakes or semi-solids |
| **Identification** | |
| Solubility | Insoluble in water, partially soluble in ethanol and ether |
| Test for magnesium | Passes test |
| Test for fatty acids | Passes test |
| **Purity** | |
| Magnesium | Not less than 6,5 % and not more than 11 % expressed as MgO |
| Free alkali | Not more than 0,1 % expressed as MgO |
| Unsaponifiable matter | Not more than 2 % |
| Free fatty acids | Not more than 3 % estimated as oleic acid |
| Arsenic | Not more than 3 mg/kg |

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

▼M42

**E 471 MONO- AND DIGLYCERIDES OF FATTY ACIDS**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Mono- and diglycerides of fatty acids consist of mixtures of glycerol mono-, di- and tri-esters of fatty acids occurring in food oils and fats. They may contain small amounts of free fatty acids and glycerol.<br>Glycerol used for the manufacture of mono- and diglycerides of fatty acids should comply with the specifications for E 422.<br>E 471 shall be produced from fats and oils complying with Union food safety requirements for edible fats and oils. |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content of mono- and di-esters: not less than 70 %<br>Content of erucic acid, including erucic acid bound in the mono/diglyceride:<br>Not more than 0,2 % (only if added to food for infants and young children)<br>Not more than 0,5 % (for all uses except for foods intended for infants and young children) |
| **Description** | The product varies from a pale yellow to pale brown oily liquid to a white or slightly off-white hard waxy solid. The solids may be in the form of flakes, powders or small beads. |
| **Identification** | |
| Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyol |
| Test for glycerol | Passes test |
| Test for fatty acids | Passes test |
| Solubility | Insoluble in water, soluble in ethanol and toluene at 50 °C |
| **Purity** | |
| Water content | Not more than 2 % (Karl Fischer method) |
| Acid value | Not more than 6 |
| Free glycerol | Not more than 7 % |
| Polyglycerols | Not more than 4 % diglycerol and not more than 1 % higher polyglycerols both based on total glycerol content |
| Arsenic | Not more than 0,1 mg/kg |
| Lead | Not more than 0,1 mg/kg |
| Mercury | Not more than 0,1 mg/kg |
| Cadmium | Not more than 0,1 mg/kg |
| Sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters, expressed as 3-MCPD | Not more than 0,75 mg/kg (only if added to food for infants and young children)<br>Not more than 2,5 mg/kg (for all uses except for foods intended for infants and young children) |
| Glycidyl esters of fatty acids, expressed as glycidol | From 30 July 2023 until 30 January 2024, not more than 5 mg/kg if added to food for infants and young children) and not more than 10 mg/kg for all other uses.<br>From 30 January 2024, not more than 5 mg/kg for all uses. |
| Total glycerol | Not less than 16 % and not more than 33 % |
| Sulphated ash | Not more than 0,5 % determined at 800 ± 25 °C |
| Soap | — |

***Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate)***

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**E 472 a ACETIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS**

| | |
|---|---|
| **Synonyms** | Acetic acid esters of mono- and diglycerides; Acetoglycerides; Acetylated mono- and diglycerides; Acetic and fatty acid esters of glycerol |
| **Definition** | Esters of glycerol with acetic and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free acetic acid and free glycerides |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | Clear, mobile liquids to solids, from white to pale yellow in colour |
| **Identification** | |
| Test for glycerol | Passes test |
| Test for fatty acids | Passes test |
| Test for acetic acid | Passes test |
| Solubility | Insoluble in water. Soluble in ethanol |
| **Purity** | |
| Acids other than acetic and fatty acids | Less than 1 % |
| Free glycerol | Not more than 2 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Total acetic acid | Not less than 9 % and not more than 32 % |
| Free fatty acids (and acetic acid) | Not more than 3 % estimated as oleic acid |
| Total glycerol | Not less than 14 % and not more than 31 % |
| Sulphated ash | Not more than 0,5 % determined at 800 ± 25 °C |

***Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate)***

**E 472 b LACTIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS**

| | |
|---|---|
| **Synonyms** | Lactic acid esters of mono- and diglycerides; Lactoglycerides; Mono- and diglycerides of fatty acids esterified with lactic acid |
| **Definition** | Esters of glycerol with lactic acid and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free lactic acid and free glycerides |

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| | |
|---|---|
| **Description** | Clear, mobile liquids to waxy solids of variable consistency, from white to pale yellow in colour |
| **Identification** | |
| Test for glycerol, | Passes test |
| Test for fatty acids | Passes test |
| Test for lactic acid | Passes test |
| Solubility | Insoluble in cold water but dispersible in hot water |
| **Purity** | |
| Acids other than lactic and fatty acids | Less than 1 % |
| Free glycerol | Not more than 2 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Total lactic acid | Not less than 13 % and not more than 45 % |
| Free fatty acids (and lactic acid) | Not more than 3 % estimated as oleic acid |
| Total glycerol | Not less than 13 % and not more than 30 % |
| Sulphated ash | Not more than 0,5 % (800 ± 25 °C) |

***Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate)***

**E 472 c CITRIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS**

| | |
|---|---|
| **Synonyms** | Citrem; Citric acid esters of mono- and diglycerides; Citroglycerides; Mono- and diglycerides of fatty acids esterified with citric acid |
| **Definition** | Esters of glycerol with citric acid and fatty acids occurring in food oils and fats. They may contain small amounts of free glycerol, free fatty acids, free citric acid and free glycerides. They may be partially or wholly neutralised with sodium, potassium or calcium salts suitable for the purpose and authorised as food additives according to this Regulation. |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | Yellowish or light brown liquids to waxy solids or semi-solids |
| **Identification** | |
| Test for glycerol | Passes test |

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|---|---|
| Test for fatty acids | Passes test |
| Test for citric acid | Passes test |
| Solubility | Insoluble in cold water, dispersible in hot water, soluble in oils and fats, insoluble in cold ethanol |
| **Purity** | |
| Acids other than citric and fatty acids | Less than 1 % |
| Free glycerol | Not more than 2 % |
| Total glycerol | Not less than 8 % and not more than 33 % |
| Total citric acid | Not less than 13 % and not more than 50 % |
| Sulphated ash | Non-neutralised products: not more than 0,5 % (800 ± 25 °C)<br>Partially or wholly neutralised products: not more than 10 % (800 ± 25 °C) |
| Lead | Not more than 2 mg/kg |
| Acid value | Not more than 130 |

***Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however, these substances may be present up to a maximum level of 6 % (expressed as sodium oleate)***

**E 472 d TARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS**

| | |
|---|---|
| **Synonyms** | Tartaric acid esters of mono- and diglycerides; Mono- and diglycerides of fatty acids esterified with tartaric acid |
| **Definition** | Esters of glycerol with tartaric acid and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free tartaric acid and free glycerides |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | Sticky viscous yellowish liquids to hard yellow waxes |
| **Identification** | |
| Test for glycerol | Passes test |
| Test for fatty acids | Passes test |
| Test for tartaric acid | Passes test |
| **Purity** | |
| Acids other than tartaric and fatty acids | Less than 1,0 % |
| Free glycerol | Not more than 2 % |
| Total glycerol | Not less than 12 % and not more than 29 % |
| Arsenic | Not more than 3 mg/kg |

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|---|---|
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Total tartaric acid | Not less than 15 % and not more than 50 % |
| Free fatty acids | Not more than 3 % estimated as oleic acid |
| Sulphated ash | Not more than 0,5 % (800 ± 25 °C) |

***Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate)***

**E 472 e MONO- AND DIACETYLTARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS**

| | |
|---|---|
| **Synonyms** | Diacetyltartaric acid esters of mono- and diglycerides; Mono-and diglycerides of fatty acids esterified with mono- and diacetyltartaric acid; Diacetyltartaric and fatty acid esters of glycerol |
| **Definition** | Mixed esters of glycerol with mono- and diacetyltartaric acids (obtained from tartaric acid) and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free tartaric and acetic acids and their combinations, and free glycerides. Contains also tartaric and acetic esters of fatty acids |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | Sticky viscous liquids through a fat-like consistency to yellow waxes which hydrolyse in moist air to liberate acetic acid |
| **Identification** | |
| Test for glycerol | Passes test |
| Test for fatty acids | Passes test |
| Test for tartaric acid | Passes test |
| Test for acetic acid | Passes test |
| **Purity** | |
| Acids other than acetic, tartaric and fatty acids | Less than 1 % |
| Free glycerol | Not more than 2 % |
| Total glycerol | Not less than 11 % and not more than 28 % |
| Sulphated ash | Not more than 0,5 % determined at 800 ± 25 °C |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

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| | |
|---|---|
| Total tartaric acid | Not less than 10 % and not more than 40 % |
| Total acetic acid | Not less than 8 % and not more than 32 % |
| Acid value | Not less than 40 and not more than 130 |

***Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate)***

**E 472 f MIXED ACETIC AND TARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS**

| | |
|---|---|
| **Synonyms** | Mono- and diglycerides of fatty acids esterified with acetic acid and tartaric acid |
| **Definition** | Esters of glycerol with acetic and tartaric acids and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free tartaric and acetic acids, and free glycerides. May contain mono- and diacetyltartaric esters of mono- and diglycerides of fatty acids |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | Sticky liquids to solids, from white to pale-yellow in colour |
| **Identification** | |
| Test for glycerol | Passes test |
| Test for fatty acids | Passes test |
| Test for tartaric acid | Passes test |
| Test for acetic acid | Passes test |
| **Purity** | |
| Acids other than acetic, tartaric and fatty acids | Less than 1,0 % |
| Free glycerol | Not more than 2 % |
| Total glycerol | Not less than 12 % and not more than 27 % |
| Sulphated ash | Not more than 0,5 % (800 ± 25 °C) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Total acetic acid | Not less than 10 % and not more than 20 % |
| Total tartaric acid | Not less than 20 % and not more than 40 % |
| Free fatty acids | Not more than 3 % estimated as oleic acid |

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***Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate)***

**E 473 SUCROSE ESTERS OF FATTY ACIDS**

| | |
|---|---|
| **Synonyms** | Sucroesters; Sugar esters |
| **Definition** | Essentially the mono-, di- and triesters of sucrose with fatty acids occurring in food fats and oils. They may be prepared from sucrose and the methyl, ethyl and vinyl esters of food fatty acids (including lauric acid) or by extraction from sucroglycerides. No organic solvent other than dimethylsulphoxide, dimethylformamide, ethyl acetate, propan-2-ol, 2-methyl-1-propanol, propylene glycol, methyl ethyl ketone and supercritical carbondioxide may be used for their preparation. *p*-methoxy phenol can be used as a stabiliser during the manufacturing procedure. |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content not less than 80 % |
| **Description** | Stiff gels, soft solids or white to slightly greyish-white powders |
| **Identification** | |
| Test for sugar | Passes test |
| Test for fatty acids | Passes test |
| Solubility | Sparingly soluble in water, soluble in ethanol |
| **Purity** | |
| Sulphated ash | Not more than 2 % (800 ± 25 °C) |
| Free sugar | Not more than 5 % |
| Free fatty acids | Not more than 3 % estimated as oleic acid |
| *p*-methoxy-phenol | Not more than 100 µg/kg |
| Acetaldehyde | Not more than 50 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Methanol | Not more than 10 mg/kg |
| Dimethylsulphoxide | Not more than 2 mg/kg |
| Dimethylformamide | Not more than 1 mg/kg |
| 2-methyl-1-propanol | Not more than 10 mg/kg |
| Ethyl acetate<br>Propan-2-ol<br>Propylene glycol | } Not more than 350 mg/kg, singly or in combination |
| Methyl ethyl ketone | Not more than 10 mg/kg |

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***Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate)***

**E 474 SUCROGLYCERIDES**

| | |
|---|---|
| **Synonyms** | Sugar glycerides |
| **Definition** | Sucroglycerides are produced by reacting sucrose with an edible fat or oil to produce a mixture of essentially mono-, di- and triesters of sucrose and fatty acids (including lauric acid) together with residual mono-, di- and triglycerides from fat or oil. No organic solvents shall be used in their preparation other than cyclohexane, dimethylformamide, ethyl acetate, 2-methyl-1-propanol and propan-2-ol |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content not less than 40 % and not more than 60 % of sucrose fatty acid esters |
| **Description** | Soft solid masses, stiff gels or white to off-white powders |
| **Identification** | |
| Test for sugar | Passes test |
| Test for fatty acids | Passes test |
| Solubility | Insoluble in cold water, soluble in ethanol |
| **Purity** | |
| Sulphated ash | Not more than 2 % (800 ± 25 °C) |
| Free sugar | Not more than 5 % |
| Free fatty acids | Not more than 3 % (estimated as oleic acid) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Methanol | Not more than 10 mg/kg |
| Dimethylformamide | Not more than 1 mg/kg |
| 2-Methyl-1-propanol | Not more than 10 mg/kg, single or in combination |
| Cyclohexane | |
| Ethyl acetate | Not more than 350 mg/kg, single or in combination |
| Propan-2-ol | |

***Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate)***

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**E 475 POLYGLYCEROL ESTERS OF FATTY ACIDS**

| | |
|---|---|
| **Synonyms** | Polyglycerol fatty acid esters; Polyglycerin esters of fatty acid esters |
| **Definition** | Polyglycerol esters of fatty acids are produced by the esterification of polyglycerol with food fats and oils or with fatty acids occurring in foods fats and oils. The polyglycerol moiety is predominantly di-, tri- and tetraglycerol and contains not more than 10 % of polyglycerols equal to or higher than heptaglycerol.<br>The polyglycerol is produced from glycerol complying with the specifications for E 422. |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content of total fatty acid ester not less than 90 % |
| **Description** | Light yellow to amber, oily to very viscous liquids; light tan to medium brown, plastic or soft solids; and light tan to brown, hard, waxy solids |
| **Identification** | |
| Test for glycerol | Passes test |
| Test for polyglycerols | Passes test |
| Test for fatty acids | Passes test |
| Solubility | The esters range from very hydrophilic to very lipophilic, but as a class tend to be dispersible in water and soluble in organic solvents and oils |
| **Purity** | |
| Sulphated ash | Not more than 0,5 % (800 ± 25 °C) |
| Acids other than fatty acids | Less than 1 % |
| Free fatty acids | Not more than 6 % estimated as oleic acid |
| Total glycerol and polyglycerol | Not less than 18 % and not more than 60 % |
| Free glycerol and polyglycerol | Not more than 7 % |
| Arsenic | Not more than 0,1 mg/kg |
| Lead | Not more than 0,3 mg/kg |
| Mercury | Not more than 0,1 mg/kg |
| Cadmium | Not more than 0,1 mg/kg |
| Sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters, expressed as 3-MCPD | Not more than 2,5 mg/kg |
| Glycidyl fatty acid esters, expressed as glycidol | Not more than 10 mg/kg. This applies from 20 July 2023 until 20 January 2024.<br>Not more than 5 mg/kg. This applies from 20 January 2024. |
| Erucic acid | Not more than 2 % |

***Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate).***

**E 476 POLYGLYCEROL POLYRICINOLEATE**

| | |
|---|---|
| **Synonyms** | Glycerol esters of condensed castor oil fatty acids; Polyglycerol esters of polycondensed fatty acids from castor oil; Polyglycerol esters of interesterified ricinoleic acid; PGPR |

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|---|---|
| **Definition** | Polyglycerol polyricinoleate is prepared by the esterification of polyglycerol with condensed castor oil fatty acids. Castor oil used for the production of polyglycerol polyricinoleate is free of ricin.<br>The polyglycerol is produced from glycerol complying with the specifications for E 422. |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | Clear, highly viscous liquid |
| **Identification** | |
| Solubility | Insoluble in water and in ethanol; soluble in ether, hydrocarbons and halogenated hydrocarbons |
| Test for glycerol | Passes test |
| Test for polyglycerols | Passes test |
| Test for ricinoleic acid | Passes test |
| Refractive index | $[n]_D^{65}$ between 1,4630 and 1,4665 |
| **Purity** | |
| Polyglycerols | The polyglycerol moiety shall be composed of not less than 75 % of di-, tri- and tetraglycerols and shall contain not more than 10 % of polyglycerols equal to or higher than heptaglycerol |
| Hydroxyl value | Not less than 80 and not more than 100 |
| Acid value | Not more than 6 |
| Arsenic | Not more than 0,1 mg/kg |
| Lead | Not more than 0,1 mg/kg |
| Mercury | Not more than 0,1 mg/kg |
| Cadmium | Not more than 0,1 mg/kg |
| Sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD) | Not more than 2,5 mg/kg |
| Glycidyl fatty acid esters (expressed as glycidol) | Not more than 1 mg/kg |

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**E 477 PROPANE-1,2-DIOL ESTERS OF FATTY ACIDS**

| | |
|---|---|
| **Synonyms** | Propylene glycol esters of fatty acids |
| **Definition** | Consists of mixtures of propane-1,2-diol mono- and diesters of fatty acids occurring in food fats and oils. The alcohol moiety is exclusively propane-1,2-diol together with dimer and traces of trimer. Organic acids other than food fatty acids are absent |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content of total fatty acid ester not less than 85 % |
| **Description** | Clear liquids or waxy white flakes, beads or solids having a bland odour |
| **Identification** | |
| Test for propylene glycol | Passes test |

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|---|---|
| Test for fatty acids | Passes test |
| **Purity** | |
| Sulphated ash | Not more than 0,5 % (800 ± 25 °C) |
| Acids other than fatty acids | Less than 1 % |
| Free fatty acids | Not more than 6 % estimated as oleic acid |
| Total propane-1,2-diol | Not less than 11 % and not more than 31 % |
| Free propane-1,2-diol | Not more than 5 % |
| Dimer and trimer of propylene glycol | Not more than 0,5 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

***Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate)***

**E 479 b THERMALLY OXIDISED SOYA BEAN OIL INTERACTED WITH MONO- AND DIGLYCERIDES OF FATTY ACIDS**

| | |
|---|---|
| **Synonyms** | TOSOM |
| **Definition** | Thermally oxidised soya bean oil interacted with mono- and diglycerides of fatty acids is a complex mixture of esters of glycerol and fatty acids found in edible fat and fatty acids from thermally oxidised soya bean oil. It is produced by interaction and deodorisation under vacuum at 130 °C of 10 % of thermally oxidised soya bean oil and 90 % mono- and diglycerides of food fatty acids. Soya bean oil is exclusively made from strains of soya beans |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | Pale yellow to light brown a waxy or solid consistency |
| **Identification** | |
| Solubility | Insoluble in water. Soluble in hot oil or fat |
| **Purity** | |
| Melting range | 55-65 °C |
| Free fatty acids | Not more than 1,5 % estimated as oleic acid |
| Free glycerol | Not more than 2 % |
| Total fatty acids | 83-90 % |
| Total glycerol | 16-22 % |
| Fatty acid methyl esters, not forming adduct with urea | Not more than 9 % of total fatty acid methyl esters |

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| Fatty acids, insoluble in petroleum ether | Not more than 2 % of total fatty acids |
| Peroxide value | Not more than 3 |
| Epoxides | Not more than 0,03 % oxirane oxygen |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 481 SODIUM STEAROYL-2-LACTYLATE**

| | |
|---|---|
| **Synonyms** | Sodium stearoyl lactylate; Sodium stearoyl lactate |
| **Definition** | A mixture of the sodium salts of stearoyl lactylic acids and its polymers and minor amounts of sodium salts of other related acids, manufactured by the reaction of stearic acid and lactic acid. Other food fatty acids may also be present, free or esterified, due to their presence in the stearic acid used |
| Einecs | 246-929-7 |
| Chemical name | Sodium di-2-stearoyl lactate<br>Sodium di(2-stearoyloxy)propionate |
| Chemical formula | $C_{21}H_{39}O_4Na$; $C_{19}H_{35}O_4Na$ (major components) |
| Molecular weight | |
| Assay | |
| **Description** | White or slightly yellowish powder or brittle solid with a characteristic odour |
| **Identification** | |
| Test for sodium | Passes test |
| Test for fatty acids | Passes test |
| Test for lactic acid | Passes test |
| Solubility | Insoluble in water. Soluble in ethanol |
| **Purity** | |
| Sodium | Not less than 2,5 % and not more than 5 % |
| Ester value | Not less than 90 and not more than 190 |
| Acid value | Not less than 60 and not more than 130 |
| Total lactic acid | Not less than 15 % and not more than 40 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 482 CALCIUM STEAROYL-2-LACTYLATE**

| | |
|---|---|
| **Synonyms** | Calcium stearoyl lactate |
| **Definition** | A mixture of the calcium salts of stearoyl lactylic acids and its polymers and minor amounts of calcium salts of other related acids, manufactured by the reaction of stearic acid and lactic acid. Other food fatty acids may also be present, free or esterified, due to their presence in the stearic acid used |

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|---|---|
| Einecs | 227-335-7 |
| Chemical name | Calcium di-2-stearoyl lactate<br>Calcium di(2-stearoyloxy)propionate |
| Chemical formula | $C_{42}H_{78}O_8Ca$; $C_{38}H_{70}O_8Ca$, $C_{40}H_{74}O_8Ca$ (major components) |
| Molecular weight | |
| Assay | |
| **Description** | White or slightly yellowish powder or brittle solid with a characteristic odour |
| **Identification** | |
| Test for calcium | Passes test |
| Test for fatty acids | Passes test |
| Test for lactid acid | Passes test |
| Solubility | Slightly soluble in hot water |
| **Purity** | |
| Calcium | Not less than 1 % and not more than 5,2 % |
| Ester value | Not less than 125 and not more than 190 |
| Total lactic acid | Not less than 15 % and not more than 40 % |
| Acid value | Not less than 50 and not more than 130 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 483 STEARYL TARTRATE**

| | |
|---|---|
| **Synonyms** | Stearyl palmityl tartrate |
| **Definition** | Product of the esterification of tartaric acid with commercial stearyl alcohol, which consists essentially of stearyl and palmityl alcohols. It consists mainly of diester, with minor amounts of monoester and of unchanged starting materials |
| Einecs | |
| Chemical name | Distearyl tartrate<br>Dipalmityl tartrate<br>Stearylpalmityl tartrate |
| Chemical formula | $C_{40}H_{78}O_6$ (Distearyl tartrate)<br>$C_{36}H_{70}O_6$ (Dipalmityl tartrate)<br>$C_{38}H_{74}O_6$ (Stearylpalmityl tartrate) |
| Molecular weight | 655 (Distearyl tartrate)<br>599 (Dipalmityl tartrate)<br>627 (Stearylpalmityl tartrate) |
| Assay | Content of total ester not less than 90 % corresponding to an ester value of not less than 163 and not more than 180 |
| **Description** | Cream-coloured unctuous solid (at 25 °C) |

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| | |
|---|---|
| **Identification** | |
| Test for tartrate | Passes test |
| Melting range | Between 67 °C and 77 °C. After saponification the saturated long chain fatty alcohols have a melting range of 49 °C to 55 °C |
| **Purity** | |
| Hydroxyl value | Not less than 200 and not more than 220 |
| Acid value | Not more than 5,6 |
| Total tartaric acid | Not less than 18 % and not more than 35 % |
| Sulphated ash | Not more than 0,5 % (800 ± 25 °C) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Unsaponifiable matter | Not less than 77 % and not more than 83 % |
| Iodine value | Not more than 4 (Wijs method) |

**E 491 SORBITAN MONOSTEARATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial stearic acid |
| Einecs | 215-664-9 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters |
| **Description** | Light, cream- to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour |
| **Identification** | |
| Solubility | Soluble at temperatures above its melting point in toluene, dioxane, carbon tetrachloride, ether, methanol, ethanol and aniline; insoluble in petroleum ether and acetone; insoluble in cold water but dispersible in warm water; soluble with haze at temperatures above 50 °C in mineral oil and ethyl acetate |

▼M28

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|---|---|
| Identification test | By acid value, iodine value (not more than 4), gas chromatography |

▼B

| | |
|---|---|
| Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyol |
| **Purity** | |
| Water content | Not more than 2 % (Karl Fischer method) |
| Sulphated ash | Not more than 0,5 % |
| Acid value | Not more than 10 |
| Saponification value | Not less than 147 and not more than 157 |

▼B

| | |
|---|---|
| Hydroxyl value | Not less than 235 and not more than 260 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 492 SORBITAN TRISTEARATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial stearic acid |
| Einecs | 247-891-4 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters |
| **Description** | Light, cream- to tan-coloured beads or flakes or hard, waxy solid with a slight odour |
| **Identification** | |
| Solubility | Slightly soluble in toluene, ether, carbon tetrachloride and ethyl acetate; dispersible in petroleum ether, mineral oil, vegetable oils, acetone and dioxane; insoluble in water, methanol and ethanol |

▼M28

| | |
|---|---|
| Identification test | By acid value, iodine value (not more than 4), gas chromatography |

▼B

| | |
|---|---|
| Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyol |
| **Purity** | |
| Water content | Not more than 2 % (Karl Fischer method) |
| Sulphated ash | Not more than 0,5 % |
| Acid value | Not more than 15 |
| Saponification value | Not less than 176 and not more than 188 |
| Hydroxyl value | Not less than 66 and not more than 80 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 493 SORBITAN MONOLAURATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial lauric acid |
| Einecs | 215-663-3 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |

