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**COMMISSION DIRECTIVE 96/77/EC
of 2 December 1996**

laying down specific purity criteria on food additives other than colours and sweeteners

(Text with EEA relevance)

(OJ L 339, 30.12.1996, p. 1)

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COMMISSION DIRECTIVE 96/77/EC

of 2 December 1996

laying down specific purity criteria on food additives other than colours and sweeteners

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption⁽¹⁾, as amended by European Parliament and Council Directive 94/34/EC⁽²⁾, and in particular Article 3 (3) (a) thereof,

After consulting the Scientific Committee for Food,

Whereas it is necessary to establish purity criteria for all additives other than colours and sweeteners mentioned in European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners⁽³⁾;

Whereas it is necessary to replace the purity criteria set out in Council Directive 65/66/EEC of 26 January 1965 laying down specific criteria of purity for preservatives authorized for use in foodstuffs intended for human consumption⁽⁴⁾, as last amended by Directive 86/604/EEC⁽⁵⁾;

Whereas it is necessary to replace the purity criteria set out in Council Directive 78/664/EEC of 25 July 1978 laying down specific criteria of purity for antioxidants which may be used in foodstuffs intended for human consumption⁽⁶⁾, as amended by Directive 82/712/EEC⁽⁷⁾;

Whereas Directives 65/66/EEC and 78/664/EEC should be repealed accordingly;

Whereas it is necessary to take into account the specifications and analytical techniques for additives as set out in the *Codex Alimentarius* as drafted by the Joint FAO/WHO Expert Committee on Food Additives (Jecfa);

Whereas food additives, if prepared by production methods or starting materials significantly different from those included in the evaluation of the Scientific Committee for Food, or if different from those mentioned in this Directive, should be submitted for evaluation by the Scientific Committee for Food for the purposes of a full evaluation with emphasis on the purity criteria;

Whereas, the measures provided for in this Directive are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The purity criteria referred to in Article 3 (3) (a) of Directive 89/107/EEC for food additives other than colours and sweeteners, as mentioned in Directive 95/2/EC, are set out in the Annex hereto.



Article 2

The purity criteria referred to in Article 1 replace the purity criteria set out in Directives 65/66/EEC, 78/663/EEC and 78/664/EEC.

⁽¹⁾ OJ No L 40, 11. 2. 1989, p. 27.

⁽²⁾ OJ No L 237, 10. 9. 1994, p. 1.

⁽³⁾ OJ No L 61, 18. 3. 1995, p. 1.

⁽⁴⁾ OJ No 22, 9. 2. 1965, p. 373.

⁽⁵⁾ OJ No L 352, 13. 12. 1986, p. 45.

⁽⁶⁾ OJ No L 223, 14. 8. 1978, p. 30.

⁽⁷⁾ OJ No L 297, 23. 10. 1982, p. 31.

▼B*Article 3*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1997. They shall immediately inform the Commission thereof.

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

2. Products put on the market or labelled before 1 July 1997 which do not comply with this Directive may be marketed until stocks are exhausted.

Article 4

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

Article 5

This Directive is addressed to the Member States.



ANNEX

E 200 SORBIC ACID**Definition**

| | |
|-------------------------|--|
| <i>Chemical name</i> | Sorbic acid Trans, trans-2,4-hexadienoic acid |
| Einecs | 203-768-7 |
| <i>Chemical formula</i> | C ₆ H ₈ O ₂ |
| <i>Molecular weight</i> | 112,12 |
| <i>Assay</i> | Content not less than 99 % on the anhydrous basis |
| <i>Description</i> | 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

| | |
|-----------------------------------|--|
| A. Melting range | Between 133 °C and 135 °C, after vacuum drying for four hours in a sulphuric acid desiccator |
| B. Spectrometry | An isopropanol solution (1 in 4 000 000) shows absorbance maximum at 254 ± 2 nm |
| C. Positive test for double bonds | |
| D. Sublimation point | 80 °C |

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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 202 POTASSIUM SORBATE**Definition**

| | |
|-------------------------|--|
| <i>Chemical name</i> | Potassium sorbate Potassium (E,E)-2,4-hexadienoate Potassium salt of trans, trans 2,4-hexadienoic acid |
| Einecs | 246-376-1 |
| <i>Chemical formula</i> | C ₆ H ₇ O ₂ K |
| <i>Molecular weight</i> | 150,22 |
| <i>Assay</i> | Content not less than 99 % on the dried basis |
| <i>Description</i> | White crystalline powder showing no change in colour after heating for 90 minutes at 105 °C |

Identification

| | |
|--|---|
| A. Melting range of sorbic acid isolated by acidification and not recrystallized | 133 °C to 135 °C after vacuum drying in a sulphuric acid desiccator |
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|--|---|
| <p>B. Positive tests for potassium and for double bonds</p> <p>Purity</p> <p>Loss on drying</p> <p>Acidity or alkalinity</p> <p>Aldehydes</p> <p>Arsenic</p> <p>Lead</p> <p>Mercury</p> <p>Heavy metals (as Pb)</p> | <p>Not more than 1,0 % (105 °C, 3h)</p> <p>Not more than about 1,0 % (as sorbic acid or K₂CO₃)</p> <p>Not more than 0,1 %, calculated as formaldehyde</p> <p>Not more than 3 mg/kg</p> <p>Not more than 5 mg/kg</p> <p>Not more than 1 mg/kg</p> <p>Not more than 10 mg/kg</p> |
| E 203 CALCIUM SORBATE | |
| <p>Definition</p> <p><i>Chemical name</i></p> <p>Einecs</p> <p><i>Chemical formula</i></p> <p><i>Molecular weight</i></p> <p><i>Assay</i></p> <p><i>Description</i></p> <p>Identification</p> <p>A. Melting range of sorbic acid isolated by acidification and not recrystallized 133 °C to 135 °C after vacuum drying in a sulphuric acid desiccator</p> <p>B. Positive tests for calcium and for double bonds</p> <p>Purity</p> <p>Loss on drying</p> <p>Aldehydes</p> <p>Fluoride</p> <p>Arsenic</p> <p>Lead</p> <p>Mercury</p> <p>Heavy metals (as Pb)</p> | <p>Calcium sorbate Calcium salts of trans, trans-2,4-hexadienoic acid</p> <p>231-321-6</p> <p>C₁₂H₁₄O₄Ca</p> <p>262,32</p> <p>Content not less than 98 % on the dried basis</p> <p>Fine white crystalline powder not showing any change in colour after heating at 105 °C for 90 minutes</p> |
| E 210 BENZOIC ACID | |
| <p>Definition</p> <p><i>Chemical name</i></p> <p>Einecs</p> <p><i>Chemical formula</i></p> | <p>Benzoic acid Benzenecarboxylic acid Phenylcarboxylic acid</p> <p>200-618-2</p> <p>C₇H₆O₂</p> |

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| | |
|--|--|
| <i>Molecular weight</i> | 122,12 |
| <i>Assay</i> | Content not less than 99,5 % on the anhydrous basis |
| <i>Description</i> | White crystalline powder |
| Identification | |
| A. Melting range | 121,5 °C to 123,5 °C |
| B. Positive sublimation test and test for benzoate | |
| Purity | |
| Loss on drying | Not more than 0,5 % after drying for three hours over sulphuric acid |
| pH | About 4 (solution in water) |
| 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 oxidizable 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 carbonizable 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 neutralized 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 211 SODIUM BENZOATE

| | |
|---|--|
| Definition | |
| <i>Chemical name</i> | Sodium benzoate Sodium salt of benzenecarboxylic acid Sodium salt of phenylcarboxylic acid |
| Einecs | 208-534-8 |
| <i>Chemical formula</i> | C ₇ H ₅ O ₂ Na |
| <i>Molecular weight</i> | 144,11 |
| <i>Assay</i> | Not less than 99 % of C ₇ H ₅ O ₂ Na, after drying at 105 °C for four hours |
| <i>Description</i> | A white, almost odourless, crystalline powder or granules |
| Identification | |
| A. Solubility | Freely soluble in water, sparingly soluble in ethanol |
| B. Melting range for benzoic acid | Melting range of benzoic acid isolated by acidification and not recrystallized 121,5 °C to 123,5 °C, after drying in a sulphuric acid desiccator |
| C. Positive tests for benzoate and for sodium | |
| Purity | |
| Loss on drying | Not more than 1,5 % after drying at 105 °C for four hours |

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| Readily oxidizable 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 (neutralized) 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 |
| Degree of acidity or alkalinity | Neutralization 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 212 POTASSIUM BENZOATE

Definition*Chemical name*

Potassium benzoate
 Potassium salt of benzenecarboxylic acid
 Potassium salt of phenylcarboxylic acid

Einecs

209-481-3

*Chemical formula*C₇H₅KO₂·3H₂O*Molecular weight*

214,27

*Assay*Content not less than 99 % C₇H₅O₂K after drying at 105 °C to constant weight*Description*

White crystalline powder

Identification

A. Melting range of benzoic acid isolated by acidification and not recrystallized 121,5 °C to 123,5 °C, after vacuum drying in a sulphuric acid desiccator

B. Positive tests for benzoate and for potassium

Purity

Loss on drying

Not more than 26,5 %, determined by drying at 105 °C

Chlorinated organic compounds

Not more than 0,06 % expressed as chloride, corresponding to 0,25 % expressed as monochlorobenzoic acid

Readily oxidizable substances

Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N KMnO₄ 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 KMnO₄ to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required

Readily carbonizable 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 (neutralized) solution of potassium benzoate, the first precipitate must not have a different melting range from that of benzoic acid

Degree of acidity or alkalinity

Neutralization 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

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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 |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 213 CALCIUM BENZOATE

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|--|--|
| Synonyms | Monocalcium benzoate |
| Definition | |
| <i>Chemical name</i> | Calcium benzoate Calcium dibenzoate |
| Einecs | 218-235-4 |
| <i>Chemical formula</i> | Anhydrous: $C_{14}H_{10}O_4Ca$ Monohydrate: $C_{14}H_{10}O_4Ca \cdot H_2O$ Trihydrate: $C_{14}H_{10}O_4Ca \cdot 3H_2O$ |
| <i>Molecular weight</i> | Anhydrous: 282,31 Monohydrate: 300,32 Trihydrate: 336,36 |
| <i>Assay</i> | Content not less than 99 % after drying at 105 °C |
| <i>Description</i> | White or colourless crystals, or white powder |
| Identification | |
| A. Melting range of benzoic acid isolated by acidification and not recrystallized 121,5 °C to 123,5 °C, after vacuum drying in a sulphuric acid desiccator | |
| B. Positive tests for benzoate and for calcium | |
| Purity | |
| Loss on drying | Not more than 17,5 % determined by drying at 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 acids |
| Readily oxidizable 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 carbonizable 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 (neutralized) solution of calcium benzoate, the first precipitate must not be a different melting range from that of benzoic acid |
| Degree of acidity or alkalinity | Neutralization 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 5 mg/kg |

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|----------------------|------------------------|
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 214 ETHYL *p*-HYDROXYBENZOATE

| | |
|--|---|
| Synonyms | Ethylparaben Ethyl <i>p</i> -oxybenzoate |
| Definition | |
| <i>Chemical name</i> | Ethyl- <i>p</i> -hydroxybenzoate Ethyl ester of <i>p</i> -hydroxybenzoic acid |
| Einecs | 204-399-4 |
| <i>Chemical formula</i> | C ₉ H ₁₀ O ₃ |
| <i>Molecular weight</i> | 166,8 |
| <i>Assay</i> | Content not less than 99,5 % after drying for two hours at 80 °C |
| <i>Description</i> | Almost odourless, small, colourless crystals or a white, crystalline powder |
| Identification | |
| A. Melting range | 115 °C to 118 °C |
| B. Positive test for <i>p</i> -hydroxybenzoate | Melting range of <i>p</i> -hydroxybenzoic acid isolated by acidification and not recrystallized: 213 °C to 217 °C, after vacuum drying in a sulphuric acid desiccator |
| C. Positive test for alcohol | |
| Purity | |
| Loss on drying | Not more than 0,5 % after drying for two hours at 80 °C |
| Sulphated ash | Not more than 0,05 % |
| <i>p</i> -Hydroxybenzoic acid and salicylic acid | Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 215 SODIUM ETHYL *p*-HYDROXYBENZOATE

| | |
|--|---|
| Definition | |
| <i>Chemical name</i> | Sodium ethyl <i>p</i> -hydroxybenzoate Sodium compound of the ethyl ester of <i>p</i> -hydroxybenzoic acid |
| Einecs | 252-487-6 |
| <i>Chemical formula</i> | C ₉ H ₉ O ₃ Na |
| <i>Molecular weight</i> | 188,8 |
| <i>Assay</i> | Content of ethylester of <i>p</i> -hydroxybenzoic acid not less than 83 % on the anhydrous basis |
| <i>Description</i> | White, crystalline hygroscopic powder |
| Identification | |
| A. Melting range | 115 °C to 118 °C, after vacuum drying in a sulphuric acid desiccator |
| B. Positive test for <i>p</i> -hydroxybenzoate | Melting range of <i>p</i> -hydroxybenzoic acid derived from the sample is 213 °C to 217 °C |

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|--|---|
| C. Positive test for sodium | |
| D. pH of a 0,1 % aqueous solution must be between 9,9 and 10,3 | |
| Purity | |
| Loss on drying | Not more than 5 %, determined by vacuum drying in a sulphuric acid desiccator |
| Sulphated ash | 37 to 39 % |
| <i>p</i> -Hydroxybenzoic acid and salicylic acid | Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 216 PROPYL *p*-HYDROXYBENZOATE

| | |
|--|--|
| Synonyms | Propylparaben Propyl <i>p</i> -oxybenzoate |
| Definition | |
| <i>Chemical name</i> | Propyl <i>p</i> -hydroxybenzoate n-Propyl <i>p</i> -hydroxybenzoic acid |
| Einecs | 202-307-7 |
| <i>Chemical formula</i> | C ₁₀ H ₁₂ O ₃ |
| <i>Molecular weight</i> | 180,21 |
| <i>Assay</i> | Content not less than 99,5 % after drying for two hours at 80 °C |
| <i>Description</i> | Almost odourless, small, colourless crystals or a white, crystalline powder |
| Identification | |
| A. Melting range | 95 °C to 97 °C after drying for two hours at 80 °C |
| B. Positive test for <i>p</i> -hydroxybenzoate | Melting range of <i>p</i> -hydroxybenzoic acid derived from the sample is 213 °C to 217 °C |
| Purity | |
| Loss on drying | Not more than 0,5 % after drying for two hours at 80 °C |
| Sulphated ash | Not more than 0,05 % |
| <i>p</i> -Hydroxybenzoic acid and salicylic acid | Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 217 SODIUM PROPYL *p*-HYDROXYBENZOATE

| | |
|-------------------------|--|
| Definition | |
| <i>Chemical name</i> | Sodium n-propyl <i>p</i> -hydroxybenzoate Sodium compound of the n-propylester of <i>p</i> -hydroxybenzoic acid |
| Einecs | 252-488-1 |
| <i>Chemical formula</i> | C ₁₀ H ₁₁ O ₃ Na |

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| | |
|--|--|
| <i>Molecular weight</i> | 202,21 |
| <i>Assay</i> | Content of the propyl ester of <i>p</i> -hydroxybenzoic acid not less than 85 % on the anhydrous basis |
| <i>Description</i> | White, or almost white, crystalline hygroscopic powder |
| Identification | |
| A. Melting range of ester isolated by acidification and not recrystallized: 94 °C to 97 °C, after vacuum drying in a sulphuric acid desiccator | |
| B. Positive test for sodium | |
| C. pH of a 0,1 % aqueous solution must be between 9,8 and 10,2 | |
| Purity | |
| Loss on drying | Not more than 5 %, determined by vacuum drying in a sulphuric acid desiccator |
| Sulphated ash | 34 to 36 % |
| <i>p</i> -Hydroxybenzoic acid and salicylic acid | Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 218 METHYL *p*-HYDROXYBENZOATE

| | |
|--|--|
| Synonyms | Methylparaben Methyl- <i>p</i> -oxybenzoate |
| Definition | |
| <i>Chemical name</i> | Methyl <i>p</i> -hydroxybenzoate Methyl ester of <i>p</i> -hydroxybenzoic acid |
| Einecs | 243-171-5 |
| <i>Chemical formula</i> | C ₈ H ₈ O ₃ |
| <i>Molecular weight</i> | 152,15 |
| <i>Assay</i> | Content not less than 99 % after drying for two hours at 80 °C |
| <i>Description</i> | Almost odourless, small colourless crystals or white crystalline powder |
| Identification | |
| A. Melting range | 125 °C to 128 °C |
| B. Positive test for <i>p</i> -hydroxybenzoate | Melting range of <i>p</i> -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 %, after drying for two hours at 80 °C |
| Sulphated ash | Not more than 0,05 % |
| <i>p</i> -Hydroxybenzoic acid and salicylic acid | Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

**E 219 SODIUM METHYL *p*-HYDROXYBENZOATE****Definition**

| | |
|-------------------------|--|
| <i>Chemical name</i> | Sodium methyl <i>p</i> -hydroxybenzoate Sodium compound of the methylester of <i>p</i> -hydroxybenzoic acid |
| <i>Chemical formula</i> | C ₈ H ₇ O ₃ Na |
| <i>Molecular weight</i> | 174,15 |
| <i>Assay</i> | Content not less than 99,5 % on the anhydrous basis |
| <i>Description</i> | White, hygroscopic powder |

Identification

- A. 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
- B. Positive test for sodium
- C. pH of a 0,1 % solution in carbon dioxide free water, not less than 9,7 and not more than 10,3

Purity

| | |
|--|---|
| Water content | Not more than 5 % (Karl Fischer method) |
| Sulphated ash | 40 % to 44,5 % on the anhydrous basis |
| <i>p</i> -Hydroxybenzoic acid and salicylic acid | Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 220 SULPHUR DIOXIDE**Definition**

| | |
|----------------------|--|
| <i>Chemical name</i> | Sulphur dioxide Sulphurous acid anhydride |
|----------------------|--|

Einecs 231-195-2

Chemical formula SO₂

Molecular weight 64,07

Assay Content not less than 99 %

Description Colourless, non-flammable gas with strong pungent suffocating odour

Identification

- A. Positive test for sulphurous substances

Purity

| | |
|----------------------|----------------------|
| Water content | Not more than 0,05 % |
| Non-volatile residue | Not more than 0,01 % |
| Sulphur trioxide | Not more than 0,1 % |

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| | |
|---|------------------------|
| 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 |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 221 SODIUM SULPHITE**Definition**

| | |
|-------------------------|---|
| <i>Chemical name</i> | Sodium sulphite (anhydrous or heptahydrate) |
| Einecs | 231-821-4 |
| <i>Chemical formula</i> | Anhydrous: Na_2SO_3 Heptahydrate: $\text{Na}_2\text{SO}_3 \cdot 7\text{H}_2\text{O}$ |
| <i>Molecular weight</i> | Anhydrous: 126,04 Heptahydrate: 252,16 |
| <i>Assay</i> | 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 |
| <i>Description</i> | White crystalline powder or colourless crystals |

Identification

- A. Positive tests for sulphite and for sodium
- B. pH of a 10 % solution (anhydrous) or a 20 % solution (heptahydrate) between 8,5 and 11,5

Purity

| | |
|----------------------|---|
| Thiosulphate | Not more than 0,1 % based on the SO_2 content |
| Iron | Not more than 50 mg/kg based on the SO_2 content |
| Selenium | Not more than 10 mg/kg based on the SO_2 content |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 222 SODIUM BISULPHITE**Definition**

| | |
|-------------------------|---|
| <i>Chemical name</i> | Sodium bisulphite Sodium hydrogen sulphite |
| Einecs | 231-921-4 |
| <i>Chemical formula</i> | NaHSO_3 in aqueous solution |
| <i>Molecular weight</i> | 104,06 |
| <i>Assay</i> | Content not less than 32 % w/w NaHSO_3 |
| <i>Description</i> | A clear, colourless to yellow solution |

