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)

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Whereas Directives 65/66/EEC and 78/664/EEC should be repealed accordingly;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

(1) OJ No L 40, 11. 2. 1989, p. 27.
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.

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
Chemical name
Sorbic acid

Einecs
Chemical name
Trans, trans-2,4-hexadienoic acid
203-768-7

Chemical formula
C6H8O2

Molecular weight
112.12

Assay
Content not less than 99 % on the anhydrous basis

Description
Colourless needles or white free flowing powder, having a slight characteristic odour and showing no change in colour after heating for 90 minutes at 105 °C

Identification
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
Chemical name
Potassium sorbate

Einecs
Chemical name
Potassium (E,E)-2,4-hexadienoate
246-376-1

Chemical formula
C6H7O2K

Molecular weight
150.22

Assay
Content not less than 99 % on the dried basis

Description
White crystalline powder showing no change in colour after heating for 90 minutes at 105 °C

Identification
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

B. Positive tests for potassium and for double bonds

Purity
Loss on drying
Not more than 1.0 % (105 °C, 3h)

Acidity or alkalinity
Not more than about 1.0 % (as sorbic acid or K2CO3)

Aldehydes
Not more than 0.1 %, calculated as formaldehyde

Arsenic
Not more than 3 mg/kg

Lead
Not more than 5 mg/kg
### E 203 CALCIUM SORBATE

**Definition**

- **Chemical name**: Calcium sorbate
- **Einecs**: 231-321-6
- **Chemical formula**: \( \text{C}_{12}\text{H}_{14}\text{O}_{4}\text{Ca} \)
- **Molecular weight**: 262.32
- **Assay**: Content not less than 98 % on the dried basis
- **Description**: Fine white crystalline powder not showing any change in colour after heating at 105 °C for 90 minutes

**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
- B. Positive tests for calcium and for double bonds

**Purity**

- Loss on drying: Not more than 2.0 %, determined by vacuum drying for four hours in a sulphuric acid desiccator
- Aldehydes: Not more than 0.1 % (as formaldehyde)
- 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 210 BENZOIC ACID

**Definition**

- **Chemical name**: Benzoic acid
- **Einecs**: 200-618-2
- **Chemical formula**: \( \text{C}_{7}\text{H}_{6}\text{O}_{2} \)
- **Molecular weight**: 122.12
- **Assay**: Content not less than 99.5 % on the anhydrous basis
- **Description**: White crystalline powder

**Identification**

- A. Melting range
- 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 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 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 ferrie 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

Chemical name

Sodium benzoate
Sodium salt of benzenecarboxylic acid
Sodium salt of phenylcarboxylic acid

Einecs

208-534-8

Chemical formula

C₇H₅O₂Na

Molecular weight

144,11

Assay

Not less than 99 % of C₇H₅O₂Na, after drying at 105 °C for four hours

Description

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

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

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**

$\text{C}_7\text{H}_5\text{KO}_2 \cdot 3\text{H}_2\text{O}$

**Molecular weight**

214,27

**Assay**

Content not less than 99 % $\text{C}_7\text{H}_5\text{O}_2\text{K}$ 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 $\text{KMnO}_4$ 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 $\text{KMnO}_4$ 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 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

**E 213 CALCIUM BENZOATE**

**Synonyms**

Monocalcium benzoate

*Chemical name*

Calcium benzoate

Calcium dibenzoate

**Einecs**

218-235-4

**Chemical formula**

Anhydrous: $\text{C}_{14}\text{H}_{10}\text{O}_4\text{Ca}$

Monohydrate: $\text{C}_{14}\text{H}_{10}\text{O}_4\text{Ca} \cdot \text{H}_2\text{O}$

Trihydrate: $\text{C}_{14}\text{H}_{10}\text{O}_4\text{Ca} \cdot 3\text{H}_2\text{O}$

**Molecular weight**

Anhydrous: 282,31
**B**

**Assay**

**Description**

**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 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

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

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 p-oxybenzoate

**Definition**

**Chemical name**

Ethyl-p-hydroxybenzoate

Ethyl ester of p-hydroxybenzoic acid

**Einecs**

**Chemical formula**

C₈H₁₀O₃

**Molecular weight**

166.8

**Assay**

Content not less than 99.5 % after drying for two hours at 80 °C

**Description**

Almost odourless, small, colourless crystals or a white, crystalline powder

**Identification**

A. Melting range

115 °C to 118 °C
B. Positive test for \( p \)-hydroxybenzoate

Melting range of \( p \)-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 % |
| \( p \)-Hydroxybenzoic acid and salicylic acid | Not more than 0,35 % expressed as \( p \)-hydroxybenzoic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

SODIUM ETHYL \( p \)-HYDROXYBENZOATE

Definition

Chemical name

Sodium ethyl \( p \)-hydroxybenzoate

Sodium compound of the ethyl ester of \( p \)-hydroxybenzoic acid

Einecs

252-487-6

Chemical formula

C\(_9\)H\(_9\)O\(_3\)Na

Molecular weight

188,8

Assay

Content of ethylester of \( p \)-hydroxybenzoic acid not less than 83 % on the anhydrous basis

Description

White, crystalline hygroscopic powder

Identification

A. Melting range

115 °C to 118 °C, after vacuum drying in a sulphuric acid desiccator

B. Positive test for \( p \)-hydroxybenzoate

Melting range of \( p \)-hydroxybenzoic acid derived from the sample is 213 °C to 217 °C

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 % |
| \( p \)-Hydroxybenzoic acid and salicylic acid | Not more than 0,35 % expressed as \( p \)-hydroxybenzoic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

METHYL \( p \)-HYDROXYBENZOATE

Synonyms

Methylparaben

Methyl-\( p \)-oxybenzoate

Definition

Chemical name

Methyl \( p \)-hydroxybenzoate

Methyl ester of \( p \)-hydroxybenzoic acid

Einecs

243-171-5

Chemical formula

C\(_8\)H\(_8\)O\(_3\)
**▼B**

**Molecular weight**

152.15

**Assay**

Content not less than 99 % after drying for two hours at 80 °C

**Description**

Almost odourless, small colourless crystals or white crystalline powder

**Identification**

A. Melting range

125 °C to 128 °C

B. Positive test for \( p \)-hydroxybenzoate

Melting range of \( p \)-hydroxybenzoic acid derived from the sample is 213 °C to 217 °C after drying for two hours at 80 °C

**Purity**

- **Loss on drying**
  - Not more than 0.5 %, after drying for two hours at 80 °C
  - Not more than 0.05 %

- **Sulphated ash**
  - Not more than 0.35 % expressed as \( p \)-hydroxybenzoic acid

- **\( p \)-Hydroxybenzoic acid and salicylic acid**
  - Not more than 3 mg/kg

- **Arsenic**
  - Not more than 5 mg/kg

- **Lead**
  - Not more than 1 mg/kg

- **Mercury**
  - Not more than 10 mg/kg

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

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**E 219 SODIUM METHYL \( p \)-HYDROXYBENZOATE**

**Definition**

**Chemical name**

Sodium methyl \( p \)-hydroxybenzoate

Sodium compound of the methylester of \( p \)-hydroxybenzoic acid

**Chemical formula**

\( \text{C}_{8}\text{H}_{7}\text{O}_{3}\text{Na} \)

**Molecular weight**

174.15

**Assay**

Content not less than 99.5 % on the anhydrous basis

**Description**

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

- **\( p \)-Hydroxybenzoic acid and salicylic acid**
  - Not more than 0.35 % expressed as \( p \)-hydroxybenzoic acid

- **Arsenic**
  - Not more than 3 mg/kg

- **Lead**
  - Not more than 5 mg/kg

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

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

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**E 220 SULPHUR DIOXIDE**

**Definition**

**Chemical name**

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 %
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
Chemical name Sodium sulphite (anhydrous or heptahydrate)

Einecs 231-821-4

Chemical formula Anhydrous: Na₂SO₃

Molecular weight Anhydrous: 126,04

Assay Heptahydrate: Na₂SO₃7H₂O

Molecular weight Heptahydrate: 252,16

Assay Anhydrous: Not less than 95 % of Na₂SO₃ and not less than 48 % of SO₂

Heptahydrate: Not less than 48 % of Na₂SO₃ and not less than 24 % of SO₂

Description 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 SO₂ content
Iron Not more than 50 mg/kg based on the SO₂ content
Selenium Not more than 10 mg/kg based on the SO₂ 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
Chemical name Sodium bisulphite

Chemical formula Sodium hydrogen sulphite
E 223 SODIUM METABISULPHITE

Synonyms
Pyrosulphite
Sodium pyrosulphite

Definition
Chemical name
Sodium disulphite
Disodium pentaoxodisulphate

Einecs
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 SO₂ content
Iron
Not more than 50 mg/kg based on the SO₂ content
Selenium
Not more than 10 mg/kg based on the SO₂ 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
**K2S2O5**

**Chemical formula**
K2S2O5

**Molecular weight**
222,33

**Assay**
Content not less than 90 % of K2S2O5 and not less than 51.8 % of SO2, the remainder being composed almost entirely of potassium sulphate

**Description**
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 SO2 content
- Iron
  - Not more than 50 mg/kg based on the SO2 content
- Selenium
  - Not more than 10 mg/kg based on the SO2 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**
Chemical name: Calcium sulphite

**Einecs**
218-235-4

**Chemical formula**
CaSO3·2H2O

**Molecular weight**
156,17

**Assay**
Content not less than 95 % of CaSO3·2H2O and not less than 39 % of SO2

**Description**
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 SO2 content
- Selenium
  - Not more than 10 mg/kg based on the SO2 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**
Chemical name: Calcium bisulphite

**Einecs**
237-423-7

**Chemical formula**
Ca(HSO3)2

**Molecular weight**
202,22

**Assay**
6 to 8 % (w/v) of sulphur dioxide and 2.5 to 3.5 % (w/v) of calcium dioxide corresponding to 10 to 14 % (w/v) of calcium bisulphite [Ca(HSO3)2]

**Description**
Clear greenish-yellow aqueous solution having a distinct odour of sulphur dioxide

**Identification**
A. Positive tests for sulphite and for calcium
### E 228 POTASSIUM BISULPHITE

**Definition**

*Chemical name*
- Potassium bisulphite
- Potassium hydrogen sulphite

**Einecs**
- 231-870-1

**Chemical formula**
- KHSO₃ in aqueous solution

**Molecular weight**
- 120,17

**Assay**
- Content not less than 280 g KHSO₃ per litre (or 150 g SO₂ per litre)

**Description**
- Clear colourless aqueous solution

### Identification

A. Positive tests for sulphite and for potassium

**Purity**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
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<tbody>
<tr>
<td>Iron</td>
<td>Not more than 50 mg/kg based on the SO₂ content</td>
</tr>
<tr>
<td>Selenium</td>
<td>Not more than 10 mg/kg based on the SO₂ content</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
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### E 230 BIPHENYL

**Synonyms**
- Diphenyl

**Definition**

*Chemical name*
- 1,1′-biphenyl
- Phenylbenzene

**Einecs**
- 202-163-5

**Chemical formula**
- C₁₂H₁₀

**Molecular weight**
- 154,20

**Assay**
- Content not less than 99,8 %

**Description**
- 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**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzene</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Aromatic amines</td>
<td>Not more than 2 mg/kg (as aniline)</td>
</tr>
<tr>
<td>Phenol derivatives</td>
<td>Not more than 5 mg/kg (as phenol)</td>
</tr>
<tr>
<td>Readily carbonizable substances</td>
<td>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</td>
</tr>
</tbody>
</table>
### E 231 ORTHOPHENYLPHENOL

**Synonyms**
- Orthoxenol

**Definition**
- **Chemical name**: (1,1'-Biphenyl)-2-ol
- 2-Hydroxydiphenyl
- o-Hydroxydiphenyl

**Einecs**
- 201-993-5

**Chemical formula**
- \( \text{C}_{12}\text{H}_{10}\text{O} \)

**Molecular weight**
- 170,20

**Assay**
- Content not less than 99 %

**Description**
- 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 %
- \( p \)-Phenylphenol: Not more than 0,1 %
- 1-Napthol: 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 \( o \)-phenylphenol

**Definition**
- **Chemical name**: Sodium orthophenylphenol

**Einecs**
- 205-055-6

**Chemical formula**
- \( \text{C}_{12}\text{H}_{9}\text{ONa}\cdot \text{4H}_{2}\text{O} \)

**Molecular weight**
- 264,26

**Assay**
- Content not less than 97 % of \( \text{C}_{12}\text{H}_{9}\text{ONa}\cdot \text{4H}_{2}\text{O} \)

**Description**
- 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

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphenylether</td>
<td>Not more than 0.3 %</td>
</tr>
<tr>
<td>p-phenylphenol</td>
<td>Not more than 0.1 %</td>
</tr>
<tr>
<td>1-naphthol</td>
<td>Not more than 0.01 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

E 233 THIABENDAZOLE

**Definition**

*Chemical name*

4-(2-benzimidazolyl)thiazole

2-(4-thiazolyl)-1H-benzimidazole

**Einacs**

1205-725-8

**Chemical formula**

$C_{10}H_{7}N_{3}S$

**Molecular weight**

201.26

**Assay**

Content not less than 98 % on the anhydrous basis

**Description**

White, or almost white, odourless powder

**Identification**

<table>
<thead>
<tr>
<th>Test</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Melting range</td>
<td>296 °C to 303 °C</td>
</tr>
<tr>
<td>B. Spectrometry</td>
<td>Absorption maxima in 0.1 N HCl (0.0005 % w/v) at 302 nm, 258 nm and 243 nm</td>
</tr>
<tr>
<td></td>
<td>$E_{1}%$ at 302 nm ± 2 nm: approximately 1 230</td>
</tr>
<tr>
<td></td>
<td>$E_{1}%$ at 258 nm ± 2 nm: approximately 200</td>
</tr>
<tr>
<td></td>
<td>$E_{1}%$ at 243 nm ± 2 nm: approximately 620</td>
</tr>
<tr>
<td>Ratio of absorption</td>
<td>243 nm/302 nm = 0.47 to 0.53</td>
</tr>
<tr>
<td></td>
<td>258 nm/302 nm = 0.14 to 0.18</td>
</tr>
</tbody>
</table>

Purity

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water content</td>
<td>Not more than 0.5 % (Karl Fischer method)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.2 %</td>
</tr>
<tr>
<td>Selenium</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

E 234 NISIN

**Definition**

Nisin consists of several closely related polypeptides produced by natural strains of *Streptococcus lactis*, Lancefield group N

**Einacs**

215-807-5

**Chemical formula**

$C_{143}H_{230}N_{42}O_{37}S_{7}$

**Molecular weight**

3 354.12

**Assay**

Nisin concentrate contains not less than 900 units per mg in a mixture of non-fat milk solids and a minimum sodium chloride content of 50 %

**Description**

White powder

**Purity**

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 3 % when dried to constant weight at 102 °C to 103 °C</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
</tbody>
</table>
Mercury
Heavy metals (as Pb)

E 235 NATAMYCIN

Synonyms
Pimaricin

Definition
Natamycin is a fungicide of the polyene macrolide group, and is produced by natural strains of *Streptomyces natalensis* or of *Streptococcus lactis*.

Einecs
231-683-5

Chemical formula
C_{33}H_{47}O_{13}N

Molecular weight
665,74

Assay
Content not less than 95 % on the anhydrous basis

Description
White to creamy-white crystalline powder

Identification
A. Colour reactions
- 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
$\left[\alpha\right]_{D}^{20} = +250^\circ$ 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
Chemical name
1,3,5,7-Tetraazatricyclo [3.3.1.1^{3,7}]-decane, hexamethylenetetramine

Einecs
202-905-8

Chemical formula
C_{6}H_{12}N_{4}

Molecular weight
140,19

Assay
Content not less than 99 % on the anhydrous basis

Description
Colourless or white crystalline powder
\section*{B
Identification}  
A. Positive tests for formaldehyde and for ammonia  
B. Sublimation point approximately 260 °C  
\section*{Purity}  
Loss on drying  Not more than 0.5 \% after drying at 105 °C in vacuum over \(\text{P}_2\text{O}_5\) for two hours  
Sulphated ash  Not more than 0.05 \%  
Sulphates  Not more than 0.005 \% expressed as \(\text{SO}_4\)  
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  
Mercury  Not more than 1 mg/kg  
Heavy metals (as Pb)  Not more than 10 mg/kg  
\section*{E 242 DIMETHYL DICARBONATE}  
\subsection*{Synonyms}  
DMDC  
Dimethyl pyrocarbonate  
\subsection*{Definition}  
Einecs  224-859-8  
Chemical name  Dimethyl dicarbonate  
\textit{Chemical formula}  \text{C}_4\text{H}_6\text{O}_5  
\textit{Molecular weight}  134.09  
\textit{Assay}  Content not less than 99.8 \%  
\textit{Description}  Colourless liquid, decomposes in aqueous solution. It is corrosive to skin and eyes and toxic by inhalation and ingestion  
\section*{Identification}  
A. Decomposition  After dilution positive tests for \(\text{CO}_2\) 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\(^{-1}\)  
\section*{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  
\section*{E 249 POTASSIUM NITRITE}  
\subsection*{Definition}  
Chemical name  Potassium nitrite  
Einecs  231-832-4  
\textit{Chemical formula}  \text{KNO}_2  
\textit{Molecular weight}  85.11  
\textit{Assay}  Content not less than 95 \% on the anhydrous basis (\(^{(*)}\))  
\textit{Description}  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
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
Chemical name
Sodium nitrite
Einecs
231-555-9
Chemical formula
NaNO₂
Molecular weight
69,00
Assay
Content not less than 97 % on the anhydrous basis

Description
White crystalline powder or yellowish lumps

Identification
A. Positive tests for nitrite and for sodium
B. pH of a 5 % solution: not less than 5,5 and not more than 8,3

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

M5

E 251 SODIUM NITRATE

1. SOLID SODIUM NITRATE

Synonyms
Chile saltpetre
Cubic or soda nitre

Definition
Chemical name
Sodium nitrate
EINECS
231-554-3
Chemical formula
NaNO₃
Molecular weight
85,00
Assay
Content not less than 99 % after drying

Description
White crystalline, slightly hygroscopic powder

Identification
A. Positive tests for nitrate and for sodium
B. pH of a 5 % solution
Not less than 5,5 and not 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 NaNO₂
Arsenic
Not more than 3 mg/kg
\textbf{Lead} & Not more than 5 mg/kg \\
\textbf{Mercury} & Not more than 1 mg/kg \\

\textbf{E 251 SODIUM NITRATE}

\textbf{2. LIQUID SODIUM NITRATE}

\textbf{Definition}

Liquid sodium nitrate is an aqueous solution of sodium nitrate as the direct result of the chemical reaction between sodium hydroxide and nitric acid in stoichiometric amounts, without subsequent crystallisation. Standardised forms prepared from liquid sodium nitrate meeting these specifications may contain nitric acid in excessive amounts, if clearly stated or labelled.

\textit{Chemical name}

Sodium nitrate

\textit{EINECS}

231-554-3

\textit{Chemical formula}

NaNO₃

\textit{Molecular weight}

85,00

\textit{Assay}

Content between 33,5 % and 40,0 % of NaNO₃

\textit{Description}

Clear colourless liquid

\textbf{Identification}

A. Positive tests for nitrate and for sodium

B. \textbf{pH}

Not less than 1,5 and not more than 3,5

\textbf{Purity}

\textbf{Free nitric acid}

Not more than 0,01 %

\textbf{Nitrites}

Not more than 10 mg/kg expressed as NaNO₂

\textbf{Arsenic}

Not more than 1 mg/kg

\textbf{Lead}

Not more than 1 mg/kg

\textbf{Mercury}

Not more than 0,3 mg/kg

This specification refers to a 35 % aqueous solution.

\textbf{E 252 POTASSIUM NITRATE}

\textbf{Synonyms}

Chile saltpetre

Cubic or soda nitre

\textbf{Definition}

\textit{Chemical name}

Potassium nitrate

\textit{EINECS}

231-818-8

\textit{Chemical formula}

KNO₃

\textit{Molecular weight}

101,11

\textit{Assay}

Content not less than 99 % on the anhydrous basis

\textit{Description}

White crystalline powder or transparent prisms having a cooling, saline, pungent taste

\textbf{Identification}

A. Positive tests for nitrate and for potassium

B. \textbf{pH} of a 5 % solution

Not less than 4,5 and not more than 8,5

\textbf{Purity}

\textbf{Loss on drying}

Not more than 1 % after drying at 105 °C for four hours

\textbf{Nitrites}

Not more than 20 mg/kg expressed as KNO₂

\textbf{Arsenic}

Not more than 3 mg/kg

\textbf{Lead}

Not more than 5 mg/kg

\textbf{Mercury}

Not more than 1 mg/kg

\textbf{Heavy metals (as Pb)}

Not more than 10 mg/kg
\textbf{E 260 ACETIC ACID}

\textbf{Definition}

\textit{Chemical name}  
Acetic acid  
Ethanoic acid

\textit{Einecs} 
200-580-7

\textit{Chemical formula}  
C$_2$H$_4$O$_2$

\textit{Molecular weight}  
60,05

\textit{Assay}  
Content not less than 99,8 %

\textit{Description}  
Clear, colourless liquid having a pungent, characteristic odour

\textbf{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

\textbf{Purity}

Non-volatile residue  
Not more than 100 mg/kg

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

\textbf{E 261 POTASSIUM ACETATE}

\textbf{Definition}

\textit{Chemical name}  
Potassium acetate

\textit{Einecs}  
204-822-2

\textit{Chemical formula}  
C$_2$H$_3$O$_2$K

\textit{Molecular weight}  
98,14

\textit{Assay}  
Content not less than 99 % on the anhydrous basis

\textit{Description}  
Colourless, deliquescent crystals or a white crystalline powder, odourless or with a faint acetic odour

\textbf{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

\textbf{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

\textbf{E 262 (i) SODIUM ACETATE}

\textbf{Definition}

\textit{Chemical name}  
Sodium acetate
### E 262 (ii) SODIUM DIACETATE

**Definition**

Sodium diacetate is a molecular compound of sodium acetate and acetic acid

**Chemical name**

Sodium hydrogen diacetate

**Einecs**

204-814-9

**Chemical formula**

C₄H₇NaO₄·nH₂O (n = 0 or 3)

**Molecular weight**

142,09 (anhydrous)

**Assay**

Content 39 to 41 % of free acetic acid and 58 to 60 % of sodium acetate

**Description**

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
### Anhydrous calcium acetate

**Chemical formula**
- Anhydrous: \( \text{C}_4\text{H}_6\text{O}_4\text{Ca} \)
- Monohydrate: \( \text{C}_4\text{H}_6\text{O}_4\text{Ca}\cdot\text{H}_2\text{O} \)

**Molecular weight**
- Anhydrous: 158.17
- Monohydrate: 176.18

**Assay**
- Content not less than 98 % on the anhydrous basis

**Description**
- Anhydrous calcium acetate is a white, hygroscopic, bulky, crystalline solid with a slightly bitter taste. A slight odour of acetic acid may be present. The monohydrate may be needles, granules or powder

**Identification**
- 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

### Lactic acid

**Definition**

**Chemical name**
- Lactic acid
- 2-Hydroxypropionic acid
- 1-Hydroxyethane-1-carboxylic acid

**Einecs**
- \( \text{C}_3\text{H}_6\text{O}_3 \)
- 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 \( (\text{C}_3\text{H}_6\text{O}_3) \) and lactic acid lactate \( (\text{C}_6\text{H}_{10}\text{O}_5) \). It is obtained by the lactic fermentation of sugars or is prepared synthetically

**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

**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
**E 280 PROPIONIC ACID**

**Definition**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Propionic acid</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Einecs</strong></td>
<td>Propanoic acid</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C₃H₆O₂</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>74,08</td>
</tr>
<tr>
<td><strong>Assay</strong></td>
<td>Content not less than 99.5 %</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Colourless or slightly yellowish, oily liquid with a slightly pungent odour</td>
</tr>
</tbody>
</table>

**Identification**

- A. Melting point: - 22 °C
- B. Distillation range: 138,5 °C to 142,5 °C

**Purity**

<table>
<thead>
<tr>
<th>Non-volatile residue</th>
<th>Not more than 0,01 % when dried at 140 °C to constant weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aldehydes</td>
<td>Not more than 0,1 % expressed as formaldehyde</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

**E 281 SODIUM PROPIONATE**

**Definition**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Sodium propionate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Einecs</strong></td>
<td>Sodium propanoate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C₃H₅O₂Na</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>96,06</td>
</tr>
<tr>
<td><strong>Assay</strong></td>
<td>Content not less than 99 % after drying for two hours at 105 °C</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>White crystalline hygroscopic powder, or a fine white powder</td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>Loss on drying</th>
<th>Not more than 4 % determined by drying for two hours at 105 °C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water insolubles</td>
<td>Not more than 0,1 %</td>
</tr>
<tr>
<td>Iron</td>
<td>Not more than 50 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>
**E 282 CALCIUM PROPIONATE**

**Definition**

<table>
<thead>
<tr>
<th><strong>Chemical name</strong></th>
<th>Calcium propionate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Einecs</strong></td>
<td>223-795-8</td>
</tr>
<tr>
<td><strong>Chemical formula</strong></td>
<td>C₆H₁₀O₄Ca</td>
</tr>
<tr>
<td><strong>Molecular weight</strong></td>
<td>186,22</td>
</tr>
<tr>
<td><strong>Assay</strong></td>
<td>Content not less than 99 %, after drying for two hours at 105 °C</td>
</tr>
</tbody>
</table>

**Description**

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**

<table>
<thead>
<tr>
<th><strong>Loss on drying</strong></th>
<th>Not more than 4 %, determined by drying for two hours at 105 °C</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Water insolubles</strong></td>
<td>Not more than 0,3 %</td>
</tr>
<tr>
<td><strong>Iron</strong></td>
<td>Not more than 50 mg/kg</td>
</tr>
<tr>
<td><strong>Fluoride</strong></td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td><strong>Arsenic</strong></td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td><strong>Lead</strong></td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td><strong>Mercury</strong></td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td><strong>Heavy metals (as Pb)</strong></td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

**E 283 POTASSIUM PROPIONATE**

**Definition**

<table>
<thead>
<tr>
<th><strong>Chemical name</strong></th>
<th>Potassium propionate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Einecs</strong></td>
<td>206-323-5</td>
</tr>
<tr>
<td><strong>Chemical formula</strong></td>
<td>C₃H₅KO₂</td>
</tr>
<tr>
<td><strong>Molecular weight</strong></td>
<td>112,17</td>
</tr>
<tr>
<td><strong>Assay</strong></td>
<td>Content not less than 99 %, after drying for two hours at 105 °C</td>
</tr>
</tbody>
</table>

**Description**

White crystalline powder

**Identification**

A. Positive tests for propionate and for potassium

**Purity**

<table>
<thead>
<tr>
<th><strong>Loss on drying</strong></th>
<th>Not more than 4 %, determined by drying for two hours at 105 °C</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Water-insoluble substances</strong></td>
<td>Not more than 0,3 %</td>
</tr>
<tr>
<td><strong>Iron</strong></td>
<td>Not more than 30 mg/kg</td>
</tr>
<tr>
<td><strong>Fluoride</strong></td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td><strong>Arsenic</strong></td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td><strong>Lead</strong></td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td><strong>Mercury</strong></td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td><strong>Heavy metals (as Pb)</strong></td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

**E 284 BORIC ACID**

**Synonyms**

<table>
<thead>
<tr>
<th><strong>Boric acid</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Orthoboric acid</strong></td>
</tr>
<tr>
<td><strong>Borofax</strong></td>
</tr>
</tbody>
</table>
**Definition**

**Einecs**

**Chemical formula**  
H$_3$BO$_3$

**Molecular weight**  
61,84

**Assay**  
Content not less than 99.5 %

**Description**  
Colourless, odourless, transparent crystals or white granules or powder; slightly unctuous to the touch; occurs in nature as the mineral sassolite

**Identification**

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**

**Chemical name**  
Sodium tetraborate

**Einecs**

**Chemical formula**  
Na$_2$B$_4$O$_7$

**Molecular weight**  
201,27

**Description**  
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

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**

**Chemical name**  
Carbon dioxide

**Einecs**

**Chemical formula**  
CO$_2$

**Molecular weight**  
44,01

**Assay**  
Content not less than 99 % v/v on the gaseous basis
\[ \textit{B} \]

**Description**

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 methyl- lorange 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**

*Chemical name*

L-ascorbic acid

Ascorbic acid

2,3-Didehydro-L-threo-hexono-1,4-lactone

3-Keto-L-gulofuranolactone

**Einecs**

**Chemical formula**

$C_6H_8O_6$

**Molecular weight**

176,13

**Assay**

Ascorbic acid, after drying in a vacuum desiccator over sulphuric acid for 24 hours, contains not less than 99 % of $C_6H_8O_6$

**Description**

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

**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**

*Chemical name*

Sodium ascorbate

Sodium L-ascorbate

2,3-Didehydro-L-threo-hexono-1,4-lactone sodium
E 302 CALCIUM ASCORBATE

Definition
Chemical name
Calcium ascorbate dihydrate
Calcium salt of 2,3-didehydro-L-threo-hexono-1,4-lactone dihydrate

Einencs
227-261-5
Chemical formula
C12H14O12Ca·2H2O
Molecular weight
426,35
Assay
Content not less than 98 % on a volatile matter-free basis

Description
White to slightly pale greyish-yellow odourless crystalline powder

Identification
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
Chemical name
Ascorbyl palmitate
**E 304 (ii) ASCORBYL STEARATE**

**Definition**

- **Chemical name**
  - Ascorbyl stearate
  - L-ascorbyl stearate
- **Chemical formula**
  - C\(_{22}\)H\(_{38}\)O\(_{7}\)
  - C\(_{24}\)H\(_{42}\)O\(_{7}\)
- **Molecular weight**
  - 414.55
  - 442.6
- **Assay**
  - Content not less than 98 %
- **Description**
  - 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 %
- **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 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-\(\alpha\)-, d-\(\beta\)-, d-\(\gamma\)- and d-\(\delta\)-tocopherols
- Molecular weight 430.71 (d-\(\alpha\)-tocopherol)
- Assay Content not less than 34 % of total tocopherols
- Description Brownish red to red, clear, viscous oil having a mild, characteristic odour and taste. May show a slight
B

Identification
A. By suitable gas liquid chromatographic method
B. Solubility tests

Purity
- Sulphated ash
- Specific rotation
- Arsenic
- Lead
- Mercury
- Heavy metals (as Pb)

α

M7

E 307 ALPHA-TOCOPHEROL

Synonyms
DL-α-Tocopherol

Definition
Chemical name

EINECS
Chemical formula
Molecular weight
Assay
Description

Identification
A. Solubility tests
B. Spectrophotometry

Purity
- Refractive index
- Specific absorption E 2%1cm in ethanol
- Sulphated ash
- Specific rotation
- Lead

α

B

E 308 GAMMA-TOCOPHEROL

Synonyms
dl-γ-Tocopherol

Definition
Chemical name

EINECS
Chemical formula
Molecular weight
Assay
Description

Identification
A. Spectrometry

α
### E 309 DELTA-TOCOPHEROL

**Definition**
- **Chemical name**: 2,8-dimethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol
- **Einecs**: 204-299-0
- **Chemical formula**: C_{27}H_{46}O_{2}
- **Molecular weight**: 402.7