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| | |
|---|---|
| Assay | Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters |
| **Description** | Amber-coloured oily viscous liquid, light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight odour |
| **Identification** | |
| Solubility | Dispersible in hot and cold water |
| Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyol |
| **Purity** | |
| Water content | Not more than 2 % (Karl Fischer method) |
| Sulphated ash | Not more than 0,5 % |
| Acid value | Not more than 7 |
| Saponification value | Not less than 155 and not more than 170 |
| Hydroxyl value | Not less than 330 and not more than 358 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 494 SORBITAN MONOOLEATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial oleic acid. Major constituent is 1,4-sorbitan monooleate. Other constituents include isosorbide monooleate, sorbitan dioleate and sorbitan trioleate |
| Einecs | 215-665-4 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content not less than 95 % of a mixture of sorbitol, sorbitan and isosorbide esters |
| **Description** | Amber-coloured viscous liquid, light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour |
| **Identification** | |
| Solubility | Soluble at temperatures above its melting point in ethanol, ether, ethyl acetate, aniline, toluene, dioxane, petroleum ether and carbon tetra-chloride. Insoluble in cold water, dispersible in warm water |
| Iodine value | The residue of oleic acid, obtained from the saponification of the sorbitan monooleate in assay, has a iodine value between 80 and 100 |
| **Purity** | |
| Water content | Not more than 2 % (Karl Fischer method) |
| Sulphated ash | Not more than 0,5 % |

▼B

| | |
|---|---|
| Acid value | Not more than 8 |
| Saponification value | Not less than 145 and not more than 160 |
| Hydroxyl value | Not less than 193 and not more than 210 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 495 SORBITAN MONOPALMITATE**

| | |
|---|---|
| **Synonyms** | Sorbitan palmitate |
| **Definition** | A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial palmitic acid |
| Einecs | 247-568-8 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters |
| **Description** | Light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour |
| **Identification** | |
| Solubility | Soluble at temperatures above its melting point in ethanol, methanol, ether, ethyl acetate, aniline, toluene, dioxane, petroleum ether and carbon tetrachloride. Insoluble in cold water but dispersible in warm water |

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| | |
|---|---|
| Identification test | By acid value, iodine value (not more than 4), gas chromatography |

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| | |
|---|---|
| Infrared absorption spectrum | Characteristic of a partial fatty acid ester of polyol |
| **Purity** | |
| Water content | Not more than 2 % (Karl Fischer method) |
| Sulphate ash | Not more than 0,5 % |
| Acid value | Not more than 7,5 |
| Saponification value | Not less than 140 and not more than 150 |
| Hydroxyl value | Not less than 270 and not more than 305 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

▼M5

**E 499 STIGMASTEROL-RICH PLANT STEROLS**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Stigmasterol-rich plant sterols are derived from soybeans and are a chemically defined simple mixture that comprises not less than 95 % of plant sterols (stigmasterol, β-sitosterol, campesterol and brassicasterol), with stigmasterol representing not less than 85 % of the stigmasterol-rich plant sterols. |

▼M5

| | |
|---|---|
| Einecs | |
| Chemical name | |
| Stigmasterol | (3S,8S,9S,10R,13R,14S,17R)-17-(5-ethyl-6-methyl-hept-3-en-2-yl)-10,13-dimethyl-2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1Hcyclopenta[a]phenanthren-3-ol |
| β-Sitosterol | (3S,8S,9S,10R,13R,14S,17R)-17-[(2S,5S)-5-ethyl-6-methylheptan-2-yl]-10,13-dimethyl-2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1Hcyclopenta[a]phenanthren-3-ol |
| Campesterol | (3S,8S,9S,10R,13R,14S,17R)-17-(5,6-dimethylheptan-2-yl)-10,13-dimethyl-2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1Hcyclopenta[a]phenanthren-3-ol |
| Brassicasterol | (3S,8S,9S,10R,13R,14S,17R)-17-[(E,2R,5R)-5,6-dimethylhept-3-en-2-yl]-10,13-dimethyl-2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1Hcyclopenta[a]phenanthren-3-ol |
| Chemical formula | |
| Stigmasterol | $C_{29}H_{48}O$ |
| β-Sitosterol | $C_{29}H_{50}O$ |
| Campesterol | $C_{28}H_{48}O$ |
| Brassicasterol | $C_{28}H_{46}O$ |
| Molecular weight | |
| Stigmasterol | 412,6 g/mol |
| β-Sitosterol | 414,7 g/mol |
| Campesterol | 400,6 g/mol |
| Brassicasterol | 398,6 g/mol |
| Assay (products containing only free sterols and stanols) | Content not less than 95 % on a total free sterol/stanol basis on the anhydrous basis |
| **Description** | Free-flowing, white to off-white powders, pills or pastilles; colourless to pale yellow liquids |
| **Identification** | |
| Solubility | Practically insoluble in water. Phytosterols and phytostanols are soluble in acetone and ethyl acetate. |
| Stigmasterol content | Not less than 85 % (w/w) |
| Other plant sterols/stanols: either singularly or in combination including Brassicasterol, campestanol, campesterol, Δ-7-campesterol, cholesterol, chlerosterol, sitostanol and β-sitosterol. | Not more than 15 % (w/w) |
| **Purity** | |
| Total Ash | Not more than 0,1 % |
| Residual Solvents | Ethanol: Not more than 5 000 mg/kg |
| | Methanol: Not more than 50 mg/kg |
| Water content | Not more than 4 % (Karl Fischer method) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 1 mg/kg |
| **Microbiological criteria** | |
| Total plate count | Not more than 1 000 CFU/g |
| Yeasts | Not more than 100 CFU/g |
| Moulds | Not more than 100 CFU/g |

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|---|---|
| *Escherichia coli* | Not more than 10 CFU/g |
| *Salmonella* spp. | Absent in 25 g |

▼B

**E 500 (i) SODIUM CARBONATE**

| | |
|---|---|
| **Synonyms** | Soda ash |
| **Definition** | |
| Einecs | 207-838-8 |
| Chemical name | Sodium carbonate |
| Chemical formula | $Na_2CO_3 \cdot nH_2O$ (n = 0, 1 or 10) |
| Molecular weight | 106,00 (anhydrous) |
| Assay | Content not less than 99 % of $Na_2CO_3$ on the anhydrous basis |
| **Description** | Colourless crystals or white, granular or crystalline powder<br>The anhydrous form is hygroscopic, the decahydrate efflorescent |
| **Identification** | |
| Test for sodium | Passes test |
| Test for carbonate | Passes test |
| 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 2 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** | |
| Einecs | 205-633-8 |
| Chemical name | Sodium hydrogen carbonate |
| Chemical formula | $NaHCO_3$ |
| Molecular weight | 84,01 |
| Assay | Content not less than 99 % on the anhydrous basis |
| **Description** | Colourless or white crystalline masses or crystalline powder |
| **Identification** | |
| Test for sodium | Passes test |
| Test for carbonate | Passes test |
| pH | Between 8,0 and 8,6 (1 % solution) |
| Solubility | Soluble in water. Insoluble in ethanol |
| **Purity** | |
| Loss on drying | Not more than 0,25 % (over silica gel, 4 hours) |
| Ammonium salts | No odour of ammonia detectable after heating |

▼B

| | |
|---|---|
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 500 (iii) SODIUM SESQUICARBONATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 208-580-9 |
| Chemical name | Sodium monohydrogen dicarbonate |
| Chemical formula | $Na_2CO_3 \cdot NaHCO_3 \cdot 2H_2O$ |
| 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** | |
| Test for sodium | Passes test |
| Test for carbonate | Passes test |
| 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 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 501 (i) POTASSIUM CARBONATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 209-529-3 |
| Chemical name | Potassium carbonate |
| Chemical formula | $K_2CO_3 \cdot nH_2O$ (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.<br>The hydrate occurs as small, white, translucent crystals or granules |
| **Identification** | |
| Test for potassium | Passes test |
| Test for carbonate | Passes test |
| Solubility | Very soluble in water. Insoluble in ethanol |
| **Purity** | |
| Loss on drying | Not more than 5 % (anhydrous) or 18 % (hydrate) (180 °C, 4 hours) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |

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| | |
|---|---|
| Mercury | Not more than 1 mg/kg |

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

| | |
|---|---|
| **Synonyms** | Potassium bicarbonate; Acid potassium carbonate |
| **Definition** | |
| Einecs | 206-059-0 |
| Chemical name | Potassium hydrogen carbonate |
| Chemical formula | $KHCO_3$ |
| Molecular weight | 100,11 |
| Assay | Content not less than 99,0 % and not more than 101,0 % $KHCO_3$ on the anhydrous basis |
| **Description** | Colourless crystals or white powder or granules |
| **Identification** | |
| Test for potassium | Passes test |
| Test for carbonate | Passes test |
| Solubility | Freely soluble in water. Insoluble in ethanol |
| **Purity** | |
| Loss on drying | Not more than 0,25 % (over silica gel, 4 hours) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 503 (i) AMMONIUM CARBONATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Ammonium carbonate consists of ammonium carbamate, ammonium carbonate and ammonium hydrogen carbonate in varying proportions |
| Einecs | 233-786-0 |
| Chemical name | Ammonium carbonate |
| Chemical formula | $CH_6N_2O_2$, $CH_8N_2O_3$ and $CH_5NO_3$ |
| Molecular weight | Ammonium carbamate 78,06; ammonium carbonate 98,73; ammonium hydrogen carbonate 79,06 |
| Assay | Content not less than 30,0 % and not more than 34,0 % of $NH_3$ |
| **Description** | 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** | |
| Test for ammonium | Passes test |
| Test for carbonate | Passes test |
| pH | About 8,6 (5 % solution) |
| Solubility | Soluble in water |

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|---|---|
| **Purity** | |
| Non-volatile matter | Not more than 500 mg/kg |
| Chlorides | Not more than 30 mg/kg |
| Sulphate | Not more than 30 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

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

| | |
|---|---|
| **Synonyms** | Ammonium bicarbonate |
| **Definition** | |
| Einecs | 213-911-5 |
| Chemical name | Ammonium hydrogen carbonate |
| Chemical formula | $CH_5NO_3$ |
| Molecular weight | 79,06 |
| Assay | Content not less than 99,0 % |
| **Description** | White crystals or crystalline powder |
| **Identification** | |
| Test for ammonium | Passes test |
| Test for carbonate | Passes test |
| pH | About 8,0 (5 % solution) |
| Solubility | Freely soluble in water. Insoluble in ethanol |
| **Purity** | |
| Non-volatile matter | Not more than 500 mg/kg |
| Chlorides | Not more than 30 mg/kg |
| Sulphate | Not more than 30 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 504 (i) MAGNESIUM CARBONATE**

| | |
|---|---|
| **Synonyms** | Hydromagnesite |
| **Definition** | Magnesium carbonate is a basic hydrated or a monohydrated magnesium carbonate or a mixture of the two. |
| Einecs | 208-915-9 |
| Chemical name | Magnesium carbonate |
| Chemical formula | $MgCO_3 \cdot nH_2O$ |
| Assay | Not less than 24 % and not more than 26,4 % of Mg |
| **Description** | Odourless, light, white friable masses or as a bulky white powder |

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| | |
|---|---|
| **Identification** | |
| Test for magnesium | Passes test |
| Test for carbonate | Passes test |
| Solubility | Practically insoluble both in water or ethanol |
| **Purity** | |
| Acid insoluble matter | Not more than 0,05 % |
| Water soluble matter | Not more than 1,0 % |
| Calcium | Not more than 0,4 % |
| Arsenic | Not more than 4 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 504 (ii) MAGNESIUM HYDROXIDE CARBONATE**

| | |
|---|---|
| **Synonyms** | Magnesium hydrogen carbonate; Magnesium subcarbonate (light or heavy); Hydrated basic magnesium carbonate; Magnesium carbonate hydroxide |
| **Definition** | |
| Einecs | 235-192-7 |
| Chemical name | Magnesium carbonate hydroxide hydrated |
| Chemical formula | $4MgCO_3Mg(OH)_2 \cdot 5H_2O$ |
| Molecular weight | 485 |
| Assay | Mg content not less than 40,0 % and not more than 45,0 % calculated as MgO |
| **Description** | Light, white friable mass or bulky white powder |
| **Identification** | |
| Test for magnesium | Passes test |
| Test for carbonate | Passes test |
| Solubility | Practically insoluble in water. Insoluble in ethanol |
| **Purity** | |
| Acid insoluble matter | Not more than 0,05 % |
| Water soluble matter | Not more than 1,0 % |
| Calcium | Not more than 1,0 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 507 HYDROCHLORIC ACID**

| | |
|---|---|
| **Synonyms** | Hydrogen chloride; Muriatic acid |
| **Definition** | |
| Einecs | 231-595-7 |
| Chemical name | Hydrochloric acid |

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| | |
|---|---|
| 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** | |
| Test for acid | Passes test |
| Test for chloride | Passes test |
| Solubility | Soluble in water and in ethanol |
| **Purity** | |
| Total organic compounds | Total organic compounds (non-fluorine containing): not more than 5 mg/kg<br>Benzene: not more than 0,05 mg/kg<br>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 $SO_2$) |
| Oxidising substances | Not more than 30 mg/kg (as $Cl_2$) |
| 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 508 POTASSIUM CHLORIDE**

| | |
|---|---|
| **Synonyms** | Sylvine; Sylvite |
| **Definition** | |
| Einecs | 231-211-8 |
| Chemical name | Potassium chloride |
| Chemical formula | KCl |
| Molecular weight | 74,56 |
| Assay | Content not less than 99 % on the dried basis |
| **Description** | Colourless, elongated, prismatic or cubital crystals or white granular powder. Odourless |
| **Identification** | |
| Solubility | Freely soluble in water. Insoluble in ethanol |
| Test for potassium | Passes test |
| Test for chloride | Passes test |
| **Purity** | |
| Loss on drying | Not more than 1 % (105 °C, 2 hours) |
| Test for sodium | Negative |

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| | |
|---|---|
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 509 CALCIUM CHLORIDE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 233-140-8 |
| Chemical name | Calcium chloride |
| Chemical formula | $CaCl_2 \cdot nH_2O$ (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** | |
| Test for calcium | Passes test |
| Test for chloride | Passes test |
| Solubility | Soluble in water and in ethanol |
| **Purity** | |
| Magnesium and alkali salts | Not more than 5 % on the dried basis (calculated as sulphates) |
| Fluoride | Not more than 40 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 511 MAGNESIUM CHLORIDE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 232-094-6 |
| Chemical name | Magnesium chloride |
| Chemical formula | $MgCl_2 \cdot 6H_2O$ |
| Molecular weight | 203,30 |
| Assay | Content not less than 99,0 % |
| **Description** | Colourless, odourless, very deliquescent flakes or crystals |
| **Identification** | |
| Test for magnesium | Passes test |
| Test for chloride | Passes test |
| Solubility | Very soluble in water, freely soluble in ethanol |
| **Purity** | |
| Ammonium | Not more than 50 mg/kg |
| Arsenic | Not more than 3 mg/kg |

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

**E 512 STANNOUS CHLORIDE**

| | |
|---|---|
| **Synonyms** | Tin chloride; Tin dichloride |
| **Definition** | |
| Einecs | 231-868-0 |
| Chemical name | Stannous chloride dihydrate |
| Chemical formula | $SnCl_2 \cdot 2H_2O$ |
| Molecular weight | 225,63 |
| Assay | Content not less than 98,0 % |
| **Description** | Colourless or white crystals<br>May have a slight odour of hydrochloric acid |
| **Identification** | |
| Test for tin (II) | Passes test |
| Test for chloride | Passes test |
| Solubility | Water: soluble in less than its own weight of water, but it forms an insoluble basic salt with excess water<br>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 2 mg/kg |

**E 513 SULPHURIC ACID**

| | |
|---|---|
| **Synonyms** | Oil of vitriol; Dihydrogen sulphate |
| **Definition** | |
| Einecs | 231-639-5 |
| Chemical name | Sulphuric acid |
| Chemical formula | $H_2SO_4$ |
| Molecular weight | 98,07 |
| Assay | Sulphuric acid is commercially available in varying concentrations. The concentrated form contains not less than 96,0 % |
| **Description** | Clear, colourless or slightly brown, very corrosive oily liquid |
| **Identification** | |
| Test for acid | Passes test |
| Test for sulphate | Passes test |
| Solubility | Miscible with water, with generation of much heat, also with ethanol |

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| | |
|---|---|
| **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 $H_2SO_4$ 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 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 514 (i) SODIUM SULPHATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | |
| Chemical name | Sodium sulphate |
| Chemical formula | $Na_2SO_4 \cdot nH_2O$ (n = 0 or 10) |
| Molecular weight | 142,04 (anhydrous)<br>322,04 (decahydrate) |
| Assay | Content not less than 99,0 % on the anhydrous basis |
| **Description** | Colourless crystals or a fine, white, crystalline powder<br>The decahydrate is efflorescent |
| **Identification** | |
| Test for sodium | Passes test |
| Test for sulphate | Passes test |
| pH | Neutral or slightly alkaline to litmus paper (5 % solution) |
| **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 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

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

| | |
|---|---|
| **Synonyms** | Acid sodium sulphate; Sodium bisulphate; Nitre cake |
| **Definition** | |
| Chemical name | Sodium hydrogen sulphate |
| Chemical formula | $NaHSO_4$ |
| Molecular weight | 120,06 |

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| | |
|---|---|
| Assay | Content not less than 95,2 % |
| **Description** | White, odourless crystals or granules |
| **Identification** | |
| Test for sodium | Passes test |
| Test for sulphate | Passes test |
| pH | Solutions are strongly acidic |
| **Purity** | |
| Loss on drying | Not more than 0,8 % |
| Water insoluble matter | Not more than 0,05 % |
| Selenium | Not more than 30 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 515 (i) POTASSIUM SULPHATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | |
| Chemical name | Potassium sulphate |
| Chemical formula | $K_2SO_4$ |
| Molecular weight | 174,25 |
| Assay | Content not less than 99,0 % |
| **Description** | Colourless or white crystals or crystalline powder |
| **Identification** | |
| Test for potassium | Passes test |
| Test for sulphate | Passes test |
| pH | Between 5,5 and 8,5 (5 % solution) |
| 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 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

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

| | |
|---|---|
| **Synonyms** | Potassium bisulphate; Potassium acid sulphate |
| **Definition** | |
| Einecs | |
| Chemical name | Potassium hydrogen sulphate |
| Chemical formula | $KHSO_4$ |

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| | |
|---|---|
| Molecular weight | 136,17 |
| Assay | Content not less than 99 % |
| **Description** | White deliquescent crystals, pieces or granules |
| **Identification** | |
| Melting point | 197 °C |
| Test for potassium | Passes test |
| 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 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 516 CALCIUM SULPHATE**

| | |
|---|---|
| **Synonyms** | Gypsum; Selenite; Anhydrite |
| **Definition** | |
| Einecs | 231-900-3 |
| Chemical name | Calcium sulphate |
| Chemical formula | $CaSO_4 \cdot nH_2O$ (n = 0 or 2) |
| Molecular weight | 136,14 (anhydrous), 172,18 (dihydrate) |
| Assay | Content not less than 99,0 % on the anhydrous basis |
| **Description** | Fine, white to slightly yellowish-white odourless powder |
| **Identification** | |
| Test for calcium | Passes test |
| Test for sulphate | Passes test |
| Solubility | Slightly soluble in water, insoluble in ethanol |
| **Purity** | |
| Loss on drying | Anhydrous: not more than 1,5 % (250 °C, constant weight)<br>Dihydrate: not more than 23 % (250 °C, constant weight) |
| 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 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 517 AMMONIUM SULPHATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 231-984-1 |
| Chemical name | Ammonium sulphate |

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| | |
|---|---|
| Chemical formula | $(NH_4)_2SO_4$ |
| 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** | |
| Test for ammonium | Passes test |
| Test for sulphate | Passes test |
| 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 3 mg/kg |

**E 520 ALUMINIUM SULPHATE**

| | |
|---|---|
| **Synonyms** | Alum |
| **Definition** | |
| Einecs | |
| Chemical name | Aluminium sulphate |
| Chemical formula | $Al_2(SO_4)_3$ |
| Molecular weight | 342,13 |
| Assay | Content not less than 99,5 % on the ignited basis |
| **Description** | White powder, shining plates or crystalline fragments |
| **Identification** | |
| Test for aluminium | Passes test |
| Test for sulphate | Passes test |
| pH | 2,9 or above (5 % solution) |
| Solubility | Freely soluble in water, insoluble in ethanol |
| **Purity** | |
| Loss on ignition | Not more than 5 % (500 °C, 3 hours) |
| 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 521 ALUMINIUM SODIUM SULPHATE**

| | |
|---|---|
| **Synonyms** | Soda alum; Sodium alum |
| **Definition** | |
| Einecs | 233-277-3 |

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| | |
|---|---|
| Chemical name | Aluminium sodium sulphate |
| Chemical formula | $AlNa(SO_4)_2 \cdot nH_2O$ (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** | |
| Test for aluminium | Passes test |
| Test for sodium | Passes test |
| Test for sulphate | Passes test |
| 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, 16 hours)<br>Dodecahydrate: not more than 47,2 % (50-55 °C, 1 hour then 200 °C, 16 hours) |
| 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** | |
| Einecs | 233-141-3 |
| Chemical name | Aluminium potassium sulphate dodecahydrate |
| Chemical formula | $AlK(SO_4)_2 \cdot 12\ H_2O$ |
| Molecular weight | 474,38 |
| Assay | Content not less than 99,5 % |
| **Description** | Large, transparent crystals or white crystalline powder |
| **Identification** | |
| Test for aluminium | Passes test |
| Test for potassium | Passes test |
| Test for sulphate | Passes test |
| pH | Between 3,0 and 4,0 (10 % solution) |
| 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 |

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| | |
|---|---|
| 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** | |
| Einecs | 232-055-3 |
| Chemical name | Aluminium ammonium sulphate |
| Chemical formula | $AlNH_4(SO_4)_2 \cdot 12\ H_2O$ |
| Molecular weight | 453,32 |
| Assay | Content not less than 99,5 % |
| **Description** | Large, colourless crystals or white powder |
| **Identification** | |
| Test for aluminium | Passes test |
| Test for ammonium | Passes test |
| Test for sulphate | Passes test |
| 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 3 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 524 SODIUM HYDROXIDE**

| | |
|---|---|
| **Synonyms** | Caustic soda; Lye |
| **Definition** | |
| Einecs | 215-185-5 |
| Chemical name | Sodium hydroxide |
| 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 |

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| | |
|---|---|
| **Identification** | |
| Test for sodium | Passes test |
| pH | Strongly alkaline (1 % solution) |
| 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 $Na_2CO_3$) |
| 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** | |
| Einecs | 215-181-3 |
| Chemical name | Potassium hydroxide |
| 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** | |
| Test for potassium | Passes test |
| pH | Strongly alkaline (1 % solution) |
| 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 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 526 CALCIUM HYDROXIDE**

| | |
|---|---|
| **Synonyms** | Slaked lime; Hydrated lime |
| **Definition** | |
| Einecs | 215-137-3 |
| Chemical name | Calcium hydroxide |
| Chemical formula | $Ca(OH)_2$ |
| Molecular weight | 74,09 |

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| | |
|---|---|
| Assay | Content not less than 92,0 % |
| **Description** | White powder |
| **Identification** | |
| Test for alkali | Passes test |
| Test for calcium | Passes test |
| 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 2,7 % |
| 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 2 mg/kg |

**E 527 AMMONIUM HYDROXIDE**

| | |
|---|---|
| **Synonyms** | Aqua ammonia; Strong ammonia solution |
| **Definition** | |
| Einecs | |
| Chemical name | Ammonium hydroxide |
| Chemical formula | $NH_4OH$ |
| Molecular weight | 35,05 |
| Assay | Content not less than 27 % of $NH_3$ |
| **Description** | Clear, colourless solution, having an exceedingly pungent, characteristic odour |
| **Identification** | |
| Test for ammonia | Passes test |
| **Purity** | |
| Non-volatile matter | Not more than 0,02 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |

**E 528 MAGNESIUM HYDROXIDE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | |
| Chemical name | Magnesium hydroxide |
| Chemical formula | $Mg(OH)_2$ |
| Molecular weight | 58,32 |
| Assay | Content not less than 95,0 % on the anhydrous basis |
| **Description** | Odourless, white bulky powder |

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| | |
|---|---|
| **Identification** | |
| Test for magnesium | Passes test |
| Test for alkali | Passes test |
| Solubility | Practically insoluble in water and in ethanol |
| **Purity** | |
| Loss on drying | Not more than 2,0 % (105 °C, 2 hours) |
| 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 2 mg/kg |

**E 529 CALCIUM OXIDE**

| | |
|---|---|
| **Synonyms** | Burnt lime |
| **Definition** | |
| Einecs | 215-138-9 |
| Chemical name | Calcium oxide |
| Chemical formula | CaO |
| Molecular weight | 56,08 |
| Assay | Content not less than 95,0 % on the ignited basis |
| **Description** | Odourless, hard, white or greyish white masses of granules, or white to greyish powder |
| **Identification** | |
| Test for alkali | Passes test |
| Test for calcium | Passes test |
| Reaction with water | Heat is generated on moistening the sample with water |
| 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 3,6 % |
| Fluoride | Not more than 50 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |

**E 530 MAGNESIUM OXIDE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 215-171-9 |
| Chemical name | Magnesium oxide |

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| | |
|---|---|
| Chemical formula | MgO |
| Molecular weight | 40,31 |
| Assay | Content not less than 98,0 % on the ignited basis |
| **Description** | 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 at least 33 ml, while 5 g of heavy magnesium oxide occupy a volume of not more than 20 ml |
| **Identification** | |
| Test for alkali | Passes test |
| Test for magnesium | Passes test |
| 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 2 mg/kg |

