

Commission Directive 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners (Text with EEA relevance) (Codified version) (repealed)

COMMISSION DIRECTIVE 2008/84/EC

of 27 August 2008

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

(Text with EEA relevance)

(Codified version) (repealed)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption<sup>(1)</sup>, and in particular Article 3(3)(a) thereof,

Whereas:

- (1) Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners<sup>(2)</sup> has been substantially amended several times<sup>(3)</sup>. In the interests of clarity and rationality the said Directive should be codified.
- (2) 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<sup>(4)</sup>.
- (3) 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).
- (4) Food additives prepared by production methods or starting materials significantly different from those evaluated by the Scientific Committee for Food or different from those mentioned in this Directive should be submitted for safety evaluation by the European Food Safety Authority with emphasis on the purity criteria.
- (5) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.
- (6) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex II, part B,

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 Annex I to this Directive.

*Article 2*

Directive 96/77/EC, as amended by the Directives listed in Annex II, part A, is repealed, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law set out in Annex II, part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex III.

*Article 3*

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

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 27 August 2008.

*For the Commission*

*The President*

José Manuel BARROSO

## ANNEX I

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

## E 170 (i) CALCIUM CARBONATE

Purity criteria for this additive are the same as set out for this additive in the Annex to Commission Directive 95/45/EC<sup>(5)</sup>.

## E 200 SORBIC ACID

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

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*Status: This is the original version (as it was originally adopted).*

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<b>Definition</b>	
Chemical name	Potassium sorbate
	Potassium (E, E)-2,4-hexadienoate
	Potassium salt of trans, trans 2,4-hexadienoic acid
Einecs	246-376-1
Chemical formula	C <sub>6</sub> H <sub>7</sub> O <sub>2</sub> K
Molecular weight	150,22
Assay	Content not less than 99 % on the dried basis
<b>Description</b>	White crystalline powder showing no change in colour after heating for 90 minutes at 105 °C
<b>Identification</b>	
A. Melting range of sorbic acid isolated by acidification and not recrystallised 133 °C to 135 °C after vacuum drying in a sulphuric acid desiccator	
B. Positive tests for potassium and for double bonds	
<b>Purity</b>	
Loss on drying	Not more than 1,0 % (105 °C, 3h)
Acidity or alkalinity	Not more than about 1,0 % (as sorbic acid or K <sub>2</sub> CO <sub>3</sub> )
Aldehydes	Not more than 0,1 %, calculated 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 203 CALCIUM SORBATE

<b>Definition</b>	
Chemical name	Calcium sorbate
	Calcium salts of trans, trans-2,4-hexadienoic acid
Einecs	231-321-6

Chemical formula	$C_{12}H_{14}O_4Ca$
Molecular weight	262,32
Assay	Content not less than 98 % on the dried basis
<b>Description</b>	Fine white crystalline powder not showing any change in colour after heating at 105 °C for 90 minutes
<b>Identification</b>	
A. Melting range of sorbic acid isolated by acidification and not recrystallised 133 °C to 135 °C after vacuum drying in a sulphuric acid desiccator	
B. Positive tests for calcium and for double bonds	
<b>Purity</b>	
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

<b>Definition</b>	
Chemical name	Benzoic acid Benzenecarboxylic acid Phenylcarboxylic acid
Einecs	200-618-2
Chemical formula	$C_7H_6O_2$
Molecular weight	122,12
Assay	Content not less than 99,5 % on the anhydrous basis
<b>Description</b>	White crystalline powder

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*Status: This is the original version (as it was originally adopted).*

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<b>Identification</b>	
A. Melting range	121,5 °C to 123,5 °C
B. Positive sublimation test and test for benzoate	
<b>Purity</b>	
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 oxidisable substances	Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N KMnO <sub>4</sub> in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N KMnO <sub>4</sub> to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required
Readily carbonisable substances	A cold solution of 0,5 g of benzoic acid in 5 ml of 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC <sup>b</sup> , 0,3 ml of ferric chloride TSC <sup>c</sup> , 0,1 ml of copper sulphate TSC <sup>d</sup> and 4,4 ml of water
Polycyclic acids	On fractional acidification of a neutralised solution of benzoic acid, the first precipitate must not have a different melting point from that of the benzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

**a** Starch TS: triturate 0,5 g starch (potato starch, maize starch or 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.

**b** Cobalt chloride TSC: dissolve approximately 65 g of cobalt chloride CoCl<sub>2</sub>·6H<sub>2</sub>O in a sufficient quantity of a mixture of 25 ml hydrochloric acid and 975 ml of water to give a total volume of 1 litre. Place exactly 5 ml of this solution in a round-bottomed flask containing 250 ml of iodine solution, add 5 ml of 3 % hydrogen peroxide, then 15 ml of a

20 % solution of sodium hydroxide. Boil for 10 minutes, allow to cool, add 2 g of potassium iodide and 20 ml of 25 % sulphuric acid. After the precipitate is completely dissolved, titrate the liberated iodine with sodium thiosulphate (0,1 N) in the presence of starch TS. 1 ml of sodium thiosulphate (0,1 N) corresponds to 23,8 mg of  $\text{CoCl}_2 \cdot 6\text{H}_2\text{O}$ . Adjust final volume of solution by the addition of a sufficient quantity of the hydrochloric acid/water mixture to give a solution containing 59,5 mg of  $\text{CoCl}_2 \cdot 6\text{H}_2\text{O}$  per ml.

- c** Ferric chloride TSC: dissolve approximately 55 g of ferric chloride in a sufficient quantity of a mixture of 25 ml of hydrochloric acid and 975 ml of water to give a total volume of 1 litre. Place 10 ml of this solution in a round-bottomed flask containing 250 ml of iodine solution, add 15 ml of water and 3 g of potassium iodide; leave the mixture to stand for 15 minutes. Dilute with 100 ml of water then titrate the liberated iodine with sodium thiosulphate (0,1 N) in the presence of starch TS. 1 ml of sodium thiosulphate (0,1 N) corresponds to 27,03 mg of  $\text{FeCl}_3 \cdot 6\text{H}_2\text{O}$ . Adjust final volume of solution by the addition of a sufficient quantity of the hydrochloric acid/water to give a solution containing 45,0 mg of  $\text{FeCl}_3 \cdot 6\text{H}_2\text{O}$  per ml.
- d** Copper sulphate TSC: dissolve approximate by 65 g of copper sulphate  $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$  in a sufficient quantity of a mixture of 25 ml of hydrochloric acid and 975 ml of water to give a total volume of 1 litre. Place 10 ml of this solution in a round-bottomed flask containing 250 ml of iodine solution, add 40 ml of water, 4 ml of acetic acid and 3 g of potassium iodide. Titrate the liberated iodine with sodium thiosulphate (0,1 N) in the presence of starch TS. 1 ml of sodium thiosulphate (0,1 N) corresponds to 24,97 mg of  $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$ . Adjust final volume of solution by the addition of a sufficient quantity of the hydrochloric acid/water mixture to give a solution containing 62,4 mg of  $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$  per ml.

## E 211 SODIUM BENZOATE

<b>Definition</b>	
Chemical name	Sodium benzoate Sodium salt of benzenecarboxylic acid Sodium salt of phenylcarboxylic acid
Einecs	208-534-8
Chemical formula	$\text{C}_7\text{H}_5\text{O}_2\text{Na}$
Molecular weight	144,11
Assay	Not less than 99 % of $\text{C}_7\text{H}_5\text{O}_2\text{Na}$ , after drying at 105 °C for four hours
<b>Description</b>	A white, almost odourless, crystalline powder or granules
<b>Identification</b>	
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 recrystallised 121,5 °C to 123,5 °C, after drying in a sulphuric acid desiccator
C. Positive tests for benzoate and for sodium	
<b>Purity</b>	
Loss on drying	Not more than 1,5 % after drying at 105 °C for four hours

*Status: This is the original version (as it was originally adopted).*

Readily oxidisable 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
Polycyclic acids	On fractional acidification of a (neutralised) solution of sodium benzoate, the first precipitate must not have a different melting range from that of benzoic acid
Chlorinated organic compounds	Not more than 0,06 % expressed as chloride, corresponding to 0,25 % expressed as monochlorobenzoic acid
Degree of acidity or alkalinity	Neutralisation of 1 g of sodium benzoate, in the presence of phenolphthalein, must not require more than 0,25 ml of 0,1 N NaOH or 0,1 N HCl
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

#### E 212 POTASSIUM BENZOATE

<b>Definition</b>	
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 % $\text{C}_7\text{H}_5\text{KO}_2$ after drying at 105 °C to constant weight
<b>Description</b>	White crystalline powder
<b>Identification</b>	
A.	Melting range of benzoic acid isolated by acidification and not recrystallised 121,5 °C to 123,5 °C,



	after vacuum drying in a sulphuric acid desiccator
B.	Positive tests for benzoate and for potassium
<b>Purity</b>	
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 oxidisable substances	Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N KMnO <sub>4</sub> in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N KMnO <sub>4</sub> to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required
Readily carbonisable substances	A cold solution of 0,5 g of benzoic acid in 5 ml 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC, 0,3 ml of ferric chloride TSC, 0,1 ml of copper sulphate TSC and 4,4 ml of water
Polycyclic acids	On fractional acidification of a (neutralised) solution of potassium benzoate, the first precipitate must not have a different melting range from that of benzoic acid
Degree of acidity or alkalinity	Neutralisation of 1 g of potassium benzoate, in the presence of phenolphthalein, must not require more than 0,25 ml of 0,1 N NaOH or 0,1 N HCl
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 213 CALCIUM BENZOATE

<b>Synonyms</b>	Monocalcium benzoate
<b>Definition</b>	

*Status: This is the original version (as it was originally adopted).*

Chemical name	Calcium benzoate	
	Calcium dibenzoate	
Einecs	218-235-4	
Chemical formula	Anhydrous:	$C_{14}H_{10}O_4Ca$
	Monohydrate:	$C_{14}H_{10}O_4Ca \cdot H_2O$
	Trihydrate:	$C_{14}H_{10}O_4Ca \cdot 3H_2O$
Molecular weight	Anhydrous:	282,31
	Monohydrate:	300,32
	Trihydrate:	336,36
Assay	Content not less than 99 % after drying at 105 °C	
<b>Description</b>	White or colourless crystals, or white powder	
<b>Identification</b>		
A.	Melting range of benzoic acid isolated by acidification and not recrystallised 121,5 °C to 123,5 °C, after vacuum drying in a sulphuric acid desiccator	
B.	Positive tests for benzoate and for calcium	
<b>Purity</b>		
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 oxidisable substances	Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N $KMnO_4$ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N $KMnO_4$ to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required	
Readily carbonisable substances	Cold solution of 0,5 g of benzoic acid in 5 ml of 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt	

	chloride TSC, 0,3 ml of ferric chloride TSC, 0,1 ml of copper sulphate TSC and 4,4 ml of water
Polycyclic acids	On fractional acidification of a (neutralised) solution of calcium benzoate, the first precipitate must not be a different melting range from that of benzoic acid
Degree of acidity or alkalinity	Neutralisation of 1 g of calcium benzoate, in the presence of phenolphthalein, must not require more than 0,25 ml of 0,1 N NaOH or 0,1 N HCl
Fluoride	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 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

<b>Synonyms</b>	Ethylparaben
	Ethyl <i>p</i> -oxybenzoate
<b>Definition</b>	
Chemical name	Ethyl- <i>p</i> -hydroxybenzoate
	Ethyl ester of <i>p</i> -hydroxybenzoic acid
Einecs	204-399-4
Chemical formula	C <sub>9</sub> H <sub>10</sub> O <sub>3</sub>
Molecular weight	166,8
Assay	Content not less than 99,5 % after drying for two hours at 80 °C
<b>Description</b>	Almost odourless, small, colourless crystals or a white, crystalline powder
<b>Identification</b>	
A. Melting range	115 °C to 118 °C
B. Positive test for <i>p</i> -hydroxybenzoate	Melting range of <i>p</i> -hydroxybenzoic acid isolated by acidification and not recrystallised: 213 °C to 217 °C, after vacuum drying in a sulphuric acid desiccator
C. Positive test for alcohol	
<b>Purity</b>	
Loss on drying	Not more than 0,5 % after drying for two hours at 80 °C

*Status: This is the original version (as it was originally adopted).*

Sulphated ash	Not more than 0,05 %
<i>p</i> -Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

#### E 215 SODIUM ETHYL *p*-HYDROXYBENZOATE

<b>Definition</b>	
Chemical name	Sodium ethyl <i>p</i> -hydroxybenzoate Sodium compound of the ethyl ester of <i>p</i> -hydroxybenzoic acid
Einecs	252-487-6
Chemical formula	C <sub>9</sub> H <sub>9</sub> O <sub>3</sub> Na
Molecular weight	188,8
Assay	Content of ethylester of <i>p</i> -hydroxybenzoic acid not less than 83 % on the anhydrous basis
<b>Description</b>	White, crystalline hygroscopic powder
<b>Identification</b>	
A. Melting range	115 °C to 118 °C, after vacuum drying in a sulphuric acid desiccator
B. Positive test for <i>p</i> -hydroxybenzoate	Melting range of <i>p</i> -hydroxybenzoic acid derived from the sample is 213 °C to 217 °C
C. Positive test for sodium	
D. pH of a 0,1 % aqueous solution must be between 9,9 and 10,3	
<b>Purity</b>	
Loss on drying	Not more than 5 %, determined by vacuum drying in a sulphuric acid desiccator
Sulphated ash	37 to 39 %
<i>p</i> -Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

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

E 218 METHYL *p*-HYDROXYBENZOATE

<b>Synonyms</b>	Methylparaben
	Methyl- <i>p</i> -oxybenzoate
<b>Definition</b>	
Chemical name	Methyl <i>p</i> -hydroxybenzoate
	Methyl ester of <i>p</i> -hydroxybenzoic acid
Einecs	243-171-5
Chemical formula	C <sub>8</sub> H <sub>8</sub> O <sub>3</sub>
Molecular weight	152,15
Assay	Content not less than 99 % after drying for two hours at 80 °C
<b>Description</b>	Almost odourless, small colourless crystals or white crystalline powder
<b>Identification</b>	
A. Melting range	125 °C to 128 °C
B. Positive test for <i>p</i> -hydroxybenzoate	Melting range of <i>p</i> -hydroxybenzoic acid derived from the sample is 213 °C to 217 °C after drying for two hours at 80 °C
<b>Purity</b>	
Loss on drying	Not more than 0,5 %, after drying for two hours at 80 °C
Sulphated ash	Not more than 0,05 %
<i>p</i> -Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 219 SODIUM METHYL *p*-HYDROXYBENZOATE

<b>Definition</b>	
Chemical name	Sodium methyl <i>p</i> -hydroxybenzoate

*Status: This is the original version (as it was originally adopted).*

	Sodium compound of the methylester of <i>p</i> -hydroxybenzoic acid
Chemical formula	C <sub>8</sub> H <sub>7</sub> O <sub>3</sub> Na
Molecular weight	174,15
Assay	Content not less than 99,5 % on the anhydrous basis
<b>Description</b>	White, hygroscopic powder
<b>Identification</b>	
A.	The white precipitate formed by acidifying with hydrochloric acid a 10 % (w/v) aqueous solution of the sodium derivative of methyl <i>p</i> -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
<b>Purity</b>	
Water content	Not more than 5 % (Karl Fischer method)
Sulphated ash	40 % to 44,5 % on the anhydrous basis
<i>p</i> -Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 220 SULPHUR DIOXIDE

<b>Definition</b>	
Chemical name	Sulphur dioxide Sulphurous acid anhydride
Einecs	231-195-2
Chemical formula	SO <sub>2</sub>

Molecular weight	64,07
Assay	Content not less than 99 %
<b>Description</b>	Colourless, non-flammable gas with strong pungent suffocating odour
<b>Identification</b>	
A. Positive test for sulphurous substances	
<b>Purity</b>	
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

<b>Definition</b>		
Chemical name	Sodium sulphite (anhydrous or heptahydrate)	
Einecs	231-821-4	
Chemical formula	Anhydrous:	Na <sub>2</sub> SO <sub>3</sub>
	Heptahydrate:	Na <sub>2</sub> SO <sub>3</sub> ·7H <sub>2</sub> O
Molecular weight	Anhydrous:	126,04
	Heptahydrate:	252,16
Assay	Anhydrous:	Not less than 95 % of Na <sub>2</sub> SO <sub>3</sub> and not less than 48 % of SO <sub>2</sub>
	Heptahydrate:	Not less than 48 % of Na <sub>2</sub> SO <sub>3</sub> and not less than 24 % of SO <sub>2</sub>
<b>Description</b>	White crystalline powder or colourless crystals	
<b>Identification</b>		