**Assay**
- Content not less than 97 %

**Description**
Clear, viscous, pale yellowish or orange oil which 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 $E_{1\%}^{1\text{cm}}$ in ethanol
  - $E_{1\%}^{1\text{cm}}$ (298 nm) between 89 and 95
  - $E_{1\%}^{1\text{cm}}$ (257 nm) between 3,0 and 6,0
- Refractive index
  - $n_{20}^{D}$ 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 310 PROPYL GALLATE

**Definition**
- **Chemical name**: Propyl gallate
- **Einecs**: 204-498-2
- **Chemical formula**: C_{10}H_{12}O_{5}
- **Molecular weight**: 212.20

**Assay**
- Content not less than 98 % on the anhydrous basis
- 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)
### E 311 OCTYL GALLATE

**Definition**

*Chemical name*

Octyl gallate

Octyl ester of gallic acid

n-octyl ester of 3,4,5-trihydroxybenzoic acid

**Einecs**

*Chemical formula*

C_{15}H_{22}O_{5}

**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 C1)
- Specific absorption $E_{1\%}^{1\text{cm}}$ in ethanol

$E_{1\%}^{1\text{cm}}$ (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**

*Chemical formula*

C_{19}H_{30}O_{5}

**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 %
▼B

Free acid Not more than 0,5 % (as gallic acid)
Chlorinated organic compound Not more than 100 mg/kg (as Cl)
Specific absorption $E_{1\%}^{1cm}$ in ethanol $E_{1\%}^{1cm}$ (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

▼M7

E 315 ERYTHORBIC ACID

Synonyms
- Isoascorbic acid
- D-Araboascorbic acid

Definition

Chemical name
- D-Erythro-hex-2-enoic acid $\gamma$-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 $[\alpha]_D^{25D}$ 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

Lead Not more than 2 mg/kg

▼B

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

Chemical formula
$C_6H_7O_6Na\cdotH_2O$

Molecular weight
216,13

Assay
Content not less than 98 % after drying in a vacuum desiccator over sulphuric acid for 24 hours expressed on the monohydrate basis

Description
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

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 0,25 % after drying in a vacuum desiccator over sulphuric acid for 24 hours</td>
</tr>
<tr>
<td>Specific rotation</td>
<td>$[\alpha]_D^{25}$ 10 % (w/v) aqueous solution between + 95 ° and + 98 °</td>
</tr>
<tr>
<td>pH of a 10 % aqueous solution</td>
<td>5,5 to 8,0</td>
</tr>
<tr>
<td>Oxalate</td>
<td>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</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

### Identification

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Solubility</td>
<td>Practically insoluble in water; soluble in ethanol</td>
</tr>
<tr>
<td>B. Melting point</td>
<td>Not less than 126,5 °C</td>
</tr>
<tr>
<td>C. Phenolics</td>
<td>Dissolve about 5 mg of the sample in 10 ml of methanol and add 10,5 ml of dimethylamine solution (1 in 4). A red to pink colour is produced</td>
</tr>
</tbody>
</table>

### Purity

| Tertiary-Butyl-p-benzoquinone                  | Not more than 0,2 %                                                        |
| 2,5-Di-tertiary-butyl hydroquinone            | Not more than 0,2 %                                                        |
| Hydroxyquinone                                | Not more than 0,1 %                                                        |
| Toluene                                       | Not more than 25 mg/kg                                                     |
| Lead                                          | Not more than 2 mg/kg                                                      |

### E 319 TERTIARY-BUTYLHYDROQUINONE (TBHQ)

#### Synonyms

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>TBHQ</th>
</tr>
</thead>
</table>

#### Definition

**Chemical names**
- Tert-butyl-1,4-benzenediol
- 2-(1,1-Dimethylethyl)-1,4-benzenediol

#### EINECS

- 217-752-2

#### Chemical formula

**C10H14O2**

#### Molecular weight

166,22

#### Assay

Content not less than 99 % of C10H14O2

#### Description

White crystalline solid having a characteristic odour

### Identification

<table>
<thead>
<tr>
<th>A. Solubility</th>
<th>Practically insoluble in water; soluble in ethanol</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Melting point</td>
<td>Not less than 126,5 °C</td>
</tr>
<tr>
<td>C. Phenolics</td>
<td>Dissolve about 5 mg of the sample in 10 ml of methanol and add 10,5 ml of dimethylamine solution (1 in 4). A red to pink colour is produced</td>
</tr>
</tbody>
</table>

### Purity

| Tertiary-Butyl-p-benzoquinone                  | Not more than 0,2 %                                                        |
| 2,5-Di-tertiary-butyl hydroquinone            | Not more than 0,2 %                                                        |
| Hydroxyquinone                                | Not more than 0,1 %                                                        |
| Toluene                                       | Not more than 25 mg/kg                                                     |
| Lead                                          | Not more than 2 mg/kg                                                      |

### E 320 BUTYLATED HYDROXYANISOLE (BHA)

#### Synonyms

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>BHA</th>
</tr>
</thead>
</table>

#### Definition

**Chemical names**
- 3-Tertiary-butyl-4-hydroxyanisole
- A mixture of 2-tertiary-butyl-4-hydroxyanisole and 3-tertiary-butyl-4-hydroxyanisole

#### EINECS

- 246-563-8

#### Chemical formula

**C11H16O2**

#### Formula weight

180,25

#### Assay

Content not less than 98,5 % of C11H16O2 and not less than 85 % of 3-tertiary-butyl-4-hydroxyanisole isomer

#### Description

White or slightly yellow crystals or waxy solid with a slight aromatic smell
Identification
A. Solubility Insoluble in water, freely soluble in ethanol
B. Melting range Between 48 °C and 63 °C
C. Colour reaction Passes test for phenol groups

Purity
- Sulphated ash Not more than 0,05 % after calcination at 800 ± 25 °C
- Phenolic impurities Not more than 0,5 %
- Specific absorption $E_{1\%}^{1\text{cm}}$ $E_{1\%}^{1\text{cm}}$ (290 nm) not less than 190 and not more than 210
- Specific absorption $E_{1\%}^{1\text{cm}}$ $E_{1\%}^{1\text{cm}}$ (228 nm) not less than 326 and not more than 345
- Arsenic Not more than 3 mg/kg
- Lead Not more than 5 mg/kg
- Mercury Not more than 1 mg/kg

**E 321 BUTYLATED HYDROXYTOLUENE (BHT)**

**Synonyms**
- BHT

**Definition**
*Chemical name*
- 2,6-Ditertiary-butyl-p-cresol
- 4-Methyl-2,6-ditertiarybutylphenol

**Einces**
- 204-881-4

**Chemical formula**
- C15H24O

**Molecular weight**
- 220,36

**Description**
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
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 $E_{1\%}^{1\text{cm}}$ $E_{1\%}^{1\text{cm}}$ (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

**Einces**
- 232-307-2
### B

**Assay**
- Lecithins: not less than 60.0% of substances insoluble in acetone
- Hydrolysed lecithins: not less than 56.0% of substances insoluble in acetone

**Description**
- Lecithins: brown liquid or viscous semi-liquid or powder
- Hydrolysed lecithins: light brown to brown viscous liquid or paste

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

**Purity**
- Loss on drying: Not more than 2.0% determined by drying at 105°C for one hour
- Toluene-insoluble matter: Not more than 0.3%
- Acid value:
  - Lecithins: not more than 35 mg of potassium hydroxide per gram
  - Hydrolysed lecithins: not more than 45 mg of potassium hydroxide per gram
- Peroxide value: Equal to or less than 10
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 5 mg/kg
- Mercury: Not more than 1 mg/kg
- Heavy metals (as Pb): Not more than 10 mg/kg

### E 325 SODIUM LACTATE

**Definition**
- **Chemical name**
  - Sodium lactate
  - Sodium 2-hydroxypropanoate
- **Einects**
  - 200-772-0
- **Chemical formula**
  - C₃H₅NaO₃
- **Molecular weight**
  - 112.06 (anhydrous)
- **Assay**
- **Description**
  - Colourless, transparent, liquid
  - Odourless, or with a slight, characteristic odour

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

**Purity**
- **Acidity**
  - Not more than 0.5% after drying expressed as lactic acid
- **pH of a 20 % aqueous solution**
  - 6.5 to 7.5
- **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
- **Reducing substances**
  - No reduction of Fehling's solution
### E 326 POTASSIUM LACTATE

**Definition**  
Chemical name: Potassium lactate  
Potassium 2-hydroxypropanoate  
Potassium 2-hydroxypropanolate  
Einecs: 213-631-3  
Chemical formula: \( \text{C}_3\text{H}_5\text{O}_3\text{K} \)  
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  

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

### E 327 CALCIUM LACTATE

**Definition**  
Chemical name: Calcium dilactate  
Calcium dilactate hydrate  
2-Hydroxypropanoic acid calcium salt  
Einecs: 212-406-7  
Chemical formula: \((\text{C}_3\text{H}_5\text{O}_2)\text{Ca}_n\text{H}_2\text{O} (n = 0—5)\)  
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  

**Purity**  
Loss on drying: Determined by drying at 120 °C for four hours:  
— anhydrous: not more than 3.0 %
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
Citric acid may be anhydrous or it may contain 1 molecule of water. Citric acid contains not less than 99.5 % of C₆H₈O₇, calculated on the anhydrous basis.

Description
Citric acid is a white or colourless, odourless, crystalline solid, having a strongly acid taste. The monohydrate effloresces in dry air.

Identification
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).

E 331 (i) MONOSODIUM CITRATE

Synonyms
Monosodium citrate
Monobasic sodium citrate
### Monosodium Citrate

**Chemical name**  
Monosodium citrate  
Monosodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid

**Chemical formula**  
(a) $C_6H_7O_7Na$ (anhydrous)  
(b) $C_6H_7O_7Na\cdot H_2O$ (monohydrate)

**Molecular weight**  
(a) 214.11 (anhydrous)  
(b) 232.23 (monohydrate)

**Assay**  
Content not less than 99 % on the anhydrous basis

**Description**  
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

### Disodium Citrate

**Chemical name**  
Disodium citrate  
Disodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid  
Disodium salt of citric acid with 1,5 molecules of water

**Chemical formula**  
$C_6H_6O_7Na_2\cdot 1.5H_2O$

**Molecular weight**  
263.11

**Assay**  
Content not less than 99 % on the anhydrous basis

**Description**  
Crystalline white powder or colourless crystals

**Identification**

**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

**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**
- **Chemical name**
  - Trisodium citrate
  - Trisodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid
  - Trisodium salt of citric acid, in anhydrous, dihydrate or pentahydrate form

**Einecs**
- **Chemical formula**
  - Anhydrous: C6H5O7Na3
  - Hydrated: C6H5O7Na3·nH2O (n = 2 or 5)
- **Molecular weight**
- **Assay**
- **Description**

**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**
- **pH of a 5 % aqueous solution**
- **Arsenic**
- **Lead**
- **Mercury**
- **Heavy metals (as Pb)**

### E 332 (i) MONOPOTASSIUM CITRATE

**Synonyms**
- Monopotassium citrate
- Monobasic potassium citrate

**Definition**
- **Chemical name**
  - Monopotassium citrate
  - Monopotassium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid
  - Anhydrous monopotassium salt of citric acid

**Einecs**
- **Chemical formula**
  - C6H7O7K
- **Molecular weight**
- **Assay**
- **Description**

**Identification**
- A. Positive tests for citrate and for potassium

**Purity**
- **Loss on drying**
- **Oxalates**
- **pH of a 1 % aqueous solution**

B

<table>
<thead>
<tr>
<th>Arsenic</th>
<th>Not more than 1 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 5 mg/kg</td>
</tr>
</tbody>
</table>

E 332 (ii) TRIPOTASSIUM CITRATE

Synonyms
Tripotassium citrate
Tribasic potassium citrate

Definition
Chemical name
Tripotassium citrate
Tripotassium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid
Monohydrated tripotassium salt of citric acid

Einecs
212-755-5

Chemical formula
C$_6$H$_5$O$_7$K$_3$·H$_2$O

Molecular weight
324,42

Assay
Content not less than 99 % on the anhydrous basis

Description
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
Chemical name
Monocalcium citrate
Monocalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid
Monohydrate monocalcium salt of citric acid

Chemical formula
(C$_6$H$_7$O$_7$)$_2$Ca·H$_2$O

Molecular weight
440,32

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

Description
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
Arsenic
Lead
Mercury
Heavy metals (as Pb)
Carbonates

Not more than 30 mg/kg (expressed as fluorine)
Not more than 1 mg/kg
Not more than 1 mg/kg
Not more than 1 mg/kg
Not more than 5 mg/kg
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
Chemical name
Dicalcium citrate
Dicalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid
Trihydrated dicalcium salt of citric acid

Chemical formula
(C₆H₇O₇)₂Ca₂·3H₂O
Molecular weight
530.42
Assay
Not less than 97.5 % on the anhydrous basis
Description
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

E 333 (iii) TRICALCIUM CITRATE

Synonyms
Tricalcium citrate
Tribasic calcium citrate

Definition
Chemical name
Tricalcium citrate
Tricalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid
Tetrahydrated tricalcium salt of citric acid

Einccs
212-391-7
Chemical formula
(C₆H₆O₇)₂Ca₃·4H₂O
Molecular weight
570.51
Assay
Not less than 97.5 % on the anhydrous basis
Description
Fine white powder

Identification
A. Positive tests for citrate and for calcium
### Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 14.0% determined by drying at 180 °C for four hours</td>
</tr>
<tr>
<td>Oxalates</td>
<td>Not more than 100 mg/kg expressed as oxalic acid, after drying</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 30 mg/kg (expressed as fluorine)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Carbonates</td>
<td>Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles</td>
</tr>
</tbody>
</table>

### E 334 L(+)TARTARIC ACID

**Definition**

Chemical name

- L-tartaric acid
- L-2,3-dihydroxybutanedioic acid
- d-α,β-dihydroxysuccinic acid

**Einescs**

Chemical formula: C_4H_6O_6

Molecular weight: 150.09

**Assay**

Content not less than 99.5% on the anhydrous basis

**Description**

Colourless or translucent crystalline solid or white crystalline powder

### Identification

A. Melting range

Between 168 °C and 170 °C

### Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 0.5% (over P_2O_5, three hours)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 1000 mg/kg after calcination at 800 ± 25 °C</td>
</tr>
<tr>
<td>Specific optical rotation of a 20% w/v aqueous solution</td>
<td>[α]_D&lt;sup&gt;20&lt;/sup&gt; between +11.5° and +13.5°</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Oxalates</td>
<td>Not more than 100 mg/kg expressed as oxalic acid, after drying</td>
</tr>
</tbody>
</table>

### E 335 (i) MONOSODIUM TARTRATE

**Synonyms**

Monosodium salt of L-(+)-tartaric acid

**Definition**

Chemical name

Monosodium salt of L-2,3-dihydroxybutanedioic acid

Monohydrated monosodium salt of L-(+)tartaric acid

Chemical formula: C_4H_5O_6Na·H_2O

Molecular weight: 194.05

**Assay**

Content not less than 99% on the anhydrous basis

**Description**

Transparent colourless crystals

### Identification

A. Positive tests for tartrate and for sodium

### Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td></td>
</tr>
</tbody>
</table>
**E 335 (ii) DISODIUM TARTRATE**

**Definition**

*Chemical name*

Disodium L-tartrate  
Disodium (+)-tartrate  
Disodium (+)-2,3-dihydroxybutanedioic acid  
Dihydrated disodium salt of L-(+)-tartaric acid

**Einescs**

*Chemical formula*  
C₄H₄O₆Na₂·2H₂O

*Molecular weight*  
230.8

*Assay*

Content not less than 99 % on the anhydrous basis

*Description*

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

*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

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**E 336 (i) MONOPOTASSIUM TARTRATE**

**Synonyms**

Monobasic potassium tartrate

**Definition**

*Chemical name*

Anhydrous monopotassium salt of L-(+)-tartaric acid  
Monopotassium salt of L-2,3-dihydroxybutanedioic acid

*Chemical formula*  
C₄H₅O₆K

*Molecular weight*  
188.16

*Assay*

Content not less than 98 % on the anhydrous basis

*Description*

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*
### E 336 (ii) DIPOTASSIUM TARTRATE

**Synonyms**
- Dipotassium salt of L-2,3-dihydroxybutanedioic acid
- Dipotassium salt with half a molecule of water of L-(+)-tartaric acid

**Definition**
- **Chemical name**: Dipotassium salt of L-2,3-dihydroxybutanedioic acid
- **Einecs**: 213-067-8
- **Chemical formula**: $\text{C}_4\text{H}_4\text{O}_6\text{K}_2\cdot \text{H}_2\text{O}$
- **Molecular weight**: 235.2
- **Assay**: Content not less than 99 % on the anhydrous basis
- **Description**: White crystalline or granulated powder

**Identification**
- A. Positive tests for tartrate and for potassium
- B. Solubility tests
- C. Melting range: Between 70 and 80 °C

**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
- **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**
- **Chemical name**: Potassium sodium salt of L-2,3-dihydroxybutanedioic acid
- **Einecs**: 206-156-8
- **Chemical formula**: $\text{C}_4\text{H}_4\text{O}_6\text{KNa} \cdot 4\text{H}_2\text{O}$
- **Molecular weight**: 282.23
- **Assay**: Content not less than 99 % on the anhydrous basis
- **Description**: Colourless crystals or white crystalline powder

**Identification**
- A. Positive tests for tartrate, for potassium and for sodium
- B. Solubility tests
- 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
**E 338 PHOSPHORIC ACID**

**Synonyms**
- Orthophosphoric acid
- Monophosphoric acid

**Definition**
- **Chemical name**: Phosphoric acid
- **Einecs**: 231-633-2
- **Chemical formula**: $\text{H}_3\text{PO}_4$
- **Molecular weight**: 98.00

**Assay**
Phosphoric acid is commercially available as an aqueous solution at variable concentrations. Content not less than 67.0 % and not more than 85.7 %.

**Description**
Clear, colourless, viscous liquid

**Identification**
- A. Positive tests for acid and for phosphate

**Purity**
- **Volatile acids**: Not more than 10 mg/kg (as acetic acid)
- **Chlorides**: Not more than 200 mg/kg (expressed as chlorine)
- **Nitrites**: Not more than 5 mg/kg (as NaNO$_2$)
- **Sulphates**: Not more than 1 500 mg/kg (as CaSO$_4$)
- **Fluoride**: Not more than 10 mg/kg (expressed as fluorine)
- **Arsenic**: Not more than 3 mg/kg
- **Cadmium**: Not more than 1 mg/kg
- **Lead**: Not more than 4 mg/kg
- **Mercury**: Not more than 1 mg/kg

**Note:**
This specification refers to a 75 % aqueous solution.

**E 339 (i) MONOSODIUM PHOSPHATE**

**Synonyms**
- Monosodium monophosphate
- Acid monosodium monophosphate
- Monosodium orthophosphate
- Monobasic sodium phosphate
- Sodium dihydrogen monophosphate

**Definition**
- **Chemical name**: Sodium dihydrogen monophosphate
- **Einecs**: 231-449-2
- **Chemical formula**
  - Anhydrous: $\text{NaH}_2\text{PO}_4$
  - Monohydrate: $\text{NaH}_2\text{PO}_4 \cdot \text{H}_2\text{O}$
  - Dihydrate: $\text{NaH}_2\text{PO}_4 \cdot 2\text{H}_2\text{O}$
- **Molecular weight**
  - Anhydrous: 119.98
  - Monohydrate: 138.00
Dihydrate: 156,01

After drying at 60 °C for one hour and then at 105 °C for four hours, contains not less than 97 % of NaH₂PO₄

Between 58,0 % and 60,0 % on the anhydrous basis

A white odourless, slightly deliquescent powder, crystals or granules

A. Positive tests for sodium and for phosphate

B. Solubility

Freely soluble in water. Insoluble in ethanol or ether

C. pH of a 1 % solution

Between 4,1 and 5,0

The anhydrous salt loses not more than 2,0 %, the monohydrate not more than 15,0 %, and the dihydrate not more than 25 % when dried first at 60 °C for one hour, then at 105 °C for four hours

Not more than 0,2 % on the anhydrous basis

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

Not more than 3 mg/kg

Not more than 1 mg/kg

Not more than 4 mg/kg

Not more than 1 mg/kg

Disodium monophosphate

Secondary sodium phosphate

Disodium orthophosphate

Acid disodium phosphate

Disodium hydrogen monophosphate

Disodium hydrogen orthophosphate

231-448-7

Anhydrous: Na₂HPO₄

Hydrat: Na₂HPO₄ · nH₂O (n = 2, 7 or 12)

141,98 (anhydrous)

After drying at 40 °C for three hours and subsequently at 105 °C for five hours, contains not less than 98 % of Na₂HPO₄

Between 49 % and 51 % on the anhydrous basis

Anhydrous disodium hydrogen phosphate is a white, hygroscopic, odourless powder. Hydrated forms available include the dihydrate: a white crystalline, odourless solid; the heptahydrate: white, efflorescent, efflorescent crystals or granular powder; and the dodecahydrate: white, efflorescent, odourless powder or crystals

A. Positive tests for sodium and for phosphate

B. Solubility

Freely soluble in water. Insoluble in ethanol

Between 8,4 and 9,6
C. pH of a 1 % solution

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 %, dode-
cahydrate not more than 61,0 %

Water-insoluble substances
Not more than 0,2 % on the anhydrous basis
Fluoride
Not more than 10 mg/kg (expressed as fluorine)
Arsenic
Not more than 3 mg/kg
Cadmium
Not more than 1 mg/kg
Lead
Not more than 4 mg/kg
Mercury
Not more than 1 mg/kg

E 339 (iii) TRISODIUM PHOSPHATE

Synonyms
Sodium phosphate
Tribasic sodium phosphate
Trisodium orthophosphate

Definition
Trisodium phosphate is obtained from aqueous solutions and crystallises in the anhydrous form and with 1/2, 1, 6, 8 or 12 H₂O. The dodecahydrate always crystallises from aqueous solutions with an excess of sodium hydroxide. It contains molecule of NaOH

Chemical name
Trisodium monophosphate
Trisodium phosphate
Trisodium orthophosphate

Einecs
231-509-8

Chemical formula
Anhydrous: Na₃PO₄
Hydrated: Na₃PO₄ · nH₂O (n = 1/2, 1, 6, 8, or 12)

Molecular weight
163,94 (anhydrous)

Assay
Sodium phosphate anhydrous and the hydrated forms, with the exception of the dodecahydrate, contain not less than 97,0 % of Na₃PO₄ calculated on the dried basis. Sodium phosphate dodecahydrate contains not less than 92,0 % of Na₃PO₄ calculated on the ignited basis

P₂O₅ content
Between 40,5 % and 43,5 % on the anhydrous basis

Description
White odourless crystals, granules or crystalline powder

Identification
A. Positive tests for sodium and for phosphate
B. Solubility
Freely soluble in water. Insoluble in ethanol
C. pH of a 1 % solution
Between 11,5 and 12,5

Purity
Loss on ignition
When dried at 120 °C for two hours and then ignited at about 800 °C for 30 minutes, the losses in weight are as follows: anhydrous not more than 2,0 %, monohydrate not more than 11,0 %, dodecahydrate: between 45,0 % and 58,0 %

Water insoluble substances
Not more than 0,2 % on the anhydrous basis
Fluoride
Not more than 10 mg/kg (expressed as fluorine)
Arsenic
Not more than 3 mg/kg
Cadmium | Not more than 1 mg/kg
Lead | Not more than 4 mg/kg
Mercury | Not more than 1 mg/kg

**E 340 (i) MONOPOTASSIUM PHOSPHATE**

**Synonyms**
- Monobasic potassium phosphate
- Monopotassium monophosphate
- Potassium orthophosphate

**Definition**
*Chemical name*  
Potassium dihydrogen phosphate  
Monopotassium dihydrogen orthophosphate  
Monopotassium dihydrogen monophosphate

**Einecs**  
231-913-4

**Chemical formula**  
KH₂PO₄

**Molecular weight**  
136,09

**Assay**  
Content not less than 98.0 % after drying at 105 °C for four hours

**P₂O₅ content**  
Between 51.0 % and 53.0 % on the anhydrous basis

**Description**  
Odourless, colourless crystals or white granular or crystalline powder, hygroscopic

**Identification**

A. Positive tests for potassium and for phosphate

B. Solubility  
Freely soluble in water. Insoluble in ethanol

C. pH of a 1 % solution  
Between 4.2 and 4.8

**Purity**

Loss on drying  
Not more than 2.0 % determined by drying at 105 °C for four hours

Water-insoluble substances  
Not more than 0.2 % on the anhydrous basis

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

Arsenic  
Not more than 3 mg/kg

Cadmium  
Not more than 1 mg/kg

Lead  
Not more than 4 mg/kg

Mercury  
Not more than 1 mg/kg

**E 340 (ii) DIPOTASSIUM PHOSPHATE**

**Synonyms**
- Dipotassium monophosphate
- Secondary potassium phosphate
- Dipotassium acid phosphate
- Dipotassium orthophosphate
- Dibasic potassium phosphate

**Definition**
*Chemical name*  
Dipotassium hydrogen monophosphate  
Dipotassium hydrogen phosphate  
Dipotassium hydrogen orthophosphate

**Einecs**  
231-834-5

**Chemical formula**  
K₂HPO₄

**Molecular weight**  
174,18

**Assay**  
Content not less than 98 % after drying at 105 °C for four hours
**M4**

**\( P_2O_5 \) content**

| Between 40,3 % and 41,5 % on the anhydrous basis |

**Description**

| Colourless or white granular powder, crystals or masses; deliquescent substance |

**Identification**

**A. Positive tests for potassium and for phosphate**

**B. Solubility**

| Freely soluble in water. Insoluble in ethanol |

**C. pH of a 1 % solution**

| Between 8,7 and 9,4 |

**Purity**

**Loss on drying**

| Not more than 2,0 % determined by drying at 105 °C for four hours |

**Water-insoluble substances**

| Not more than 0,2 % on the anhydrous basis |

**Fluoride**

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

**Arsenic**

| Not more than 3 mg/kg |

**Cadmium**

| Not more than 1 mg/kg |

**Lead**

| Not more than 4 mg/kg |

**Mercury**

| Not more than 1 mg/kg |

---

**E 340 (iii) TRIPOTASSIUM PHOSPHATE**

**Synonyms**

| Potassium phosphate |

| Tribasic potassium phosphate |

| Tripotassium orthophosphate |

**Definition**

**Chemical name**

| Tripotassium monophosphate |

| Tripotassium phosphate |

| Tripotassium orthophosphate |

| 231-907-1 |

**Chemical formula**

| Anhydrous: \( K_3PO_4 \) |

| Hydrated: \( K_3PO_4 \cdot nH_2O \ (n = 1 \ or \ 3) \) |

| 212,27 (anhydrous) |

**Molecular weight**

| Content not less than 97 % calculated on the ignited basis |

**Assay**

| Between 30,5 % and 33,0 % on the ignited basis |

**\( P_2O_5 \) content**

| Colourless or white, odourless hygroscopic crystals or granules. Hydrated forms available include the mono-hydrate and trihydrate |

**Description**

**Identification**

**A. Positive tests for potassium and for phosphate**

**B. Solubility**

| Freely soluble in water. Insoluble in ethanol |

**C. pH of a 1 % solution**

| Between 11,5 and 12,3 |

**Purity**

**Loss on ignition**

| Anhydrous: not more than 3,0 %; hydrated: not more than 23,0 %. Determined by drying at 105 °C for one hour and then ignite at about 800 °C ± 25 °C for 30 minutes |

**Water insoluble substances**

| Not more than 0,2 % on the anhydrous basis |

**Fluoride**

| Not more than 10 mg/kg (expressed as fluorine) |
Arsenic: Not more than 3 mg/kg
Cadmium: Not more than 1 mg/kg
Lead: Not more than 4 mg/kg
Mercury: Not more than 1 mg/kg

E 341 (i) MONOCALCIUM PHOSPHATE

**Synonyms**
Monobasic calcium phosphate
Monocalcium orthophosphate

**Definition**
Chemical name: Calcium dihydrogen phosphate

**Einecs**
231-837-1

**Chemical formula**
Anhydrous: Ca(H₂PO₄)₂
Monohydrate: Ca(H₂PO₄)₂·H₂O

**Molecular weight**
234.05 (anhydrous)
252.08 (monohydrate)

**Assay**
Content not less than 95 % on the dried basis

**P₂O₅ content**
Between 55.5 % and 61.1 % on the anhydrous basis

**Description**
Granular powder or white, deliquescent crystals or granules

**Identification**
A. Positive tests for calcium and for phosphate
B. CaO content
   Between 23.0 % and 27.5 % (anhydrous)
   Between 19.0 % and 24.8 % (monohydrate)

**Purity**
Loss on drying
Not more than 14 % determined by drying at 105 °C for four hours (anhydrous)
Not more than 17.5 % determined by drying at 60 °C for one hour, then at 105 °C for four hours (monohydrate)
Loss on ignition
Not more than 17.5 % after ignition at 800 °C ± 25 °C for 30 minutes (anhydrous)
Not more than 25.0 % determined by drying at 105 °C for one hour, then ignite at 800 °C ± 25 °C for 30 minutes (monohydrate)
Fluoride
Not more than 30 mg/kg (expressed as fluorine)

Arsenic: Not more than 3 mg/kg
Cadmium: Not more than 1 mg/kg
Lead: Not more than 4 mg/kg
Mercury: Not more than 1 mg/kg

E 341 (ii) DICALCIUM PHOSPHATE

**Synonyms**
Dibasic calcium phosphate
Dicalcium orthophosphate

**Definition**
Chemical name: Calcium monohydrogen phosphate
Calcium hydrogen orthophosphate
Secondary calcium phosphate

**Einecs**
231-826-1

**Chemical formula**
Anhydrous: CaHPO₄
Dihydrate: CaHPO₄·2H₂O

**Molecular weight**
136.06 (anhydrous)
172.09 (dihydrate)
M4

**Assay**

Dicalcium phosphate, after drying at 200 °C for three hours, contains not less than 98 % and not more than the equivalent of 102 % of CaHPO₄

**P₂O₅ content**

Between 50.0 % and 52.5 % on the anhydrous basis

**Description**

White crystals or granules, granular powder or powder

<table>
<thead>
<tr>
<th><strong>Identification</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Positive tests for calcium and for phosphate</td>
<td></td>
</tr>
<tr>
<td>B. Solubility tests</td>
<td>Sparingly soluble in water. Insoluble in ethanol</td>
</tr>
</tbody>
</table>

**Purity**

| **Loss on ignition** | Not more than 8.5 % (anhydrous), or 26.5 % (dihydrate) after ignition at 800 °C ± 25 °C for 30 minutes |
| **Fluoride** | Not more than 50 mg/kg (expressed as fluorine) |
| **Arsenic** | Not more than 3 mg/kg |
| **Cadmium** | Not more than 1 mg/kg |
| **Lead** | Not more than 4 mg/kg |
| **Mercury** | Not more than 1 mg/kg |

**E 341 (iii) TRICALCIUM PHOSPHATE**

**Synonyms**

Calcium phosphate, tribasic
Calcium orthophosphate
Pentacalcium hydroxy monophosphate
Calcium hydroxyapatite

**Definition**

Tricalcium phosphate consists of a variable mixture of calcium phosphates obtained from neutralisation of phosphoric acid with calcium hydroxide and having the approximate composition of 10CaO · 3P₂O₅ · H₂O

**Chemical name**

Pentacalcium hydroxy monophosphate
Tricalcium monophosphate

**Einecs**

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

**Chemical formula**

Ca₅(PO₄)₃ · OH or Ca₃(PO₄)₂

**Molecular weight**

502 or 310

**Assay**

Content not less than 90 % calculated on the ignited basis

**P₂O₅ content**

Between 38.5 % and 48.0 % on the anhydrous basis

**Description**

A white, odourless powder which is stable in air

<table>
<thead>
<tr>
<th><strong>Identification</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Positive tests for calcium and for phosphate</td>
<td></td>
</tr>
<tr>
<td>B. Solubility</td>
<td>Practically insoluble in water; insoluble in etanol, soluble in dilute hydrochloric and nitric acid</td>
</tr>
</tbody>
</table>

**Purity**

| **Loss on ignition** | Not more than 8 % after ignition at 800 °C ± 25 °C, to constant weight |
| **Fluoride** | Not more than 50 mg/kg (expressed as fluorine) |
| **Arsenic** | Not more than 3 mg/kg |
| **Cadmium** | Not more than 1 mg/kg |
| **Lead** | Not more than 4 mg/kg |
| **Mercury** | Not more than 1 mg/kg |
### E 385 Calcium Disodium Ethylenediaminetetraacetate

**Synonyms**
- Calcium disodium EDTA
- Calcium disodium edetate

**Definition**

*Chemical name*
- N,N′-1,2-Ethanediylbis[N-(carboxymethyl)-glycinate]
- [(4-)O,O′,O,N,ON]calcium(2)-disodium
- Calcium disodium ethylenediaminetetraacetate
- Calcium disodium (ethylenedinitrilo)tetra acetate

**Einacs**
- 200-529-9

*Chemical formula*
- C₁₀H₁₂O₈CaN₂Na₂·2H₂O

*Molecular weight*
- 410.31

*Assay*
- Content not less than 97 % on the anhydrous basis

*Description*
- White, odourless crystalline granules or white to nearly white powder, slightly hygroscopic

**Identification**

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

**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

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### 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 (*Phaeophyceae*).