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**E 534 IRON TARTRATE**

| | |
|---|---|
| **Synonyms** | Iron *meso*-tartrate; complexation product of sodium tartrate with iron(III) chloride |
| **Definition** | Iron tartrate is manufactured by the isomerisation of L-tartrate to an equilibrium mixture of D-, L- and *meso*-tartrate followed by addition of iron(III) chloride. |
| CAS number | 1280193-05-9 |
| Chemical name | Iron(III) complexation product of D(+)-, L(-)- and meso-2,3 dihydroxybutanedioic acids |
| Chemical formula | $Fe(OH)_2$ $C_4H_4O_6Na$ |
| Molecular weight | 261,93 |
| **Assay** | |
| meso-tartrate | > 28 %, expressed as the anion on dry basis |
| D(-)- and L(+)-tartrate | > 10 %, expressed as the anion on dry basis |
| Iron(III) | > 8 %, expressed as the anion on dry basis |
| **Description** | Dark green aqueous solution typically comprising ca 35 % by weight complexation products |
| **Identification** | Highly soluble in water |
| | Positive tests for tartrate and iron |
| | pH of a 35 % aqueous solution of complexation products between 3,5 and 3,9 |
| **Purity** | |
| Chloride | Not more than 25 % |
| Sodium | Not more than 23 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Oxalate | Not more than 1,5 % expressed as oxalate on dry basis |

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**E 535 SODIUM FERROCYANIDE**

| | |
|---|---|
| **Synonyms** | Yellow prussiate of soda; Sodium hexacyanoferrate |
| **Definition** | |
| Einecs | 237-081-9 |
| Chemical name | Sodium ferrocyanide |
| Chemical formula | $Na_4Fe(CN)_6 \cdot 10\ H_2O$ |
| Molecular weight | 484,1 |
| Assay | Content not less than 99,0 % |
| **Description** | Yellow crystals or crystalline powder |
| **Identification** | |
| Test for sodium | Passes test |
| Test for ferrocyanide | Passes test |
| **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** | |
| Einecs | 237-722-2 |
| Chemical name | Potassium ferrocyanide |
| Chemical formula | $K_4Fe(CN)_6 \cdot 3\ H_2O$ |
| Molecular weight | 422,4 |
| Assay | Content not less than 99,0 % |
| **Description** | Lemon yellow crystals |
| **Identification** | |
| Test for potassium | Passes test |
| Test for ferrocyanide | Passes test |
| **Purity** | |
| Free moisture | Not more than 1,0 % |
| Water insoluble matter | Not more than 0,03 % |
| Chloride | Not more than 0,2 % |

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| | |
|---|---|
| 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** | |
| Einecs | 215-476-7 |
| Chemical name | Calcium ferrocyanide |
| Chemical formula | $Ca_2Fe(CN)_6 \cdot 12H_2O$ |
| Molecular weight | 508,3 |
| Assay | Content not less than 99,0 % |
| **Description** | Yellow crystals or crystalline powder |
| **Identification** | |
| Test for calcium | Passes test |
| Test for ferrocyanide | Passes test |
| **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** | |
| Einecs | 232-090-4 |
| Chemical name | Sodium trialuminium tetradecahydrogen octaphosphate tetrahydrate (A); Trisodium dialuminium pentadecahydrogen octaphosphate (B) |
| Chemical formula | $NaAl_3H_{14}(PO_4)_8 \cdot 4H_2O$ (A)<br>$Na_3Al_2H_{15}(PO_4)_8$ (B) |
| Molecular weight | 949,88 (A)<br>897,82 (B) |
| Assay | Content not less than 95,0 % (both forms) |

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| | |
|---|---|
| **Description** | White odourless powder |
| **Identification** | |
| Test for sodium | Passes test |
| Test for aluminium | Passes test |
| Test for phosphate | Passes test |
| pH | Acid to litmus |
| Solubility | Insoluble in water. Soluble in hydrochloric acid |
| **Purity** | |
| Loss on ignition | 19,5-21,0 % (A) (750-800 °C, 2 hours)<br>15-16 % (B) (750-800 °C, 2 hours) |
| 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 |
| Einecs | 231-545-4 |
| Chemical name | Silicon dioxide |
| Chemical formula | $(SiO_2)_n$ |
| Molecular weight | 60,08 ($SiO_2$) |
| Assay | Content after ignition not less than 99,0 % (fumed silica) or 94,0 % (hydrated forms) |
| **Description** | White, fluffy powder or granules. Hygroscopic |
| **Identification** | |
| Test for silica | Positive |
| **Purity** | |
| Loss on drying | Not more than 2,5 % (fumed silica, 105 °C, 2 hours)<br>Not more than 8,0 % (precipitated silica and silica gel, 105 °C, 2 hours) |

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| | |
|---|---|
| | Not more than 70 % (hydrous silica, 105 °C, 2 hours) |
| Loss on ignition | Not more than 2,5 % after drying (1 000 °C, fumed silica)<br>Not more than 8,5 % after drying (1 000 °C, hydrated forms) |
| Soluble ionisable salts | Not more than 5,0 % (as $Na_2SO_4$) |
| 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**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Calcium silicate is a hydrous or anhydrous silicate with varying proportions of CaO and $SiO_2$. The product should be free of asbestos. |
| Einecs | 215-710-8 |
| Chemical name | Calcium silicate |
| Chemical formula | |
| Molecular weight | |
| Assay | Content on the anhydrous basis:<br>— as $SiO_2$ not less than 50 % and not more than 95 %<br>— as CaO not less than 3 % and not more than 35 % |
| **Description** | White to off-white free-flowing powder that remains so after absorbing relatively large amounts of water or other liquids |
| **Identification** | |
| Test for silicate | Passes test |
| Test for calcium | Passes test |
| Gel formation | Forms a gel with mineral acids |
| **Purity** | |
| Loss on drying | Not more than 10 % (105 °C, 2 hours) |
| 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 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

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

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Magnesium silicate is a synthetic compound of which the molar ratio of magnesium oxide to silicon dioxide is approximately 2:5 |
| Einecs | |
| Chemical name | |

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| | |
|---|---|
| Chemical formula | |
| Molecular weight | |
| Assay | Content not less than 15 % of MgO and not less than 67 % of $SiO_2$ on the ignited basis |
| **Description** | Very fine, white, odourless powder, free from grittiness |
| **Identification** | |
| Test for magnesium | Passes test |
| Test for silicate | Passes test |
| pH | Between 7,0 and 10,8 (10 % slurry) |
| **Purity** | |
| Loss on drying | Not more than 15 % (105 °C, 2 hours) |
| 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**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 239-076-7 |
| Chemical name | Magnesium trisilicate |
| Chemical formula | $Mg_2Si_3O_8 \cdot nH_2O$ (approximate composition) |
| Molecular weight | |
| Assay | Content not less than 29,0 % of MgO and not less than 65,0 % of $SiO_2$ both on the ignited basis |
| **Description** | Fine, white powder, free from grittiness |
| **Identification** | |
| Test for magnesium | Passes test |
| Test for silicate | Passes test |
| pH | Between 6,3 and 9,5 (5 % slurry) |
| **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 |

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**E 553b TALC**

| | |
|---|---|
| **Synonyms** | Talcum |
| **Definition** | Naturally occurring form of hydrous magnesium silicate containing varying proportions of such associated minerals as alpha-quartz, calcite, chlorite, dolomite, magnesite, and phlogopite. The product should be free of asbestos. |
| Einecs | 238-877-9 |
| Chemical name | Magnesium hydrogen metasilicate |
| Chemical formula | $Mg_3(Si_4O_{10})(OH)_2$ |
| Molecular weight | 379,22 |
| Assay | |
| **Description** | Light, homogeneous, white or almost white powder, greasy to the touch |
| **Identification** | |
| Infrared absorption spectrum | Characteristic peaks at 3 677, 1 018 and 669 $cm^{-1}$ |
| X-ray diffraction | Peaks at 9,34/4,66/3,12 Å |
| Solubility | Insoluble in water and ethanol |
| **Purity** | |
| Loss on drying | Not more than 0,5 % (105 °C, 1 hour) |
| Acid soluble matter | Not more than 6 % |
| Water soluble matter | Not more than 0,2 % |
| Acid-soluble iron | Not detectable |
| Arsenic | Not more than 10 mg/kg |
| Lead | Not more than 2 mg/kg |

**E 554 SODIUM ALUMINIUM SILICATE**

| | |
|---|---|
| **Synonyms** | Sodium silicoaluminate; Sodium aluminosilicate; Aluminium sodium silicate |
| **Definition** | |
| Einecs | |
| Chemical name | Sodium aluminium silicate |
| Chemical formula | |
| Molecular weight | |
| Assay | Content on the anhydrous basis:<br>— as $SiO_2$ not less than 66,0 % and not more than 88,0 %<br>— as $Al_2O_3$ not less than 5,0 % and not more than 15,0 % |
| **Description** | Fine white amorphous powder or beads |
| **Identification** | |
| Test for sodium | Passes test |
| Test for aluminium | Passes test |
| Test for silicate | Passes test |
| pH | Between 6,5 and 11,5 (5 % slurry) |

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| | |
|---|---|
| **Purity** | |
| Loss on drying | Not more than 8,0 % (105 °C, 2 hours) |
| Loss on ignition | Not less than 5,0 % and not more than 11,0 % on the anhydrous basis (1 000 °C to constant weight) |
| Sodium | Not less than 5 % and not more than 8,5 % (as $Na_2O$) on the anhydrous basis |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 555 POTASSIUM ALUMINIUM SILICATE**

| | |
|---|---|
| **Synonyms** | Mica |
| **Definition** | Natural mica consists of mainly potassium aluminium silicate (muscovite) |
| Einecs | 310-127-6 |
| Chemical name | Potassium aluminium silicate |
| Chemical formula | $KAl_2[AlSi_3O_{10}](OH)_2$ |
| Molecular weight | 398 |
| Assay | Content not less than 98 % |
| **Description** | Light grey to white crystalline platelets or powder |
| **Identification** | |
| Solubility | Insoluble in water, diluted acids and alkali and organic solvents |
| **Purity** | |
| Loss on drying | Not more than 0,5 % (105 °C, 2 hours) |
| Antimony | Not more than 20 mg/kg |
| Zinc | Not more than 25 mg/kg |
| Barium | Not more than 25 mg/kg |
| Chromium | Not more than 100 mg/kg |
| Copper | Not more than 25 mg/kg |
| Nickel | Not more than 50 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 2 mg/kg |
| Lead | Not more than 5 mg/kg |

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**E 556 CALCIUM ALUMINIUM SILICATE** [1]

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| | |
|---|---|
| **Synonyms** | Calcium aluminosilicate; Calcium silicoaluminate; Aluminium calcium silicate |
| **Definition** | |
| Einecs | |
| Chemical name | Calcium aluminium silicate |

[1] Period of application: until 31 January 2014.

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| | |
|---|---|
| Chemical formula | |
| Molecular weight | |
| Assay | Content on the anhydrous basis:<br>— as $SiO_2$ not less than 44,0 % and not more than 50,0 %<br>— as $Al_2O_3$ not less than 3,0 % and not more than 5,0 %<br>— as CaO not less than 32,0 % and not more than 38,0 % |
| **Description** | Fine white, free-flowing powder |
| **Identification** | |
| Test for calcium | Passes test |
| Test for aluminium | Passes test |
| Test for silicate | Passes test |
| **Purity** | |
| Loss on drying | Not more than 10,0 % (105 °C, 2 hours) |
| Loss on ignition | Not less than 14,0 % and not more than 18,0 on the anhydrous basis (1 000 °C, constant weight) |
| 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 |

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**E 559 ALUMINIUM SILICATE (KAOLIN)** [1]

▼B

| | |
|---|---|
| **Synonyms** | Kaolin, light or heavy |
| **Definition** | Aluminium silicate hydrous (kaolin) is a purified white plastic clay composed of kaolinite, potassium aluminium silicate, feldspar and quartz. Processing should not include calcination. The raw kaolinitic clay used in the production of aluminium silicate shall have a level of dioxin which does not make it injurious to health or unfit for human consumption. The product should be free of asbestos |
| Einecs | 215-286-4 (kaolinite) |
| Chemical name | |
| Chemical formula | $Al_2Si_2O_5(OH)_4$ (kaolinite) |
| Molecular weight | 264 |
| Assay | Content not less than 90 % (sum of silica and alumina, after ignition)<br>Silica ($SiO_2$) Between 45 % and 55 %<br>Alumina ($Al_2O_3$) Between 30 % and 39 % |
| **Description** | Fine, white or greyish white, unctuous powder. Kaolin is made up of loose aggregations of randomly oriented stacks of kaolinite flakes or of individual hexagonal flakes |
| **Identification** | |
| Test for alumina | Passes test |
| Test for silicate | Passes test |
| X-ray diffraction | Characteristic peaks at 7,18/3,58/2,38/1,78 Å |
| Infrared absorption spectrum | Peaks at 3 700 and 3 620 $cm^{-1}$ |

[1] Period of application: until 31 January 2014.

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| | |
|---|---|
| **Purity** | |
| Loss on ignition | Between 10 and 14 % (1 000 °C, constant weight) |
| Water soluble matter | Not more than 0,3 % |
| Acid soluble matter | Not more than 2 % |
| Iron | Not more than 5 % |
| Potassium oxide ($K_2O$) | Not more than 5 % |
| Carbon | Not more than 0,5 % |
| 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**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Linear fatty acids, caprylic acid ($C_8$), capric acid ($C_{10}$), lauric acid ($C_{12}$), myristic acid ($C_{14}$), palmitic acid ($C_{16}$), stearic acid ($C_{18}$), oleic acid ($C_{18:1}$) |
| Einecs | |
| Chemical name | Octanoic acid ($C_8$); decanoic acid ($C_{10}$); dodecanoic acid ($C_{12}$); tetradecanoic acid ($C_{14}$); hexadecanoic acid ($C_{16}$); octadecanoic acid ($C_{18}$); 9-octadecenoic acid ($C_{18:1}$) |
| Chemical formula | |
| Molecular weight | |
| Assay | Not less than 98 % by chromatography |
| **Description** | A colourless liquid or white solid obtained from oils and fats |
| **Identification** | |
| Identification test | Individual fatty acids can be identified by acid value, iodine value, gas chromatography |
| **Purity** | |
| Residue on ignition | Not more than 0,1 % |
| Unsaponifiable matter | Not more than 1,5 % |
| Water content | 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 |
| Einecs | |
| Chemical name | Gluconic acid |
| Chemical formula | $C_6H_{12}O_7$ (gluconic acid) |

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| | |
|---|---|
| Molecular weight | 196,2 |
| Assay | Content not less than 49,0 % (as gluconic acid) |
| **Description** | Colourless to light yellow, clear syrupy liquid |
| **Identification** | |
| 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 % 550 °C +/– 20 °C till disappearance of organic residues (black spots). |
| Reducing matter | Not more than 2,0 % (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 1 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 |
| Einecs | 202-016-5 |
| Chemical name | D-Glucono-1,5-lactone |
| Chemical formula | $C_6H_{10}O_6$ |
| Molecular weight | 178,14 |
| Assay | Content not less than 99,0 % on the anhydrous basis |
| **Description** | Fine, white, nearly odourless, crystalline powder |
| **Identification** | |
| Formation of phenylhydrazine derivative of gluconic acid | Positive. Compound formed melts between 196 °C and 202 °C with decomposition |
| Solubility | Freely soluble in water. Sparingly soluble in ethanol |
| **Purity** | |
| Water content | Not more than 0,2 % (Karl Fischer method) |
| Reducing substances | Not more than 0,5 % (as D-glucose) |
| Lead | Not more than 1 mg/kg |

**E 576 SODIUM GLUCONATE**

| | |
|---|---|
| **Synonyms** | Sodium salt of D-gluconic acid |
| **Definition** | Manufactured by fermentation or chemical catalytic oxidation |

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| | |
|---|---|
| Einecs | 208-407-7 |
| Chemical name | Sodium D-gluconate |
| Chemical formula | $C_6H_{11}NaO_7$ (anhydrous) |
| Molecular weight | 218,14 |
| Assay | Content not less than 99,0 % |
| **Description** | White to tan, granular to fine, crystalline powder |
| **Identification** | |
| Test for sodium | Passes test |
| Test for gluconate | Passes test |
| Solubility | Very soluble in water. Sparingly soluble in ethanol |
| pH | Between 6,5 and 7,5 (10 % solution) |
| **Purity** | |
| Reducing matter | Not more than 1,0 % (as D-glucose) |
| Lead | Not more than 1 mg/kg |

**E 577 POTASSIUM GLUCONATE**

| | |
|---|---|
| **Synonyms** | Potassium salt of D-gluconic acid |
| **Definition** | |
| Einecs | 206-074-2 |
| Chemical name | Potassium D-gluconate |
| Chemical formula | $C_6H_{11}KO_7$ (anhydrous)<br>$C_6H_{11}KO_7 \cdot H_2O$ (monohydrate) |
| Molecular weight | 234,25 (anhydrous)<br>252,26 (monohydrate) |
| Assay | Content not less than 97,0 % and not more than 103,0 % on dried basis |
| **Description** | Odourless, free flowing white to yellowish white, crystalline powder or granules |
| **Identification** | |
| Test for potassium | Passes test |
| Test for gluconate | Passes test |
| pH | Between 7,0 and 8,3 (10 % solution) |
| **Purity** | |
| Loss on drying | Anhydrous: not more than 3,0 % (105 °C, 4 hours, vacuum)<br>Monohydrate: not less than 6 % and not more than 7,5 % (105 °C, 4 hours, 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** | |
| Einecs | 206-075-8 |
| Chemical name | Calcium di-D-gluconate |

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| | |
|---|---|
| Chemical formula | $C_{12}H_{22}CaO_{14}$ (anhydrous)<br>$C_{12}H_{22}CaO_{14} \cdot H_2O$ (monohydrate) |
| Molecular weight | 430,38 (anhydrous form)<br>448,39 (monohydrate) |
| Assay | anhydrous: Content not less than 98 % and not more than 102 % on the dried basis<br>monohydrate: not less than 98 % and not more than 102 % on the 'as is' basis. |
| **Description** | Odourless, white crystalline granules or powder, stable in air |
| **Identification** | |
| Test for calcium | Passes test |
| Test for gluconate | Passes test |
| Solubility | Soluble in water, insoluble in ethanol |
| pH | Between 6,0 and 8,0 (5 % solution) |
| **Purity** | |
| Loss on drying | Not more than 3,0 % (105 °C, 16 hours) (anhydrous)<br>Not more than 2,0 % (105 °C, 16 hours) (monohydrate) |
| Reducing substances | Not more than 1,0 % (as D-glucose) |
| Lead | Not more than 2 mg/kg |

**E 579 FERROUS GLUCONATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 206-076-3 |
| Chemical name | Ferrous di-D-gluconate dihydrate; Iron(II) di-gluconate dihydrate |
| Chemical formula | $C_{12}H_{22}FeO_{14} \cdot 2H_2O$ |
| Molecular weight | 482,17 |
| Assay | Content not less than 95 % on the dried basis |
| **Description** | Pale greenish-yellow to yellowish-grey powder or granules, which may have a faint odour of burnt sugar |
| **Identification** | |
| Solubility | Soluble with slight heating in water. Practically insoluble in ethanol |
| Test for ferrous ion | Passes test |
| Formation of phenylhy-drazine derivative of gluconic acid | Positive |
| pH | Between 4 and 5,5 (10 % solution) |
| **Purity** | |
| Loss on drying | Not more than 10 % (105 °C, 16 hours) |
| Oxalic acid | Not detectable |
| Iron (Fe III) | Not more than 2 % |
| Arsenic | Not more than 3 mg/kg |

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| | |
|---|---|
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Reducing substances | Not more than 0,5 % expressed as glucose |

**E 585 FERROUS LACTATE**

| | |
|---|---|
| **Synonyms** | Iron(II) lactate; Iron(II) 2-hydroxy propanoate;<br>Propanoic acid, 2-hydroxy-iron(2 +) salt (2:1) |
| **Definition** | |
| Einecs | 227-608-0 |
| Chemical name | Ferrous 2-hydroxy propanoate |
| Chemical formula | $C_6H_{10}FeO_6 \cdot nH_2O$ (n = 2 or 3) |
| Molecular weight | 270,02 (dihydrate)<br>288,03 (trihydrate) |
| Assay | Content not less than 96 % on the dried basis |
| **Description** | Greenish-white crystals or light green powder having a characteristic smell |
| **Identification** | |
| Solubility | Soluble in water. Practically insoluble in ethanol |
| Test for ferrous ion | Passes test |
| Test for lactate | Passes test |
| pH | Between 4 and 6 (2 % solution) |
| **Purity** | |
| Loss on drying | Not more than 18 % (100 °C, under vacuum, approximately 700 mm Hg) |
| Iron (Fe III) | Not more than 0,6 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 586 4-HEXYLRESORCINOL**

| | |
|---|---|
| **Synonyms** | 4-Hexyl-1,3-benzenediol; Hexylresorcinol |
| **Definition** | |
| Einecs | 205-257-4 |
| Chemical name | 4-Hexylresorcinol |
| Chemical formula | $C_{12}H_{18}O_2$ |
| Molecular weight | 197,24 |
| Assay | Not less than 98 % on the dried basis (4 hours at room temperature) |
| **Description** | White powder |

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| | |
|---|---|
| **Identification** | |
| Solubility | Freely soluble in ether and acetone; very slightly soluble in water |
| Nitric acid test | To 1 ml of a saturated solution of the sample, add 1 ml of nitric acid. A light red colour appears |
| Bromine test | To 1 ml of saturated solution of the sample, add 1 ml of bromine TS. A yellow, flocculent precipitate dissolves producing a yellow solution |
| **Purity** | |
| Melting range | 62 to 67 °C |
| Acidity | Not more than 0,05 % |
| Sulphated ash | Not more than 0,1 % |
| Resorcinol and other phenols | Shake about 1 g of the sample with 50 ml of water for a few minutes, filter, and to the filtrate add 3 drops of ferric chloride TS. No red or blue colour is produced |
| Nickel | Not more than 2 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 3 mg/kg |

**E 620 GLUTAMIC ACID**

| | |
|---|---|
| **Synonyms** | L-Glutamic acid; L-α-Aminoglutaric acid |
| **Definition** | |
| Einecs | 200-293-7 |
| Chemical name | L-Glutamic acid; L-2-amino-pentanedioic acid |
| Chemical formula | $C_5H_9NO_4$ |
| Molecular weight | 147,13 |
| Assay | Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis |
| Solubility | Sparingly soluble in water; practically insoluble in ethanol or ether |
| **Description** | White crystals or crystalline powder |
| **Identification** | |
| Test for glutamic acid (by thin layer chromatography) | Passes test |
| Specific rotation | $[\alpha]_D^{20}$ between + 31,5° and + 32,2°<br>(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube) |
| pH | Between 3,0 and 3,5 (saturated solution) |
| **Purity** | |
| Loss on drying | Not more than 0,2 % (80 °C, 3 hours) |
| Sulphated ash | Not more than 0,2 % |
| Chloride | Not more than 0,2 % |
| Pyrrolidone carboxylic acid | Not more than 0,2 % |
| Arsenic | Not more than 2,5 mg/kg |
| Lead | Not more than 1 mg/kg |

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**E 621 MONOSODIUM GLUTAMATE**

| | |
|---|---|
| **Synonyms** | Sodium glutamate; MSG |
| **Definition** | |
| Einecs | 205-538-1 |
| Chemical name | Monosodium L-glutamate monohydrate |
| Chemical formula | $C_5H_8NaNO_4 \cdot H_2O$ |
| Molecular weight | 187,13 |
| Assay | Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis |
| Solubility | Freely soluble in water; practically insoluble in ethanol or ether |
| **Description** | White, practically odourless crystals or crystalline powder |
| **Identification** | |
| Test for sodium | Passes test |
| Test for glutamic acid (by thin-layer chromatography) | Passes test |
| Specific rotation | $[\alpha]_D^{20}$ between + 24,8° and + 25,3°<br>(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube) |
| pH | Between 6,7 and 7,2 (5 % solution) |
| **Purity** | |
| Loss on drying | Not more than 0,5 % (98 °C, 5 hours) |
| Chloride | Not more than 0,2 % |
| Pyrrolidone carboxylic acid | Not more than 0,2 % |
| Lead | Not more than 1 mg/kg |

**E 622 MONOPOTASSIUM GLUTAMATE**

| | |
|---|---|
| **Synonyms** | Potassium glutamate; MPG |
| **Definition** | |
| Einecs | 243-094-0 |
| Chemical name | Monopotassium L-glutamate monohydrate |
| Chemical formula | $C_5H_8KNO_4 \cdot H_2O$ |
| Molecular weight | 203,24 |
| Assay | Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis |
| Solubility | Freely soluble in water; practically insoluble in ethanol or ether |
| **Description** | White, practically odourless crystals or crystalline powder |
| **Identification** | |
| Test for potassium | Passes test |
| Test for glutamic acid (by thin-layer chromatography) | Passes test |

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| | |
|---|---|
| Specific rotation | $[\alpha]_D^{20}$ between + 22,5° and + 24,0°<br>(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube) |
| pH | Between 6,7 and 7,3 (2 % solution) |
| **Purity** | |
| Loss on drying | Not more than 0,2 % (80 °C, 5 hours) |
| Chloride | Not more than 0,2 % |
| Pyrrolidone carboxylic acid | Not more than 0,2 % |
| Lead | Not more than 1 mg/kg |

**E 623 CALCIUM DIGLUTAMATE**

| | |
|---|---|
| **Synonyms** | Calcium glutamate |
| **Definition** | |
| Einecs | 242-905-5 |
| Chemical name | Monocalcium di-L-glutamate |
| Chemical formula | $C_{10}H_{16}CaN_2O_8 \cdot nH_2O$ (n = 0, 1, 2 or 4) |
| Molecular weight | 332,32 (anhydrous) |
| Assay | Content not less than 98,0 % and not more than 102,0 % on the anhydrous basis |
| Solubility | Freely soluble in water; practically insoluble in ethanol or ether |
| **Description** | White, practically odourless crystals or crystalline powder |
| **Identification** | |
| Test for calcium | Passes test |
| Test for glutamic acid (by thin-layer chromatography) | Passes test |
| Specific rotation | $[\alpha]_D^{20}$ between + 27,4° and + 29,2° (for calcium diglutamate with n = 4) (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube) |
| **Purity** | |
| Water content | Not more than 19,0 % (for calcium diglutamate with n = 4) (Karl Fischer) |
| Chloride | Not more than 0,2 % |
| Pyrrolidone carboxylic acid | Not more than 0,2 % |
| Lead | Not more than 1 mg/kg |