*Status: This is the original version (as it was originally adopted).*

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	
<b>Purity</b>		
Thiosulphate		Not more than 0,1 % based on the SO <sub>2</sub> content
Iron		Not more than 50 mg/kg based on the SO <sub>2</sub> content
Selenium		Not more than 10 mg/kg based on the SO <sub>2</sub> 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

<b>Definition</b>		
Chemical name		Sodium bisulphite Sodium hydrogen sulphite
Einecs		231-921-4
Chemical formula		NaHSO <sub>3</sub> in aqueous solution
Molecular weight		104,06
Assay		Content not less than 32 % w/w NaHSO <sub>3</sub>
<b>Description</b>		A clear, colourless to yellow solution
<b>Identification</b>		
A.	Positive tests for sulphite and for sodium	
B.	pH of a 10 % aqueous solution between 2,5 and 5,5	
<b>Purity</b>		
Iron		Not more than 50 mg/kg of Na <sub>2</sub> SO <sub>3</sub> based on the SO <sub>2</sub> content



Selenium	Not more than 10 mg/kg based on the SO <sub>2</sub> content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 223 SODIUM METABISULPHITE

<b>Synonyms</b>	Pyrosulphite
	Sodium pyrosulphite
<b>Definition</b>	
Chemical name	Sodium disulphite
	Disodium pentaoxodisulphate
Einecs	231-673-0
Chemical formula	Na <sub>2</sub> S <sub>2</sub> O <sub>5</sub>
Molecular weight	190,11
Assay	Content not less than 95 % Na <sub>2</sub> S <sub>2</sub> O <sub>5</sub> and not less than 64 % of SO <sub>2</sub>
<b>Description</b>	White crystals or crystalline powder
<b>Identification</b>	
A.	Positive tests for sulphite and for sodium
B.	pH of a 10 % aqueous solution between 4,0 and 5,5
<b>Purity</b>	
Thiosulphate	Not more than 0,1 % based on the SO <sub>2</sub> content
Iron	Not more than 50 mg/kg based on the SO <sub>2</sub> content
Selenium	Not more than 10 mg/kg based on the SO <sub>2</sub> 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

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*Status: This is the original version (as it was originally adopted).*

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## E 224 POTASSIUM METABISULPHITE

<b>Synonyms</b>	Potassium pyrosulphite
<b>Definition</b>	
Chemical name	Potassium disulphite Potassium pentaoxo disulphate
Einecs	240-795-3
Chemical formula	$K_2S_2O_5$
Molecular weight	222,33
Assay	Content not less than 90 % of $K_2S_2O_5$ and not less than 51,8 % of $SO_2$ , the remainder being composed almost entirely of potassium sulphate
<b>Description</b>	Colourless crystals or white crystalline powder
<b>Identification</b>	
A. Positive tests for sulphite and for potassium	
<b>Purity</b>	
Thiosulphate	Not more than 0,1 % based on the $SO_2$ content
Iron	Not more than 50 mg/kg based on the $SO_2$ content
Selenium	Not more than 10 mg/kg based on the $SO_2$ content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 226 CALCIUM SULPHITE

<b>Definition</b>	
Chemical name	Calcium sulphite
Einecs	218-235-4
Chemical formula	$CaSO_3 \cdot 2H_2O$
Molecular weight	156,17

Assay	Content not less than 95 % of $\text{CaSO}_3 \cdot 2\text{H}_2\text{O}$ and not less than 39 % of $\text{SO}_2$
<b>Description</b>	White crystals or white crystalline powder
<b>Identification</b>	
A. Positive tests for sulphite and for calcium	
<b>Purity</b>	
Iron	Not more than 50 mg/kg based on the $\text{SO}_2$ content
Selenium	Not more than 10 mg/kg based on the $\text{SO}_2$ content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 227 CALCIUM BISULPHITE

<b>Definition</b>	
Chemical name	Calcium bisulphite Calcium hydrogen sulphite
Einecs	237-423-7
Chemical formula	$\text{Ca}(\text{HSO}_3)_2$
Molecular weight	202,22
Assay	6 to 8 % (w/v) of sulphur dioxide and 2,5 to 3,5 % (w/v) of calcium dioxide corresponding to 10 to 14 % (w/v) of calcium bisulphite [ $\text{Ca}(\text{HSO}_3)_2$ ]
<b>Description</b>	Clear greenish-yellow aqueous solution having a distinct odour of sulphur dioxide
<b>Identification</b>	
A. Positive tests for sulphite and for calcium	
<b>Purity</b>	
Iron	Not more than 50 mg/kg based on the $\text{SO}_2$ content
Selenium	Not more than 10 mg/kg based on the $\text{SO}_2$ content

*Status: This is the original version (as it was originally adopted).*

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

#### E 228 POTASSIUM BISULPHITE

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

#### E 230 BIPHENYL

<b>Synonyms</b>	Diphenyl
<b>Definition</b>	
Chemical name	1,1'-biphenyl Phenylbenzene
Einecs	202-163-5
Chemical formula	C <sub>12</sub> H <sub>10</sub>

Molecular weight	154,2
Assay	Content not less than 99,8 %
<b>Description</b>	White or pale yellow to amber crystalline solid having a characteristic odour
<b>Identification</b>	
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
<b>Purity</b>	
Benzene	Not more than 10 mg/kg
Aromatic amines	Not more than 2 mg/kg (as aniline)
Phenol derivatives	Not more than 5 mg/kg (as phenol)
Readily carbonisable substances	Cold solution of 0,5 g of biphenyl in 5 ml of 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC, 0,3 ml of ferric chloride TSC, 0,1 ml of copper sulphate TSC and 4,4 ml of water
Terphenyl and higher polyphenyl derivatives	Not more than 0,2 %
Polycyclic aromatic hydrocarbons	Absent
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 231 ORTHOPHENYLPHENOL

<b>Synonyms</b>	Orthoxenol
<b>Definition</b>	
Chemical name	(1,1'-Biphenyl)-2-ol 2-Hydroxydiphenyl o-Hydroxydiphenyl
Einecs	201-993-5
Chemical formula	C <sub>12</sub> H <sub>10</sub> O
Molecular weight	170,2
Assay	Content not less than 99 %

*Status: This is the original version (as it was originally adopted).*

<b>Description</b>	White or slightly yellowish crystalline powder
<b>Identification</b>	
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
<b>Purity</b>	
Sulphated ash	Not more than 0,05 %
Diphenyl ether	Not more than 0,3 %
<i>p</i> -Phenylphenol	Not more than 0,1 %
1-Naphthol	Not more than 0,01 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

#### E 232 SODIUM ORTHOPHENYLPHENOL

<b>Synonyms</b>	Sodium orthophenylphenate Sodium salt of <sup>o</sup> -phenylphenol
<b>Definition</b>	
Chemical name	Sodium orthophenylphenol
Einecs	205-055-6
Chemical formula	C <sub>12</sub> H <sub>9</sub> ONa· 4H <sub>2</sub> O
Molecular weight	264,26
Assay	Content not less than 97 % of C <sub>12</sub> H <sub>9</sub> ONa· 4H <sub>2</sub> O
<b>Description</b>	White or slightly yellowish crystalline powder
<b>Identification</b>	
A. Positive tests for phenolate and for sodium	
B. Melting range of orthophenylphenol isolated by acidification and not recrystallised 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	
<b>Purity</b>		
	Diphenylether	Not more than 0,3 %
	<i>p</i> -phenylphenol	Not more than 0,1 %
	1-naphthol	Not more than 0,01 %
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 5 mg/kg
	Mercury	Not more than 1 mg/kg
	Heavy metals (as Pb)	Not more than 10 mg/kg

## E 233 THIABENDAZOLE

<b>Definition</b>		
	Chemical name	4-(2-benzimidazolyl)thiazole 2-(4-thiazolyl)-1H-benzimidazole
	Einecs	205-725-8
	Chemical formula	C <sub>10</sub> H <sub>7</sub> N <sub>3</sub> S
	Molecular weight	201,26
	Assay	Content not less than 98 % on the anhydrous basis
<b>Description</b>		White, or almost white, odourless powder
<b>Identification</b>		
A.	Melting range	296 °C to 303 °C
B.	Spectrometry	Absorption maxima in 0,1 N HCl (0,0005 % w/v) at 302 nm, 258 nm and 243 nm $E_{1\%}^{1cm}$ at 302 nm ± 2 nm: approximately 1 230 $E_{1\%}^{1cm}$ at 258 nm ± 2 nm: approximately 200 $E_{1\%}^{1cm}$ at 243 nm ± 2 nm: approximately 620 Ratio of absorption 243 nm/302 nm = 0,47 to 0,53

*Status: This is the original version (as it was originally adopted).*

	Ratio of absorption 258 nm/302 nm = 0,14 to 0,18
<b>Purity</b>	
Water content	Not more than 0,5 % (Karl Fischer method)
Sulphated ash	Not more than 0,2 %
Selenium	Not more than 3 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 234 NISIN

<b>Definition</b>	Nisin consists of several closely related polypeptides produced by natural strains of <i>Streptococcus lactis</i> , Lancefield group N
Einecs	215-807-5
Chemical formula	C <sub>143</sub> H <sub>230</sub> N <sub>42</sub> O <sub>37</sub> S <sub>7</sub>
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 %
<b>Description</b>	White powder
<b>Purity</b>	
Loss on drying	Not more than 3 % when dried to constant weight at 102 °C to 103 °C
Arsenic	Not more than 1 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 235 NATAMYCIN

<b>Synonyms</b>	Pimaricin
<b>Definition</b>	Natamycin is a fungicide of the polyene macrolide group, and is produced by natural strains of <i>Streptomyces natalensis</i> or of <i>Streptococcus lactis</i>
Einecs	231-683-5



Chemical formula	C <sub>33</sub> H <sub>47</sub> O <sub>13</sub> N
Molecular weight	665,74
Assay	Content not less than 95 % on the anhydrous basis
<b>Description</b>	White to creamy-white crystalline powder
<b>Identification</b>	
A. Colour reactions	On adding a few crystals of natamycin on a spot plate, to a drop of: — concentrated hydrochloric acid, a blue colour develops, — concentrated phosphoric acid, a green colour develops, which changes into pale red after a few minutes
B. Spectrometry	A 0,0005 % w/v solution in 1 % methanolic acetic acid solution has absorption maxima at about 290 nm, 303 nm and 318 nm, a shoulder at about 280 nm and exhibits minima at about 250 nm, 295,5 nm and 311 nm
C. pH	5,5 to 7,5 (1 % w/v solution in previously neutralised mixture of 20 parts dimethylformamide and 80 parts of water)
D. Specific rotation	$[\alpha]_D^{20} = + 250^\circ$ to $+ 295^\circ$ (a 1 % w/v solution in glacial acetic acid, at 20 °C and calculated with reference to the dried material)
<b>Purity</b>	
Loss on drying	Not more than 8 % (over P <sub>2</sub> O <sub>5</sub> , 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
<b>E 239 HEXAMETHYLENE TETRAMINE</b>	
<b>Synonyms</b>	Hexamine Methenamine
<b>Definition</b>	

*Status: This is the original version (as it was originally adopted).*

Chemical name	1,3,5,7-Tetraazatricyclo [3.3.1.1 <sup>3,7</sup> ]-decane, hexamethylenetetramine
Einecs	202-905-8
Chemical formula	C <sub>6</sub> H <sub>12</sub> N <sub>4</sub>
Molecular weight	140,19
Assay	Content not less than 99 % on the anhydrous basis
<b>Description</b>	Colourless or white crystalline powder
<b>Identification</b>	
A. Positive tests for formaldehyde and for ammonia	
B. Sublimation point approximately 260 °C	
<b>Purity</b>	
Loss on drying	Not more than 0,5 % after drying at 105 °C in vacuum over P <sub>2</sub> O <sub>5</sub> for two hours
Sulphated ash	Not more than 0,05 %
Sulphates	Not more than 0,005 % expressed as SO <sub>4</sub>
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

#### E 242 DIMETHYL DICARBONATE

<b>Synonyms</b>	DMDC
	Dimethyl pyrocarbonate
<b>Definition</b>	
Chemical name	Dimethyl dicarbonate
	Pyrocarbonic acid dimethyl ester
Einecs	224-859-8
Chemical formula	C <sub>4</sub> H <sub>6</sub> O <sub>5</sub>
Molecular weight	134,09

Assay	Content not less than 99,8 %
<b>Description</b>	Colourless liquid, decomposes in aqueous solution. It is corrosive to skin and eyes and toxic by inhalation and ingestion
<b>Identification</b>	
A. Decomposition	After dilution positive tests for CO <sub>2</sub> and methanol
B. Melting point	17 °C
Boiling point	172 °C with decomposition
C. Density 20 °C	Approximately 1,25 g/cm <sup>3</sup>
D. Infrared spectrum	Maxima at 1 156 and 1 832 cm <sup>-1</sup>
<b>Purity</b>	
Dimethyl carbonate	Not more than 0,2 %
Chlorine, total	Not more than 3 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 249 POTASSIUM NITRITE

<b>Definition</b>	
Chemical name	Potassium nitrite
Einecs	231-832-4
Chemical formula	KNO <sub>2</sub>
Molecular weight	85,11
Assay	Content not less than 95 % on the anhydrous basis <sup>a</sup>
<b>Description</b>	White or slightly yellow, deliquescent granules
<b>Identification</b>	
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

<sup>a</sup> When labelled 'for food use', nitrite may only be sold in a mixture with salt or a salt substitute.

*Status: This is the original version (as it was originally adopted).*

<b>Purity</b>	
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
a	When labelled 'for food use', nitrite may only be sold in a mixture with salt or a salt substitute.

#### E 250 SODIUM NITRITE

<b>Definition</b>	
Chemical name	Sodium nitrite
Einecs	231-555-9
Chemical formula	NaNO <sub>2</sub>
Molecular weight	69,0
Assay	Content not less than 97 % on the anhydrous basis <sup>a</sup>
<b>Description</b>	White crystalline powder or yellowish lumps
<b>Identification</b>	
A.	Positive tests for nitrite and for sodium
<b>Purity</b>	
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
a	When labelled 'for food use', nitrite may only be sold in a mixture with salt or a salt substitute.