▼B

Identification

- A. Positive tests for sulphite and for sodium
- B. pH of a 10 % aqueous solution between 2,5 and 5,5

Purity

| | |
|----------------------|--|
| Iron | Not more than 50 mg/kg of Na ₂ SO ₃ based on the SO ₂ content |
| Selenium | Not more than 10 mg/kg based on the SO ₂ content |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 223 SODIUM METABISULPHITE**Synonyms**

Pyrosulphite
Sodium pyrosulphite

Definition

Chemical name Sodium disulphite
Disodium pentaoxodisulphate

Einecs 231-673-0

Chemical formula Na₂S₂O₅

Molecular weight 190,11

Assay Content not less than 95 % Na₂S₂O₅ and not less than 64 % of SO₂

Description White crystals or crystalline powder

Identification

- A. Positive tests for sulphite and for sodium
- B. pH of a 10 % aqueous solution between 4,0 and 5,5

Purity

| | |
|----------------------|---|
| Thiosulphate | Not more than 0,1 % based on the SO ₂ content |
| Iron | Not more than 50 mg/kg based on the SO ₂ content |
| Selenium | Not more than 10 mg/kg based on the SO ₂ content |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 224 POTASSIUM METABISULPHITE**Synonyms**

Potassium pyrosulphite

Definition

Chemical name Potassium disulphite
Potassium pentaoxo disulphate

Einecs 240-795-3

Chemical formula K₂S₂O₅

▼B

| | |
|--|---|
| <i>Molecular weight</i> | 222,33 |
| <i>Assay</i> | Content not less than 90 % of $K_2S_2O_5$ and not less than 51,8 % of SO_2 , the remainder being composed almost entirely of potassium sulphate |
| <i>Description</i> | Colourless crystals or white crystalline powder |
| Identification | |
| A. Positive tests for sulphite and for potassium | |
| Purity | |
| Thiosulphate | Not more than 0,1 % based on the SO_2 content |
| Iron | Not more than 50 mg/kg based on the SO_2 content |
| Selenium | Not more than 10 mg/kg based on the SO_2 content |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 226 CALCIUM SULPHITE

| | |
|--|---|
| Definition | |
| <i>Chemical name</i> | Calcium sulphite |
| Einecs | 218-235-4 |
| <i>Chemical formula</i> | $CaSO_3 \cdot 2H_2O$ |
| <i>Molecular weight</i> | 156,17 |
| <i>Assay</i> | Content not less than 95 % of $CaSO_3 \cdot 2H_2O$ and not less than 39 % of SO_2 |
| <i>Description</i> | White crystals or white crystalline powder |
| Identification | |
| A. Positive tests for sulphite and for calcium | |
| Purity | |
| Iron | Not more than 50 mg/kg based on the SO_2 content |
| Selenium | Not more than 10 mg/kg based on the SO_2 content |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 227 CALCIUM BISULPHITE

| | |
|-------------------------|---|
| Definition | |
| <i>Chemical name</i> | Calcium bisulphite Calcium hydrogen sulphite |
| Einecs | 237-423-7 |
| <i>Chemical formula</i> | $Ca(HSO_3)_2$ |
| <i>Molecular weight</i> | 202,22 |

▼B

| | |
|--|---|
| <i>Assay</i> | 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] |
| <i>Description</i> | Clear greenish-yellow aqueous solution having a distinct odour of sulphur dioxide |
| Identification | |
| A. Positive tests for sulphite and for calcium | |
| Purity | |
| Iron | Not more than 50 mg/kg based on the SO ₂ content |
| Selenium | Not more than 10 mg/kg based on the SO ₂ content |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 228 POTASSIUM BISULPHITE

| | |
|--|--|
| Definition | |
| <i>Chemical name</i> | Potassium bisulphite Potassium hydrogen sulphite |
| Einecs | 231-870-1 |
| <i>Chemical formula</i> | KHSO ₃ in aqueous solution |
| <i>Molecular weight</i> | 120,17 |
| <i>Assay</i> | Content not less than 280 g KHSO ₃ per litre (or 150 g SO ₂ per litre) |
| <i>Description</i> | Clear colourless aqueous solution |
| Identification | |
| A. Positive tests for sulphite and for potassium | |
| Purity | |
| Iron | Not more than 50 mg/kg based on the SO ₂ content |
| Selenium | Not more than 10 mg/kg based on the SO ₂ content |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 230 BIPHENYL

| | |
|-------------------------|---------------------------------|
| Synonyms | |
| | Diphenyl |
| Definition | |
| <i>Chemical name</i> | 1,1'-biphenyl Phenylbenzene |
| Einecs | 202-163-5 |
| <i>Chemical formula</i> | C ₁₂ H ₁₀ |
| <i>Molecular weight</i> | 154,20 |
| <i>Assay</i> | Content not less than 99,8 % |

▼B

| | |
|---|---|
| <i>Description</i> | White or pale yellow to amber crystalline solid having a characteristic odour |
| Identification | |
| A. Melting range | 68,5 °C to 70,5 °C |
| B. Distillation range | It distils completely within a 2,5 °C range between 252,5 °C and 257,5 °C |
| Purity | |
| Benzene | Not more than 10 mg/kg |
| Aromatic amines | Not more than 2 mg/kg (as aniline) |
| Phenol derivatives | Not more than 5 mg/kg (as phenol) |
| Readily carbonizable substances | Cold solution of 0,5 g of biphenyl 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 |
| Terphenyl and higher polyphenyl derivatives | Not more than 0,2 % |
| Polycyclic aromatic hydrocarbons | Absent |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 231 ORTHOPHENYLPHENOL

| | |
|--------------------------------|---|
| Synonyms | Orthoxenol |
| Definition | |
| <i>Chemical name</i> | (1,1'-Biphenyl)-2-ol 2-Hydroxydiphenyl <i>o</i> -Hydroxydiphenyl |
| Einecs | 201-993-5 |
| <i>Chemical formula</i> | C ₁₂ H ₁₀ O |
| <i>Molecular weight</i> | 170,20 |
| <i>Assay</i> | Content not less than 99 % |
| <i>Description</i> | White or slightly yellowish crystalline powder |
| Identification | |
| A. Melting range | 56 °C to 58 °C |
| B. Positive test for phenolate | An ethanolic solution (1 g in 10 ml) produces a green colour on addition of 10 % ferric chloride solution |
| Purity | |
| Sulphated ash | Not more than 0,05 % |
| Diphenyl ether | Not more than 0,3 % |
| <p><i>p</i>-Phenylphenol</p> | Not more than 0,1 % |
| 1-Naphthol | Not more than 0,01 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

**E 232 SODIUM ORTHOPHENYLPHENOL**

| | |
|---|--|
| Synonyms | Sodium orthophenylphenate Sodium salt of <i>o</i> -phenylphenol |
| Definition | |
| <i>Chemical name</i> | Sodium orthophenylphenol |
| Einecs | 205-055-6 |
| <i>Chemical formula</i> | C ₁₂ H ₉ ONa·4H ₂ O |
| <i>Molecular weight</i> | 264,26 |
| <i>Assay</i> | Content not less than 97 % of C ₁₂ H ₉ ONa·4H ₂ O |
| <i>Description</i> | White or slightly yellowish crystalline powder |
| Identification | |
| A. Positive tests for phenolate and for sodium | |
| B. Melting range of orthophenylphenol isolated by acidification and not recrystallized derived from the sample 56 °C to 58 °C after drying in a sulphuric acid desiccator | |
| C. pH of a 2 % aqueous solution must be between 11,1 and 11,8 | |
| Purity | |
| Diphenylether | Not more than 0,3 % |
| <i>p</i> -phenylphenol | Not more than 0,1 % |
| 1-naphthol | Not more than 0,01 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 233 THIABENDAZOLE

| | |
|-------------------------|--|
| Definition | |
| <i>Chemical name</i> | 4-(2-benzimidazolyl)thiazole 2-(4-thiazolyl)-1H-benzimidazole |
| Einecs | 1205-725-8 |
| <i>Chemical formula</i> | C ₁₀ H ₇ N ₃ S |
| <i>Molecular weight</i> | 201,26 |
| <i>Assay</i> | Content not less than 98 % on the anhydrous basis |
| <i>Description</i> | White, or almost white, odourless powder |
| Identification | |
| A. Melting range | 296 °C to 303 °C |
| B. Spectrometry | Absorption maxima in 0,1 N HCl (0,0005 % w/v) at 302 nm, 258 nm and 243 nm E _{1 cm} ^{1 %} at 302 nm ± 2 nm: approximately 1 230 E _{1 cm} ^{1 %} at 258 nm ± 2 nm: approximately 200 E _{1 cm} ^{1 %} at 243 nm ± 2 nm: approximately 620 Ratio of absorption 243 nm/302 nm = 0,47 to 0,53 Ratio of absorption 258 nm/302 nm = 0,14 to 0,18 |

▼B

| | |
|-------------------------|---|
| Purity | |
| Water content | Not more than 0,5 % (Karl Fischer method) |
| Sulphated ash | Not more than 0,2 % |
| Selenium | Not more than 3 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| | |
| E 234 NISIN | |
| Definition | Nisin consists of several closely related polypeptides produced by natural strains of <i>Streptococcus lactis</i> , Lancefield group N |
| Einecs | 215-807-5 |
| <i>Chemical formula</i> | $C_{143}H_{230}N_{42}O_{37}S_7$ |
| <i>Molecular weight</i> | 3 354,12 |
| <i>Assay</i> | 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 % |
| <i>Description</i> | White powder |
| Purity | |
| Loss on drying | Not more than 3 % when dried to constant weight at 102 °C to 103 °C |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| | |
| E 235 NATAMYCIN | |
| Synonyms | Pimaricin |
| Definition | Natamycin is a fungicide of the polyene macrolide group, and is produced by natural strains of <i>Streptomyces natalensis</i> or of <i>Streptococcus lactis</i> |
| Einecs | 231-683-5 |
| <i>Chemical formula</i> | $C_{33}H_{47}O_{13}N$ |
| <i>Molecular weight</i> | 665,74 |
| <i>Assay</i> | Content not less than 95 % on the anhydrous basis |
| <i>Description</i> | White to creamy-white crystalline powder |

▼B

| | |
|--|--|
| Identification | |
| A. Colour reactions | On adding a few crystals of natamycin on a spot plate, to a drop of: — concentrated hydrochloric acid, a blue colour develops, — concentrated phosphoric acid, a green colour develops, which changes into pale red after a few minutes |
| B. 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 |
| C. pH | 5,5 to 7,5 (1 % w/v solution in previously neutralized mixture of 20 parts dimethylformamide and 80 parts of water) |
| D. Specific rotation | $[\alpha]_D^{20} = +250^\circ$ to $+295^\circ$ (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 ₂ O 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| Microbiological criteria: total viable count | Not more than 100/g |

E 239 HEXAMETHYLENE TETRAMINE

| | |
|--|---|
| Synonyms | Hexamine Methenamine |
| Definition | |
| <i>Chemical name</i> | 1,3,5,7-Tetraazatricyclo [3.3.1.1 ^{3,7}]-decane, hexamethylenetetramine |
| Einecs | 202-905-8 |
| <i>Chemical formula</i> | C ₆ H ₁₂ N ₄ |
| <i>Molecular weight</i> | 140,19 |
| <i>Assay</i> | Content not less than 99 % on the anhydrous basis |
| <i>Description</i> | Colourless or white crystalline powder |
| Identification | |
| A. Positive tests for formaldehyde and for ammonia | |
| B. Sublimation point approximately 260 °C | |
| Purity | |
| Loss on drying | Not more than 0,5 % after drying at 105 °C in vacuum over P ₂ O ₅ for two 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 5 mg/kg |

▼B

| | |
|----------------------|------------------------|
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 242 DIMETHYL DICARBONATE

| | |
|-------------------------|---|
| Synonyms | DMDC Dimethyl pyrocarbonate |
| Definition | |
| <i>Einecs</i> | 224-859-8 |
| Chemical name | Dimethyl dicarbonate Pyrocarbonic acid dimethyl ester |
| <i>Chemical formula</i> | C ₄ H ₆ O ₅ |
| <i>Molecular weight</i> | 134,09 |
| <i>Assay</i> | Content not less than 99,8 % |
| <i>Description</i> | Colourless liquid, decomposes in aqueous solution. It is corrosive to skin and eyes and toxic by inhalation and ingestion |
| Identification | |
| A. Decomposition | After dilution positive tests for CO ₂ and methanol |
| B. Melting point | 17 °C |
| Boiling point | 172 °C with decomposition |
| C. Density 20 °C | Approximately 1,25 g/cm ³ |
| D. Infrared 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 249 POTASSIUM NITRITE

| | |
|--|--|
| Definition | |
| <i>Chemical name</i> | Potassium nitrite |
| Einecs | 231-832-4 |
| <i>Chemical formula</i> | KNO ₂ |
| <i>Molecular weight</i> | 85,11 |
| <i>Assay</i> | Content not less than 95 % on the anhydrous basis ⁽⁴⁾ |
| <i>Description</i> | White or slightly yellow, deliquescent granules |
| Identification | |
| A. Positive tests for nitrite and for potassium | |
| B. pH of a 5 % solution: not less than 6,0 and not more than 9,0 | |
| Purity | |
| Loss on drying | Not more than 3 % after drying for four hours over silica gel |

▼B

| | |
|----------------------|------------------------|
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 250 SODIUM NITRITE**Definition**

| | |
|-------------------------|--|
| <i>Chemical name</i> | Sodium nitrite |
| Einecs | 231-555-9 |
| <i>Chemical formula</i> | NaNO ₂ |
| <i>Molecular weight</i> | 69,00 |
| <i>Assay</i> | Content not less than 97 % on the anhydrous basis ⁽⁴⁾ |
| <i>Description</i> | White crystalline powder or yellowish lumps |

Identification

- A. Positive tests for nitrite and for sodium

Purity

| | |
|----------------------|--|
| Loss on drying | Not more than 0,25 % after drying over silica gel for four hours |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 251 SODIUM NITRATE**Synonyms**

Chile saltpetre
Cubic or soda nitre

Definition

| | |
|-------------------------|--|
| <i>Chemical name</i> | Sodium nitrate |
| Einecs | 231-554-3 |
| <i>Chemical formula</i> | NaNO ₃ |
| <i>Molecular weight</i> | 85,00 |
| <i>Assay</i> | Content not less than 99 % after drying at 105 °C for four hours |
| <i>Description</i> | White crystalline, slightly hygroscopic powder |

Identification

- A. Positive tests for nitrate and for sodium
- B. pH of a 5 % solution
- C. Melting point: ± 308 °C

Not less than 5,5 and more than 8,3

Purity

| | |
|----------------|---|
| Loss on drying | Not more than 2 % after drying at 105 °C for four hours |
| Nitrites | Not more than 30 mg/kg expressed as NaNO ₂ |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |

▼B

| | |
|----------------------|------------------------|
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 252 POTASSIUM NITRATE

| | |
|---|--|
| Synonyms | Chile saltpetre Cubic or soda nitre |
| Definition | |
| <i>Chemical name</i> | Potassium nitrate |
| Einecs | 231-818-8 |
| <i>Chemical formula</i> | KNO ₃ |
| <i>Molecular weight</i> | 101,11 |
| <i>Assay</i> | Content not less than 99 % on the anhydrous basis |
| <i>Description</i> | White crystalline powder or transparent prisms having a cooling, saline, pungent taste |
| Identification | |
| A. Positive tests for nitrate and for potassium | |
| B. pH of a 5 % solution | Not less than 4,5 and not more than 8,5 |
| Purity | |
| Loss on drying | Not more than 1 % after drying at 105 °C for four hours |
| Nitrites | Not more than 20 mg/kg expressed as KNO ₂ |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 260 ACETIC ACID

| | |
|---|---|
| Definition | |
| <i>Chemical name</i> | Acetic acid Ethanoic acid |
| Einecs | 200-580-7 |
| <i>Chemical formula</i> | C ₂ H ₄ O ₂ |
| <i>Molecular weight</i> | 60,05 |
| <i>Assay</i> | Content not less than 99,8 % |
| <i>Description</i> | Clear, colourless liquid having a pungent, characteristic odour |
| Identification | |
| A. Boiling point | 118 °C at 760 mm pressure (of mercury) |
| B. Specific gravity | About 1,049 |
| C. A one in three solution gives positive tests for acetate | |
| D. Solidification point | Not lower than 14,5 °C |
| Purity | |
| Non-volatile residue | Not more than 100 mg/kg |

▼B

| | |
|---|---|
| Formic acid, formates and other oxidizable substances | Not more than 1 000 mg/kg expressed as formic acid |
| Readily oxidizable 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 |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 261 POTASSIUM ACETATE**Definition**

| | |
|-------------------------|---|
| <i>Chemical name</i> | Potassium acetate |
| Einecs | 204-822-2 |
| <i>Chemical formula</i> | C ₂ H ₃ O ₂ K |
| <i>Molecular weight</i> | 98,14 |
| <i>Assay</i> | Content not less than 99 % on the anhydrous basis |
| <i>Description</i> | Colourless, deliquescent crystals or a white crystalline powder, odourless or with a faint acetic odour |

Identification

| | |
|---|---|
| A. pH of a 5 % aqueous solution | Not less than 7,5 and not more than 9,0 |
| B. Positive tests for acetate and for potassium | |

Purity

| | |
|---|--|
| Loss on drying | Not more than 8 % after drying at 150 °C for two hours |
| Formic acid, formates and other oxidizable substances | Not more than 1 000 mg/kg expressed as formic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 262 (i) SODIUM ACETATE**Definition**

| | |
|-------------------------|---|
| <i>Chemical name</i> | Sodium acetate |
| Einecs | 204-823-8 |
| <i>Chemical formula</i> | C ₂ H ₃ NaO ₂ ·nH ₂ O (n = 0 or 3) |
| <i>Molecular weight</i> | Anhydrous: 82,03 Trihydrate: 136,08 |
| <i>Assay</i> | Content (for both of anhydrous and trihydrate form) not less than 98,5 % on the anhydrous basis |
| <i>Description</i> | 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 | |
| A. pH of a 1 % aqueous solution | Not less than 8,0 and not more than 9,5 |
| B. Positive tests for acetate and for sodium | |
| 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 oxidizable substances | Not more than 1 000 mg/kg expressed as formic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 262 (ii) SODIUM DIACETATE

| | |
|---|--|
| Definition | Sodium diacetate is a molecular compound of sodium acetate and acetic acid |
| <i>Chemical name</i> | Sodium hydrogen diacetate |
| Einecs | 204-814-9 |
| <i>Chemical formula</i> | $C_4H_7NaO_4 \cdot nH_2O$ (n = 0 or 3) |
| <i>Molecular weight</i> | 142,09 (anhydrous) |
| <i>Assay</i> | Content 39 to 41 % of free acetic acid and 58 to 60 % of sodium acetate |
| <i>Description</i> | White, hygroscopic crystalline solid with an acetic odour |
| Identification | |
| A. pH of a 10 % aqueous solution | Not less than 4,5 and not more than 5,0 |
| B. Positive tests for acetate and for sodium | |
| Purity | |
| Water content | Not more than 2 % (Karl Fischer method) |
| Formic acid, formates and other oxidizable substances | Not more than 1 000 mg/kg expressed as formic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 263 CALCIUM ACETATE

| | |
|-------------------------|---|
| Definition | |
| <i>Chemical name</i> | Calcium acetate |
| Einecs | 200-540-9 |
| <i>Chemical formula</i> | Anhydrous: $C_4H_6O_4Ca$ Monohydrate: $C_4H_6O_4Ca \cdot H_2O$ |
| <i>Molecular weight</i> | Anhydrous: 158,17 Monohydrate: 176,18 |