**E 624 MONOAMMONIUM GLUTAMATE**

| | |
|---|---|
| **Synonyms** | Ammonium glutamate |
| **Definition** | |
| Einecs | 231-447-1 |
| Chemical name | Monoammonium L-glutamate monohydrate |
| Chemical formula | $C_5H_{12}N_2O_4 \cdot H_2O$ |
| Molecular weight | 182,18 |
| Assay | Content not less than 99,0 % and not more 101,0 % on the anhydrous basis |

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| | |
|---|---|
| Solubility | Freely soluble in water; practically insoluble in ethanol or ether |
| **Description** | White, practically odourless crystals or crystalline powder |
| **Identification** | |
| Test for ammonium | Passes test |
| Test for glutamic acid (by thin-layer chromatography) | Passes test |
| Specific rotation | $[\alpha]_D^{20}$ between + 25,4° and + 26,4°<br>(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube) |
| pH | Between 6,0 and 7,0 (5 % solution) |
| **Purity** | |
| Loss on drying | Not more than 0,5 % (50 °C, 4 hours) |
| Sulphated ash | Not more than 0,1 % |
| Pyrrolidone carboxylic acid | Not more than 0,2 % |
| Lead | Not more than 1 mg/kg |

**E 625 MAGNESIUM DIGLUTAMATE**

| | |
|---|---|
| **Synonyms** | Magnesium glutamate |
| **Definition** | |
| Einecs | 242-413-0 |
| Chemical name | Monomagnesium di-L-glutamate tetrahydrate |
| Chemical formula | $C_{10}H_{16}MgN_2O_8 \cdot 4H_2O$ |
| Molecular weight | 388,62 |
| Assay | Content not less than 95,0 % and not more than 105,0 % on the anhydrous basis |
| Solubility | Very soluble in water; practically insoluble in ethanol or ether |
| **Description** | Odourless, white or off-white crystals or powder |
| **Identification** | |
| Test for magnesium | Passes test |
| Test for glutamic acid (by thin-layer chromatography) | Passes test |
| Specific rotation | $[\alpha]_D^{20}$ between + 23,8° and + 24,4°<br>(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube) |
| pH | Between 6,4 and 7,5 (10 % solution) |
| **Purity** | |
| Water content | Not more than 24 % (Karl Fischer) |
| Chloride | Not more than 0,2 % |
| Pyrrolidone carboxylic acid | Not more than 0,2 % |
| Lead | Not more than 1 mg/kg |

**E 626 GUANYLIC ACID**

| | |
|---|---|
| **Synonyms** | 5'-Guanylic acid |
| **Definition** | |
| Einecs | 201-598-8 |

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| | |
|---|---|
| Chemical name | Guanosine-5'-monophosphoric acid |
| Chemical formula | $C_{10}H_{14}N_5O_8P$ |
| Molecular weight | 363,22 |
| Assay | Content not less than 97,0 % on the anhydrous basis |
| Solubility | Slightly soluble in water, practically insoluble in ethanol |
| **Description** | Odourless, colourless or white crystals or white crystalline powder |
| **Identification** | |
| Test for ribose | Passes test |
| Test for organic phosphate | Passes test |
| pH | Between 1,5 and 2,5 (0,25 % solution) |
| Spectrometry | Maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm |
| **Purity** | |
| Loss on drying | Not more than 1,5 % (120 °C, 4 hours) |
| Other nucleotides | Not detectable by thin-layer chromatography |
| Lead | Not more than 1 mg/kg |

**E 627 DISODIUM GUANYLATE**

| | |
|---|---|
| **Synonyms** | Sodium guanylate; Sodium 5'-guanylate |
| **Definition** | |

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| | |
|---|---|
| Einecs | 226-914-1 |

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| | |
|---|---|
| Chemical name | Disodium guanosine-5'-monophosphate |
| Chemical formula | $C_{10}H_{12}N_5Na_2O_8P \cdot nH_2O$ (n = ca. 7) |
| Molecular weight | 407,19 (anhydrous) |
| Assay | Content not less than 97,0 % on the anhydrous basis |
| Solubility | Soluble in water, sparingly soluble in ethanol, practically insoluble in ether |
| **Description** | Odourless, colourless or white crystals or white crystalline powder |
| **Identification** | |
| Test for ribose | Passes test |
| Test for organic phosphate | Passes test |
| Test for sodium | Passes test |
| pH | Between 7,0 and 8,5 (5 % solution) |
| Spectrometry | maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm |
| **Purity** | |
| Loss on drying | Not more than 25 % (120 °C, 4 hours) |
| Other nucleotides | Not detectable by thin-layer chromatography |
| Lead | Not more than 1 mg/kg |

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**E 628 DIPOTASSIUM GUANYLATE**

| | |
|---|---|
| **Synonyms** | Potassium guanylate; Potassium 5'-guanylate |
| **Definition** | |
| ▼M3 | |
| Einecs | 221-849-5 |
| ▼B | |
| Chemical name | Dipotassium guanosine-5'-monophosphate |
| Chemical formula | $C_{10}H_{12}K_2N_5O_8P$ |
| Molecular weight | 439,40 |
| Assay | Content not less than 97,0 % on the anhydrous basis |
| Solubility | Freely soluble in water, practically insoluble in ethanol |
| **Description** | Odourless, colourless or white crystals or white crystalline powder |
| **Identification** | |
| Test for ribose | Passes test |
| Test for organic phosphate | Passes test |
| Test for potassium | Passes test |
| pH | Between 7,0 and 8,5 (5 % solution) |
| Spectrometry | Maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm |
| **Purity** | |
| Loss on drying | Not more than 5 % (120 °C, 4 hours) |
| Other nucleotides | Not detectable by thin-layer chromatography |
| Lead | Not more than 1 mg/kg |

**E 629 CALCIUM GUANYLATE**

| | |
|---|---|
| **Synonyms** | Calcium 5'-guanylate |
| **Definition** | |
| Einecs | |
| Chemical name | Calcium guanosine-5'-monophosphate |
| Chemical formula | $C_{10}H_{12}CaN_5O_8P \cdot nH_2O$ |
| Molecular weight | 401,20 (anhydrous) |
| Assay | Content not less than 97,0 % on the anhydrous basis |
| Solubility | Sparingly soluble in water |
| **Description** | Odourless, white or off-white crystals or powder |
| **Identification** | |
| Test for ribose | Passes test |
| Test for organic phosphate | Passes test |
| Test for calcium | Passes test |
| pH | Between 7,0 and 8,0 (0,05 % solution) |
| Spectrometry | Maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm |

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| | |
|---|---|
| **Purity** | |
| Loss on drying | Not more than 23,0 % (120 °C, 4 hours) |
| Other nucleotides | Not detectable by thin-layer chromatography |
| Lead | Not more than 1 mg/kg |

**E 630 INOSINIC ACID**

| | |
|---|---|
| **Synonyms** | 5'-Inosinic acid |
| **Definition** | |
| Einecs | 205-045-1 |
| Chemical name | Inosine-5'-monophosphoric acid |
| Chemical formula | $C_{10}H_{13}N_4O_8P$ |
| Molecular weight | 348,21 |
| Assay | Content not less than 97,0 % on the anhydrous basis |
| Solubility | Freely soluble in water, slightly soluble in ethanol |
| **Description** | Odourless, colourless or white crystals or powder |
| **Identification** | |
| Test for ribose | Passes test |
| Test for organic phosphate | Passes test |
| pH | Between 1,0 and 2,0 (5 % solution) |
| Spectrometry | Maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm |
| **Purity** | |
| Loss on drying | Not more than 3,0 % (120 °C, 4 hours) |
| Other nucleotides | Not detectable by thin-layer chromatography |
| Lead | Not more than 1 mg/kg |

**E 631 DISODIUM INOSINATE**

| | |
|---|---|
| **Synonyms** | Sodium inosinate; Sodium 5'-inosinate |
| **Definition** | |
| Einecs | 225-146-4 |
| Chemical name | Disodium inosine-5'-monophosphate |
| Chemical formula | $C_{10}H_{11}N_4Na_2O_8P \cdot H_2O$ |
| Molecular weight | 392,17 (anhydrous) |
| Assay | Content not less than 97,0 % on the anhydrous basis |
| Solubility | Soluble in water, sparingly soluble in ethanol, practically insoluble in ether |
| **Description** | Odourless, colourless or white crystals or powder |
| **Identification** | |
| Test for ribose | Passes test |
| Test for organic phosphate | Passes test |
| Test for sodium | Passes test |

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| | |
|---|---|
| pH | Between 7,0 and 8,5 |
| Spectrometry | Maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm |
| **Purity** | |
| Water content | Not more than 28,5 % (Karl Fischer) |
| Other nucleotides | Not detectable by thin-layer chromatography |
| Lead | Not more than 1 mg/kg |

**E 632 DIPOTASSIUM INOSINATE**

| | |
|---|---|
| **Synonyms** | Potassium inosinate; Potassium 5'-inosinate |
| **Definition** | |
| Einecs | 243-652-3 |
| Chemical name | Dipotassium inosine-5'-monophosphate |
| Chemical formula | $C_{10}H_{11}K_2N_4O_8P$ |
| Molecular weight | 424,39 |
| Assay | Content not less than 97,0 % on the anhydrous basis |
| Solubility | Freely soluble in water; practically insoluble in ethanol |
| **Description** | Odourless, colourless or white crystals or powder |
| **Identification** | |
| Test for ribose | Passes test |
| Test for organic phosphate | Passes test |
| Test for potassium | Passes test |
| pH | Between 7,0 and 8,5 (5 % solution) |
| Spectrometry | Maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm |
| **Purity** | |
| Water content | Not more than 10,0 % (Karl Fischer) |
| Other nucleotides | Not detectable by thin-layer chromatography |
| Lead | Not more than 1 mg/kg |

**E 633 CALCIUM INOSINATE**

| | |
|---|---|
| **Synonyms** | Calcium 5'-inosinate |
| **Definition** | |
| Einecs | |
| Chemical name | Calcium inosine-5'-monophosphate |
| Chemical formula | $C_{10}H_{11}CaN_4O_8P \cdot nH_2O$ |
| Molecular weight | 386,19 (anhydrous) |
| Assay | Content not less than 97,0 % on the anhydrous basis |
| Solubility | Sparingly soluble in water |
| **Description** | Odourless, colourless or white crystals or powder |

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| | |
|---|---|
| **Identification** | |
| Test for ribose | Passes test |
| Test for organic phosphate | Passes test |
| Test for calcium | Passes test |
| pH | Between 7,0 and 8,0 (0,05 % solution) |
| Spectrometry | Maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm |
| **Purity** | |
| Water content | Not more than 23,0 % (Karl Fischer) |
| Other nucleotides | Not detectable by thin-layer chromatography |
| Lead | Not more than 1 mg/kg |

**E 634 CALCIUM 5'-RIBONUCLEOTIDE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | |
| Chemical name | Calcium 5′-ribonucleotide is essentially a mixture of calcium inosine-5′-monophosphate and calcium guanosine-5′-monophosphate |
| Chemical formula | $C_{10}H_{11}N_4CaO_8P \cdot nH_2O$<br>$C_{10}H_{12}N_5CaO_8P \cdot nH_2O$ |
| Molecular weight | |
| Assay | Content of both major components not less than 97,0 %, and of each component not less than 47,0 % and not more than 53 %, in every case on the anhydrous basis |
| Solubility | Sparingly soluble in water |
| **Description** | Odourless, white or nearly white crystals or powder |
| **Identification** | |
| Test for ribose | Passes test |
| Test for organic phosphate | Passes test |
| Test for calcium | Passes test |
| pH | Between 7,0 and 8,0 (0,05 % solution) |
| **Purity** | |
| Water content | Not more than 23,0 % (Karl Fischer) |
| Other nucleotides | Not detectable by thin-layer chromatography |
| Lead | Not more than 1 mg/kg |

**E 635 DISODIUM 5'-RIBONUCLEOTIDE**

| | |
|---|---|
| **Synonyms** | Sodium 5'-ribonucleotide |
| **Definition** | |
| Einecs | |
| Chemical name | Disodium 5'-ribonucleotide is essentially a mixture of disodium inosine-5'-monophosphate and disodium guanosine-5'-monophosphate |

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| | |
|---|---|
| Chemical formula | $C_{10}H_{11}N_4O_8P \cdot nH_2O$<br>$C_{10}H_{12}N_5Na_2O_8P \cdot nH_2O$ |
| Molecular weight | |
| Assay | Content of both major components not less than 97,0 %, and of each component not less than 47,0 % and not more than 53 %, in every case on the anhydrous basis |
| Solubility | Soluble in water, sparingly soluble in ethanol practically insoluble in ether |
| **Description** | Odourless, white or nearly white crystals or powder |
| **Identification** | |
| Test for ribose | Passes test |
| Test for organic phosphate | Passes test |
| Test for sodium | Passes test |
| pH | Between 7,0 and 8,5 (5 % solution) |
| **Purity** | |
| Water content | Not more than 26,0 % (Karl Fischer) |
| Other nucleotides | Not detectable by thin-layer chromatography |
| Lead | Not more than 1 mg/kg |

**E 640 GLYCINE AND ITS SODIUM SALT**

(i) GLYCINE

| | |
|---|---|
| **Synonyms** | Aminoacetic acid; Glycocoll |
| **Definition** | |
| Einecs | 200-272-2 |
| Chemical name | Aminoacetic acid |
| Chemical formula | $C_2H_5NO_2$ |
| Molecular weight | 75,07 |
| Assay | Content not less than 98,5 % on the anhydrous basis |
| **Description** | White crystals or crystalline powder |
| **Identification** | |
| Test for amino acid | Passes test |
| **Purity** | |
| Loss on drying | Not more than 0,2 % (105 °C, 3 hours) |
| Residue on ignition | 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 |

(ii) SODIUM GLYCINATE

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 227-842-3 |

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| | |
|---|---|
| Chemical name | Sodium glycinate |
| Chemical formula | $C_2H_5NO_2$ Na |
| Molecular weight | 98 |
| Assay | Content not less than 98,5 % on the anhydrous basis |
| **Description** | White crystals or crystalline powder |
| **Identification** | |
| Test for amino acid | Passes test |
| Test for sodium | Passes test |
| **Purity** | |
| Loss on drying | Not more than 0,2 % (105 °C, 3 hours) |
| Residue on ignition | 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 |

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**E 641 L-LEUCINE**

| | |
|---|---|
| **Synonyms** | 2-Aminoisobutylacetic acid; L-2-Amino-4-methylvaleric acid; alpha-Aminoisocaproic acid; (*S*)-2-Amino-4-methylpentanoic acid; L-Leu |
| **Definition** | |
| Einecs | 200-522-0 |
| CAS number | 61-90-5 |
| Chemical name | L-Leucine; L-2-Amino-4-methylpentanoic acid |
| Chemical formula | $C_6H_{13}NO_2$ |
| Molecular Weight | 131,17 |
| Assay | Content not less than 98,5 % and not more than 101,0 % on the anhydrous basis |
| **Description** | White or almost white crystalline powder or shiny flakes |
| **Identification** | |
| Solubility | Soluble in water, acetic acid, dilute HCl and alkaline hydroxides and carbonates; slightly soluble in ethanol |
| Specific rotation | $[\alpha]_D^{20}$ between + 14,5° and + 16,5°<br>(4 % solution (anhydrous basis) in 6N HCl) |
| **Purity** | |
| Loss on drying | Not more than 0,5 % (100 °C – 105 °C) |
| Sulphated Ash | Not more than 0,1 % |
| Chlorides | Not more than 200 mg/kg |
| Sulphates | Not more than 300 mg/kg |
| Ammonium | Not more than 200 mg/kg |
| Iron | 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 |

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**E 650 ZINC ACETATE**

| | |
|---|---|
| **Synonyms** | Acetic acid, zinc salt, dihydrate |
| **Definition** | |
| Einecs | |
| Chemical name | Zinc acetate dihydrate |
| Chemical formula | $C_4H_6O_4$ Zn · $2H_2O$ |
| Molecular weight | 219,51 |
| Assay | Content not less than 98 % and not more than 102 % of $C_4H_6O_4$ Zn · $2H_2O$ |
| **Description** | Colourless crystals or fine, off-white powder |
| **Identification** | |
| Test for acetate | Passes test |
| Test for zinc | Passes test |
| pH | Between 6,0 and 8,0 (5 % solution) |
| **Purity** | |
| Water 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 900 DIMETHYL POLYSILOXANE**

| | |
|---|---|
| **Synonyms** | Polydimethyl siloxane; Silicone fluid; Silicone oil; Dimethyl silicone |

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|---|---|
| **Definition** | Dimethylpolysiloxane is a mixture of fully methylated linear siloxane polymers containing repeating units of the formula $(CH_3)_2$ SiO and stabilised with trimethylsiloxy end-blocking units of the formula $(CH_3)_3$ SiO |
| Einecs | |
| Chemical name | Siloxanes and silicones, di-methyl |
| Chemical formula | $(CH_3)_3$-Si-[O-Si$(CH_3)_2]_n$-O-Si$(CH_3)_3$ |
| Molecular weight | |
| Assay | Content of total silicon not less than 37,3 % and not more than 38,5 % |
| **Description** | Clear, colourless, viscous liquid |
| **Identification** | |
| Specific gravity (25 °C/25 °C) | Between 0,964 and 0,977 |
| Refractive index | $[n]_D^{25}$ between 1,400 and 1,405 |
| Infrared absorption spectrum | The infrared absorption spectrum of a liquid film of the sample between two sodium chloride plates exhibits relative maxima at the same wavelengths as those of a similar preparation of Dimethylpolysiloxane Reference Standard |
| **Purity** | |
| Loss on drying | Not more than 0,5 % (150 °C, 4h) |
| Viscosity | Not less than $1{,}00 \cdot 10^{-4}$ $m^2s^{-1}$ at 25 °C |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 901 BEESWAX, WHITE AND YELLOW**

| | |
|---|---|
| **Synonyms** | White wax; Yellow wax |
| **Definition** | Yellow 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<br>White beeswax is obtained by bleaching yellow beeswax |
| Einecs | 232-383-7 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **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** | |
| Melting range | Between 62 °C and 65 °C |

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| | |
|---|---|
| Specific gravity | About 0,96 |
| 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 | Transfer 3,0 g of the sample to a 100 ml round-bottomed flask, add 30 ml of a 4 % w/v solution of potassium hydroxide in aldehyde-free ethanol and boil gently under a reflux condenser for 2 h. Remove the condenser and immediately insert a thermometer. Place the flask in water at 80 °C and allow to cool, swirling the solution continuously. No precipitate is formed before the temperature reaches 65 °C, although the solution may be opalescent. |
| Fats, Japan wax, rosin and soaps | Boil 1 g of the sample for 30 min with 35 ml of a 1 in 7 solution of sodium hydroxide, maintaining the volume by the occasional addition of water, and cool the mixture. The wax separates and the liquid remains clear. Filter the cold mixture and acidify the filtrate with hydrochloric acid. No precipitate is formed. |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 902 CANDELILLA WAX**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Candelilla wax is a purified wax obtained from the leaves of the candelilla plant, *Euphorbia antisyphilitica* |
| Einecs | 232-347-0 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | Hard, yellowish brown, opaque to translucent wax |
| **Identification** | |
| Specific gravity | About 0,98 |
| Melting range | Between 68,5 °C and 72,5 °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 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

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**E 903 CARNAUBA WAX**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Carnauba wax is a purified wax obtained from the leaf buds and leaves of the Brazilian Mart wax palm, *Copernicia cerifera* |
| Einecs | 232-399-4 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | Light brown to pale yellow powder or flakes or hard and brittle solid with a resinous fracture |
| **Identification** | |
| Specific gravity | About 0,997 |
| Melting range | Between 82 °C and 86 °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 2 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 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | Bleached shellac — off-white, amorphous, granular resin<br>Wax-free bleached shellac — light yellow, amorphous, granular resin |
| **Identification** | |
| Solubility | Insoluble in water; freely (though very slowly) soluble in alcohol; slightly soluble in acetone |
| Acid value | Between 60 and 89 |

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

**E 905 MICROCRYSTALLINE WAX**

| | |
|---|---|
| **Synonyms** | Petroleum wax; Hydrocarbon wax; Fischer-Tropsch wax; Synthetic wax; Synthetic paraffin |
| **Definition** | Refined mixtures of solid, saturated hydrocarbons, obtained from petroleum or synthetic feedstocks |
| **Description** | White to amber, odourless wax |
| **Identification** | |
| Solubility | Insoluble in water, very slightly soluble in ethanol |
| Refractive index | $[n]_D^{100}$ 1,434-1,448<br>Alternative $[n]_D^{120}$1,426-1,440 |
| **Purity** | |
| Molecular weight | Average not less than 500 |
| Viscosity | Not less than $1,1 \times 10^{-5}$ $m^2s^{-1}$at 100 °C<br>Alternative: Not less than $0,8 \times 10^{-5}$ $m^2s^{-1}$at 120 °C, if solid at 100 °C |
| Residue on ignition | Not more than 0,1 % |
| Carbon number at 5 % distillation point | Not more than 5 % of molecules with carbon number less than 25 |
| Colour | Passes test |
| Sulphur | Not more than 0,4 wt % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 3 mg/kg |
| Polycyclic aromatic compounds | Benzo(a)pyrene no more than 50 μg/kg |

**E 907 HYDROGENATED POLY-1-DECENE**

| | |
|---|---|
| **Synonyms** | Hydrogenated polydec-1-ene; Hydrogenated poly-alpha-olefin |
| **Definition** | |
| Einecs | |
| Chemical name | |
| Chemical formula | $C_{10n}H_{20n+2}$ where n = 3-6 |
| Molecular weight | 560 (average) |
| Assay | Not less than 98,5 % of hydrogenated poly-1-decene, having the following oligomer distribution:<br>$C_{30}$: 13-37 %<br>$C_{40}$: 35-70 %<br>$C_{50}$: 9-25 %<br>$C_{60}$: 1-7 % |

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| | |
|---|---|
| **Description** | |
| **Identification** | |
| Solubility | Insoluble in water; slightly soluble in ethanol; soluble in toluene |
| Burning | Burns with a bright flame and a paraffin-like characteristic smell |
| Viscosity | Between $5{,}7 \times 10^{-6}$ and $6{,}1 \times 10^{-6}$ $m^2s^{-1}$ at 100 °C |
| **Purity** | |
| Compounds with carbon number less than 30 | Not more than 1,5 % |
| Readily carbonisable substances | After 10 minutes shaking in a boiling water bath, a tube of sulphuric acid with a 5 g sample of hydrogenated poly-1-decene is not darker than a very slight straw colour |
| Nickel | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |

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**E 914 OXIDISED POLYETHYLENE WAX**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Polar reaction products from mild oxidation of polyethylene |
| Einecs | |
| Chemical name | Oxidised polyethylene |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | Almost white flakes, powder, granules or pellets |
| **Identification** | |
| Density | Between 0,92 and 1,05 (20 °C) |
| Drop point | Greater than 95 °C |
| **Purity** | |
| Acid value | Not more than 70 |
| Viscosity | Not less than $8{,}1 \cdot 10^{-5}$ $m^2s^{-1}$ at 120 °C |
| Other wax types | Not detectable (by differential scanning calorimetry and/or infrared spectroscopy) |
| Oxygen | Not more than 9,5 % |
| Chromium | Not more than 5 mg/kg |
| Lead | Not more than 2 mg/kg |

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**E 920 L-CYSTEINE**

| | |
|---|---|
| **Synonyms** | |
| **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 name | |
| Chemical formula | $C_3H_7NO_2S \cdot HCl \cdot nH_2O$ (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** | |
| Solubility | Freely soluble in water and in ethanol |
| Melting range | Anhydrous form melts at about 175 °C |
| Specific rotation | $[\alpha]_D^{20}$: between + 5,0° and + 8,0° or<br>$[\alpha]_D^{25}$: between + 4,9° and 7,9° |
| **Purity** | |
| Loss on drying | Between 8,0 % and 12,0 %<br>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 name | |
| Chemical formula | $CH_4N_2O$ |
| Molecular weight | 60,06 |
| Assay | Content not less than 99,0 % on the anhydrous basis |

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| | |
|---|---|
| **Description** | Colourless to white, prismatic, crystalline powder or small, white pellets |
| **Identification** | |
| Solubility | Very soluble in water<br>Soluble in ethanol |
| Precipitation with nitric acid | To pass the test a white, crystalline precipitate is formed |
| Colour reaction | To pass the test a reddish-violet colour is produced |
| Melting range | 132 °C to 135 °C |
| **Purity** | |
| Loss on drying | Not more than 1,0 % (105 °C, 1 hour) |
| 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 2 mg/kg |

**E 938 ARGON**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 231-147-0 |
| Chemical name | Argon |
| Chemical formula | Ar |
| Atomic weight | 40 |
| Assay | Not less than 99 % |
| **Description** | Colourless, odourless, non-flammable gas |
| **Identification** | |
| **Purity** | |
| Water content | Not more than 0,05 % |
| Methane and other hydrocarbons | Not more than 100 µl/l (calculated as methane) |

**E 939 HELIUM**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 231-168-5 |
| Chemical name | Helium |
| Chemical formula | He |
| Atomic weight | 4 |
| Assay | Not less than 99 % |

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| | |
|---|---|
| **Description** | Colourless, odourless, non-flammable gas |
| **Identification** | |
| **Purity** | |
| Water content | Not more than 0,05 % |
| Methane and other hydrocarbons | Not more than 100 µl/l (calculated as methane) |