#### E 251 SODIUM NITRATE

##### 1. SOLID SODIUM NITRATE

<b>Synonyms</b>	Chile saltpetre Cubic or soda nitre
<b>Definition</b>	

Chemical name	Sodium nitrate
Einecs	231-554-3
Chemical formula	NaNO <sub>3</sub>
Molecular weight	85,0
Assay	Content not less than 99 % after drying
<b>Description</b>	White crystalline, slightly hygroscopic powder
<b>Identification</b>	
A. Positive tests for nitrate and for sodium	
B. pH of a 5 % solution	Not less than 5,5 and more than 8,3
<b>Purity</b>	
Loss on drying	Not more than 2 % after drying at 105 °C for four hours
Nitrites	Not more than 30 mg/kg expressed as NaNO <sub>2</sub>
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

## E 251 SODIUM NITRATE

## 2. LIQUID SODIUM NITRATE

<b>Definition</b>	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.
Chemical name	Sodium nitrate
Einecs	231-554-3
Chemical formula	NaNO <sub>3</sub>
Molecular weight	85,0
Assay	Content between 33,5 % and 40,0 % of NaNO <sub>3</sub>
<b>Description</b>	Clear colourless liquid

*Status: This is the original version (as it was originally adopted).*

<b>Identification</b>	
A.	Positive tests for nitrate and for sodium
B.	pH
<b>Purity</b>	
Free nitric acid	Not more than 0,01 %
Nitrites	Not more than 10 mg/kg expressed as NaNO <sub>2</sub>
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 0,3 mg/kg
This specification refers to a 35 % aqueous solution	

#### E 252 POTASSIUM NITRATE

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

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

## E 260 ACETIC ACID

<b>Definition</b>	
Chemical name	Acetic acid Ethanoic acid
Einecs	200-580-7
Chemical formula	C <sub>2</sub> H <sub>4</sub> O <sub>2</sub>
Molecular weight	60,05
Assay	Content not less than 99,8 %
<b>Description</b>	Clear, colourless liquid having a pungent, characteristic odour
<b>Identification</b>	
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
<b>Purity</b>	
Non-volatile residue	Not more than 100 mg/kg
Formic acid, formates and other oxidisable substances	Not more than 1 000 mg/kg expressed as formic acid
Readily oxidisable substances	Dilute 2 ml of the sample in a glass-stoppered container with 10 ml of water and add 0,1 ml of 0,1 N potassium permanganate. The pink colour does not change to brown within 30 minutes
Arsenic	Not more than 1 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 261 POTASSIUM ACETATE

<b>Definition</b>	
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*Status: This is the original version (as it was originally adopted).*

Chemical name	Potassium acetate
Einecs	204-822-2
Chemical formula	$C_2H_3O_2K$
Molecular weight	98,14
Assay	Content not less than 99 % on the anhydrous basis
<b>Description</b>	Colourless, deliquescent crystals or a white crystalline powder, odourless or with a faint acetic odour
<b>Identification</b>	
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	
<b>Purity</b>	
Loss on drying	Not more than 8 % after drying at 150 °C for two hours
Formic acid, formates and other oxidisable substances	Not more than 1 000 mg/kg expressed as formic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

#### E 262 (i) SODIUM ACETATE

<b>Definition</b>		
Chemical name	Sodium acetate	
Einecs	204-823-8	
Chemical formula	$C_2H_3NaO_2 \cdot nH_2O$ (n = 0 or 3)	
Molecular weight	Anhydrous:	82,03
	Trihydrate:	136,08
Assay	Content (for both of anhydrous and trihydrate form) not less than 98,5 % on the anhydrous basis	
<b>Description</b>	Anhydrous:	White, odourless, granular, hygroscopic powder
	Trihydrate:	Colourless, transparent crystals or a granular crystalline powder, odourless



		or with a faint, acetic odour. Effloresces in warm, dry air
<b>Identification</b>		
A.	pH of a 1 % aqueous solution	Not less than 8,0 and not more than 9,5
B.	Positive tests for acetate and for sodium	
<b>Purity</b>		
Loss on drying	Anhydrous:	Not more than 2 % (120 °C, 4 hours)
	Trihydrate:	Between 36 and 42 % (120 °C, 4 hours)
Formic acid, formates and other oxidisable substances		Not more than 1 000 mg/kg expressed as formic acid
Arsenic		Not more than 3 mg/kg
Lead		Not more than 5 mg/kg
Mercury		Not more than 1 mg/kg
Heavy metals (as Pb)		Not more than 10 mg/kg

## E 262 (ii) SODIUM DIACETATE

<b>Definition</b>	Sodium diacetate is a molecular compound of sodium acetate and acetic acid	
Chemical name	Sodium hydrogen diacetate	
Einecs	204-814-9	
Chemical formula	$C_4H_7NaO_4 \cdot nH_2O$ (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	
<b>Description</b>	White, hygroscopic crystalline solid with an acetic odour	
<b>Identification</b>		
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	
<b>Purity</b>		

*Status: This is the original version (as it was originally adopted).*

Water content	Not more than 2 % (Karl Fischer method)
Formic acid, formates and other oxidisable substances	Not more than 1 000 mg/kg expressed as formic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

### E 263 CALCIUM ACETATE

<b>Definition</b>		
Chemical name	Calcium acetate	
Einecs	200-540-9	
Chemical formula	Anhydrous:	$C_4H_6O_4Ca$
	Monohydrate:	$C_4H_6O_4Ca \cdot H_2O$
Molecular weight	Anhydrous:	158,17
	Monohydrate:	176,18
Assay	Content not less than 98 % on the anhydrous basis	
<b>Description</b>	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	
<b>Identification</b>		
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	
<b>Purity</b>		
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 oxidisable 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
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## E 270 LACTIC ACID

<b>Definition</b>	
Chemical name	Lactic acid 2-Hydroxypropionic acid 1-Hydroxyethane-1-carboxylic acid
Einecs	200-018-0
Chemical formula	C <sub>3</sub> H <sub>6</sub> O <sub>3</sub>
Molecular weight	90,08
Assay	Content not less than 76 % and not more than 84 %
<b>Description</b>	Colourless or yellowish, nearly odourless, syrupy liquid with an acid taste, consisting of a mixture of lactic acid (C <sub>3</sub> H <sub>6</sub> O <sub>3</sub> ) and lactic acid lactate (C <sub>6</sub> H <sub>10</sub> O <sub>5</sub> ). It is obtained by the lactic fermentation of sugars or is prepared synthetically
<i>Note:</i> 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	
<b>Identification</b>	
A. Positive test for lactate	
<b>Purity</b>	
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
<i>Note:</i> This specification refers to a 80 % aqueous solution; for weaker aqueous solutions,	

*Status: This is the original version (as it was originally adopted).*

calculate values corresponding to their lactic acid content

#### E 280 PROPIONIC ACID

<b>Definition</b>	
Chemical name	Propionic acid Propanoic acid
Einecs	201-176-3
Chemical formula	$C_3H_6O_2$
Molecular weight	74,08
Assay	Content not less than 99,5 %
<b>Description</b>	Colourless or slightly yellowish, oily liquid with a slightly pungent odour
<b>Indentification</b>	
A. Melting point	- 22 °C
B. Distillation range	138,5 °C to 142,5 °C
<b>Purity</b>	
Non-volatile residue	Not more than 0,01 % when dried at 140 °C to constant weight
Aldehydes	Not more than 0,1 % expressed as formaldehyde
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

#### E 281 SODIUM PROPIONATE

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

<b>Description</b>	White crystalline hygroscopic powder, or a fine white powder
<b>Identification</b>	
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
<b>Purity</b>	
Loss on drying	Not more than 4 % determined by drying for two hours at 105 °C
Water insolubles	Not more than 0,1 %
Iron	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 282 CALCIUM PROPIONATE

<b>Definition</b>	
Chemical name	Calcium propionate
Einecs	223-795-8
Chemical formula	$C_6H_{10}O_4Ca$
Molecular weight	186,22
Assay	Content not less than 99 %, after drying for two hours at 105 °C
<b>Description</b>	White crystalline powder
<b>Identification</b>	
A. Positive tests for propionate and for calcium	
B. pH of a 10 % aqueous solution	Between 6,0 and 9,0
<b>Purity</b>	
Loss on drying	Not more than 4 %, determined by drying for two hours at 105 °C
Water insolubles	Not more than 0,3 %
Iron	Not more than 50 mg/kg

*Status: This is the original version (as it was originally adopted).*

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

#### E 283 POTASSIUM PROPIONATE

<b>Definition</b>	
Chemical name	Potassium propionate Potassium propanoate
Einecs	206-323-5
Chemical formula	C <sub>3</sub> H <sub>5</sub> KO <sub>2</sub>
Molecular weight	112,17
Assay	Content not less than 99 % after drying for two hours at 105 °C
<b>Description</b>	White crystalline powder
<b>Identification</b>	
A. Positive tests for propionate and for potassium	
<b>Purity</b>	
Loss on drying	Not more than 4 %, determined by drying for two hours at 105 °C
Water-insoluble substances	Not more than 0,3 %
Iron	Not more than 30 mg/kg
Fluoride	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

#### E 284 BORIC ACID

<b>Synonyms</b>	Boracic acid
	Orthoboric acid
	Borofax

<b>Definition</b>	
Einecs	233-139-2
Chemical formula	H <sub>3</sub> BO <sub>3</sub>
Molecular weight	61,84
Assay	Content not less than 99,5 %
<b>Description</b>	Colourless, odourless, transparent crystals or white granules or powder; slightly unctuous to the touch; occurs in nature as the mineral sassolite
<b>Identification</b>	
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
<b>Purity</b>	
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)

<b>Synonyms</b>	Sodium borate
<b>Definition</b>	
Chemical name	Sodium tetraborate Sodium diborate Sodium pyroborate Anhydrous tetraborate
Einecs	215-540-4
Chemical formula	Na <sub>2</sub> B <sub>4</sub> O <sub>7</sub> Na <sub>2</sub> B <sub>4</sub> O <sub>7</sub> ·10H <sub>2</sub> O
Molecular weight	201,27
<b>Description</b>	Powder or glass-like plates becoming opaque on exposure to air; slowly soluble in water
<b>Identification</b>	

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*Status: This is the original version (as it was originally adopted).*

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A. Melting range	Between 171 °C and 175 °C with decomposition
<b>Purity</b>	
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

<b>Synonyms</b>	Carbonic acid gas
	Dry ice (solid form)
	Carbonic anhydride
<b>Definition</b>	
Chemical name	Carbon dioxide
Einecs	204-696-9
Chemical formula	CO <sub>2</sub>
Molecular weight	44,01
Assay	Content not less than 99 % v/v on the gaseous basis
<b>Description</b>	A colourless gas under normal environmental conditions with a slight pungent odour. Commercial carbon dioxide is shipped and handled as a liquid in pressurised cylinders or bulk storage systems, or in compressed solid blocks of 'dry ice'. Solid (dry ice) forms usually contain added substances, such as propylene glycol or mineral oil, as binders
<b>Identification</b>	
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
<b>Purity</b>	
Acidity	915 ml of gas bubbled through 50 ml of freshly boiled water must not render the latter more acid to methylorange than is 50 ml freshly boiled water to which has been added 1 ml of hydrochloric acid (0,01 N)



Reducing substances, hydrogen phosphide and sulphide	915 ml of gas bubbled through 25 ml of ammoniacal silver nitrate reagent to which has been added 3 ml of ammonia must not cause clouding or blackening of this solution
Carbon monoxide	Not more than 10 µl/l
Oil content	Not more than 0,1 mg/l

## E 296 MALIC ACID

<b>Synonyms</b>	DL-Malic acid, pomalous acid
<b>Definition</b>	
Chemical name	DL-Malic acid, hydroxybutanedioic acid, hydroxysuccinic acid
Einecs	230-022-8
Chemical formula	C <sub>4</sub> H <sub>6</sub> O <sub>5</sub>
Molecular weight	134,09
Assay	Content not less than 99,0 %
<b>Description</b>	White or nearly white crystalline powder or granules
<b>Identification</b>	
A. Melting range between 127 °C and 132 °C	
B. Positive test for malate	
C. Solutions of this substance are optically inactive in all concentrations	
<b>Purity</b>	
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

<b>Definition</b>	
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*Status: This is the original version (as it was originally adopted).*

Chemical name	Trans-butenedioic acid, trans-1,2-ethylenedicarboxylic acid
Einecs	203-743-0
Chemical formula	C <sub>4</sub> H <sub>4</sub> O <sub>4</sub>
Molecular weight	116,07
Assay	Content not less than 99,0 % on the anhydrous basis
<b>Description</b>	White crystalline powder or granules
<b>Identification</b>	
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
<b>Purity</b>	
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 300 ASCORBIC ACID

<b>Definition</b>	
Chemical name	L-ascorbic acid Ascorbic acid 2,3-Didehydro-L-threo-hexono-1,4-lactone 3-Keto-L-gulofuranolactone
Einecs	200-066-2
Chemical formula	C <sub>6</sub> H <sub>8</sub> O <sub>6</sub>
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 <sub>6</sub> H <sub>8</sub> O <sub>6</sub>

<b>Description</b>	White to pale yellow, odourless crystalline solid
<b>Identification</b>	
A. Melting range	Between 189 °C and 193 °C with decomposition
B. Positive tests for ascorbic acid	
<b>Purity</b>	
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

<b>Definition</b>	
Chemical name	Sodium ascorbate Sodium L-ascorbate 2,3-Didehydro-L-threo-hexono-1,4-lactone sodium enolate 3-Keto-L-gulofurano-lactone sodium enolate
Einecs	205-126-1
Chemical formula	$C_6H_7O_6Na$
Molecular weight	198,11
Assay	Sodium ascorbate, after drying in a vacuum desiccator over sulphuric acid for 24 hours, contains not less than 99 % of $C_6H_7O_6Na$
<b>Description</b>	White or almost white, odourless crystalline solid which darkens on exposure to light
<b>Identification</b>	

*Status: This is the original version (as it was originally adopted).*

A.	Positive tests for ascorbate and for sodium	
<b>Purity</b>		
Loss on drying		Not more than 0,25 % after drying in a vacuum desiccator over sulphuric acid for 24 hours
Specific rotation		$[\alpha]_D^{20}$ between + 103° and + 106° (10 % w/v aqueous solution)
pH of 10 % aqueous solution		Between 6,5 and 8,0
Arsenic		Not more than 3 mg/kg
Lead		Not more than 5 mg/kg
Mercury		Not more than 1 mg/kg
Heavy metals (as Pb)		Not more than 10 mg/kg

#### E 302 CALCIUM ASCORBATE

<b>Definition</b>		
Chemical name		Calcium ascorbate dihydrate Calcium salt of 2,3-didehydro-L-threo-hexono-1,4-lactone dihydrate
Einecs		227-261-5
Chemical formula		$C_{12}H_{14}O_{12}Ca \cdot 2H_2O$
Molecular weight		426,35
Assay		Content not less than 98 % on a volatile matter-free basis
<b>Description</b>		White to slightly pale greyish-yellow odourless crystalline powder
<b>Identification</b>		
A.	Positive tests for ascorbate and for calcium	
<b>Purity</b>		
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

<b>Definition</b>	
Chemical name	Ascorbyl palmitate L-ascorbyl palmitate 2,3-didehydro-L-threo-hexono-1,4-lactone-6-palmitate 6-palmitoyl-3-keto-L-gulofuranolactone
Einecs	205-305-4
Chemical formula	C <sub>22</sub> H <sub>38</sub> O <sub>7</sub>
Molecular weight	414,55
Assay	Content not less than 98 % on the dried basis
<b>Description</b>	White or yellowish-white solid with a citrus-like odour
<b>Identification</b>	
A. Melting range	Between 107 °C and 117 °C
<b>Purity</b>	
Loss on drying	Not more than 2,0 % after drying in a vacuum oven at 56 °C and 60 °C for one hour
Sulphated ash	Not more than 0,1 %
Specific rotation	[ $\alpha$ ] <sub>D</sub> <sup>20</sup> between + 21° and + 24° (5 % w/v in methanol solution)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 304 (ii) ASCORBYL STEARATE

<b>Definition</b>	
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*Status: This is the original version (as it was originally adopted).*

Chemical name	Ascorbyl stearate
	L-ascorbyl stearate
	2,3-didehydro-L-threo-hexono-1,4-lactone-6-stearate
	6-stearoyl-3-keto-L-gulofuranolactone
Einecs	246-944-9
Chemical formula	C <sub>24</sub> H <sub>42</sub> O <sub>7</sub>
Molecular weight	442,6
Assay	Content not less than 98 %
<b>Description</b>	White or yellowish, white solid with a citrus-like odour
<b>Identification</b>	
A. Melting point	About 116 °C
<b>Purity</b>	
Loss on drying	Not more than 2,0 % after drying in a vacuum oven at 56 °C to 60 °C for one hour
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

#### E 306 TOCOPHEROL-RICH EXTRACT

<b>Definition</b>	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- $\zeta$ -tocopherols
Molecular weight	430,71 (d- $\alpha$ -tocopherol)
Assay	Content not less than 34 % of total tocopherols
<b>Description</b>	Brownish red to red, clear, viscous oil having a mild, characteristic odour and taste. May show a slight separation of wax-like constituents in microcrystalline form
<b>Identification</b>	

A.	By suitable gas liquid chromatographic method	
B.	Solubility tests	Insoluble in water. Soluble in ethanol. Miscible in ether
<b>Purity</b>		
Sulphated ash		Not more than 0,1 %
Specific rotation		$[\alpha]_D^{20}$ not less than + 20°
Arsenic		Not more than 3 mg/kg
Lead		Not more than 5 mg/kg
Mercury		Not more than 1 mg/kg
Heavy metals (as Pb)		Not more than 10 mg/kg