▼B

| | |
|---|--|
| <i>Assay</i> | Content not less than 98 % on the anhydrous basis |
| <i>Description</i> | 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 | |
| A. pH of a 10 % aqueous solution | Not less than 6,0 and not more than 9,0 |
| B. Positive tests for acetate and for calcium | |
| Purity | |
| Loss on drying | Not more than 11 % after drying (155 °C to constant weight, for the monohydrate) |
| Water insoluble matter | Not more than 0,3 % |
| Formic acid, formates and other oxidizable substances | Not more than 1 000 mg/kg expressed as formic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 270 LACTIC ACID**Definition***Chemical name*Lactic acid
2-Hydroxypropionic acid
1-Hydroxyethane-1-carboxylic acid**Einecs**

200-018-0

*Chemical formula*C₃H₆O₃*Molecular weight*

90,08

Assay

Content not less than 76 % and not more than 84 %

*Description*Colourless or yellowish, nearly odourless, syrupy liquid with an acid taste, consisting of a mixture of lactic acid (C₃H₆O₃) and lactic acid lactate (C₆H₁₀O₅). It is obtained by the lactic fermentation of sugars or is prepared synthetically**Identification**

A. Positive test for lactate

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 5 mg/kg

Mercury

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 mg/kg

▼B

E 280 PROPIONIC ACID**Definition***Chemical name*Propionic acid
Propanoic acid**Einecs**

201-176-3

*Chemical formula*C₃H₆O₂*Molecular weight*

74,08

Assay

Content not less than 99,5 %

Description

Colourless or slightly yellowish, oily liquid with a slightly pungent odour

Identification

A. Melting point

– 22 °C

B. 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 5 mg/kg

Mercury

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 mg/kg

E 281 SODIUM PROPIONATE**Definition***Chemical name*Sodium propionate
Sodium propanoate**Einecs**

205-290-4

*Chemical formula*C₃H₅O₂Na*Molecular weight*

96,06

Assay

Content not less than 99 % after drying for two hours at 105 °C

Description

White crystalline hygroscopic powder, or a fine white powder

Identification

A. Positive tests for propionate and for sodium

B. pH of a 10 % aqueous solution

Not less than 7,5 and not more than 10,5

Purity

Loss on drying

Not more than 4 % determined by drying for two hours at 105 °C

Water insolubles

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

Heavy metals (as Pb)

Not more than 10 mg/kg

**E 282 CALCIUM PROPIONATE****Definition**

| | |
|-------------------------|--|
| <i>Chemical name</i> | Calcium propionate |
| Einecs | 223-795-8 |
| <i>Chemical formula</i> | C ₆ H ₁₀ O ₄ Ca |
| <i>Molecular weight</i> | 186,22 |
| <i>Assay</i> | Content not less than 99 %, after drying for two hours at 105 °C |
| <i>Description</i> | White crystalline powder |

Identification

- | | |
|--|---------------------|
| A. Positive tests for propionate and for calcium | |
| B. pH of a 10 % aqueous solution | Between 6,0 and 9,0 |

Purity

| | |
|----------------------|---|
| Loss on drying | Not more than 4 %, determined by drying for two hours at 105 °C |
| Water insolubles | Not more than 0,3 % |
| Iron | Not more than 50 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 |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 283 POTASSIUM PROPIONATE**Definition**

| | |
|-------------------------|---|
| <i>Chemical name</i> | Potassium propionate Potassium propanoate |
| Einecs | 206-323-5 |
| <i>Chemical formula</i> | C ₃ H ₅ KO ₂ |
| <i>Molecular weight</i> | 112,17 |
| <i>Assay</i> | Content not less than 99 % after drying for two hours at 105 °C |
| <i>Description</i> | White crystalline powder |

Identification

- | | |
|--|--|
| A. Positive tests for propionate and for potassium | |
|--|--|

Purity

| | |
|----------------------------|---|
| Loss on drying | Not more than 4 %, determined by drying for two hours at 105 °C |
| Water-insoluble substances | Not more than 0,3 % |
| 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 |

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| | |
|---|--|
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| E 284 BORIC ACID | |
| Synonyms | Boracic acid Orthoboric acid Borofax |
| Definition | |
| Einecs | 233-139-2 |
| <i>Chemical formula</i> | H ₃ BO ₃ |
| <i>Molecular weight</i> | 61,84 |
| <i>Assay</i> | Content not less than 99,5 % |
| <i>Description</i> | Colourless, odourless, transparent crystals or white granules or powder; slightly unctuous to the touch; occurs in nature as the mineral sassolite |
| Identification | |
| A. Melting point | At approximately 171 °C |
| B. Burns with a nice green flame | |
| C. pH of a 3,3 % aqueous solution | Between 3,8 and 4,8 |
| 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 |
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| E 285 SODIUM TETRABORATE (BORAX) | |
| Synonyms | Sodium borate |
| Definition | |
| <i>Chemical name</i> | Sodium tetraborate Sodium diborate Sodium pyroborate Anhydrous tetraborate |
| Einecs | 215-540-4 |
| <i>Chemical formula</i> | Na ₂ B ₄ O ₇ Na ₂ B ₄ O ₇ ·10H ₂ O |
| <i>Molecular weight</i> | 201,27 |
| <i>Description</i> | Powder or glass-like plates becoming opaque on exposure to air; slowly soluble in water |
| Identification | |
| A. 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 |

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| | |
|--|--|
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| E 290 CARBON DIOXIDE | |
| Synonyms | Carbonic acid gas Dry ice (solid form) Carbonic anhydride |
| Definition | |
| <i>Chemical name</i> | Carbon dioxide |
| Einecs | 204-696-9 |
| <i>Chemical formula</i> | CO ₂ |
| <i>Molecular weight</i> | 44,01 |
| <i>Assay</i> | Content not less than 99 % v/v on the gaseous basis |
| <i>Description</i> | A colourless gas under normal environmental conditions with a slight pungent odour. Commercial carbon dioxide is shipped and handled as a liquid in pressurized 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 | |
| A. Precipitation (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) |
| 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 0,1 mg/l |
| E 300 ASCORBIC ACID | |
| Definition | |
| <i>Chemical name</i> | L-ascorbic acid Ascorbic acid 2,3-Didehydro-L-threo-hexono-1,4-lactone 3-Keto-L-gulofuranolactone |
| Einecs | 200-066-2 |
| <i>Chemical formula</i> | C ₆ H ₈ O ₆ |
| <i>Molecular weight</i> | 176,13 |
| <i>Assay</i> | Ascorbic acid, after drying in a vacuum desiccator over sulphuric acid for 24 hours, contains not less than 99 % of C ₆ H ₈ O ₆ |
| <i>Description</i> | White to pale yellow, odourless crystalline solid |
| Identification | |
| A. Melting range | Between 189 °C and 193 °C with decomposition |
| B. Positive tests for ascorbic acid | |

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| | |
|------------------------------|--|
| Purity | |
| Loss on drying | Not more than 0,4 % after drying in a vacuum desiccator over sulphuric acid for 24 hours |
| Sulphated ash | Not more than 0,1 % |
| Specific rotation | $[\alpha]_D^{20}$ between + 20,5 ° and + 21,5 ° (10 % w/v aqueous solution) |
| pH of a 2 % aqueous solution | Between 2,4 and 2,8 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 301 SODIUM ASCORBATE

| | |
|--|--|
| Definition | |
| <i>Chemical name</i> | Sodium ascorbate Sodium L-ascorbate 2,3-Didehydro-L-threo-hexono-1,4-lactone sodium enolate 3-Keto-L-gulofurano-lactone sodium enolate |
| Einecs | 205-126-1 |
| <i>Chemical formula</i> | C ₆ H ₇ O ₆ Na |
| <i>Molecular weight</i> | 198,11 |
| <i>Assay</i> | Sodium ascorbate, after drying in a vacuum desiccator over sulphuric acid for 24 hours, contains not less than 99 % of C ₆ H ₇ O ₆ Na |
| <i>Description</i> | White or almost white, odourless crystalline solid which darkens on exposure to light |
| Identification | |
| A. Positive tests for ascorbate and for sodium | |
| Purity | |
| Loss on drying | Not more than 0,25 % after drying in a vacuum desiccator over sulphuric acid for 24 hours |
| Specific rotation | $[\alpha]_D^{20}$ between + 103 ° and + 106 ° (10 % w/v aqueous solution) |
| pH of 10 % aqueous solution | Between 6,5 and 8,0 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 302 CALCIUM ASCORBATE

| | |
|-------------------------|---|
| Definition | |
| <i>Chemical name</i> | Calcium ascorbate dihydrate Calcium salt of 2,3-didehydro-L-threo-hexono-1,4-lactone dihydrate |
| Einecs | 227-261-5 |
| <i>Chemical formula</i> | C ₁₂ H ₁₄ O ₁₂ Ca·2H ₂ O |
| <i>Molecular weight</i> | 426,35 |
| <i>Assay</i> | Content not less than 98 % on a volatile matter-free basis |

▼B

| | |
|---|---|
| <i>Description</i> | White to slightly pale greyish-yellow odourless crystalline powder |
| Identification | |
| A. Positive tests for ascorbate and for calcium | |
| Purity | |
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |
| Specific rotation | $[\alpha]_D^{20}$ between + 95 ° and + 97 ° (5 % w/v aqueous solution) |
| pH of 10 % aqueous solution | Between 6,0 and 7,5 |
| 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 304 (i) ASCORBYL PALMITATE**Definition**

| | |
|----------------------|--|
| <i>Chemical name</i> | Ascorbyl palmitate L-ascorbyl palmitate 2,3-didehydro-L-threo-hexono-1,4-lactone-6-palmitate 6-palmitoyl-3-keto-L-gulofuranolactone |
|----------------------|--|

Einecs 205-305-4

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 solid with a citrus-like odour

Identification

A. Melting range Between 107 °C and 117 °C

Purity

| | |
|----------------------|---|
| Loss on drying | Not more than 2,0 % after drying in a vacuum oven at 56 °C and 60 °C for one hour |
| Sulphated ash | Not more than 0,1 % |
| Specific rotation | $[\alpha]_D^{20}$ between + 21 ° and + 24 ° (5 % w/v in methanol solution) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 304 (ii) ASCORBYL STEARATE**Definition**

| | |
|----------------------|--|
| <i>Chemical name</i> | Ascorbyl stearate L-ascorbyl stearate 2,3-didehydro-L-threo-hexono-1,4-lactone-6-stearate 6-stearoyl-3-keto-L-gulofuranolactone |
|----------------------|--|

Einecs 246-944-9

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| | |
|-------------------------|--|
| <i>Chemical formula</i> | C ₂₄ H ₄₂ O ₇ |
| <i>Molecular weight</i> | 442,6 |
| <i>Assay</i> | Content not less than 98 % |
| <i>Description</i> | White or yellowish, white solid with a citrus-like odour |
| Identification | |
| A. Melting point | About 116 °C |
| Purity | |
| Loss on drying | Not more than 2,0 % after drying in a vacuum oven at 56 °C to 60 °C for one hour |
| Sulphated ash | 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 |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 306 TOCOPHEROL-RICH EXTRACT

| | |
|--|---|
| Definition | Product obtained by the vacuum steam distillation of edible vegetable oil products, comprising concentrated tocopherols and tocotrienols Contains tocopherols such as d- α -, d- β -, d- γ - and d- ζ -tocopherols |
| <i>Molecular weight</i> | 430,71 (d- α -tocopherol) |
| <i>Assay</i> | Content not less than 34 % of total tocopherols |
| <i>Description</i> | 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 | |
| A. By suitable gas liquid chromatographic method | |
| B. Solubility tests | Insoluble in water. Soluble in ethanol. Miscible in ether |
| Purity | |
| Sulphated ash | Not more than 0,1 % |
| Specific rotation | $[\alpha]_D^{20}$ not less than + 20 ° |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 307 ALPHA-TOCOPHEROL

| | |
|-------------------------|--|
| Synonyms | dl- α -Tocopherol |
| Definition | |
| <i>Chemical name</i> | dl-5,7,8-Trimethyltolcol dl-2,5,7,8-tetramethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol |
| Einecs | 200-412-2 |
| <i>Chemical formula</i> | C ₂₉ H ₅₀ O ₂ |
| <i>Molecular weight</i> | 430,71 |

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| | |
|--|---|
| <i>Assay</i> | Content not less than 96 % |
| <i>Description</i> | Slightly yellow to amber, nearly odourless, clear, viscous oil which oxidizes and darkens on exposure to air or light |
| Identification | |
| A. Solubility tests | Insoluble in water, freely soluble in ethanol, miscible in ether |
| B. Spectrophotometry | In absolute ethanol the maximum absorption is about 292 nm |
| Purity | |
| Refractive index | n_D^{20} 1,503 — 1,507 |
| Specific absorption $E_{1\text{ cm}}^{1\%}$ in ethanol | $E_{1\text{ cm}}^{1\%}$ (292 nm) 72—76 (0,01 g in 200 ml of absolute ethanol) |
| Sulphated ash | Not more than 0,1 % |
| Specific rotation | $[\alpha]_D^{20}$ 0 ° ± 0,05 ° (1 in 10 solution in chloroform) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 308 GAMMA-TOCOPHEROL

| | |
|--|--|
| Synonyms | dl- γ -Tocopherol |
| Definition | |
| <i>Chemical name</i> | 2,7,8-trimethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol |
| Einecs | 231-523-4 |
| <i>Chemical formula</i> | $C_{28}H_{48}O_2$ |
| <i>Molecular weight</i> | 416,69 |
| <i>Assay</i> | Content not less than 97 % |
| <i>Description</i> | Clear, viscous, pale yellow oil which oxidizes and darkens on exposure to air or light |
| Identification | |
| A. Spectrometry | Maximum absorptions in absolute ethanol at about 298 nm and 257 nm |
| Purity | |
| Specific absorption $E_{1\text{ cm}}^{1\%}$ in ethanol | $E_{1\text{ cm}}^{1\%}$ (298 nm) between 91 and 97 $E_{1\text{ cm}}^{1\%}$ (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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 309 DELTA-TOCOPHEROL

| | |
|----------------------|--|
| Definition | |
| <i>Chemical name</i> | 2,8-dimethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol |

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| | |
|---|--|
| Einecs | 204-299-0 |
| <i>Chemical formula</i> | C ₂₇ H ₄₆ O ₂ |
| <i>Molecular weight</i> | 402,7 |
| <i>Assay</i> | Content not less than 97 % |
| <i>Description</i> | Clear, viscous, pale yellowish or orange oil which oxidizes and darkens on exposure to air or light |
| Identification | |
| A. Spectrometry | Maximum absorptions in absolute ethanol at about 298 nm and 257 nm |
| Purity | |
| Specific absorption E _{1 cm} ^{1 %} in ethanol | E _{1 cm} ^{1 %} (298 nm) between 89 and 95 E _{1 cm} ^{1 %} (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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 310 PROPYL GALLATE

| | |
|---|---|
| Definition | |
| <i>Chemical name</i> | Propyl gallate Propyl ester of gallic acid n-propyl ester of 3,4,5-trihydroxybenzoic acid |
| Einecs | 204-498-2 |
| <i>Chemical formula</i> | C ₁₀ H ₁₂ O ₅ |
| <i>Molecular weight</i> | 212,20 |
| <i>Assay</i> | Content not less than 98 % on the anhydrous basis |
| <i>Description</i> | White to creamy-white, crystalline, odourless solid |
| Identification | |
| A. Solubility tests | Slightly soluble in water, freely soluble in ethanol, ether and propane-1,2-diol |
| B. Melting range | Between 146 °C and 150 °C after drying at 110 °C for four hours |
| Purity | |
| Loss on drying | Not more than 1,0 % (110 °C, four 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 E _{1 cm} ^{1 %} in ethanol | E _{1 cm} ^{1 %} (275 nm) not less than 485 and not more than 520 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

**E 311 OCTYL GALLATE****Definition**

Chemical name Octyl gallate
Octyl ester of gallic acid
n-octyl ester of 3,4,5-trihydroxybenzoic acid

Einecs 213-853-0

Chemical formula C₁₅H₂₂O₅

Molecular weight 282,34

Assay Content not less than 98 % after drying at 90 °C for six hours

Description White to creamy-white odourless solid

Identification

A. Solubility tests Insoluble in water, freely soluble in ethanol, ether and propane-1,2-diol

B. Melting range Between 99 °C and 102 °C after drying at 90 °C for six hours

Purity

Loss on drying Not more than 0,5 % (90 °C, six hours)

Sulphated ash Not more than 0,05 %

Free acid Not more than 0,5 % (as gallic acid)

Chlorinated organic compound Not more than 100 mg/kg (as Cl)

Specific absorption E₁^{1%}_{1 cm} in ethanol E₁^{1%}_{1 cm} (275 nm) not less than 375 and not more than 390

Arsenic Not more than 3 mg/kg

Lead Not more than 5 mg/kg

Mercury Not more than 1 mg/kg

Heavy metals (as Pb) Not more than 10 mg/kg

E 312 DODECYL GALLATE**Synonyms**

Lauryl gallate

Definition

Chemical name Dodecyl gallate
n-dodecyl (or lauryl) ester of 3,4,5-trihydroxybenzoic acid
Dodecyl ester of gallic acid

Einecs 214-620-6

Chemical formula C₁₉H₃₀O₅

Molecular weight 338,45

Assay Content not less than 98 % after drying at 90 °C for six hours

Description White or creamy-white odourless solid

Identification

A. Solubility tests Insoluble in water, freely soluble in ethanol and ether

B. Melting range Between 95 °C and 98 °C after drying at 90 °C for six hours

Purity

Loss on drying Not more than 0,5 % (90 °C, six hours)

Sulphated ash Not more than 0,05 %

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| | |
|--|--|
| Free acid | Not more than 0,5 % (as gallic acid) |
| Chlorinated organic compound | Not more than 100 mg/kg (as Cl) |
| Specific absorption $E_{1\text{ cm}}^{1\%}$ in ethanol | $E_{1\text{ cm}}^{1\%}$ (275 nm) not less than 300 and not more than 325 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 10 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 30 mg/kg |

E 315 ERYTHORBIC ACID**Synonyms**

Isoascorbic acid
D-araboascorbic acid

Definition*Chemical name*

D-Erythro-hex-2-enoic acid γ -lactone
Isoascorbic acid
D-isoascorbic acid

Einecs

201-928-0

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

A. Melting range

About 164 °C to 172 °C with decomposition

B. Positive test for ascorbic acid/colour reaction

Purity

Loss on drying

Not more than 0,4 % after drying under reduced pressure on silica gel for 3 hours

Sulphated ash

Not more than 0,3 %

Specific rotation

$[\alpha]_D^{25}$ 10 % (w/v) aqueous solution between $-16,5^\circ$ to $-18,0^\circ$