**E 941 NITROGEN**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 231-783-9 |
| Chemical name | Nitrogen |
| Chemical formula | $N_2$ |
| Molecular weight | 28 |
| Assay | Not less than 99 % |
| **Description** | Colourless, odourless, non-flammable gas |
| **Identification** | |
| **Purity** | |
| Water content | Not more than 0,05 % |
| Carbon monoxide | Not more than 10 µl/l |
| Methane and other hydrocarbons | Not more than 100 µl/l (calculated as methane) |
| Nitrogen dioxide and nitrogen oxide | Not more than 10 µl/l |
| Oxygen | Not more than 1 % |

**E 942 NITROUS OXIDE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 233-032-0 |
| Chemical name | Nitrous oxide |
| Chemical formula | $N_2O$ |
| Molecular weight | 44 |
| Assay | Not less than 99 % |
| **Description** | Colourless, non-flammable gas, sweetish odour |
| **Identification** | |
| **Purity** | |
| Water content | Not more than 0,05 % |
| Carbon monoxide | Not more than 30 µl/l |
| Nitrogen dioxide and nitrogen oxide | Not more than 10 µl/l |

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**E 943a BUTANE**

| | |
|---|---|
| **Synonyms** | n-Butane |
| **Definition** | |
| Einecs | |
| 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** | |
| 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** | |
| Einecs | |
| Chemical name | 2-methyl propane |
| Chemical formula | $(CH_3)_2CH\ CH_3$ |
| Molecular weight | 58,12 |
| Assay | Content not less than 94 % |
| **Description** | Colourless gas or liquid with mild, characteristic odour |
| **Identification** | |
| 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 % |

▼B

**E 944 PROPANE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | |
| Chemical name | Propane |
| Chemical formula | $CH_3CH_2CH_3$ |
| Molecular weight | 44,09 |
| Assay | Content not less than 95 % |
| **Description** | Colourless gas or liquid with mild, characteristic odour |
| **Identification** | |
| 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 948 OXYGEN**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 231-956-9 |
| Chemical name | Oxygen |
| Chemical formula | $O_2$ |
| Molecular weight | 32 |
| Assay | Not less than 99 % |
| **Description** | Colourless, odourless, non-flammable gas |
| **Identification** | |
| **Purity** | |
| Water content | Not more than 0,05 % |
| Methane and other hydrocarbons | Not more than 100 µl/l (calculated as methane) |

**E 949 HYDROGEN**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 215-605-7 |
| Chemical name | Hydrogen |
| Chemical formula | $H_2$ |
| Molecular weight | 2 |

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| | |
|---|---|
| Assay | Content not less than 99,9 % |
| **Description** | Colourless, odourless, highly flammable gas |
| **Identification** | |
| **Purity** | |
| Water content | Not more than 0,005 % v/v |
| Oxygen | Not more than 0,001 % v/v |
| Nitrogen | Not more than 0,07 % v/v |

**E 950 ACESULFAME K**

| | |
|---|---|
| **Synonyms** | Acesulfame potassium; Potassium salt of 3,4-dihydro-6-methyl-1,2,3-oxathiazin-4-one-2,2-dioxide |
| **Definition** | |
| Einecs | 259-715-3 |
| Chemical name | 6-methyl-1,2,3-oxathiazin-4(3H)-one-2,2-dioxide potassium salt |
| Chemical formula | $C_4H_4KNO_4S$ |
| Molecular weight | 201,24 |
| Assay | Content not less than 99 % of $C_4H_4KNO_4S$ on the anhydrous basis |
| **Description** | Odourless, white, crystalline powder. Approximately 200 times as sweet as sucrose |
| **Identification** | |
| Solubility | Very soluble in water, very slightly soluble in ethanol |
| Ultraviolet absorption | Maximum 227 ± 2 nm for a solution of 10 mg in 1 000 ml of water |
| Test for potassium | Passes test (test the residue obtained by igniting 2 g of the sample) |
| Precipitation test | Add a few drops of a 10 % solution of sodium cobaltnitrite to a solution of 0,2 g of the sample in 2 ml of acetic acid and 2 ml of water. A yellow precipitate is produced |
| **Purity** | |
| Loss on drying | Not more than 1 % (105 °C, 2 hours) |
| Organic impurities | Passes test for 20 mg/kg of UV active components |
| Fluoride | Not more than 3 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 951 ASPARTAME**

| | |
|---|---|
| **Synonyms** | Aspartyl phenylalanine methyl ester |
| **Definition** | |
| Einecs | 245-261-3 |
| Chemical name | N-L-α-Aspartyl-L-phenylalanine-1-methyl ester, 3-amino-N-(α-carbomethoxy-phenethyl)-succinamic acid-N-methyl ester |
| Chemical formula | $C_{14}H_{18}N_2O_5$ |
| Molecular weight | 294,31 |

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| | |
|---|---|
| Assay | Not less than 98 % and not more than 102 % of $C_{14}H_{18}N_2O_5$ on the anhydrous basis |
| **Description** | White, odourless, crystalline powder having a sweet taste. Approximately 200 times as sweet as sucrose |
| **Identification** | |
| Solubility | Slightly soluble in water and in ethanol |
| pH | Between 4,5 and 6,0 (1 in 125 solution) |
| Specific rotation | $[\alpha]_D^{20}$: + 14,5° to + 16,5°<br>Determine in a 4 in 100/15 N formic acid solution within 30 minutes after preparation of the sample solution |
| **Purity** | |
| Loss on drying | Not more than 4,5 % (105 °C, 4 hours) |
| Sulphated ash | Not more than 0,2 % (expressed on dry weight basis) |
| Transmittance | The transmittance of a 1 % solution in 2N hydrochloric acid, determined in a 1-cm cell at 430 nm with a suitable spectrophotometer, using 2N hydrochloric acid as a reference, is not less than 0,95, equivalent to an absorbance of not more than approximately 0,022 |
| Arsenic | Not more than 3 mg/kg (expressed on dry weight basis) |
| Lead | Not more than 1 mg/kg (expressed on dry weight basis) |
| 5-Benzyl-3,6-dioxo-2-piperazineacetic acid | Not more than 1,5 % (expressed on dry weight basis) |

**E 952 CYCLAMIC ACID AND ITS Na AND Ca SALTS**

(i) CYCLAMIC ACID

| | |
|---|---|
| **Synonyms** | Cyclohexylsulphamic acid; Cyclamate |
| **Definition** | |
| Einecs | 202-898-1 |
| Chemical name | Cyclohexanesulphamic acid; cyclohexylaminosulphonic acid |
| Chemical formula | $C_6H_{13}NO_3S$ |
| Molecular weight | 179,24 |
| Assay | Cyclohexylsulphamic acid contains not less than 98 % and not more than the equivalent of 102 % of $C_6H_{13}NO_3S$, calculated on the anhydrous basis |
| **Description** | A practically colourless, white crystalline powder. Approximately 40 times as sweet as sucrose |
| **Identification** | |
| Solubility | Soluble in water and in ethanol |
| Precipitation test | Acidify a 2 % solution with hydrochloric acid, add 1 ml of an approximately molar solution of barium chloride in water and filter if any haze or precipitate forms. To the clear solution add 1 ml of a 10 % solution of sodium nitrite. A white precipitate forms. |
| **Purity** | |
| Loss on drying | Not more than 1 % (105 °C, 1 hour) |
| Selenium | Not more than 30 mg/kg (expressed as selenium on dry weight basis) |

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| | |
|---|---|
| Lead | Not more than 1 mg/kg (expressed on dry weight basis) |
| Arsenic | Not more than 3 mg/kg (expressed on dry weight basis) |
| Cyclohexylamine | Not more than 10 mg/kg (expressed on dry weight basis) |
| Dicyclohexylamine | Not more than 1 mg/kg (expressed on dry weight basis) |
| Aniline | Not more than 1 mg/kg (expressed on dry weight basis) |

(ii) SODIUM CYCLAMATE

| | |
|---|---|
| **Synonyms** | Cyclamate; Sodium salt of cyclamic acid |
| **Definition** | |
| Einecs | 205-348-9 |
| Chemical name | Sodium cyclohexanesulphamate, sodium cyclohexylsulphamate |
| Chemical formula | $C_6H_{12}NNaO_3S$ and the dihydrate form $C_6H_{12}NNaO_3S{\cdot}2H_2O$ |
| Molecular weight | 201,22 calculated on the anhydrous form<br>237,22 calculated on the hydrated form |
| Assay | Not less than 98 % and not more than 102 % on the dried basis<br>Dihydrate form: not less than 84 % on the dried basis |
| **Description** | White, odourless crystals or crystalline powder. Approximately 30 times as sweet as sucrose |
| **Identification** | |
| Solubility | Soluble in water, practically insoluble in ethanol |
| **Purity** | |
| Loss on drying | Not more than 1 % (105 °C, 1 hour)<br>Not more than 15,2 % (105 °C, 2 hours) for the dihydrate form |
| Selenium | Not more than 30 mg/kg (expressed as selenium on dry weight basis) |
| Arsenic | Not more than 3 mg/kg (expressed on dry weight basis) |
| Lead | Not more than 1 mg/kg (expressed on dry weight basis) |
| Cyclohexylamine | Not more than 10 mg/kg (expressed on dry weight basis) |
| Dicyclohexylamine | Not more than 1 mg/kg (expressed on dry weight basis) |
| Aniline | Not more than 1 mg/kg (expressed on dry weight basis) |

(iii) CALCIUM CYCLAMATE

| | |
|---|---|
| **Synonyms** | Cyclamate; Calcium salt of cyclamic acid |
| **Definition** | |
| Einecs | 205-349-4 |
| Chemical name | Calcium cyclohexanesulphamate, calcium cyclohexylsulphamate |
| Chemical formula | $C_{12}H_{24}CaN_2O_6S_2{\cdot}\ 2H_2O$ |
| Molecular weight | 432,57 |
| Assay | Not less than 98 % and not more than 101 % on the dried basis |
| **Description** | White, colourless crystals or crystalline powder. Approximately 30 times as sweet as sucrose |
| **Identification** | |
| Solubility | Soluble in water, sparingly soluble in ethanol |

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| | |
|---|---|
| **Purity** | |
| Loss on drying | Not more than 1 % (105 °C, 1 hour)<br>Not more than 8,5 % (140 °C, 4 hours) for the dihydrate form |
| Selenium | Not more than 30 mg/kg (expressed as selenium on dry weight basis) |
| Arsenic | Not more than 3 mg/kg (expressed on dry weight basis) |
| Lead | Not more than 1 mg/kg (expressed on dry weight basis) |
| Cyclohexylamine | Not more than 10 mg/kg (expressed on dry weight basis) |
| Dicyclohexylamine | Not more than 1 mg/kg (expressed on dry weight basis) |
| Aniline | Not more than 1 mg/kg (expressed on dry weight basis) |

**E 953 ISOMALT**

| | |
|---|---|
| **Synonyms** | Hydrogenated isomaltulose. |
| **Definition** | Manufactured by enzymatic conversion of sucrose with nonviable cells of *Protaminobacter rubrum* followed by catalytic hydrogenation |
| Einecs | |
| Chemical name | Isomalt is a mixture of hydrogenated mono- and disaccharides whose principal components are the disaccharides:<br>6-O-α-D-Glucopyranosyl-D-sorbitol (1,6-GPS) and<br>1-O-α-D-Glucopyranosyl-D-mannitol dihydrate (1,1-GPM) |
| Chemical formula | 6-O-α-D-Glucopyranosyl-D-sorbitol: $C_{12}H_{24}O_{11}$<br>1-O-α-D-Glucopyranosyl-D-mannitol dihydrate: $C_{12}H_{24}O_{11}.2H_2O$ |
| Molecular weight | 6-O-α-D-Glucopyranosyl-D-sorbitol: 344,3<br>1-O-α-D-Glucopyranosyl-D-mannitol dihydrate: 380,3 |
| Assay | Content not less than 98 % of hydrogenated mono- and disaccharides and not less than 86 % of the mixture of 6-O-α-D-Glucopyranosyl-D-sorbitol and 1-O-α-D-Glucopyranosyl-D-mannitol dihydrate determined on the anhydrous basis. |

▼M4

| | |
|---|---|
| **Description** | Odourless, white, slightly hygroscopic, crystalline mass or aqueous solution with a minimum concentration of 60 % |

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| | |
|---|---|
| **Identification** | |
| Solubility | Soluble in water, very slightly soluble in ethanol. |
| HPLC test | Comparison with an appropriate reference standard of Isomalt shows that the 2 principal peaks in the chromatogram of the test solution are similar in retention time to the 2 principal peaks in the chromatogram obtained with the reference solution. |

▼M4

| | |
|---|---|
| **Purity** | |
| Water content | Not more than 7 % for solid product (Karl Fischer Method) |
| Conductivity | Not more than 20 µS/cm (on 20 % dry solids solution) at temperature 20 °C |
| D-Mannitol | Not more than 3 % |
| D-Sorbitol | Not more than 6 % |

▼M4

| | |
|---|---|
| Reducing sugars | Not more than 0,3 % (expressed as glucose on dry weight basis) |
| Nickel | Not more than 2 mg/kg (expressed on dry weight basis) |
| Arsenic | Not more than 3 mg/kg (expressed on dry weight basis) |
| Lead | Not more than 1 mg/kg (expressed on dry weight basis) |

▼B

**E 954 SACCHARIN AND ITS Na. K AND Ca SALTS**

(i) SACCHARIN

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 201-321-0 |
| Chemical name | 3-Oxo-2,3dihydrobenzo(d)isothiazol-1,1-dioxide |
| Chemical formula | $C_7H_5NO_3S$ |
| Molecular weight | 183,18 |
| Assay | Not less than 99 % and not more than 101 % of $C_7H_5NO_3S$ on the anhydrous basis |
| **Description** | White crystals or a white crystalline powder, odourless or with a faint, aromatic odour. Approximately between 300 and 500 times as sweet as sucrose |
| **Identification** | |
| Solubility | Slightly soluble in water, soluble in basic solutions, sparingly soluble in ethanol |
| **Purity** | |
| Loss on drying | Not more than 1 % (105 °C, 2 hours) |
| Melting range | 226 to 230 °C |
| Sulphated ash | Not more than 0,2 % (expressed on dry weight basis) |
| Benzoic and salicylic acid | To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears |
| *o*-Toluenesulphonamide | Not more than 10 mg/kg (expressed on dry weight basis) |
| *p*-Toluenesulphonamide | Not more than 10 mg/kg (expressed on dry weight basis) |
| Benzoic acid *p*-sulphonamide | Not more than 25 mg/kg (expressed on dry weight basis) |
| Readily carbonisable substances | Absent |
| Arsenic | Not more than 3 mg/kg (expressed on dry weight basis) |
| Selenium | Not more than 30 mg/kg (expressed on dry weight basis) |
| Lead | Not more than 1 mg/kg (expressed on dry weight basis) |

(ii) SODIUM SACCHARIN

| | |
|---|---|
| **Synonyms** | Saccharin; Sodium salt of saccharin |
| **Definition** | |
| Einecs | 204-886-1 |
| Chemical name | Sodium o-benzosulphimide; sodium salt of 2,3-dihydro-3-oxobenzisosulphonazole; oxobenzisosulphonazole; 1,2-benzisothiazolin-3-one-1, 1-dioxide sodium salt dihydrate |

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| | |
|---|---|
| Chemical formula | $C_7H_4NNaO_3S \cdot 2H_2O$ |
| Molecular weight | 241,19 |
| Assay | Not less than 99 % and not more than 101 % of $C_7H_4NNaO_3S$ on the anhydrous basis |
| **Description** | White crystals or a white crystalline efflorescent powder, odourless or with a faint odour. Approximately between 300 and 500 times as sweet as sucrose in dilute solutions |
| **Identification** | |
| Solubility | Freely soluble in water, sparingly soluble in ethanol |
| **Purity** | |
| Loss on drying | Not more than 15 % (120 °C, 4 hours) |
| Benzoic and salicylic acid | To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears |
| *o*-Toluenesulphonamide | Not more than 10 mg/kg (expressed on dry weight basis) |
| *p*-Toluenesulphonamide | Not more than 10 mg/kg (expressed on dry weight basis) |
| Benzoic acid *p*-sulphonamide | Not more than 25 mg/kg (expressed on dry weight basis) |
| Readily carbonisable substances | Absent |
| Arsenic | Not more than 3 mg/kg (expressed on dry weight basis) |
| Selenium | Not more than 30 mg/kg (expressed on dry weight basis) |
| Lead | Not more than 1 mg/kg (expressed on dry weight basis) |

(iii) CALCIUM SACCHARIN

| | |
|---|---|
| **Synonyms** | Saccharin; Calcium salt of saccharin |
| **Definition** | |
| Chemical name | Calcium o-benzosulphimide; calcium salt of 2,3-dihydro-3-oxobenzisosulphonazole; 1,2-benzisothiazolin-3-one-1,1-dioxide calcium salt hydrate (2:7) |
| Einecs | 229-349-9 |
| Chemical formula | $C_{14}H_8CaN_2O_6S_2 \cdot 3½H_2O$ |
| Molecular weight | 467,48 |
| Assay | Not less than 95 % of $C_{14}H_8CaN_2O_6S_2$ on the anhydrous basis |
| **Description** | White crystals or a white crystalline powder, odourless or with a faint odour. Approximately between 300 and 500 times as sweet as sucrose in dilute solutions |
| **Identification** | |
| Solubility | Freely soluble in water, soluble in ethanol |
| **Purity** | |
| Loss on drying | Not more than 13,5 % (120 °C, 4 hours) |
| Benzoic and salicylic acid | To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears |

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| | |
|---|---|
| *o*-Toluenesulphonamide | Not more than 10 mg/kg expressed (on dry weight basis) |
| *p*-Toluenesulphonamide | Not more than 10 mg/kg expressed (on dry weight basis) |
| Benzoic acid *p*-sulphonamide | Not more than 25 mg/kg expressed (on dry weight basis) |
| Readily carbonisable substances | Absent |
| Arsenic | Not more than 3 mg/kg (expressed on dry weight basis) |
| Selenium | Not more than 30 mg/kg (expressed on dry weight basis) |
| Lead | Not more than 1 mg/kg (expressed on dry weight basis) |

(iv) POTASSIUM SACCHARIN

| | |
|---|---|
| **Synonyms** | Saccharin; Potassium salt of saccharin |
| **Definition** | |
| Einecs | |
| Chemical name | Potassium o-benzosulphimide; potassium salt of 2,3-dihydro-3-oxobenzisosulphonazole; potassium salt of 1,2-benzisothiazolin-3-one-1,1-dioxide monohydrate |
| Chemical formula | $C_7H_4KNO_3S \cdot H_2O$ |
| Molecular weight | 239,77 |
| Assay | Not less than 99 % and not more than 101 % of $C_7H_4KNO_3S$ on the anhydrous basis |
| **Description** | White crystals or a white crystalline powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose |
| **Identification** | |
| Solubility | Freely soluble in water, sparingly soluble in ethanol |
| **Purity** | |
| Loss on drying | Not more than 8 % (120 °C, 4 hours) |
| Benzoic and salicylic acid | To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears |
| *o*-Toluenesulphonamide | Not more than 10 mg/kg (expressed on dry weight basis) |
| *p*-Toluenesulphonamide | Not more than 10 mg/kg (expressed on dry weight basis) |
| Benzoic acid *p*-sulphonamide | Not more than 25 mg/kg (expressed on dry weight basis) |
| Readily carbonisable substances | Absent |
| Arsenic | Not more than 3 mg/kg (expressed on dry weight basis) |
| Selenium | Not more than 30 mg/kg (expressed on dry weight basis) |
| Lead | Not more than 1 mg/kg (expressed on dry weight basis) |

**E 955 SUCRALOSE**

| | |
|---|---|
| **Synonyms** | 4,1’,6’-Trichlorogalactosucrose |
| **Definition** | |
| Einecs | 259-952-2 |
| Chemical name | 1,6-Dichloro-1,6-dideoxy-β-D-fructofuranosyl-4-chloro-4-deoxy-α-D-galactopyranoside |
| Chemical formula | $C_{12}H_{19}Cl_3O_8$ |
| Molecular weight | 397,64 |

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| | |
|---|---|
| Assay | Content not less than 98 % and not more than 102 % $C_{12}H_{19}Cl_3O_8$ calculated on an anhydrous basis. |
| **Description** | White to off-white, practically odourless, crystalline powder. |
| **Identification** | |
| Solubility | Freely soluble in water, methanol and ethanol<br>Slightly soluble in ethyl acetate |
| Infrared absorption spectrum | The infrared spectrum of a potassium bromide dispersion of the sample exhibits relative maxima at similar wave numbers as those shown in the reference spectrum obtained using a sucralose reference standard. |
| Thin layer chromatography | The main spot in the test solution has the same Rf value as that of the main spot of standard solution A referred to in the test for other chlorinated disaccharides. This standard solution is obtained by dissolving 1,0g of sucralose reference standard in 10 ml of methanol. |
| Specific rotation | $[\alpha]_D^{20}$ + 84,0° to + 87,5° calculated on the anhydrous basis (10 % w/v solution) |
| **Purity** | |
| Water content | Not more than 2,0 % (Karl Fischer method) |
| Sulphated ash | Not more than 0,7 % |
| Other chlorinated disaccharides | Not more than 0,5 % |
| Chlorinated monosaccharides | Not more than 0,1 % |
| Triphenylphosphine oxide | Not more than 150 mg/kg |
| Methanol | Not more than 0,1 % |
| Lead | Not more than 1 mg/kg |

**E 957 THAUMATIN**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | |
| Einecs | 258-822-2 |
| Chemical name | Thaumatin is obtained by aqueous extraction (pH 2,5 to 4) of the arils of the fruit of strains of *Thaumatococcus daniellii* (Benth) and consists essentially of the proteins thaumatin I and thaumatin II together with minor amounts of plant constituents derived from the source material |
| Chemical formula | Polypeptide of 207 amino acids |
| Molecular weight | Thaumatin I 22209<br>Thaumatin II 22293 |
| Assay | Not less than 15,1 % nitrogen on the dried basis equivalent to not less than 93 % proteins (N × 6,2) |
| **Description** | Odourless, cream-coloured powder. Approximately 2 000 to 3 000 times as sweet as sucrose |
| **Identification** | |
| Solubility | Very soluble in water, insoluble in acetone |
| **Purity** | |
| Loss on drying | Not more than 9 % (105 °C to constant weight) |
| Carbohydrates | Not more than 3 % (expressed on dry weight basis) |
| Sulphated ash | Not more than 2 % (expressed on dry weight basis) |
| Aluminium | Not more than 100 mg/kg (expressed on dry weight basis) |

▼B

| | |
|---|---|
| Arsenic | Not more than 3 mg/kg (expressed on dry weight basis) |
| Lead | Not more than 3 mg/kg (expressed on dry weight basis) |
| **Microbiological criteria** | |
| Total aerobic microbial count | Not more than 1 000 colonies per gram |
| *Escherichia coli* | Absent in 1 g |

**E 959 NEOHESPERIDINE DIHYDROCHALCONE**

| | |
|---|---|
| **Synonyms** | Neohesperidin dihydrochalcone; NHDC; Hesperetin dihydrochalcone-4′-β-neohesperidoside; Neohesperidin DC |
| **Definition** | It is obtained by catalytic hydrogenation of neohesperidin |
| Einecs | 243-978-6 |
| Chemical name | 2-O-α-L-rhamnopyranosyl-4′-β-D-glucopyranosyl hesperetin dihydrochalcone. |
| Chemical formula | $C_{28}H_{36}O_{15}$ |
| Molecular weight | 612,6 |
| Assay | Content not less than 96 % on the dried basis |
| **Description** | Off-white, odourless, crystalline powder. Approximately between 1 000 and 1 800 times as sweet as sucrose |
| **Identification** | |
| Solubility | Freely soluble in hot water, very slightly soluble in cold water, practically insoluble in ether and benzene |
| Ultraviolet absorption maximum | 282 to 283 nm for a solution of 2 mg in 100 ml methanol |
| Neu's test | Dissolve about 10 mg of neohesperidine DC in 1 ml methanol, add 1 ml of a 1 % 2-aminoethyl diphenyl borate methanolic solution. A bright yellow colour is produced |
| **Purity** | |
| Loss on drying | Not more than 11 % (105 °C, 3 hours) |
| Sulphated ash | Not more than 0,2 % (expressed on dry weight basis) |
| Arsenic | Not more than 3 mg/kg expressed on dry weight basis |
| Lead | Not more than 2 mg/kg (expressed on dry weight basis) |

▼M33

**E 960a STEVIOL GLYCOSIDES FROM STEVIA**

▼M21

| | |
|---|---|
| **Synonyms** | |
| **Definition** | The manufacturing process comprises two main phases: the first involving water extraction of the leaves of the *Stevia rebaudiana* Bertoni plant and preliminary purification of the extract by employing ion exchange chromatography to yield a steviol glycoside primary extract, and the second involving recrystallisation of the steviol glycosides from methanol or aqueous ethanol resulting in a final product containing not less than 95 % of the below identified 11 related steviol glycosides, in any combination and ratio.<br><br>The additive may contain residues of ion-exchange resins used in the manufacturing process. Several other related steviol glycosides that may be generated as a result of the production process, but do not occur naturally in the *Stevia rebaudiana* plant have been identified in small amounts (0,10 to 0,37 % w/w). |