**Einacs**
- 232-680-1

*Chemical formula*
- (C₆H₈O₆)ₙ

*Molecular weight*
- 10 000—600 000 (typical average)

*Assay*
- Alginic acid yields, on the anhydrous basis, not less than 20 % and not more than 23 % of carbon dioxide (CO₂), equivalent to not less than 91 % and not more than 104.5 % of alginic acid (C₆H₈O₆)ₙ (calculated on equivalent weight basis of 200)

*Description*
- Alginic acid occurs in filamentous, grainy, granular and powdered forms. It is a white to yellowish brown and nearly odourless

**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, gela-
tinous 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
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
E. coli Negative in 5 g
Salmonella spp. Negative in 10 g

E 401 SODIUM ALGINATE

Definition
Chemical name Sodium salt of alginic acid
Chemical formula \((\text{C}_\text{6}\text{H}_\text{7}\text{NaO}_\text{6})_\text{n}\)
Molecular weight 10 000-600 000 (typical average)
Assay Yields, on the anhydrous basis, not less than 18 % and not more than 21 % of carbon dioxide corresponding to not less than 90,8 % and not more than 106,0 % of sodium alginate (calculated on equivalent weight basis of 222)

Description
Nearly odourless, white to yellowish fibrous or granular powder

Identification
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
E. coli Negative in 5 g
### E 402 POTASSIUM ALGINATE

**Definition**
- **Chemical name**: Potassium salt of alginic acid
- **Chemical formula**: $(C_6H_7KO_6)_n$
- **Molecular weight**: 10 000-600 000 (typical average)
- **Assay**: Yields, on the anhydrous basis, not less than 16.5 % and not more than 19.5 % of carbon dioxide corresponding to not less than 89.2 % and not more than 105.5 % of potassium alginate (calculated on an equivalent weight basis of 238)

**Description**: Nearly odourless, white to yellowish fibrous or granular powder

**Identification**
- A. Positive test for potassium and for 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
- **E. coli**: Negative in 5 g
- **Salmonella spp.**: Negative in 10 g

### E 403 AMMONIUM ALGINATE

**Definition**
- **Chemical name**: Ammonium salt of alginic acid
- **Chemical formula**: $(C_6H_{11}NO_6)_n$
- **Molecular weight**: 10 000-600 000 (typical average)
- **Assay**: Yields, on the anhydrous basis, not less than 18 % and not more than 21 % of carbon dioxide corresponding to not less than 88.7 % and not more than 103.6 % ammonium alginate (calculated on an equivalent weight basis of 217)

**Description**: White to yellowish fibrous or granular powder

**Identification**
- 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
### E 404 CALCIUM ALGINATE

**Synonyms**

Calcium salt of alginate

**Definition**

- **Chemical name**: Calcium salt of alginic acid
- **Chemical formula**: \((C_6H_7Ca_1/2O_6)_n\)
- **Molecular weight**: 10 000-600 000 (typical average)
- **Assay**: Yields, on the anhydrous basis, not less than 18 % and not more than 21 % carbon dioxide corresponding to not less than 89,6 % and not more than 104,5 % of calcium alginate (calculated on an equivalent weight basis of 219)

**Description**

Nearly odourless, white to yellowish fibrous or granular powder

**Identification**

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
- **E. coli**: Negative in 5 g
- **Salmonella 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**

- **Chemical name**: Propane-1,2-diyl ester of alginic acid; varies in composition according to its degree of esterification and the percentage of free and neutralised carboxyl groups in the molecule
- **Chemical formula**: \((C_9H_{14}O_7)_n\) (esterified)
- **Molecular weight**: 10 000—600 000 (typical average)
- **Assay**: Yields, on the anhydrous basis, not less than 16 % and not more than 20 % of CO2 of carbon dioxide

**Description**

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 %
M1

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
E. coli Negative in 5 g
Salmonella 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 stan-
dardised 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 approxi-
mately 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
### M1

**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.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 20 mg/kg</td>
</tr>
</tbody>
</table>

### M6

#### E 407 CARRAGEenan

**Synonyms**

Products of commerce are sold under different names such as:

- Irish moss gelose
- Eucheuman (from *Eucheuma* spp.)
- Iridophycan (from *Iridaea* spp.)
- Hypnæan (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**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methanol, ethanol, propane-2-ol content</td>
<td>Not more than 0.1 % singly or in combination</td>
</tr>
<tr>
<td>Viscosity of a 1,5 % solution at 75 °C</td>
<td>Not less than 5 mPa.s</td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Not more than 12 % (105 °C, four hours)</td>
</tr>
<tr>
<td>Sulphate</td>
<td>Not less than 15 % and not more than 40 % on the dried basis (as SO₄₂⁻)</td>
</tr>
<tr>
<td>Ash</td>
<td>Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C</td>
</tr>
<tr>
<td>Acid-insoluble ash</td>
<td>Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)</td>
</tr>
<tr>
<td>Acid-insoluble matter</td>
<td>Not more than 2 % on the dried basis (insoluble in 1 % v/v sulphuric acid)</td>
</tr>
<tr>
<td>Low molecular weight carrageenan (Molecular weight fraction below 50 kDa)</td>
<td>Not more than 5 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>
### M6

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Total plate count</td>
<td>Not more than 5 000 colonies per gram</td>
</tr>
<tr>
<td>Yeast and moulds</td>
<td>Not more than 300 colonies per gram</td>
</tr>
<tr>
<td><em>E. coli</em></td>
<td>Negative in 5 g</td>
</tr>
<tr>
<td><em>Salmonella</em> spp.</td>
<td>Negative in 10 g</td>
</tr>
</tbody>
</table>

### 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 *Eucheuma cottonii* and *Eucheuma spinosum*, of the class *Rhodophyceae* (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 consist chiefly of the potassium salt 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.

#### Description
- 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, four hours)
- Sulphate: Not less than 15 % and not more than 40 % on the dried basis (as SO₄)
- Ash: Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C
- Acid-insoluble ash: Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)
- Acid-insoluble matter: Not less than 8 % and not more than 15 % on the dried basis (insoluble in 1 % v/v sulphuric acid)
- Low molecular weight carrageenan (Molecular weight fraction below 50 kDa): Not more than 5 %
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 5 mg/kg
- Mercury: Not more than 1 mg/kg
- Cadmium: Not more than 1 mg/kg
- Total plate count: Not more than 5 000 colonies per gram
- Yeast and moulds: Not more than 300 colonies per gram
- *E. coli*: Negative in 5 g
- *Salmonella* spp.: Negative in 10 g

### M1

#### E410 LOCUST BEAN GUM

#### Synonyms
- Carob bean gum
- Algaroba gum

#### Definition
Locust bean gum is the ground endosperm of the seeds of the natural strains of carob tree, *Ceratonia siliqua* (L.) Taub. (family *Leguminosae*). Consists mainly of a high molecular weight hydrocolloidal polysaccharide, composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as galactomannan.

**Molecular weight**

50 000—3 000 000

**Einecs**

232-541-5

**Assay**

Galactomannan content not less than 75 %

**Description**

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

**E412 GUAR GUM**

**Synonyms**

Gum cyamopsis

Guar flour

**Definition**

Guar gum is the ground endosperm of the seeds of natural strains of the guar plant, *Cyamopsis tetragonolobus* (L.) Taub. (family *Leguminosae*). Consists mainly of a high molecular weight hydrocolloidal polysaccharide composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as galactomannan.

**Einecs**

232-536-0

**Molecular weight**

50 000—8 000 000

**Assay**

Galactomannan content not less than 75 %

**Description**

A white to yellowish-white, nearly odourless powder

**Identification**

A. Positive tests for galactose and for mannose

B. Solubility

Soluble in cold water

**Purity**

Loss on drying

Not more than 15 % (105 °C, 5 hours)
### E413 TRAGACANTH

**Synonyms**
- Tragacanth gum
- Tragant

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

**Molecular weight**
Approximately 8,000,000

**Einecs**
232-252-5

**Description**
Unground Tragacanth gum occurs as flattened, lamellated, straight or curved fragments or as spirally twisted pieces 0.5-2.5 mm thick and up to 3 cm in length. It is white to pale yellow in colour but some pieces may have a red tinge. The pieces are horny in texture, with a short fracture. It is odourless and solutions have an insipid mucilaginous taste. Powdered tragacanth is white to pale yellow or pinkish brown (pale tan) in colour.

**Identification**

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.

- **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
- **Salmonella spp.**
  Negative in 10 g
- **E. coli**
  Negative in 5 g

### E414 ACACIA GUM

**Synonyms**
Gum arabic
M1

Definition

Acacia gum is a dried exudation obtained from the stems and branches of natural strains of *Acacia senegal* (L) Willdenow or closely related species of *Acacia* (family *Leguminosae*). It consists mainly of high molecular weight polysaccharides and their calcium, magnesium and potassium salts, which on hydrolysis yield arabinose, galactose, rhamnose and glucuronic acid.

*Molecular weight*

Approximately 350 000

*Einecs*

232-519-5

*Description*

Unground acacia gum occurs as white or yellowish-white spheroidal tears of varying sizes or as angular fragments and is sometimes mixed with darker fragments. It is also available in the form of white to yellowish-white flakes, granules, powder or spray-dried material.

*Identification*

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 FeCl₃·6H₂O 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)

*Salmonella* spp.

Negative in 10 g

*E. coli*

Negative in 5 g

M7

E415 XANTHAN GUM

Definition

Xanthan gum is a high molecular weight polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with natural strains of *Xanthomonas campestris*, purified by recovery with ethanol or propan-2-ol, dried and milled. It contains D-glucose and D-mannose as the dominant hexose units, along with D-glucuronic acid and pyruvic acid, and is prepared as the sodium, potassium or calcium salt. Its solutions are neutral.

*Molecular weight*

Approximately 1 000 000

*Einecs*

234-394-2

*Assay*

Yields, on dried basis, not less than 4,2 % and not more than 5 % of CO₂ corresponding to between 91 % and 108 % of xanthan gum

*Description*

Cream-coloured powder

*Identification*

A. Solubility

Soluble in water. Insoluble in ethanol
**Purity**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 15 % (105 °C, 2½ hours)</td>
</tr>
<tr>
<td>Total ash</td>
<td>Not more than 16 % on the anhydrous basis determined at 650 °C after drying at 105 °C for four hours</td>
</tr>
<tr>
<td>Pyruvic acid</td>
<td>Not less than 1.5 %</td>
</tr>
<tr>
<td>Nitrogen</td>
<td>Not more than 1.5 %</td>
</tr>
<tr>
<td>Ethanol and propan-2-ol</td>
<td>Not more than 500 mg/kg singly or in combination</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Total plate count</td>
<td>Not more than 5,000 colonies per gram</td>
</tr>
<tr>
<td>Yeast and mould</td>
<td>Not more than 300 colonies per gram</td>
</tr>
<tr>
<td><em>E. coli</em></td>
<td>Absent in 5 g</td>
</tr>
<tr>
<td><em>Salmonella</em> spp.</td>
<td>Absent in 10 g</td>
</tr>
<tr>
<td><em>Xanthomonas campestris</em></td>
<td>Viable cells absent in 1 g</td>
</tr>
</tbody>
</table>

**Synonyms**

- Katilo
- Kadaya
- Gum *sterculia*
- *Sterculia*
- Karaya, gum karaya
- Kullo
- Kuterra

**Definition**

Karaya gum is a dried exudation from the stems and branches of natural strains of *Sterculia urens* Roxburgh and other species of *Sterculia* (family *Sterculiaceae*) or from *Cochlospermum* gossypium A.P. De Candolle or other species of *Cochlospermum* (family *Bixaceae*). It consists mainly of high molecular weight acetylated polysaccharides, which on hydrolysis yield galactose, rhamnose, and galacturonic acid, together with minor amounts of gluconic acid.

**Einecs**

<table>
<thead>
<tr>
<th>EINECS</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>232-539-4</td>
<td></td>
</tr>
</tbody>
</table>

**Identification**

- A. Solubility
  - Insoluble in ethanol

- B. Swelling in ethanol solution
  - Karaya gum swells in 60 % ethanol distinguishing it from other gums
### E417 TARA GUM

**Definition**
Tara gum is obtained by grinding the endosperm of the seeds of natural strains of *Caesalpinia spinosa* (family Leguminosae). It consists chiefly of polysaccharides of high molecular weight composed mainly of galactomannans. The principal component consists of a linear chain of (1-4)-β-D-mannopyranose units with α-D-galactopyranose units attached by (1-6) linkages. The ratio of mannoe 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

**Description**
A white to white-yellow odourless powder

**Identification**

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Solubility</td>
<td>Soluble in water</td>
</tr>
<tr>
<td></td>
<td>Insoluble in ethanol</td>
</tr>
<tr>
<td>B. Gel formation</td>
<td>To an aqueous solution of the sample add small amounts of sodium borate. A gel is formed</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 15 %</td>
</tr>
<tr>
<td>Ash</td>
<td>Not more than 1.5 %</td>
</tr>
<tr>
<td>Acid insoluble matter</td>
<td>Not more than 2 %</td>
</tr>
<tr>
<td>Protein</td>
<td>Not more than 3.5 % (factor N x 5.7)</td>
</tr>
<tr>
<td>Starch</td>
<td>Not detectable</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 20 mg/kg</td>
</tr>
</tbody>
</table>

### E418 GELLAN GUM

**Definition**
Gellan gum is a high molecular weight polysaccharide gum produced by a pure culture fermentation of a carbohydrate by natural strains of *Pseudomonas elodea*, 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 glucose, 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

**Molecular weight**
Approximately 500 000

**Assay**
Yields, on the dried basis, not less than 3,3 % and not more than 6,8 % of CO₂

**Description**
An off-white powder

**Identification**

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Solubility</td>
<td>Soluble in water, forming a viscous solution.</td>
</tr>
<tr>
<td></td>
<td>Insoluble in ethanol</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 15 % after drying (105 °C, 2½ hours)</td>
</tr>
<tr>
<td>Nitrogen</td>
<td>Not more than 3 %</td>
</tr>
<tr>
<td>Propane-2-ol</td>
<td>Not more than 750 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>
E 422 GLYCEROL

Synonyms
Glycerin
Glycerine

Definition
Chemical names
1,2,3-propanetriol
Glycerol
Trihydroxypropane

Einecs
200-289-5

Chemical formula
C₃H₈O₃

Molecular weight
92.10

Assay
Content not less than 98 % of glycerol on the anhydrous basis

Description
Clear, colourless hygroscopic syrupy liquid with not more than a slight characteristic odour, which is neither harsh nor disagreeable

Identification
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]D²⁰
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 2 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

Assay
Content not less than 97.5 % on the anhydrous basis

Description
Cream-coloured flakes or waxy solid at 25 °C with a faint odour
Identification
A. Solubility Soluble in water, ethanol, methanol and ethyl acetate. Insoluble in mineral oil
B. Congealing range 39 °C — 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
Ethylene oxide Not more than 0,2 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

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 di-anhydrides with edible commercial lauric acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides

Assay
Content not less than 70 % of oxyethylene groups, equivalent to not less than 97,3 % of polyoxyethylene (20) sorbitan monolaurate on the anhydrous basis

Description
A lemon to amber-coloured oily liquid at 25 °C with a faint characteristic odour

Identification
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
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

Assay
Content not less than 65 % of oxyethylene groups,
equivalent to not less than 96,5 % of polyoxyethylene
(20) sorbitan monooleate on the anhydrous basis

Description
A lemon to amber-coloured oily liquid at 25 °C with a
faint characteristic odour

Identification
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 polyox-
eylated 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 65 and not more than 80
1,4-dioxane
Not more than 5 mg/kg
Ethylene oxide
Not more than 0,2 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

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

Assay
Content not less than 66 % of oxyethylene groups,
equivalent to not less than 97 % of polyoxyethylene
(20) sorbitan monopalmitate on the anhydrous basis

Description
A lemon to orange-coloured oily liquid or semi-gel at 25 °C
with a faint characteristic odour

Identification
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 polyoxy-
eylated 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
Ethylene oxide
Not more than 0,2 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

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

**Synonyms**
- Polysorbate 60
- Polyethylene (20) sorbitan monostearate

**Definition**
A mixture of the partial esters of sorbitol and its mono- and di-anhydrides with edible commercial stearic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides.

**Assay**
Content not less than 65 % of oxyethylene groups, equivalent to not less than 97 % of polyethylene (20) sorbitan monostearate on the anhydrous basis.

**Description**
A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour.

**Identification**
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 POLYETHYLENE SORBITAN TRISTEARATE (POLYSORBATE 65)**

**Synonyms**
- Polysorbate 65
- Polyethylene (20) sorbitan tristearate

**Definition**
A mixture of the partial esters of sorbitol and its mono- and di-anhydrides with edible commercial stearic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides.

**Assay**
Content not less than 46 % of oxyethylene groups, equivalent to not less than 96 % of polyethylene (20) sorbitan tristearate on the anhydrous basis.

**Description**
A tan-coloured, waxy solid at 25 °C with a faint characteristic odour.

**Identification**
A. Solubility
- Dispersible in water. Soluble in mineral oil, vegetal oils, petroleum ether, acetone, ether, dioxane, ethanol and methanol.

B. Congealing range
- 29 — 33 °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 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
**Ethylene oxide** | Not more than 0.2 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

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### 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**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 12 % (105 °C, 2 hours)</td>
</tr>
<tr>
<td>Acid insoluble ash</td>
<td>Not more than 1 % (insoluble in approximately 3N hydrochloric acid)</td>
</tr>
<tr>
<td>Sulphur dioxide</td>
<td>Not more than 50 mg/kg on the anhydrous basis</td>
</tr>
<tr>
<td>Nitrogen content</td>
<td>Not more than 1.0 % after washing with acid and ethanol</td>
</tr>
<tr>
<td>Free methanol, ethanol and propane-2-ol</td>
<td>Not more than 1 %, singly or in combination, on the anhydrous basis</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 20 mg/kg</td>
</tr>
</tbody>
</table>

### 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

**Assay**

Content not less than 65 % of galacturonic acid on the ash-free and anhydrous basis after washing with acid and alcohol

**Description**

White, light yellow, light greyish or light brownish powder
Identification
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
Assay The phosphorus content is not less than 3 % and not more than 3,4 % by weight; the ammonium content is not less than 1,2 % and not more than 1,5 % (calculated as N)
Description 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

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
Chemical name Sucrose diacetate hexaisobutyrate
### M1

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical formulae</td>
<td>$C_{40}H_{62}O_{19}$</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>832-856 (approximate), $C_{40}H_{62}O_{19}$: 846.9</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 98.8 % and not more than 101.9 % of $C_{40}H_{62}O_{19}$</td>
</tr>
<tr>
<td>Description</td>
<td>A pale straw-coloured liquid, clear and free of sediment and having a bland odour</td>
</tr>
<tr>
<td>Identification</td>
<td></td>
</tr>
<tr>
<td>A. Solubility</td>
<td>Insoluble in water. Soluble in most organic solvents</td>
</tr>
<tr>
<td>B. Refractive index</td>
<td>$\left[ n^2 \right]_D$ $= 1.4492 - 1.4504$</td>
</tr>
<tr>
<td>C. Specific gravity</td>
<td>$\left[ d^2 \right]_D$ $= 1.141 - 1.151$</td>
</tr>
<tr>
<td>Purity</td>
<td></td>
</tr>
<tr>
<td>Triacetin</td>
<td>Not more than 0.1 %</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not more than 0.2</td>
</tr>
<tr>
<td>Saponification value</td>
<td>Not less than 524 and not more than 540</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 5 mg/kg</td>
</tr>
</tbody>
</table>

### E 445 GLYCEROL ESTERS OF WOOD ROSIN

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>Ester gum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td>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</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description</th>
<th>Hard, yellow to pale amber-coloured solid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification</td>
<td></td>
</tr>
<tr>
<td>A. Solubility</td>
<td>Insoluble in water, soluble in acetone</td>
</tr>
<tr>
<td>B. Infrared absorption spectrum</td>
<td>Characteristic of the compound</td>
</tr>
<tr>
<td>Purity</td>
<td></td>
</tr>
<tr>
<td>Specific gravity of solution</td>
<td>$\left[ d^2 \right]_D$ not less than 0.935 when determined in a 50 % solution in d-limonene (97 %, boiling point 175.5-176 °C, $d^{20}_D$: 0.84)</td>
</tr>
<tr>
<td>Ring and ball softening range</td>
<td>Between 82 °C and 90 °C</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not less than 3 and not more than 9</td>
</tr>
<tr>
<td>Hydroxyl value</td>
<td>Not less than 15 and not more than 45</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Test for absence of tall oil rosin (sulphur test)</td>
<td>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</td>
</tr>
</tbody>
</table>
test indicates the use of tall oil rosin instead of wood rosin

E 450 (i) DISODIUM DIPHOSPHATE

Synonyms
- Disodium dihydrogen diphosphate
- Disodium dihydrogen pyrophosphate
- Sodium acid pyrophosphate
- Disodium pyrophosphate

Definition

Chemical name
- Disodium dihydrogen diphosphate

Eines
- 231-835-0

Chemical formula
- Na$_2$H$_2$P$_2$O$_7$

Molecular weight
- 221.94

Assay
- Content not less than 95 % of disodium diphosphate.

$P_2O_5$ Content
- Not less than 63.0 % and not more than 64.5 %

Description
- White powder or grains

Identification

A. Positive tests for sodium and for phosphate

B. Solubility
- Soluble in water

C. pH of a 1 % solution
- Between 3.7 and 5.0

Purity

Loss on drying
- Not more than 0.5 % (105 °C, four hours)

Water-insoluble matter
- Not more than 1 %

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

Arsenic
- Not more than 3 mg/kg

Cadmium
- Not more than 1 mg/kg

Lead
- Not more than 4 mg/kg

Mercury
- Not more than 1 mg/kg

E 450 (ii) TRISODIUM DIPHOSPHATE

Synonyms
- Acid trisodium pyrophosphate
- Trisodium monohydrogen diphosphate

Definition

Eines
- 238-735-6

Chemical formula
- Monohydrate: Na$_3$HP$_2$O$_7$ · H$_2$O
- Anhydrous: Na$_3$HP$_2$O$_7$

Molecular weight
- Monohydrate: 261.95
- Anhydrous: 243.93

Assay
- Content not less than 95 % on the anhydrous basis

$P_2O_5$ content
- Not less than 57 % and not more than 59 %

Description
- White powder or grains, occurs anhydrous or as a mono-hydrate

Identification

A. Positive tests for sodium and for phosphate
### E 450 (iii) TETRASODIUM DIPHOSPHATE

**Synonyms**
- Tetrasodium pyrophosphate
- Sodium pyrophosphate

**Definition**
- **Chemical name**: Tetrasodium diphosphate
- **Einecs**: 231-767-1
- **Chemical formula**: Anhydrous: Na₄P₂O₇, Decahydrate: Na₄P₂O₇ · 10H₂O
- **Molecular weight**: Anhydrous: 265.94, Decahydrate: 446.09
- **Assay**: Content not less than 95 % of Na₄P₂O₇ on the ignited basis
- **P₂O₅ content**: Not less than 52.5 % and not more than 54.0 %
- **Description**: Colourless or white crystals, or a white crystalline or granular powder. The decahydrate effloresces slightly in dry air

**Identification**
- **A. Positive tests for sodium and for phosphate**
- **B. Solubility**: Soluble in water. Insoluble in ethanol
- **C. pH of a 1 % solution**: Between 9.8 and 10.8

**Purity**
- **Loss on ignition**: Not more than 4.5 % on the anhydrous compound, not more than 11.5 % on the monohydrous basis
- **Loss on drying**: Not more than 0.5 % (105 °C, four hours)
- **Water-insoluble matter**: Not more than 0.2 %
- **Fluoride**: Not more than 10 mg/kg (expressed as fluorine)
- **Arsenic**: Not more than 3 mg/kg
- **Cadmium**: Not more than 1 mg/kg
- **Lead**: Not more than 4 mg/kg
- **Mercury**: Not more than 1 mg/kg
### E 450 (v) TETRAPOTASSIUM DIPHOSPHATE

**Synonyms**
- Potassium pyrophosphate
- Tetrapotassium pyrophosphate

**Definition**

- **Chemical name**: Tetrapotassium diphosphate
- **Einecs**: 230-785-7
- **Chemical formula**: $K_4P_2O_7$
- **Molecular weight**: 330.34 (anhydrous)
- **Assay**: Content not less than 95 % on the ignited basis
- **$P_2O_5$ content**: Not less than 42.0 % and not more than 43.7 % on the anhydrous basis

**Description**
- Colourless crystals or white, very hygroscopic powder

**Identification**

- A. Positive tests for potassium and for phosphate
- B. Solubility: Soluble in water, insoluble in ethanol
- C. $pH$ of a 1 % solution: Between 10.0 and 10.8

**Purity**

- **Loss on ignition**: Not more than 2 % after drying at 105 °C for four hours and then ignition at 550 °C for 30 minutes
- **Water-insoluble substances**: Not more than 0.2 %
- **Fluoride**: Not more than 10 mg/kg (expressed as fluorine)
- **Arsenic**: Not more than 3 mg/kg
- **Cadmium**: Not more than 1 mg/kg
- **Lead**: Not more than 4 mg/kg
- **Mercury**: Not more than 1 mg/kg

### E 450 (vi) DICALCIUM DIPHOSPHATE

**Synonyms**
- Calcium pyrophosphate

**Definition**

- **Chemical name**: Dicalcium diphosphate
- **Einecs**: 232-221-5
- **Chemical formula**: $Ca_2P_2O_7$
- **Molecular weight**: 254.12
- **Assay**: Content not less than 96 %
- **$P_2O_5$ content**: Not less than 55 % and not more than 56 %

**Description**
- A fine, white, odourless powder

**Identification**

- A. Positive tests for calcium and for phosphate
- B. Solubility: Insoluble in water. Soluble in dilute hydrochloric and nitric acids
- C. $pH$ of a 10 % suspension in water: Between 5.5 and 7.0
**Purity**

Loss on ignition | Not more than 1.5 % at 800 °C ± 25 °C for 30 minutes  
Fluoride | Not more than 50 mg/kg (expressed as fluorine)  
Arsenic | Not more than 3 mg/kg  
Cadmium | Not more than 1 mg/kg  
Lead | Not more than 4 mg/kg  
Mercury | Not more than 1 mg/kg  

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

**Synonyms**

Acid calcium pyrophosphate  
Monocalcium dihydrogen pyrophosphate  

**Definition**

**Chemical name**

Calcium dihydrogen diphosphate  

**Einecs**

238-933-2  

**Chemical formula**

CaH$_2$P$_2$O$_7$  

**Molecular weight**

215.97  

**Assay**

Content not less than 90 % on the anhydrous basis  

**P$_2$O$_5$ content**

Not less than 61 % and not more than 64 %  

**Description**

White crystals or powder  

**Identification**

A. Positive tests for calcium and for phosphate  

**Purity**

Acid-insoluble matter | Not more than 0.4 %  
Fluoride | Not more than 30 mg/kg (expressed as fluorine)  
Arsenic | Not more than 3 mg/kg  
Cadmium | Not more than 1 mg/kg  
Lead | Not more than 4 mg/kg  
Mercury | Not more than 1 mg/kg  

**E 451 (i) PENTASODIUM TRIPHOSPHATE**

**Synonyms**

Pentasodium tripolyphosphate  
Sodium tripolyphosphate  

**Definition**

**Chemical name**

Pentasodium triphosphate  

**Einecs**

231-838-7  

**Chemical formula**

Na$_5$O$_{10}$P$_3$ · nH$_2$O (n = 0 or 6)  

**Molecular weight**

367.86  

**Assay**

Content not less than 85.0 % (anhydrous) or 65.0 % (hexahydrate)  

**P$_2$O$_5$ content**

Not less than 56 % and not more than 59 % (anhydrous) or not less than 43 % and not more than 45 % (hexahydrate)  

**Description**

White, slightly hygroscopic granules or powder  

**Identification**

A. Solubility

Freely soluble in water. Insoluble in ethanol  

B. Positive tests for sodium and for phosphate  

C. pH of a 1 % solution

Between 9.1 and 10.2
Purity

Loss on drying
Anhydrous: Not more than 0.7 % (105 °C, one hour)
Hexahydrate: Not more than 23.5 % (60 °C, one hour,
followed by drying at 105 °C, four hours)

Water-insoluble substances
Not more than 0.1 %

Higher polyphosphates
Not more than 1 %

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

Arsenic
Not more than 3 mg/kg

Cadmium
Not more than 1 mg/kg

Lead
Not more than 4 mg/kg

Mercury
Not more than 1 mg/kg

E 451 (ii) PENTAPOTASSIUM TRIPHOSPHATE

Synonyms
Pentapotassium tripolyphosphate
Potassium tripolyphosphate
Potassium tripolyphosphate

Definition

Chemical name
Pentapotassium tripolyphosphate
Pentapotassium tripolyphosphate

Einecs

K₅O₁₀P₃

Chemical formula

Molar weight
448.42

Assay
Content not less than 85 % on the anhydrous basis

P₂O₅ content
Not less than 46.5 % and not more than 48 %

Description
White, very hygroscopic powder or granules

Identification

A. Solubility
Very soluble in water

B. Positive tests for potassium and for
phosphate

C. pH of a 1 % solution
Between 9.2 and 10.5

Purity

Loss on ignition
Not more than 0.4 % (after drying at 105 °C, four hours,
followed by ignition at 550 °C, 30 minutes)

Water-insoluble matter
Not more than 2 %

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

Arsenic
Not more than 3 mg/kg

Cadmium
Not more than 1 mg/kg

Lead
Not more than 4 mg/kg

Mercury
Not more than 1 mg/kg

E 452 (i) SODIUM POLYPHOSPHATE

1. SOLUBLE POLYPHOSPHATE

Synonyms
Sodium hexametaphosphate
Sodium tetrapolyphosphate
Graham’s salt
Sodium polyphosphates, glassy
Sodium polymetaphosphate
Sodium metaphosphate

1996L0077 — EN — 29.12.2006 — 007.001 — 76
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, (NaPO₃)ₓ where x ≥ 2, terminated by Na₂PO₄ groups. These substances are usually identified by their Na₂O/P₂O₅ ratio or their P₂O₅ content. The Na₂O/P₂O₅ ratios vary from about 1.3 for sodium tetrapolyphosphate, where x = approximately 4; to about 1.1 for Graham's salt, commonly called sodium hexametaphosphate, where x = 13 to 18; and to about 1.0 for the higher molecular weight sodium polyphosphates, where x = 20 to 100 or more. The pH of their solutions varies from 3.0 to 9.0.