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 5 mg/kg

Mercury

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 mg/kg

E 316 SODIUM ERYTHORBATE**Synonyms**

Sodium isoascorbate

Definition*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

Einecs

228-973-9

▼B

| | |
|--|---|
| <i>Chemical formula</i> | C ₆ H ₇ O ₆ Na·H ₂ O |
| <i>Molecular weight</i> | 216,13 |
| <i>Assay</i> | Content not less than 98 % after drying in a vacuum desiccator over sulphuric acid for 24 hours expressed on the monohydrate basis |
| <i>Description</i> | White crystalline solid |
| Identification | |
| A. Solubility tests | Freely soluble in water, very slightly soluble in ethanol |
| B. Positive test for ascorbic acid/colour reaction | |
| C. Positive test for sodium | |
| Purity | |
| Loss on drying | Not more than 0,25 % after drying in a vacuum desiccator over sulphuric acid for 24 hours |
| Specific rotation | $[\alpha]_{\text{D}}^{25}$ 10 % (w/v) aqueous solution between + 95 ° and + 98 ° |
| pH of a 10 % aqueous solution | 5,5 to 8,0 |
| 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 320 BUTYLATED HYDROXYANISOLE (BHA)

| | |
|---|--|
| Synonyms | BHA |
| Definition | |
| <i>Chemical name</i> | 3-Tertiary-butyl-4-hydroxyanisole A mixture of 2-tertiarybutyl-4-hydroxyanisole and 3-tertiarybutyl-4-hydroxyanisole |
| Einecs | 246-563-8 |
| <i>Chemical formula</i> | C ₁₁ H ₁₆ O ₂ |
| <i>Molecular weight</i> | 180,25 |
| <i>Assay</i> | Content not less than 98,5 % of C ₁₁ H ₁₆ O ₂ and not less than 85 % of 3-tertiary-butyl-4-hydroxyanisole isomer |
| <i>Description</i> | White or slightly yellow crystals or waxy solid with a slight aromatic smell |
| Identification | |
| A. Solubility tests | Insoluble in water |
| B. Melting range | Between 48 °C and 55 °C |
| 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 cm} ^{1 %} in ethanol | E _{1 cm} ^{1 %} (290 nm) not less than 190 and not more than 210 E _{1 cm} ^{1 %} (228 nm) not less than 326 and not more than 345 |
| Arsenic | Not more than 3 mg/kg |

▼B

| | |
|----------------------|------------------------|
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 321 BUTYLATED HYDROXYTOLUENE (BHT)

| | |
|---|--|
| Synonyms | BHT |
| Definition | |
| <i>Chemical name</i> | 2,6-Ditertiary-butyl- <i>p</i> -cresol 4-Methyl-2,6-ditertiarybutylphenol |
| Einecs | 204-881-4 |
| <i>Chemical formula</i> | C ₁₅ H ₂₄ O |
| <i>Molecular weight</i> | 220,36 |
| <i>Assay</i> | Content not less than 99 % |
| <i>Description</i> | White, crystalline or flaked solid, odourless or having a characteristic faint aromatic odour |
| Identification | |
| A. Solubility tests | Insoluble in water and propane- 1,2-diol Freely soluble in ethanol |
| B. Melting point | At 70 °C |
| C. Absorbance maximum | 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 E _{1 cm} ^{1 %} in ethanol | E _{1 cm} ^{1 %} (278 nm) not less than 81 and not more than 88 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 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 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 |
| <i>Assay</i> | — Lecithins: not less than 60,0 % of substances insoluble in acetone — Hydrolysed lecithins: not less than 56,0 % of substances insoluble in acetone |
| <i>Description</i> | — Lecithins: brown liquid or viscous semi-liquid or powder — Hydrolysed lecithins: light brown to brown viscous liquid or paste |

▼B

Identification

- A. Positive tests for choline, for phosphorus and fatty acids
- B. Test for hydrolysed lecithin

To a 800 ml beaker add 500 ml of water (30 °C—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
- Toluene-insoluble matter
- Acid value
- Peroxide value
- Arsenic
- Lead
- Mercury
- Heavy metals (as Pb)

Not more than 2,0 % determined by drying at 105 °C for one hour

Not more than 0,3 %

— Lecithins: not more than 35 mg of potassium hydroxide per gram
— Hydrolysed lecithins: not more than 45 mg of potassium hydroxide per gram

Equal to or less than 10

Not more than 3 mg/kg

Not more than 5 mg/kg

Not more than 1 mg/kg

Not more than 10 mg/kg

E 325 SODIUM LACTATE**Definition**

Chemical name

Sodium lactate
Sodium 2-hydroxypropanoate

Einecs

200-772-0

Chemical formula

C₃H₅NaO₃

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

- A. Positive test for lactate
- B. Positive test for potassium

Purity

- Acidity
- pH of a 20 % aqueous solution
- Arsenic
- Lead
- Mercury
- Heavy metals (as Pb)
- Reducing substances

Not more than 0,5 % after drying expressed as lactic acid

6,5 to 7,5

Not more than 3 mg/kg

Not more than 5 mg/kg

Not more than 1 mg/kg

Not more than 10 mg/kg

No reduction of Fehling's solution

**E 326 POTASSIUM LACTATE****Definition**

Chemical name

Potassium lactate
Potassium 2-hydroxypropanoate**Einecs**

213-631-3

*Chemical formula*C₃H₅O₃K*Molecular weight*

128,17 (anhydrous)

Assay

Content not less than 57 % and not more than 66 %

Description

Slightly viscous, almost odourless clear liquid. Odourless, or with a slight, characteristic odour

Identification

A. Ignition

Ignite potassium lactate solution to an ash. The ash is alkaline, and an effervescence occurs when acid is added

B. 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

C. Positive tests for potassium and for lactate

Purity

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 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

Potassium lactate solution shall not cause any reduction of Fehling's solution

E 327 CALCIUM LACTATE**Definition***Chemical name*Calcium dilactate
Calcium dilactate hydrate
2-Hydroxypropanoic acid calcium salt**Einecs**

212-406-7

Chemical formula(C₃H₅O₂)₂ Ca·nH₂O (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

A. Positive tests for lactate and for calcium

B. Solubility tests

Soluble in water and practically insoluble in ethanol

▼B

| | |
|---------------------------------|---|
| Purity | |
| Loss on drying | Determined by drying at 120 °C for four hours: — anhydrous: not more than 3,0 % — with 1 molecule of water: not more than 8,0 % — with 3 molecules of water: not more than 20,0 % — with 4,5 molecules of water: not more than 27,0 % |
| Acidity | Not more than 0,5 % of the dry matter expressed as lactic acid |
| Fluoride | Not more than 30 mg/kg (expressed as fluorine) |
| pH of a 5 % solution | Between 6,0 and 8,0 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| Reducing substances | No reduction of Fehling's solution |
| E 330 CITRIC ACID | |
| Definition | |
| <i>Chemical name</i> | Citric acid 2-Hydroxy-1,2,3-propanetricarboxylic acid β-Hydroxytricarballic acid |
| Einecs | 201-069-1 |
| <i>Chemical formula</i> | (a) C ₆ H ₈ O ₇ (anhydrous) (b) C ₆ H ₈ O ₇ ·H ₂ O (monohydrate) |
| <i>Molecular weight</i> | (a) 192,13 (anhydrous) (b) 210,15 (monohydrate) |
| <i>Assay</i> | Citric acid may be anhydrous or it may contain 1 molecule of water. Citric acid contains not less than 99,5 % of C ₆ H ₈ O ₇ , calculated on the anhydrous basis |
| <i>Description</i> | Citric acid is a white or colourless, odourless, crystalline solid, having a strongly acid taste. The monohydrate effloresces in dry air |
| Identification | |
| A. Solubility tests | 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 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 5 mg/kg |
| Oxalates | Not more than 100 mg/kg, expressed as oxalic acid, after drying |
| Readily carbonizable 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 | Monosodium citrate Monobasic sodium citrate |
| Definition | |
| <i>Chemical name</i> | Monosodium citrate Monosodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid |
| <i>Chemical formula</i> | (a) $C_6H_7O_7Na$ (anhydrous) (b) $C_6H_7O_7Na \cdot H_2O$ (monohydrate) |
| <i>Molecular weight</i> | (a) 214,11 (anhydrous) (b) 232,23 (monohydrate) |
| <i>Assay</i> | Content not less than 99 % on the anhydrous basis |
| <i>Description</i> | Crystalline white powder or colourless crystals |
| Identification | |
| A. Positive tests for citrate and for sodium | |
| Purity | |
| Loss on drying | Determined by drying at 180 °C for four hours: — anhydrous: not more than 1,0 % — monohydrate: not more than 8,8 % |
| Oxalates | Not more than 100 mg/kg expressed as oxalic acid, after drying |
| pH of a 1 % aqueous solution | Between 3,5 and 3,8 |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 5 mg/kg |

E 331 (ii) DISODIUM CITRATE

| | |
|--|--|
| Synonyms | Disodium citrate Dibasic sodium citrate |
| Definition | |
| <i>Chemical name</i> | Disodium citrate Disodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Disodium salt of citric acid with 1,5 molecules of water |
| Einecs | 205-623-3 |
| <i>Chemical formula</i> | $C_6H_6O_7Na_2 \cdot 1,5H_2O$ |
| <i>Molecular weight</i> | 263,11 |
| <i>Assay</i> | Content not less than 99 % on the anhydrous basis |
| <i>Description</i> | Crystalline white powder or colourless crystals |
| Identification | |
| A. Positive tests for citrate and for sodium | |
| Purity | |
| Loss on drying | Not more than 13,0 % by drying at 180 °C for four hours |
| Oxalates | Not more than 100 mg/kg expressed as oxalic acid, after drying |
| pH of a 1 % aqueous solution | Between 4,9 and 5,2 |

▼B

| | |
|----------------------|-----------------------|
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 5 mg/kg |

E 331 (iii) TRISODIUM CITRATE

| | |
|--|---|
| Synonyms | Trisodium citrate Tribasic sodium citrate |
| Definition | |
| <i>Chemical name</i> | Trisodium citrate Trisodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Trisodium salt of citric acid, in anhydrous, dihydrate or pentahydrate form |
| Einecs | 200-675-3 |
| <i>Chemical formula</i> | Anhydrous: $C_6H_5O_7Na_3$ Hydrated: $C_6H_5O_7Na_3 \cdot nH_2O$ (n = 2 or 5) |
| <i>Molecular weight</i> | 258,07 (anhydrous) |
| <i>Assay</i> | Not less than 99 % on the anhydrous basis |
| <i>Description</i> | Crystalline white powder or colourless crystals |
| Identification | |
| A. Positive tests for citrate and for sodium | |
| Purity | |
| Loss on drying | Determined by drying at 180 °C for four hours: — anhydrous: not more than 1,0 % — dihydrate: not more than 13,5 % — pentahydrate: not more than 30,3 % |
| Oxalates | Not more than 100 mg/kg expressed as oxalic acid, after drying |
| pH of a 5 % aqueous solution | Between 7,5 and 9,0 |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 5 mg/kg |

E 332 (i) MONOPOTASSIUM CITRATE

| | |
|-------------------------|---|
| Synonyms | Monopotassium citrate Monobasic potassium citrate |
| Definition | |
| <i>Chemical name</i> | Monopotassium citrate Monopotassium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Anhydrous monopotassium salt of citric acid |
| Einecs | 212-753-4 |
| <i>Chemical formula</i> | $C_6H_7O_7K$ |
| <i>Molecular weight</i> | 230,21 |

▼B

| | |
|---|---|
| <i>Assay</i> | Content not less than 99 % on the anhydrous basis |
| <i>Description</i> | White, hygroscopic, granular powder or transparent crystals |
| Identification | |
| A. Positive tests for citrate and for potassium | |
| Purity | |
| Loss on drying | Not more than 1,0 % determined by drying at 180 °C for four hours |
| Oxalates | Not more than 100 mg/kg expressed as oxalic acid, after drying |
| pH of a 1 % aqueous solution | Between 3,5 and 3,8 |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 5 mg/kg |

E 332 (ii) TRIPOTASSIUM CITRATE

| | |
|---|---|
| Synonyms | Tripotassium citrate Tribasic potassium citrate |
| Definition | |
| <i>Chemical name</i> | Tripotassium citrate Tripotassium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Monohydrated tripotassium salt of citric acid |
| Einecs | 212-755-5 |
| <i>Chemical formula</i> | $C_6H_5O_7K_3 \cdot H_2O$ |
| <i>Molecular weight</i> | 324,42 |
| <i>Assay</i> | Content not less than 99 % on the anhydrous basis |
| <i>Description</i> | White, hygroscopic, granular powder or transparent crystals |
| Identification | |
| A. Positive tests for citrate and for potassium | |
| Purity | |
| Loss on drying | Not more than 6,0 % determined by drying at 180 °C for four hours |
| Oxalates | Not more than 100 mg/kg expressed as oxalic acid, after drying |
| pH of a 5 % aqueous solution | Between 7,5 and 9,0 |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 5 mg/kg |

E 333 (i) MONOCALCIUM CITRATE

| | |
|----------------------|---|
| Synonyms | Monocalcium citrate Monobasic calcium citrate |
| Definition | |
| <i>Chemical name</i> | Monocalcium citrate Monocalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Monohydrate monocalcium salt of citric acid |

▼B

| | |
|---|---|
| <i>Chemical formula</i> | (C ₆ H ₇ O ₇) ₂ Ca·H ₂ O |
| <i>Molecular weight</i> | 440,32 |
| <i>Assay</i> | Content not less than 97,5 % on the anhydrous basis |
| <i>Description</i> | Fine white powder |
| Identification | |
| A. Positive tests for citrate and for calcium | |
| Purity | |
| Loss on drying | Not more than 7,0 % determined by drying at 180 °C for four hours |
| Oxalates | Not more than 100 mg/kg expressed as oxalic acid, after drying |
| pH of a 1 % aqueous solution | Between 3,2 and 3,5 |
| 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 |
| Heavy metals (as Pb) | Not more than 5 mg/kg |
| 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 | Dicalcium citrate Dibasic calcium citrate |
| Definition | |
| <i>Chemical name</i> | Dicalcium citrate Dicalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Trihydrated dicalcium salt of citric acid |
| <i>Chemical formula</i> | (C ₆ H ₇ O ₇) ₂ Ca ₂ ·3H ₂ O |
| <i>Molecular weight</i> | 530,42 |
| <i>Assay</i> | Not less than 97,5 % on the anhydrous basis |
| <i>Description</i> | Fine white powder |
| Identification | |
| A. Positive tests for citrate and for calcium | |
| Purity | |
| Loss on drying | Not more than 20,0 % determined by drying at 180 °C for four 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 |
| Heavy metals (as Pb) | Not more than 5 mg/kg |
| Carbonates | Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles |

▼B

E 333 (iii) TRICALCIUM CITRATE

| | |
|---|--|
| Synonyms | Tricalcium citrate Tribasic calcium citrate |
| Definition | |
| <i>Chemical name</i> | Tricalcium citrate Tricalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Tetrahydrated tricalcium salt of citric acid |
| Einecs | 212-391-7 |
| <i>Chemical formula</i> | $(C_6H_6O_7)_2Ca_3 \cdot 4H_2O$ |
| <i>Molecular weight</i> | 570,51 |
| <i>Assay</i> | Not less than 97,5 % on the anhydrous basis |
| <i>Description</i> | Fine white powder |
| Identification | |
| A. Positive tests for citrate and for calcium | |
| Purity | |
| Loss on drying | Not more than 14,0 % determined by drying at 180 °C for four 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 |
| Heavy metals (as Pb) | Not more than 5 mg/kg |
| 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

| | |
|--|---|
| Definition | |
| <i>Chemical name</i> | L-tartaric acid L-2,3-dihydroxybutanedioic acid d- α , β -dihydroxysuccinic acid |
| Einecs | 201-766-0 |
| <i>Chemical formula</i> | $C_4H_6O_6$ |
| <i>Molecular weight</i> | 150,09 |
| <i>Assay</i> | Content not less than 99,5 % on the anhydrous basis |
| <i>Description</i> | Colourless or translucent crystalline solid or white crystalline powder |
| Identification | |
| A. Melting range | Between 168 °C and 170 °C |
| B. Positive test for tartrate | |
| Purity | |
| Loss on drying | Not more than 0,5 % (over P ₂ O ₅ , three hours) |
| Sulphated ash | Not more than 1 000 mg/kg after calcination at 800 ± 25 °C |
| Specific optical rotation of a 20 % w/v aqueous solution | $[\alpha]_D^{20}$ between + 11,5 ° and + 13,5 ° |

▼B

| | |
|----------------------|--|
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 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 | |
| <i>Chemical name</i> | Monosodium salt of L-2,3-dihydroxybutanedioic acid Monohydrated monosodium salt of L-(+)-tartaric acid |
| <i>Chemical formula</i> | C ₄ H ₅ O ₆ Na·H ₂ O |
| <i>Molecular weight</i> | 194,05 |
| <i>Assay</i> | Content not less than 99 % on the anhydrous basis |
| <i>Description</i> | Transparent colourless crystals |
| Identification | |
| A. Positive tests for tartrate and for sodium | |
| Purity | |
| Loss on drying | Not more than 10,0 % determined by drying at 105 °C for four 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 335 (ii) DISODIUM TARTRATE

| | |
|---|---|
| Definition | |
| <i>Chemical name</i> | Disodium L-tartrate Disodium (+)-tartrate Disodium (+)-2,3-dihydroxybutanedioic acid Dihydrated disodium salt of L-(+)-tartaric acid |
| Einecs | 212-773-3 |
| <i>Chemical formula</i> | C ₄ H ₄ O ₆ Na ₂ ·2H ₂ O |
| <i>Molecular weight</i> | 230,8 |
| <i>Assay</i> | Content not less than 99 % on the anhydrous basis |
| <i>Description</i> | Transparent, colourless crystals |
| Identification | |
| A. Positive tests for tartrate and for sodium | |
| B. Solubility tests | 1 gram is insoluble in 3 ml of water. Insoluble in ethanol |
| Purity | |
| Loss on drying | Not more than 17,0 % determined by drying at 150 °C for four hours |
| Oxalates | Not more than 100 mg/kg expressed as oxalic acid, after drying |
| pH of a 1 % aqueous solution | Between 7,0 and 7,5 |

▼B

| | |
|----------------------|------------------------|
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 336 (i) MONOPOTASSIUM TARTRATE

| | |
|--|--|
| Synonyms | Monobasic potassium tartrate |
| Definition | |
| <i>Chemical name</i> | Anhydrous monopotassium salt of L-(+)-tartaric acid Monopotassium salt of L-2,3-dihydroxybutanedioic acid |
| <i>Chemical formula</i> | C ₄ H ₅ O ₆ K |
| <i>Molecular weight</i> | 188,16 |
| <i>Assay</i> | Content not less than 98 % on the anhydrous basis |
| <i>Description</i> | White crystalline or granulated powder |
| Identification | |
| A. Positive tests for tartrate and for potassium | |
| B. Melting point | 230 °C |
| Purity | |
| pH of a 1 % aqueous solution | 3,4 |
| Loss on drying | Not more than 1,0 % determined by drying at 105 °C for four 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 336 (ii) DIPOTASSIUM TARTRATE

| | |
|--|--|
| Synonyms | Dibasic potassium tartrate |
| Definition | |
| <i>Chemical name</i> | Dipotassium salt of L-2,3-dihydroxybutanedioic acid Dipotassium salt with half a molecule of water of L-(+)-tartaric acid |
| Einecs | 213-067-8 |
| <i>Chemical formula</i> | C ₄ H ₄ O ₆ K ₂ ·½H ₂ O |
| <i>Molecular weight</i> | 235,2 |
| <i>Assay</i> | Content not less than 99 % on the anhydrous basis |
| <i>Description</i> | White crystalline or granulated powder |
| Identification | |
| A. Positive tests for tartrate and for potassium | |
| Purity | |
| pH of a 1 % aqueous solution | Between 7,0 and 9,0 |
| Loss on drying | Not more than 4,0 % determined by drying at 150 °C for four hours |

▼B

| | |
|----------------------|--|
| Oxalates | Not more than 100 mg/kg expressed as oxalic acid, after drying |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 337 POTASSIUM SODIUM TARTRATE

| | |
|--|--|
| Synonyms | Potassium sodium L-(+)-tartrate Rochelle salt Seignette salt |
| Definition | |
| <i>Chemical name</i> | Potassium sodium salt of L-2,3-dihydroxybutanedioic acid Potassium sodium L-(+)-tartrate |
| Einecs | 206-156-8 |
| <i>Chemical formula</i> | C ₄ H ₄ O ₆ KNa·4H ₂ O |
| <i>Molecular weight</i> | 282,23 |
| <i>Assay</i> | Content not less than 99 % on the anhydrous basis |
| <i>Description</i> | Colourless crystals or white crystalline powder |
| Identification | |
| A. Positive tests for tartrate, for potassium and for sodium | |
| B. Solubility tests | 1 gram is soluble in 1 ml of water, insoluble in ethanol |
| C. Melting range | Between 70 and 80 °C |
| Purity | |
| Loss on drying | Not more than 26,0 % and not less than 21,0 % determined by drying at 150 °C for three hours |
| Oxalates | Not more than 100 mg/kg expressed as oxalic acid, after drying |
| pH of 1 % aqueous solution | Between 6,5 and 8,5 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 338 PHOSPHORIC ACID

| | |
|-------------------------|---|
| Synonyms | Orthophosphoric acid Monophosphoric acid |
| Definition | |
| <i>Chemical name</i> | Phosphoric acid |
| Einecs | 231-633-2 |
| <i>Chemical formula</i> | H ₃ PO ₄ |
| <i>Molecular weight</i> | 98,00 |
| <i>Assay</i> | Content not less than 71 % and not more than 83 % |
| <i>Description</i> | Clear, colourless, viscous liquid |