## E 307 ALPHA-TOCOPHEROL

<b>Synonyms</b>		DL- $\alpha$ -Tocopherol
<b>Definition</b>		
Chemical name		DL-5,7,8-Trimethyltolcol DL-2,5,7,8-tetramethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol
Einecs		233-466-0
Chemical formula		C <sub>29</sub> H <sub>50</sub> O <sub>2</sub>
Molecular weight		430,71
Assay		Content not less than 96 %
<b>Description</b>		Slightly yellow to amber, nearly odourless, clear, viscous oil which oxidises and darkens on exposure to air or light
<b>Identification</b>		
A.	Solubility tests	Insoluble in water, freely soluble in ethanol, miscible in ether
B.	Spectro-photometry	In absolute ethanol the maximum absorption is about 292 nm
<b>Purity</b>		
Refractive index		$n_D^{20}$ 1,503-1,507
Specific absorption $E_{1\%}^{1cm}$ in ethanol		$E_{1\%}^{1cm}$ (292 nm) 72-76 (0,01 g in 200 ml of absolute ethanol)
Sulphated ash		Not more than 0,1 %

*Status: This is the original version (as it was originally adopted).*

Specific rotation	$[\alpha]_D^{25} 0^\circ \pm 0,05^\circ$ (1 in 10 solution in chloroform)
Lead	Not more than 2 mg/kg

#### E 308 GAMMA-TOCOPHEROL

<b>Synonyms</b>	dl- $\gamma$ -Tocopherol
<b>Definition</b>	
Chemical name	2,7,8-trimethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol
Einecs	231-523-4
Chemical formula	C <sub>28</sub> H <sub>48</sub> O <sub>2</sub>
Molecular weight	416,69
Assay	Content not less than 97 %
<b>Description</b>	Clear, viscous, pale yellow oil which oxidises and darkens on exposure to air or light
<b>Identification</b>	
A. Spectrometry	Maximum absorptions in absolute ethanol at about 298 nm and 257 nm
<b>Purity</b>	
Specific absorption $E_{1\%}^{1cm}$ in ethanol	$E_{1\%}^{1cm}$ (298 nm) between 91 and 97 $E_{1\%}^{1cm}$ (257 nm) between 5,0 and 8,0
Refractive index	$[\eta]_{20}^D$ 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 309 DELTA-TOCOPHEROL

<b>Definition</b>	
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 %
<b>Description</b>	Clear, viscous, pale yellowish or orange oil which oxidises and darkens on exposure to air or light
<b>Identification</b>	
A. Spectrometry	Maximum absorptions in absolute ethanol at about 298 nm and 257 nm
<b>Purity</b>	
Specific absorption $E_{1\%}^{1cm}$ in ethanol	$E_{1\%}^{1cm}$ (298 nm) between 89 and 95
	$E_{1\%}^{1cm}$ (257 nm) between 3,0 and 6,0
Refractive index	$n_D^{20}$ 1,5-1,504
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 310 PROPYL GALLATE

<b>Definition</b>	
Chemical name	Propyl gallate Propyl ester of gallic acid n-propyl ester of 3,4,5-trihydroxybenzoic acid
Einecs	204-498-2
Chemical formula	$C_{10}H_{12}O_5$
Molecular weight	212,2
Assay	Content not less than 98 % on the anhydrous basis
<b>Description</b>	White to creamy-white, crystalline, odourless solid
<b>Identification</b>	

*Status: This is the original version (as it was originally adopted).*

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
<b>Purity</b>		
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 Cl)
Specific absorption $E_{1\%}^{1\text{cm}}$ in ethanol		$E_{1\%}^{1\text{cm}}$ (275 nm) not less than 485 and not more than 520
Arsenic		Not more than 3 mg/kg
Lead		Not more than 5 mg/kg
Mercury		Not more than 1 mg/kg
Heavy metals (as Pb)		Not more than 10 mg/kg

## E 311 OCTYL GALLATE

<b>Definition</b>		
Chemical name		Octyl gallate Octyl ester of gallic acid n-octyl ester of 3,4,5-trihydroxybenzoic acid
Einecs		213-853-0
Chemical formula		C <sub>15</sub> H <sub>22</sub> O <sub>5</sub>
Molecular weight		282,34
Assay		Content not less than 98 % after drying at 90 °C for six hours
<b>Description</b>		White to creamy-white odourless solid
<b>Identification</b>		
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
<b>Purity</b>		
Loss on drying		Not more than 0,5 % (90 °C, six hours)

Sulphated ash	Not more than 0,05 %
Free acid	Not more than 0,5 % (as gallic acid)
Chlorinated organic compound	Not more than 100 mg/kg (as Cl)
Specific absorption $E_{1\%}^{1cm}$ in ethanol	$E_{1\%}^{1cm}$ (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

<b>Synonyms</b>	Lauryl gallate
<b>Definition</b>	
Chemical name	Dodecyl gallate n-dodecyl (or lauryl) ester of 3,4,5-trihydroxybenzoic acid Dodecyl ester of gallic acid
Einecs	214-620-6
Chemical formula	C <sub>19</sub> H <sub>30</sub> O <sub>5</sub>
Molecular weight	338,45
Assay	Content not less than 98 % after drying at 90 °C for six hours
<b>Description</b>	White or creamy-white odourless solid
<b>Identification</b>	
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
<b>Purity</b>	
Loss on drying	Not more than 0,5 % (90 °C, six hours)
Sulphated ash	Not more than 0,05 %
Free acid	Not more than 0,5 % (as gallic acid)
Chlorinated organic compound	Not more than 100 mg/kg (as Cl)
Specific absorption $E_{1\%}^{1cm}$	$E_{1\%}^{1cm}$

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*Status: This is the original version (as it was originally adopted).*

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in ethanol	(275 nm) not less than 300 and not more than 325
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 30 mg/kg

### E 315 ERYTHORBIC ACID

<b>Synonyms</b>	Isoascorbic acid
	D-Araboascorbic acid
<b>Definition</b>	
Chemical name	D-Erythro-hex-2-enoic acid $\gamma$ -lactone
	Isoascorbic acid
	D-Isoascorbic acid
Einecs	201-928-0
Chemical formula	C <sub>6</sub> H <sub>8</sub> O <sub>6</sub>
Molecular weight	176,13
Assay	Content not less than 98 % on the anhydrous basis
<b>Description</b>	White to slightly yellow crystalline solid which darkens gradually on exposure to light
<b>Identification</b>	
A. Melting range	About 164 °C to 172 °C with decomposition
B. Positive test for ascorbic acid/ colour reaction	
<b>Purity</b>	
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	[ $\alpha$ ] <sub>D</sub> 10 % (w/v) aqueous solution between -16,5° to -18,0°
Oxalate	To a solution of 1 g in 10 ml of water add 2 drops of glacial acetic acid and 5 ml of 10 % calcium acetate solution. The solution should remain clear
Lead	Not more than 2 mg/kg

## E 316 SODIUM ERYTHORBATE

<b>Synonyms</b>	Sodium isoascorbate
<b>Definition</b>	
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 <sub>6</sub> H <sub>7</sub> O <sub>6</sub> Na · H <sub>2</sub> O
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
<b>Description</b>	White crystalline solid
<b>Identification</b>	
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	
<b>Purity</b>	
Loss on drying	Not more than 0,25 % after drying in a vacuum desiccator over sulphuric acid for 24 hours
Specific rotation	[α] <sub>D</sub> 10 % (w/v) aqueous solution between + 95° and + 98°
pH of a 10 % aqueous solution	5,5 to 8,0
Oxalate	To a solution of 1 g in 10 ml of water add 2 drops of glacial acetic acid and 5 ml of 10 % calcium acetate solution. The solution should remain clear
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 319 TERTIARY-BUTYLHYDROQUINONE (TBHQ)

<b>Synonyms</b>	TBHQ
<b>Definition</b>	
Chemical names	Tert-butyl-1,4-benzenediol 2-(1,1-Dimethylethyl)-1,4-benzenediol
Einecs	217-752-2
Chemical formula	C <sub>10</sub> H <sub>14</sub> O <sub>2</sub>
Molecular weight	166,22
Assay	Content not less than 99 % of C <sub>10</sub> H <sub>14</sub> O <sub>2</sub>
<b>Description</b>	White crystalline solid having a characteristic odour
<b>Identification</b>	
A. Solubility	Practically insoluble in water; soluble in ethanol
B. Melting point	Not less than 126,5 °C
C. Phenolics	Dissolve about 5 mg of the sample in 10 ml of methanol and add 10,5 ml of dimethylamine solution (1 in 4). A red to pink colour is produced
<b>Purity</b>	
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)

<b>Synonyms</b>	BHA
<b>Definition</b>	
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	C <sub>11</sub> H <sub>16</sub> O <sub>2</sub>
Formula weight	180,25

Assay	Content not less than 98,5 % of C <sub>11</sub> H <sub>16</sub> O <sub>2</sub> and not less than 85 % of 3-tertiary-butyl-4-hydroxyanisole isomer
<b>Description</b>	White or slightly yellow crystals or waxy solid with a slight aromatic smell
<b>Identification</b>	
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
<b>Purity</b>	
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)

<b>Synonyms</b>	BHT
<b>Definition</b>	
Chemical name	2,6-Ditertiary-butyl- <i>p</i> -cresol 4-Methyl-2,6-ditertiarybutylphenol
Einecs	204-881-4
Chemical formula	C <sub>15</sub> H <sub>24</sub> O
Molecular weight	220,36
Assay	Content not less than 99 %
<b>Description</b>	White, crystalline or flaked solid, odourless or having a characteristic faint aromatic odour
<b>Identification</b>	

*Status: This is the original version (as it was originally adopted).*

A.	Solubility tests	Insoluble in water and propane- 1,2-diol Freely soluble in ethanol
B.	Melting point	At 70 °C
C.	Absorbance maximum	The absorption in the range 230 to 320 nm of a 2 cm layer of a 1 in 100 000 solution in dehydrated ethanol exhibits a maximum only at 278 nm
<b>Purity</b>		
	Sulphated ash	Not more than 0,005 %
	Phenolic impurities	Not more than 0,5 %
	Specific absorption $E_{1\%}^{1cm}$ in ethanol	$E_{1\%}^{1cm}$ (278 nm) not less than 81 and not more than 88
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 5 mg/kg
	Mercury	Not more than 1 mg/kg
	Heavy metals (as Pb)	Not more than 10 mg/kg

## E 322 LECITHINS

<b>Synonyms</b>	Phosphatides
	Phospholipids
<b>Definition</b>	Lecithins are mixtures or fractions of phosphatides obtained by physical procedures from animal or vegetable foodstuffs; they also include hydrolysed products obtained through the use of harmless and appropriate enzymes. The final product must not show any signs of residual enzyme activity The lecithins may be slightly bleached in aqueous medium by means of hydrogen peroxide. This oxidation must not chemically modify the lecithin phosphatides
Einecs	232-307-2
Assay	— Lecithins: not less than 60,0 % of substances insoluble in acetone
	— Hydrolysed lecithins: not less than 56,0 % of substances insoluble in acetone
<b>Description</b>	— Lecithins: brown liquid or viscous semi-liquid or powder



	—	Hydrolysed lecithins: light brown to brown viscous liquid or paste
<b>Identification</b>		
A.	Positive tests for choline, for phosphorus and fatty acids	
B.	Test for hydrolysed lecithin	To a 800 ml beaker add 500 ml of water (30 °C-35 °C). Then slowly add 50 ml of the sample with constant stirring. Hydrolysed lecithin will form a homogeneous emulsion. Non-hydrolysed lecithin will form a distinct mass of about 50 g
<b>Purity</b>		
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

<b>Definition</b>	
Chemical name	Sodium lactate
	Sodium 2-hydroxypropanoate
Einecs	200-772-0
Chemical formula	C <sub>3</sub> H <sub>5</sub> NaO <sub>3</sub>
Molecular weight	112,06 (anhydrous)
Assay	Content not less than 57 % and not more than 66 %
<b>Description</b>	Colourless, transparent, liquid. Odourless, or with a slight, characteristic odour
<b>Identification</b>	

*Status: This is the original version (as it was originally adopted).*

A.	Positive test for lactate	
B.	Positive test for sodium	
<b>Purity</b>		
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
<i>Note:</i> This specification refers to a 60 % aqueous solution		

#### E 326 POTASSIUM LACTATE

<b>Definition</b>		
Chemical name		Potassium lactate Potassium 2-hydroxypropanoate
Einecs		213-631-3
Chemical formula		C <sub>3</sub> H <sub>5</sub> O <sub>3</sub> K
Molecular weight		128,17 (anhydrous)
Assay		Content not less than 57 % and not more than 66 %
<b>Description</b>		Slightly viscous, almost odourless clear liquid. Odourless, or with a slight, characteristic odour
<b>Identification</b>		
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	

<b>Purity</b>	
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
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
<i>Note:</i> This specification refers to a 60 % aqueous solution	

## E 327 CALCIUM LACTATE

<b>Definition</b>	
Chemical name	Calcium dilactate Calcium dilactate hydrate 2-Hydroxypropanoic acid calcium salt
Einecs	212-406-7
Chemical formula	$(C_3H_5O_2)_2 Ca \cdot nH_2O$ (n = 0-5)
Molecular weight	218,22 (anhydrous)
Assay	Content not less than 98 % on the anhydrous basis
<b>Description</b>	Almost odourless, white crystalline powder or granules
<b>Identification</b>	
A. Positive tests for lactate and for calcium	
B. Solubility tests	Soluble in water and practically insoluble in ethanol
<b>Purity</b>	
Loss on drying	Determined by drying at 120 °C for four hours: — anhydrous: not more than 3,0 %

*Status: This is the original version (as it was originally adopted).*

	—	with 1 molecule of water: not more than 8,0 %
	—	with 3 molecules of water: not more than 20,0 %
	—	with 4,5 molecules of water: not more than 27,0 %
Acidity	Not more than 0,5 % of the dry matter expressed as lactic acid	
Fluoride	Not more than 30 mg/kg (expressed as fluorine)	
pH of a 5 % solution	Between 6,0 and 8,0	
Arsenic	Not more than 3 mg/kg	
Lead	Not more than 5 mg/kg	
Mercury	Not more than 1 mg/kg	
Heavy metals (as Pb)	Not more than 10 mg/kg	
Reducing substances	No reduction of Fehling's solution	

### E 330 CITRIC ACID

<b>Definition</b>	
Chemical name	Citric acid 2-Hydroxy-1,2,3-propanetricarboxylic acid β-Hydroxytricarballic acid
Einecs	201-069-1
Chemical formula	(a) $C_6H_8O_7$ (anhydrous) (b) $C_6H_8O_7 \cdot H_2O$ (monohydrate)
Molecular weight	(a) 192,13 (anhydrous) (b) 210,15 (monohydrate)
Assay	Citric acid may be anhydrous or it may contain 1 molecule of water. Citric acid contains not less than 99,5 % of $C_6H_8O_7$ , calculated on the anhydrous basis
<b>Description</b>	Citric acid is a white or colourless, odourless, crystalline solid, having a strongly acid taste. The monohydrate effloresces in dry air
<b>Identification</b>	
A. Solubility tests	Very soluble in water; freely soluble in ethanol; soluble in ether
<b>Purity</b>	

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 carbonisable substances	Heat 1 g of powdered sample with 10 ml of 98 % minimum sulphuric acid in a water bath at 90 °C in the dark for one hour. Not more than a pale brown colour should be produced (Matching Fluid K)

## E 331 (i) MONOSODIUM CITRATE

<b>Synonyms</b>	Monosodium citrate Monobasic sodium citrate
<b>Definition</b>	
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
<b>Description</b>	Crystalline white powder or colourless crystals
<b>Identification</b>	
A. Positive tests for citrate and for sodium	
<b>Purity</b>	
Loss on drying	Determined by drying at 180 °C for four hours:

*Status: This is the original version (as it was originally adopted).*

	— anhydrous: not more than 1,0 %
	— monohydrate: not more than 8,8 %
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 1 % aqueous solution	Between 3,5 and 3,8
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

#### E 331 (ii) DISODIUM CITRATE

<b>Synonyms</b>	Disodium citrate Dibasic sodium citrate
<b>Definition</b>	
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
Einecs	205-623-3
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
<b>Description</b>	Crystalline white powder or colourless crystals
<b>Identification</b>	
A. Positive tests for citrate and for sodium	
<b>Purity</b>	
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