**Chemical name**
Sodium polyphosphate

**Einecs**
272-808-3

**Chemical formula**
Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula H(n+2)PnO(3n+1) where ‘n’ is not less than 2

**Molecular weight**
(102)ₙ

**Assay**
P₂O₅ content
Not less than 60 % and not more than 71 % on the ignited basis

**Description**
Colourless or white, transparent platelets, granules, or powders

**Identification**

A. Solubility
Very soluble in water

B. Positive tests for sodium and for phosphate

C. pH of a 1 % solution
Between 3.0 and 9.0

**Purity**

Loss on ignition
Not more than 1 %

Water-insoluble matter
Not more than 0.1 %

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

Arsenic
Not more than 3 mg/kg

Cadmium
Not more than 1 mg/kg

Lead
Not more than 4 mg/kg

Mercury
Not more than 1 mg/kg

2. **INSOLUBLE POLYPHOSPHATE I**

**Synonyms**
Insoluble sodium metaphosphate
Maddrell's salt
Insoluble sodium polyphosphate, IMP

**Definition**
Insoluble sodium metaphosphate is a high molecular weight sodium polyphosphate composed of two long metaphosphate chains (NaPO₃)ₓ that spiral in opposite directions about a common axis. The Na₂O/P₂O₅ ratio is about 1.0. The pH of 1 in 3 suspension in water is about 6.5

**Chemical name**
Sodium polyphosphate

**Einecs**
272-808-3

**Chemical formula**
Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula H(n+2)PnO(3n+1) + 3P₂O₅(3n + 1) where ‘n’ is not less than 2

**Molecular weight**
(102)ₙ

**P₂O₅ content**
Not less than 68.7 % and not more than 70.0 %
M4

Description
White crystalline powder

Identification
A. Solubility
Insoluble in water, soluble in mineral acids and in solutions of potassium and ammonium (but not sodium) chlorides

B. Positive tests for sodium and for phosphate

C. pH of 1 in 3 suspension in water
About 6.5

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

Arsenic
Not more than 3 mg/kg

Cadmium
Not more than 1 mg/kg

Lead
Not more than 4 mg/kg

Mercury
Not more than 1 mg/kg

E 452 (ii) POTASSIUM POLYPHOSPHATE

Synonyms
Potassium metaphosphate
Potassium polymetaphosphate
Kurrol salt

Definition
Chemical name
Potassium polyphosphate

Einecs
232-212-6

Chemical formula
(KPO_3)_n

Molecular weight
(118)_n

P_2O_5 content
Not less than 53.5 % and not more than 61.5 % on the ignited basis

Description
Fine white powder or crystals or colourless glassy platelets

Identification
A. Solubility
1 g dissolves in 100 ml of a 1 in 25 solution of sodium acetate

B. Positive tests for potassium and for phosphate

C. pH of a 1 % suspension
Not more than 7.8

Purity
Loss on ignition
Not more than 2 % (105 °C, four hours followed by ignition at 550 °C, 30 minutes)

Cyclic phosphate
Not more than 8 % on P_2O_5 content

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

Arsenic
Not more than 3 mg/kg

Cadmium
Not more than 1 mg/kg

Lead
Not more than 4 mg/kg

Mercury
Not more than 1 mg/kg

E 452 (iv) CALCIUM POLYPHOSPHATE

Synonyms
Calcium metaphosphate
Calcium polymetaphosphate
**Definition**

*Chemical name*  
Calcium polyphosphate  

*Einecs*  
236-769-6  

*Chemical formula*  
(Ca$_{P_{2}O_{6}}$)$_{n}$  

Heterogenous mixtures 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  

*Molecular weight*  
(198)$_{n}$  

*$P_{2}O_{5}$ content*  
Not less than 71% and not more than 73% on the ignited basis  

*Description*  
Odourless, colourless crystals or white powder  

**Identification**

A. *Solubility*  
Usually sparingly soluble in water. Soluble in acid medium  

B. Positive tests for calcium and for phosphate  

C. *CaO content*  
27 to 29.5%  

**Purity**

A. *Loss on ignition*  
Not more than 2% (105°C, four hours followed by ignition at 550°C, 30 minutes)  

B. *Cyclic phosphate*  
Not more than 8% on $P_{2}O_{5}$ content  

C. *Fluoride*  
Not more than 30 mg/kg (expressed as fluorine)  

D. *Arsenic*  
Not more than 3 mg/kg  

E. *Cadmium*  
Not more than 1 mg/kg  

F. *Lead*  
Not more than 4 mg/kg  

G. *Mercury*  
Not more than 1 mg/kg  

---

**E 460 (i) MICROCRYSTALLINE 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$_{6}$H$_{10}$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-following suspension or a heavy, lumpy suspension which flows poorly, if at all, settles only slightly and contains many trapped air bubbles. If a free-flowing suspension is
obtained, transfer 100 ml into a 100-ml graduated
cylinder and allow to stand for 1 hour. The solids
settles and a supernatant liquid appears

Purity
Loss on drying
Water-soluble matter
Sulphated ash
pH of a 10 % suspension in water
Starch

Particle size
Carboxyl groups
Arsenic
Lead
Mercury
Cadmium
Heavy metals (as Pb)

E 460 (ii) POWDERED CELLULOSE

Purified, mechanically disintegrated cellulose prepared
by processing alpha-cellulose obtained as a pulp from
natural strains of fibrous plant materials

Chemical name
Cellulose

Einecs
232-674-9

Chemical formula
(C₆H₁₀O₅)ₙ

Molecular weight
(162)ₙ (n is predominantly 1 000 and greater)

Assay
Content not less than 92 %

Description
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 settles and a super-
natant 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
purlplish to blue or blue colour should be produced

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

Not more than 1 %
Not more than 3 mg/kg
Not more than 5 mg/kg
Not more than 1 mg/kg
Not more than 1 mg/kg
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
M1

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
Chemical name Methyl ether of cellulose
Chemical formula The polymers contain substituted anhydroglucose units with the following general formula:
  \[ C_6H_7O_2(OR_1)(OR_2)(OR_3) \]
  where R₁, R₂, R₃ each may be one of the following:
  - H
  - CH₃ or
  - CH₂CH₃

Molecular weight From about 20 000 to 380 000
Assay Content not less than 25% and not more than 33% of methoxyl groups (-OCH₃) and not more than 5% of hydroxyethoxyl groups (-OCH₂CH₂OH)
Description Slightly hydroscopic 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

M7

E 462 ETHYL CELLULOSE

Synonyms Cellulose ethyl ether
Definition Ethyl cellulose is cellulose obtained directly from fibrous plant material and partially etherified with ethyl groups
Chemical names Ethyl ether of cellulose
Chemical formula The polymers contain substituted anhydroglucose units with the following general formula:
  \[ C_6H_7O_2(OR_1)(OR_2) \]
  where R₁ and R₂ may be any of the following:
  - H
  - CH₂CH₃

Assay Content not less than 44% and not more than 50% of ethoxyl groups (-OC₂H₅) on the dried basis (equivalent to not more than 2.6 ethoxyl groups per anhydroglucose unit)
**M7**

**Description**

Slightly hygroscopic, white to off white, odourless and tasteless powder

**Identification**

A. Solubility

Practically insoluble in water, in glycerol and in propan-1,2-diol but soluble in varying proportions in certain organic solvents depending upon the ethoxyl content. Ethyl cellulose containing less than 46 to 48 % of ethoxyl groups is freely soluble in tetrahydrofuran, in methyl acetate, in chloroform and in aromatic hydrocarbon ethanol mixtures. Ethyl cellulose containing 46 to 48 % or more of ethoxyl groups is freely soluble in ethanol, in methanol, in toluene, in chloroform and in ethyl acetate

B. Film forming test

Dissolve 5 g of the sample in 95 g of an 80:20 (w/w) mixture of toluene ethanol. A clear, stable, slightly yellow solution is formed. Pour a few ml of the solution onto a glass plate and allow the solvent to evaporate. A thick, tough, continuous, clear film remains. The film is flammable

**Purity**

- **Loss on drying**: Not more than 3 % (105 °C, 2 h)
- **Sulphated ash**: Not more than 0,4 %
- **pH of a 1 % colloidal solution**: Neutral to litmus
- **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

**M1**

**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

**Chemical name**

Hydroxypropyl ether of cellulose

**Chemical formula**

The polymers contain substituted anhydroglucose units with the following general formula:

\[ \text{C}_6\text{H}_7\text{O}_2(\text{OR}_1)(\text{OR}_2)(\text{OR}_3), \] where \( \text{R}_1, \text{R}_2, \text{R}_3 \) each may be one of the following:

- \( \text{H} \)
- \( \text{CH}_2\text{CHOHCH}_3 \)
- \( \text{CH}_2\text{CHO}(\text{CH}_2\text{CHOHCH}_3)\text{CH}_3 \)
- \( \text{CH}_2\text{CHO}(\text{CH}_2\text{CHOHCH}_3)\text{CH}_2\text{CHOHCH}_3\text{CH}_3 \)

**Molecular weight**

From about 30 000 to 1 000 000

**Assay**

Content not less than 80,5 % of hydroxypropoxyl groups (-OCH2CHOHCH3) equivalent to not more than 4,6 hydroxypropyl groups per anhydroglucose unit on the anhydrous basis

**Description**

Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder

**Identification**

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

**Purity**

- **Loss on drying**: Not more than 10 % (105 °C, 3 hours)
**M1**

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.5 % determined at 800 ± 25 °C</td>
</tr>
<tr>
<td>pH of a 1 % colloidal solution</td>
<td>Not less than 5.0 and not more than 8.0</td>
</tr>
<tr>
<td>Propylene chlorohydrins</td>
<td>Not more than 0.1 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 20 mg/kg</td>
</tr>
</tbody>
</table>

### 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.

**Chemical name**

2-Hydroxypropyl ether of methylcellulose

**Chemical formula**

The polymers contain substituted anhydroglucose units with the following general formula:

\[ C_6H_7O_2(\text{OR}_1)(\text{OR}_2)(\text{OR}_3) \], where \( \text{R}_1, \text{R}_2, \text{R}_3 \) each may be:

- \( \text{H} \)
- \( \text{CH}_3 \)
- \( \text{CH}_2\text{CHOHCH}_3 \)
- \( \text{CH}_2\text{CHO}(\text{CH}_2\text{CHOHCH}_3)\text{CH}_3 \)
- \( \text{CH}_2\text{CHO}(\text{CH}_2\text{CHOHCH}_3)\text{CH}_2\text{CH}_3 \)

**Molecular weight**

From about 13 000 to 200 000

**Assay**

Content not less than 19 % and not more than 30 % methoxyl groups (-OCH₃) and not less than 3 % and not more than 12 % hydroxypropoxy groups (-OCH₂CHOHCH₃), on the anhydrous basis.

**Description**

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.

### E 465 ETHYL METHYL CELLULOSE

**Synonyms**

Methylethylcellulose

**Definition**
### Ethyl methyl cellulose

**Chemical name**
Ethyl methyl ether of cellulose

**Chemical formula**
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:
- \( \text{-} \)
- \( \text{-} \)
- \( \text{-} \)

**Molecular weight**
From about 30,000 to 40,000

**Assay**
Content on the anhydrous basis not less than 3.5% and not more than 6.5% of methoxyl groups (\(-\text{OCH}_3\)) and not less than 14.5% and not more than 19% of ethoxy groups (\(-\text{OCH}_2\text{CH}_3\)), and not less than 13.2% and not more than 19.6% of total alkoxyl groups, calculated as methoxyl

**Description**
Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder

**Identification**
A. Solubility
Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Soluble in ethanol. Insoluble in ether

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 15% for the fibrous form, and not more than 10% for the powdered form (105 °C to constant weight)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.6%</td>
</tr>
<tr>
<td>pH of a 1% colloidal solution</td>
<td>Not less than 5.0 and not more than 8.0</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 20 mg/kg</td>
</tr>
</tbody>
</table>

### 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

**Chemical name**
Sodium salt of the carboxymethyl ether of cellulose

**Chemical formula**
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:
- \( \text{-} \)
- \( \text{-} \)
- \( \text{-} \)
### M1

<table>
<thead>
<tr>
<th><strong>Molecular weight</strong></th>
<th>Higher than approximately 17 000 (degree of polymerisation approximately 100)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assay</strong></td>
<td>Content on the anhydrous basis not less than 99.5 %</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder</td>
</tr>
</tbody>
</table>

#### 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 (-CH₂COOH) 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

#### Assay

Content on the anhydrous basis not less than 95 %

#### Description

White or creamy white light powders, flakes or semisolids

#### 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 Na₂O
**M1**

| **Potassium** | Not less than 13 % and not more than 21.5 % expressed as K₂O |
| **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

**Assay**

Content on the anhydrous basis not less than 95 %

**Description**

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

**Assay**

Content of mono- and diesters: not less than 70 %

**Description**

The product varies from a pale yellow to pale brown oily liquid to a white or slightly off-white hard waxy solid. The solids may be in the form of flakes, powders or small beads

**Identification**

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

Description
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 %

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
### M1

<table>
<thead>
<tr>
<th>Lactoglycerides</th>
<th>Mono- and diglycerides of fatty acids esterified with lactic acid</th>
</tr>
</thead>
</table>

**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.

**Description**

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
Free glycerol
Arsenic
Lead
Mercury
Cadmium
Heavy metals (as Pb)
Total lactic acid
Total fatty acids (and lactic acid)
Total glycerol
Sulphated ash

Acids other than citric and fatty acids
Free glycerol
Total glycerol
Total citric 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).

---

### M7

<table>
<thead>
<tr>
<th>E 472c CITRIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS</th>
</tr>
</thead>
</table>

**Synonyms**

Citrem
Citric acid esters of mono- and diglycerides
Citroglycerides
Mono- and diglycerides of fatty acids esterified with citric acid

**Definition**

Esters of glycerol with citric acid and fatty acids occurring in food oils and fats. They may contain small amounts of free glycerol, free fatty acids, free citric acid and free glycerides. They may be partially or wholly neutralised with sodium hydroxide or with potassium hydroxide.

**Description**

Yellowish or light brown liquids to waxy solids or semi-solids

**Identification**

A. Positive test for glycerol, for fatty acids and for citric acid
B. Solubility

Insoluble in cold water
Dispersible in hot water
Soluble in oils and fats
In soluble in cold ethanol

**Purity**

Acids other than citric and fatty acids
Free glycerol
Total glycerol
Total citric acid

Not detectable
Not more than 2 %
Not more than 2 %
Not more than 3 % estimated as oleic acid
Not less than 13 % and not more than 33 %
Not less than 13 % and not more than 50 %

Not more than 3 % and not more than 45 %
Not more than 3 % estimated as oleic acid
Not less than 13 % and not more than 30 %
Not more than 0,5 % determined at 800 ± 25 °C
**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

**Description**
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 DIACETYL TARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS**

**Synonyms**
Diacetyltartaric acid esters of mono- and diglycerides
Mono- and diglycerides of fatty acids esterified with mono- and diacetyltartaric acid
Diacetyltartaric and fatty acid esters of glycerol

**Definition**
Mixed esters of glycerol with mono- and diacetyltartaric acids (obtained from tartaric acid) and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free tartaric and acetic acids and their combinations, and free glycerides. Contains also tartaric and acetic esters of fatty acids

**Description**
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
### M1

<table>
<thead>
<tr>
<th><strong>Purity</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Acids other than acetic, tartaric and fatty acids</td>
<td>Not detectable</td>
</tr>
<tr>
<td>Free glycerol</td>
<td>Not more than 2 %</td>
</tr>
<tr>
<td>Total glycerol</td>
<td>Not less than 11 % and not more than 28 %</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0,5 % determined at 800 ± 25 °C</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Total tartaric acid</td>
<td>Not less than 10 % and not more than 40 %</td>
</tr>
<tr>
<td>Total acetic acid</td>
<td>Not less than 8 % and not more than 32 %</td>
</tr>
<tr>
<td>Free fatty acids</td>
<td>Not more than 3 % estimated as oleic acid</td>
</tr>
</tbody>
</table>

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

---

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

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>Mono- and diglycerides of fatty acids esterified with acetic acid and tartaric acid</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>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 ecetic acids, and free glycerides. May contain mono- and diacetyltartaric esters of mono- and diglycerides of fatty acids</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Sticky liquids to solids, from white to pale-yellow in colour</td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td>A. Positive tests for glycerol, for fatty acids, for tartaric acid and for acetic acid</td>
</tr>
</tbody>
</table>

---

### E 473 SUCROSE ESTERS OF FATTY ACIDS

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>Sucroesters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sugar esters</td>
<td></td>
</tr>
</tbody>
</table>
### E 474 SUCROGLYCERIDES

**Synonyms**

Sugar glycerides

**Definition**

Sucroglycerides are produced by reacting sucrose with an edible fat or oil to produce a mixture of essentially mono-, di- and triesters of sucrose and fatty acids 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

**Assay**

Content not less than 40 % and not more than 60 % of sucrose fatty acid esters

**Description**

Soft solid masses, stiff gels or white to off-white powders

**Identification**

A. Positive tests for sugar and for fatty acids

B. Solubility

Insoluble in cold water

Soluble in ethanol
### Purity

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit/Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulphated ash</td>
<td>Not more than 2 % determined at 800 ± 25 °C</td>
</tr>
<tr>
<td>Free sugar</td>
<td>Not more than 5 %</td>
</tr>
<tr>
<td>Free fatty acids</td>
<td>Not more than 3 % estimated as oleic acid</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Methanol</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Dimethylformamide</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>2-methyl-1-propanol</td>
<td>Not more than 10 mg/kg, single or in combination</td>
</tr>
<tr>
<td>Cyclohexane</td>
<td></td>
</tr>
<tr>
<td>Ethyl acetate</td>
<td>Not more than 350 mg/kg, single or in combination</td>
</tr>
<tr>
<td>Propane-2-ol</td>
<td></td>
</tr>
</tbody>
</table>

*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 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.

#### Assay
Content of total fatty acid ester not less than 90 %

#### Description
Light yellow to amber, oily to very viscous liquids; light tan to medium brown, plastic or soft solids; and light tan to brown, hard, waxy solids

#### Identification
- 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

#### Purity
<table>
<thead>
<tr>
<th>Component</th>
<th>Limit/Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0,5 % determined at 800 ± 25 °C</td>
</tr>
<tr>
<td>Acids other than fatty acids</td>
<td>Not detectable</td>
</tr>
<tr>
<td>Free fatty acids</td>
<td>Not more than 6 % estimated as oleic acid</td>
</tr>
<tr>
<td>Total glycerol and polyglycerol</td>
<td>Not less than 18 % and not more than 60 %</td>
</tr>
<tr>
<td>Free glycerol and polyglycerol</td>
<td>Not more than 7 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

*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.

**Description**
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 \( \left[ n^0 \right]_{65} \)**
  - Between 1.4630 and 1.4665

**Purity**

#### Polyglycerols
- **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.

**Assay**
Content of total fatty acid ester not less than 85 %

**Description**
Clear liquids or waxy white flakes, beads or solids having a bland odour

**Identification**
- **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
### 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.

**Description**
Pale yellow to light brown a waxy or solid consistency

**Identification**
- A. Solubility
  - Insoluble in water. Soluble in hot oil or fat

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting range</td>
<td>55—65 °C</td>
</tr>
<tr>
<td>Free fatty acids</td>
<td>Not more than 1.5 % estimated as oleic acid</td>
</tr>
<tr>
<td>Free glycerol</td>
<td>Not more than 2 %</td>
</tr>
<tr>
<td>Total fatty acids</td>
<td>83—90 %</td>
</tr>
<tr>
<td>Total glycerol</td>
<td>16—22 %</td>
</tr>
<tr>
<td>Fatty acid methyl esters, not forming adduct with urea</td>
<td>Not more than 9 % of total fatty acid methyl esters</td>
</tr>
<tr>
<td>Fatty acids, insoluble in petroleum ether</td>
<td>Not more than 2 % of total fatty acids</td>
</tr>
<tr>
<td>Peroxide value</td>
<td>Not more than 3</td>
</tr>
<tr>
<td>Epoxides</td>
<td>Not more than 0.03 % oxirane oxygen</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

### E 481 SODIUM STEAROYL-2-LACTYLATE

**Synonyms**
- Sodium stearoyl lactylate
- Sodium stearoyl lactate

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

**Chemical names**
- Sodium di-2-stearoyl lactate
- Sodium di(2-stearoyloxoy)propionate

**Chemical formula**
- C\(_{31}\)H\(_{58}\)O\(_4\)Na
- C\(_{33}\)H\(_{60}\)O\(_2\)Na

**Description**
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

<table>
<thead>
<tr>
<th>Component</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>Not less than 2.5 % and not more than 5 %</td>
</tr>
<tr>
<td>Ester value</td>
<td>Not less than 90 and not more than 190</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not less than 60 and not more than 130</td>
</tr>
<tr>
<td>Total lactic acid</td>
<td>Not less than 15 % and not more than 40 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

### E 482 CALCIUM STEAROYL-2-LACTYLATE

#### Synonyms

Calcium stearoyl lactate

#### Definition

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

#### Chemical name

- Calcium di-2-stearoyl lactate
  - Calcium di(2-stearoyloxy)propionate
- Distearyl tartrate
  - Dipalmityl tartrate

#### Description

White or slightly yellowish powder or brittle solid with a characteristic odour

### 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

#### Chemical name

- Distearyl tartrate
  - Dipalmityl tartrate
M1

**Chemical formula**
C\textsubscript{38}H\textsubscript{74}O\textsubscript{6} to C\textsubscript{40}H\textsubscript{78}O\textsubscript{6}

**Molecular weight**
627 to 655

**Assay**
Content of total ester not less than 90 % corresponding to an ester value of not less than 163 and not more than 180

**Description**
Cream-coloured unctuous solid (at 25 °C)

**Identification**
A. Positive tests for tartare
B. Melting range

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydroxyl value</td>
<td>Not less than 200 and not more than 220</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not more than 5,6</td>
</tr>
<tr>
<td>Total tartaric acid content</td>
<td>Not less than 18 % and not more than 35 %</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0,5 % determined at 800 ± 25 °C</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Unsaponifiable matter</td>
<td>Not less than 77 % and not more than 83 %</td>
</tr>
<tr>
<td>Iodine value</td>
<td>Not more than 4 (Wijs)</td>
</tr>
</tbody>
</table>

**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

**Assay**
Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters

**Description**
Light, cream- to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour

**Identification**
A. Solubility
B. Congealing range
C. Infrared absorption spectrum

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not more than 2 % (Karl Fischer method)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0,5 %</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not more than 10</td>
</tr>
<tr>
<td>Saponification value</td>
<td>Not less than 147 and not more than 157</td>
</tr>
<tr>
<td>Hydroxyl value</td>
<td>Not less than 235 and not more than 260</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

**Unsaponifiable matter**
Not less than 77 % and not more than 83 %

**Iodine value**
Not more than 4 (Wijs)
### E 492 SORBITAN TRISTEARATE

**Definition**
A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial stearic acid

**Ein ecs**
247-891-4

**Assay**
Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters

**Description**
Light, cream- to tan-coloured beads or flakes or hard, waxy solid with a slight odour

**Identification**

<table>
<thead>
<tr>
<th>A. Solubility</th>
<th>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</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Congealing range</td>
<td>47—50 °C</td>
</tr>
<tr>
<td>C. Infrared absorption spectrum</td>
<td>Characteristic of a partial fatty acid ester of a polyol</td>
</tr>
</tbody>
</table>

**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

**Ein ecs**
215-663-3

**Assay**
Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters

**Description**
Amber-coloured oily viscous liquid, light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight odour

**Identification**

<table>
<thead>
<tr>
<th>A. Solubility</th>
<th>Dispersible in hot and cold water</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Infrared absorption spectrum</td>
<td>Characteristic of a partial fatty acid ester of a polyol</td>
</tr>
</tbody>
</table>

**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

**Assay**
Content not less than 95 % of a mixture of sorbitol, sorbitan and isosorbide esters

**Description**
Amber-coloured viscous liquid, light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour

**Identification**

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 an iodine value between 80 and 100

**Purity**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not more than 2 % (Karl Fischer method)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.5 %</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not more than 8</td>
</tr>
<tr>
<td>Saponification value</td>
<td>Not less than 145 and not more than 160</td>
</tr>
<tr>
<td>Hydroxyl value</td>
<td>Not less than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

**E 495 SORBITAN MONOPALMITATE**

**Synonyms**
Sorbitan palmitate

**Definition**
A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial palmitic acid

**Einecs**
247-568-8

**Assay**
Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters

**Description**
Light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour

**Identification**

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**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not more than 2 % (Karl Fischer method)</td>
</tr>
<tr>
<td>Sulphate ash</td>
<td>Not more than 0.5 %</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not more than 7.5</td>
</tr>
<tr>
<td>Saponification value</td>
<td>Not less than 140 and not more than 150</td>
</tr>
<tr>
<td>Hydroxyl value</td>
<td>Not less than 270 and not more than 305</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
</tbody>
</table>
### M1

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

### E 508 POTASSIUM CHLORIDE

#### Synonyms
- Sylvine
- Sylvite

#### Definition
- **Chemical name**: Potassium chloride
- **Einecs**: 231-211-8
- **Chemical formulae**: KCl
- **Molecular weight**: 74.56
- **Assay**: Content not less than 99 % on the dried basis
- **Description**: Colourless, elongated, prismatic or cubital crystals or white granular powder. Odourless

#### Identification
- **A. Solubility**: Freely soluble in water. Insoluble in ethanol

#### 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
- **Chemical name**: Ferrous di-D-gluconate dihydrate
- **Einecs**: 206-076-3
- **Chemical formulae**: C_{12}H_{22}FeO_{14}·2H_{2}O
- **Molecular weight**: 482.17
- **Assay**: Content not less than 95 % on the dried basis
- **Description**: Pale greenish-yellow to yellowish-grey powder or granules, which may have a faint odour of burnt sugar

#### Identification
- **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

#### Purity
- **Loss on drying**: Not more than 10 % (105 °C, 16 hours)
- **Oxalic acid**: Not detectable
- **Iron (Fe III)**: Not more than 2 %
- **Arsenic**: Not more than 3 mg/kg
M1

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Reducing substances</td>
<td>Not more than 0.5 % expressed as glucose</td>
</tr>
</tbody>
</table>

**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$_6$H$_{10}$FeO$_6$·xH$_2$O (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
Soluble in water. Practically insoluble in ethanol

B. Positive test for ferrous ion and for lactate

C. pH of a 2 % solution
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

M4

**E 650 ZINC ACETATE**

**Synonyms**
Acetic acid, zinc salt, dihydrate

**Definition**

**Chemical name**
Zinc acetate dihydrate

**Chemical formula**
C$_4$H$_6$O$_4$ Zn · 2H$_2$O

**Molecular weight**
219.51

**Assay**
Content not less than 98 % and not more than 102 % of C$_4$H$_6$O$_4$ Zn · 2H$_2$O

**Description**
Colourless crystals or fine, off-white powder

**Identification**

A. Positive tests for acetate and for zinc

B. pH of a 5 % solution
Between 6.0 and 8.0

**Purity**

Insoluble matter
Not more than 0.005 %

Chlorides
Not more than 50 mg/kg

Sulphates
Not more than 100 mg/kg

Alkalines and alkaline earths
Not more than 0.2 %
Organic volatile impurities Passes test
Iron Not more than 50 mg/kg
Arsenic Not more than 3 mg/kg
Lead Not more than 20 mg/kg
Cadmium Not more than 5 mg/kg

**E 943a BUTANE**

**Synonyms**

n-Butane

**Definition**

*Chemical name*
Butane

*Chemical formula*
CH₃CH₂CH₂CH₃

*Molecular weight*
58,12

*Assay*
Content not less than 96 %

*Description*
Colourless gas or liquid with mild, characteristic odour

**Identification**

A. Vapour pressure
108,935 kPa at 20 °C

**Purity**

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methane</td>
<td>Not more than 0,15 % v/v</td>
</tr>
<tr>
<td>Ethane</td>
<td>Not more than 0,5 % v/v</td>
</tr>
<tr>
<td>Propane</td>
<td>Not more than 1,5 % v/v</td>
</tr>
<tr>
<td>Isobutane</td>
<td>Not more than 3,0 % v/v</td>
</tr>
<tr>
<td>1,3-butadiene</td>
<td>Not more than 0,1 % v/v</td>
</tr>
<tr>
<td>Moisture</td>
<td>Not more than 0,005 %</td>
</tr>
</tbody>
</table>

**E 943b ISOBUTANE**

**Synonyms**

2-methyl propane

**Definition**

*Chemical name*
2-methyl propane

*Chemical formula*
(CH₃)₂CH CH₃

*Molecular weight*
58,12

*Assay*
Content not less than 94 %

*Description*
Colourless gas or liquid with mild, characteristic odour

**Identification**

A. Vapour pressure
205,465 kPa at 20 °C

**Purity**

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methane</td>
<td>Not more than 0,15 % v/v</td>
</tr>
<tr>
<td>Ethane</td>
<td>Not more than 0,5 % v/v</td>
</tr>
<tr>
<td>Propane</td>
<td>Not more than 2,0 % v/v</td>
</tr>
<tr>
<td>n-Butane</td>
<td>Not more than 4,0 % v/v</td>
</tr>
<tr>
<td>1,3-butadiene</td>
<td>Not more than 0,1 % v/v</td>
</tr>
<tr>
<td>Moisture</td>
<td>Not more than 0,005 %</td>
</tr>
</tbody>
</table>