▼B

Identification

A. Positive tests for acid and for phosphate

Purity

| | |
|----------------------|--|
| Volatile acids | Not more than 10 mg/kg (as acetic acid) |
| Chlorides | Not more than 200 mg/kg (expressed as chlorine) |
| Nitrates | Not more than 5 mg/kg (as NaNO ₃) |
| Sulphates | Not more than 1500 mg/kg (as CaSO ₄) |
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 339 (i) MONOSODIUM PHOSPHATE**Synonyms**

Monosodium monophosphate
 Acid monosodium monophosphate
 Monosodium orthophosphate
 Monobasic sodium phosphate

Definition*Chemical name*

Sodium dihydrogen monophosphate

Einecs

231-449-2

*Chemical formula*Anhydrous: NaH₂PO₄Monohydrate: NaH₂PO₄·H₂ODihydrate: NaH₂PO₄·2H₂O*Molecular weight*

Anhydrous: 119,98

Monohydrate: 138,00

Dihydrate: 156,01

*Assay*After drying at 6,0 °C for one hour and then at 105 °C for four hours, contains not less than 97 % of NaH₂PO₄*Description*

A white odourless, slightly deliquescent powder, crystals or granules

Identification

A. Positive tests for sodium and for phosphate

B. Solubility tests

Freely soluble in water. Insoluble in ethanol, ether or chloroform

C. P₂O₅ content

Between 58,0% and 60,0%

Purity

Loss on drying

The anhydrous salt loses no more than 2,0 %, the monohydrate no more than 15,0 %, and the dihydrate no more than 25 % when dried first at 60 °C for one hour, then at 105 °C for four hours

Water-insoluble substances

Not more than 0,2 % on the anhydrous basis

Fluoride

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

pH of a 1 % aqueous solution

Between 4,1 and 5,0

Arsenic

Not more than 3 mg/kg

▼B

| | |
|----------------------|------------------------|
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 339 (ii) DISODIUM PHOSPHATE

| | |
|--|---|
| Synonyms | Disodium monophosphate Secondary sodium phosphate Disodium orthophosphate Acid disodium phosphate |
| Definition | |
| <i>Chemical name</i> | Disodium hydrogen monophosphate Disodium hydrogen orthophosphate |
| Einecs | 231-448-7 |
| <i>Chemical formula</i> | Anhydrous: Na_2HPO_4 Hydrated: $\text{Na}_2\text{HPO}_4 \cdot n\text{H}_2\text{O}$ (n = 2, 7 or 12) |
| <i>Molecular weight</i> | 141,98 (anhydrous) |
| <i>Assay</i> | 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 |
| <i>Description</i> | Anhydrous disodium hydrogen phosphate is a white, hygroscopic, odourless powder. Hydrated forms available include the dihydrate: a white crystalline, odourless solid; the heptahydrate: white, odourless, efflorescent crystals or granular powder; and the dodecahydrate: white, efflorescent, odourless powder or crystals |
| Identification | |
| A. Positive tests for sodium and for phosphate | |
| B. Solubility tests | Freely soluble in water. Insoluble in ethanol |
| C. P_2O_5 content | Between 49 % and 51 % (anhydrous) |
| Purity | |
| Loss on drying | When dried at 40 °C for three hours and then at 105 °C for five hours, the losses in weight are as follows: anhydrous not more than 5,0 %, dihydrate not more than 22,0 %, heptahydrate not more than 50,0 %, dodecahydrate not more than 61,0 % |
| Water-insoluble substances | Not more than 0,2 % on the anhydrous basis |
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |
| pH of a 1,0 % aqueous solution | Between 8,4 and 9,6 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 339 (iii) TRISODIUM PHOSPHATE

| | |
|----------------------|--|
| Synonyms | Sodium phosphate Tribasic sodium phosphate Trisodium orthophosphate |
| Definition | |
| <i>Chemical name</i> | Trisodium monophosphate Trisodium phosphate Trisodium orthophosphate |

▼B

| | |
|--|--|
| Einecs | 231-509-8 |
| <i>Chemical formula</i> | Anhydrous: Na_3PO_4 Hydrated: $\text{Na}_3\text{PO}_4 \cdot n\text{H}_2\text{O}$ ($n = 0,5, 1$ or 12) |
| <i>Molecular weight</i> | 163,94 (anhydrous) |
| <i>Assay</i> | Sodium phosphate anhydrous, and also the hemi- and monohydrates, contains 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 |
| <i>Description</i> | White odourless crystals, granules or a crystalline powder. Hydrated forms available include hemi- and monohydrates, hexahydrate, octahydrate, decahydrate and dodecahydrate. The dodecahydrate contains $\frac{1}{4}$ molecule of sodium hydroxide |
| Identification | |
| A. Positive tests for sodium and for phosphate | |
| B. Solubility tests | Freely soluble in water. Insoluble in ethanol |
| C. P_2O_5 content | Between 40,5 % and 43,5 % (anhydrous) |
| Purity | |
| Loss on ignition | When dried at 120 °C for two hours and then ignited at about 800 °C for 30 minutes, the losses in weight are as follows: anhydrous not more than 2,0 %, monohydrate: not more than 11,0 %, dodecahydrate: between 45,0 % and 58,0 % |
| Water-insoluble substances | Not more than 0,2 % on the anhydrous basis |
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |
| pH of a 1,0 % aqueous solution | Between 11,5 and 12,5 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 340 (i) MONOPOTASSIUM PHOSPHATE

| | |
|---|--|
| Synonyms | Monobasic potassium phosphate Monopotassium monophosphate Potassium acid phosphate Potassium orthophosphate |
| Definition | |
| <i>Chemical name</i> | Potassium dihydrogen phosphate Monopotassium dihydrogen orthophosphate Monopotassium dihydrogen monophosphate |
| Einecs | 231-913-4 |
| <i>Chemical formula</i> | KH_2PO_4 |
| <i>Molecular weight</i> | 136,09 |
| <i>Assay</i> | Content not less than 98,0 % after drying at 105 °C for four hours |
| <i>Description</i> | Odourless, colourless crystals or white granular or crystalline powder, hygroscopic |
| Identification | |
| A. Positive tests for potassium and for phosphate | |
| B. Solubility tests | Freely soluble in water. Insoluble in ethanol |

▼B

| | |
|---|---|
| C. P ₂ O ₅ content | Between 51,0 % and 53,0 % |
| Purity | |
| Loss on drying | Not more than 2,0 % determined by drying at 105 °C for four hours |
| Water-insoluble substances | Not more than 0,2 % on the anhydrous basis |
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |
| pH of a 1 % aqueous solution | Between 4,2 and 4,8 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| | |
| E 340 (ii) DIPOTASSIUM PHOSPHATE | |
| | |
| Synonyms | Dipotassium monophosphate Secondary potassium phosphate Dipotassium acid phosphate Dipotassium orthophosphate Dibasic potassium phosphate |
| | |
| Definition | |
| <i>Chemical name</i> | Dipotassium hydrogen monophosphate Dipotassium hydrogen phosphate Dipotassium hydrogen orthophosphate |
| | |
| Einecs | 231-834-5 |
| | |
| <i>Chemical formula</i> | K ₂ HPO ₄ |
| | |
| <i>Molecular weight</i> | 174,18 |
| | |
| <i>Assay</i> | Content not less than 98 % after drying at 105 °C for four hours |
| | |
| <i>Description</i> | Colourless or white granular powder, crystals or masses; deliquescent substance |
| | |
| Identification | |
| A. Positive tests for potassium and for phosphate | |
| B. Solubility tests | Freely soluble in water. Insoluble in ethanol |
| C. P ₂ O ₅ content | Between 40,3 % and 41,5 % |
| | |
| Purity | |
| Loss on drying | Not more than 2,0 % determined by drying at 105 °C for four hours |
| Water-insoluble substances | Not more than 0,2 % on the anhydrous basis |
| Fluoride | Not more than 10 mg/kg (expressed as fluorine) |
| pH of a 1 % aqueous solution | Between 8,7 and 9,4 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

▼B

E 340 (iii) TRIPOTASSIUM PHOSPHATE

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

E 341 (i) MONOCALCIUM PHOSPHATE

| | |
|-------------------------|---|
| Synonyms | Monobasic calcium phosphate Monocalcium orthophosphate |
| Definition | |
| <i>Chemical name</i> | Calcium dihydrogen phosphate |
| Einecs | 231-837-1 |
| <i>Chemical formula</i> | Anhydrous: $Ca(H_2PO_4)_2$ Monohydrate: $Ca(H_2PO_4)_2 \cdot H_2O$ |
| <i>Molecular weight</i> | 234,05 (anhydrous) 252,08 (monohydrate) |
| <i>Assay</i> | Content not less than 95 % on the dried basis |
| <i>Description</i> | Granular powder or white, deliquescent crystals or granules |

▼B

| | |
|---|--|
| Identification | |
| A. Positive tests for calcium and for phosphate | |
| B. P ₂ O ₅ content | Between 55,5 % and 61,1 % (anhydrous) |
| C. CaO content | Between 23,0 % and 27,5 % (anhydrous) Between 19,0 % and 24,8 % (monohydrate) |
| Purity | |
| Loss on drying | Not less than 14 % determined by drying at 105 °C for four hours (anhydrous) Not more than 17,5 % determined by drying at 60 °C for one hour, then at 105 °C for four hours (monohydrate) |
| Loss on ignition | Not more than 17,5 % after ignition at 800 °C ± 25 °C for 30 minutes (anhydrous) Not more than 25,0 % determined by drying at 105 °C for one hour, then ignite at 800 °C ± 25 °C for 30 minutes (monohydrate) |
| Fluoride | Not more than 30 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 341 (ii) DICALCIUM PHOSPHATE

| | |
|---|--|
| Synonyms | Dibasic calcium phosphate Dicalcium orthophosphate |
| Definition | |
| <i>Chemical name</i> | Calcium monohydrogen phosphate Calcium hydrogen orthophosphate Secondary calcium phosphate |
| Einecs | 231-826-1 |
| <i>Chemical formula</i> | Anhydrous: CaHPO ₄ Dihydrate: CaHPO ₄ ·2H ₂ O |
| <i>Molecular weight</i> | 136,06 (anhydrous) 172,09 (dihydrate) |
| <i>Assay</i> | 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 |
| <i>Description</i> | White crystals or granules, granular powder or powder |
| Identification | |
| A. Positive tests for calcium and for phosphate | |
| B. Solubility tests | Sparingly soluble in water. Insoluble in ethanol |
| C. P ₂ O ₅ content | Between 50,0 % and 52,5 % (anhydrous) |
| 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 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

▼B

| | |
|---|--|
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| E 341 (iii) TRICALCIUM PHOSPHATE | |
| Synonyms | Calcium phosphate, tribasic Calcium orthophosphate |
| Definition | |
| <i>Chemical name</i> | Tricalcium monophosphate |
| Einecs | 231-840-8 |
| <i>Chemical formula</i> | Ca ₃ (PO ₄) ₂ |
| <i>Molecular weight</i> | 310,17 |
| <i>Assay</i> | Not less than 90 % calculated on the ignited basis |
| <i>Description</i> | A white, odourless and tasteless powder which is stable in air |
| Identification | |
| A. Positive tests for calcium and for phosphate | |
| B. Solubility tests | Practically insoluble in water; insoluble in ethanol, soluble in dilute hydrochloric and nitric acid |
| C. P ₂ O ₅ content | Between 38,5 % and 48,0 % (anhydrous) |
| Purity | |
| Loss on ignition | Not more than 8 % after ignition at 800 °C ± 25 °C, to constant weight |
| Fluoride | Not more than 50 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| E 385 CALCIUM DISODIUM ETHYLENEDIAMINETETRAACETATE | |
| Synonyms | Calcium disodium EDTA Calcium disodium edetate |
| Definition | |
| <i>Chemical name</i> | N,N'-1,2-Ethanediybis [N-(carboxymethyl)-glycinate] [[4-)-O,O',O ^N ,O ^N]calciate(2)-disodium Calcium disodium ethylenediaminetetra acetate Calcium disodium (ethylenedinitrilo)tetra acetate |
| Einecs | 200-529-9 |
| <i>Chemical formula</i> | C ₁₀ H ₁₂ O ₈ CaN ₂ Na ₂ ·2H ₂ O |
| <i>Molecular weight</i> | 410,31 |
| <i>Assay</i> | Content not less than 97 % on the anhydrous basis |
| <i>Description</i> | White, odourless crystalline granules or white to nearly white powder, slightly hygroscopic |
| Identification | |
| A. Positive tests for sodium and for calcium | |
| B. Chelating activity to metal ions positive | |
| C. pH of a 1 % solution between 6,5 and 7,5 | |

▼B

| Purity | |
|----------------------|---------------------------------|
| Water content | 5 to 13 % (Karl Fischer method) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

▼M1

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

E 400 ALGINIC ACID

| | |
|---|---|
| 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 natural strains of various species of brown seaweeds (<i>Phaeophyceae</i>) |
| Einecs | 232-680-1 |
| <i>Chemical formula</i> | $(C_6H_8O_6)_n$ |
| <i>Molecular weight</i> | 10 000—600 000 (typical average) |
| <i>Assay</i> | 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 ₆ H ₈ O ₆) _n (calculated on equivalent weight basis of 200) |
| <i>Description</i> | Alginic acid occurs in filamentous, grainy, granular and powdered forms. It is a white to yellowish brown and nearly odourless |
| Identification | |
| A. Solubility | Insoluble in water and organic solvents, slowly soluble in solutions of sodium carbonate, sodium hydroxide and trisodium phosphate |
| B. 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 |
| C. 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 |
| D. 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 |
| Purity | |
| pH of a 3 % suspension | Between 2,0 and 3,5 |
| 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) | Not more than 2 % on the anhydrous basis insoluble matter |
| 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 |

▼M1

| | |
|------------------------|---------------------------------------|
| Heavy metals (as Pb) | Not more than 20 mg/kg |
| Total plate count | Not more than 5 000 colonies per gram |
| Yeast and moulds | Not more than 500 colonies per gram |
| <i>E. coli</i> | Negative in 5 g |
| <i>Salmonella</i> spp. | Negative in 10 g |

E 401 SODIUM ALGINATE**Definition**

| | |
|-------------------------|---|
| <i>Chemical name</i> | Sodium salt of alginic acid |
| <i>Chemical formula</i> | $(C_6H_7NaO_6)_n$ |
| <i>Molecular weight</i> | 10 000-600 000 (typical average) |
| <i>Assay</i> | 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) |
| <i>Description</i> | Nearly odourless, white to yellowish fibrous or granular powder |

Identification

- A. Positive test for sodium and alginic acid

Purity

| | |
|------------------------|--|
| Loss on drying | Not more than 15 % (105 °C, 4 hours) |
| Water-insoluble matter | Not more than 2 % 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 |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 20 mg/kg |
| Total plate count | Not more than 5 000 colonies per gram |
| Yeast and moulds | Not more than 500 colonies per gram |
| <i>E. coli</i> | Negative in 5 g |
| <i>Salmonella</i> spp. | Negative in 10 g |

E 402 POTASSIUM ALGINATE**Definition**

| | |
|-------------------------|---|
| <i>Chemical name</i> | Potassium salt of alginic acid |
| <i>Chemical formula</i> | $(C_6H_7KO_6)_n$ |
| <i>Molecular weight</i> | 10 000-600 000 (typical average) |
| <i>Assay</i> | 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) |
| <i>Description</i> | Nearly odourless, white to yellowish fibrous or granular powder |

Identification

- A. Positive test for potassium and for alginic acid

▼M1

| | |
|------------------------|--|
| Purity | |
| Loss on drying | Not more than 15 % (105 °C, 4 hours) |
| Water-insoluble matter | Not more than 2 % 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 |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 20 mg/kg |
| Total plate count | Not more than 5 000 colonies per gram |
| Yeast and moulds | Not more than 500 colonies per gram |
| <i>E. coli</i> | Negative in 5 g |
| <i>Salmonella</i> spp. | Negative in 10 g |

E 403 AMMONIUM ALGINATE**Definition**

| | |
|-------------------------|---|
| <i>Chemical name</i> | Ammonium salt of alginic acid |
| <i>Chemical formula</i> | (C ₆ H ₁₁ NO ₆) _n |
| <i>Molecular weight</i> | 10 000-600 000 (typical average) |
| <i>Assay</i> | 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) |
| <i>Description</i> | White to yellowish fibrous or granular powder |

Identification

A. Positive test for ammonium and alginic acid

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 |
| 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 |
| Heavy metals | Not more than 20 mg/kg |
| Total plate count | Not more than 5 000 colonies per gram |
| Yeast and moulds | Not more than 500 colonies per gram |
| <i>E. coli</i> | Negative in 5 g |
| <i>Salmonella</i> spp. | Negative in 10 g |

E 404 CALCIUM ALGINATE**Synonyms**

Calcium salt of alginate

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| Definition | |
| <i>Chemical name</i> | Calcium salt of alginic acid |
| <i>Chemical formula</i> | $(C_6H_7Ca_{1/2}O_6)_n$ |
| <i>Molecular weight</i> | 10 000-600 000 (typical average) |
| <i>Assay</i> | 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) |
| <i>Description</i> | Nearly odourless, white to yellowish fibrous or granular powder |
| Identification | |
| A. Positive test for calcium and alginic acid | |
| Purity | |
| Loss on drying | Not more than 15,0 % (105 °C, 4 hours) |
| 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 |
| Heavy metals (as Pb) | Not more than 20 mg/kg |
| Total plate count | Not more than 5 000 colonies per gram |
| Yeast and moulds | Not more than 500 colonies per gram |
| <i>E. coli</i> | Negative in 5 g |
| <i>Salmonella</i> spp. | Negative in 10 g |

E 405 PROPANE-1,2-DIOL ALGINATE

| | |
|--|--|
| Synonyms | Hydroxypropyl alginate 1,2-propanediol ester of alginic acid Propylene glycol alginate |
| Definition | |
| <i>Chemical name</i> | Propane-1,2-diol 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 |
| <i>Chemical formula</i> | $(C_9H_{14}O_7)_n$ (esterified) |
| <i>Molecular weight</i> | 10 000—600 000 (typical average) |
| <i>Assay</i> | Yields, on the anhydrous basis, not less than 16 % and not more than 20 % of CO ₂ of carbon dioxide |
| <i>Description</i> | Nearly odourless, white to yellowish brown fibrous or granular powder |
| Identification | |
| A. Positive test for 1,2-propanediol and alginic acid 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 |

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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 |
| Heavy metals (as Pb) | Not more than 20 mg/kg |
| Total plate count | Not more than 5 000 colonies per gram |
| Yeast and moulds | Not more than 500 colonies per gram |
| <i>E. coli</i> | Negative in 5 g |
| <i>Salmonella</i> spp. | Negative in 10 g |

E 406 AGAR**Synonyms**

Gelose
Japan agar
Bengal, Ceylon, Chinese or Japanese isinglass
Layor Carang

Definition*Chemical name*

Agar is a hydrophilic colloidal polysaccharide consisting mainly of D-galactose units. 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 natural strains of marine algae of the families *Gelidiaceae* and *Sphaerococcaceae* and related red algae of the class *Rhodophyceae*

Einecs

232-658-1

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, the agar appears granular and somewhat filamentous. A few fragments of the spicules of sponges and a few frustules of diatoms may be present. 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

Identification

A. 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 (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

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| 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 |
| Heavy metals (as Pb) | Not more than 20 mg/kg |

E 407 CARRAGEENAN**Synonyms**

Products of commerce are sold under different names such as:

- Irish moss gelose
- Eucheuman (from *Eucheuma* spp.)
- Iridophycan (from *Irididaea* spp.)
- Hypnean (from *Hypnea* spp.)
- Furcellaran or Danish agar (from *Furcellaria fastigiata*)
- Carrageenan (from *Chondrus* and *Gigartina* spp.)