*Status: This is the original version (as it was originally adopted).*

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

## E 331 (iii) TRISODIUM CITRATE

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

## E 332 (i) MONOPOTASSIUM CITRATE

*Status: This is the original version (as it was originally adopted).*

<b>Synonyms</b>	Monopotassium citrate Monobasic potassium citrate
<b>Definition</b>	
Chemical name	Monopotassium citrate Monopotassium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Anhydrous monopotassium salt of citric acid
Einecs	212-753-4
Chemical formula	C <sub>6</sub> H <sub>7</sub> O <sub>7</sub> K
Molecular weight	230,21
Assay	Content not less than 99 % on the anhydrous basis
<b>Description</b>	White, hygroscopic, granular powder or transparent crystals
<b>Identification</b>	
A. Positive tests for citrate and for potassium	
<b>Purity</b>	
Loss on drying	Not more than 1,0 % determined by drying at 180 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 1 % aqueous solution	Between 3,5 and 3,8
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

#### E 332 (ii) TRIPOTASSIUM CITRATE

<b>Synonyms</b>	Tripotassium citrate Tribasic potassium citrate
<b>Definition</b>	
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	$C_6H_5O_7K_3 \cdot H_2O$
Molecular weight	324,42
Assay	Content not less than 99 % on the anhydrous basis
<b>Description</b>	White, hygroscopic, granular powder or transparent crystals
<b>Identification</b>	
A. Positive tests for citrate and for potassium	
<b>Purity</b>	
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

<b>Synonyms</b>	Monocalcium citrate Monobasic calcium citrate
<b>Definition</b>	
Chemical name	Monocalcium citrate Monocalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Monohydrate monocalcium salt of citric acid
Chemical formula	$(C_6H_7O_7)_2Ca \cdot H_2O$
Molecular weight	440,32
Assay	Content not less than 97,5 % on the anhydrous basis
<b>Description</b>	Fine white powder
<b>Identification</b>	
A. Positive tests for citrate and for calcium	

*Status: This is the original version (as it was originally adopted).*

<b>Purity</b>	
Loss on drying	Not more than 7,0 % determined by drying at 180 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 1 % aqueous solution	Between 3,2 and 3,5
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg
Carbonates	Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles

#### E 333 (ii) DICALCIUM CITRATE

<b>Synonyms</b>	Dicalcium citrate Dibasic calcium citrate
<b>Definition</b>	
Chemical name	Dicalcium citrate Dicalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Trihydrated dicalcium salt of citric acid
Chemical formula	$(C_6H_7O_7)_2Ca_2 \cdot 3H_2O$
Molecular weight	530,42
Assay	Not less than 97,5 % on the anhydrous basis
<b>Description</b>	Fine white powder
<b>Identification</b>	
A. Positive tests for citrate and for calcium	
<b>Purity</b>	
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

<b>Synonyms</b>	Tricalcium citrate Tribasic calcium citrate
<b>Definition</b>	
Chemical name	Tricalcium citrate Tricalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Tetrahydrated tricalcium salt of citric acid
Einecs	212-391-7
Chemical formula	$(C_6H_6O_7)_2Ca_3 \cdot 4H_2O$
Molecular weight	570,51
Assay	Not less than 97,5 % on the anhydrous basis
<b>Description</b>	Fine white powder
<b>Identification</b>	
A. Positive tests for citrate and for calcium	
<b>Purity</b>	
Loss on drying	Not more than 14,0 % determined by drying at 180 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

*Status: This is the original version (as it was originally adopted).*

Carbonates	Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles
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#### E 334 L(+)-TARTARIC ACID

<b>Definition</b>	
Chemical name	L-tartaric acid L-2,3-dihydroxybutanedioic acid d- $\alpha$ , $\beta$ -dihydroxysuccinic acid
Einecs	201-766-0
Chemical formula	C <sub>4</sub> H <sub>6</sub> O <sub>6</sub>
Molecular weight	150,09
Assay	Content not less than 99,5 % on the anhydrous basis
<b>Description</b>	Colourless or translucent crystalline solid or white crystalline powder
<b>Identification</b>	
A. Melting range	Between 168 °C and 170 °C
B. Positive test for tartrate	
<b>Purity</b>	
Loss on drying	Not more than 0,5 % (over P <sub>2</sub> O <sub>5</sub> , three hours)
Sulphated ash	Not more than 1 000 mg/kg after calcination at 800 ± 25 °C
Specific optical rotation of a 20 % w/v aqueous solution	$[\alpha]^{20}_{\text{D}}$ between 11,5° and 13,5°
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying

#### E 335 (i) MONOSODIUM TARTRATE

<b>Synonyms</b>	Monosodium salt of L-(+)-tartaric acid
<b>Definition</b>	
Chemical name	Monosodium salt of L-2,3-dihydroxybutanedioic acid

	Monohydrated monosodium salt of L-(+)-tartaric acid
Chemical formula	$C_4H_5O_6Na \cdot H_2O$
Molecular weight	194,05
Assay	Content not less than 99 % on the anhydrous basis
<b>Description</b>	Transparent colourless crystals
<b>Identification</b>	
A. Positive tests for tartrate and for sodium	
<b>Purity</b>	
Loss on drying	Not more than 10,0 % determined by drying at 105 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 335 (ii) DISODIUM TARTRATE

<b>Definition</b>	
Chemical name	Disodium L-tartrate Disodium (+)-tartrate Disodium (+)-2,3-dihydroxybutanedioic acid Dihydrated disodium salt of L-(+)-tartaric acid
Einecs	212-773-3
Chemical formula	$C_4H_4O_6Na_2 \cdot 2H_2O$
Molecular weight	230,8
Assay	Content not less than 99 % on the anhydrous basis
<b>Description</b>	Transparent, colourless crystals
<b>Identification</b>	
A. Positive tests for tartrate and for sodium	

*Status: This is the original version (as it was originally adopted).*

B. Solubility tests	1 gram is insoluble in 3 ml of water. Insoluble in ethanol
<b>Purity</b>	
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

#### E 336 (i) MONOPOTASSIUM TARTRATE

<b>Synonyms</b>	Monobasic potassium tartrate
<b>Definition</b>	
Chemical name	Anhydrous monopotassium salt of L-(+)-tartaric acid Monopotassium salt of L-2,3-dihydroxybutanedioic acid
Chemical formula	C <sub>4</sub> H <sub>5</sub> O <sub>6</sub> K
Molecular weight	188,16
Assay	Content not less than 98 % on the anhydrous basis
<b>Description</b>	White crystalline or granulated powder
<b>Identification</b>	
A. Positive tests for tartrate and for potassium	
B. Melting point	230 °C
<b>Purity</b>	
pH of a 1 % aqueous solution	3,4
Loss on drying	Not more than 1,0 % determined by drying at 105 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
Arsenic	Not more than 3 mg/kg

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

## E 336 (ii) DIPOTASSIUM TARTRATE

<b>Synonyms</b>	Dibasic potassium tartrate
<b>Definition</b>	
Chemical name	Dipotassium salt of L-2,3-dihydroxybutanedioic acid Dipotassium salt with half a molecule of water of L-(+)-tartaric acid
Einecs	213-067-8
Chemical formula	$C_4H_4O_6K_2 \cdot 1/2H_2O$
Molecular weight	235,2
Assay	Content not less than 99 % on the anhydrous basis
<b>Description</b>	White crystalline or granulated powder
<b>Identification</b>	
A. Positive tests for tartrate and for potassium	
<b>Purity</b>	
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

<b>Synonyms</b>	Potassium sodium L-(+)-tartrate
	Rochelle salt
	Seignette salt
<b>Definition</b>	

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*Status: This is the original version (as it was originally adopted).*

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

#### E 338 PHOSPHORIC ACID

<b>Synonyms</b>	Orthophosphoric acid
	Monophosphoric acid
<b>Definition</b>	
Chemical name	Phosphoric acid
Einecs	231-633-2
Chemical formula	H <sub>3</sub> PO <sub>4</sub>
Molecular weight	98,0



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 %.
<b>Description</b>	Clear, colourless, viscous liquid
<b>Identification</b>	
A. Positive tests for acid and for phosphate	
<b>Purity</b>	
Volatile acids	Not more than 10 mg/kg (as acetic acid)
Chlorides	Not more than 200 mg/kg (expressed as chlorine)
Nitrates	Not more than 5 mg/kg (as NaNO <sub>3</sub> )
Sulphates	Not more than 1 500 mg/kg (as CaSO <sub>4</sub> )
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
<i>Note:</i> This specification refers to a 75 % aqueous solution	

## E 339 (i) MONOSODIUM PHOSPHATE

<b>Synonyms</b>	Monosodium monophosphate
	Acid monosodium monophosphate
	Monosodium orthophosphate
	Monobasic sodium phosphate
	Sodium dihydrogen monophosphate
<b>Definition</b>	
Chemical name	Sodium dihydrogen monophosphate
Einecs	231-449-2
Chemical formula	Anhydrous: NaH <sub>2</sub> PO <sub>4</sub>
	Monohydrate: NaH <sub>2</sub> PO <sub>4</sub> · H <sub>2</sub> O
	Dihydrate: NaH <sub>2</sub> PO <sub>4</sub> · 2H <sub>2</sub> O

*Status: This is the original version (as it was originally adopted).*

Molecular weight	Anhydrous: 119,98
	Monohydrate: 138,0
	Dihydrate: 156,01
Assay	After drying at 60 °C for one hour and then at 105 °C for four hours, contains not less than 97 % of NaH <sub>2</sub> PO <sub>4</sub>
P <sub>2</sub> O <sub>5</sub> content	Between 58,0 % and 60,0 % on the anhydrous basis
<b>Description</b>	A white odourless, slightly deliquescent powder, crystals or granules
<b>Identification</b>	
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
<b>Purity</b>	
Loss on drying	The anhydrous salt loses not more than 2,0 %, the monohydrate not more than 15,0 %, and the dihydrate not more than 25 % when dried first at 60 °C for one hour, then at 105 °C for four hours
Water-insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

#### E 339 (ii) DISODIUM PHOSPHATE

<b>Synonyms</b>	Disodium monophosphate
	Secondary sodium phosphate
	Disodium orthophosphate
	Acid disodium phosphate
<b>Definition</b>	
Chemical name	Disodium hydrogen monophosphate

	Disodium hydrogen orthophosphate
Einecs	231-448-7
Chemical formula	Anhydrous: Na <sub>2</sub> HPO <sub>4</sub> Hydrat: Na <sub>2</sub> HPO <sub>4</sub> · nH <sub>2</sub> O (n = 2,7 or 12)
Molecular weight	141,98 (anhydrous)
Assay	After drying at 40 °C for three hours and subsequently at 105 °C for five hours, contains not less than 98 % of Na <sub>2</sub> HPO <sub>4</sub>
P <sub>2</sub> O <sub>5</sub> content	Between 49 % and 51 % on the anhydrous basis
<b>Description</b>	Anhydrous disodium hydrogen phosphate is a white, hygroscopic, odourless powder. Hydrated forms available include the dihydrate: a white crystalline, odourless solid; the heptahydrate: white, odourless, efflorescent crystals or granular powder; and the dodecahydrate: white, efflorescent, odourless powder or crystals
<b>Identification</b>	
A. Positive tests for sodium and for phosphate	
B. Solubility	Freely soluble in water. Insoluble in ethanol
C. pH of a 1 % solution	Between 8,4 and 9,6
<b>Purity</b>	
Loss on drying	When dried at 40 °C for three hours and then at 105 °C for five hours, the losses in weight are as follows: anhydrous not more than 5,0 %, dihydrate not more than 22,0 %, heptahydrate not more than 50,0 %, dodecahydrate not more than 61,0 %
Water-insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

<b>Synonyms</b>	Sodium phosphate
	Tribasic sodium phosphate
	Trisodium orthophosphate
<b>Definition</b>	Trisodium phosphate is obtained from aqueous solutions and crystallises in the anhydrous form and with 1/2, 1, 6, 8 or 12 H <sub>2</sub> O. The dodecahydrate always crystallises from aqueous solutions with an excess of sodium hydroxide. It contains 1/4 molecule of NaOH
Chemical name	Trisodium monophosphate
	Trisodium phosphate
	Trisodium orthophosphate
Einecs	231-509-8
Chemical formula	Anhydrous: Na <sub>3</sub> PO <sub>4</sub>
	Hydrated: Na <sub>3</sub> PO <sub>4</sub> · nH <sub>2</sub> O (n = 1/2, 1, 6, 8, or 12)
Molecular weight	163,94 (anhydrous)
Assay	Sodium phosphate anhydrous and the hydrated forms, with the exception of the dodecahydrate, contain not less than 97,0 % of Na <sub>3</sub> PO <sub>4</sub> calculated on the dried basis. Sodium phosphate dodecahydrate contains not less than 92,0 % of Na <sub>3</sub> PO <sub>4</sub> calculated on the ignited basis
P <sub>2</sub> O <sub>5</sub> content	Between 40,5 % and 43,5 % on the anhydrous basis
<b>Description</b>	White odourless crystals, granules or crystalline powder
<b>Identification</b>	
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
<b>Purity</b>	
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

<b>Synonyms</b>	Monobasic potassium phosphate
	Monopotassium monophosphate
	Potassium orthophosphate
<b>Definition</b>	
Chemical name	Potassium dihydrogen phosphate
	Monopotassium dihydrogen orthophosphate
	Monopotassium dihydrogen monophosphate
Einecs	231-913-4
Chemical formula	$\text{KH}_2\text{PO}_4$
Molecular weight	136,09
Assay	Content not less than 98,0 % after drying at 105 °C for four hours
P <sub>2</sub> O <sub>5</sub> content	Between 51,0 % and 53,0 % on the anhydrous basis
<b>Description</b>	Odourless, colourless crystals or white granular or crystalline powder, hygroscopic
<b>Identification</b>	
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
<b>Purity</b>	
Loss on drying	Not more than 2,0 % determined by drying at 105 °C for four hours

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*Status: This is the original version (as it was originally adopted).*

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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

<b>Synonyms</b>	Dipotassium monophosphate
	Secondary potassium phosphate
	Dipotassium acid phosphate
	Dipotassium orthophosphate
	Dibasic potassium phosphate
<b>Definition</b>	
Chemical name	Dipotassium hydrogen monophosphate
	Dipotassium hydrogen phosphate
	Dipotassium hydrogen orthophosphate
Einecs	231-834-5
Chemical formula	$K_2HPO_4$
Molecular weight	174,18
Assay	Content not less than 98 % after drying at 105 °C for four hours
P <sub>2</sub> O <sub>5</sub> content	Between 40,3 % and 41,5 % on the anhydrous basis
<b>Description</b>	Colourless or white granular powder, crystals or masses; deliquescent substance
<b>Identification</b>	
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
<b>Purity</b>	
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

<b>Synonyms</b>	Potassium phosphate
	Tribasic potassium phosphate
	Tripotassium orthophosphate
<b>Definition</b>	
Chemical name	Tripotassium monophosphate
	Tripotassium phosphate
	Tripotassium orthophosphate
Einecs	231-907-1
Chemical formula	Anhydrous: $K_3PO_4$
	Hydrated: $K_3PO_4 \cdot nH_2O$ (n = 1 or 3)
Molecular weight	212,27 (anhydrous)
Assay	Content not less than 97 % calculated on the ignited basis
P <sub>2</sub> O <sub>5</sub> content	Between 30,5 % and 33,0 % on the ignited basis
<b>Description</b>	Colourless or white, odourless hygroscopic crystals or granules. Hydrated forms available include the monohydrate and trihydrate
<b>Identification</b>	
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
<b>Purity</b>	
Loss on ignition	Anhydrous: not more than 3,0 %; hydrated: not more than 23,0 %. Determined by drying

*Status: This is the original version (as it was originally adopted).*

	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

<b>Synonyms</b>	Monobasic calcium phosphate
	Monocalcium orthophosphate
<b>Definition</b>	
Chemical name	Calcium dihydrogen phosphate
Einecs	231-837-1
Chemical formula	Anhydrous: $\text{Ca}(\text{H}_2\text{PO}_4)_2$
	Monohydrate: $\text{Ca}(\text{H}_2\text{PO}_4)_2 \cdot \text{H}_2\text{O}$
Molecular weight	234,05 (anhydrous)
	252,08 (monohydrate)
Assay	Content not less than 95 % on the dried basis
P <sub>2</sub> O <sub>5</sub> content	Between 55,5 % and 61,1 % on the anhydrous basis
<b>Description</b>	Granular powder or white, deliquescent crystals or granules
<b>Identification</b>	
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)
<b>Purity</b>	
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