▼**M21**

| | |
|---|---|
| Chemical name | Steviolbioside: 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl) oxy]kaur-16-en-18-oic acid |
| | Rubusoside: 13-β-D-glucopyranosyloxykaur-16-en-18-oic acid, β-D-glucopyranosyl ester |
| | Dulcoside A: 13-[(2-O-α–L-rhamnopyranosyl-β–D-glucopyranosyl) oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester |
| | Stevioside: 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester |
| | Rebaudioside A: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester |
| | Rebaudioside B: 13-[(2-O-β–D-glucopyranosyl-3-O-β–D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid |
| | Rebaudioside C: 13-[(2-O-α–L-rhamnopyranosyl-3-O-β–D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester |
| | Rebaudioside D: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester |
| | Rebaudioside E: 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester |
| | Rebaudioside F: 13[(2-O-β-D-xylofurananosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester |
| | Rebaudioside M: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester |

Molecular formula

| **Trivial name** | **Formula** | **Conversion factor** |
|---|---|---|
| Steviol | $C_{20}$ $H_{30}$ $O_3$ | 1,00 |
| Steviolbioside | $C_{32}$ $H_{50}$ $O_{13}$ | 0,50 |
| Rubusoside | $C_{32}$ $H_{50}$ $O_{13}$ | 0,50 |
| Dulcoside A | $C_{38}$ $H_{60}$ $O_{17}$ | 0,40 |
| Stevioside | $C_{38}$ $H_{60}$ $O_{18}$ | 0,40 |
| Rebaudioside A | $C_{44}$ $H_{70}$ $O_{23}$ | 0,33 |
| Rebaudioside B | $C_{38}$ $H_{60}$ $O_{18}$ | 0,40 |
| Rebaudioside C | $C_{44}$ $H_{70}$ $O_{22}$ | 0,34 |
| Rebaudioside D | $C_{50}$ $H_{80}$ $O_{28}$ | 0,29 |
| Rebaudioside E | $C_{44}$ $H_{70}$ $O_{23}$ | 0,33 |
| Rebaudioside F | $C_{43}$ $H_{68}$ $O_{22}$ | 0,34 |
| Rebaudioside M | $C_{56}$ $H_{90}$ $O_{33}$ | 0,25 |

▼M21

| | | | |
|---|---|---|---|
| Molecular weight and CAS No | **Trivial name** | **CAS Number** | **Molecular weight** (g/mol) |
| | Steviol | | 318,46 |
| | Steviolbioside | 41093-60-1 | 642,73 |
| | Rubusoside | 64849-39-4 | 642,73 |
| | Dulcoside A | 64432-06-0 | 788,87 |
| | Stevioside | 57817-89-7 | 804,88 |
| | Rebaudioside A | 58543-16-1 | 967,01 |
| | Rebaudioside B | 58543-17-2 | 804,88 |
| | Rebaudioside C | 63550-99-2 | 951,02 |
| | Rebaudioside D | 63279-13-0 | 1 129,15 |
| | Rebaudioside E | 63279-14-1 | 967,01 |
| | Rebaudioside F | 438045-89-7 | 936,99 |
| | Rebaudioside M | 1220616-44-3 | 1 291,30 |
| Assay | Not less than 95 % steviolbioside, rubusoside, dulcoside A, stevioside, rebaudiosides A, B, C, D, E, F and M on the dried basis, in any combination and ratio. | | |
| **Description** | White to light yellow powder, approximately between 200 and 350 times sweeter than sucrose (at 5 % sucrose equivalency). | | |
| **Identification** | | | |
| Solubility | Freely soluble to slightly soluble in water | | |
| pH | Between 4,5 and 7,0 (1 in 100 solution) | | |
| **Purity** | | | |
| Total ash | Not more than 1 % | | |
| Loss on drying | Not more than 6 % (105 °C, 2h) | | |
| Residual solvents | Not more than 200 mg/kg methanol<br>Not more than 5 000 mg/kg ethanol | | |
| Arsenic | Not more than 1 mg/kg | | |
| Lead | Not more than 1 mg/kg | | |

▼M33

**E 960c(i) REBAUDIOSIDE M PRODUCED VIA ENZYME MODIFICATION OF STEVIOL GLYCOSIDES FROM STEVIA**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Rebaudioside M is a steviol glycoside composed predominantly of rebaudioside M with minor amounts of other steviol glycosides such as rebaudioside A, rebaudioside B, rebaudioside D, rebaudioside I, and stevioside.<br>Rebaudioside M is obtained via enzymatic bioconversion of purified steviol glycoside leaf extracts (95% steviol glycosides) of the *Stevia rebaudiana* Bertoni plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by the genetically modified yeasts *K. phaffi* (formerly known as *Pichia pastoris*) UGT-a and *K. phaffi* UGT-b that facilitate the transfer of glucose from sucrose and UDP-glucose to steviol glycosides via glycosidic bonds. |

▼**M33**

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|---|---|---|---|
| | After removal of the enzymes by solid-liquid separation and heat treatment, the purification involves concentration of the rebaudioside M by resin adsorption, followed by recrystallisation of rebaudioside M resulting in a final product containing not less than 95 % of rebaudioside M. ►**M38** Viable cells of the yeasts *K. phaffii* UGT-a and *K. phaffii* UGT-b and their DNA shall not be detected in the food additive. ◄ | | |
| Chemical name | Rebaudioside M: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester | | |
| Molecular formula | Trivial name | Formula | Conversion factor |
| | Rebaudioside M | $C_{56}$ $H_{90}$ $O_{33}$ | 0,25 |
| Molecular weight and CAS No | Trivial name | CAS Number | Molecular weight (g/mol) |
| | | | |
| | Rebaudioside M | 1220616-44-3 | 1,291.29 |
| Assay | Not less than 95 % rebaudioside M on the dried basis. | | |
| **Description** | White to light yellow powder, approximately between 200 and 350 times sweeter than sucrose (at 5 % sucrose equivalency). | | |
| **Identification** | | | |
| Solubility | Freely soluble to slightly soluble in water | | |
| pH | Between 4,5 and 7,0 (1 in 100 solution) | | |
| **Purity** | | | |
| Total ash | Not more than 1 % | | |
| Loss on drying | Not more than 6 % (105 °C, 2h) | | |
| Residual solvent | Not more than 5 000 mg/kg ethanol | | |
| Arsenic | Not more than 0,015 mg/kg | | |
| Lead | Not more than 0,2 mg/kg | | |
| Cadmium | Not more than 0,015 mg/kg | | |
| Mercury | Not more than 0,07 mg/kg | | |
| Residual protein | Not more than 5 mg/kg | | |
| Particle size | Not less than 74 μm [using a mesh #200 sieve with a particle size limit of 74 μm] | | |

▼M38

**E 960c(ii) REBAUDIOSIDE M PRODUCED VIA ENZYMATIC CONVERSION OF HIGHLY PURIFIED REBAUDIOSIDE A STEVIA LEAF EXTRACTS**

| | | | |
|---|---|---|---|
| **Synonyms** | | | |
| **Definition** | Rebaudioside M produced via enzymatic conversion of highly purified rebaudioside A stevia leaf extracts is a steviol glycoside composed predominantly of rebaudioside M with minor amounts of other steviol glycosides such as rebaudioside A and rebaudioside D.<br>Rebaudioside M is produced via enzymatic conversion of highly purified steviol glycoside rebaudioside A extracts (95 % steviol glycosides) obtained from *Stevia rebaudiana* Bertoni plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by the genetically modified strains of *E. coli* (pPM294, pFAF170 and pSK401) that facilitate the transfer of glucose from sucrose and UDP-glucose to steviol glycosides via glycosidic bonds. After removal of the enzymes by solid-liquid separation and heat treatment, the purification involves concentration of the rebaudioside M by resin adsorption, followed by recrystallisation of the steviol glycosides resulting in a final product containing not less than 95 % of rebaudioside M. Viable cells of *E. coli* (pPM294, pFAF170 and pSK401) and their DNA shall not be detected in the food additive. | | |
| Chemical name | Rebaudioside M: 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl ester | | |
| Molecular formula | Trivial name | Formula | Conversion factor |
| | Rebaudioside M | $C_{56}H_{90}O_{33}$ | 0,25 |
| Molecular weight and CAS No | Trivial name | CAS Number | Molecular weight (g/mol) |
| | Rebaudioside M | 1220616-44-3 | 1 291,29 |
| Assay | Not less than 95 % rebaudioside M on the dried basis. | | |
| **Description** | White to light yellow powder, approximately between 150 and 350 times sweeter than sucrose (at 5 % sucrose equivalency). | | |
| **Identification** | | | |
| Solubility | Freely soluble to slightly soluble in water | | |
| pH | Between 4,5 and 7,0 (1 in 100 solution) | | |
| **Purity** | | | |
| Total ash | Not more than 1 % | | |
| Loss on drying | Not more than 6 % (105 °C, 2h) | | |
| Residual solvent | Not more than 5 000 mg/kg ethanol | | |
| Arsenic | Not more than 0,015 mg/kg | | |
| Lead | Not more than 0,2 mg/kg | | |
| Cadmium | Not more than 0,015 mg/kg | | |

▼M38

| | |
|---|---|
| Mercury | Not more than 0,07 mg/kg |
| Residual protein | Not more than 5 mg/kg |
| Particle size | Not less than 74 μm [using a mesh #200 sieve with a particle size limit of 74 μm] |

**E 960c(iii) REBAUDIOSIDE D PRODUCED VIA ENZYMATIC CONVERSION OF HIGHLY PURIFIED REBAUDIOSIDE A STEVIA LEAF EXTRACTS**

| | | | |
|---|---|---|---|
| **Synonyms** | | | |
| **Definition** | Rebaudioside D produced via enzymatic conversion of highly purified rebaudioside A stevia leaf extracts is a steviol glycoside composed predominantly of rebaudioside D with minor amounts of other steviol glycosides such as rebaudioside A and rebaudioside M.<br>Rebaudioside D is produced via enzymatic conversion of highly purified steviol glycoside rebaudioside A extracts (95 % steviol glycosides) obtained from *Stevia rebaudiana* Bertoni plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by the genetically modified strains of *E. coli* (pPM294, pFAF170 and pSK401) that facilitate the transfer of glucose from sucrose and UDP-glucose to steviol glycosides via glycosidic bonds. After removal of the enzymes by solid-liquid separation and heat treatment, the purification involves concentration of the rebaudioside D by resin adsorption, followed by recrystallisation of the steviol glycosides resulting in a final product containing not less than 95 % of rebaudioside D and rebaudioside A. Viable cells of *E. coli* (pPM294, pFAF170 and pSK401) and their DNA shall not be detected in the food additive. | | |
| Chemical name | Rebaudioside D: 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl ester.<br>Rebaudioside A: 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester | | |
| Molecular formula | Trivial name | Formula | Conversion factor |
| | Rebaudioside D | $C_{50}H_{80}O_{28}$ | 0,29 |
| | Rebaudioside A | $C_{44}H_{70}O_{23}$ | 0,33 |
| Molecular weight and CAS No | Trivial name | CAS Number | Molecular weight (g/mol) |
| | Rebaudioside D | 63279-13-0 | 1 291,15 |
| | Rebaudioside A | 58543-16-1 | 967,01 |
| Assay | Not less than 95 % rebaudiosides D and A on the dried basis. | | |
| **Description** | White to light yellow powder, approximately between 150 and 350 times sweeter than sucrose (at 5 % sucrose equivalency). | | |

**Identification**

| | |
|---|---|
| Solubility | Freely soluble to slightly soluble in water |
| pH | Between 4,5 and 7,0 (1 in 100 solution) |

▼M38

| **Purity** | |
|---|---|
| Total ash | Not more than 1 % |
| Loss on drying | Not more than 6 % (105 °C, 2h) |
| Residual solvent | Not more than 5 000 mg/kg ethanol |
| Arsenic | Not more than 0,015 mg/kg |
| Lead | Not more than 0,2 mg/kg |
| Cadmium | Not more than 0,015 mg/kg |
| Mercury | Not more than 0,07 mg/kg |
| Residual protein | Not more than 5 mg/kg |
| Particle size | Not less than 74 μm [using a mesh #200 sieve with a particle size limit of 74 μm] |

**E 960c(iv) REBAUDIOSIDE AM PRODUCED VIA ENZYMATIC CONVERSION OF HIGHLY PURIFIED STEVIOSIDE STEVIA LEAF EXTRACTS**

| **Synonyms** | | | |
|---|---|---|---|
| **Definition** | Rebaudioside AM produced via enzymatic convertion of highly purified stevioside stevia leaf extracts is a steviol glycoside composed predominantly of rebaudioside AM with minor amounts of other steviol glycosides such as stevioside and rebaudioside E.<br><br>Rebaudioside AM is produced via enzymatic conversion of highly purified steviol glycoside stevioside extracts (95 % steviol glycosides) obtained from *Stevia rebaudiana* Bertoni plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by the genetically modified strains of *E. coli* (pPM294, pFAF170 and pSK401) that facilitate the transfer of glucose from sucrose and UDP-glucose to steviol glycosides via glycosidic bonds. After removal of the enzymes by solid-liquid separation and heat treatment, the purification involves concentration of the rebaudioside AM by resin adsorption, followed by recrystallisation of the steviol glycosides resulting in a final product containing not less than 95 % of rebaudioside AM. Viable cells of *E. coli* (pPM294, pFAF170 and pSK401) and their DNA shall not be detected in the food additive. | | |
| Chemical name | Rebaudioside AM: 13-[(2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2- *O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl ester. | | |
| Molecular formula | Trivial name | Formula | Conversion factor |
| | Rebaudioside AM | $C_{50}$ $H_{80}$ $O_{28}$ | 0,29 |
| Molecular weight and CAS No | Trivial name | CAS Number | Molecular weight (g/mol) |
| | Rebaudioside AM | 2222580-26-7 | 1 291,15 |

▼M38

| | |
|---|---|
| Assay | Not less than 95 % rebaudioside AM on the dried basis. |
| **Description** | White to light yellow powder, approximately between 150 and 350 times sweeter than sucrose (at 5 % sucrose equivalency). |
| **Identification** | |
| Solubility | Freely soluble to slightly soluble in water |
| pH | Between 4,5 and 7,0 (1 in 100 solution) |
| **Purity** | |
| Total ash | Not more than 1 % |
| Loss on drying | Not more than 6 % (105 °C, 2h) |
| Residual solvent | Not more than 5 000 mg/kg ethanol |
| Arsenic | Not more than 0,015 mg/kg |
| Lead | Not more than 0,2 mg/kg |
| Cadmium | Not more than 0,015 mg/kg |
| Mercury | Not more than 0,07 mg/kg |
| Residual protein | Not more than 5 mg/kg |
| Particle size | Not less than 74 μm [using a mesh #200 sieve with a particle size limit of 74 μm] |

▼M40

**E 960d GLUCOSYLATED STEVIOL GLYCOSIDES**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Mixture of larger glycosides of steviol derived by glucosylation of steviol glycosides extracted from leaves of *Stevia rebaudiana* Bertoni plant. The mixture is composed of glucosylated steviol glycosides and residual parent steviol glycosides from Stevia leaf. Glucosylated steviol glycosides are produced by treating the steviol glycosides, extracted from Stevia leaf, and starch suitable for human consumption with Cyclomaltodextrin glucanotransferase (EC 2.4.1.19) derived from a non-GMO strain of *Anoxybacillus caldiproteolyticus St-88*. The enzyme transfers glucose units from the starch to the steviol glycosides. The resulting material is heated and treated with activated carbon to remove the enzyme, then passed through adsorption/desorption resin to remove residual hydrolysed starch (dextrin), followed by purification and preparation of the final product using processes that may include decolourisation, concentration and spray drying. |
| Chemical name | Steviolbioside: 13-[(2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)-oxy]kaur-16-en-18-oic acid<br>Rubusoside: 13-β-D-glucopyranosyloxykaur-16-en-18-oic acid, β-D-glucopyranosyl ester<br>Dulcoside A: 13-[(2-*O*-α–L-rhamnopyranosyl-β–D-glucopyranosyl)-oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester<br>Stevioside: 13-[(2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]-kaur-16-en-18-oic acid, β-D-glucopyranosyl ester<br>Rebaudioside A: 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D- glucopyranosyl ester |

▼M40

| | | | |
|---|---|---|---|
| | Rebaudioside B: 13-[(2-*O*-β–D-glucopyranosyl-3-*O*-β–D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid<br>Rebaudioside C: 13-[(2-*O*-α–L-rhamnopyranosyl-3-*O*-β–D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester<br>Rebaudioside D: 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl ester<br>Rebaudioside E: 13-[(2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl ester<br>Rebaudioside F: 13-[(2-*O*-β-D-xylofurananosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester<br>Rebaudioside M: 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl ester<br>And their glucosylated derivatives (1-20 added glucose units) | | |
| Molecular formula | **Trivial name** | **Formula** | **Conversion factor** |
| | n-Glucosylated Steviolbioside | $C_{(32+n*6)}H_{(50+n*10)}O_{(13+n*5)}$ | |
| | n-Glucosylated Rubusoside | $C_{(32+n*6)}H_{(50+n*10)}O_{(13+n*5)}$ | |
| | n-Glucosylated Dulcoside A | $C_{(38+n*6)}H_{(60+n*10)}O_{(17+n*5)}$ | |
| | n-Glucosylated Stevioside | $C_{(38+n*6)}H_{(60+n*10)}O_{(18+n*5)}$ | |
| | n-Glucosylated Rebaudioside A | $C_{(44+n*6)}H_{(70+n*10)}O_{(23+n*5)}$ | |
| | n-Glucosylated Rebaudioside B | $C_{(38+n*6)}H_{(60+n*10)}O_{(18+n*5)}$ | |
| | n-Glucosylated Rebaudioside C | $C_{(44+n*6)}H_{(70+n*10)}O_{(22+n*5)}$ | |
| | n-Glucosylated Rebaudioside D | $C_{(50+n*6)}H_{(80+n*10)}O_{(28+n*5)}$ | |
| | n-Glucosylated Rebaudioside E | $C_{(44+n*6)}H_{(70+n*10)}O_{(23+n*5)}$ | |
| | n-Glucosylated Rebaudioside F | $C_{(43+n*6)}H_{(68+n*10)}O_{(22+n*5)}$ | |
| | n-Glucosylated Rebaudioside M | $C_{(56+n*6)}H_{(90+n*10)}O_{(33+n*5)}$ | |
| | n: number of glucose units enzymatically added to the parent steviol glycoside (n = 1-20)<br>Typical conversion factor for glucosylated steviol glycosides mixtures = 0,20 (on the dried, dextrin-free, basis) | | |
| | Steviol | $C_{20}H_{30}O_3$ | 1,00 |

▼M40

| | | | |
|---|---|---|---|
| | Steviolbioside | $C_{32}H_{50}O_{13}$ | 0,50 |
| | Rubusoside | $C_{32}H_{50}O_{13}$ | 0,50 |
| | Dulcoside A | $C_{38}H_{60}O_{17}$ | 0,40 |
| | Stevioside | $C_{38}H_{60}O_{18}$ | 0,40 |
| | Rebaudioside A | $C_{44}H_{70}O_{23}$ | 0,33 |
| | Rebaudioside B | $C_{38}H_{60}O_{18}$ | 0,40 |
| | Rebaudioside C | $C_{44}H_{70}O_{22}$ | 0,34 |
| | Rebaudioside D | $C_{50}H_{80}O_{28}$ | 0,29 |
| | Rebaudioside E | $C_{44}H_{70}O_{23}$ | 0,33 |
| | Rebaudioside F | $C_{43}H_{68}O_{22}$ | 0,34 |
| | Rebaudioside M | $C_{56}H_{90}O_{33}$ | 0,25 |
| Molecular weight and CAS No | **Trivial name** | **CAS Number** | **Molecular weight (g/mol)** |
| | n-Glucosylated Steviolbioside | Not available | 642,73+n*162,15 |
| | n-Glucosylated Rubusoside | Not available | 642,73+n*162,15 |
| | n-Glucosylated Dulcoside A | Not available | 788,87+n*162,15 |
| | n-Glucosylated Stevioside | Not available | 804,88+n*162,15 |
| | n-Glucosylated Rebaudioside A | Not available | 967,01+n*162,15 |
| | n-Glucosylated Rebaudioside B | Not available | 804,88+n*162,15 |
| | n-Glucosylated Rebaudioside C | Not available | 951,02+n*162,15 |
| | n-Glucosylated Rebaudioside D | Not available | 1129,15+n*162,15 |
| | n-Glucosylated Rebaudioside E | Not available | 967,01+n*162,15 |
| | n-Glucosylated Rebaudioside F | Not available | 936,99+n*162,15 |
| | n-Glucosylated Rebaudioside M | Not available | 1291,30+n*162,15 |
| | Steviol | | 318,46 |
| | Steviolbioside | 41093-60-1 | 642,73 |
| | Rubusoside | 64849-39-4 | 642,73 |
| | Dulcoside A | 64432-06-0 | 788,87 |
| | Stevioside | 57817-89-7 | 804,88 |
| | Rebaudioside A | 58543-16-1 | 967,01 |
| | Rebaudioside B | 58543-17-2 | 804,88 |
| | Rebaudioside C | 63550-99-2 | 951,02 |
| | Rebaudioside D | 63279-13-0 | 1 129,15 |
| | Rebaudioside E | 63279-14-1 | 967,01 |
| | Rebaudioside F | 438045-89-7 | 936,99 |
| | Rebaudioside M | 1220616-44-3 | 1 291,30 |

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|---|---|
| Assay | Not less than 95 % of total steviol glycosides, comprised of above mentioned steviol glycosides along with their glucosylated derivatives (1-20 added glucose units), on the dried, dextrin-free, basis. |
| **Description** | White to light yellow powder, approximately between 100 and 200 times sweeter than sucrose (at 5 % sucrose equivalency). |
| **Identification** | |
| Solubility | Soluble in water |
| pH | Between 4,5 and 7,0 (1 in 100 solution) |
| **Purity** | |
| Total ash | Not more than 1 % |
| Loss on drying | Not more than 6 % (105 °C, 2 h) |
| Residual solvent | Not more than 200 mg/kg methanol<br>Not more than 3 000 mg/kg ethanol |
| Arsenic | Not more than 0,015 mg/kg |
| Lead | Not more than 0,1 mg/kg |
| Cadmium | Not more than 0,1 mg/kg |
| Mercury | Not more than 0,1 mg/kg |
| Microbiological criteria | |
| Total (aerobic) plate count | Not more than 1 000 CFU/g |
| Yeast and moulds | Not more than 200 CFU/g |
| *E. coli* | Negative in 1 g |
| *Salmonella* | Negative in 25 g |

▼B

**E 961 NEOTAME**

| | |
|---|---|
| **Synonyms** | N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine 1-methyl ester;<br>N(3,3-dimethylbutyl)-L-aspartyl-L-phenylalanine methyl ester. |
| **Definition** | Neotame is manufactured by reaction under hydrogen pressure of aspartame with 3,3,-dimethylbutyraldehyde in methanol in presence of a palladium/carbon catalyst. It is isolated and purified by filtration, where diatomaceous earth may be used. After solvent removal via distillation, neotame is washed with water, isolated by centrifugation and finally vacuum dried. |
| CAS Nr. | 165450-17-9 |
| Chemical name | N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine 1-methyl ester |
| Chemical formula | $C_{20}H_{30}N_2O_5$ |
| Molecular weight | 378,47 |
| **Description** | white to off-white powder |
| Assay | Not less than 97,0 % on the dried basis |
| **Identification** | |
| Solubility | 4,75 % (w/w) at 60 °C in water, soluble in ethanol and ethyl acetate |

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| | |
|---|---|
| **Purity** | |
| Water content | Not more than 5 % (Karl Fischer, sample size 25 ± 5mg) |
| pH | 5,0-7,0 (0,5 % aqueous solution) |
| Melting range | 81 °C to 84 °C |
| N-[(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine | Not more than 1,5 % |
| Lead | Not more than 1 mg/kg |

**E 962 SALT OF ASPARTAME-ACESULFAME**

| | |
|---|---|
| **Synonyms** | Aspartame-acesulfame; Aspartame-acesulfame salt |
| **Definition** | The salt is prepared by heating an approximately 2:1 ratio (w/w) of aspartame and acesulfame K in solution at acidic pH and allowing crystallisation to occur. The potassium and moisture are eliminated. The product is more stable than aspartame alone. |
| Einecs | |
| Chemical name | 6-Methyl-1,2,3-oxathiazine-4(3H)-one-2,2-dioxide salt of L-phenylalanyl-2-methyl-L-α-aspartic acid |
| Chemical formula | $C_{18}H_{23}O_9N_3S$ |
| Molecular weight | 457,46 |
| Assay | 63,0 % to 66,0 % aspartame (dry basis) and 34,0 % to 37,0 % acesulfame (acid form on a dry basis) |
| **Description** | A white, odourless, crystalline powder |
| **Identification** | |
| Solubility | Sparingly soluble water; slightly soluble in ethanol |
| Transmittance | The transmittance of a 1 % solution in water determined in a 1 cm cell at 430 nm with a suitable spectrophotometer using water as a reference, is not less than 0,95, equivalent to an absorbance of not more than approximately 0,022. |
| Specific rotation | $[\alpha]_D^{20}$ + 14,5° to + 16,5°<br>Determine at a concentration of 6,2 g in 100 ml formic acid (15N) within 30 min of preparation of the solution. Divide the calculated specific rotation by 0,646 to correct for the aspartame content of the salt of aspartame-acesulfame |

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|---|---|
| **Purity** | |
| Loss on drying | Not more than 0,5 % (105 °C, 4 hours) |
| 5-Benzyl-3,6-dioxo-2-piperazineacetic acid | Not more than 0,5 % |
| Lead | Not more than 1 mg/kg |