Definition

Carrageenan is obtained by aqueous extraction of natural strains of seaweeds of *Gigartinaceae*, *Solieriaceae*, *Hypneaceae* and *Furcellariaceae*, families of the class *Rhodophyceae* (red seaweeds). No organic precipitant shall be used other than methanol, ethanol and propane-2-ol. Carrageenan consists chiefly of the potassium, sodium, magnesium and calcium salts of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3,6-anhydrogalactose. Carrageenan shall not be hydrolysed or otherwise chemically degraded

Einecs

232-524-2

Description

Yellowish to colourless, coarse to fine powder which is practically odourless

Identification

- A. Positive tests for galactose, for anhydrogalactose and for sulphate

Purity

| | |
|--|--|
| Methanol, ethanol propane-2-ol content | Not more than 0,1 % singly or in combination |
| Viscosity of a 1,5 % solution at 75 °C | Not less than 5 mPa.s |
| Loss on drying | Not more than 12 % (105 °C, 4 hours) |
| Sulphate | Not less than 15 % and not more than 40 % on the anhydrous basis (as SO ₄) |
| Ash | Not less than 15 % and not more than 40 % determined on the anhydrous basis at 550 °C |
| Acid-insoluble ash | Not more than 1 % on the anhydrous basis (insoluble in 10 % hydrochloric acid) |
| Acid-insoluble matter | Not more than 2 % on the anhydrous basis (insoluble in 1 % v/v sulphuric acid) |
| 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 |
| Heavy metals (as Pb) | Not more than 20 mg/kg |
| 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 |
| <i>E. coli</i> | Negative in 5 g |
| <i>Salmonella</i> spp. | Negative in 10 g |
| E 407a PROCESSED EUCHEUMA SEAWEED | |
| Synonyms | PES (acronym for processed eucheuma seaweed) |
| Definition | Processed eucheuma seaweed is obtained by aqueous alkaline (KOH) treatment of the natural strains of seaweeds <i>Eucheuma cottonii</i> and <i>Eucheuma spinosum</i> , of the class <i>Rhodophyceae</i> (red seaweeds) to remove impurities and by fresh water washing and drying to obtain the product. Further purification may be achieved by washing with methanol, ethanol or propane-2-ol and drying. The product consists chiefly of the potassium salts of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3,6-anhydrogalactose. Sodium, calcium and magnesium salts of the polysaccharide sulphate esters are present in lesser amounts. Up to 15 % algal cellulose is also present in the product. The carrageenan in processed eucheuma seaweed shall not be hydrolysed or otherwise chemically degraded |
| <i>Description</i> | Tan to yellowish, coarse to fine powder which is practically odourless |
| Identification | |
| A. Positive tests for galactose, for anhydrogalactose and for sulphate | |
| B. Solubility | Forms cloudy viscous suspensions in water. Insoluble in ethanol |
| Purity | |
| Methanol, ethanol, propane-2-ol content | Not more than 0,1 % singly or in combination |
| Viscosity of a 1,5 % solution at 75 °C | Not less than 5 mPa.s |
| 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 1 % 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) |
| 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 |
| Heavy metals (as Pb) | Not more than 20 mg/kg |
| Total plate count | Not more than 5 000 colonies per gram |
| Yeast and mould | Not more than 300 colonies per gram |
| <i>E. coli</i> | Negative in 5 g |
| <i>Salmonella</i> spp. | Negative in 10 g |

E 410 LOCUST BEAN GUM

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| Synonyms | Carob bean gum Algaroba gum |
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| Definition | Locust bean gum is the ground endosperm of the seeds of the natural strains of carob tree, <i>Ceratonia siliqua</i> (L.) Taub. (family <i>Leguminosae</i>). 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 |
| <i>Molecular weight</i> | 50 000—3 000 000 |
| Einecs | 232-541-5 |
| <i>Assay</i> | Galactomannan content not less than 75 % |
| <i>Description</i> | White to yellowish-white, nearly odourless powder |
| Identification | |
| A. Positive tests for galactose mannose | |
| B. 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 in guar gum. Guar gum shows close groups of round to pear shaped cells. Their contents are yellow to brown |
| C. 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 20 mg/kg |
| Ethanol and propane-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 natural strains of the guar plant, <i>Cyamopsis tetragonolobus</i> (L.) Taub. (family <i>Leguminosae</i>). 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 | 232-536-0 |
| <i>Molecular weight</i> | 50 000—8 000 000 |
| <i>Assay</i> | Galactomannan content not less than 75 % |
| <i>Description</i> | A white to yellowish-white, nearly odourless powder |
| Identification | |
| A. Positive tests for galactose and for mannose | |
| B. Solubility | Soluble in cold water |

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|------------------------------|--|
| Purity | |
| Loss on drying | Not more than 15 % (105 °C, 5 hours) |
| Ash | Not more than 1,5 % determined at 800 °C |
| Acid-insoluble matter | Not more than 7 % |
| Protein (N × 6,25) | Not more than 10 % |
| 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 20 mg/kg |
| E 413 TRAGACANTH | |
| Synonyms | Tragacanth gum Tragant |
| Definition | Tragacanth is a dried exudation obtained from the stems and branches of natural strains of <i>Astragalus gummifer</i> Labillardiere and other Asiatic species of <i>Astragalus</i> (family <i>Leguminosae</i>). 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 |
| <i>Molecular weight</i> | Approximately 8 000 000 |
| Einecs | 232-252-5 |
| <i>Description</i> | 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 | |
| A. 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 | |
| Negative test for Karaya gum | 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 20 mg/kg |

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| <i>Salmonella</i> spp. | Negative in 10 g |
| <i>E. coli</i> | Negative in 5 g |
| E 414 ACACIA GUM | |
| Synonyms | Gum arabic |
| Definition | Acacia gum is a dried exudation obtained from the stems and branches of natural strains of <i>Acacia senegal</i> (L) Willdenow or closely related species of <i>Acacia</i> (family <i>Leguminosae</i>). 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 |
| <i>Molecular weight</i> | Approximately 350 000 |
| Einecs | 232-519-5 |
| <i>Description</i> | 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 | |
| A. 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 ₂ O 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 20 mg/kg |
| Hydrolysis products | Mannose, xylose and galacturonic acid are absent (determined by chromatography) |
| <i>Salmonella</i> spp. | Negative in 10 g |
| <i>E. coli</i> | Negative in 5 g |

E 415 XANTHAN GUM

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| Definition | Xanthan gum is a high molecular weight polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with natural strains of <i>Xanthomonas campestris</i> , 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 |
| <i>Molecular weight</i> | Approximately 1 000 000 |

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| Einecs | 234-394-2 |
| <i>Assay</i> | 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 |
| <i>Description</i> | Cream-coloured powder |
| Identification | |
| A. Solubility | Soluble in water. Insoluble in ethanol |
| Purity | |
| Loss on drying | Not more than 15 % (105 °C, 2½ 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 % |
| Propane-2-ol | Not more than 500 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 |
| Heavy metals (as Pb) | Not more than 20 mg/kg |
| Total plate count | Not more than 10 000 colonies per gram |
| Yeast and mould | Not more than 300 colonies per gram |
| <i>E. coli</i> | Negative in 5 g |
| <i>Salmonella</i> spp. | Negative in 10 g |
| <i>Xanthomonas campestris</i> | Viable cells absent |

E 416 KARAYA-GUM

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|---------------------------------|--|
| Synonyms | Katilo Kadaya Gum <i>sterculia</i> <i>Sterculia</i> Karaya, gum karaya Kullo Kuterra |
| Definition | Karaya gum is a dried exudation from the stems and branches of natural strains of: <i>Sterculia urens</i> Roxburgh and other species of <i>Sterculia</i> (family <i>Sterculiaceae</i>) or from <i>Cochlospermum gossypium</i> A.P. De Candolle or other species of <i>Cochlospermum</i> (family <i>Bixaceae</i>). 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 |
| <i>Description</i> | 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 | |
| A. Solubility | Insoluble in ethanol |
| B. Swelling in ethanol solution | Karaya gum swells in 60 % ethanol distinguishing it from other gums |

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| Purity | |
|------------------------|--------------------------------------|
| Loss on drying | Not more than 20 % (105 °C, 5 hours) |
| 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 20 mg/kg |
| <i>Salmonella</i> spp. | Negative in 10 g |
| <i>E. coli</i> | Negative in 5 g |

E 417 TARA GUM

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|-----------------------|---|
| Definition | Tara gum is obtained by grinding the endosperm of the seeds of natural strains of <i>Caesalpinia spinosa</i> (family <i>Leguminosae</i>). 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 |
| <i>Description</i> | A white to white-yellow odourless powder |
| Identification | |
| A. Solubility | Soluble in water Insoluble in ethanol |
| B. 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 20 mg/kg |

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E 418 GELLAN GUM

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| Definition | Gellan gum is a high molecular weight polysaccharide gum produced by a pure culture fermentation of a carbohydrate by natural strains of <i>Pseudomonas elodea</i> , purified by recovery with isopropyl alcohol, 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 |
| <i>Molecular weight</i> | Approximately 500 000 |
| <i>Assay</i> | Yields, on the dried basis, not less than 3,3 % and not more than 6,8 % of CO ₂ |
| <i>Description</i> | An off-white powder |
| Identification | |
| A. Solubility | Soluble in water, forming a viscous solution. Insoluble in ethanol |
| Purity | |
| Loss on drying | Not more than 15 % after drying (105 °C, 2½ hours) |
| Nitrogen | Not more than 3 % |
| Propane-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 |
| Heavy metals (as Pb) | Not more than 20 mg/kg |
| Total plate count | Not more than 10 000 colonies per gram |
| Yeast and mould | Not more than 400 colonies per gram |
| <i>E. coli</i> | Negative in 5 g |
| <i>Salmonella</i> spp. | Negative in 10 g |

E 422 GLYCEROL

| | |
|-------------------------|---|
| Synonyms | Glycerin Glycerine |
| Definition | |
| <i>Chemical names</i> | 1,2,3-propanetriol Glycerol Trihydroxypropane |
| Einecs | 200-289-5 |
| <i>Chemical formula</i> | C ₃ H ₈ O ₃ |
| <i>Molecular weight</i> | 92,10 |
| <i>Assay</i> | Content not less than 98 % of glycerol on the anhydrous basis |
| <i>Description</i> | Clear, colourless hygroscopic syrupy liquid with not more than a slight characteristic odour, which is neither harsh nor disagreeable |

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| Identification | |
| A. Acrolein formation on heating | Heat a few drops of the sample in a test tube with about 0,5 g of potassium bisulphate. The characteristic pungent vapours of acrolein are evolved |
| B. Specific gravity (25/25 °C) | Not less than 1,257 |
| C. Refractive index [n] _D ²⁰ | Between 1,471 and 1,474 |
| Purity | |
| Water | 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, glucose and ammonium compounds | Heat a mixture of 5 ml of glycerol and 5 ml of potassium hydroxide solution (1 in 10) at 60 °C for five minutes. It neither becomes yellow nor emits an odour of ammonia |
| Fatty acids and esters | Not more than 0,1 % calculated as butyric acid |
| Chlorinated compounds | Not more than 30 mg/kg (as chlorine) |
| 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 |
| Heavy metals (as Pb) | Not more than 5 mg/kg |

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 |
| <i>Assay</i> | Content not less than 97,5 % on the anhydrous basis |
| <i>Description</i> | Cream-coloured flakes or waxy solid at 25 °C with a faint odour |
| Identification | |
| A. Solubility | Soluble in water, ethanol, methanol and ethyl acetate Insoluble in mineral oil |
| B. Congealing range | 39-44 °C |
| C. Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyoxyethylated polyol |
| Purity | |
| Water | 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 |
| Free ethylene oxide | Not more than 1 mg/kg |
| Ethylene glycols (mono- and di-) | Not more than 0,25 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

▼M1

| | |
|----------------------|------------------------|
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 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 |
| <i>Assay</i> | Content not less than 70 % of oxyethylene groups, equivalent to not less than 97,3 % of polyoxyethylene (20) sorbitan monolaurate on the anhydrous basis |
| <i>Description</i> | A lemon to amber-coloured oily liquid at 25 °C with a faint characteristic odour |
| Identification | |
| A. Solubility | Soluble in water, ethanol, methanol, ethyl acetate and dioxane. Insoluble in mineral oil and petroleum ether |
| B. Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyoxyethylated polyol |
| Purity | |
| Water | 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 |
| Free ethylene oxide | Not more than 1 mg/kg |
| Ethylene glycols (mono- and di-) | Not more than 0,25 % |
| 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 |
| Heavy metals (as Pb) | Not more than 10 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 |
| <i>Assay</i> | Content not less than 65 % of oxyethylene groups, equivalent to not less than 96,5 % of polyoxyethylene (20) sorbitan monooleate on the anhydrous basis |
| <i>Description</i> | A lemon to amber-coloured oily liquid at 25 °C with a faint characteristic odour |
| Identification | |
| A. Solubility | Soluble in water, ethanol, methanol, ethyl acetate and toluene. Insoluble in mineral oil and petroleum ether |
| B. Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyoxyethylated polyol |

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| | |
|----------------------------------|---|
| Purity | |
| Water | 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 |
| Free ethylene oxide | Not more than 1 mg/kg |
| Ethylene glycols (mono- and di-) | Not more than 0,25 % |
| 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 |
| Heavy metals (as Pb) | Not more than 10 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 |
| <i>Assay</i> | Content not less than 66 % of oxyethylene groups, equivalent to not less than 97 % of polyoxyethylene (20) sorbitan monopalmitate on the anhydrous basis |
| <i>Description</i> | A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour |
| Identification | |
| A. Solubility | Soluble in water, ethanol, methanol, ethyl acetate and acetone. Insoluble in mineral oil |
| B. Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyoxyethylated polyol |
| Purity | |
| Water | 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 |
| Free ethylene oxide | Not more than 1 mg/kg |
| Ethylene glycols (mono- and di-) | Not more than 0,25 % |
| 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 |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

▼M1

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 |
| <i>Assay</i> | Content not less than 65 % of oxyethylene groups, equivalent to not less than 97 % of polyoxyethylene (20) sorbitan monostearate on the anhydrous basis |
| <i>Description</i> | A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour |
| Identification | |
| A. Solubility | Soluble in water, ethyl acetate and toluene. Insoluble in mineral oil and vegetable oils |
| B. Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyoxyethylated polyol |
| Purity | |
| Water | 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 |
| Free ethylene oxide | Not more than 1 mg/kg |
| Ethylene glycols (mono- and di-) | Not more than 0,25 % |
| 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 |
| Heavy metals (as Pb) | Not more than 10 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 |
| <i>Assay</i> | Content not less than 46 % of oxyethylene groups, equivalent to not less than 96 % of polyoxyethylene (20) sorbitan tristearate on the anhydrous basis |
| <i>Description</i> | A tan-coloured, waxy solid at 25 °C with a faint characteristic odour |
| Identification | |
| A. Solubility | Dispersible in water. Soluble in mineral oil, vegetable oils, petroleum ether, acetone, ether, dioxane, ethanol and methanol |
| B. Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyoxyethylated polyol |
| C. Congealing range | 29-33 °C |
| Purity | |
| Water | Not more than 3 % (Karl Fischer method) |

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| | |
|----------------------------------|---------------------------------------|
| 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 |
| Free ethylene oxide | Not more than 1 mg/kg |
| Ethylene glycols (mono- and di-) | Not more than 0,25 % |
| 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 |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 440 (i) PECTIN**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 natural strains of appropriate edible plant material, usually citrus fruits or apples. No organic precipitant shall be used other than methanol, ethanol and propane-2-ol

Einecs

232-553-0

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

A. 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

Free methanol, ethanol and propane-2-ol

Not more than 1 %, singly or in combination, 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

Cadmium

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 20 mg/kg

E 440 (ii) AMIDATED PECTIN**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 natural 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 propane-2-ol

▼M1

| | |
|---|---|
| <i>Assay</i> | Content not less than 65 % of galacturonic acid on the ash-free and anhydrous basis after washing with acid and alcohol |
| <i>Description</i> | White, light yellow, light greyish or light brownish powder |
| Identification | |
| A. 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 |
| Free methanol, ethanol and propane-2-ol | Not more than 1 % single 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 |
| Heavy metals (as Pb) | Not more than 20 mg/kg |

E 442 AMMONIUM PHOSPHATIDES

| | |
|--|--|
| Synonyms | Ammonium salts of phosphatidic acid, mixed ammonium salts of phosphorylated glycerides |
| Definition | A mixture of the ammonium compounds of phosphatidic acids derived from edible fat and oil (usually partially hardened rapeseed oil). One or two or three glyceride moieties may be attached to phosphorus. Moreover, two phosphorus esters may be linked together as phosphatidyl phosphatides |
| <i>Assay</i> | 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) |
| <i>Description</i> | Unctuous semi-solid |
| Identification | |
| A. Solubility | Soluble in fats. Insoluble in water. Partially soluble in ethanol and in acetone |
| B. Positive tests for glycerol, for fatty acid and for phosphate | |
| Purity | |
| Petroleum ether insoluble matter | Not more than 2,5 % |
| 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 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

▼M1

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 |
| <i>Chemical name</i> | Sucrose diacetate hexaisobutyrate |
| <i>Chemical formulae</i> | $C_{40}H_{62}O_{19}$ |
| <i>Molecular weight</i> | 832-856 (approximate), $C_{40}H_{62}O_{19}$: 846,9 |
| <i>Assay</i> | Content not less than 98,8 % and not more than 101,9 % of $C_{40}H_{62}O_{19}$ |
| <i>Description</i> | A pale straw-coloured liquid, clear and free of sediment and having a bland odour |
| Identification | |
| A. Solubility | Insoluble in water. Soluble in most organic solvents |
| B. Refractive index | $[n]_D^{40}$: 1,4492 - 1,4504 |
| C. Specific gravity | $[d]_D^{25}$: 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 |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 3 mg/kg |
| Heavy metals (as Pb) | Not more than 5 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) 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 |
| <i>Description</i> | Hard, yellow to pale amber-coloured solid |
| Identification | |
| A. Solubility | Insoluble in water, soluble in acetone |
| B. Infrared absorption spectrum | Characteristic of the compound |

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| | |
|---|---|
| Purity | |
| Specific gravity of solution | $[d]_{25}^{20}$ not less than 0,935 when determined in a 50 % solution in d-limonene (97 %, boiling point 175,5-176 °C, d_{4}^{20} : 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 |
| Heavy metals (as Pb) | Not more than 10 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

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|--|--|
| Synonyms | Disodium dihydrogen diphosphate Disodium dihydrogen pyrophosphate Sodium acid pyrophosphate |
| Definition | |
| <i>Chemical name</i> | Disodium dihydrogen diphosphate |
| Einecs | |
| 231-835-0 | |
| <i>Chemical formula</i> | $\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$ |
| <i>Molecular weight</i> | 221,94 |
| <i>Assay</i> | Content not less than 95 % of disodium diphosphate and not less than 63 % and not more than 64,5 % expressed as P_2O_5 |
| <i>Description</i> | White powder or grains |
| Identification | |
| A. Positive tests for sodium and for phosphate | |
| B. Solubility | Soluble in water |
| Purity | |
| pH of a 1 % solution | Between 3,7 and 5,0 |
| 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 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 20 mg/kg |