**E 944 PROPANE**

**Definition**

*Chemical name*
Propane

*Chemical formula*
CH₃CH₂CH₃

*Molecular weight*
44,09

*Assay*
Content not less than 95 %
**M4**

**Description**
Colourless gas or liquid with mild, characteristic odour

**Identification**
A. Vapour pressure
732,910 kPa at 20 °C

**Purity**
- Methane: Not more than 0,15 % v/v
- Ethane: Not more than 1,5 % v/v
- Isobutane: Not more than 2,0 % v/v
- n-Butane: Not more than 1,0 % v/v
- 1,3-butadiene: Not more than 0,1 % v/v
- Moisture: Not more than 0,005 %

**E 949 HYDROGEN**

**Definition**
Chemical name: Hydrogen
Einecs: 215-605-7
Chemical formula: H₂
Molecular weight: 2
Assay: Content not less than 99,9 %

**Description**
Colourless, odourless, highly flammable gas

**Purity**
- Water: Not more than 0,005 % v/v
- Oxygen: Not more than 0,001 % v/v
- Nitrogen: Not more than 0,75 % v/v

**E 1105 LYSOZYMES**

**Synonyms**
Lysozyme hydrochloride
Muramidase

**Definition**
Lysozyme is a linear polypeptide obtained from hens’ egg whites consisting of 129 amino acids. It possesses enzymatic activity in its ability to hydrolyse the β(1-4) linkages between N-acetylmuramic acid and N-acetylglucosamine in the outer membranes of bacterial species, in particular gram-positive organisms. Is usually obtained as the hydrochloride

**Chemical name**
Enzyme Commission (EC) No: 3.2.1.17
Einecs: 232-620-4
Molecular weight: About 14 000
Assay: Content not less than 950 mg/g on the anhydrous basis

**Description**
White, odourless powder having a slightly sweet taste

**Identification**
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
### E 1201 POLYVINYLPYRROLIDONE

**Synonyms**
- Povidone
- PVP
- Soluble polyvinylpyrrolidone

**Definition**

**Chemical name**
Polyvinylpyrrolidone, \( \text{poly-}\{1-(2-\text{oxo}-1\text{-pyrrolidinyl})\text{-ethylene}\}\)

**Chemical formula**
\( (\text{C}_6\text{H}_9\text{NO})_n \)

**Molecular weight**
Not less than 25 000

**Assay**
Content not less than 11.5 % and not more than 12.8 % of nitrogen (N) on the anhydrous basis

**Description**
White or nearly white powder

**Identification**

A. Solubility
Soluble in water and in ethanol. Insoluble in ether

B. pH of a 5 % solution
Between 3.0 and 7.0

**Purity**

- Water: Not more than 5 % (Karl Fischer)
- Total ash: Not more than 0.1 %
- Aldehyde: Not more than 500 mg/kg (as acetaldehyde)
- Free-N-vinylpyrrolidone: Not more than 10 mg/kg
- Hydrazine: Not more than 1 mg/kg
- Lead: Not more than 5 mg/kg

---

### E 1202 POLYVINYLPOLYPYRROLIDONE

**Synonyms**
- Crospovidone
- Cross linked polyvidone
- Insoluble polyvinylpyrrolidone

**Definition**
Polyvinylpolypyrrolidone is a poly-\{1-(2-oxo-1-pyrrolidinyl)-ethylene\}, cross linked in a random fashion. It is produced by the polymerisation of N-vinyl-2-pyrrolidone in the presence of either caustic catalyst or N,N'-divinyl-imidazolidone. Due to its insolvency in all common solvents the molecular weight range is not amenable to analytical determination

**Chemical name**
Polyvinylpyrrolidone, \( \text{poly-}\{1-(2-\text{oxo}-1\text{-pyrrolidinyl})\text{-ethylene}\}\)

**Chemical formula**
\( (\text{C}_6\text{H}_9\text{NO})_n \)

**Assay**
Content not less than 11 % and not more than 12.8 % nitrogen (N) on the anhydrous basis

**Description**
A white hygroscopic powder with a faint, non-objectionable odour
**M4**

**Identification**

A. Solubility  
Insoluble in water, ethanol and ether

B. pH of a 1% suspension in water  
Between 5.0 and 8.0

**Purity**

Water Not more than 6% (Karl Fischer)

Sulphated ash Not more than 0.4%

Water-soluble matter Not more than 1%

Free-N-vinylpyrrolidone Not more than 10 mg/kg

Free-N,N'-divinyl-imidazolidone Not more than 2 mg/kg

Lead Not more than 5 mg/kg

**M5**

**POLYETHYLENE GLYCOL 6000**

**Synonyms**  
PEG 6000  
Macrogol 6000

**Definition**

Polyethylene glycol 6000 is a mixture of polymers with the general formula \(H - (OCH_2 - CH) - OH\) corresponding to an average relative molecular mass of approximately 6000

**Chemical formula**

\((C_2H_4O)_n\) \(H_2O\) \((n = \text{number of ethylene oxide units corresponding to a molecular weight of 6000, about 140})\)

**Molecular weight**

5600 — 7000

**Assay**

Not less than 90.0% and not more than 110.0%

**Description**

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

**M2**

**E 296 MALIC ACID**

**Synonyms**  
DL-Malic acid, pomalous acid

**Definition**

Chemical name  
DL-Malic acid, hydroxybutanedioic acid, hydroxy-succinic acid

**Einecs**

Chemical formula  
C_4H_6O_5

Molecular weight  
134.09

Assay

Content not less than 99.0%

Description

White or nearly white crystalline powder or granules
B. Positive test for malate
C. Solutions of this substance are optically inactive in all concentrations

Purity
- Sulphated ash: Not more than 0.1%
- Fumaric acid: Not more than 1.0%
- Maleic acid: Not more than 0.05%
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 5 mg/kg
- Mercury: Not more than 1 mg/kg

E 297 FUMARIC ACID

Definition
- Chemical name: Trans-butenedioic acid, trans-1,2-ethylene-dicarboxylic acid
- Einescs: 203-743-0
- Chemical formula: C₄H₄O₄
- Molecular weight: 116.07
- Assay: Content not less than 99.0 % on the anhydrous basis
- Description: White crystalline powder or granules

Identification
- A. Melting range: 286 °C - 302 °C (closed capillary, rapid heating)
- B. Positive tests for double bonds and for 1,2-dicarboxylic acid
- C. pH of a 0.05 % solution at 25 °C: 3.0 - 3.2

Purity
- Loss on drying: Not more than 0.5 % (120 °C, 4h)
- Sulphated ash: Not more than 0.1%
- Maleic acid: Not more than 0.1%
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 5 mg/kg
- Mercury: Not more than 1 mg/kg

E 343(i) MONOMAGNESIUM PHOSPHATE

Synonyms
- Magnesiumdihydrogenphosphate
- Magnesiumphosphate, monobasic
- Monomagnesium orthophosphate

Definition
- Chemical name: Monomagnesiumdihydrogenmonophosphate
- Einescs: 236-004-6
- Chemical formula: Mg(H₂PO₄)₂·nH₂O (where n = 0 to 4)
- Molecular weight: 218.30 (anhydrous)
- Assay: Not less than 51.0 % after ignition
- Description: White, odourless, crystalline powder, slightly soluble in water

Identification
- A. Positive test for magnesium and for phosphate
- B. MgO content: Not less than 21.5 % after ignition
M2

Purity

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoride</td>
<td>Not more than 10 mg/kg (as fluorine)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 4 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

E 343(ii) DIMAGNESIUM PHOSPHATE

Synonyms

Magnesiumhydrogenphosphate
Magnesiumphosphate, dibasic
Dimagnesium orthophosphate
Secondary magnesiumpophosphate

Definition

Chemical name
Dimagnesiummonohydrogenmonophosphate

Einecs
231-823-5

Chemical formula
MgHPO₄·nH₂O (where n = 0 - 3)

Molecular weight
120,30 (anhydrous)

Assay
Not less than 96 % after ignition

Description
White, odourless, crystalline powder, slightly soluble in water

Identification

A. Positive test for magnesium and for phosphate
B. MgO content: Not less than 33,0 % calculated on an anhydrous basis

Purity

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoride</td>
<td>Not more than 10 mg/kg (as fluorine)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 4 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

E 350 (i) SODIUM MALATE

Synonyms

Sodium salt of malic acid

Definition

Chemical name
Disodium DL-malate, disodium salt of hydroxybutanedioic acid

Chemical formula
Hemihydrate: C₄H₄Na₂O₅·H₂O
Trihydrate: C₄H₄Na₂O₅·3H₂O

Molecular weight
Hemihydrate: 187,05
Trihydrate: 232,10

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

Description
White crystalline powder or lumps

Identification

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

Purity

Loss on drying
Not more than 7,0 % (130 °C, 4h) for the hemihydrate, or 20,5 % - 23,5 % (130 °C, 4h) for the trihydrate
### E 350 (ii) SODIUM HYDROGEN MALATE

**Synonyms**
Monosodium salt of DL-malic acid

**Definition**

- **Chemical name**: Monosodium DL-malate, monosodium 2-DL-hydroxy succinate
- **Chemical formula**: $\text{C}_4\text{H}_5\text{NaO}_5$
- **Molecular weight**: 156,07
- **Assay**: Content not less than 99,0 % on the anhydrous basis
- **Description**: White powder

**Identification**

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

B. Azo dye formation: Positive

**Purity**

- **Loss on drying**: Not more than 2,0 % (110 °C, 3h)
- **Maleic acid**: Not more than 0,05 %
- **Fumaric acid**: Not more than 1,0 %
- **Arsenic**: Not more than 3 mg/kg
- **Lead**: Not more than 5 mg/kg
- **Mercury**: Not more than 1 mg/kg

### E 351 POTASSIUM MALATE

**Synonyms**
Potassium salt of malic acid

**Definition**

- **Chemical name**: Dipotassium DL-malate, dipotassium salt of hydroxybutanedioic acid
- **Chemical formula**: $\text{C}_4\text{H}_4\text{K}_2\text{O}_5$
- **Molecular weight**: 210,27
- **Assay**: Content not less than 59,5 %
- **Description**: Colourless or almost colourless aqueous solution

**Identification**

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

B. Azo dye formation: Positive

**Purity**

- **Alkalinity**: Not more than 0,2 % as $\text{K}_2\text{CO}_3$
- **Fumaric acid**: Not more than 1,0 %
- **Maleic acid**: Not more than 0,05 %
- **Arsenic**: Not more than 3 mg/kg
- **Lead**: Not more than 5 mg/kg
- **Mercury**: Not more than 1 mg/kg
E 352 (i) CALCIUM MALATE

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>Calcium salt of malic acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>Calcium DL-malate, calcium-α-hydroxy succinate, calcium salt of hydroxybutanedioic acid</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C₄H₅CaO₅</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>172,14</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 97,5 % on the anhydrous basis</td>
</tr>
<tr>
<td>Description</td>
<td>White powder</td>
</tr>
<tr>
<td>Identification</td>
<td></td>
</tr>
<tr>
<td>A. Positive tests for malate, 1,2-dicarboxylic acid and for calcium</td>
<td>Positive</td>
</tr>
<tr>
<td>B. Azo dye formation</td>
<td></td>
</tr>
<tr>
<td>C. Solubility</td>
<td>Slightly soluble in water</td>
</tr>
</tbody>
</table>

Purity

| Loss on drying         | Not more than 2 % (100 °C, 3h) |
| Alkalinity             | Not more than 0,2 % as CaCO₃   |
| Maleic acid            | Not more than 0,05 %           |
| Fumaric acid           | Not more than 1,0 %            |
| Fluoride               | Not more than 30 mg/kg         |
| Arsenic                | Not more than 3 mg/kg          |
| Lead                   | Not more than 5 mg/kg          |
| Mercury                | Not more than 1 mg/kg          |

E 352 (ii) CALCIUM HYDROGEN MALATE

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>Monocalcium salt of DL-malic acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>Monocalcium DL-malate, monocalcium 2-DL-hydroxy succinate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>((\text{C}_4\text{H}_5\text{O}_5)_2\text{Ca})</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 97,5 % on the anhydrous basis</td>
</tr>
<tr>
<td>Description</td>
<td>White powder</td>
</tr>
<tr>
<td>Identification</td>
<td></td>
</tr>
<tr>
<td>A. Positive tests for 1,2-dicarboxylic acid and for calcium</td>
<td>Positive</td>
</tr>
<tr>
<td>B. Azo dye formation</td>
<td></td>
</tr>
</tbody>
</table>

Purity

| Loss on drying         | Not more than 2,0 % (110 °C, 3h) |
| Maleic acid            | Not more than 0,05 %              |
| Fumaric acid           | Not more than 1,0 %               |
| Fluoride               | Not more than 30 mg/kg            |
| Arsenic                | Not more than 3 mg/kg             |
| Lead                   | Not more than 5 mg/kg             |
| Mercury                | Not more than 1 mg/kg             |
E 355 ADIPIC ACID

**Definition**
- **Chemical name**: Hexanedioic acid, 1,4-butanedicarboxylic acid
- **EINECS**: 204-673-3
- **Chemical formula**: C₆H₁₀O₄
- **Molecular weight**: 146,14
- **Assay**: Content not less than 99,6 %
- **Description**: White odourless crystals or crystalline powder

**Identification**
- A. Melting range: 151,5-154,0 °C
- B. Solubility: Slightly soluble in water. Freely soluble in ethanol

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

E 363 SUCCINIC ACID

**Definition**
- **Chemical name**: Butanedioic acid
- **EINECS**: 203-740-4
- **Chemical formula**: C₄H₆O₄
- **Molecular weight**: 118,09
- **Assay**: Content no less than 99,0 %
- **Description**: Colourless or white, odourless crystals

**Identification**
- A. Melting range: Between 185,0 °C and 190,0 °C

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

E 380 TRIAMMONIUM CITRATE

**Synonyms**
- Tribasic ammonium citrate

**Definition**
- **Chemical name**: Triammonium salt of 2-hydroxypropan-1,2,3-tricarboxylic acid
- **EINECS**: 222-394-5
- **Chemical formula**: C₆H₁₇N₃O₇
- **Molecular weight**: 243,22
- **Assay**: Content not less than 97,0 %
- **Description**: White to off-white crystals or powder

**Identification**
- A. Positive tests for ammonium and for citrate
**E 452 (iii) SODIUM CALCIUM POLYPHOSPHATE**

<table>
<thead>
<tr>
<th><strong>Synonym</strong></th>
<th>Sodium calcium polyphosphate, glassy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Sodium calcium polyphosphate</td>
</tr>
<tr>
<td><strong>EINECS</strong></td>
<td>233-782-9</td>
</tr>
<tr>
<td><strong>Chemical name</strong></td>
<td>Sodium calcium polyphosphate</td>
</tr>
<tr>
<td><strong>Chemical formula</strong></td>
<td>(NaPO₃)ₙCaO where n is typically 5</td>
</tr>
<tr>
<td><strong>Assay</strong></td>
<td>Not less than 61 % and not more than 69 % as P₂O₅</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>White glassy crystals, spheres</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Identification</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A. pH of a 1 % m/m slurry</td>
<td>Approximately 5 to 7</td>
</tr>
<tr>
<td>B. CaO content</td>
<td>7 %-15 % m/m</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Purity</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoride</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 4 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**M5**

**E 459 BETA-CYCLODEXTRIN**

**Definition**

Beta-cyclodextrin is a non-reducing cyclic saccharide consisting of seven α-1,4-linked D-glucopyranosyl units. The product is manufactured by the action of the enzyme cycloglycosyltransferase (CGTase) obtained from *Bacillus circulans*, *Paenibacillus macerans* or recombinant *Bacillus licheniformis* strain SJ1608 on partially hydrolysed starch.

<table>
<thead>
<tr>
<th><strong>Chemical name</strong></th>
<th>Cycloheptaamylose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EINECS</strong></td>
<td>231-493-2</td>
</tr>
<tr>
<td><strong>Chemical formula</strong></td>
<td>(C₆H₁₀O₅)₇</td>
</tr>
<tr>
<td><strong>Molecular weight</strong></td>
<td>1 135</td>
</tr>
<tr>
<td><strong>Assay</strong></td>
<td>Content not less than 98,0 % of (C₆H₁₀O₅)₇ on an anhydrous basis</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Virtually odourless white or almost white crystalline solid</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Identification</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Solubility</td>
<td>Sparingly soluble in water; freely soluble in hot water; slightly soluble in ethanol</td>
</tr>
<tr>
<td>B. Specific rotation</td>
<td>[α]₂₅⁺ +160 ° to +164 ° (1 % solution)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Purity</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not more than 14 % (Karl Fischer method)</td>
</tr>
<tr>
<td>Other cyclodextrins</td>
<td>Not more than 2 % on an anhydrous basis</td>
</tr>
<tr>
<td>Residual solvents (toluene and trichloroethylene)</td>
<td>Not more than 1 mg/kg for each solvent</td>
</tr>
</tbody>
</table>
E 468 CROSS-LINKED SODIUM CARBOXYMETHYLCELLULOSE

Synonyms
Cross-linked carboxymethyl cellulose
Cross-linked CMC
Cross-linked sodium CMC
Cross-linked cellulose gum

Definition
Cross-linked sodium carboxymethyl cellulose is the sodium salt of thermally cross-linked partly O-carboxymethylated cellulose

Chemical name
Sodium salt of the cross-linked carboxymethyl ether cellulose

Chemical formula
The polymers containing substituted anhydroglucose units with the general formula:
\[ C_6H_7O_2(OR_1)(OR_2)(OR_3) \]
where \( R_1, R_2 \) and \( R_3 \) may be any of the following:
- \( H \)
- \( CH_2COONa \)
- \( CH_2COOH \)

Description
Slightly hygroscopic, white to off white, odourless powder

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

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

E 469 ENZYMATICALLY HYDROLYSED CARBOXYMETHYLCELLULOSE

Synonyms
Sodium carboxymethyl cellulose, enzymatically hydrolysed

Definition
Enzymatically hydrolysed carboxymethylcellulose is obtained from carboxymethylcellulose by enzymatic digestion with a cellulase produced by Trichoderma longibrachiatum (formerly T. reesei)
### Chemical name
Carboxymethyl cellulose, sodium, partially enzymatically hydrolysed

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

\[
\frac{1}{2} C_6H_7O_2(\text{OH})_x(\text{OCH}_2\text{COONa})_y/z
\]

where \( n \) is the degree of polymerisation

\[
x = 1.50 \text{ to } 2.80
\]

\[
y = 0.2 \text{ to } 1.50
\]

\[
x + y = 3.0
\]

\( y \) = degree of substitution

### Formula weight
- \( 178.14 \) where \( y = 0.20 \)
- \( 282.18 \) where \( y = 1.50 \)

### Assay
Not less than 99.5 %, including mono- and disaccharides, on the dried basis

### Description
White or slightly yellowish or greyish, odourless, slightly hygroscopic granular or fibrous powder

### Identification

#### A. Solubility
Soluble in water, insoluble in ethanol

#### B. Foam test
Vigorously shake a 0.1 % solution of the sample. No layer of foam appears. This test distinguishes sodium carboxymethyl cellulose, whether hydrolysed or not, from other cellulose ethers and from alginates and natural gums

#### C. Precipitate formation
To 5 ml of a 0.5 % solution of the sample add 5 ml of a 5 % solution of copper or aluminium sulphate. A precipitate appears. This test distinguishes sodium carboxymethyl cellulose, whether hydrolysed or not, from other cellulose ethers and from gelatine, carob bean gum and tragacanth gum

#### D. Colour reaction
Add 0.5 g of the powdered sample to 50 ml of water, while stirring to produce a uniform dispersion. Continue the stirring until a clear solution is produced. Dilute 1 ml of the solution with 1 ml of water in a small test tube. Add 5 drops of 1-naphthol TS. Incline the tube, and carefully introduce down the side of the tube 2 ml of sulphuric acid so that it forms a lower layer. A red-purple colour develops at the interface

#### E. Viscosity (60 % solids)
Not less than 2,500 kg m\(^{-1}\)s\(^{-1}\) at 25 °C corresponding to an average molecule weight of 5,000 D

### Purity

#### Loss on drying
Not more than 12 % (105 °C to constant weight)

#### Degree of substitution
Not less than 0.2 and not more than 1.5 carboxymethyl groups per anhydroglucose unit on the dried basis

#### pH of a 1 % colloidal solution
Not less than 6.0 and not more than 8.5

#### Sodium chloride and sodium glycolate
Not more than 0.5 % singly or in combination

#### Residual enzyme activity
Passes test. No change in viscosity of test solution occurs, which indicates hydrolysis of the sodium carboxymethyl cellulose

#### Lead
Not more than 3 mg/kg

### E 500(i) SODIUM CARBONATE

#### Synonyms
Soda ash

#### Definition

**Chemical name**
Sodium carbonate

**EINECS**
207-838-8
### M2

**Chemical formula**  
$\text{Na}_2\text{CO}_3 \cdot \text{nH}_2\text{O}$ (n = 0, 1 or 10)

**Molecular weight**  
106,00 (anhydrous)

**Assay**  
Content not less than 99 % of $\text{Na}_2\text{CO}_3$ on the anhydrous basis

**Description**  
Colourless crystals or white, granular or crystalline powder  
The anhydrous form is hygroscopic, the decahydrate efflorescent

**Identification**

A. Positive tests for sodium and for carbonate

B. Solubility  
Freely soluble in water. Insoluble in ethanol

**Purity**

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

**Arsenic**  
Not more than 3 mg/kg

**Lead**  
Not more than 5 mg/kg

**Mercury**  
Not more than 1 mg/kg

### E 500(ii) SODIUM HYDROGEN CARBONATE

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

**Definition**

**Chemical name**  
Sodium hydrogen carbonate

**EINECS**  
205-633-8

**Chemical formula**  
$\text{NaHCO}_3$

**Molecular weight**  
84,01

**Assay**  
Content not less than 99 % on the anhydrous basis

**Description**  
Colourless or white crystalline masses or crystalline powder

**Identification**

A. Positive tests for sodium and for carbonate

B. pH of a 1 % solution  
Between 8,0 and 8,6

C. Solubility  
Soluble in water. Insoluble in ethanol

**Purity**

**Loss on drying**  
Not more than 0,25 % (over silica gel, 4h)

**Ammonium salts**  
No odour of ammonia detectable after heating

**Arsenic**  
Not more than 3 mg/kg

**Lead**  
Not more than 5 mg/kg

**Mercury**  
Not more than 1 mg/kg

### E 500(iii) SODIUM SESQUICARBONATE

**Definition**

**Chemical name**  
Sodium monohydrogen dicarbonate

**EINECS**  
208-580-9

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

**Molecular weight**  
226,03

**Assay**  
Content between 35,0 % and 38,6 % of $\text{NaHCO}_3$ and between 46,4 % and 50,0 % of $\text{Na}_2\text{CO}_3$
M2

**Description**
White flakes, crystals or crystalline powder

**Identification**

A. Positive tests for sodium and for carbonate
B. Solubility
Freely soluble in water

**Purity**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>Not more than 0.5 %</td>
</tr>
<tr>
<td>Iron</td>
<td>Not more than 20 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 501(i) POTASSIUM CARBONATE**

**Definition**

**Chemical name**
Potassium carbonate

**EINECS**
209-529-3

**Chemical formula**
K₂CO₃·nH₂O (n = 0 or 1,5)

**Molecular weight**
138,21 (anhydrous)

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

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

**Identification**

A. Positive tests for potassium and for carbonate
B. Solubility
Very soluble in water. Insoluble in ethanol

**Purity**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 5 % (anhydrous) or 18 % (hydrate) (180 °C, 4h)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

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

**Synonyms**
Potassium bicarbonate, acid potassium carbonate

**Definition**

**Chemical name**
Potassium hydrogen carbonate

**EINECS**
206-059-0

**Chemical formula**
KHCO₃

**Molecular weight**
100,11

**Assay**
Content not less than 99,0 % and not more than 101,0 % KHCO₃ on the anhydrous basis

**Description**
Colourless crystals or white powder or granules

**Identification**

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

**Purity**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 0,25 % (over silica gel, 4h)</td>
</tr>
</tbody>
</table>
M2

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

E 503(i) AMMONIUM CARBONATE

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

Chemical name Ammonium carbonate
EINECS 233-786-0
Chemical formula CH₆N₂O₂, CH₈N₂O₃ and CH₅NO₃
Molecular weight Ammonium carbamate 78,06; ammonium carbonate 98,73; ammonium hydrogen carbonate 79,06
Assay Content not less than 30,0 % and not more than 34,0 % of NH₃

Description White powder or hard, white or translucent masses or crystals. Becomes opaque on exposure to air and is finally converted into white porous lumps or powder (of ammonium bicarbonate) due to loss of ammonia and carbon dioxide

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

Purity
Non-volatile matter Not more than 500 mg/kg
Chlorides Not more than 30 mg/kg
Sulphate Not more than 30 mg/kg
Arsenic Not more than 3 mg/kg
Lead Not more than 5 mg/kg
Mercury Not more than 1 mg/kg

E 503(ii) AMMONIUM HYDROGEN CARBONATE

Synonyms Ammonium bicarbonate

Definition
Chemical name Ammonium hydrogen carbonate
EINECS 213-911-5
Chemical formula CH₅NO₃
Molecular weight 79,06
Assay Content not less than 99,0 %

Description White crystals or crystalline powder

Identification
A. Positive tests for ammonium and for carbonate
B. pH of a 5 % solution about 8,0
C. Solubility Freely soluble in water. Insoluble in ethanol

Purity
Non-volatile matter Not more than 500 mg/kg
Chlorides Not more than 30 mg/kg
M2

Sulphate Not more than 30 mg/kg
Arsenic Not more than 3 mg/kg
Lead Not more than 5 mg/kg
Mercury Not more than 1 mg/kg

E 507 HYDROCHLORIC ACID

Synonyms
Hydrogen chloride, muriatic acid

Definition
Chemical name Hydrochloric acid
EINECS 231-595-7
Chemical formula HCl
Molecular weight 36.46
Assay Hydrochloric acid is commercially available in varying concentrations. Concentrated hydrochloric acid contains not less than 35.0 % HCl

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

Identification
A. Positive tests for acid and for chloride
B. Solubility Soluble in water and in ethanol

Purity
Total organic compounds Total organic compounds (non-fluorine containing): not more than 5 mg/kg
Benzene: not more than 0.05 mg/kg
Fluorinated compounds (total): not more than 25 mg/kg
Non-volatile matter Not more than 0.5 %
Reducing substances Not more than 70 mg/kg (as SO₂)
Oxidising substances Not more than 30 mg/kg (as Cl₂)
Sulphate Not more than 0.5 %
Iron Not more than 5 mg/kg
Arsenic Not more than 1 mg/kg
Lead Not more than 1 mg/kg
Mercury Not more than 1 mg/kg

E 509 CALCIUM CHLORIDE

Definition
Chemical name Calcium chloride
EINECS 233-140-8
Chemical formula CaCl₂·nH₂O (n = 0.2 or 6)
Molecular weight 110.99 (anhydrous), 147.02 (dihydrate), 219.08 (hexahydrate)
Assay Content not less than 93.0 % on the anhydrous basis
Description White, odourless, hygroscopic powder or deliquescent crystals

Identification
A. Positive tests for calcium and for chloride
B. Solubility Anhydrous calcium chloride: freely soluble in water and ethanol
Dihydrate: freely soluble in water, soluble in ethanol
Hexahydrate: very soluble in water and ethanol
E 511 MAGNESIUM CHLORIDE

Definition

Chemical name: Magnesium chloride
EINECS: 232-094-6
Chemical formula: MgCl2·6H2O
Molecular weight: 203,30
Assay: Content not less than 99,0 %
Description: Colourless, odourless, very deliquescent flakes or crystals

Identification

A. Positive tests for magnesium and for chloride
B. Solubility: Very soluble in water, freely soluble in ethanol

Purity

Ammonium: Not more than 50 mg/kg
Arsenic: Not more than 3 mg/kg
Lead: Not more than 10 mg/kg
Mercury: Not more than 1 mg/kg

E 512 STANNOUS CHLORIDE

Synonyms: Tin chloride, tin dichloride

Definition

Chemical name: Stannous chloride dihydrate
EINECS: 231-868-0
Chemical formula: SnCl2·2H2O
Molecular weight: 225,63
Assay: Content not less than 98,0 %
Description: Colourless or white crystals, may have a slight odour of hydrochloric acid

Identification

A. Positive tests for tin (II) and for chloride
B. Solubility: Water: soluble in less than its own weight of water, but it forms an insoluble basic salt with excess water. Ethanol: soluble

Purity

Sulphate: Not more than 30 mg/kg
Arsenic: Not more than 2 mg/kg
Mercury: Not more than 1 mg/kg
Lead: Not more than 5 mg/kg

E 513 SULPHURIC ACID

Synonyms: Oil of vitriol, dihydrogen sulphate
**M2**

**Definition**

**Chemical name**
Sulphuric acid

**EINECS**
231-639-5

**Chemical formula**
H₂SO₄

**Molecular weight**
98.07

**Assay**
Sulphuric acid is commercially available in varying concentrations. The concentrated form contains not less than 96.0 %

**Description**
Clear, colourless or slightly brown, very corrosive oily liquid

**Identification**

A. Positive tests for acid and for sulphate

B. Solubility
Miscible with water, with generation of much heat, also with ethanol

**Purity**

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ash</td>
<td>Not more than 0.02 %</td>
</tr>
<tr>
<td>Reducing matter</td>
<td>Not more than 40 mg/kg (as SO₂)</td>
</tr>
<tr>
<td>Nitrate</td>
<td>Not more than 10 mg/kg (on H₂SO₄ basis)</td>
</tr>
<tr>
<td>Chloride</td>
<td>Not more than 50 mg/kg</td>
</tr>
<tr>
<td>Iron</td>
<td>Not more than 20 mg/kg</td>
</tr>
<tr>
<td>Selenium</td>
<td>Not more than 20 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 514(i) SODIUM SULPHATE**

**Definition**

**Chemical name**
Sodium sulphate

**Chemical formula**
Na₂SO₄·nH₂O (n = 0 or 10)

**Molecular weight**
142.04 (anhydrous)
322.04 (decahydrate)

**Assay**
Content not less than 99.0 % on the anhydrous basis

**Description**
Colourless crystals or a fine, white, crystalline powder
The decahydrate is efflorescent

**Identification**

A. Positive tests for sodium and for sulphate

B. Acidity of a 5 % solution: neutral or slightly alkaline to litmus paper

**Purity**

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 1,0 % (anhydrous) or not more than 57 % (decahydrate) at 130 °C</td>
</tr>
<tr>
<td>Selenium</td>
<td>Not more than 30 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

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

**Synonyms**
Acid sodium sulphate, sodium bisulphate, nitre cake

**Definition**

**Chemical name**
Sodium hydrogen sulphate
<table>
<thead>
<tr>
<th>Chemical formula</th>
<th>NaHSO₄</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular weight</td>
<td>120,06</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 95,2 %</td>
</tr>
<tr>
<td>Description</td>
<td>White, odourless crystals or granules</td>
</tr>
</tbody>
</table>

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

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

#### E 515(i) POTASSIUM SULPHATE

### Definition
- **Chemical name**: Potassium sulphate
- **Chemical formula**: K₂SO₄
- **Molecular weight**: 174,25
- **Assay**: Content not less than 99,0 %
- **Description**: Colourless or white crystals or crystalline powder

### Identification
- A. Positive tests for potassium and for sulphate
- B. pH of a 5 % solution: Between 5,5 and 8,5
- C. Solubility: Freely soluble in water, insoluble in ethanol