<b>Synonyms</b>	Dibasic calcium phosphate
	Dicalcium orthophosphate
<b>Definition</b>	
Chemical name	Calcium monohydrogen phosphate
	Calcium hydrogen orthophosphate
	Secondary calcium phosphate
Einecs	231-826-1
Chemical formula	Anhydrous: $\text{CaHPO}_4$
	Dihydrate: $\text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$
Molecular weight	136,06 (anhydrous)
	172,09 (dihydrate)
Assay	Dicalcium phosphate, after drying at 200 °C for three hours, contains not less than 98 % and not more than the equivalent of 102 % of $\text{CaHPO}_4$
$\text{P}_2\text{O}_5$ content	Between 50,0 % and 52,5 % on the anhydrous basis
<b>Description</b>	White crystals or granules, granular powder or powder
<b>Identification</b>	
A. Positive tests for calcium and for phosphate	
B. Solubility tests	Sparingly soluble in water. Insoluble in ethanol

*Status: This is the original version (as it was originally adopted).*

<b>Purity</b>	
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

<b>Synonyms</b>	Calcium phosphate, tribasic
	Calcium orthophosphate
	Pentacalcium hydroxy monophosphate
	Calcium hydroxyapatite
<b>Definition</b>	Tricalcium phosphate consists of a variable mixture of calcium phosphates obtained from neutralisation of phosphoric acid with calcium hydroxide and having the approximate composition of $10\text{CaO} \cdot 3\text{P}_2\text{O}_5 \cdot \text{H}_2\text{O}$
Chemical name	Pentacalcium hydroxy monophosphate
	Tricalcium monophosphate
Einecs	235-330-6 (Pentacalcium hydroxy monophosphate)
	231-840-8 (Calcium orthophosphate)
Chemical formula	$\text{Ca}_5(\text{PO}_4)_3 \cdot \text{OH}$ or $\text{Ca}_3(\text{PO}_4)_2$
Molecular weight	502 or 310
Assay	Content not less than 90 % calculated on the ignited basis
P2O5 content	Between 38,5 % and 48,0 % on the anhydrous basis
<b>Description</b>	A white, odourless powder which is stable in air
<b>Identification</b>	
A.	Positive tests for calcium and for phosphate

B. Solubility	Practically insoluble in water; insoluble in ethanol soluble in dilute hydrochloric and nitric acid
<b>Purity</b>	
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 343(i) MONOMAGNESIUM PHOSPHATE

<b>Synonyms</b>	Magnesiumdihydrogenphosphate
	Magnesiumphosphate, monobasic
	Monomagnesium orthophosphate
<b>Definition</b>	
Chemical name	Monomagnesiumdihydrogenmonophosphate
Einecs	236-004-6
Chemical formula	$Mg(H_2PO_4)_2 \cdot nH_2O$ (where n = 0 to 4)
Molecular weight	218,3 (anhydrous)
Assay	Not less than 51,0 % after ignition
<b>Description</b>	White, odourless, crystalline powder, slightly soluble in water
<b>Identification</b>	
A. Positive test for magnesium and for phosphate	
B. MgO content	Not less than 21,5 % after ignition
<b>Purity</b>	
Fluoride	Not more than 10 mg/kg (as fluorine)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 4 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

## E 343(ii) DIMAGNESIUM PHOSPHATE

<b>Synonyms</b>	Magnesiumhydrogenphosphate
	Magnesiumphosphate, dibasic
	Dimagnesium orthophosphate
	Secondary magnesiumphosphate
<b>Definition</b>	
Chemical name	Dimagnesiummonohydrogenmonophosphate
Einecs	231-823-5
Chemical formula	MgHPO <sub>4</sub> · nH <sub>2</sub> O (where n = 0-3)
Molecular weight	120,3 (anhydrous)
Assay	Not less than 96 % after ignition
<b>Description</b>	White, odourless, crystalline powder, slightly soluble in water
<b>Identification</b>	
A. Positive test for magnesium and for phosphate	
B. MgO content:	Not less than 33,0 % calculated on an anhydrous basis
<b>Purity</b>	
Fluoride	Not more than 10 mg/kg (as fluorine)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 4 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

## E 350 (i) SODIUM MALATE

<b>Synonyms</b>	Sodium salt of malic acid
<b>Definition</b>	
Chemical name	Disodium DL-malate, disodium salt of hydroxybutanedioic acid
Chemical formula	Hemihydrate: C <sub>4</sub> H <sub>4</sub> Na <sub>2</sub> O <sub>5</sub> · 1/2 H <sub>2</sub> O
	Trihydrate: C <sub>4</sub> H <sub>4</sub> Na <sub>2</sub> O <sub>5</sub> · 3H <sub>2</sub> O
Molecular weight	Hemihydrate: 187,05
	Trihydrate: 232,1

Assay	Content not less than 98,0 % on the anhydrous basis
<b>Description</b>	White crystalline powder or lumps
<b>Identification</b>	
A. Positive tests for 1,2-dicarboxylic acid and for sodium	
B. Azo dye formation	Positive
C. Solubility	Freely soluble in water
<b>Purity</b>	
Loss on drying	Not more than 7,0 % (130 °C, 4h) for the hemihydrate, or 20,5 %-23,5 % (130 °C, 4h) for the trihydrate
Alkalinity	Not more than 0,2 % as Na <sub>2</sub> CO <sub>3</sub>
Fumaric acid	Not more than 1,0 %
Maleic acid	Not more than 0,05 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

## E 350 (ii) SODIUM HYDROGEN MALATE

<b>Synonyms</b>	Monosodium salt of DL-malic acid
<b>Definition</b>	
Chemical name	Monosodium DL-malate, monosodium 2-DL-hydroxy succinate
Chemical formula	C <sub>4</sub> H <sub>5</sub> NaO <sub>5</sub>
Molecular weight	156,07
Assay	Content not less than 99,0 % on the anhydrous basis
<b>Description</b>	White powder
<b>Identification</b>	
A. Positive tests for 1,2-dicarboxylic acid and for sodium	
B. Azo dye formation	Positive
<b>Purity</b>	

*Status: This is the original version (as it was originally adopted).*

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

<b>Synonyms</b>	Potassium salt of malic acid
<b>Definition</b>	
Chemical name	Dipotassium DL-malate, dipotassium salt of hydroxybutanedioic acid
Chemical formula	C <sub>4</sub> H <sub>4</sub> K <sub>2</sub> O <sub>5</sub>
Molecular weight	210,27
Assay	Content not less than 59,5 %
<b>Description</b>	Colourless or almost colourless aqueous solution
<b>Identification</b>	
A. Positive tests for 1,2-dicarboxylic acid and for potassium	
B. Azo dye formation	Positive
<b>Purity</b>	
Alkalinity	Not more than 0,2 % as K <sub>2</sub> CO <sub>3</sub>
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

<b>Synonyms</b>	Calcium salt of malic acid
<b>Definition</b>	
Chemical name	Calcium DL-malate, calcium- $\alpha$ -hydroxysuccinate, calcium salt of hydroxybutanedioic acid

Chemical formula	$C_4H_5CaO_5$
Molecular weight	172,14
Assay	Content not less than 97,5 % on the anhydrous basis
<b>Description</b>	White powder
<b>Identification</b>	
A. Positive tests for malate, 1,2-dicarboxylic acid and for calcium	
B. Azo dye formation	Positive
C. Solubility	Slightly soluble in water
<b>Purity</b>	
Loss on drying	Not more than 2 % (100 °C, 3h)
Alkalinity	Not more than 0,2 % as $CaCO_3$
Maleic acid	Not more than 0,05 %
Fumaric acid	Not more than 1,0 %
Fluoride	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

## E 352 (ii) CALCIUM HYDROGEN MALATE

<b>Synonyms</b>	Monocalcium salt of DL-malic acid
<b>Definition</b>	
Chemical name	Monocalcium DL-malate, monocalcium 2-DL-hydroxysuccinate
Chemical formula	$(C_4H_5O_5)_2Ca$
Assay	Content not less than 97,5 % on the anhydrous basis
<b>Description</b>	White powder
<b>Identification</b>	
A. Positive tests for 1,2-dicarboxylic acid and for calcium	
B. Azo dye formation	Positive

*Status: This is the original version (as it was originally adopted).*

<b>Purity</b>	
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 353 METATARTARIC ACID

<b>Synonyms</b>	Ditartaric acid
<b>Definition</b>	
Chemical name	Metatartaric acid
Chemical formula	C <sub>4</sub> H <sub>6</sub> O <sub>6</sub>
Assay	Not less than 99,5 %
<b>Description</b>	Crystalline or powder form with a white or yellowish colour. Very deliquescent with a faint odour of caramel
<b>Identification</b>	
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
<b>Purity</b>	
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

<b>Synonyms</b>	L-Calcium tartrate
<b>Definition</b>	
Chemical name	Calcium L(+)-2,3-dihydroxybutanedioate dihydrate
Chemical formula	C <sub>4</sub> H <sub>4</sub> CaO <sub>6</sub> · 2H <sub>2</sub> O



Molecular weight	224,18
Assay	Not less than 98,0 %
<b>Description</b>	Fine crystalline powder with a white or off-white colour
<b>Identification</b>	
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 $[\alpha]_D^{20}$	7,0° to 7,4° (0,1 % in a 1N de HCl solution)
C. pH of a 5 % slurry	Between 6,0 and 9,0
<b>Purity</b>	
Sulphates (as H <sub>2</sub> SO <sub>4</sub> )	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

## E 355 ADIPIC ACID

<b>Definition</b>	
Chemical name	Hexanedioic acid, 1,4-butanedicarboxylic acid
Einecs	204-673-3
Chemical formula	C <sub>6</sub> H <sub>10</sub> O <sub>4</sub>
Molecular weight	146,14
Assay	Content not less than 99,6 %
<b>Description</b>	White odourless crystals or crystalline powder
<b>Identification</b>	
A. Melting range	151,5 °C-154,0 °C
B. Solubility	Slightly soluble in water. Freely soluble in ethanol
<b>Purity</b>	
Water	Not more than 0,2 % (Karl Fischer method)
Sulphated ash	Not more than 20 mg/kg

*Status: This is the original version (as it was originally adopted).*

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

#### E 356 SODIUM ADIPATE

<b>Definition</b>	
Chemical name	Sodium adipate
Einecs	231-293-5
Chemical formula	$C_6H_8Na_2O_4$
Molecular weight	190,11
Assay	Content not less than 99,0 % (on anhydrous basis)
<b>Description</b>	
White odourless crystals or crystalline powder	
<b>Identification</b>	
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	
<b>Purity</b>	
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

<b>Definition</b>	
Chemical name	Potassium adipate
Einecs	242-838-1
Chemical formula	$C_6H_8K_2O_4$
Molecular weight	222,32
Assay	Content not less than 99,0 % (on anhydrous basis)
<b>Description</b>	
White odourless crystals or crystalline powder	

<b>Identification</b>	
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	
<b>Purity</b>	
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 363 SUCCINIC ACID

<b>Definition</b>	
Chemical name	Butanedioic acid
Einecs	203-740-4
Chemical formula	C <sub>4</sub> H <sub>6</sub> O <sub>4</sub>
Molecular weight	118,09
Assay	Content no less than 99,0 %
<b>Description</b>	Colourless or white, odourless crystals
<b>Identification</b>	
A. Melting range	Between 185,0 °C and 190,0 °C
<b>Purity</b>	
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

<b>Synonyms</b>	Tribasic ammonium citrate
<b>Definition</b>	
Chemical name	Triammonium salt of 2-hydroxypropan-1,2,3-tricarboxylic acid
Einecs	222-394-5
Chemical formula	C <sub>6</sub> H <sub>17</sub> N <sub>3</sub> O <sub>7</sub>

*Status: This is the original version (as it was originally adopted).*

Molecular weight	243,22
Assay	Content not less than 97,0 %
<b>Description</b>	White to off-white crystals or powder
<b>Identification</b>	
A. Positive tests for ammonium and for citrate	
B. Solubility	Freely soluble in water
<b>Purity</b>	
Oxalate	Not more than 0,04 % (as oxalic acid)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

#### E 385 CALCIUM DISODIUM ETHYLENEDIAMINETETRAACETATE

<b>Synonyms</b>	Calcium disodium EDTA
	Calcium disodium edetate
<b>Definition</b>	
Chemical name	N, N'-1,2-EthanediyIbis [N-(carboxymethyl)-glycinate] [(4-)-O,O',O <sup>N</sup> ,O <sup>N</sup> ]calciate(2)-disodium Calcium disodium ethylenediaminetetra acetate Calcium disodium (ethylenedinitrilo)tetra acetate
Einecs	200-529-9
Chemical formula	C <sub>10</sub> H <sub>12</sub> O <sub>8</sub> CaN <sub>2</sub> Na <sub>2</sub> ·2H <sub>2</sub> O
Molecular weight	410,31
Assay	Content not less than 97 % on the anhydrous basis
<b>Description</b>	White, odourless crystalline granules or white to nearly white powder, slightly hygroscopic
<b>Identification</b>	
A. Positive tests for sodium and for calcium	
B. Chelating activity to metal ions positive	

C.	pH of a 1 % solution between 6,5 and 7,5	
<b>Purity</b>		
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

## E 400 ALGINIC ACID

<b>Definition</b>	Linear glycuronoglycan consisting mainly of $\beta$ -(1-4) linked D-mannuronic and $\alpha$ -(1-4) linked L-guluronic acid units in pyranose ring form. Hydrophilic colloidal carbohydrate extracted by the use of dilute alkali from natural strains of various species of brown seaweeds ( <i>Phaeophyceae</i> )	
Einecs	232-680-1	
Chemical formula	$(C_6H_8O_6)_n$	
Molecular weight	10 000-600 000 (typical average)	
Assay	Alginic acid yields, on the anhydrous basis, not less than 20 % and not more than 23 % of carbon dioxide (CO <sub>2</sub> ), equivalent to not less than 91 % and not more than 104,5 % of alginic acid $(C_6H_8O_6)_n$ (calculated on equivalent weight basis of 200)	
<b>Description</b>	Alginic acid occurs in filamentous, grainy, granular and powdered forms. It is a white to yellowish brown and nearly odourless	
<b>Identification</b>		
A.	Solubility	Insoluble in water and organic solvents, slowly soluble in solutions of sodium carbonate, sodium hydroxide and trisodium phosphate
B.	Calcium chloride precipitation test	To a 0,5 % solution of the sample in 1 M sodium hydroxide solution, add one fifth of its volume of a 2,5 % solution of calcium chloride. A voluminous, gelatinous precipitate is formed. This test distinguishes alginic acid from acacia gum, sodium carboxymethyl cellulose, carboxymethyl starch, carrageenan, gelatin, gum ghatti,

*Status: This is the original version (as it was originally adopted).*

	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
<b>Purity</b>	
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
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

#### E 401 SODIUM ALGINATE

<b>Definition</b>	
Chemical name	Sodium salt of alginic acid
Chemical formula	(C <sub>6</sub> H <sub>7</sub> NaO <sub>6</sub> ) <sub>n</sub>
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)
<b>Description</b>	Nearly odourless, white to yellowish fibrous or granular powder
<b>Identification</b>	
A. Positive test for sodium and alginic acid	
<b>Purity</b>	
Loss on drying	Not more than 15 % (105 °C, 4 hours)
Water-insoluble matter	Not more than 2 % on the anhydrous basis
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

## E 402 POTASSIUM ALGINATE

<b>Definition</b>	
Chemical name	Potassium salt of alginic acid
Chemical formula	(C <sub>6</sub> H <sub>7</sub> KO <sub>6</sub> ) <sub>n</sub>
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)
<b>Description</b>	Nearly odourless, white to yellowish fibrous or granular powder
<b>Identification</b>	
A. Positive test for potassium and for alginic acid	

*Status: This is the original version (as it was originally adopted).*

<b>Purity</b>	
Loss on drying	Not more than 15 % (105 °C, 4 hours)
Water-insoluble matter	Not more than 2 % on the anhydrous basis
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