▼M1

E 450 (ii) TRISODIUM DIPHOSPHATE

| | |
|--|---|
| Synonyms | Acid trisodium pyrophosphate Trisodium monohydrogen diphosphate |
| Definition | |
| Einecs | 238-735-6 |
| <i>Chemical formula</i> | Monohydrate: $\text{Na}_3\text{HP}_2\text{O}_7 \cdot \text{H}_2\text{O}$ Anhydrous: $\text{Na}_3\text{HP}_2\text{O}_7$ |
| <i>Molecular weight</i> | Monohydrate: 261,95 Anhydrous: 243,93 |
| <i>Assay</i> | Content not less than 95 % on the anhydrous basis and not less than 57 % and not more than 59 % expressed as P_2O_5 |
| <i>Description</i> | White powder or grains, occurs anhydrous or as a monohydrate |
| Identification | |
| A. Positive tests for sodium and for phosphate | |
| B. Soluble in water | |
| Purity | |
| pH of a 1 % solution | Between 6,7 and 7,3 |
| Loss on ignition | 4,5 % on the anhydrous compound 11,5 % on the monohydrated basis |
| Loss on drying | Not more than 0,5 % (105 °C, 4 hours) |
| Water-insoluble matter | Not more than 0,2 % |
| Fluoride | Not more than 10 mg/kg expressed as fluorine |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 20 mg/kg |

E 450 (iii) TETRASODIUM DIPHOSPHATE

| | |
|-------------------------|--|
| Synonyms | Tetrasodium pyrophosphate Sodium pyrophosphate |
| Definition | |
| <i>Chemical name</i> | Tetrasodium diphosphate |
| Einecs | |
| 231-767-1 | |
| <i>Chemical formula</i> | Anhydrous: $\text{Na}_4\text{P}_2\text{O}_7$ Decahydrate: $\text{Na}_4\text{P}_2\text{O}_7 \cdot 10 \text{H}_2\text{O}$ |
| <i>Molecular weight</i> | Anhydrous: 265,94 Decahydrate: 446,09 |
| <i>Assay</i> | Content not less than 95 % of $\text{Na}_4\text{P}_2\text{O}_7$, in the ignited basis and not less than 52,5 % and not more than 54 % expressed as P_2O_5 |

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|--|--|
| <i>Description</i> | Colourless or white crystals, or a white crystalline or granular powder. The decahydrate effloresces slightly in dry air |
| Identification | |
| A. Positive tests for sodium and for phosphate | |
| B. Solubility | Soluble in water. Insoluble in ethanol |
| Purity | |
| pH of a 1 % solution | Between 9,8 and 10,8 |
| Loss on ignition | Not more than 0,5 % for the anhydrous salt, not less than 38 % and not more than 42 % for the decahydrate, in both cases determined after drying at 105 °C for four hours, followed by ignition at 550 °C for 30 minutes |
| Water-insoluble matter | Not more than 0,2 % |
| Fluoride | Not more than 10 mg/kg expressed as fluorine |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 20 mg/kg |

E 450 (v) TETRAPOTASSIUM DIPHOSPHATE

| | |
|---|---|
| Synonyms | Potassium pyrophosphate Tetrapotassium pyrophosphate |
| Definition | |
| <i>Chemical name</i> | Tetrapotassium diphosphate |
| Einecs | 230-785-7 |
| <i>Chemical formula</i> | $K_4P_2O_7$ |
| <i>Molecular weight</i> | 330,34 (anhydrous) |
| <i>Assay</i> | Content not less than 95 % on the ignited basis and not less than 42 % and not more than 43,7 % expressed as P_2O_5 |
| <i>Description</i> | Colourless crystals or white, very hygroscopic powder |
| Identification | |
| A. Positive tests for potassium and for phosphate | |
| B. Solubility | Soluble in water, insoluble in ethanol |
| Purity | |
| pH of a 1 % solution | Between 10,0 and 10,8 |
| Loss on ignition | Not more than 2 % after drying at 105 °C for 4 hours then ignition at 550 °C for 30 minutes |
| Water-insoluble matter | Not more than 0,2 % |
| Fluoride | Not more than 10 mg/kg expressed as fluorine |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 20 mg/kg |

▼M1

E 450 (vi) DICALCIUM DIPHOSPHATE

| | |
|---|---|
| Synonyms | Calcium pyrophosphate |
| Definition | |
| <i>Chemical name</i> | Dicalcium diphosphate Dicalcium pyrophosphate |
| Einecs | 232-221-5 |
| <i>Chemical formula</i> | Ca ₂ P ₂ O ₇ |
| <i>Molecular weight</i> | 254,12 |
| <i>Assay</i> | Content not less than 96 % and not less than 55 % and not more than 56 % expressed as P ₂ O ₅ |
| <i>Description</i> | A fine, white, odourless powder |
| Identification | |
| A. Positive tests for calcium and for phosphate | |
| B. Solubility | Insoluble in water. Soluble in dilute hydrochloric and nitric acids |
| Purity | |
| pH of a 10 % suspension in water | Between 5,5 and 7,0 |
| Loss on ignition | Not more than 1,5 % at 800 ± 25 °C for 30 minutes |
| Fluoride | Not more than 50 mg/kg expressed as fluorine |
| 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 |
| Heavy metals (as Pb) | Not more than 20 mg/kg |

E 450 (vii) CALCIUM DIHYDROGEN DIPHOSPHATE

| | |
|---|--|
| Synonyms | Acid calcium pyrophosphate Monocalcium dihydrogen pyrophosphate |
| Definition | |
| <i>Chemical name</i> | Calcium dihydrogen diphosphate |
| Einecs | 238-933-2 |
| <i>Chemical formula</i> | CaH ₂ P ₂ O ₇ |
| <i>Molecular weight</i> | 215,97 |
| <i>Assay</i> | Content not less than 90 % on the anhydrous basis and not less than 61 % and not more than 64 % expressed as P ₂ O ₅ |
| <i>Description</i> | White crystals or powder |
| Identification | |
| A. Positive tests for calcium and for phosphate | |
| Purity | |
| Acid-insoluble matter | Not more than 0,4 % |
| Fluoride | Not more than 30 mg/kg expressed as fluorine |
| Arsenic | Not more than 3 mg/kg |

▼M1

| | |
|----------------------|------------------------|
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 20 mg/kg |

E 451 (i) PENTASODIUM TRIPHOSPHATE

| | |
|--|--|
| Synonyms | Pentasodium tripolyphosphate Sodium tripolyphosphate |
| Definition | |
| <i>Chemical name</i> | Pentasodium triphosphate |
| Einecs | 231-838-7 |
| <i>Chemical formulae</i> | Na ₅ O ₁₀ P ₃ ·xH ₂ O (x = 0 or 6) |
| <i>Molecular weight</i> | 367,86 |
| <i>Assay</i> | Content not less than 85 % Content in P ₂ O ₅ not less than 56 % and not more than 58 % (anhydrous) or not less than 43 % and not more than 45 % (hexahydrate) |
| <i>Description</i> | White, slightly hygroscopic granules or powder |
| Identification | |
| A. Solubility | Freely soluble in water. Insoluble in ethanol |
| B. Positive tests for sodium and for phosphate | |
| C. pH of a 1 % solution | Between 9,1 and 10,2 |
| Purity | |
| Loss on drying | Anhydrous: Not more than 0,7 % (105 °C, 1 hour) Hexahydrate: Not more than 23,5 % (60 °C, 1 hour, followed by drying at 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 |
| 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 |
| Heavy metals (as Pb) | Not more than 20 mg/kg |

E 451 (ii) PENTAPOTASSIUM TRIPHOSPHATE

| | |
|--------------------------|---|
| <i>Synonyms</i> | Pentapotassium tripolyphosphate Potassium triphosphate Potassium tripolyphosphate |
| Definition | |
| <i>Chemical name</i> | Pentapotassium triphosphate Pentapotassium tripolyphosphate |
| Einecs | 237-574-9 |
| <i>Chemical formulae</i> | K ₅ O ₁₀ P ₃ |
| <i>Molecular weight</i> | 448,42 |

▼M1

| | |
|---|---|
| <i>Assay</i> | Content not less than 85 % on the dried basis Content in P ₂ O ₅ not less than 46,5 % and not more than 48 % |
| <i>Description</i> | White, hygroscopic powder or granules |
| Identification | |
| A. Solubility | Very soluble in water |
| B. Positive tests for potassium and for phosphate | |
| C. pH of a 1 % solution | Between 9,2 and 10,5 |
| Purity | |
| Loss on ignition | Not more than 0,4 % (105 °C, 4 hours, followed by ignition at 550 °C, 30 minutes) |
| Water insoluble matter | Not more than 2 % |
| 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 |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 20 mg/kg |

E 452 (i) SODIUM POLYPHOSPHATE

1. SOLUBLE POLYPHOSPHATE

| | |
|--|--|
| Synonyms | Sodium hexametaphosphate Sodium tetrapolyphosphate Graham's salt Sodium polyphosphates, glassy Sodium polymetaphosphate Sodium metaphosphate |
| Definition | Soluble sodium polyphosphates are obtained by fusion and subsequent chilling of sodium orthophosphates. These compounds are a class consisting of several amorphous, water-soluble polyphosphates composed of linear chains of metaphosphate units, (NaPO ₃) _x where x ≥ 2, terminated by Na ₂ PO ₄ groups. These substances are usually identified by their Na ₂ O/P ₂ O ₅ ratio or their P ₂ O ₅ content. The Na ₂ O/P ₂ O ₅ ratios vary from about 1,3 for sodium tetrapolyphosphate, where x = approximately 4; to about 1,1 for Graham's salt, commonly called sodium hexametaphosphate, where x = 13 to 18; and to about 1,0 for the higher molecular weight sodium polyphosphates, where x = 20 to 100 or more. The pH of their solutions varies between 3,0 and 9,0 |
| <i>Chemical name</i> | Sodium polyphosphate |
| Einecs | 272-808-3 |
| <i>Chemical formulae</i> | Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula H _(n+2) P _n O _(3n+1) where 'n' is not less than 2 |
| <i>Molecular weight</i> | (102) _n |
| <i>Assay</i> | Content in P ₂ O ₅ not less than 60 % and not more than 71 % on the ignited basis |
| <i>Description</i> | Colourless or white, transparent platelets, granules, or powders |
| Identification | |
| A. Solubility | Very soluble in water |
| B. Positive tests for sodium and for phosphate | |
| C. pH of a 1 % solution | Between 3,0 and 9,0 |

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| | |
|--|--|
| Purity | |
| Loss on ignition | Not more than 1 % |
| Water insoluble matter | Not more than 0,1 % |
| 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 |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| 2. INSOLUBLE POLYPHOSPHATE | |
| Synonyms | Insoluble sodium metaphosphateMaddrell'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 ₂ O/P ₂ O ₅ ratio is about 1,0. The pH of 1 in 3 suspension in water is about 6,5 |
| <i>Chemical name</i> | Sodium polyphosphate |
| Einecs | 272-808-3 |
| <i>Chemical formulae</i> | Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula H _(n+2) P _n O _(3n+1) where 'n' is not less than 2 |
| <i>Molecular weight</i> | (102) _n |
| <i>Assay</i> | Not less than 68,7 % and not more than 70 % of P ₂ O ₅ |
| <i>Description</i> | White crystalline powder |
| Identification | |
| A. Solubility | Insoluble in water, soluble in mineral acids and in solutions of potassium and ammonium (but not sodium) chlorides |
| B. Positive tests for sodium and for phosphate | |
| C. pH of a 1 in 3 suspension in water | About 6,5 |
| Purity | |
| 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 |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| E 452 (ii) POTASSIUM POLYPHOSPHATE | |
| Synonyms | Potassium metaphosphate Potassium polymetaphosphate Kurrol salt |
| Definition | |
| <i>Chemical name</i> | Potassium polyphosphate |
| Einecs | 232-212-6 |

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| | |
|---|---|
| <i>Chemical formulae</i> | (KPO ₃) _n Heterogenous mixtures of potassium salts of linear condensed polyphosphoric acids of general formula H _(n + 2) P _n O _(3n + 1) where 'n' is not less than 2 |
| <i>Molecular weight</i> | (134) _n |
| <i>Assay</i> | Content in P ₂ O ₅ not less than 53,5 % and not more than 61,5 % on the ignited basis |
| <i>Description</i> | Fine white powder or crystals or colourless glassy platelets |
| Identification | |
| A. Solubility | 1 g dissolves in 100 ml of a 1 in 25 solution of sodium acetate |
| B. Positive tests for potassium and for phosphate | |
| C. pH of a 1 % solution | Not more than 7,8 |
| Purity | |
| Loss on ignition | Not more than 2 % (105 °C, 4 hours followed by ignition at 550 °C, 30 minutes) |
| Water insoluble matter | Not more than 0,2 % |
| Cyclic phosphate | Not more than 8 % on P ₂ O ₅ content |
| 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 |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 20 mg/kg |

E 452 (iv) CALCIUM POLYPHOSPHATES

| | |
|---|--|
| Synonyms | Calcium metaphosphate Calcium polymetaphosphate |
| Definition | |
| <i>Chemical name</i> | Calcium polyphosphate |
| Einecs | 236-769-6 |
| <i>Chemical formulae</i> | (CaP ₂ O ₆) _n A heterogeneous mixture of calcium salts of condensed polyphosphoric acids of general formula H _(n + 2) P _n O _(n + 1) where 'n' is not less than 2 |
| <i>Molecular weight</i> | (198) _n |
| <i>Assay</i> | Content in P ₂ O ₅ not less than 50 % and not more than 71 % on the ignited basis |
| <i>Description</i> | Odourless, colourless crystals or white powder |
| Identification | |
| A. Solubility | Usually sparingly soluble in water. Soluble in acid medium |
| B. Positive tests for calcium and for phosphate | |
| C. CaO content | 27-29,5 % |
| Purity | |
| Loss on ignition | Not more than 2 % (105 °C, 4 hours followed by ignition at 550 °C, 30 minutes) |
| Cyclic phosphate | Not more than 8 % on P ₂ O ₅ content |

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| | |
|----------------------|------------------------|
| 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 |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 20 mg/kg |

E 460 (i) MICROCRISTALLINE CELLULOSE**Synonyms**

Cellulose gel

Definition

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

Chemical name

Cellulose

Einecs

232-674-9

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

Description

A fine white or almost white odourless powder

Identification

A. Solubility

Insoluble in water, ethanol, ether and dilute mineral acids. Slightly soluble in sodium hydroxide solution

B. 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

C. To be identified by IR spectroscopy

D. 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

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 % determined at 800 ± 25 °C

pH of a 10 % suspension in water

The pH of the supernatant liquid is between 5,0 and 7,5

Starch

Not detectable

To 20 ml of the dispersion obtained in identification, test D, add a few drops of iodine solution and mix. No purplish to blue or blue colour should be produced

Particle size

Not less than 5 µm (not more than 10 % of particles of less than 5 µm)

Carboxyl groups

Not more than 1 %

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

▼M1

| | |
|----------------------|------------------------|
| Heavy metals (as Pb) | Not more than 10 mg/kg |
|----------------------|------------------------|

E 460 (ii) POWDERED CELLULOSE

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|----------------------------------|--|
| Definition | Purified, mechanically disintegrated cellulose prepared by processing alpha-cellulose obtained as a pulp from natural strains of fibrous plant materials |
| <i>Chemical name</i> | Cellulose Linear polymer of 1:4 linked glucose residues |
| Einecs | 232-674-9 |
| <i>Chemical formula</i> | (C ₆ H ₁₀ O ₅) _n |
| <i>Molecular weight</i> | (162) _n (n is predominantly 1 000 and greater) |
| <i>Assay</i> | Content not less than 92 % |
| <i>Description</i> | A white, odourless powder |
| Identification | |
| A. Solubility | Insoluble in water, ethanol, ether and dilute mineral acids. Slightly soluble in sodium hydroxide solution |
| B. 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 settle and a supernatant liquid appears |
| 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 % determined at 800 ± 25 °C |
| pH of a 10 % suspension in water | The pH of the supernatant liquid is between 5,0 and 7,5 |
| Starch | Not detectable To 20 ml of the dispersion obtained in identification, test B, 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| Particle size | Not less than 5 µm (not more than 10 % of particles of less than 5 µm) |

E 461 METHYL CELLULOSE

| | |
|----------------------|--|
| Synonyms | Cellulose methyl ether |
| Definition | Methyl cellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with methyl groups |
| <i>Chemical name</i> | Methyl ether of cellulose |

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| | |
|--------------------------------|--|
| <i>Chemical formula</i> | The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$ where R_1, R_2, R_3 each may be one of the following: — H — CH_3 or — CH_2CH_3 |
| <i>Molecular weight</i> | From about 20 000 to 380 000 |
| <i>Assay</i> | Content not less than 25 % and not more than 33 % of methoxyl groups ($-OCH_3$) and not more than 5 % of hydroxyethoxyl groups ($-OCH_2CH_2OH$) |
| <i>Description</i> | Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder |
| Identification | |
| A. Solubility | Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol, ether and chloroform. Soluble in glacial acetic acid |
| Purity | |
| Loss on drying | Not more than 10 % (105 °C, 3 hours) |
| Sulphated ash | Not more than 1,5 % determined at 800 ± 25 °C |
| pH of a 1 % colloidal solution | Not less than 5,0 and not more than 8,0 |
| 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 |
| Heavy metals (as Pb) | Not more than 20 mg/kg |

E 463 HYDROXYPROPYL CELLULOSE

| | |
|-------------------------|--|
| Synonyms | Cellulose hydroxypropyl ether |
| Definition | Hydroxypropylcellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with hydroxypropyl groups |
| <i>Chemical name</i> | Hydroxypropyl ether of cellulose |
| <i>Chemical formula</i> | The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$, where R_1, R_2, R_3 each may be one of the following: — H — $CH_2CHOHCH_3$ — $CH_2CHO(CH_2CHOHCH_3)CH_3$ — $CH_2CHO[CH_2CHO(CH_2CHOHCH_3)CH_3]CH_3$ |
| <i>Molecular weight</i> | From about 30 000 to 1 000 000 |
| <i>Assay</i> | Content not less 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 |
| <i>Description</i> | Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder |
| Identification | |
| A. Solubility | Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Soluble in ethanol. Insoluble in ether |
| B. Gas chromatography | Determine the substituents by gas chromatography |

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| | |
|---|--|
| Purity | |
| Loss on drying | Not more than 10 % (105 °C, 3 hours) |
| Sulphated ash | Not more than 0,5 % determined at 800 ± 25 °C |
| pH of a 1 % colloidal solution | Not less than 5,0 and not more than 8,0 |
| Propylene chlorohydrins | Not more than 0,1 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 |
| Heavy metals (as Pb) | Not more than 20 mg/kg |
| E 464 HYDROXYPROPYL METHYL CELLULOSE | |
| Definition | Hydroxypropyl methyl cellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with methyl groups and containing a small degree of hydroxypropyl substitution |
| <i>Chemical name</i> | 2-Hydroxypropyl ether of methylcellulose |
| <i>Chemical formula</i> | The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$, where R_1, R_2, R_3 each may be one of the following: — H — CH_3 — $CH_2CHOHCH_3$ — $CH_2CHO(CH_2CHOHCH_3)CH_3$ — $CH_2CHO[CH_2CHO(CH_2CHOHCH_3)CH_3]CH_3$ |
| <i>Molecular weight</i> | From about 13 000 to 200 000 |
| <i>Assay</i> | 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 |
| <i>Description</i> | Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder |
| Identification | |
| A. Solubility | Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol |
| B. Gas chromatography | Determine the substituents by gas chromatography |
| 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 Not more than 3 % for products with viscosities below 50 mPa.s |
| pH of a 1 % colloidal solution | Not less than 5,0 and not more than 8,0 |
| Propylene chlorohydrins | Not more than 0,1 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 |
| Heavy metals (as Pb) | Not more than 20 mg/kg |