### Purity
- Selenium: Not more than 30 mg/kg
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 5 mg/kg
- Mercury: Not more than 1 mg/kg

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

### Definition
- **Synonyms**: Potassium bisulphate, potassium acid sulphate
- **Chemical name**: Potassium hydrogen sulphate
- **Chemical formula**: KHSO₄
- **Molecular weight**: 136,17
- **Assay**: Content not less than 99 %
- **Melting point**: 197 °C
- **Description**: White deliquescent crystals, pieces or granules

### Identification
- A. Positive test for potassium
- B. Solubility: Freely soluble in water, insoluble in ethanol

### Purity
- Selenium: Not more than 30 mg/kg
E 516 CALCIUM SULPHATE

Synonyms
Gypsum, selenite, anhydrite

Definition
Chemical name
Calcium sulphate
EINECS
231-900-3
Chemical formula
CaSO₄·nH₂O (n = 0 or 2)
Molecular weight
136,14 (anhydrous), 172,18 (dihydrate)
Assay
Content not less than 99,0 % on the anhydrous basis
Description
Fine, white to slightly yellowish-white odourless powder

Identification
A. Positive tests for calcium and for sulphate
B. Solubility
Slightly soluble in water, insoluble in ethanol

Purity
Loss on drying
Anhydrous: not more than 1,5 % (250 °C, constant weight)
Dihydrate: not more than 23 % (ibid.)
Fluoride
Not more than 30 mg/kg
Selenium
Not more than 30 mg/kg
Arsenic
Not more than 3 mg/kg
Lead
Not more than 5 mg/kg
Mercury
Not more than 1 mg/kg

E 517 AMMONIUM SULPHATE

Definition
Chemical name
Ammonium sulphate
EINECS
231-984-1
Chemical formula
(NH₄)₂SO₄
Molecular weight
132,14
Assay
Content not less than 99,0 % and not more than 100,5 %
Description
White powder, shining plates or crystalline fragments

Identification
A. Positive tests for ammonium and for sulphate
B. Solubility
Freely soluble in water, insoluble in ethanol

Purity
Loss on ignition
Not more than 0,25 %
Selenium
Not more than 30 mg/kg
Lead
Not more than 5 mg/kg

E 520 ALUMINIUM SULPHATE

Synonyms
Alum

Definition
Chemical name
Aluminium sulphate
EINECS
233-135-0
Chemical formula
Al₂(SO₄)₃
Molecular weight | 342,13
--- | ---
Assay | Content not less than 99,5% on the ignited basis
Description | White powder, shining plates or crystalline fragments

Identification

A. Positive tests for aluminium and for sulphate
B. pH of a 5% solution 2,9 or above
C. Solubility | Freely soluble in water, insoluble in ethanol

Purity

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

E 521 ALUMINIUM SODIUM SULPHATE

Synonyms | Soda alum, sodium alum
Definition
Chemical name | Aluminium sodium sulphate
EINECS | 233-277-3
Chemical formula | AlNa\(\text{SO}_4\)_\(\text{nH}_2\text{O}\) (n = 0 or 12)
Molecular weight | 242,09 (anhydrous)
Assay | Content on the anhydrous basis not less than 96,5% (anhydrous) and 99,5% (dodecahydrate)
Description | Transparent crystals or white crystalline powder
Identification
A. Positive tests for aluminium, for sodium and for sulphate
B. Solubility | Dodecahydrate is freely soluble in water. The anhydrous form is slowly soluble in water. Both forms are insoluble in ethanol
Purity
Loss on drying | Anhydrous form: not more than 10,0% (220 °C, 16h)
Dodecahydrate: not more than 47,2% (50 °C-55 °C, 1h then 200 °C, 16h)
Ammonium salts | No odour of ammonia detectable after heating
Selenium | Not more than 30 mg/kg
Fluoride | Not more than 30 mg/kg
Arsenic | Not more than 3 mg/kg
Lead | Not more than 5 mg/kg
Mercury | Not more than 1 mg/kg

E 522 ALUMINIUM POTASSIUM SULPHATE

Synonyms | Potassium alum, potash alum
Definition
Chemical name | Aluminium potassium sulphate dodecahydrate
EINECS | 233-141-3
Chemical formula | AlK\(\text{SO}_4\)_\(\text{12H}_2\text{O}\)
Molecular weight | 474,38
Assay | Content not less than 99,5%
M2

Description
Large, transparent crystals or white crystalline powder

Identification
A. Positive tests for aluminium, for potassium and for sulphate
B. pH of a 10 % solution between 3,0 and 4,0
C. Solubility Freely soluble in water, insoluble in ethanol

Purity
Ammonium salts No odour of ammonia detectable after heating
Selenium Not more than 30 mg/kg
Fluoride Not more than 30 mg/kg
Arsenic Not more than 3 mg/kg
Lead Not more than 5 mg/kg
Mercury Not more than 1 mg/kg

E 523 ALUMINIUM AMMONIUM SULPHATE

Synonyms Ammonium alum

Definition
Chemical name Aluminium ammonium sulphate
EINECS 232-055-3
Chemical formula AlNH₄(SO₄)₂·12H₂O
Molecular weight 453,32
Assay Content not less than 99,5 %
Description Large, colourless crystals or white powder

Identification
A. Positive tests for aluminium, for ammonium and for sulphate
B. Solubility Freely soluble in water, soluble in ethanol

Purity
Alkali metals and alkaline earths Not more than 0,5 %
Selenium Not more than 30 mg/kg
Fluoride Not more than 30 mg/kg
Arsenic Not more than 3 mg/kg
Lead Not more than 5 mg/kg
Mercury Not more than 1 mg/kg

E 524 SODIUM HYDROXIDE

Synonyms Caustic soda, lye

Definition
Chemical name Sodium hydroxide
EINECS 215-185-5
Chemical formula NaOH
Molecular weight 40,0
Assay Content of solid forms not less than 98,0 % of total alkali (as NaOH). Content of solutions accordingly, based on the stated or labelled percentage of NaOH

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

Identification
A. Positive tests for sodium
B. A 1 % solution is strongly alkaline
E 525 POTASSIUM HYDROXIDE

Synonyms
Caustic potash

Definition

Chemical name
Potassium hydroxide

EINECS
215-181-3

Chemical formula
KOH

Molecular weight
56,11

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

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

Identification

A. Positive tests for potassium
B. A 1 % solution is strongly alkaline
C. Solubility

Purity

Water insoluble and organic matter
A 5 % solution is completely clear and colourless
colourless to slightly coloured

Carbonate
Not more than 0,5 % (as Na₂CO₃)

Arsenic
Not more than 3 mg/kg

Lead
Not more than 0,5 mg/kg

Mercury
Not more than 1 mg/kg

E 526 CALCIUM HYDROXIDE

Synonyms
Slaked lime, hydrated lime

Definition

Chemical name
Calcium hydroxide

EINECS
215-137-3

Chemical formula
Ca(OH)₂

Molecular weight
74,09

Assay
Content not less than 92,0 %

Description
White powder

Identification

A. Positive tests for alkali and for calcium
B. Solubility

Purity

Acid insoluble ash
Not more than 1,0 %

Magnesium and alkali salts
Not more than 1,0 %

Barium
Not more than 300 mg/kg

Fluoride
Not more than 50 mg/kg
### E 527 AMMONIUM HYDROXIDE

**Synonyms**
- Aqua ammonia, strong ammonia solution

**Definition**
- **Chemical name**: Ammonium hydroxide
- **Chemical formula**: \( \text{NH}_4\text{OH} \)
- **Molecular weight**: 35.05
- **Assay**: Content not less than 27 % of \( \text{NH}_3 \)
- **Description**: Clear, colourless solution, having an exceedingly pungent, characteristic odour

**Identification**
- A. Positive tests for ammonia

**Purity**
- Non-volatile matter: Not more than 0,02 %
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 5 mg/kg

### E 528 MAGNESIUM HYDROXIDE

**Definition**
- **Chemical name**: Magnesium hydroxide
- **EINECS**: 215-170-3
- **Chemical formula**: \( \text{Mg(OH)}_2 \)
- **Molecular weight**: 58.32
- **Assay**: Content not less than 95.0 % on the anhydrous basis
- **Description**: Odourless, white bulky powder

**Identification**
- A. Positive test for magnesium and for alkali
- B. Solubility: Practically insoluble in water and in ethanol

**Purity**
- Loss on drying: Not more than 2,0 % (105 °C, 2h)
- Loss on ignition: Not more than 33 % (800 °C to constant weight)
- Calcium oxide: Not more than 1,5 %
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 10 mg/kg

### E 529 CALCIUM OXIDE

**Synonyms**
- Burnt lime

**Definition**
- **Chemical name**: Calcium oxide
- **EINECS**: 215-138-9
- **Chemical formula**: \( \text{CaO} \)
- **Molecular weight**: 56.08
- **Assay**: Content not less than 95.0 % on the ignited basis
- **Description**: Odourless, hard, white or greyish white masses of granules, or white to greyish powder

**Identification**
- A. Positive test for alkali and for calcium
B. Heat is generated on moistening the sample with water

C. Solubility

<table>
<thead>
<tr>
<th>Purity</th>
<th>Slightly soluble in water. Insoluble in ethanol. Soluble in glycerol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on ignition</td>
<td>Not more than 10.0 % (ca 800 °C to constant weight)</td>
</tr>
<tr>
<td>Acid insoluble matter</td>
<td>Not more than 1.0 %</td>
</tr>
<tr>
<td>Barium</td>
<td>Not more than 300 mg/kg</td>
</tr>
<tr>
<td>Magnesium and alkali salts</td>
<td>Not more than 1.5 %</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 50 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

**E 530 MAGNESIUM OXIDE**

**Definition**

- **Chemical name**: Magnesium oxide
- **EINECS**: 215-171-9
- **Chemical formula**: MgO
- **Molecular weight**: 40.31
- **Assay**: Content not less than 98.0 % on the ignited basis
- **Description**: A very bulky, white powder known as light magnesium oxide or a relative dense, white powder known as heavy magnesium oxide. 5 g of light magnesium oxide occupy a volume of 40 to 50 ml, while 5 g of heavy magnesium oxide occupy a volume of 10 to 20 ml

**Identification**

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

**Purity**

<table>
<thead>
<tr>
<th>Purity</th>
<th>Not more than 5.0 % (ca 800 °C to constant weight)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium oxide</td>
<td>Not more than 1.5 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

**E 535 SODIUM FERROCYANIDE**

**Synonyms**

- Yellow prussiate of soda, sodium hexacyanoferrate

**Definition**

- **Chemical name**: Sodium ferrocyanide
- **EINECS**: 237-081-9
- **Chemical formula**: $\text{Na}_4\text{Fe(CN)}_6\cdot10\text{H}_2\text{O}$
- **Molecular weight**: 484.1
- **Assay**: Content not less than 99.0 %
- **Description**: Yellow crystals or crystalline powder

**Identification**

- **A. Positive test for sodium and for ferrocyanide**

**Purity**

<table>
<thead>
<tr>
<th>Purity</th>
<th>Not more than 1.0 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Free moisture</td>
<td>Not more than 1.0 %</td>
</tr>
<tr>
<td>Water insoluble matter</td>
<td>Not more than 0.03 %</td>
</tr>
<tr>
<td>Chloride</td>
<td>Not more than 0.2 %</td>
</tr>
<tr>
<td>Sulphate</td>
<td>Not more than 0.1 %</td>
</tr>
<tr>
<td>Free cyanide</td>
<td>Not detectable</td>
</tr>
</tbody>
</table>
M2

Ferricyanide  Not detectable
Lead  Not more than 5 mg/kg

E 536 POTASSIUM FERROCYANIDE

Synonyms  Yellow prussiate of potash, potassium hexacyanoferrate
Definition
   Chemical name  Potassium ferrocyanide
   EINECS  237-722-2
   Chemical formula  K₄Fe(CN)₆·3H₂O
   Molecular weight  422.4
   Assay  Content not less than 99.0 %
   Description  Lemon yellow crystals
Identification
   A. Positive test for potassium and for ferrocyanide
Purity
   Free moisture  Not more than 1.0 %
   Water insoluble matter  Not more than 0.03 %
   Chloride  Not more than 0.2 %
   Sulphate  Not more than 0.1 %
   Free cyanide  Not detectable
   Ferricyanide  Not detectable
   Lead  Not detectable

E 538 CALCIUM FERROCYANIDE

Synonyms  Yellow prussiate of lime, calcium hexacyanoferrate
Definition
   Chemical name  Calcium ferrocyanide
   EINECS  215-476-7
   Chemical formula  Ca₂Fe(CN)₆·12H₂O
   Molecular weight  508.3
   Assay  Content not less than 99.0 %
   Description  Yellow crystals or crystalline powder
Identification
   A. Positive test for calcium and for ferrocyanide
Purity
   Free moisture  Not more than 1.0 %
   Water insoluble matter  Not more than 0.03 %
   Chloride  Not more than 0.2 %
   Sulphate  Not more than 0.1 %
   Free cyanide  Not detectable
   Ferricyanide  Not detectable
   Lead  Not detectable

E 541 SODIUM ALUMINIUM PHOSPHATE, ACIDIC

Synonyms  SALP
Definition
   Chemical name  Sodium trialuminium tetradecahydrogen octaphosphate tetrahydrate (A) or
Trisodium dialuminium pentadecaehydrogen octophosphate (B)  

**EINECS**  
Chemical formula  
\( \text{NaAl}_3\text{H}_4\{\text{PO}_4\}_\text{k} \cdot 4\text{H}_2\text{O} \) (A)  
\( \text{Na}_3\text{Al}_2\text{H}_15\{\text{PO}_4\}_\text{k} \) (B)  

**Molecular weight**  
949.88 (A)  
897.82 (B)  

**Assay**  
Content not less than 95.0 % (both forms)  

**Description**  
White odourless powder  

**Identification**  
A. Positive test for sodium, for aluminium and for phosphate  
B. pH  
C. Solubility  
Insoluble in water. Soluble in hydrochloric acid  

**Purity**  
Loss on ignition  
19.5 % - 21.0 % (A) \( \{750 \, ^\circ \text{C} - 800 \, ^\circ \text{C}, 2\, h\} \)  
15 % - 16 % (B) \( \{750 \, ^\circ \text{C} - 800 \, ^\circ \text{C}, 2\, h\} \)  
Fluoride  
Not more than 25 mg/kg  
Arsenic  
Not more than 3 mg/kg  
Lead  
Not more than 4 mg/kg  
Cadmium  
Not more than 1 mg/kg  
Mercury  
Not more than 1 mg/kg  

**E 551 SILICON DIOXIDE**  
Silica, silicium dioxide  

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

**Chemical name**  
Silicon dioxide  

**EINECS**  
231-545-4  

**Chemical formula**  
\( \{\text{SiO}_2\}_\text{n} \)  

**Molecular weight**  
60.08 (SiO2)  

**Assay**  
Content after ignition not less than 99.0 % (fumed silica) or 94.0 % (hydrated forms)  

**Description**  
White, fluffy powder or granules  
Hygroscopic  

**Identification**  
A. Positive test for silica  

**Purity**  
Loss on drying  
Not more than 2.5 % (fumed silica, 105 °C, 2h)  
Not more than 8.0 % (precipitated silica and silica gel, 105 °C, 2h)  

Loss on ignition  
Not more than 70 % (hydrous silica, 105 °C, 2h)  
Not more than 2.5 % after drying (1 000 °C, fumed silica)  
Not more than 8.5 % after drying (1 000 °C, hydrated forms)  

Soluble ionisable salts  
Not more than 5.0 % (as Na2SO4)  
Arsenic  
Not more than 3 mg/kg  
Lead  
Not more than 5 mg/kg  
Mercury  
Not more than 1 mg/kg
E 552 CALCIUM SILICATE

Definition
Calcium silicate is a hydrous or anhydrous silicate with varying proportions of CaO and SiO₂

Chemical name
Calcium silicate

EINECS
215-710-8

Assay
Content on the hydrated basis:
— as SiO₂ not less than 50 % and not more than 95 %
— as CaO not less than 3 % and not more than 35 %

Description
White to off-white free-flowing powder that remains so after absorbing relatively large amounts of water or other liquids

Identification
A. Positive test for silicate and for calcium
B. Forms a gel with mineral acids

Purity
<table>
<thead>
<tr>
<th>Test</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 10 % (105 °C, 2h)</td>
</tr>
<tr>
<td>Loss on ignition</td>
<td>Not less than 5 % and not more than 14 % (1 000 °C, constant weight)</td>
</tr>
<tr>
<td>Sodium</td>
<td>Not more than 3 %</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 50 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

E 553a(i) MAGNESIUM SILICATE

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

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

Description
Very fine, white, odourless powder, free from grittiness

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

Between 7,0 and 10,8

Purity
<table>
<thead>
<tr>
<th>Test</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 15 % (105 °C, 2h)</td>
</tr>
<tr>
<td>Loss on ignition</td>
<td>Not more than 15 % after drying (1 000 °C, 20 min)</td>
</tr>
<tr>
<td>Water soluble salts</td>
<td>Not more than 3 %</td>
</tr>
<tr>
<td>Free alkali</td>
<td>Not more than 1 % (as NaOH)</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

E 553a(ii) MAGNESIUM TRISILICATE

Definition
Magnesium trisilicate

Chemical name
Magnesium trisilicate

Chemical formula
Mg₂Si₃O₈·xH₂O (approximate composition)

EINECS
239-076-7

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

**Description**

**Identification**

A. Positive test for magnesium and for silicate

B. pH of a 5 % slurry 

**Purity**

Loss on ignition

Water soluble salts

Free alkali

Fluoride

Arsenic

Lead

Mercury

---

**E 570 FATTY ACIDS**

**Definition**

Linear fatty acids, caprylic acid (C8), capric acid (C10), lauric acid (C12), myristic acid (C14), palmitic acid (C16), stearic acid (C18), oleic acid (C18:1)

**Chemical name**

octanoic acid (C8), decanoic acid (C10), dodecanoic acid (C12), tetradecanoic acid (C14), hexadecanoic acid (C16), octadecanoic acid (C18), 9-octadecenoic acid (C18:1)

**Assay**

Not less than 98 % by chromatography

**Description**

A colourless liquid or white solid obtained from oils and fats

**Identification**

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

**Purity**

Residue on ignition

Unsaponifiable matter

Water

Arsenic

Lead

Mercury

---

**E 574 GLUCONIC ACID**

**Synonyms**

D-gluconic acid, dextronic acid

**Definition**

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

**Chemical name**

Gluconic acid

**Chemical formula**

C6H12O7 (gluconic acid)

**Molecular weight**

196,2

**Assay**

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

**Description**

Colourless to light yellow, clear syrupy liquid

**Identification**

A. Formation of phenylhydrazine derivative positive

**Purity**

Residue on ignition

Reducing matter

---
### E 575 GLUCONO-DELTA-LACTONE

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloride</td>
<td>Not more than 350 mg/kg</td>
</tr>
<tr>
<td>Sulphate</td>
<td>Not more than 240 mg/kg</td>
</tr>
<tr>
<td>Sulphite</td>
<td>Not more than 20 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

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

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

**Chemical name**
D-Glucono-1,5-lactone

**EINECS**
202-016-5

**Chemical formula**
C₆H₁₀O₆

**Molecular weight**
178,14

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

**Description**
Fine, white, nearly odourless, crystalline powder

**Identification**

A. Formation of phenylhydrazine derivative of gluconic acid positive

B. Solubility
Freely soluble in water. Sparingly soluble in ethanol

C. Melting point
152 °C ± 2 °C

**Purity**

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

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

Lead
Not more than 2 mg/kg

### E 576 SODIUM GLUCONATE

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not more than 1,0 %</td>
</tr>
<tr>
<td>Reducing matter</td>
<td>Not more than 1,0 % (as D-glucose)</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
</tbody>
</table>

**Synonyms**
Sodium salt of D-gluconic acid

**Definition**
Sodium D-gluconate

**Chemical name**
Sodium D-gluconate

**EINECS**
208-407-7

**Chemical formula**
C₆H₁₁NaO₇ (anhydrous)

**Molecular weight**
218,14

**Assay**
Content not less than 98,0 %

**Description**
White to tan, granular to fine, crystalline powder

**Identification**

A. Positive test for sodium and for gluconate

B. Solubility
Very soluble in water. Sparingly soluble in ethanol

C. pH of a 10 % solution
Between 6,5 and 7,5

**Purity**

Reducing matter
Not more than 1,0 % (as D-glucose)

Lead
Not more than 2 mg/kg

### E 577 POTASSIUM GLUCONATE

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not more than 1,0 %</td>
</tr>
<tr>
<td>Reducing matter</td>
<td>Not more than 1,0 % (as D-glucose)</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
</tbody>
</table>

**Synonyms**
Potassium salt of D-gluconic acid

**Definition**
Potassium D-gluconate

**Chemical name**
Potassium D-gluconate
### EINECS

<table>
<thead>
<tr>
<th><strong>EINECS</strong></th>
<th>206-074-2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chemical formula</strong></td>
<td>C₆H₁₁KO₇ (anhydrous)</td>
</tr>
<tr>
<td></td>
<td>C₆H₁₁KO₇·H₂O (monohydrate)</td>
</tr>
<tr>
<td><strong>Molecular weight</strong></td>
<td>234.25 (anhydrous)</td>
</tr>
<tr>
<td></td>
<td>252.26 (monohydrate)</td>
</tr>
<tr>
<td><strong>Assay</strong></td>
<td>Content not less than 97.0 % and not more than 103.0 % on dried basis</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Odourless, free flowing white to yellowish white, crystalline powder or granules</td>
</tr>
</tbody>
</table>

### Identification

A. Positive test for potassium and for gluconate
B. pH of a 10 % solution

### Purity

<table>
<thead>
<tr>
<th><strong>Purity</strong></th>
<th><strong>Chemical formula</strong></th>
<th><strong>Molecular weight</strong></th>
<th><strong>Assay</strong></th>
<th><strong>Description</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Loss on drying</strong></td>
<td>C₁₂H₂₂CaO₁₄ (anhydrous)</td>
<td>430.38 (anhydrous form)</td>
<td>Content not less than 98.0 % and not more than 102 % on the anhydrous and monohydrate basis</td>
<td>Odourless, white crystalline granules or powder, stable in air</td>
</tr>
<tr>
<td><strong>Reducing substances</strong></td>
<td>C₁₂H₂₂CaO₁₄·H₂O (monohydrate)</td>
<td>448.39 (monohydrate)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Lead</strong></td>
<td>Not more than 3.0 % (105 °C, 4h, vacuum)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Monohydrate:</strong></td>
<td>Not less than 6 % and not more than 7.5 % (105 °C, 4h, vacuum)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Reducing substances</strong></td>
<td>Not more than 1.0 % (as D-glucose)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Lead</strong></td>
<td>Not more than 2 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### E 578 CALCIUM GLUCONATE

<table>
<thead>
<tr>
<th><strong>Synonyms</strong></th>
<th>Calcium salt of D-gluconic acid</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Calcium di-D-gluconate</td>
</tr>
<tr>
<td><strong>Chemical name</strong></td>
<td>206-075-8</td>
</tr>
<tr>
<td><strong>Chemical formula</strong></td>
<td>C₁₂H₂₂CaO₁₄ (anhydrous)</td>
</tr>
<tr>
<td></td>
<td>C₁₂H₂₂CaO₁₄·H₂O (monohydrate)</td>
</tr>
<tr>
<td></td>
<td>430.38 (anhydrous form)</td>
</tr>
<tr>
<td></td>
<td>448.39 (monohydrate)</td>
</tr>
<tr>
<td><strong>Assay</strong></td>
<td>Content not less than 98.0 % and not more than 102 % on the anhydrous and monohydrate basis</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Odourless, white crystalline granules or powder, stable in air</td>
</tr>
</tbody>
</table>

### Identification

A. Positive test for calcium and for gluconate
B. Solubility
C. pH of a 5 % solution

### Purity

<table>
<thead>
<tr>
<th><strong>Purity</strong></th>
<th><strong>Chemical formula</strong></th>
<th><strong>Molecular weight</strong></th>
<th><strong>Assay</strong></th>
<th><strong>Description</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Loss on drying</strong></td>
<td>C₁₂H₁₈O₂</td>
<td>197.24</td>
<td>Not more than 3.0 % (105 °C, 16h) (anhydrous)</td>
<td>Not more than 2.0 % (105 °C, 16h) (monohydrate)</td>
</tr>
<tr>
<td><strong>Reducing substances</strong></td>
<td>Not more than 1.0 % (as D-glucose)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Lead</strong></td>
<td>Not more than 2 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### E 586 4-HEXYLRESORCINOL

<table>
<thead>
<tr>
<th><strong>Synonyms</strong></th>
<th>4-Hexyl-1,3-benzenediol</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Hexylresorcinol</td>
</tr>
<tr>
<td><strong>Chemical name</strong></td>
<td>205-257-4</td>
</tr>
<tr>
<td><strong>Chemical formula</strong></td>
<td>C₁₂H₁₈O₂</td>
</tr>
<tr>
<td><strong>Molecular weight</strong></td>
<td>197.24</td>
</tr>
<tr>
<td><strong>Assay</strong></td>
<td>Not less than 98.0 % on the dried basis</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>White powder</td>
</tr>
</tbody>
</table>
Identification
A. Solubility Freely soluble in ether and acetone; very slightly soluble in water
B. Nitric acid test To 1 ml of a saturated solution of the sample, add 1 ml of nitric acid. A light red colour appears
C. Bromine test To 1 ml of saturated solution of the sample, add 1 ml of bromine TS. A yellow, flocculent precipitate dissolves producing a yellow solution
D. Melting range 62 to 67 °C

Purity
Acidity Not more than 0,05 %
Sulphated ash Not more than 0,1 %
Resorcinol and other phenols Shake about 1 g of the sample with 50 ml of water for a few minutes, filter, and to the filtrate add 3 drops of ferric chloride TS. No red or blue colour is produced
Nickel Not more than 2 mg/kg
Lead Not more than 2 mg/kg
Mercury Not more than 3 mg/kg

E 640 GLYCINE AND ITS SODIUM SALT

Synonyms (gly)
Aminoacetic acid, glycocoll
(Na salt) Sodium glycinate

Definition
Chemical name (gly) Aminoacetic acid
(Na salt) Sodium glycinate
Chemical formula (gly) C₂H₅NO₂
(Na salt) C₂H₅NO₂Na
EINECS (gly) 200-272-2
(Na salt) 227-842-3
Molecular weight (gly) 75,07
(Na salt) 98
Assay Content not less than 98,5 % on the anhydrous basis
Description White crystals or crystalline powder

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

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

E 900 DIMETHYL POLYSILOXANE

Synonyms Polydimethyl siloxane, silicone fluid, silicone oil, dimethyl silicone
Definition Dimethylpolysiloxane is a mixture of fully methylated linear siloxane polymers containing repeating units of the formula (CH₃)₂SiO and stabilised with trimethylsiloxysiloxane end-blocking units of the formula (CH₃)₂SiO
### M2

**Chemical name**
Siloxanes and silicones, di-methyl

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

**Assay**
Content of total silicon not less than 37.3 % and not more than 38.5 %

**Description**
Clear, colourless, viscous liquid

**Identification**

A. Specific gravity \((25^\circ/25 \, ^\circ\text{C})\) Between 0.964 and 0.977

B. Refractive index \([\text{n}]_D^{25}\)
Between 1.400 and 1.405

C. Infrared spectrum characteristic of the compound

**Purity**

- Loss on drying: Not more than 0.5 % \((150 \, ^\circ\text{C}, 4 \text{h})\)
- Viscosity: Not less than \(1.00 \cdot 10^{-4} \text{ m}^2\text{s}^{-1}\) at \(25 \, ^\circ\text{C}\)
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 5 mg/kg
- Mercury: Not more than 1 mg/kg

---

### E 901 BEESWAX

**Synonyms**
White wax, yellow wax

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

**EINECS**
232-383-7 (beeswax)

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

**Identification**

A. Melting range: Between 62 °C and 65 °C

B. Specific gravity: About 0.96

C. Solubility: Insoluble in water

- Sparingly soluble in alcohol
- Very soluble in chloroform and ether

**Purity**

- Acid value: Not less than 17 and not more than 24
- Saponification value: 87-104
- Peroxide value: Not more than 5
- Glycerol and other polyols: Not more than 0.5 % (as glycerol)
- Ceresin, paraffins and certain other waxes: Absent
- Fats, Japan wax, rosin and soaps: Absent
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 5 mg/kg
- Mercury: Not more than 1 mg/kg

---

### E 902 CANDELILLA WAX

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

**EINECS**
232-347-0

**Description**
Hard, yellowish brown, opaque to translucent wax

**Identification**

A. Specific gravity: About 0.983
### E 903 CARNAUBA WAX

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

**EINECS**
232-399-4

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

**Identification**
- **A. Specific gravity**: About 0.997
- **B. Melting range**: Between 82 °C and 86 °C
- **C. Solubility**: Insoluble in water; partly soluble in boiling ethanol

**Purity**
- **Sulphated ash**: Not more than 0.25 %
- **Acid value**: Not less than 2 and not more than 7
- **Ester value**: Not less than 71 and not more than 88
- **Unsaponifiable matter**: Not less than 50 % and not more than 55 %
- **Arsenic**: Not more than 3 mg/kg
- **Lead**: Not more than 5 mg/kg
- **Mercury**: Not more than 1 mg/kg

### E 904 SHELLAC

**Synonyms**
Bleached shellac, white shellac

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

**EINECS**
232-549-9

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

**Identification**
- **A. Solubility**: Insoluble in water; freely (though very slowly) soluble in alcohol; slightly soluble in acetone
- **B. Acid value**: Between 60 and 89

**Purity**
- **Loss on drying**: Not more than 6.0 % (40 °C, over silica gel, 15h)
- **Rosin**: Absent
- **Wax**: Absent
Bleached shellac: not more than 5.5%
Wax-free bleached shellac: not more than 0.2%

Lead
Not more than 2 mg/kg

E 920 L-CYSTEINE

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

EINECS
200-157-7 (anhydrous)

Chemical formula
C_3H_7NO_2S.HCl.nH_2O (where n = 0 or 1)

Molecular weight
157.62 (anhydrous)

Assay
Content not less than 98.0% and not more than 101.5% on the anhydrous basis

Description
White powder or colourless crystals

Identification
A. Solubility
Freely soluble in water and in ethanol

B. Melting range
Anhydrous form melts at about 175 °C

C. Specific rotation
\([\alpha]_D^{20}: \text{between } +5.0^\circ \text{ and } +8.0^\circ \text{ or }\]
\([\alpha]_D^{25}: \text{between } +4.9^\circ \text{ and } 7.9^\circ \]

Purity
Loss on drying
Between 8.0 % and 12.0 %

Residue on ignition
Not more than 0.1%

Ammonium-ion
Not more than 200 mg/kg

Arsenic
Not more than 1.5 mg/kg

Lead
Not more than 5 mg/kg

E 927b CARBAMIDE

Synonyms
Urea

Definition

EINECS
200-315-5

Chemical formula
CH_4N_2O

Molecular weight
60.06

Assay
Content not less than 99.0% on the anhydrous basis

Description
Colourless to white, prismatic, crystalline powder or small, white pellets