#### E 403 AMMONIUM ALGINATE

<b>Definition</b>	
Chemical name	Ammonium salt of alginic acid
Chemical formula	(C <sub>6</sub> H <sub>11</sub> NO <sub>6</sub> ) <sub>n</sub>
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)
<b>Description</b>	White to yellowish fibrous or granular powder
<b>Identification</b>	
A. Positive test for ammonium and alginic acid	
<b>Purity</b>	
Loss on drying	Not more than 15 % (105 °C, 4 hours)
Sulphated ash	Not more than 7 % on the dried basis
Water-insoluble matter	Not more than 2 % on the anhydrous basis
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg



Cadmium	Not more than 1 mg/kg
Heavy metals	Not more than 20 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

## E 404 CALCIUM ALGINATE

<b>Synonyms</b>	Calcium salt of alginate
<b>Definition</b>	
Chemical name	Calcium salt of alginic acid
Chemical formula	$(C_6H_7Ca_{1/2}O_6)_n$
Molecular weight	10 000-600 000 (typical average)
Assay	Yields, on the anhydrous basis, not less than 18 % and not more than 21 % carbon dioxide corresponding to not less than 89,6 % and not more than 104,5 % of calcium alginate (calculated on an equivalent weight basis of 219)
<b>Description</b>	Nearly odourless, white to yellowish fibrous or granular powder
<b>Identification</b>	
A. Positive test for calcium and alginic acid	
<b>Purity</b>	
Loss on drying	Not more than 15,0 % (105 °C, 4 hours)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

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

*Status: This is the original version (as it was originally adopted).*

<b>Synonyms</b>	Hydroxypropyl alginate
	1,2-propanediol ester of alginic acid
	Propylene glycol alginate
<b>Definition</b>	
Chemical name	Propane-1,2-diol ester of alginic acid; varies in composition according to its degree of esterification and the percentage of free and neutralised carboxyl groups in the molecule
Chemical formula	(C <sub>9</sub> H <sub>14</sub> O <sub>7</sub> ) <sub>n</sub> (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 CO <sub>2</sub> of carbon dioxide
<b>Description</b>	Nearly odourless, white to yellowish brown fibrous or granular powder
<b>Identification</b>	
A.	Positive test for 1,2-propanediol and alginic acid after hydrolysis
<b>Purity</b>	
Loss on drying	Not more than 20 % (105 °C, 4 hours)
Total propane-1,2-diol content	Not less than 15 % and not more than 45 %
Free propane-1,2-diol content	Not more than 15 %
Water-insoluble matter	Not more than 2 % on the anhydrous basis
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

#### E 406 AGAR

<b>Synonyms</b>	Gelose
	Japan agar

	Bengal, Ceylon, Chinese or Japanese isinglass
	Layor Carang
<b>Definition</b>	
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 <i>Gelidiaceae</i> and <i>Sphaerococcaceae</i> and related red algae of the class <i>Rhodophyceae</i>
Einecs	232-658-1
Assay	The threshold gel concentration should not be higher than 0,25 %
<b>Description</b>	Agar is odourless or has a slight characteristic odour. Unground agar usually occurs in bundles consisting of thin, membranous, agglutinated strips, or in cut, flaked or granulated forms. It may be light yellowish-orange, yellowish-grey to pale yellow, or colourless. It is tough when damp, brittle when dry. Powdered agar is white to yellowish-white or pale yellow. When examined in water under a microscope, the agar appears granular and somewhat filamentous. A few fragments of the spicules of sponges and a few frustules of diatoms may be present. In chloral hydrate solution, the powdered agar appears more transparent than in water, more or less granular, striated, angular and occasionally contains frustules of diatoms. Gel strength may be standardised by the addition of dextrose and maltodextrines or sucrose
<b>Identification</b>	
A. Solubility	Insoluble in cold water; soluble in boiling water
<b>Purity</b>	
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

*Status: This is the original version (as it was originally adopted).*

Acid-insoluble ash (insoluble in approximately 3N Hydrochloric acid)	Not more than 0,5 % determined at 550 °C on the anhydrous basis
Insoluble matter (in hot water)	Not more than 1,0 %
Starch	Not detectable by the following method: to a 1 in 10 solution of the sample add a few drops of iodine solution. No blue colour is produced
Gelatin and other proteins	Dissolve about 1 g of agar in 100 ml of boiling water and allow to cool of about 50 °C. To 5 ml of the solution add 5 ml of trinitrophenol solution (1 g of anhydrous trinitrophenol/100 ml of hot water). No turbidity appears within 10 minutes
Water absorption	Place 5 g to agar in a 100 ml graduated cylinder, fill to the mark with water, mix and allow to stand at about 25 °C for 24 hours. Pour the contents of the cylinder through moistened glass wool, allowing the water to drain into a second 100 ml graduated cylinder. Not more than 75 ml of water is obtained
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

#### E 407 CARRAGEENAN

<b>Synonyms</b>	Products of commerce are sold under different names such as:
	Irish moss gelose
	Eucheuman (from <i>Eucheuma</i> spp.)
	Iridophycan (from <i>Iridaea</i> spp.)
	Hypnean (from <i>Hypnea</i> spp.)
	Furcellaran or Danish agar (from <i>Furcellaria fastigiata</i> )
	Carrageenan (from <i>Chondrus</i> and <i>Gigartina</i> spp.)
<b>Definition</b>	Carrageenan is obtained by aqueous extraction of natural strains of seaweeds of <i>Gigartinaceae</i> , <i>Solieriaceae</i> , <i>Hypneaceae</i> and <i>Furcellariaceae</i> , families of the

	class <i>Rhodophyceae</i> (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
<b>Description</b>	Yellowish to colourless, coarse to fine powder which is practically odourless
<b>Identification</b>	
A. Positive tests for galactose, for anhydrogalactose and for sulphate	
<b>Purity</b>	
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 SO <sub>4</sub> )
Ash	Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C
Acid-insoluble ash	Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)
Acid-insoluble matter	Not more than 2 % on the dried basis (insoluble in 1 % v/v sulphuric acid)
Low molecular weight carrageenan (Molecular weight fraction below 50 kDa)	Not more than 5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

<b>Synonyms</b>	PES (acronym for processed eucheuma seaweed)
<b>Definition</b>	Processed eucheuma seaweed is obtained by aqueous alkaline (KOH) treatment of the natural strains of seaweeds <i>Eucheuma cottonii</i> and <i>Eucheuma spinosum</i> , of the class <i>Rhodophyceae</i> (red seaweeds) to remove impurities and by fresh water washing and drying to obtain the product. Further purification may be achieved by washing with methanol, ethanol or propane-2-ol and drying. The product consists chiefly of the potassium salts of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3,6-anhydrogalactose. Sodium, calcium and magnesium salts of the polysaccharide sulphate esters are present in lesser amounts. Up to 15 % algal cellulose is also present in the product. The carrageenan in processed eucheuma seaweed shall not be hydrolysed or otherwise chemically degraded
<b>Description</b>	Tan to yellowish, coarse to fine powder which is practically odourless
<b>Identification</b>	
A. Positive tests for galactose, for anhydrogalactose and for sulphate	
B. Solubility	Forms cloudy viscous suspensions in water. Insoluble in ethanol
<b>Purity</b>	
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 SO <sub>4</sub> )
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
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

## E 410 LOCUST BEAN GUM

<b>Synonyms</b>	Carob bean gum
	Algaroba gum
<b>Definition</b>	Locust bean gum is the ground endosperm of the seeds of the natural strains of carob tree, <i>Cerastionia siliqua</i> (L.) Taub. (family <i>Leguminosae</i> ). Consists mainly of a high molecular weight hydrocolloidal polysaccharide, composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as galactomannan
Molecular weight	50 000-3 000 000
Einecs	232-541-5
Assay	Galactomannan content not less than 75 %
<b>Description</b>	White to yellowish-white, nearly odourless powder
<b>Identification</b>	
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

*Status: This is the original version (as it was originally adopted).*

C. Solubility	Soluble in hot water, insoluble in ethanol
<b>Purity</b>	
Loss on drying	Not more than 15 % (105 °C, 5 hours)
Ash	Not more than 1,2 % determined at 800 °C
Protein (N × 6,25)	Not more than 7 %
Acid-insoluble matter	Not more than 4 %
Starch	Not detectable by the following method: to a 1 in 10 solution of the sample add a few drops of iodine solution. No blue colour is produced
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Ethanol and propane-2-ol	Not more than 1 %, single or in combination

#### E 412 GUAR GUM

<b>Synonyms</b>	Gum cyamopsis
	Guar flour
<b>Definition</b>	Guar gum is the ground endosperm of the seeds of natural strains of the guar plant, <i>Cyamopsis tetragonolobus</i> (L.) Taub. (family <i>Leguminosae</i> ). Consists mainly of a high molecular weight hydrocolloidal polysaccharide composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as galactomannan
Einecs	232-536-0
Molecular weight	50 000-8 000 000
Assay	Galactomannan content not less than 75 %
<b>Description</b>	A white to yellowish-white, nearly odourless powder
<b>Identification</b>	
A. Positive tests for galactose and for mannose	



B. Solubility	Soluble in cold water
<b>Purity</b>	
Loss on drying	Not more than 15 % (105 °C, 5 hours)
Ash	Not more than 1,5 % determined at 800 °C
Acid-insoluble matter	Not more than 7 %
Protein (N × 6,25)	Not more than 10 %
Starch	Not detectable by the following method: to a 1 in 10 solution of the sample add a few drops of iodine solution. (No blue colour is produced)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

## E 413 TRAGACANTH

<b>Synonyms</b>	Tragacanth gum
	Tragant
<b>Definition</b>	Tragacanth is a dried exudation obtained from the stems and branches of natural strains of <i>Astragalus gummifer</i> Labillardiere and other Asiatic species of <i>Astragalus</i> (family <i>Leguminosae</i> ). It consists mainly of high molecular weight polysaccharides (galactoarabans and acidic polysaccharides) which, on hydrolysis, yield galacturonic acid, galactose, arabinose, xylose and fucose. Small amounts of rhamnose and of glucose (derived from traces of starch and/or cellulose) may also be present
Molecular weight	Approximately 800 000
Einecs	232-252-5
<b>Description</b>	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

*Status: This is the original version (as it was originally adopted).*

	mucilaginous taste. Powdered tragacanth is white to pale yellow or pinkish brown (pale tan) in colour
<b>Identification</b>	
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
<b>Purity</b>	
Negative test for Karaya gum	Boil 1 g with 20 ml of water until a mucilage is formed. Add 5 ml of hydrochloric acid and again boil the mixture for five minutes. No permanent pink or red colour develops
Loss on drying	Not more than 16 % (105 °C, 5 hours)
Total ash	Not more than 4 %
Acid insoluble ash	Not more than 0,5 %
Acid insoluble matter	Not more than 2 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
<i>Salmonella</i> spp.	Negative in 10 g
<i>E. coli</i>	Negative in 5 g

#### E 414 ACACIA GUM

<b>Synonyms</b>	Gum arabic
<b>Definition</b>	Acacia gum is a dried exudation obtained from the stems and branches of natural strains of <i>Acacia senegal</i> (L) Willdenow or closely related species of Acacia (family <i>Leguminosae</i> ). It consists mainly of high molecular weight polysaccharides and their calcium, magnesium and potassium salts, which on hydrolysis yield arabinose, galactose, rhamnose and glucuronic acid
Molecular weight	Approximately 350 000
Einecs	232-519-5
<b>Description</b>	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.
<b>Identification</b>	
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
<b>Purity</b>	
Loss on drying	Not more than 17 % (105 °C, 5 hours) for granular and not more than 10 % (105 °C, 4 hours) for spray-dried material
Total ash	Not more than 4 %
Acid insoluble ash	Not more than 0,5 %
Acid insoluble matter	Not more than 1 %
Starch or dextrin	Boil a 1 in 50 solution of the gum and cool. To 5 ml add 1 drop of iodine solution. No bluish or reddish colours are produced
Tannin	To 10 ml of a 1 in 50 solution add about 0,1 ml of ferric chloride solution (9 g FeCl <sub>3</sub> .6H <sub>2</sub> O made up to 100 ml with water). No blackish colouration or blackish precipitate is formed
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Hydrolysis products	Mannose, xylose and galacturonic acid are absent (determined by chromatography)
<i>Salmonella</i> spp.	Negative in 10 g
<i>E. coli</i>	Negative in 5 g

## E 415 XANTHAN GUM

<b>Definition</b>	Xanthan gum is a high molecular weight polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with natural strains of <i>Xanthomonas campestris</i> , purified by recovery with ethanol or propane-2-ol, dried and milled. It contains D-glucose and D-mannose as the dominant hexose units, along with D-glucuronic
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*Status: This is the original version (as it was originally adopted).*

	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 CO <sub>2</sub> corresponding to between 91 % and 108 % of xanthan gum
<b>Description</b>	Cream-coloured powder
<b>Identification</b>	
A. Solubility	Soluble in water. Insoluble in ethanol
<b>Purity</b>	
Loss on drying	Not more than 15 % (105 °C, 2 1/2 hours)
Total ash	Not more than 16 % on the anhydrous basis determined at 650 °C after drying at 105 °C for four hours
Pyruvic acid	Not less than 1,5 %
Nitrogen	Not more than 1,5 %
Ethanol and propan-2-ol	Not more than 500 mg/kg singly or in combination
Lead	Not more than 2 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and mould	Not more than 300 colonies per gram
<i>E. coli</i>	Absent in 5 g
<i>Salmonella</i> spp.	Absent in 10 g
<i>Xanthomonas campestris</i>	Viable cells absent in 1 g

#### E 416 KARAYA-GUM

<b>Synonyms</b>	Katilo
	Kadaya
	Gum <i>sterculia</i>
	<i>Sterculia</i>
	Karaya, gum karaya
	Kullo
	Kuterra
<b>Definition</b>	Karaya gum is a dried exudation from the stems and branches of natural strains

	of: <i>Sterculia urens</i> Roxburgh and other species of <i>Sterculia</i> (family <i>Sterculiaceae</i> ) or from <i>Cochlospermum gossypium</i> A.P. De Candolle or other species of <i>Cochlospermum</i> (family <i>Bixaceae</i> ). It consists mainly of high molecular weight acetylated polysaccharides, which on hydrolysis yield galactose, rhamnose, and galacturonic acid, together with minor amounts of glucuronic acid
Einecs	232-539-4
<b>Description</b>	Karaya gum occurs in tears of variable size and in broken irregular pieces having a characteristic semi-crystalline appearance. It is pale yellow to pinkish brown in colour, translucent and horny. Powdered karaya gum is a pale grey to pinkish brown. The gum has a distinctive odour of acetic acid
<b>Identification</b>	
A. Solubility	Insoluble in ethanol
B. Swelling in ethanol solution	Karaya gum swells in 60 % ethanol distinguishing it from other gums
<b>Purity</b>	
Loss on drying	Not more than 20 % (105 °C, 5 hours)
Total ash	Not more than 8 %
Acid insoluble ash	Not more than 1 %
Acid insoluble matter	Not more than 3 %
Volatile acid	Not less than 10 % (as acetic acid)
Starch	Not detectable
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
<i>Salmonella</i> spp.	Negative in 10 g
<i>E. coli</i>	Negative in 5 g

## E 417 TARA GUM

<b>Definition</b>	Tara gum is obtained by grinding the endosperm of the seeds of natural strains of <i>Caesalpinia spinosa</i> (family <i>Leguminosae</i> ).
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*Status: This is the original version (as it was originally adopted).*

	It consists chiefly of polysaccharides of high molecular weight composed mainly of galactomannans. The principal component consists of a linear chain of (1-4)- $\beta$ -D-mannopyranose units with $\alpha$ -D-galactopyranose units attached by (1-6) linkages. The ratio of mannose to galactose in tara gum is 3:1. (In locust bean gum this ratio is 4:1 and in guar gum 2:1)
Einecs	254-409-6
<b>Description</b>	A white to white-yellow odourless powder
<b>Identification</b>	
A. Solubility	Soluble in water Insoluble in ethanol
B. Gel formation	To an aqueous solution of the sample add small amounts of sodium borate. A gel is formed
<b>Purity</b>	
Loss on drying	Not more than 15 %
Ash	Not more than 1,5 %
Acid insoluble matter	Not more than 2 %
Protein	Not more than 3,5 % (factor N $\times$ 5,7)
Starch	Not detectable
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

#### E 418 GELLAN GUM

<b>Definition</b>	Gellan gum is a high molecular weight polysaccharide gum produced by a pure culture fermentation of a carbohydrate by natural strains of <i>Pseudomonas elodea</i> , purified by recovery with isopropyl alcohol, dried, and milled. The high molecular weight polysaccharide is principally composed of a tetrasaccharide repeating unit of one rhamnose, one glucuronic acid, and two glucoses, and substituted with acyl (glyceryl and acetyl) groups as the O-glycosidically linked esters. The glucuronic acid is
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	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 CO <sub>2</sub>
<b>Description</b>	An off-white powder
<b>Identification</b>	
A. Solubility	Soluble in water, forming a viscous solution. Insoluble in ethanol
<b>Purity</b>	
Loss on drying	Not more than 15 % after drying (105 °C, 2 1/2 hours)
Nitrogen	Not more than 3 %
Propane-2-ol	Not more than 750 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Total plate count	Not more than 10 000 colonies per gram
Yeast and mould	Not more than 400 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

## E 420(i) SORBITOL

Purity criteria for this additive are the same as set out for this additive in Annex I to Commission Directive 2008/60/EC<sup>(6)</sup>.