▼M1

**E 964 POLYGLYCITOL SYRUP**

| | |
|---|---|
| **Synonyms** | Hydrogenated starch hydrolysate, hydrogenated glucose syrup and polyglucitol |
| **Definition** | A mixture consisting mainly of maltitol and sorbitol and lesser amounts of hydrogenated oligo- and polysaccharides and maltrotriitol. It is manufactured by the catalytic hydrogenation of a mixture of starch hydrolysates consisting of glucose, maltose and higher glucose polymers, similar to the catalytic hydrogenation process used for the manufacture of maltitol syrup. The resulting syrup is desalted by ion exchange and concentrated to the desired level. |
| Einecs | |
| Chemical name | Sorbitol: D-glucitol<br>Maltitol: (α)-D-Glucopyranosyl-1,4-D-glucitol |
| Chemical formula | Sorbitol: $C_6H_{14}O_6$<br>Maltitol: $C_{12}H_{24}O_{11}$ |
| Molecular weight | Sorbitol: 182,2<br>Maltitol: 344,3 |
| Assay | Content not less than 99 % of total hydrogenated saccharides on the anhydrous basis, not less than 50 % higher molecular weight polyols, not more than 50 % of maltitol and not more than 20 % of sorbitol on the anhydrous basis. |
| **Description** | Colourless and odourless clear viscous liquid |
| **Identification** | |
| Solubility | Very soluble in water and slightly soluble in ethanol |
| Test for maltitol | Passes test |
| Test for sorbitol | To 5 g of the sample add 7 ml of methanol, 1 ml of benzaldehyde and 1 ml of hydrochloric acid. Mix and shake in a mechanical shaker until crystals appear. Filter the crystals and dissolve in 20 ml of boiling water containing 1 g of sodium bicarbonate. Filter the crystals, wash with 5 ml of a water-methanol mixture (1 in 2) and dry in the air. The crystals of the monobenzylidine derivative of sorbitol so obtained melt between 173 and 179 °C. |
| **Purity** | |
| Water content | Not more than 31 % (Karl Fischer method) |
| Chlorides | Not more than 50 mg/kg |
| Sulphates | Not more than 100 mg/kg |
| Reducing sugars | Not more than 0,3 % |
| Nickel | Not more than 2 mg/kg |
| Lead | Not more than 1 mg/kg |

▼B

**E 965 (i) MALTITOL**

| | |
|---|---|
| **Synonyms** | D-Maltitol; Hydrogenated maltose |
| **Definition** | Maltitol is obtained by hydrogenation of D-maltose. It is mainly composed of D-maltitol. It may contain small amounts of sorbitol and related polyhydric alcohols. |
| Einecs | 209-567-0 |
| Chemical name | (α)-D-Glucopyranosyl-1,4-D-glucitol |
| Chemical formula | $C_{12}H_{24}O_{11}$ |
| Molecular weight | 344,3 |
| Assay | Content not less than 98 % D-maltitol $C_{12}H_{24}O_{11}$ on the anhydrous basis |
| **Description** | White crystalline powder |
| **Identification** | |
| Solubility | Very soluble in water, slightly soluble in ethanol |
| Melting range | 148 to 151 °C |
| Specific rotation | $[\alpha]_D^{20}$ + 105,5° to + 108,5° (5 % w/v solution) |

▼M4

| | |
|---|---|
| **Purity** | |
| Appearance of the aqueous solution | The solution is clear and colourless |
| Water content | Not more than 1 % (Karl Fischer Method) |
| Conductivity | Not more than 20 µS/cm (on 20 % dry solids solution) at temperature 20 °C |
| Reducing sugars | Not more than 0,1 % (expressed as glucose on an anhydrous basis) |
| Nickel | Not more than 2 mg/kg (expressed on anhydrous basis) |
| Arsenic | Not more than 3 mg/kg (expressed on anhydrous basis) |
| Lead | Not more than 1 mg/kg (expressed on anhydrous basis) |

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**E 965 (ii) MALTITOL SYRUP**

| | |
|---|---|
| **Synonyms** | Hydrogenated high-maltose-glucose syrup; Hydrogenated glucose syrup; Maltitol liquid |
| **Definition** | A mixture consisting of mainly maltitol with sorbitol and hydrogenated oligo- and polysaccharides. It is manufactured by the catalytic hydrogenation of high maltose-content glucose syrup or by the hydrogenation of its individual components followed by blending. The article of commerce is supplied both as a syrup and as a solid product. |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | Content not less than 99 % of total hydrogenated saccharides on the anhydrous basis and not less than 50 % of maltitol on the anhydrous basis |
| **Description** | Colourless and odourless, clear viscous liquids or white crystalline masses |

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|---|---|
| **Identification** | |
| Solubility | Very soluble in water, slightly soluble in ethanol |
| HPLC test | Comparison with an appropriate reference standard of Maltitol shows that the principle peak in the chromatogram of the test solution is similar in retention time to the principal peak in the chromatogram obtained with the reference solution (ISO 10504:1998). |

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| | |
|---|---|
| **Purity** | |
| Appearance of the aqueous solution | The solution is clear and colourless |
| Water content | Not more than 31 % (Karl Fischer Method) |
| Conductivity | Not more than 10 µS/cm (on the product as such) at temperature 20 °C |
| Reducing sugars | Not more than 0,3 % (expressed as glucose on an anhydrous basis) |
| Nickel | Not more than 2 mg/kg |
| Lead | Not more than 1 mg/kg |

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**E 966 LACTITOL**

| | |
|---|---|
| **Synonyms** | Lactit; Lactositol; Lactobiosit |
| **Definition** | Lactitol is manufactured via catalytic hydrogenation of lactose |
| Einecs | 209-566-5 |
| Chemical name | 4-O-β-D-Galactopyranosyl-D-glucitol |
| Chemical formula | $C_{12}H_{24}O_{11}$ |
| Molecular weight | 344,3 |
| Assay | Not less than 95 % on the dry weight basis |
| **Description** | Crystalline powder or colourless solution. Crystalline products occur in anhydrous, monohydrate and dihydrate forms. Nickel is used as a catalyst. |
| **Identification** | |
| Solubility | Very soluble in water |
| Specific rotation | $[\alpha]_D^{20}$ = + 13° to + 16° calculated on the anhydrous basis (10 % w/v aqueous solution) |
| **Purity** | |
| Water content | Crystalline products; not more than 10,5 % (Karl Fischer method) |
| Other polyols | Not more than 2,5 % (on the anhydrous basis) |
| Reducing sugars | Not more than 0,2 % (expressed as glucose on dry weight basis) |
| Chlorides | Not more than 100 mg/kg (expressed on dry weight basis) |
| Sulphates | Not more than 200 mg/kg (expressed on dry weight basis) |
| Sulphated ash | Not more than 0,1 % (expressed on dry weight basis) |
| Nickel | Not more than 2 mg/kg (expressed on dry weight basis) |
| Arsenic | Not more than 3 mg/kg (expressed on dry weight basis |
| Lead | Not more than 1 mg/kg (expressed on dry weight basis) |

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**E 967 XYLITOL**

| | |
|---|---|
| **Synonyms** | Xylitol |
| **Definition** | Xylitol is mainly composed of D-xylitol. The part which is not D-xylitol is composed of related substances such as L-arabinitol, galactitol, mannitol, sorbitol |
| Einecs | 201-788-0 |
| Chemical name | D-xylitol |
| Chemical formula | $C_5H_{12}O_5$ |
| Molecular weight | 152,2 |
| Assay | Not less than 98,5 % as xylitol on the anhydrous basis |
| **Description** | White, crystalline powder, practically odourless. |
| **Identification** | |
| Solubility | Very soluble in water, sparingly soluble in ethanol |
| Melting range | 92 to 96 °C |
| pH | 5 to 7 (10 % w/v aqueous solution) |
| Infrared absorption spectroscopy | Comparison with a reference standard e.g. EP or USP. |

▼M4

| | |
|---|---|
| **Purity** | |
| Water content | Not more than 1 % (Karl Fischer Method) |
| Conductivity | Not more than 20 µS/cm (on 20 % dry solids solution) at temperature 20 °C |
| Reducing sugars | Not more than 0,2 % (expressed as glucose on dry weight basis) |
| Other polyhydric alcohols | Not more than 1 % (expressed on dry weight basis) |
| Nickel | Not more than 2 mg/kg (expressed on dry weight basis) |
| Arsenic | Not more than 3 mg/kg (expressed on dry weight basis) |
| Lead | Not more than 1 mg/kg (expressed on dry weight basis) |

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**E 968 ERYTHRITOL**

| | |
|---|---|
| **Synonyms** | Meso-erythritol; Tetrahydroxybutane; Erythrite |
| **Definition** | Obtained by fermentation of carbohydrate source by safe and suitable food grade osmophilic yeasts such as *Moniliella pollinis* or *Moniliella megachilensis*, followed by purification and drying |
| Einecs | 205-737-3 |
| Chemical name | 1,2,3,4-Butanetetrol |
| Chemical formula | $C_4H_{10}O_4$ |
| Molecular weight | 122,12 |
| Assay | Not less than 99 % after drying |
| **Description** | White, odourless, non-hygroscopic, heat-stable crystals with a sweetness of approximately 60-80 % that of sucrose. |

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|---|---|
| **Identification** | |
| Solubility | Freely soluble in water, slightly soluble in ethanol, insoluble in diethyl ether. |
| Melting range | 119-123 °C |

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|---|---|
| **Purity** | |
| Loss on drying | Not more than 0,2 % (70 °C, 6 hours, in a vacuum desiccator) |
| Conductivity | Not more than 20 µS/cm (on 20 % dry solids solution) at temperature 20 °C |
| Reducing substances | Not more than 0,3 % expressed as D-glucose |
| Ribitol and glycerol | Not more than 0,1 % |
| Lead | Not more than 0,5 mg/kg |

▼M11

**E 969 ADVANTAME**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Advantame (ANS9801) is produced by chemical synthesis in a three-step process; production of the principal manufacturing intermediate, 3-hydroxy-4-methoxycinnamaldehyde (HMCA), followed by hydrogenation to form 3-(3-hydroxy-4-methoxyphenyl) propionaldehyde (HMPA). In the final step, the HMPA methanol solution (filtrate) is combined with aspartame to give the imine that under selective hydrogenation forms advantame. The solution is allowed to crystallise and crude crystals are washed. The product is re-crystallised and crystals are separated, washed and dried. |
| CAS No. | 714229-20-6 |
| Chemical name | N-[*N*-[3-(3-hydroxy-4-methoxyphenyl) propyl]-α-aspartyl]-L-phenylalanine 1-methyl ester, monohydrate (IUPAC);<br>L-phenylalanine, N-[3-(3-hydroxy-4-methoxyphenyl)propyl]-L-alpha-aspartyl-, 2-methyl ester, monohydrate (CA) |
| Molecular formula | $C24H30N2O7 \cdot H_2O$ |
| Molecular weight | 476,52 g/mol (monohydrate) |
| Assay | Not less than 97,0 % and not more than 102,0 % on an anhydrous basis |
| **Description** | White to yellow powder |
| **Identification** | |
| Melting Point | 101,5 °C |
| **Purity** | |
| N-[N-[3-(3-hydroxy-4-methoxyphenyl)propyl-α-aspartyl]-L-phenylalanine (ANS9801-acid) | Not more than 1,0 % |
| Total other related substances | Not more than 1,5 % |
| Residual Solvents | Isopropyl acetate: Not more than 2 000 mg/kg<br>Methyl acetate: Not more than 500 mg/kg<br>Methanol: Not more than 500 mg/kg<br>2-Propanol: Not more than 500 mg/kg |

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| | |
|---|---|
| Water content | Not more than 5,0 % (Karl Fischer method) |
| Residue on ignition | Not more than 0,2 % |
| Arsenic | Not more than 2 mg/kg |
| Lead | Not more than 1 mg/kg |
| Palladium | Not more than 5,3 mg/kg |
| Platinum | Not more than 1,7 mg/kg |

▼B

**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 *Quillaia 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 |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | Quillaia extract in the powder form is light brown with a pink tinge. It is also available as an aqueous solution |
| **Identification** | |
| pH | Between 3,7 and 5,5 (4 % solution) |
| **Purity** | |
| Water content | Not more than 6,0 % (Karl Fischer method) (powder form only) |
| Arsenic | Not more than 2 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 1103 INVERTASE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Invertase is produced from *Saccharomyces cerevisiae* |
| Einecs | 232-615-7 |
| Enzyme Commission No | EC 3.2.1.26 |
| Systematic name | β-D-Fructofuranoside fructohydrolase |

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| | |
|---|---|
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | |
| **Identification** | |
| **Purity** | |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Cadmium | Not more than 0,5 mg/kg |
| **Microbiological criteria** | |
| Total bacterial count | Not more than 50 000 colonies per gram |
| *Salmonella* spp. | Absent in 25 g |
| Coliforms | Not more than 30 colonies per gram |
| *Escherichia coli* | Absent in 25 g |

**E 1105 LYSOZYME**

| | |
|---|---|
| **Synonyms** | Lysozyme hydrochloride; Muramidase |
| **Definition** | Lysozyme is a linear polypeptide obtained from hens' egg whites consisting of 129 amino acids. It possesses enzymatic activity in its ability to hydrolyse the β(1-4) linkages between N-acetylmuramic acid and N-acetylglucosamine in the outer membranes of bacterial species, in particular gram-positive organisms. Is usually obtained as the hydrochloride |
| Einecs | 232-620-4 |
| Enzyme Commission No | EC 3.2.1.17 |
| Chemical name | |
| Chemical formula | |
| Molecular weight | About 14 000 |
| Assay | Content not less than 950 mg/g on the anhydrous basis |
| **Description** | White, odourless powder having a slightly sweet taste |
| **Identification** | |
| Isoelectric point | 10,7 |
| pH | Between 3,0 and 3,6 (2 % aqueous solution) |
| Spectrophotometry | Absorption maximum of an aqueous solution (25 mg/100 ml) at 281 nm, a minimum at 252 nm |
| **Purity** | |
| Water content | Not more than 6,0 % (Karl Fischer method) (powder form only) |
| Residue on ignition | Not more than 1,5 % |
| Nitrogen | Not less than 16,8 % and not more than 17,8 % |
| Arsenic | Not more than 1 mg/kg |

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|---|---|
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| **Microbiological criteria** | |
| Total bacterial count | Not more than $5 \times 10^4$ colonies per gram |
| *Salmonella* spp. | Absent in 25 g |
| *Staphylococcus aureus* | Absent in 1 g |
| *Escherichia coli* | Absent in 1 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 and/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 decolourised 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 |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| 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** | |
| Test for sugar | Passes test |
| Test for reducing sugar | Passes test |
| pH | Between 2,5 and 7,0 for polydextrose (10 % solution)<br>Between 5,0 and 6,0 for polydextrose-N (10 % solution) |
| **Purity** | |
| Water content | Not more than 4,0 % (Karl Fischer method) |
| Sulphated ash | Not more than 0,3 % (polydextrose)<br>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 |

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|---|---|
| 5-Hydroxy-methylfurfural | Not more than 0,1 % (polydextrose)<br>Not more than 0,05 % (polydextrose-N) |
| Lead | Not more than 0,5 mg/kg |

**E 1201 POLYVINYLPYRROLIDONE**

| | |
|---|---|
| **Synonyms** | Povidone; PVP; Soluble polyvinylpyrrolidone |
| **Definition** | |
| Einecs | |
| Chemical name | Polyvinylpyrrolidone, poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene] |
| Chemical formula | $(C_6H_9NO)_n$ |
| Average molecular weight | Not less than 25 000 |
| Assay | Content not less than 11,5 % and not more than 12,8 % of nitrogen (N) on the anhydrous basis |
| **Description** | White or nearly white powder |
| **Identification** | |
| Solubility | Soluble in water and in ethanol. Insoluble in ether |
| pH | Between 3,0 and 7,0 (5 % solution) |
| **Purity** | |
| Water content | 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 2 mg/kg |

**E 1202 POLYVINYLPOLYPYRROLIDONE**

| | |
|---|---|
| **Synonyms** | Crospovidone; Cross-linked polyvidone; Insoluble polyvinylpyrrolidone |
| **Definition** | Polyvinylpolypyrrolidone is a poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene], cross linked in a random fashion. It is produced by the polymerisation of N-vinyl-2-pyrrolidone in the presence of either caustic catalyst or N, N'-divinyl-imidazolidone. Due to its insolubility in all common solvents the molecular weight range is not amenable to analytical determination |
| Einecs | |
| Chemical name | Polyvinylpyrrolidone; poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene] |
| Chemical formula | $(C_6H_9NO)_n$ |
| Molecular weight | |
| 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** | |
| Solubility | Insoluble in water, ethanol and ether |

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| | |
|---|---|
| pH | Between 5,0 and 8,0 (1 % suspension in water) |
| **Purity** | |
| Water content | 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 2 mg/kg |

**E 1203 POLYVINYL ALCOHOL**

| | |
|---|---|
| **Synonyms** | Vinyl alcohol polymer, PVOH |
| **Definition** | Polyvinyl alcohol is a synthetic resin prepared by the polymerisation of vinyl acetate, followed by partial hydrolysis of the ester in the presence of an alkaline catalyst. The physical characteristics of the product depend on the degree of polymerisation and the degree of hydrolysis. |
| Chemical name | Ethenol homopolymer |
| Chemical formula | $(C_2H_3OR)_n$ where R = H or $COCH_3$ |
| **Description** | Odourless, tasteless, translucent, white or cream-coloured granular powder |
| **Identification** | |

▼M17

| | |
|---|---|
| Solubility | Soluble in water; Practically insoluble or insoluble in ethanol (≥ 99,8 %) |

▼B

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|---|---|
| Precipitation reaction | Dissolve 0,25 g of the sample in 5 ml of water with warming and let the solution cool to room temperature. The addition of 10 ml of ethanol to this solution leads to a white, turbid or flocculent precipitate. |
| Colour reaction | Dissolve 0,01 g of the sample in 100 ml of water with warming and let the solution cool to room temperature. A blue colour is produced when adding (to 5 ml solution) one drop of iodine test solution (TS) and a few drops of boric acid solution<br>Dissolve 0,5 g of the sample in 10 ml of water with warming and let the solution cool to room temperature. A dark red to blue colour is produced after adding one drop of iodine TS to 5 ml of solution. |
| Viscosity | 4,8 to 5,8 mPa.s (4 % solution at 20 °C) corresponding to an average molecular weight of 26 000-30 000 Da |
| **Purity** | |
| Water insoluble matter | Not more than 0,1 % |
| Ester value | Between 125 and 153 mg KOH/g |
| Degree of hydrolysis | 86,5 to 89,0 % |
| Acid value | Not more than 3,0 |
| Solvent residues | Not more than 1,0 % Methanol, 1,0 % Methyl acetate |
| pH | 5,0 to 6,5 (4 % solution) |
| Loss on drying | Not more than 5,0 % (105 °C, 3 hours) |
| Residue in ignition | Not more than 1,0 % |
| Lead | Not more than 2 mg/kg |

▼B

**E 1204 PULLULAN**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Linear, neutral glucan consisting mainly of maltotriose units connected by -1,6 glycosidic bonds. It is produced by fermentation from a food-grade hydrolysed starch using a non-toxin-producing strain of *Aureobasidium pullulans*. After completion of the fermentation, the fungal cells are removed by microfiltration, the filtrate is heat-sterilised and pigments and other impurities are removed by adsorption and ion exchange chromatography |
| Einecs | 232-945-1 |
| Chemical name | |
| Chemical formula | $(C_6H_{10}O_5)_n$ |
| Molecular weight | |
| Assay | Not less than 90 % of glucan on the dried basis |
| **Description** | White to off-white odourless powder |
| **Identification** | |
| Solubility | Soluble in water, practically insoluble in ethanol |
| pH | 5,0 to 7,0 (10 % solution) |
| Precipitation with polyethylene glycol 600 | Add 2 ml of polyethylene glycol 600 to 10 ml of a 2 % aqueous solution of pullulan. A white precipitate is formed |
| Depolymerisation with pullulanase | Prepare two test tubes each with 10 ml of a 10 % pullulan solution. Add 0,1 ml pullulanase solution having activity 10 units/g to one test tube, and 0,1 ml water to the other. After incubation at about 25 °C for 20 minutes, the viscosity of the pullulanase-treated solution is visibly lower than that of the untreated solution |
| Viscosity | 100 to 180 $mm^2/s$ (10 % w/w aqueous solution at 30 °C) |
| **Purity** | |
| Loss on drying | Not more than 6 % (90 °C, pressure not more than 50 mm Hg, 6 hours) |
| Mono-, di- and oligosaccharides | Not more than 10 % expressed as glucose |
| Lead | Not more than 1 mg/kg |
| **Microbiological criteria** | |
| Yeast and moulds | Not more than 100 colonies per gram |
| Coliforms | Absent in 25 g |
| *Salmonella* spp. | Absent in 25 g |

**E 1205 BASIC METHACRYLATE COPOLYMER**

| | |
|---|---|
| **Synonyms** | Basic butylated methacrylate copolymer; amino methacrylate copolymer; aminoalkyl methacrylate copolymer E; butyl methacrylate, dimethylaminoethyl methacrylate, methyl methacrylate polymer; butyl methacrylate, methyl methacrylate, dimethylaminoethyl methacrylate polymer |

▼M22

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|---|---|
| **Definition** | Basic methacrylate copolymer is manufactured by thermic controlled polymerisation of the monomers methyl methacrylate, butyl methacrylate and dimethylaminoethyl methacrylate (dissolved in propan-2-ol), by using a free radical donor initiator system. An alkyl mercaptane is used as chain modifying agent. The polymer solution is extruded and granulated under vacuum to remove residual volatile components. The granules resulting are commercialized as such or undergo a milling step (micronisation). |

▼B

| | |
|---|---|
| Chemical name | Poly(butyl methacrylate-*co*-(2-dimethylaminoethyl)methacrylate-*co*-methyl methacrylate) 1:2:1 |
| Chemical formula | Poly[($CH_2$:$C(CH_3)CO_2(CH_2)_2N(CH_3)_2$)-co-($CH_2$:$C(CH_3)CO_2CH_3$)-co-($CH_2$:$C(CH_3)CO_2(CH_2)_3CH_3$)] |
| Weight average molecular weight estimated by gel permeation chromatography | Approximately 47 000 g/mol |

▼M22

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|---|---|
| Particle size of the powder (when used forms a film) | < 50 μm at least 95 %<br>< 20 μm at least 50 %<br>< 3 μm not more than 10 % |

▼B

| | |
|---|---|
| Assay<br>*(according to Ph. Eur. 2.2.20 'potentiometric titration')* | 20,8-25,5 % dimethylaminoethyl (DMAE) groups on dry substance |
| **Description** | Granules are colourless to yellow tinged, the powder is white |
| **Identification** | |
| Infrared absorption spectroscopy | To be identified |
| Viscosity of a 12,5 % solution in 60:40 (w/w/) propan-2-ol to acetone | 3-6 mPa.s |
| Refractive index | $[n]_D^{20}$ 1,380-1,385 |
| Solubility | 1 g dissolves in 7 g Methanol, Ethanol, propan-2-ol, dichloromethane, aqueous Hydrochloric acid 1N.<br>Not soluble in petroleum ether. |

▼M6

| | |
|---|---|
| **Purity** | |
| Loss of drying | Not more than 2,0 % (105 °C, 3 h) |
| Alkali value | 162-198 mg KOH/g of dried substance |
| Sulphated ash | Not more than 0,1 % |
| Residual monomers | Butylmethacrylate < 1 000 mg/kg<br>Methyl methacrylate < 1 000 mg/kg<br>Dimethylaminoethyl methacrylate < 1 000 mg/kg |
| Solvent residues | propan-2-ol < 0,5 %<br>Butanol < 0,5 %<br>Methanol < 0,1 % |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 3 mg/kg |
| Mercury | Not more than 0,1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**E 1206 NEUTRAL METHACRYLATE COPOLYMER**

| | |
|---|---|
| **Synonyms** | Ethyl acrylate methyl methacrylate polymer; Ethyl acrylate, methyl methacrylate polymer; Ethyl acrylate, polymer with methyl methacrylate; Methyl methacrylate, ethyl acrylate polymer; Methyl methacrylate, polymer with ethyl acrylate |

▼M6

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|---|---|
| **Definition** | Neutral methacrylate copolymer is a fully polymerised copolymer of methyl methacrylate and ethyl acrylate. It is produced using a process of emulsion polymerisation. It is manufactured by redox initiated polymerisation of the monomers ethyl acrylate, methyl methacrylate by using a free radical donor redox initiator system stabilised with polyethylene glycol monostearyl ether and vinylic acid/sodium hydroxide. Residual monomers are removed by means of water vapour distillation. |
| CAS No | 9010-88-2 |
| Chemical name | Poly(ethylacrylate-co-methyl methacrylate) 2:1 |
| Chemical formula | Poly[($CH_2$:$CHCO_2CH_2CH_3$)-co-($CH_2$:$C(CH_3)CO_2CH_3$)] |
| Weight average molecular weight | Approximately 600 000 g/mol |
| Assay/Residue on evaporation | 28,5–31,5 %<br>1 g dispersion is dried in an oven for 3 hours at 110 °C. |
| **Description** | Milky-white dispersion (the commercial form is a 30 % dispersion of the dry substance in water) of low viscosity with a faint characteristic odour. |
| **Identification** | |
| Infrared absorption spectroscopy | Characteristic of the compound |
| Viscosity | Max. 50 mPa.s, 30 rpm/20 °C (Brookfield viscosimetry) |
| pH-value | 5,5–8,6 |
| Relative density (at 20 °C) | 1,037–1,047 |
| Solubility | The dispersion is miscible with water in any proportion. The polymer and the dispersion are freely soluble in acetone, ethanol and isopropyl alcohol. Not soluble when mixed with 1 N sodium hydroxide in a ratio of 1:2. |
| **Purity** | |
| Sulphated ash | Not more than 0,4 % in the dispersion |
| Residual monomers | Total of monomers (sum of methyl methacrylate and ethyl acrylate): not more than 100 mg/kg in the dispersion |
| Residual emulsifier | Polyethylene glycol monostearyl ether (macrogol stearyl ether 20) not more than 0,7 % in the dispersion |
| Solvent residues | Ethanol not more than 0,5 % in the dispersion<br>Methanol not more than 0,1 % in the dispersion |
| Arsenic | Not more than 0,3 mg/kg in the dispersion |
| Lead | Not more than 0,9 mg/kg in the dispersion |
| Mercury | Not more than 0,03 mg/kg in the dispersion |
| Cadmium | Not more than 0,3 mg/kg in the dispersion |