Identification
A. Solubility
Very soluble in water

B. Precipitation with nitric acid
To pass the test a white, crystalline precipitate is formed

C. Colour reaction
To pass the test a reddish-violet colour is produced

D. Melting range
132 °C to 135 °C

Purity
Loss on drying
Not more than 1.0% (105 °C, 1h)

Sulphated ash
Not more than 0.1%

Ethanol-insoluble matter
Not more than 0.04%

Alkalinity
Passes test

Ammonium-ion
Not more than 500 mg/kg

Biuret
Not more than 0.1%

Arsenic
Not more than 3 mg/kg

Lead
Not more than 5 mg/kg
### E 938 ARGON

<table>
<thead>
<tr>
<th>Definition</th>
<th>Chemical name</th>
<th>Argon</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS</td>
<td>231-147-0</td>
<td></td>
</tr>
<tr>
<td>Chemical formula</td>
<td>Ar</td>
<td></td>
</tr>
<tr>
<td>Molecular weight</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>Assay</td>
<td>Not less than 99 %</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Colourless, odourless, non-flammable gas</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Purity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
</tr>
<tr>
<td>Methane and other hydrocarbons calculated as methane</td>
</tr>
</tbody>
</table>

### E 939 HELIUM

<table>
<thead>
<tr>
<th>Definition</th>
<th>Chemical name</th>
<th>Helium</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS</td>
<td>231-168-5</td>
<td></td>
</tr>
<tr>
<td>Chemical formula</td>
<td>He</td>
<td></td>
</tr>
<tr>
<td>Molecular weight</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Assay</td>
<td>Not less than 99 %</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Colourless, odourless, non-flammable gas</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Purity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
</tr>
<tr>
<td>Methane and other hydrocarbons calculated as methane</td>
</tr>
</tbody>
</table>

### E 941 NITROGEN

<table>
<thead>
<tr>
<th>Definition</th>
<th>Chemical name</th>
<th>Nitrogen</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS</td>
<td>231-783-9</td>
<td></td>
</tr>
<tr>
<td>Chemical formula</td>
<td>N₂</td>
<td></td>
</tr>
<tr>
<td>Molecular weight</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>Assay</td>
<td>Not less than 99 %</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Colourless, odourless, non-flammable gas</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Purity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
</tr>
<tr>
<td>Carbon monoxide</td>
</tr>
<tr>
<td>Methane and other hydrocarbons calculated as methane</td>
</tr>
<tr>
<td>Nitrogen dioxide and nitrogen oxide</td>
</tr>
<tr>
<td>Oxygen</td>
</tr>
</tbody>
</table>

### E 942 NITROUS OXIDE

<table>
<thead>
<tr>
<th>Definition</th>
<th>Chemical name</th>
<th>Nitrous oxide</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS</td>
<td>233-032-0</td>
<td></td>
</tr>
<tr>
<td>Chemical formula</td>
<td>N₂O</td>
<td></td>
</tr>
<tr>
<td>Molecular weight</td>
<td>44</td>
<td></td>
</tr>
<tr>
<td>Assay</td>
<td>Not less than 99 %</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Colourless, non-flammable gas, sweetish odour</td>
<td></td>
</tr>
</tbody>
</table>
**M2**

**Purity**

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not more than 0.05 %</td>
</tr>
<tr>
<td>Carbon monoxide</td>
<td>Not more than 30 μl/l</td>
</tr>
<tr>
<td>Nitrogen dioxide and nitrogen oxide</td>
<td>Not more than 10 μl/l</td>
</tr>
</tbody>
</table>

**E 948 OXYGEN**

**Definition**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Oxygen</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS</td>
<td>231-956-9</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>32</td>
</tr>
<tr>
<td>Assay</td>
<td>Not less than 99 %</td>
</tr>
<tr>
<td>Description</td>
<td>Colourless, odourless, non-flammable gas</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not more than 0.05 %</td>
</tr>
<tr>
<td>Methane and other hydrocarbons</td>
<td>Not more than 100 μl/l</td>
</tr>
<tr>
<td>calculated as methane</td>
<td></td>
</tr>
</tbody>
</table>

**E 999 QUILLAIA EXTRACT**

**Synonyms**

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

**Definition**

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

**Description**

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

**Identification**

A. pH of a 2.5 % solution Between 4.5 and 5.5

**Purity**

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not more than 6.0 % (Karl Fischer method) (powder form only)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 1103 INVERTASE**

**Definition**

Invertase is produced from *Saccharomyces cerevisiae*

<table>
<thead>
<tr>
<th>Systematic name</th>
<th>β-D-Fructofuranoside fructohydrolase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enzyme Commission No</td>
<td>EC 3.2.1.26</td>
</tr>
<tr>
<td>EINECS</td>
<td>232-615-7</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 0.5 mg/kg</td>
</tr>
<tr>
<td>Total bacterial count</td>
<td>Not more than 50 000/g</td>
</tr>
<tr>
<td><em>Salmonella</em> spp.</td>
<td>Absent by test in 25 g</td>
</tr>
<tr>
<td>Coliforms</td>
<td>Not more than 30/g</td>
</tr>
<tr>
<td>E. coli</td>
<td>Absent by test in 25 g</td>
</tr>
</tbody>
</table>
**M2**

**E 1200 POLYDEXTROSE**

**Synonyms**
Modified polydextroses

**Definition**
Randomly bonded glucose polymers with some sorbitol end-groups, and with citric acid or phosphoric acid residues attached to the polymers by mono or diester bonds. They are obtained by melting and condensation of the ingredients and consist of approximately 90 parts D-glucose, 10 parts sorbitol and 1 part citric acid or 0.1 part phosphoric acid. The 1,6-glucosidic linkage predominates in the polymers but other linkages are present. The products contain small quantities of free glucose, sorbitol, levoglucosan (1,6-anhydro-D-glucose) and citric acid and may be neutralised with any food grade base and/or decolorised and deionised for further purification. The products may also be partially hydrogenated with Raney nickel catalyst to reduce residual glucose. Polydextrose-N is neutralised polydextrose

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

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

**Identification**
A. Positive tests for sugar and for reducing sugar
B. pH of a 10 % solution Between 2.5 and 7.0 for polydextrose
Between 5.0 and 6.0 for polydextrose-N

**Purity**
- Water Not more than 4.0 % (Karl Fischer method)
- Sulphated ash Not more than 0.3 % (polydextrose)
- Not more than 2.0 % (polydextrose N)
- Nickel Not more than 2 mg/kg for hydrogenated polydextroses
- Not more than 4.0 % on the ash-free and the dried basis
- 1,6-Anhydro-D-glucose Not more than 6.0 % combined on the ash-free and the dried basis; glucose and sorbitol are determined separately
- Glucose and sorbitol Not more than 0.05 % (polydextrose-N)
- Not more than 0.5 mg/kg

**M7**

**E 1204 PULLULAN**

**Definition**
Linear, neutral glucan consisting mainly of maltotriose units connected by -1,6 glycosidic bonds. It is produced by fermentation from a food grade hydrolysed starch using a non-toxin producing strain of *Aureobasidium pullulans*. After completion of the fermentation, the fungal cells are removed by microfiltration, the filtrate is heat-sterilised and pigments and other impurities are removed by adsorption and ion exchange chromatography

**EINECS**
232-945-1

**Chemical formula**
(C₆H₁₀O₅)ₓ

**Assay**
Content not less than 90 % of glucan on the dried basis

**Description**
White to off-white odourless powder

**Identification**
A. Solubility
Soluble in water, practically insoluble in ethanol.
B. pH of 10 % solution
5.0 to 7.0
**C. Precipitation with polyethylene glycol 600**

Add 2 ml of polyethylene glycol 600 to 10 ml of a 2 % aqueous solution of pullulan. A white precipitate is formed.

**D. Depolymerisation with pullulanase**

Prepare two test tubes each with 10 ml of a 10 % pullulan solution. Add 0,1 ml pullulanase solution having activity 10 units/g to one test tube, and 0,1 ml water to the other. After incubation at about 25 °C for 20 min, the viscosity of the pullulanase-treated solution is visibly lower than that of the untreated solution.

---

**E 1404 OXIDISED STARCH**

**Definition**

Oxidised starch is starch treated with sodium hypo-chlorite.

**Description**

White or nearly white powder or granules or (if pre-gelatinised) flakes, amorphous powder or coarse particles.

**Identification**

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

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 6 % (90 °C, pressure not more than 50 mm Hg, 6 h)</td>
</tr>
<tr>
<td>Mono-, di- and oligosaccharides</td>
<td>Not more than 10 % expressed as glucose</td>
</tr>
<tr>
<td>Viscosity</td>
<td>100 to 180 mm²/s (10 % w/w aqueous solution at 30 °C)</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Yeast and moulds</td>
<td>Not more than 100 colonies per gram</td>
</tr>
<tr>
<td>Coliforms</td>
<td>Absent in 25 g</td>
</tr>
<tr>
<td>Salmonella</td>
<td>Absent in 25 g</td>
</tr>
</tbody>
</table>

---

**E 1410 MONOSTARCH PHOSPHATE**

**Definition**

Monostarch phosphate is starch esterified with orthophosphoric acid, or sodium or potassium orthophosphate or sodium tripolyphosphate.

**Description**

White or nearly white powder or granules or (if pre-gelatinised) flakes, amorphous powder or coarse particles.

**Identification**

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

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 15,0 % for cereal starch</td>
</tr>
<tr>
<td>Carboxyl groups</td>
<td>Not more than 1,1 %</td>
</tr>
<tr>
<td>Sulphur dioxide</td>
<td>Not more than 50 mg/kg for modified cereal starches</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 0,1 mg/kg</td>
</tr>
</tbody>
</table>

**E 1410 MONOSTARCH PHOSPHATE**

**Definition**

Monostarch phosphate is starch esterified with orthophosphoric acid, or sodium or potassium orthophosphate or sodium tripolyphosphate.

**Description**

White or nearly white powder or granules or (if pre-gelatinised) flakes, amorphous powder or coarse particles.

**Identification**

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

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 15,0 % for cereal starch</td>
</tr>
</tbody>
</table>
E 1412 DISTARCH PHOSPHATE

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

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

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

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
</table>
| Loss on drying | Not more than 15.0 % for cereal starch  
                 | Not more than 21.0 % for potato starch |
|             | Not more than 18.0 % for other starches |
| Residual phosphate | Not more than 0.5 % (as P) for wheat or potato starch  
                      | Not more than 0.4 % (as P) for other starches |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches  
                   | Not more than 10 mg/kg for other modified starches, unless otherwise specified |
| Arsenic      | Not more than 1 mg/kg |
| Lead         | Not more than 2 mg/kg |
| Mercury      | Not more than 0.1 mg/kg |

E 1413 PHOSPHATED DISTARCH PHOSPHATE

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

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

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

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
</table>
| Loss on drying | Not more than 15.0 % for cereal starch  
                 | Not more than 21.0 % for potato starch |
|             | Not more than 18.0 % for other starches |
| Residual phosphate | Not more than 0.5 % (as P) for wheat or potato starch  
                      | Not more than 0.4 % (as P) for other starches |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches |
### E 1414 ACETYLATED DISTARCH PHOSPHATE

<table>
<thead>
<tr>
<th><strong>Definition</strong></th>
<th>Acetylated distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride and esterified by acetic anhydride or vinyl acetate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Identification</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A. If not pregelatinised: by microscopic observation</td>
<td></td>
</tr>
<tr>
<td>B. Iodine staining positive (dark blue to light red colour)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Purity</strong> (all values expressed on an anhydrous basis except for loss on drying)</th>
<th></th>
</tr>
</thead>
</table>
| Loss on drying | Not more than 15,0 % for cereal starch  
Not more than 21,0 % for potato starch  
Not more than 18,0 % for other starches |
| Acetyl groups | Not more than 2,5 % |
| Residual phosphate | Not more than 0,14 % (as P) for wheat or potato starch  
Not more than 0,04 % (as P) for other starches |
| Vinyl acetate | Not more than 0,1 mg/kg |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches  
Not more than 10 mg/kg for other modified starches, unless otherwise specified |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 0,1 mg/kg |

### E 1420 ACETYLATED STARCH

<table>
<thead>
<tr>
<th><strong>Synonyms</strong></th>
<th>Starch acetate</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Definition</strong></th>
<th>Acetylated starch is starch esterified with acetic anhydride or vinyl acetate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Identification</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A. If not pregelatinised: by microscopic observation</td>
<td></td>
</tr>
<tr>
<td>B. Iodine staining positive (dark blue to light red colour)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Purity</strong> (all values expressed on an anhydrous basis except for loss on drying)</th>
<th></th>
</tr>
</thead>
</table>
| Loss on drying | Not more than 15,0 % for cereal starch  
Not more than 21,0 % for potato starch  
Not more than 18,0 % for other starches |
| Acetyl groups | Not more than 2,5 % |
| Vinyl acetate | Not more than 0,1 mg/kg |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches  
Not more than 10 mg/kg for other modified starches, unless otherwise specified |
**M2**

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 0.1 mg/kg</td>
</tr>
</tbody>
</table>

**E 1422 ACETYLATED DISTARCH ADIPATE**

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

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

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

**Purity** (all values expressed on an anhydrous basis except for loss on drying)
- Loss on drying
  - Not more than 15.0 % for cereal starch
  - Not more than 21.0 % for potato starch
  - Not more than 18.0 % for other starches
- Acetyl groups
  - Not more than 2.5 %
- Adipate groups
  - Not more than 0.135 %
- Sulphur dioxide
  - Not more than 50 mg/kg for modified cereal starches
  - Not more than 10 mg/kg for other modified starches, unless otherwise specified
- Arsenic
  - Not more than 1 mg/kg
- Lead
  - Not more than 2 mg/kg
- Mercury
  - Not more than 0.1 mg/kg

**E 1440 HYDROXYPROPYL STARCH**

**Definition**
Hydroxypropyl starch is starch etherified with propylene oxide

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

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

**Purity** (all values expressed on an anhydrous basis except for loss on drying)
- Loss on drying
  - Not more than 15.0 % for cereal starch
  - Not more than 21.0 % for potato starch
  - Not more than 18.0 % for other starches
- Hydroxypropyl groups
  - Not more than 7.0 %
- Propylene chlorohydrin
  - Not more than 1 mg/kg
- Sulphur dioxide
  - Not more than 50 mg/kg for modified cereal starches
  - Not more than 10 mg/kg for other modified starches, unless otherwise specified
- Arsenic
  - Not more than 1 mg/kg
- Lead
  - Not more than 2 mg/kg
- Mercury
  - Not more than 0.1 mg/kg

**E 1442 HYDROXYPROPYL DISTARCH PHOSPHATE**

**Definition**
Hydroxypropyl distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride and etherified with propylene oxide
**M2**

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

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

**Purity** (all values expressed on an anhydrous basis except for loss on drying)
- **Loss on drying**
  - Not more than 15.0 % for cereal starch
  - Not more than 21.0 % for potato starch
  - Not more than 18.0 % for other starches
- **Hydroxypropyl groups**
  - Not more than 7.0 %
- **Residual phosphate**
  - Not more than 0.14 % (as P) for wheat or potato starch
  - Not more than 0.04 (as P) for other starches
- **Propylene chlorohydrin**
  - Not more than 1 mg/kg
- **Sulphur dioxide**
  - Not more than 50 mg/kg for modified cereal starches
  - Not more than 10 mg/kg for other modified starches, unless otherwise specified
- **Arsenic**
  - Not more than 1 mg/kg
- **Lead**
  - Not more than 2 mg/kg
- **Mercury**
  - Not more than 0.1 mg/kg

**E 1450 STARCH SODIUM OCTENYL SUCCINATE**

**Synonyms**
SSOS

**Definition**
Starch sodium octenyl succinate is starch esterified with octenylsuccinic anhydride

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

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

**Purity** (all values expressed on an anhydrous basis except for loss on drying)
- **Loss on drying**
  - Not more than 15.0 % for cereal starch
  - Not more than 21.0 % for potato starch
  - Not more than 18.0 % for other starches
- **Octenylsuccinyl groups**
  - Not more than 3 %
- **Octenylsuccinic acid residue**
  - Not more than 0.3 %
- **Sulphur dioxide**
  - Not more than 50 mg/kg for modified cereal starches
  - Not more than 10 mg/kg for other modified starches, unless otherwise specified
- **Arsenic**
  - Not more than 1 mg/kg
- **Lead**
  - Not more than 2 mg/kg
- **Mercury**
  - Not more than 0.1 mg/kg

**E 1451 ACETYLATED OXIDISED STARCH**

**Definition**
Acetylated oxidised starch is starch treated with sodium hypochlorite followed by esterification with acetic anhydride

**Description**
White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification
A. If not pregelatinised: by microscopic observation
B. Iodine staining positive (dark blue to light red colour)

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

| Property                  | Limit
|----------------------------|-------|
| Loss on drying            | Not more than 15.0 % for cereal starch
|                            | Not more than 21.0 % for potato starch
|                            | Not more than 18.0 % for other starches
| Carboxyl groups           | Not more than 1.3 %
| Acetyl groups             | Not more than 2.5 %
| Sulphur dioxide           | Not more than 10 mg/kg for other modified starches, unless otherwise specified
| Arsenic                   | Not more than 1 mg/kg
| Lead                      | Not more than 2 mg/kg
| Mercury                   | Not more than 0.1 mg/kg

E 1452 STARCH ALUMINIUM OCTENYL SUCCINATE

Synonyms
SAOS

Definition
Starch aluminium octenyl succinate is starch esterified with octenylsuccinic anhydride and treated with aluminium sulphate

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

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

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

| Property                  | Limit
|----------------------------|-------|
| Loss on drying            | Not more than 21 %
| Octenylsuccinyl groups    | Not more than 3 %
| Octenylsuccinic acid residue | Not more than 0.3 %
| Sulphur dioxide           | Not more than 50 mg/kg for modified cereal starches
|                            | Not more than 10 mg/kg for the other modified starches, unless otherwise specified
| Arsenic                   | Not more than 1 mg/kg
| Lead                      | Not more than 2 mg/kg
| Mercury                   | Not more than 0.1 mg/kg
| Aluminium                 | Not more than 0.3 %

E 1505 TRIETHYL CITRATE

Synonyms
Ethyl citrate

Definition
Chemical name: Triethyl-2-hydroxypropan-1,2,3-tricarboxylate
EINECS: 201-070-7
Chemical formula: C_{12}H_{20}O_{7}
Molecular weight: 276.29
Assay: Content not less than 99.0 %
E 1518 GLYCERYL TRIACETATE

Synonyms
Triacetin

Definition
Chemical name
Glyceryl triacetate

EINECS
203-051-9

Chemical formula
C₉H₁₄O₆

Molecular weight
218,21

Assay
Content not less than 98,0 %

Description
Colourless, somewhat oily liquid having a slightly fatty odour

Identification
A. Positive tests for acetate and for glycerol
B. Refractive index
Between 1,429 and 1,431 at 25 °C
C. Specific gravity (25 °C/25 °C)
Between 1,154 and 1,158
D. Boiling range
Between 258 °C and 270 °C

Purity
Water
Not more than 0,25 % (Karl Fischer method)

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

Arsenic
Not more than 3 mg/kg

Lead
Not more than 5 mg/kg

E 1520 PROPANE-1,2-DIOL

Synonyms
Propylene glycol

Definition
Chemical names
1,2-dihydroxypropane

EINECS
200-338-0

Chemical formula
C₃H₈O₂

Molecular weight
76,10

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

Description
Clear, colourless, hygroscopic, viscous liquid

Identification
A. Solubility
Soluble in water, ethanol and acetone
B. Specific gravity
\( d_{20}^{20} \): 1,035-1,040
C. Refractive index
\( \eta^{D}_{20} \): 1,431-1,433

Purity
Distillation range
99 % v/v distils between 185 °C-189 °C

Sulphated ash
Not more than 0,07 %

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

Lead
Not more than 5 mg/kg
(1) Cobalt chloride TSC: dissolve approximately 65 g of cobalt chloride CoCl₂·6H₂O 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 CoCl₂·6H₂O. 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 CoCl₂·6H₂O 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 FeCl₃·6H₂O. 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 FeCl₃·6H₂O per ml.

(3) Copper sulphate TSC: dissolve approximately 65 g of copper sulphate CuSO₄·5H₂O 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 CuSO₄·5H₂O. 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 CuSO₄·5H₂O per ml.

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

(*) When labelled 'for food use', nitrite may only be sold in a mixture with salt or a salt substitute.
E 170 (i) CALCIUM CARBONATE

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/45/EC laying down specific purity criteria concerning colours for use in foodstuffs (1).

E 353 METATARTARIC ACID

**Synonyms**
Ditartaric acid

**Definition**

*Chemical name*
Metatartaric acid

*Chemical formula*
\( \text{C}_4\text{H}_6\text{O}_6 \)

*Assay*
Not less than 99.5%

*Description*
Crystalline or powder form with a white or yellowish colour. Very deliquescent with a faint odour of caramel

**Identification**

A. Very soluble in water and ethanol.

B. Place a sample of 1 to 10 mg of this substance in a test tube with 2 ml of concentrated sulfuric acid and 2 drops of sulpho-resorcinol reagent. When heated to 150 °C, an intense violet coloration appears

**Purity**

Arsenic
Not more than 3 mg/kg

Lead
Not more than 5 mg/kg

Mercury
Not more than 1 mg/kg

E 354 CALCIUM TARTRATE

**Synonyms**
L-Calcium tartrate

**Definition**

*Chemical name*
Calcium L(+)-2,3-dihydroxybutanedioate di-hydrate

*Chemical formula*
\( \text{C}_4\text{H}_4\text{CaO}_6 \cdot 2\text{H}_2\text{O} \)

*Molecular weight*
224.18

*Assay*
Not less than 98.0%

*Description*
Fine crystalline powder with a white or off-white colour

**Identification**

A. Slightly soluble in water. Solubility approximately 0.01 g/100 ml water (20 °C). Sparingly soluble in ethanol. Slightly soluble in diethyl ether. Soluble in acids

B. Specific rotation \([\alpha]^{\text{D}}\)
\(+7.0^\circ\) to \(+7.4^\circ\) (0.1 % in a 1N de HCl solution)

C. \(\text{pH}\) of a 5 % slurry
Between 6.0 and 9.0

**Purity**

Sulphates (as \(\text{H}_2\text{SO}_4\))
Not more than 1 g/kg

Arsenic
Not more than 3 mg/kg

Lead
Not more than 5 mg/kg

Mercury
Not more than 1 mg/kg

M3

**E 356 SODIUM ADIPATE**

**Definition**

- **Chemical name**: Sodium adipate
- **EINECS**: 231-293-5
- **Chemical formula**: C₆H₈Na₂O₄
- **Molecular weight**: 190.11
- **Assay**: Content not less than 99.0 % (on anhydrous basis)
- **Description**: White odourless crystals or crystalline powder

**Identification**

A. Melting range 151 °C-152 °C (for adipic acid)
B. Solubility Approximately 50 g/100 ml water (20 °C)
C. Positive test for sodium

**Purity**

- **Water**: Not more than 3 % (Karl Fischer)
- **Arsenic**: Not more than 3 mg/kg
- **Lead**: Not more than 5 mg/kg
- **Mercury**: Not more than 1 mg/kg

**E 357 POTASSIUM ADIPATE**

**Definition**

- **Chemical name**: Potassium adipate
- **EINECS**: 242-838-1
- **Chemical formula**: C₆H₈K₂O₄
- **Molecular weight**: 222.32
- **Assay**: Content not less than 99.0 % (on anhydrous basis)
- **Description**: White odourless crystals or crystalline powder

**Identification**

A. Melting range 151 °C-152 °C (for adipic acid)
B. Solubility Approximately 60 g/100 ml water (20 °C)
C. Positive test for potassium

**Purity**

- **Water**: Not more than 3 % (Karl Fischer)
- **Arsenic**: Not more than 3 mg/kg
- **Lead**: Not more than 5 mg/kg
- **Mercury**: Not more than 1 mg/kg

**E 420(i) SORBITOL**

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs (1).

**E 420(ii) SORBITOL SYRUP**

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 421 MANNITOL

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 425(i) KONJAC GUM

Definition

Konjac gum is a water-soluble hydrocolloid obtained from the Konjac flour by aqueous extraction. Konjac flour is the unpurified raw product from the root of the perennial plant *Amorphophallus konjac*. The main component of Konjac gum is the water-soluble high-molecular-weight polysaccharide glucomannan, which consists of D-mannose and D-glucose units at a molar ratio of 1.6:1.0, connected by β(1-4)-glycosidic bonds. Shorter side chains are attached through β(1-3)-glycosidic bonds, and acetyl groups occur at random at a ratio of about 1 group per 9 to 19 sugar units.

Molecular weight

The main component, glucomannan, has an average molecular weight of 200,000 to 2,000,000.

Assay

Not less than 75% carbohydrate.

Description

A white to cream to light tan powder.

Identification

A. Solubility

Dispersible in hot or cold water forming a highly viscous solution with a pH between 4.0 and 7.0.

B. Gel formation

Add 5 ml of a 4% sodium borate solution to a 1% solution of the sample in a test tube, and shake vigorously. A gel forms.

C. Formation of heat-stable gel

Prepare a 2% solution of the sample by heating it in a boiling water bath for 30 min, with continuous agitation and then cooling the solution to room temperature. For each g of the sample used to prepare 30 g of the 2% solution, add 1 ml of 10% potassium carbonate solution to the fully hydrated sample at ambient temperature. Heat the mixture in a water bath to 85°C, and maintain for 2 h without agitation. Under these conditions a thermally stable gel is formed.

D. Viscosity (1% solution)

Not less than 3 kgm⁻¹ s⁻¹ at 25°C

Purity

Loss on drying

Not more than 12% (105°C, 5 h)

Starch

Not more than 3%

Protein

Not more than 3% (N × 5.7)

Determine nitrogen by Kjeldahl method. The percentage of nitrogen in the sample multiplied by 5.7 gives the percent of protein in the sample.

Ether-soluble material

Not more than 0.1%

Total ash

Not more than 5.0% (800°C, 3 to 4 h)

Arsenic

Not more than 3 mg/kg

Lead

Not more than 2 mg/kg

Salmonella spp.

Absent in 12.5 g

*E. coli*

Absent in 5 g

E 425(ii) KONJAC GLUCOMANNAN

Definition

Konjac glucomannan is a water-soluble hydrocolloid obtained from Konjac flour by washing with water-containing ethanol. Konjac flour is the unpurified raw product from the tuber of the perennial plant *Amorphophallus konjac*. The main component of Konjac glucomannan is the water-soluble high-molecular-weight polysaccharide glucomannan, which consists of D-mannose and D-glucose units at a molar ratio of 1.6:1.0, connected by β(1-4)-glycosidic bonds with a branch at about each 50th or 60th unit. About each 19th sugar residue is acetylated.
Molecular weight

500 000 to 2 000 000

Assay

Total dietary fibre: not less than 95 % on a dry weight basis

Description

White to slightly brownish fine particle size, free flowing and odourless powder

Identification

A. Solubility

Dispersible in hot or cold water forming a highly viscous solution with a pH between 5,0 and 7,0. Solubility is increased by heat and mechanical agitation

B. Formation of heat-stable gel

Prepare a 2 % solution of the sample by heating it in a boiling water bath for 30 min, with continuous agitation and then cooling the solution to room temperature. For each g of the sample used to prepare 30 g of the 2 % solution, add 1 ml of 10 % potassium carbonate solution to the fully hydrated sample at ambient temperature. Heat the mixture in a water bath to 85 °C, and maintain for 2 h without agitation. Under these conditions a thermally stable gel is formed

C. Viscosity (1 % solution)

Not less than 20 kgm⁻¹s⁻¹ at 25 °C

Purity

Loss on drying

Not more than 8 % (105 °C, 3h)

Starch

Not more than 1 %

Protein

Not more than 1,5 % (N × 5,7)

Determine nitrogen by Kjeldahl method. The percentage of nitrogen in the sample multiplied by 5,7 gives the percent of protein in the sample

Ether-soluble material

Not more than 0,5 %

Sulphite (as SO₂)

Not more than 4 mg/kg

Chloride

Not more than 0,02 %

50 % Alcohol-soluble

Not more than 2,0 % material

Total ash

Not more than 2,0 % (800 °C, 3 to 4h)

Lead

Not more than 1 mg/kg

Salmonella spp.