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E 465 ETHYL METHYL CELLULOSE

| | |
|--------------------------------|--|
| Synonyms | Methylethylcellulose |
| Definition | Ethyl methyl cellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with methyl and ethyl groups |
| <i>Chemical name</i> | Ethyl methyl ether of cellulose |
| <i>Chemical formula</i> | The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$, where R_1, R_2, R_3 each may be one of the following: — H — CH_3 — CH_2CH_3 |
| <i>Molecular weight</i> | From about 30 000 to 40 000 |
| <i>Assay</i> | 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 |
| <i>Description</i> | Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder |
| Identification | |
| A. Solubility | Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Soluble in ethanol. Insoluble in ether |
| 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 % |
| pH of a 1 % colloidal solution | Not less than 5,0 and not more than 8,0 |
| 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 |
| Heavy metals (as Pb) | Not more than 20 mg/kg |

E 466 SODIUM CARBOXY METHYL CELLULOSE

| | |
|-------------------------|--|
| Synonyms | Carboxy methyl cellulose CMC NaCMC Sodium CMC Cellulose gum |
| Definition | Carboxy methyl cellulose is the partial sodium salt of a carboxymethyl ether of cellulose, the cellulose being obtained directly from natural strains of fibrous plant material |
| <i>Chemical name</i> | Sodium salt of the carboxymethyl ether of cellulose |
| <i>Chemical formula</i> | The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$, where R_1, R_2, R_3 each may be one of the following: — H — CH_2COONa — CH_2COOH |

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| | |
|--------------------------------|--|
| <i>Molecular weight</i> | Higher than approximately 17 000 (degree of polymerisation approximately 100) |
| <i>Assay</i> | Content on the anhydrous basis not less than 99,5 % |
| <i>Description</i> | Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder |
| Identification | |
| A. Solubility | Yields a viscous colloidal solution with water. Insoluble in ethanol |
| B. 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) |
| C. 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) |
| D. 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: 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 |
| Purity | |
| Degree of substitution | Not less than 0,2 and not more than 1,5 carboxymethyl groups (-CH ₂ COOH) per anhydroglucose unit |
| Loss on drying | Not more than 12 % (105 °C to constant weight) |
| pH of a 1 % colloidal solution | Not less than 5,0 and not more than 8,5 |
| 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 1 mg/kg |
| Heavy metals (as Pb) | Not more than 20 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 470a SODIUM, POTASSIUM AND CALCIUM SALTS OF FATTY ACIDS

| | |
|---|--|
| 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 |
| <i>Assay</i> | Content on the anhydrous basis not less than 95 % |
| <i>Description</i> | White or creamy white light powders, flakes or semi-solids |
| Identification | |
| A. Solubility | Sodium and potassium salts: soluble in water and ethanol calcium salts: insoluble in water, ethanol and ether |
| B. Positive tests for cations and for fatty acids | |
| Purity | |
| Sodium | Not less than 9 % and not more than 14 % expressed as Na ₂ O |
| Potassium | Not less than 13 % and not more than 21,5 % expressed as K ₂ O |

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| | |
|-----------------------------|---|
| 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 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

| | |
|---|---|
| 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 |
| <i>Assay</i> | Content on the anhydrous basis not less than 95 % |
| <i>Description</i> | White or creamy-white light powders, flakes or semi-solids |
| Identification | |
| A. Solubility | Insoluble in water, partially soluble in ethanol and ether |
| B. Positive tests for magnesium and for fatty acids | |
| 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 |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 471 MONO- AND DIGLYCERIDES OF FATTY ACIDS

| | |
|--------------------|--|
| Synonyms | Glyceryl monostearate Glyceryl monopalmitate Glyceryl monooleate, etc. Monostearin, monopalmitin, monoolein, etc. GMS (for glyceryl monostearate) |
| Definition | Mono- and diglycerides of fatty acids consist of mixtures of glycerol mono-, di- and triesters of fatty acids occurring in food oils and fats. They may contain small amounts of free fatty acids and glycerol |
| <i>Assay</i> | Content of mono- and diesters: not less than 70 % |
| <i>Description</i> | 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 |

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| Identification | |
| A. Infrared spectrum | Characteristic of a partial fatty acid ester of a polyol |
| B. Positive tests for glycerol and for fatty acids | |
| C. Solubility | Insoluble in water, soluble in ethanol and toluene |
| 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 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| Total glycerol | Not less than 16 % and not more than 33 % |
| 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 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 |
| <i>Description</i> | Clear, mobile liquids to solids, from white to pale yellow in colour |
| Identification | |
| A. Positive tests for glycerol, for fatty acids and for acetic acid | |
| B. Solubility | Insoluble in water. Soluble in ethanol |
| Purity | |
| Acids other than acetic and fatty acids | Not detectable |
| Free glycerol | Not more than 2 % |
| 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 |
| Heavy metals (as Pb) | Not more than 10 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 % |

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| | |
|---------------|---|
| 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 |
| <i>Description</i> | Clear, mobile liquids to waxy solids of variable consistency, from white to pale yellow in colour |
| Identification | |
| A. Positive tests for glycerol, for fatty acids and for lactic acid | |
| B. Solubility | Insoluble in cold water but dispersible in hot water |
| Purity | |
| Acids other than lactic and fatty acids | Not detectable |
| Free glycerol | Not more than 2 % |
| 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 |
| Heavy metals (as Pb) | Not more than 10 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 % 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 c CITRIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS

| | |
|---|---|
| Synonyms | 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 hydroxide or with potassium hydroxide |
| <i>Description</i> | Yellowish or light brown liquids to waxy solids or semi-solids |
| Identification | |
| A. Positive tests for glycerol, for fatty acids and for citric acid | |
| B. Solubility | Insoluble in cold water Dispersible in hot water Soluble in oils and fats Insoluble in cold ethanol |

▼M1

| Purity | |
|---|---|
| Acids other than citric and fatty acids | Not detectable |
| 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 | Not more than 0,5 % determined at 800 ± 25 °C |
| 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 |
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| Free fatty acids | Not more than 3 % estimated as oleic acid |

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 |
| <i>Description</i> | Sticky viscous yellowish liquids to hard yellow waxes |
| Identification | |
| A. Positive tests for glycerol, for fatty acids and for tartaric acid | |
| Purity | |
| Acids other than tartaric and fatty acids | Not detectable |
| Free glycerol | Not more than 2 % |
| Total glycerol | Not less than 12 % and not more than 29 % |
| 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 |
| Heavy metals (as Pb) | Not more than 10 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 % 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 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 |
|-----------------|---|

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|--|--|
| 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 |
| <i>Description</i> | Sticky viscous liquids through a fat-like consistency to yellow waxes which hydrolyse in moist air to liberate acetic acid |
| Identification | |
| A. Positive tests for glycerol, for fatty acids, for tartaric acid and for acetic acid | |
| Purity | |
| Acids other than acetic, tartaric and fatty acids | Not detectable |
| 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| Total tartaric acid | Not less than 10 % and not more than 40 % |
| Total acetic acid | Not less than 8 % and not more than 32 % |
| Free fatty acids | Not more than 3 % estimated as oleic acid |
| <i>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)</i> | |

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 |
| <i>Description</i> | Sticky liquids to solids, from white to pale-yellow in colour |
| Identification | |
| A. Positive tests for glycerol, for fatty acids, for tartaric acid and for acetic acid | |
| Purity | |
| Acids other than acetic, tartaric and fatty acids | Not detectable |
| Free glycerol | Not more than 2 % |
| Total glycerol | Not less than 12 % and not more than 27 % |
| Sulphated ash | Not more than 0,5 % determined at 800 ± 25 °C |
| 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 |

▼M1

| | |
|----------------------|---|
| Heavy metals (as Pb) | Not more than 10 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 |

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 and ethyl esters of food fatty acids or by extraction from sucroglycerides. No organic solvent other than dimethylsulphoxide, dimethylformamide, ethyl acetate, propane-2-ol, 2-methyl-1-propanol, propylene glycol and methyl ethyl ketone may be used for their preparation

Assay

Content not less than 80 %

Description

Stiff gels, soft solids or white to slightly greyish-white powders

Identification

A. Positive tests for sugar for fatty acids

B. Solubility

Sparingly soluble in water
Soluble in ethanol

Purity

| | |
|----------------------|---|
| Sulphated ash | Not more than 2 % determined at 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 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 | Not more than 350 mg/kg, singly or in combination |
| Propane-2-ol | |
| Propylene glycol | |
| Methyl ethyl ketone | Not more than 10 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 474 SUCROGLYCERIDES

Synonyms

Sugar glycerides

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|---|---|
| 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 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 propane-2-ol |
| <i>Assay</i> | Content not less than 40 % and not more than 60 % of sucrose fatty acid esters |
| <i>Description</i> | Soft solid masses, stiff gels or white to off-white powders |
| Identification | |
| A. Positive tests for sugar and for fatty acids | |
| B. Solubility | Insoluble in cold water Soluble in ethanol |
| Purity | |
| Sulphated ash | Not more than 2 % determined at 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 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 |
| Propane-2-ol | |
| | <i>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)</i> |

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 |
| <i>Assay</i> | Content of total fatty acid ester not less than 90 % |
| <i>Description</i> | 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 | |
| A. Positive tests for glycerol, for polyglycerols and for fatty acids | |
| B. 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 |

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| Purity | |
|---------------------------------|---|
| Sulphated ash | Not more than 0,5 % determined at 800 ± 25 °C |
| Acids other than fatty acids | Not detectable |
| 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 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 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 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 |
| Definition | Polyglycerol polyricinoleate is prepared by the esterification of polyglycerol with condensed castor oil fatty acids |
| <i>Description</i> | Clear, highly viscous liquid |
| Identification | |
| A. Solubility | Insoluble in water and in ethanol. Soluble in ether, hydrocarbons and halogenated hydrocarbons |
| B. Positive tests for glycerol, polyglycerol and for ricinoleic acid | |
| C. Refractive index [n] 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 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

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. |

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| <i>Assay</i> | Content of total fatty acid ester not less than 85 % |
| <i>Description</i> | Clear liquids or waxy white flakes, beads or solids having a bland odour |
| Identification | |
| A. Positive tests for propylene glycol and for fatty acids | |
| Purity | |
| Sulphated ash | Not more than 0,5 % determined at 800 ± 25 °C |
| Acids other than fatty acids | Not detectable |
| 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 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 desodorisation 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 natural strains of soya beans |
| <i>Description</i> | Pale yellow to light brown a waxy or solid consistency |
| Identification | |
| A. 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 |
| 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 |

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| | |
|----------------------|------------------------|
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 481 SODIUM STEAROYL-2-LACTYLATE

| | |
|---|--|
| Synonyms | Sodium stearoyl lactylate Sodium stearoyl lactate |
| Definition | A mixture of the sodium salts of stearoyl lactic 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 |
| <i>Chemical names</i> | Sodium di-2-stearoyl lactate Sodium di(2-stearoyloxy)propionate |
| Einecs | 246-929-7 |
| <i>Chemical formula (major components)</i> | C ₂₁ H ₃₉ O ₄ Na C ₁₉ H ₃₅ O ₄ Na |
| <i>Description</i> | White or slightly yellowish powder or brittle solid with a characteristic odour |
| Identification | |
| A. Positive tests for sodium, for fatty acids and for lactic acid | |
| B. 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 482 CALCIUM STEAROYL-2-LACTYLATE

| | |
|-------------------------|--|
| Synonyms | Calcium stearoyl lactate |
| Definition | A mixture of the calcium salts of stearoyl lactic 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 |
| <i>Chemical name</i> | Calcium di-2-stearoyl lactate Calcium di(2-stearoyloxy)propionate |
| Einecs | 227-335-7 |
| <i>Chemical formula</i> | C ₄₂ H ₇₈ O ₈ Ca C ₃₈ H ₇₀ O ₈ Ca |

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| | |
|--|---|
| <i>Description</i> | White or slightly yellowish powder or brittle solid with a characteristic odour |
| Identification | |
| A. Positive tests for calcium, for fatty acids and for lactic acid | |
| B. 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 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 |
| <i>Chemical name</i> | Distearyl tartrate Dipalmityl tartrate |
| <i>Chemical formula</i> | C ₃₈ H ₇₄ O ₆ to C ₄₀ H ₇₈ O ₆ |
| <i>Molecular weight</i> | 627 to 655 |
| <i>Assay</i> | Content of total ester not less than 90 % corresponding to an ester value of not less than 163 and not more than 180 |
| <i>Description</i> | Cream-coloured unctuous solid (at 25 °C) |
| Identification | |
| A. Positive tests for tartare | |
| B. 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 content | Not less than 18 % and not more than 35 % |
| Sulphated ash | Not more than 0,5 % determined at 800 ± 25 °C |
| 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 |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

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|-----------------------|---|
| Unsaponifiable matter | Not less than 77 % and not more than 83 % |
| Iodine value | Not more than 4 (Wijs) |

E 491 SORBITAN MONOSTEARATE

| | |
|---------------------------------|--|
| Definition | A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial stearic acid |
| Einecs | 215-664-9 |
| <i>Assay</i> | Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters |
| <i>Description</i> | Light, cream- to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour |
| Identification | |
| A. 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 |
| B. Congealing range | 50—52 °C |
| C. Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyol |
| Purity | |
| Water | 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 |
| Hydroxyl value | Not less than 235 and not more than 260 |
| 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 |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 492 SORBITAN TRISTEARATE

| | |
|---------------------------------|--|
| Definition | A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial stearic acid |
| Einecs | 247-891-4 |
| <i>Assay</i> | Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters |
| <i>Description</i> | Light, cream- to tan-coloured beads or flakes or hard, waxy solid with a slight odour |
| Identification | |
| A. 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 |
| B. Congealing range | 47—50 °C |
| C. Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyol |

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| | |
|-----------------------------------|---|
| Purity | |
| Water | 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| | |
| E 493 SORBITAN MONOLAURATE | |
| Definition | A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial lauric acid |
| Einecs | 215-663-3 |
| <i>Assay</i> | Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters |
| <i>Description</i> | Amber-coloured oily viscous liquid, light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight odour |
| Identification | |
| A. Solubility | Dispersible in hot and cold water |
| B. Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyol |
| Purity | |
| Water | 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| | |
| E 494 SORBITAN MONOOLEATE | |
| 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 |
| <i>Assay</i> | Content not less than 95 % of a mixture of sorbitol, sorbitan and isosorbide esters |

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| | |
|-----------------------|---|
| <i>Description</i> | Amber-coloured viscous liquid, light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour |
| Identification | |
| A. Solubility | Soluble at temperatures above its melting point in ethanol, ether, ethyl acetate, aniline, toluene, dioxane, petroleum ether and carbon tetrachloride. Insoluble in cold water, dispersible in warm water |
| B. 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 | Not more than 2 % (Karl Fischer method) |
| Sulphated ash | Not more than 0,5 % |
| 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 495 SORBITAN MONOPALMITATE

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|---------------------------------|--|
| Synonyms | Sorbitan palmitate |
| Definition | A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial palmitic acid |
| Einecs | 247-568-8 |
| <i>Assay</i> | Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters |
| <i>Description</i> | Light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour |
| Identification | |
| A. 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 |
| B. Congealing range | 45—47 °C |
| C. Infrared absorption spectrum | Characteristic of a partial fatty acid ester of polyol |
| Purity | |
| Water | 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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

▼M1

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|----------------------|------------------------|
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 508 POTASSIUM CHLORIDE

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|--|---|
| Synonyms | Sylvine Sylvite |
| Definition | |
| <i>Chemical name</i> | Potassium chloride |
| Einecs | 231-211-8 |
| <i>Chemical formulae</i> | KCl |
| <i>Molecular weight</i> | 74,56 |
| <i>Assay</i> | Content not less than 99 % on the dried basis |
| <i>Description</i> | Colourless, elongated, prismatic or cubital crystals or white granular powder. Odourless |
| Identification | |
| A. Solubility | Freely soluble in water. Insoluble in ethanol |
| B. Positive tests for potassium and for chloride | |
| Purity | |
| Loss on drying | Not more than 1 % (105 °C, 2 hours) |
| Sodium | Negative test |
| 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 |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 579 FERROUS GLUCONATE

| | |
|--|--|
| Definition | |
| <i>Chemical name</i> | Ferrous di-D-gluconate dihydrate Iron(II) di-gluconate dihydrate |
| Einecs | 206-076-3 |
| <i>Chemical formulae</i> | $C_{12}H_{22}FeO_{14} \cdot 2H_2O$ |
| <i>Molecular weight</i> | 482,17 |
| <i>Assay</i> | Content not less than 95 % on the dried basis |
| <i>Description</i> | Pale greenish-yellow to yellowish-grey powder or granules, which may have a faint odour of burnt sugar |
| Identification | |
| A. Solubility | Soluble with slight heating in water. Practically insoluble in ethanol |
| B. Positive test for ferrous ion | |
| C. Formation of phenylhydrazine derivative of gluconic acid positive | |
| D. pH of a 10 % solution | Between 4 and 5,5 |

▼**M1****Purity**

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| 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 |
| Lead | Not more than 5 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
Propanoic acid, 2-hydroxy-iron(2 +) salt (2:1)

Definition

Chemical name

Ferrous 2-hydroxy propanoate

Einecs

227-608-0

Chemical formulae

$C_6H_{10}FeO_6 \cdot xH_2O$ (x = 2 or 3)

Molecular weight

270,02 (dihydrate)
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

- A. Solubility
- B. Positive test for ferrous ion and for lactate
- C. pH of a 2 % solution

Soluble in water. Practically insoluble in ethanol

Between 4 and 6

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 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

▼**B****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 $\beta(1-4)$ 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

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| <i>Chemical name</i> | Enzyme Commission (EC) No: 3.2.1.17 |
| Einecs | 232-620-4 |
| <i>Molecular weight</i> | About 14 000 |
| <i>Assay</i> | Content not less than 950 mg/g on the anhydrous basis |
| <i>Description</i> | White, odourless powder having a slightly sweet taste |
| Identification | |
| A. Isoelectric point 10,7 | |
| B. pH of a 2 % aqueous solution between 3,0 and 3,6 | |
| C. 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 |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |
| Microbiological criteria | |
| Total bacterial count | Not more than 5×10^4 col/g |
| <i>Salmonellae</i> | Absent in 25 g |
| <i>Staphylococcus aureus</i> | Absent in 1 g |
| <i>Escherichia coli</i> | Absent in 1 g |
| (1) Cobalt chloride TSC: dissolve approximately 65 g of cobalt chloride $\text{CoCl}_2 \cdot 6\text{H}_2\text{O}$ 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 $\text{CoCl}_2 \cdot 6\text{H}_2\text{O}$. 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 $\text{CoCl}_2 \cdot 6\text{H}_2\text{O}$ 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 $\text{FeCl}_3 \cdot 6\text{H}_2\text{O}$. 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 $\text{FeCl}_3 \cdot 6\text{H}_2\text{O}$ per ml. | |
| (3) Copper sulphate TSC: dissolve approximate by 65 g of copper sulphate $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$ 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 $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$. 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 $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$ per ml. | |
| (4) When labelled 'for food use', nitrite may only be sold in a mixture with salt or a salt substitute. | |
| Note: | |
| Lactic acid is hygroscopic and when concentrated by boiling, it condenses to form lactic acid lactate, which on dilution and heating hydrolyzes to lactic acid | |
| This specification refers to a 80 % aqueous solution; for weaker aqueous solutions, calculate values corresponding to their lactic acid content | |
| This specification refers to a 60 % aqueous solution | |
| This specification refers to a 60 % aqueous solution | |
| This specification refers to a 75 % aqueous solution | |