**E 1207 ANIONIC METHACRYLATE COPOLYMER**

| | |
|---|---|
| **Synonyms** | Methyl acrylate, methyl methacrylate, methacrylic acid polymer; Methacrylic acid, polymer with methyl acrylate and methyl methacrylate |

▼M6

| | |
|---|---|
| **Definition** | Anionic methacrylate copolymer is a fully polymerised copolymer of methacrylic acid, methyl methacrylate and methyl acrylate. It is manufactured in aqueous medium by emulsion polymerisation of methyl methacrylate, methyl acrylate and methacrylic acid using a free radical initiator stabilised with sodium lauryl sulphate and polyoxyethylene sorbitan monooleate (polysorbate 80). Residual monomers are removed by means of water vapour distillation. |
| CAS No | 26936-24-3 |
| Chemical name | Poly (methyl acrylate-co-methylmethacrylate-co-methacrylic acid) 7:3:1 |
| Chemical formula | Poly[($CH_2$:$CHCO_2CH_3$)-co-($CH_2$:$C(CH_3)CO_2CH_3$)-co-($CH_2$:$C(CH_3)COOH$)] |
| Weight average molecular weight | Approximately 280 000 g/mol |
| Assay/Residue on evaporation | 28,5–31,5 %<br>1 g of the dispersion is dried in an oven for 5 hours at 110 °C.<br>9,2–12,3 % methacrylic acid units on dry substance. |
| **Description** | Milky-white dispersion (the commercial form is a 30 % dispersion of the dry substance in water) of low viscosity with a faint characteristic odour. |
| **Identification** | |
| Infrared absorption spectroscopy | Characteristic of the compound |
| Viscosity | Max. 20 mPa.s, 30 rpm/20 °C (Brookfield viscosimetry) |
| pH-value | 2,0–3,5 |
| Relative density (at 20 °C) | 1,058–1,068 |
| Solubility | The dispersion is miscible with water in any proportion. The polymer and the dispersion are freely soluble in acetone, ethanol and isopropyl alcohol. Soluble when mixed with 1 N sodium hydroxide in a ratio of 1:2. Soluble above pH 7,0. |
| **Purity** | |
| Acid value | 60–80 mg KOH/g of dried substance |
| Sulphated ash | Not more than 0,2 % in the dispersion |
| Residual monomers | Total of monomers (sum of methacrylic acid, methyl methacrylate and methyl acrylate): not more than 100 mg/kg in the dispersion |
| Residual emulsifiers | Sodium lauryl sulphate not more than 0,3 % on the dry substance<br>Polysorbate 80 not more than 1,2 % on the dry substance |
| Solvent residues | Methanol not more than 0,1 % in the dispersion |
| Arsenic | Not more than 0,3 mg/kg in the dispersion |
| Lead | Not more than 0,9 mg/kg in the dispersion |
| Mercury | Not more than 0,03 mg/kg in the dispersion |
| Cadmium | Not more than 0,3 mg/kg in the dispersion |

▼M9

**E 1208 POLYVINYLPYRROLIDONE-VINYL ACETATE COPOLYMER**

| | |
|---|---|
| **Synonyms** | Copolyvidon; copovidone; 1-vinyl-2-pyrrolidone-vinyl acetate copolymer; 2-pyrrolidinone, 1-ethenyl-, polymer with ethenyl acetate |
| **Definition** | It is produced by free radical copolymerisation of N-vinyl-2-pyrrolidone and vinyl acetate in solution in propan-2-ol, in the presence of initiators. |
| Einecs | |
| Chemical name | Acetic acid, ethenyl ester, polymer with 1-ethenyl-2-pyrrolidinone |
| Chemical formula | $(C_6H_9NO)_n.(C_4H_6O_2)_m$ |
| Average Viscosity Molecular Weight | Between 26 000 and 46 000 g/mol. |
| Assay | Nitrogen content 7,0-8,0 % |
| **Description** | The physical state is described as a white to yellowish-white powder or flakes with an average particle size of 50-130 μm. |
| **Identification** | |
| Solubility | Freely soluble in water, ethanol, ethylene chloride and ether. |
| Infrared absorption spectroscopy | To be identified |
| European Colour Test (BY Colour) | Minimum BY5 |
| K-value ([1]) (1 % solids in aqueous solution) | 25,2-30,8 |
| pH value | 3,0-7,0 (10 % aqueous solution) |
| **Purity** | |
| Vinylacetate component in copolymer | Not more than 42,0 % |
| Free vinyl acetate | Not more than 5 mg/kg |
| Total ash | Not more than 0,1 % |
| Aldehyde | Not more than 2 000 mg/kg (as acetaldehyde) |
| Free-N-vinylpyrrolidone | Not more than 5 mg/kg |
| Hydrazine | Not more than 0,8 mg/kg |
| Peroxide content | Not more than 400 mg/kg |
| Propan-2-ol | Not more than 150 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

([1]) K-value: dimensionless index, calculated from kinematic viscosity measurements of dilute solutions, used to indicate the likely degree of polymerisation or molecular size of a polymer.

▼M13

**E 1209 POLYVINYL ALCOHOL-POLYETHYLENE GLYCOL-*GRAFT*-COPOLYMER**

| | |
|---|---|
| **Synonyms** | Macrogol poly(vinyl alcohol) grafted co-polymer; poly(ethan-1,2-diol-graft-ethanol); ethenol, polymer with oxirane, graft; oxirane, polymer with ethanol, graft; ethylene oxide-vinyl alcohol graft co-polymer |
| **Definition** | Polyvinyl alcohol-polyethylene glycol-graft-co-polymer is a synthetic co-polymer that consists of approximately 75 % PVA units and 25 % PEG units. |
| CAS number | 96734-39-3 |
| Chemical name | Polyvinyl alcohol-polyethylene glycol-*graft*-co-polymer |
| Chemical formula | |
| Weight Average Molecular Weight | 40 000 to 50 000 g/mol |
| **Description** | White to faintly yellow powder |
| **Identification** | |
| Solubility | Freely soluble in water and dilute acids and dilute solutions of alkali hydroxides; practically insoluble in ethanol, acetic acid, acetone, and chloroform |
| IR Spectrum | Must comply |
| pH value | 5,0-8,0 |
| **Purity** | |
| Ester Value | 10 to 75 mg/g KOH |
| Dynamic viscosity | 50 to 250 mPa·s |
| Loss on drying | Not more than 5 % |
| Sulphated Ash | Not more than 2 % |
| Vinyl Acetate | Not more than 20 mg/kg |
| Acetic acid/Total Acetate | Not more than 1,5 % |

▼M26

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|---|---|
| Ethylene glycols (mono- and di-) | Not more than 400 mg/kg (singly or in combination) |

▼M13

| | |
|---|---|
| 1,4-Dioxane | Not more than 10 mg/kg |

▼M37

———————

▼M13

| | |
|---|---|
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

▼M39

**E 1210 CARBOMER**

| | |
|---|---|
| **Synonyms** | carbomer, carboxypolymethylene; carbomer homopolymer |
| **Definition** | High-molecular mass polymers obtained by polymerisation of acrylic acid and crosslinking with allyl pentaerythritol. The polymers are synthesised in ethyl acetate using a peroxide to initiate free-radical polymerisation. |
| CAS No | 9007-20-9 (primary CAS), 9003-01-4 (secondary CAS) |

▼M39

| | | | |
|---|---|---|---|
| Chemical name | Carbomer homopolymer, allyl pentaerythritol cross-linked | | |
| Chemical formula | $-(CH_2-CH)_{\mathbf{m}}-(\mathbf{XM})_{\mathbf{p}}$<br>COOH<br>**m:** number of monomer units; **XM:** crosslinker, **p:** number of crosslinker units, **with m>>p** | | |
| Weight average molecular weight | | | |
| Assay | Carboxylic acid content not less than 56 % and not more than 68 % (on dried substance) | | |
| **Description** | White or almost white, fluffy, hygroscopic powder or granules | | |
| **Identification** | | | |
| Attenuated total reflective infra-red spectroscopy | Characteristic of the compound | | |
| Proton nuclear magnetic resonance spectroscopy | | | |
| Viscosity (Brookfield viscosimetry, 20 rpm) 25 °C | Type B<br>29 400-39 400 mPa.s | Type A<br>4 000-11 000 mPa.s | Type A |
| Physical form | powder | powder | granules |
| Pass through 40 mesh, % 425 µm | - | - | 95 min |
| Pass through 100 mesh, % 150 µm | - | - | 10 max |
| Solubility | Insoluble in water. Water-swellable and forms hydrogels in aqueous dispersions. | | |
| **Purity** | | | |
| Residual monomers | Acrylic acid not more than 100 mg/kg | | |
| Residual crosslinker | tri and tetra-allyl pentaerythritol not more than 1 000 mg/kg | | |
| Residual solvant | Ethyl acetate not more than 0,5 % w/w | | |
| 2-ethylhexanol | not more than 100 mg/kg | | |
| 2-ethylhexylacetate | not more than 100 mg/kg | | |
| Lower molecular weight fraction < 1 000 Da | Not more than 0,75 % w/w | | |
| Loss on drying | Not more than 2 % | | |
| Sulphated ashes | Not more than 2,5 % | | |

▼B

**E 1404 OXIDISED STARCH**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Oxidised starch is starch treated with sodium hypochlorite |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |

▼B

| | |
|---|---|
| **Description** | White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles |
| **Identification** | |
| Microscopic observation | Passes test (if not pregelatinised) |
| Iodine staining | Passes test (dark blue to light red colour) |
| **Purity** | |
| Loss on drying | Not more than 15,0 % for cereal starch<br>Not more than 21,0 % for potato starch<br>Not more than 18,0 % for other starches |
| Carboxyl groups | Not more than 1,1 % (on an anhydrous basis) |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)<br>Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis) |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg (on an anhydrous basis) |
| Mercury | Not more than 0,1 mg/kg |

**E 1410 MONOSTARCH PHOSPHATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Monostarch phosphate is starch esterified with ortho-phosphoric acid, or sodium or potassium ortho-phosphate or sodium tripoly-phosphate |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles |
| **Identification** | |
| Microscopic observation | Passes test (if not pregelatinised) |
| Iodine staining | Passes test (dark blue to light red colour) |
| **Purity** | |
| Loss on drying | Not more than 15,0 % for cereal starch<br>Not more than 21,0 % for potato starch<br>Not more than 18,0 % for other starches |

▼B

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

**E 1412 DISTARCH PHOSPHATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles |
| **Identification** | |
| Microscopic observation | Passes test (if not pregelatinised) |
| Iodine staining | Passes test (dark blue to light red colour) |
| **Purity** | |
| Loss on drying | Not more than 15,0 % for cereal starch<br>Not more than 21,0 % for potato starch<br>Not more than 18,0 % for other starches |
| Residual phosphate | Not more than 0,5 % (as P) for wheat or potato starch (on an anhydrous basis)<br>Not more than 0,4 % (as P) for other starches (on an anhydrous basis) |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)<br>Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis) |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg (on an anhydrous basis) |
| Mercury | Not more than 0,1 mg/kg |

▼B

**E 1413 PHOSPHATED DISTARCH PHOSPHATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Phosphated distarch phosphate is starch having undergone a combination of treatments as described for monostarch phosphate and for distarch phosphate |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles |
| **Identification** | |
| Microscopic observation | Passes test (if not pregelatinised) |
| Iodine staining | Passes test (dark blue to light red colour) |
| **Purity** | |
| Loss on drying | Not more than 15,0 % for cereal starch<br>Not more than 21,0 % for potato starch<br>Not more than 18,0 % for other starches |
| Residual phosphate | Not more than 0,5 % (as P) for wheat or potato starch (on an anhydrous basis)<br>Not more than 0,4 % (as P) for other starches (on an anhydrous basis) |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)<br>Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis) |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg (on an anhydrous basis) |
| Mercury | Not more than 0,1 mg/kg |

**E 1414 ACETYLATED DISTARCH PHOSPHATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Acetylated distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride and esterified by acetic anhydride or vinyl acetate |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles |
| **Identification** | |
| Microscopic observation | Passes test (if not pregelatinised) |
| Iodine staining | Passes test (dark blue to light red colour) |

▼B

| | |
|---|---|
| **Purity** | |
| Loss on drying | Not more than 15,0 % for cereal starch<br>Not more than 21,0 % for potato starch<br>Not more than 18,0 % for other starches |
| Acetyl groups | Not more than 2,5 % (on an anhydrous basis) |
| Residual phosphate | Not more than 0,14 % (as P) for wheat or potato starch (on an anhydrous basis)<br>Not more than 0,04 % (as P) for other starches (on an anhydrous basis) |
| Vinyl acetate | Not more than 0,1 mg/kg (on an anhydrous basis) |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)<br>Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis) |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg (on an anhydrous basis) |
| 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 |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles |
| **Identification** | |
| Microscopic observation | Passes test (if not pregelatinised) |
| Iodine staining | Passes test (dark blue to light red colour) |
| **Purity** | |
| Loss on drying | Not more than 15,0 % for cereal starch<br>Not more than 21,0 % for potato starch<br>Not more than 18,0 % for other starches |
| Acetyl groups | Not more than 2,5 % (on an anhydrous basis) |
| Vinyl acetate | Not more than 0,1 mg/kg (on an anhydrous basis) |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)<br>Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis) |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg (on an anhydrous basis) |
| Mercury | Not more than 0,1 mg/kg |

▼B

**E 1422 ACETYLATED DISTARCH ADIPATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Acetylated distarch adipate is starch cross-linked with adipic anhydride and esterified with acetic anhydride |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles |
| **Identification** | |
| Microscopic observation | Passes test (if not pregelatinised) |
| Iodine staining | Passes test (dark blue to light red colour) |
| **Purity** | |
| Loss on drying | Not more than 15,0 % for cereal starch<br>Not more than 21,0 % for potato starch<br>Not more than 18,0 % for other starches |
| Acetyl groups | Not more than 2,5 % (on an anhydrous basis) |
| Adipate groups | Not more than 0,135 % (on an anhydrous basis) |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)<br>Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis) |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg (on an anhydrous basis) |
| Mercury | Not more than 0,1 mg/kg |

**E 1440 HYDROXYPROPYL STARCH**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Hydroxypropyl starch is starch etherified with propylene oxide |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles |
| **Identification** | |
| Microscopic observation | Passes test (if not pregelatinised) |
| Iodine staining | Passes test (dark blue to light red colour) |

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

**E 1442 HYDROXYPROPYL DISTARCH PHOSPHATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Hydroxypropyl distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride and etherified with propylene oxide |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles |
| **Identification** | |
| Microscopic observation | Passes test (if not pregelatinised) |
| Iodine staining | Passes test (dark blue to light red colour) |
| **Purity** | |
| Loss on drying | Not more than 15,0 % for cereal starch<br>Not more than 21,0 % for potato starch<br>Not more than 18,0 % for other starches |
| Hydroxypropyl groups | Not more than 7,0 % (on an anhydrous basis) |
| Residual phosphate | Not more than 0,14 % (as P) for wheat or potato starch (on an anhydrous basis)<br>Not more than 0,04 % (as P) for other starches (on an anhydrous basis) |
| Propylene chlorohydrin | Not more than 1 mg/kg (on an anhydrous basis) |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)<br>Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis) |

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|---|---|
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg (on an anhydrous basis) |
| 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 |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles |
| **Identification** | |
| Microscopic observation | Passes test (if not pregelatinised) |
| Iodine staining | Passes test (dark blue to light red colour) |
| **Purity** | |
| Loss on drying | Not more than 15,0 % for cereal starch<br>Not more than 21,0 % for potato starch<br>Not more than 18,0 % for other starches |
| Octenylsuccinyl groups | Not more than 3 % (on an anhydrous basis) |
| Octenylsuccinic acid residue | Not more than 0,3 % (on an anhydrous basis) |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)<br>Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis) |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg (on an anhydrous basis) |
| Mercury | Not more than 0,1 mg/kg |

**E 1451 ACETYLATED OXIDISED STARCH**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Acetylated oxidised starch is starch treated with sodium hypochlorite followed by esterification with acetic anhydride |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles |

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| | |
|---|---|
| **Identification** | |
| Microscopic observation | Passes test (if not pregelatinised) |
| Iodine staining | Passes test (dark blue to light red colour) |
| **Purity** | |
| Loss on drying | Not more than 15,0 % for cereal starch<br>Not more than 21,0 % for potato starch<br>Not more than 18,0 % for other starches |
| Carboxyl groups | Not more than 1,3 % (on an anhydrous basis) |
| Acetyl groups | Not more than 2,5 % (on an anhydrous basis) |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)<br>Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis) |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg (on an anhydrous basis) |
| Mercury | Not more than 0,1 mg/kg |

**E 1452 STARCH ALUMINIUM OCTENYL SUCCINATE**

| | |
|---|---|
| **Synonyms** | |
| **Definition** | Starch aluminium octenyl succinate is starch esterified with octenylsuccinic anhydride and treated with aluminium sulphate |
| Einecs | |
| Chemical name | |
| Chemical formula | |
| Molecular weight | |
| Assay | |
| **Description** | White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles |
| **Identification** | |
| Microscopic observation | Passes test (if not pregelatinised) |
| Iodine staining | Passes test (dark blue to light red colour) |
| **Purity** | |
| Loss on drying | Not more than 21,0 % |
| Octenylsuccinyl groups | Not more than 3 % (on an anhydrous basis) |
| Octenylsuccinic acid residue | Not more than 0,3 % (on an anhydrous basis) |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)<br>Not more than 10 mg/kg for the other modified starches, unless otherwise specified (on an anhydrous basis) |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg (on an anhydrous basis) |
| Mercury | Not more than 0,1 mg/kg |
| Aluminium | Not more than 0,3 % (on an anhydrous basis) |

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**E 1505 TRIETHYL CITRATE**

| | |
|---|---|
| **Synonyms** | Ethyl citrate |
| **Definition** | |
| Einecs | 201-070-7 |
| Chemical name | Triethyl-2-hydroxypropan-1,2,3-tricarboxylate |
| Chemical formula | $C_{12}H_{20}O_7$ |
| Molecular weight | 276,29 |
| Assay | Content not less than 99,0 % |
| **Description** | Odourless, practically colourless, oily liquid |
| **Identification** | |
| Specific gravity (25 °C/25 °C) | 1,135-1,139 |
| Refractive index | $[n]_D^{20}$: 1,439-1,441 |
| **Purity** | |
| Water content | 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 2 mg/kg |

**E 1517 GLYCERYL DIACETATE**

| | |
|---|---|
| **Synonyms** | Diacetin |
| **Definition** | Glyceryl diacetate consist predominantly of a mixture of the 1, 2- and 1,3-diacetates of glycerol, with minor amounts of the mono- and tri-esters |
| Einecs | |
| Chemical name | Glyceryl diacetate; 1, 2, 3-propanetriol diacetate |
| Chemical formula | $C_7H_{12}O_5$ |
| Molecular weight | 176,17 |
| Assay | Not less than 94,0 % |
| **Description** | Clear, colourless, hygroscopic, somewhat oily liquid with a slight, fatty odour |
| **Identification** | |
| Solubility | Soluble in water. Miscible with ethanol |
| Test for glycerol | Passes test |
| Test for acetate | Passes test |
| Specific gravity (20 °C/20 °C) | 1,175-1,195 |
| Boiling range | Between 259 and 261 °C |
| **Purity** | |
| Total ash | Not more than 0,02 % |
| Acidity | Not more than 0,4 % (as acetic acid) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |

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**E 1518 GLYCERYL TRIACETATE**

| | |
|---|---|
| **Synonyms** | Triacetin |
| **Definition** | |
| Einecs | 203-051-9 |
| Chemical name | Glyceryl triacetate |
| Chemical formula | $C_9H_{14}O_6$ |
| Molecular weight | 218,21 |
| Assay | Content not less than 98,0 % |
| **Description** | Colourless, somewhat oily liquid having a slightly fatty odour |
| **Identification** | |
| Test for acetate | Passes test |
| Test for glycerol | Passes test |
| Refractive index | $[n]_D^{25}$ between 1,429 and 1,431 |
| Specific gravity (25 °C/25 °C) | Between 1,154 and 1,158 |
| Boiling range | Between 258 and 270 °C |
| **Purity** | |
| Water content | 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 2 mg/kg |

**E 1519 BENZYL ALCOHOL**

| | |
|---|---|
| **Synonyms** | Phenylcarbinol; Phenylmethyl alcohol; Benzenemethanol; Alpha-hydroxytoluene |
| **Definition** | |
| Einecs | |
| Chemical name | Benzyl alcohol; Phenylmethanol |
| Chemical formula | $C_7H_8O$ |
| Molecular weight | 108,14 |
| Assay | Not less than 98,0 % |
| **Description** | Colourless, clear liquid with a faint, aromatic odour |
| **Identification** | |
| Solubility | Soluble in water, ethanol and ether |
| Refractive index | $[n]_D^{20}$ 1,538-1,541 |
| Specific gravity (25 °C/25 °C) | 1,042-1,047 |
| Test for peroxides | Passes test |
| Distillation range | Not less than 95 % v/v distils between 202 and 208 °C |
| **Purity** | |
| Acid value | Not more than 0,5 |
| Aldehydes | Not more than 0,2 % v/v (as benzaldehyde) |
| Lead | Not more than 2 mg/kg |

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

| | |
|---|---|
| **Synonyms** | Propylene glycol |
| **Definition** | |
| Einecs | 200-338-0 |
| Chemical name | 1,2-dihydroxypropane |
| Chemical formula | $C_3H_8O_2$ |
| Molecular weight | 76,10 |
| Assay | Content not less than 99,5 % on the anhydrous basis |
| **Description** | Clear, colourless, hygroscopic, viscous liquid |
| **Identification** | |
| Solubility | Soluble in water, ethanol and acetone |
| Specific gravity (20 °C/20 °C) | 1,035-1,040 |
| Refractive index | $[n]_D^{20}$: 1,431-1,433 |
| **Purity** | |
| Distillation test | 99,5 % of the product distils between 185-189 °C. The remaining 0,5 % consists mainly of dimers and traces of trimers from propylene glycol. |
| Sulphated ash | Not more than 0,07 % |
| Water content | Not more than 1,0 % (Karl Fischer method) |
| Lead | Not more than 2 mg/kg |

**E 1521 POLYETHYLENE GLYCOL**

| | |
|---|---|
| **Synonyms** | PEG; Macrogol; Polyethylene oxide |
| **Definition** | Addition polymers of ethylene oxide and water usually designated by a number roughly corresponding to the molecular weight. |
| Chemical name | alpha-Hydro-omega-hydroxypoly (oxy-1,2-ethanediol) |
| Chemical formula | $(C_2H_4O)_n H_2O$ (n = number of ethylene oxide units corresponding to a molecular weight of 6 000, about 140) |
| Average molecular weight | 380 to 9 000 Da |
| Assay | PEG 400: Not less than 95 % and not more than 105 %<br>PEG 3000: Not less than 90 % and not more than 110 %<br>PEG 3350: Not less than 90 % and not more than 110 %<br>PEG 4000: Not less than 90 % and not more than 110 %<br>PEG 6000:Not less than 90 % and not more than 110 %<br>PEG 8000: Not less than 87,5 % and not more than 112,5 % |
| **Description** | PEG 400 is a clear, viscous, colourless or almost colourless hygroscopic liquid<br>PEG 3000, PEG 3350, PEG 4000, PEG 6000 and PEG 8000 are white or almost white solids with a waxy or paraffin-like appearance |

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|---|---|
| **Identification** | |
| Melting range | PEG 400: 4-8 °C |
| | PEG 3000: 50-56 °C |
| | PEG 3350: 53-57 °C |
| | PEG 4000: 53-59 °C |
| | PEG 6000:55-61 °C |
| | PEG 8000: 55-62 °C |
| Viscosity | PEG 400: 105 to 130 mPa.s at 20 °C |
| | PEG 3000: 75 to 100 mPa.s at 20 °C |
| | PEG 3350: 83 to 120 mPa.s at 20 °C |
| | PEG 4000: 110 to 170 mPa.s at 20 °C |
| | PEG 6000: 200 to 270 mPa.s at 20 °C |
| | PEG 8000: 260 to 510 mPa.s at 20 °C |
| | For polyethylene glycols having a average molecular weight greater than 400, the viscosity is determined on a 50 per cent m/m solution of the candidate substance in water |
| Solubility | PEG 400 is miscible with water, very soluble in acetone, in alcohol and in methylene chloride, practically insoluble in fatty oils and in mineral oils |
| | PEG 3000 and PEG 3350: very soluble in water and in methylene chloride, very slightly soluble in alcohol, practically insoluble in fatty oils and in mineral oils |
| | PEG 4000, PEG 6000 and PEG 8000: very soluble in water and in methylene chloride, practically insoluble in alcohol and in fatty oils and in mineral oils. |
| **Purity** | |
| Hydroxyl value | PEG 400: 264-300 |
| | PEG 3000: 34-42 |
| | PEG 3350: 30-38 |
| | PEG 4000: 25-32 |
| | PEG 6000: 16-22 |
| | PEG 8000: 12-16 |
| Sulphated ash | Not more than 0,2 % |
| 1,4-Dioxane | Not more than 10 mg/kg |

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|---|---|
| Ethylene glycol and diethylene glycol | Total not more than 0,25 % °w/w individually or in combination |
| Lead | Not more than 1 mg/kg |