Absent in 12,5 g

E. coli

Absent in 5 g

E 426 SOYBEAN HEMICELLULOSE

Synonyms

Definition

Soybean hemicellulose is a refined water-soluble polysaccharide obtained from natural strain soybean fibre by hot water extraction

Chemical names

Water soluble soybean polysaccharides

Water soluble soybean fibre

Assay

Not less than 74 % carbohydrate

Description

Free flowing spray-dried white powder

Identification

A. Solubility

Soluble in hot and cold water without gel formation

pH of 1 % solution

5,5 ± 1,5

B. Viscosity of 10 % solution

Not more than 200 mPa.s

Purity

Loss on drying

Not more than 7 % (105 °C, 4 h)

Protein

Not more than 14 %

Total ash

Not more than 9,5 % (600 °C, 4 h)
**M7**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenic</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Standard plate count</td>
<td>Not more than 3 000 colonies per gram</td>
</tr>
<tr>
<td>Yeast and mould</td>
<td>Not more than 100 colonies per gram</td>
</tr>
<tr>
<td>E. Coli</td>
<td>Negative in 10 g</td>
</tr>
</tbody>
</table>

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

**Synonyms**

Magnesium hydrogen carbonate, magnesium subcarbonate (light or heavy), hydrated basic magnesium carbonate, magnesium carbonate hydroxide

**Definition**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Magnesium carbonate hydroxide hydrated</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS</td>
<td>235-192-7</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>4MgCO&lt;sub&gt;3&lt;/sub&gt;Mg(OH)&lt;sub&gt;2&lt;/sub&gt;5H&lt;sub&gt;2&lt;/sub&gt;O</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>485</td>
</tr>
<tr>
<td>Assay</td>
<td>Mg content not less than 40,0 % and not more than 45,0 % calculated as MgO</td>
</tr>
</tbody>
</table>

**Description**

Light, white friable mass or bulky white powder

**Identification**

A. Positive tests for magnesium and for carbonate

B. Solubility

Practically insoluble in water. Insoluble in ethanol

**Purity**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acid insoluble matter</td>
<td>Not more than 0,05 %</td>
</tr>
<tr>
<td>Water soluble matter</td>
<td>Not more than 1,0 %</td>
</tr>
<tr>
<td>Calcium</td>
<td>Not more than 1,0 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 553b TALC**

**Synonyms**

Talcum

**Definition**

Naturally occurring form of hydrous magnesium silicate containing varying proportions of such associated minerals as alpha-quartz, calcite, chlorite, dolomite, magnesite, and phlogopite

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Magnesium hydrogen metasilicate</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS</td>
<td>238-877-9</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>Mg&lt;sub&gt;3&lt;/sub&gt;(Si&lt;sub&gt;4&lt;/sub&gt;O&lt;sub&gt;10&lt;/sub&gt;)(OH)&lt;sub&gt;2&lt;/sub&gt;</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>379,22</td>
</tr>
<tr>
<td>Description</td>
<td>Light, homogeneous, white or almost white powder, greasy to the touch</td>
</tr>
</tbody>
</table>

**Identification**

A. IR absorption

Characteristic peaks at 3 677, 1 018 and 669 cm<sup>-1</sup>

B. X-ray diffraction

Peaks at 9,34/4,66/3,12 Å
### M3

<table>
<thead>
<tr>
<th>Solubility</th>
<th>Insoluble in water and ethanol</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purity</strong></td>
<td></td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Not more than 0.5 % (105 °C, 1h)</td>
</tr>
<tr>
<td>Acid-soluble matter</td>
<td>Not more than 6 %</td>
</tr>
<tr>
<td>Water-soluble matter</td>
<td>Not more than 0.2 %</td>
</tr>
<tr>
<td>Acid-soluble iron</td>
<td>Not detectable</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
</tbody>
</table>

#### E 554 SODIUM ALUMINIUM SILICATE

**Synonyms**

Sodium silicoaluminate, sodium aluminosilicate, aluminium sodium silicate

**Definition**

**Chemical name**

Sodium aluminium silicate

**Assay**

Content on the anhydrous basis:

- as SiO₂ not less than 66.0 % and not more than 88.0 %
- as Al₂O₃ not less than 5.0 % and not more than 15.0 %

**Description**

Fine white amorphous powder or beads

**Identification**

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

B. pH of a 5 % slurry: Between 6.5 and 11.5

#### E 555 POTASSIUM ALUMINIUM SILICATE

**Synonyms**

Mica

**Definition**

Natural mica consists of mainly potassium aluminium silicate (muscovite)

**EINECS**

310-127-6

**Chemical name**

Potassium aluminium silicate

**Chemical formula**

\[ KAl_2[AlSi_3O_{10}](OH)_2 \]

**Molecular weight**

398

**Assay**

Content not less than 98 %

**Description**

Light grey to white crystalline platelets or powder

**Identification**

A. Solubility

Insoluble in water, diluted acids and alkali and organic solvents
M3

Purity

Loss on drying Not more than 0,5 % (105 °C, 2h)
Antimony Not more than 20 mg/kg
Zinc Not more than 25 mg/kg
Barium Not more than 25 mg/kg
Chromium Not more than 100 mg/kg
Copper Not more than 25 mg/kg
Nickel Not more than 50 mg/kg
Arsenic Not more than 3 mg/kg
Mercury Not more than 1 mg/kg
Cadmium Not more than 2 mg/kg
Lead Not more than 10 mg/kg

E 556 CALCIUM ALUMINIUM SILICATE

Synonyms
Calcium aluminosilicate, calcium silicoaluminate, aluminium calcium silicate

Definition
Chemical name Calcium aluminium silicate
Assay Content on the anhydrous basis:
— as SiO₂ not less than 44,0 % and not more than 50,0 %
— as Al₂O₃ not less than 3,0 % and not more than 5,0 %
— as CaO not less than 32,0 % and not more than 38,0 %

Description Fine white, free-flowing powder

Identification
A. Positive tests for calcium, for aluminium and for silicate

Purity
Loss on drying Not more than 10,0 % (105 °C, 2h)
Loss on ignition Not less than 14,0 % and not more than 18,0 % on the anhydrous basis (1 000 °C, constant weight)
Fluoride Not more than 50 mg/kg
Arsenic Not more than 3 mg/kg
Lead Not more than 10 mg/kg
Mercury Not more than 1 mg/kg

E 558 BENTONITE

Definition
Bentonite is a natural clay containing a high proportion of montmorillonite, a native hydrated aluminium silicate in which some aluminium and silicon atoms were naturally replaced by other atoms such as magnesium and iron. Calcium and sodium ions are trapped between the mineral layers. There are four common types of bentonite: natural sodium bentonite, natural calcium bentonite, sodium-activated bentonite and acid-activated bentonite.

EINECS
215-108-5

Chemical formula
(Al, Mg)₉(Si₂O₁₀)₉(OH)₉ · 12H₂O

Molecular weight 819

Assay Montmorillonite content not less than 80 %
**M3**

**Description**

Very fine, yellowish or greyish white powder or granules. The structure of bentonite allows it to absorb water in its structure and on its external surface (swelling properties).

**Identification**

A. Methylene blue test
B. X-Ray diffraction
C. IR absorption

**Purity**

- Loss on drying: Not more than 15.0 % (105 °C, 2h)
- Arsenic: Not more than 2 mg/kg
- Lead: Not more than 20 mg/kg

**M7**

**E 559 ALUMINIUM SILICATE (KAOLIN)**

**Synonyms**

Kaolin, light or heavy

**Definition**

Aluminium silicate hydrous (kaolin) is a purified white plastic clay composed of kaolinite, potassium aluminium silicate, feldspar and quartz. Processing should not include calcination. The raw kaolinitic clay used in the production of aluminium silicate shall have a level of dioxin which does not make it injurious to health or unfit for human consumption.

**EINECS**

215-286-4 (kaolinite)

**Chemical formula**

Al₂Si₂O₅(OH)₄ (kaolinite)

**Molecular weight**

264

**Assay**

Content not less than 90 % (sum of silica and alumina, after ignition)

Silica (SiO₂) Between 45 % and 55 %

Alumina (Al₂O₃) Between 30 % and 39 %

**Description**

Fine, white or greyish white, unctuous powder. Kaolin is made up of loose aggregations of randomly oriented stacks of kaolinite flakes or of individual hexagonal flakes.

**Identification**

A. Positive test for alumina and for silicate
B. X-ray diffraction
C. IR absorption

**Purity**

- Loss on ignition: Between 10 and 14 % (1 000 °C, constant weight)
- Water soluble matter: Not more than 0.3 %
- Acid soluble matter: Not more than 2 %
- Iron: Not more than 5 %
- Potassium oxide (K₂O): Not more than 5 %
- Carbon: Not more than 0.5 %
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 5 mg/kg
- Mercury: Not more than 1 mg/kg

**M3**

**E 620 GLUTAMIC ACID**

**Synonyms**

L-Glutamic acid, L-α-aminoglutaric acid
<table>
<thead>
<tr>
<th><strong>M3</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>L-Glutamic acid, L-2-amino-pentanedioic acid</td>
</tr>
<tr>
<td><strong>Chemical name</strong></td>
<td></td>
</tr>
<tr>
<td><strong>EINECS</strong></td>
<td>200-293-7</td>
</tr>
<tr>
<td><strong>Chemical formula</strong></td>
<td>C₅H₉NO₄</td>
</tr>
<tr>
<td><strong>Molecular weight</strong></td>
<td>147,13</td>
</tr>
<tr>
<td><strong>Assay</strong></td>
<td>Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>White crystals or crystalline powder</td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td>Between + 31,5° and + 32,2° (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)</td>
</tr>
<tr>
<td><strong>A.</strong> Positive test for glutamic acid by thin layer chromatography</td>
<td></td>
</tr>
<tr>
<td><strong>B.</strong> Specific rotation ([\alpha]D^{20})</td>
<td></td>
</tr>
<tr>
<td><strong>C.</strong> pH of a saturated solution</td>
<td>Between 3,0 and 3,5</td>
</tr>
<tr>
<td><strong>Purity</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Loss on drying</strong></td>
<td>Not more than 0,2 % (80 °C, 3h)</td>
</tr>
<tr>
<td><strong>Sulphated ash</strong></td>
<td>Not more than 0,2 %</td>
</tr>
<tr>
<td><strong>Chloride</strong></td>
<td>Not more than 0,2 %</td>
</tr>
<tr>
<td><strong>Pyrrolidone carboxylic acid</strong></td>
<td>Not more than 0,2 %</td>
</tr>
<tr>
<td><strong>Lead</strong></td>
<td>Not more than 2 mg/kg</td>
</tr>
</tbody>
</table>

**E 621 MONOSODIUM GLUTAMATE**

| **Synonyms** | Sodium glutamate, MSG |
| **Definition** | Monosodium L-glutamate monohydrate |
| **Chemical name** |  |
| **EINECS** | 205-538-1 |
| **Chemical formula** | C₅H₈NaNO₄ · H₂O |
| **Molecular weight** | 187,13 |
| **Assay** | Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis |
| **Description** | White, practically odourless crystals or crystalline powder |
| **Identification** | Between + 24,8° and + 25,3° (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube) |
| **A.** Positive test for sodium |  |
| **B.** Positive test for glutamic acid by thin-layer chromatography |  |
| **C.** Specific rotation \([\alpha]D^{20}\) |  |
| **D.** pH of a 5 % solution | Between 6,7 and 7,2 |
| **Purity** |  |
| **Loss on drying** | Not more than 0,5 % (98 °C, 5h) |
| **Chloride** | Not more than 0,2 % |
| **Pyrrolidone carboxylic acid** | Not more than 0,2 % |
| **Lead** | Not more than 2 mg/kg |

**E 622 MONOPOTASSIUM GLUTAMATE**

| **Synonyms** | Potassium glutamate, MPG |
| **Definition** | Potassium glutamate |
| **Chemical name** |  |
| **EINECS** |  |
| **Chemical formula** |  |
| **Molecular weight** |  |
| **Assay** |  |
| **Description** |  |
| **Identification** |  |
| **A.** Positive test for sodium |  |
| **B.** Positive test for glutamic acid by thin-layer chromatography |  |
| **C.** Specific rotation \([\alpha]D^{20}\) |  |
| **D.** pH of a 5 % solution |  |
| **Purity** |  |
| **Loss on drying** |  |
| **Chloride** |  |
| **Pyrrolidone carboxylic acid** |  |
| **Lead** |  |
Monopotassium L-glutamate monohydrate

**Definition**

*Chemical name*

Monopotassium L-glutamate monohydrate

**EINECS**

243-094-0

**Chemical formula**

\( \text{C}_5\text{H}_8\text{KNO}_4 \cdot \text{H}_2\text{O} \)

**Molecular weight**

203.24

**Assay**

Content not less than 99.0 % and not more than 101.0 % on the anhydrous basis

**Description**

White, practically odourless crystals or crystalline powder

**Identification**

A. Positive test for potassium

B. Positive test for glutamic acid by thin-layer chromatography

C. Specific rotation \([\alpha]D^{20}\)

Between + 22.5° and + 24.0° (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)

D. pH of a 2 % solution

Between 6.7 and 7.3

**Purity**

Loss on drying

Not more than 0.2 % (80 °C, 5h)

Chloride

Not more than 0.2 %

Pyrrolidone carboxylic acid

Not more than 0.2 %

Lead

Not more than 2 mg/kg

**E 623 CALCIUM DIGLUTAMATE**

Calcium glutamate

**Definition**

*Chemical name*

Monocalcium di-L-glutamate

**EINECS**

242-905-5

**Chemical formula**

\( \text{C}_{10}\text{H}_{16}\text{CaN}_2\text{O}_8 \cdot x\text{H}_2\text{O} \) (\( x = 0, 1, 2 \) or 4)

**Molecular weight**

332.32 (anhydrous)

**Assay**

Content not less than 98.0 % and not more than 102.0 % on the anhydrous basis

**Description**

White, practically odourless crystals or crystalline powder

**Identification**

A. Positive test for calcium

B. Positive test for glutamic acid by thin-layer chromatography

C. Specific rotation \([\alpha]D^{20}\)

Between + 27.4° and + 29.2° (for calcium diglutamate with \( x = 4 \)) (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)

**Purity**

Water

Not more than 19.0 % (for calcium diglutamate with \( x = 4 \)) (Karl Fischer)

Chloride

Not more than 0.2 %

Pyrrolidone carboxylic acid

Not more than 0.2 %

Lead

Not more than 2 mg/kg

**E 624 MONOAMMONIUM GLUTAMATE**

Ammonium glutamate

**Synonyms**

Ammonium glutamate
### M3

<table>
<thead>
<tr>
<th>Definition</th>
<th>Monoammonium L-glutamate monohydrate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Monoammonium L-glutamate monohydrate</td>
</tr>
<tr>
<td>EINECS</td>
<td>231-447-1</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C$<em>5$H$</em>{12}$N$_2$O$_4$ · H$_2$O</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>182,18</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99,0 % and not more 101,0 % on the anhydrous basis</td>
</tr>
<tr>
<td>Description</td>
<td>White, practically odourless crystals or crystalline powder</td>
</tr>
</tbody>
</table>

#### Identification

| A. Positive test for ammonium |
| B. Positive test for glutamic acid by thin-layer chromatography |
| C. Specific rotation $[\alpha]D^{20}$ Between $+25,4^\circ$ and $+26,4^\circ$ (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube) |
| D. pH of a 5 % solution Between 6,0 and 7,0 |

#### Purity

| Loss on drying | Not more than 0,5 % (50 °C, 4h) |
| Sulphated ash | Not more than 0,1 % |
| Pyrrolidone carboxylic acid | Not more than 0,2 % |
| Lead | Not more than 2 mg/kg |

### E 625 MAGNESIUM DIGLUTAMATE

| Synonyms | Magnesium glutamate |
| EINECS | Monomagnesium di-L-glutamate tetrahydrate |
| Chemical formula | C$_{10}$H$_{16}$MgN$_2$O$_8$ · 4H$_2$O |
| Molecular weight | 388,62 |
| Assay | Content not less than 95,0 % and not more than 105,0 % on the anhydrous basis |
| Description | Odourless, white or off-white crystals or powder |

#### Identification

| A. Positive test for magnesium |
| B. Positive test for glutamic acid by thin-layer chromatography |
| C. Specific rotation $[\alpha]D^{20}$ Between $+23,8^\circ$ and $+24,4^\circ$ (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube) |
| D. pH of a 10 % solution Between 6,4 and 7,5 |

#### Purity

| Water | Not more than 24 % (Karl Fischer) |
| Chloride | Not more than 0,2 % |
| Pyrrolidone carboxylic acid | Not more than 0,2 % |
| Lead | Not more than 2 mg/kg |

### E 626 GUANYLIC ACID

| Synonyms | Guanylic acid |
### M3

**Definition**

- **Chemical name**: Guanosine-5'-monophosphoric acid

**EINECS**

- **Chemical name**: 201-598-8

**Chemical formula**

- **Molecular weight**: 363.22

**Assay**

- **Description**: Content not less than 97.0 % on the anhydrous basis

- **Odourless, colourless or white crystals or white crystalline powder**

**Identification**

- **A. Positive test for ribose and for organic phosphate**
- **B. pH of a 0.25 % solution**: Between 1.5 and 2.5
- **C. Spectrometry**: maximum absorption of a 20 mg/l solution in 0.01N HCl at 256 nm

**Purity**

- **Loss on drying**: Not more than 1.5 % (120 °C, 4h)
- **Other nucleotides**: Not detectable by thin-layer chromatography
- **Lead**: Not more than 2 mg/kg

### E 627 DISODIUM GUANYLATE

**Synonyms**

- Sodium guanylate, sodium 5'-guanylate

**Definition**

- **Chemical name**: Disodium guanosine-5'-monophosphate

**EINECS**

- **Chemical name**: 221-849-5

**Chemical formula**

- **Molecular weight**: 407.19 (anhydrous)

**Assay**

- **Description**: Content not less than 97.0 % on the anhydrous basis

- **Odourless, colourless or white crystals or white crystalline powder**

**Identification**

- **A. Positive test for ribose, for organic phosphate, and for sodium**
- **B. pH of a 5 % solution**: Between 7.0 and 8.5
- **C. Spectrometry**: maximum absorption of a 20 mg/l solution in 0.01N HCl at 256 nm

**Purity**

- **Loss on drying**: Not more than 25 % (120 °C, 4h)
- **Other nucleotides**: Not detectable by thin-layer chromatography
- **Lead**: Not more than 2 mg/kg

### E 628 DIPOTASSIUM GUANYLATE

**Synonyms**

- Potassium guanylate, potassium 5'-guanylate

**Definition**

- **Chemical name**: Dipotassium guanosine-5'-monophosphate

**EINECS**

- **Chemical name**: 226-914-1

**Chemical formula**

- **Molecular weight**: 439.40

**Assay**

- **Description**: Content not less than 97.0 % on the anhydrous basis
<table>
<thead>
<tr>
<th>M3</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>Odourless, colourless or white crystals or white crystalline powder</td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td></td>
</tr>
<tr>
<td>A. Positive test for ribose, for organic phosphate, and for potassium</td>
<td></td>
</tr>
<tr>
<td>B. pH of a 5 % solution</td>
<td>Between 7,0 and 8,5</td>
</tr>
<tr>
<td>C. Spectrometry:</td>
<td>maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm</td>
</tr>
<tr>
<td><strong>Purity</strong></td>
<td></td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Not more than 5 % (120 °C, 4h)</td>
</tr>
<tr>
<td>Other nucleotides</td>
<td>Not detectable by thin-layer chromatography</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td><strong>E 629 CALCIUM GUANYLATE</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Synonyms</strong></td>
<td>Calcium 5'-guanylate</td>
</tr>
<tr>
<td><strong>Definition</strong></td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>Calcium guanosine-5'-monophosphate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C_{10}H_{12}CaN_{5}O_{8}P \cdot nH_{2}O</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>401,20 (anhydrous)</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 97,0 % on the anhydrous basis</td>
</tr>
<tr>
<td>Description</td>
<td>Odourless, white or off-white crystals or powder</td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td></td>
</tr>
<tr>
<td>A. Positive test for ribose, for organic phosphate, and for calcium</td>
<td>Between 7,0 and 8,0</td>
</tr>
<tr>
<td>B. pH of a 0,05 % solution</td>
<td>maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm</td>
</tr>
<tr>
<td>C. Spectrometry:</td>
<td></td>
</tr>
<tr>
<td><strong>Purity</strong></td>
<td></td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Not more than 23,0 % (120 °C, 4h)</td>
</tr>
<tr>
<td>Other nucleotides</td>
<td>Not detectable by thin-layer chromatography</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td><strong>E 630 INOSINIC ACID</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Synonyms</strong></td>
<td>5'-Inosinic acid</td>
</tr>
<tr>
<td><strong>Definition</strong></td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>Inosine-5'-monophosphoric acid</td>
</tr>
<tr>
<td>EINECS</td>
<td>205-045-1</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C_{10}H_{13}N_{4}O_{8}P</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>348,21</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 97,0 % on the anhydrous basis</td>
</tr>
<tr>
<td>Description</td>
<td>Odourless, colourless or white crystals or powder</td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td></td>
</tr>
<tr>
<td>A. Positive test for ribose, and for organic phosphate</td>
<td>Between 1,0 and 2,0</td>
</tr>
<tr>
<td>B. pH of a 5 % solution</td>
<td>maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm</td>
</tr>
<tr>
<td>C. Spectrometry:</td>
<td></td>
</tr>
<tr>
<td><strong>Purity</strong></td>
<td></td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Not more than 3,0 % (120 °C, 4h)</td>
</tr>
</tbody>
</table>
### E 631 DISODIUM INOSINATE

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Synonyms</strong></td>
<td>Sodium inosinate, sodium 5'-inosinate</td>
</tr>
<tr>
<td><strong>Definition</strong></td>
<td>Disodium inosine-5'-monophosphate</td>
</tr>
<tr>
<td><strong>EINECS</strong></td>
<td>225-146-4</td>
</tr>
<tr>
<td><strong>Chemical formula</strong></td>
<td>$\text{C}<em>{10}\text{H}</em>{11}\text{Na}<em>{2}\text{N}</em>{4}\text{O}<em>{8}\text{P} \cdot \text{H}</em>{2}\text{O}$</td>
</tr>
<tr>
<td><strong>Molecular weight</strong></td>
<td>392.17 (anhydrous)</td>
</tr>
<tr>
<td><strong>Assay</strong></td>
<td>Content not less than 97.0 % on the anhydrous basis</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Odourless, colourless or white crystals or powder</td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td></td>
</tr>
<tr>
<td>A. Positive test for ribose, and for organic phosphate and for sodium</td>
<td></td>
</tr>
<tr>
<td>B. pH of a 5 % solution</td>
<td>Between 7.0 and 8.5</td>
</tr>
<tr>
<td>C. Spectrometry:</td>
<td>maximum absorption of a 20 mg/l solution in 0.01N HCl at 250 nm</td>
</tr>
<tr>
<td><strong>Purity</strong></td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td>Not more than 28.5 % (Karl Fischer)</td>
</tr>
<tr>
<td>Other nucleotides</td>
<td>Not detectable by thin-layer chromatography</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
</tbody>
</table>

### E 632 DIPOTASSIUM INOSINATE

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Synonyms</strong></td>
<td>Potassium inosinate, potassium 5'-inosinate</td>
</tr>
<tr>
<td><strong>Definition</strong></td>
<td>Dipotassium inosine-5'-monophosphate</td>
</tr>
<tr>
<td><strong>EINECS</strong></td>
<td>243-652-3</td>
</tr>
<tr>
<td><strong>Chemical formula</strong></td>
<td>$\text{C}<em>{10}\text{H}</em>{11}\text{K}<em>{2}\text{N}</em>{4}\text{O}_{8}\text{P}$</td>
</tr>
<tr>
<td><strong>Molecular weight</strong></td>
<td>424.39</td>
</tr>
<tr>
<td><strong>Assay</strong></td>
<td>Content not less than 97.0 % on the anhydrous basis</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Odourless, colourless or white crystals or powder</td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td></td>
</tr>
<tr>
<td>A. Positive test for ribose, and for organic phosphate and for potassium</td>
<td></td>
</tr>
<tr>
<td>B. pH of a 5 % solution</td>
<td>Between 7.0 and 8.5</td>
</tr>
<tr>
<td>C. Spectrometry:</td>
<td>maximum absorption of a 20 mg/l solution in 0.01N HCl at 250 nm</td>
</tr>
<tr>
<td><strong>Purity</strong></td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td>Not more than 10.0 % (Karl Fischer)</td>
</tr>
<tr>
<td>Other nucleotides</td>
<td>Not detectable by thin-layer chromatography</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
</tbody>
</table>

### E 633 CALCIUM INOSINATE

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Synonyms</strong></td>
<td>Calcium 5'-inosinate</td>
</tr>
<tr>
<td><strong>Definition</strong></td>
<td>Calcium inosine-5'-monophosphate</td>
</tr>
<tr>
<td><strong>Chemical name</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Chemical formula</strong></td>
<td>$\text{C}<em>{10}\text{H}</em>{11}\text{CaN}<em>{4}\text{O}</em>{8}\text{P} \cdot \text{nH}_{2}\text{O}$</td>
</tr>
</tbody>
</table>

---

Other nucleotides: Not detectable by thin-layer chromatography  
Lead: Not more than 2 mg/kg
M3

**Molecular weight**

386.19 (anhydrous)

**Assay**

Content not less than 97.0 % on the anhydrous basis

**Description**

Odourless, colourless or white crystals or powder

**Identification**

A. Positive test for ribose, and for organic phosphate and for calcium

B. pH of a 0.05 % solution

Between 7.0 and 8.0

C. Spectrometry:

Maximum absorption of a 20 mg/l solution in 0.01N HCl at 250 nm

**Purity**

**Water**

Not more than 23.0 % (Karl Fischer)

**Other nucleotides**

Not detectable by thin-layer chromatography

**Lead**

Not more than 2 mg/kg

---

**E 634 CALCIUM 5’-RIBONUCLEOTIDE**

**Definition**

Chemical name

Calcium 5’-ribonucleotide is essentially a mixture of calcium inosine-5’-monophosphate and calcium guanosine-5’-monophosphate

Chemical formula

C_{10}H_{11}N_{4}CaO_{8}P \cdot nH_{2}O

C_{10}H_{12}N_{5}CaO_{8}P \cdot nH_{2}O

Assay

Content of both major components not less than 97.0 %, and of each component not less than 47.0 % and not more than 53 %, in every case on the anhydrous basis

Description

Odourless, white or nearly white crystals or powder

**Identification**

A. Positive test for ribose, and for organic phosphate and for calcium

B. pH of a 0.05 % solution

Between 7.0 and 8.0

**Purity**

**Water**

Not more than 23.0 % (Karl Fischer)

**Other nucleotides**

Not detectable by thin-layer chromatography

**Lead**

Not more than 2 mg/kg

---

**E 635 DISODIUM 5’-RIBONUCLEOTIDE**

**Definition**

Chemical name

Disodium 5’-ribonucleotide is essentially a mixture of disodium inosine-5’-monophosphate and disodium guanosine-5’-monophosphate

Chemical formula

C_{10}H_{11}N_{4}O_{8}P \cdot nH_{2}O

C_{10}H_{12}N_{5}Na_{2}O_{8}P \cdot nH_{2}O

Assay

Content of both major components not less than 97.0 %, and of each component not less than 47.0 % and not more than 53 %, in every case on the anhydrous basis

Description

Odourless, white or nearly white crystals or powder

**Identification**

A. Positive test for ribose, and for organic phosphate and for sodium

B. pH of a 5 % solution

Between 7.0 and 8.5

**Purity**

**Water**

Not more than 26.0 % (Karl Fischer)
**E 905 MICROCRYSTALLINE WAX**

**Synonyms**

Petroleum wax

**Definition**

Microcrystalline wax is a refined mixture of solid, saturated hydrocarbons, mainly branched paraffin, obtained from petroleum

**Description**

White to amber, odourless wax

**Identification**

A. Solubility

Insoluble in water, very slightly soluble in ethanol

B. Refractive Index

nD^100^1,434-1,448

**Purity**

- Molecular weight: Average not less than 500
- Viscosity at 100 °C: Not less than 1,1 · 10^{-5} m²s⁻¹
- Residue on ignition: Not more than 0,1 %
- Carbon number at 5 % distillation point: Not more than 5 % of molecules with carbon number less than 25
- Colour: Passes test
- Sulphur: Not more than 0,4 %
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 3 mg/kg

**Polycyclic aromatic compounds**

The polycyclic aromatic hydrocarbons, obtained by extraction with dimethyl sulfoxide, shall meet the following ultraviolet absorbency limits:

<table>
<thead>
<tr>
<th>nm</th>
<th>Maximum absorbance per cm path length</th>
</tr>
</thead>
<tbody>
<tr>
<td>280-289</td>
<td>0,15</td>
</tr>
<tr>
<td>290-299</td>
<td>0,12</td>
</tr>
<tr>
<td>300-359</td>
<td>0,08</td>
</tr>
<tr>
<td>360-400</td>
<td>0,02</td>
</tr>
</tbody>
</table>

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

**Synonyms**

Hydrogenated polydec-1-ene
Hydrogenated poly-alpha-olefin

**Definition**

Chemical formula

C_{10n}H_{20n+2} where n = 3 — 6

Molecular weight

560 (average)

Assay

Not less than 98,5 % of hydrogenated poly-1-decene, having the following oligomer distribution:

C_{30}: 13 — 37 %
C_{40}: 25 — 70 %
C_{50}: 9 — 25 %
C_{60}: 1 — 7 %

**Description**

Colourless, odourless, viscous liquid

**Identification**

A. Solubility

Insoluble in water; slightly soluble in ethanol; soluble in toluene

B. Burning

Burns with a bright flame and a paraffin-like characteristic smell
**M6**

**Purity**

- **Viscosity**: Between $5.7 \times 10^{-6}$ and $6.1 \times 10^{-6}$ m$^2$s$^{-1}$ at 100 °C
- **Compounds with carbon number less than 30**: Not more than 1.5%
- **Readily carbonisable substances**: After 10 minutes shaking in a boiling water bath, a tube of sulfuric acid with a 5 g sample of hydrogenated poly-1-decene is not darker than a very slight straw colour
- **Nickel**: Not more than 1 mg/kg
- **Lead**: Not more than 1 mg/kg

**M3**

**E 912 MONTAN ACID ESTERS**

**Definition**
Montan acids and/or esters with ethylene glycol and/or 1,3-butanediol and/or glycerol

**Chemical name**
Montan acid esters

**Description**
Almost white to yellowish flakes, powder, granules or pellets

**Identification**

- **A. Density (20 °C)**: Between 0.98 and 1.05
- **B. Drop point**: Greater than 77 °C

**Purity**

- **Acid value**: Not more than 40
- **Glycerol**: Not more than 1 % (by gas chromatography)
- **Other polyols**: Not more than 1 % (by gas chromatography)
- **Other wax types**: Not detectable (by differential scanning calorimetry and/or infrared spectroscopy)
- **Arsenic**: Not more than 2 mg/kg
- **Chromium**: Not more than 3 mg/kg
- **Lead**: Not more than 2 mg/kg

**E 914 OXIDISED POLYETHYLENE WAX**

**Definition**
Polar reaction products from mild oxidation of polyethylene

**Chemical name**
Oxidised polyethylene

**Description**
Almost white flakes, powder, granules or pellets

**Identification**

- **A. Density (20 °C)**: Between 0.92 and 1.05
- **B. Drop point**: Greater than 95 °C

**Purity**

- **Acid value**: Not more than 70
- **Viscosity at 120 °C**: Not less than $8.1 \times 10^{-5}$ m$^2$s$^{-1}$
- **Other wax types**: Not detectable (by differential scanning calorimetry and/or infrared spectroscopy)
- **Oxygen**: Not more than 9.5 %
- **Chromium**: Not more than 5 mg/kg
- **Lead**: Not more than 2 mg/kg

**E 950 ACESULFAME K**
Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.
E 951 ASPARTAME

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 953 ISOMALT

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC, as amended by Directive 98/66/EC, laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 957 THAUMATIN

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 959 NEOHESPERIDINE DIHYDROCHALCONE

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 965(i) MALTITOL

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 965(ii) MALTITOL SYRUP

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 966 LACTITOL

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 967 XYLITOL

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

---

**E 1517 GLYCERYL DIACETATE**

**Synonyms**

Diacetin

**Definition**

Glyceryl diacetate consists predominantly of a mixture of the 1,2- and 1,3-diacetates of glycerol, with minor amounts of the mono- and tri-esters

**Chemical names**

Glyceryl diacetate

**Chemical formula**

\( C_7H_{12}O_5 \)

**Molecular weight**

176,17

**Assay**

Not less than 94,0 %

**Description**

Clear, colourless, hygroscopic, somewhat oily liquid with a slight, fatty odour

**Identification**

A. Solubility

Soluble in water. Miscible with ethanol

B. Positive tests for glycerol and acetate

C. Specific gravity

\( d_{20}^\circ \): 1,175 — 1,195

D. Boiling range

Between 259 and 261 °C

**Purity**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total ash</td>
<td>Not more than 0,02 %</td>
</tr>
<tr>
<td>Acidity</td>
<td>Not more than 0,4 % (as acetic acid)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
</tbody>
</table>
M6

E 1519 BENZYL ALCOHOL

Synonyms

Phenylcarbinol
Phenylmethyl alcohol
Benzene methanol
Alpha-hydroxytoluene

Definition

Chemical names
Benzyl alcohol
Phenylmethanol

Chemical formula
C₇H₈O

Molecular weight
108.14

Assay
Not less than 98.0 %

Description

Colourless, clear liquid with a faint, aromatic odour

Identification

A. Solubility
Soluble in water, ethanol and ether

B. Refractive index
[n]D₂⁰: 1.538 – 1.541

C. Specific gravity
d₂⁵: 1.042 – 1.047

D. Positive test for peroxides

Purity

Distillation range
Not less than 95 % v/v distils between 202 and 208 °C

Acid value
Not more than 0.5

Aldehydes
Not more than 0.2 % v/v (as benzaldehyde)

Lead
Not more than 5 mg/kg