## E 420(ii) SORBITOL SYRUP

Purity criteria for this additive are the same as set out for this additive in Annex I to Directive 2008/60/EC.

## E 421 MANNITOL

Purity criteria for this additive are the same as set out for this additive in Annex I to Directive 2008/60/EC.

## E 422 GLYCEROL

<b>Synonyms</b>	Glycerin
	Glycerine

*Status: This is the original version (as it was originally adopted).*

<b>Definition</b>	
Chemical names	1,2,3-propanetriol Glycerol Trihydroxypropane
Einecs	200-289-5
Chemical formula	C <sub>3</sub> H <sub>8</sub> O <sub>3</sub>
Molecular weight	92,1
Assay	Content not less than 98 % of glycerol on the anhydrous basis
<b>Description</b>	Clear, colourless hygroscopic syrupy liquid with not more than a slight characteristic odour, which is neither harsh nor disagreeable
<b>Identification</b>	
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] <sub>D</sub> <sup>20</sup>	Between 1,471 and 1,474
<b>Purity</b>	
Water	Not more than 5 % (Karl Fischer method)
Sulphated ash	Not more than 0,01 % determined at 800 ± 25 °C
Butanetriols	Not more than 0,2 %
Acrolein, glucose and ammonium compounds	Heat a mixture of 5 ml of glycerol and 5 ml of potassium hydroxide solution (1 in 10) at 60 °C for five minutes. It neither becomes yellow nor emits an odour of ammonia
Fatty acids and esters	Not more than 0,1 % calculated as butyric acid
Chlorinated compounds	Not more than 30 mg/kg (as chlorine)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg



## E 425(i) KONJAC GUM

<b>Definition</b>	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 <i>Amorphophallus konjac</i> . 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 $\beta(1-4)$ -glycosidic bonds. Shorter side chains are attached through $\beta(1-3)$ -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
<b>Description</b>	A white to cream to light tan powder
<b>Identification</b>	
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 <sup>-1</sup> s <sup>-1</sup> at 25 °C
<b>Purity</b>	
Loss on drying	Not more than 12 % (105 °C, 5 h)
Starch	Not more than 3 %
Protein	Not more than 3 % (N × 5,7)

*Status: This is the original version (as it was originally adopted).*

	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 4h)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
<i>Salmonella</i> spp.	Absent in 12,5 g
<i>E. coli</i>	Absent in 5 g

#### E 425(ii) KONJAC GLUCOMANNAN

<b>Definition</b>	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 <i>Amorphophallus konjac</i> . The main component is the water-soluble high-molecular-weight polysaccharide glucomannan, which consists of D-mannose and D-glucose units at a molar ratio of 1,6:1,0, connected by $\beta(1-4)$ -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
<b>Description</b>	White to slightly brownish fine particle size, free flowing and odourless powder
<b>Identification</b>	
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 <sup>-1</sup> s <sup>-1</sup> at 25 °C
<b>Purity</b>	
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 SO <sub>2</sub> )	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
<i>Salmonella</i> spp.	Absent in 12,5 g
<i>E. coli</i>	Absent in 5 g

## E 426 SOYBEAN HEMICELLULOSE

<b>Definition</b>	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
<b>Description</b>	Free flowing spray-dried white powder
<b>Identification</b>	
A. Solubility pH of 1 % solution	Soluble in hot and cold water without gel formation 5,5±1,5
B. Viscosity of 10 % solution	Not more than 200 mPa.s
<b>Purity</b>	

*Status: This is the original version (as it was originally adopted).*

Loss on drying	Not more than 7 % (105 °C, 4h)
Protein	Not more than 14 %
Total ash	Not more than 9,5 % (600 °C, 4h)
Arsenic	Not more than 2 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Standard plate count	Not more than 3 000 colonies per gram
Yeast and mould	Not more than 100 colonies per gram
<i>E. coli</i>	Negative in 10 g

#### E 431 POLYOXYETHYLENE (40) STEARATE

<b>Synonyms</b>	Polyoxyl (40) stearate
	polyoxyethylene (40) monostearate
<b>Definition</b>	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
<b>Description</b>	Cream-coloured flakes or waxy solid at 25 °C with a faint odour
<b>Identification</b>	
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
<b>Purity</b>	
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)

<b>Synonyms</b>	Polysorbate 20
	Polyoxyethylene (20) sorbitan monolaurate
<b>Definition</b>	A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial lauric acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides
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
<b>Description</b>	A lemon to amber-coloured oily liquid at 25 °C with a faint characteristic odour
<b>Identification</b>	
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
<b>Purity</b>	
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
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 433 POLYOXYETHYLENE SORBITAN MONOOLEATE (POLYSORBATE 80)

<b>Synonyms</b>	Polysorbate 80
	Polyoxyethylene (20) sorbitan monooleate
<b>Definition</b>	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
<b>Description</b>	A lemon to amber-coloured oily liquid at 25 °C with a faint characteristic odour
<b>Identification</b>	
A. Solubility	Soluble in water, ethanol, methanol, ethyl acetate and toluene. Insoluble in mineral oil and petroleum ether
B. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
<b>Purity</b>	
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)

<b>Synonyms</b>	Polysorbate 40
	Polyoxyethylene (20) sorbitan monopalmitate

<b>Definition</b>	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
<b>Description</b>	A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour
<b>Identification</b>	
A. Solubility	Soluble in water, ethanol, methanol, ethyl acetate and acetone. Insoluble in mineral oil
B. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
<b>Purity</b>	
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 POLYOXYETHYLENE SORBITAN MONOSTEARATE (POLYSORBATE 60)

<b>Synonyms</b>	Polysorbate 60 Polyoxyethylene (20) sorbitan monostearate
<b>Definition</b>	A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial stearic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides
Assay	Content not less than 65 % of oxyethylene groups, equivalent to not less than 97 % of

*Status: This is the original version (as it was originally adopted).*

		polyoxyethylene (20) sorbitan monostearate on the anhydrous basis
<b>Description</b>		A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour
<b>Identification</b>		
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
<b>Purity</b>		
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
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 436 POLYOXYETHYLENE SORBITAN TRISTEARATE (POLYSORBATE 65)

<b>Synonyms</b>		Polysorbate 65 Polyoxyethylene (20) sorbitan tristearate
<b>Definition</b>		A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial stearic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides
Assay		Content not less than 46 % of oxyethylene groups, equivalent to not less than 96 % of polyoxyethylene (20) sorbitan tristearate on the anhydrous basis
<b>Description</b>		A tan-coloured, waxy solid at 25 °C with a faint characteristic odour
<b>Identification</b>		



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
<b>Purity</b>		
	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

## E 440 (i) PECTIN

<b>Definition</b>	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	
<b>Description</b>	White, light yellow, light grey or light brown powder	
<b>Identification</b>		
A.	Solubility	Soluble in water forming a colloidal, opalescent solution. Insoluble in ethanol
<b>Purity</b>		

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*Status: This is the original version (as it was originally adopted).*

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Loss on drying	Not more than 12 % (105 °C, 2 hours)
Acid insoluble ash	Not more than 1 % (insoluble in approximately 3N hydrochloric acid)
Sulphur dioxide	Not more than 50 mg/kg on the anhydrous basis
Nitrogen content	Not more than 1,0 % after washing with acid and ethanol
Free methanol, ethanol and propane-2-ol	Not more than 1 %, singly or in combination, on the anhydrous basis
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

#### E 440 (ii) AMIDATED PECTIN

<b>Definition</b>	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
<b>Description</b>	White, light yellow, light greyish or light brownish powder
<b>Identification</b>	
A. Solubility	Soluble in water forming a colloidal, opalescent solution. Insoluble in ethanol
<b>Purity</b>	
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

<b>Synonyms</b>	Ammonium salts of phosphatidic acid, mixed ammonium salts of phosphorylated glycerides
<b>Definition</b>	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
<b>Assay</b>	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)
<b>Description</b>	Unctuous semi-solid
<b>Identification</b>	
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	
<b>Purity</b>	
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

<b>Synonyms</b>	SAIB
<b>Definition</b>	Sucrose acetate isobutyrate is a mixture of the reaction products formed by the esterification of food grade sucrose with acetic acid anhydride and isobutyric anhydride, followed by distillation. The mixture contains all possible combinations of esters in which the molar ratio of acetate to butyrate is about 2:6
Einecs	204-771-6
Chemical name	Sucrose diacetate hexaisobutyrate
Chemical formulae	$C_{40}H_{62}O_{19}$
Molecular weight	832-856 (approximate), $C_{40}H_{62}O_{19}$ : 846,9
Assay	Content not less than 98,8 % and not more than 101,9 % of $C_{40}H_{62}O_{19}$
<b>Description</b>	A pale straw-coloured liquid, clear and free of sediment and having a bland odour
<b>Identification</b>	
A. Solubility	Insoluble in water. Soluble in most organic solvents
B. Refractive index	$[n]_D^{40}$ : 1,4492-1,4504
C. Specific gravity	$[d]_D^{25}$ : 1,141-1,151
<b>Purity</b>	
Triacetin	Not more than 0,1 %
Acid value	Not more than 0,2
Saponification value	Not less than 524 and not more than 540
Arsenic	Not more than 3 mg/kg
Lead	Not more than 3 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

## E 445 GLYCEROL ESTERS OF WOOD ROSIN

<b>Synonyms</b>	Ester gum
<b>Definition</b>	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 <sub>20</sub> H <sub>30</sub> O <sub>2</sub> , chiefly abietic acid. The substance is purified by steam stripping or by countercurrent steam distillation
<b>Description</b>	Hard, yellow to pale amber-coloured solid
<b>Identification</b>	
A. Solubility	Insoluble in water, soluble in acetone
B. Infrared absorption spectrum	Characteristic of the compound
<b>Purity</b>	
Specific gravity of solution	[d] <sup>20</sup> <sub>25</sub> not less than 0,935 when determined in a 50 % solution in d-limonene (97 %, boiling point 175,5-176 °C, d <sup>20</sup> <sub>4</sub> : 0,84)
Ring and ball softening range	Between 82 °C and 90 °C
Acid value	Not less than 3 and not more than 9
Hydroxyl value	Not less than 15 and not more than 45
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Test for absence of tall oil rosin (sulphur test)	When sulphur-containing organic compounds are heated in the presence of sodium formate, the sulphur is converted to hydrogen sulphide which can readily be detected by the use of lead acetate paper. A positive test indicates the use of tall oil rosin instead of wood rosin

## E 450 (i) DISODIUM DIPHOSPHATE

<b>Synonyms</b>	Disodium dihydrogen diphosphate
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*Status: This is the original version (as it was originally adopted).*

	Disodium dihydrogen pyrophosphate
	Sodium acid pyrophosphate
	Disodium pyrophosphate
<b>Definition</b>	
Chemical name	Disodium dihydrogen diphosphate
Einecs	231-835-0
Chemical formula	$\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$
Molecular weight	221,94
Assay	Content not less than 95 % of disodium diphosphate
$\text{P}_2\text{O}_5$ Content	Not less than 63,0 % and not more than 64,5 %
<b>Description</b>	White powder or grains
<b>Identification</b>	
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
<b>Purity</b>	
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

<b>Synonyms</b>	Acid trisodium pyrophosphate
	Trisodium monohydrogen diphosphate
<b>Definition</b>	
Einecs	238-735-6
Chemical formula	Monohydrate: $\text{Na}_3\text{HP}_2\text{O}_7 \cdot \text{H}_2\text{O}$

	Anhydrous: $\text{Na}_3\text{HP}_2\text{O}_7$
Molecular weight	Monohydrate: 261,95
	Anhydrous: 243,93
Assay	Content not less than 95 % on the anhydrous basis
$\text{P}_2\text{O}_5$ content	Not less than 57 % and not more than 59 %
<b>Description</b>	White powder or grains, occurs anhydrous or as a monohydrate
<b>Identification</b>	
A. Positive tests for sodium and for phosphate	
B. Solubility	Soluble in water
C. pH of a 1 % solution	Between 6,7 and 7,5
<b>Purity</b>	
Loss on ignition	Not more than 4,5 % on the anhydrous compound
	Not more than 11,5 % on the monohydrous basis
Loss on drying	Not more than 0,5 % (105 °C, four hours)
Water-insoluble matter	Not more than 0,2 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

## E 450 (iii) TETRASODIUM DIPHOSPHATE

<b>Synonyms</b>	Tetrasodium pyrophosphate
	Sodium pyrophosphate
<b>Definition</b>	
Chemical name	Tetrasodium diphosphate
Einecs	231-767-1
Chemical formula	Anhydrous: $\text{Na}_4\text{P}_2\text{O}_7$
	Decahydrate: $\text{Na}_4\text{P}_2\text{O}_7 \cdot 10\text{H}_2\text{O}$

*Status: This is the original version (as it was originally adopted).*

Molecular weight	Anhydrous: 265,94
	Decahydrate: 446,09
Assay	Content not less than 95 % of Na <sub>4</sub> P <sub>2</sub> O <sub>7</sub> on the ignited basis
P <sub>2</sub> O <sub>5</sub> content	Not less than 52,5 % and not more than 54,0 %
<b>Description</b>	Colourless or white crystals, or a white crystalline or granular powder. The decahydrate effloresces slightly in dry air
<b>Identification</b>	
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
<b>Purity</b>	
Loss on ignition	Not more than 0,5 % for the anhydrous salt, not less than 38 % and not more than 42 % for the decahydrate, in both cases determined after drying at 105 °C for four hours, followed by ignition at 550 °C for 30 minutes
Water-insoluble matter	Not more than 0,2 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

#### E 450 (v) TETRAPOTASSIUM DIPHOSPHATE

<b>Synonyms</b>	Potassium pyrophosphate
	Tetrapotassium pyrophosphate
<b>Definition</b>	
Chemical name	Tetrapotassium diphosphate
Einecs	230-785-7
Chemical formula	K <sub>4</sub> P <sub>2</sub> O <sub>7</sub>
Molecular weight	330,34 (anhydrous)



Assay	Content not less than 95 % on the ignited basis
P <sub>2</sub> O <sub>5</sub> content	Not less than 42,0 % and not more than 43,7 % on the anhydrous basis
<b>Description</b>	Colourless crystals or white, very hygroscopic powder
<b>Identification</b>	
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
<b>Purity</b>	
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

<b>Synonyms</b>	Calcium pyrophosphate
<b>Definition</b>	
Chemical name	Dicalcium diphosphate Dicalcium pyrophosphate
Einecs	232-221-5
Chemical formula	Ca <sub>2</sub> P <sub>2</sub> O <sub>7</sub>
Molecular weight	254,12
Assay	Content not less than 96 %
P <sub>2</sub> O <sub>5</sub> content	Not less than 55 % and not more than 56 %
<b>Description</b>	A fine, white, odourless powder
<b>Identification</b>	

*Status: This is the original version (as it was originally adopted).*

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
<b>Purity</b>		
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

<b>Synonyms</b>	Acid calcium pyrophosphate	
	Monocalcium dihydrogen pyrophosphate	
<b>Definition</b>		
Chemical name	Calcium dihydrogen diphosphate	
Einecs	238-933-2	
Chemical formula	CaH <sub>2</sub> P <sub>2</sub> O <sub>7</sub>	
Molecular weight	215,97	
Assay	Content not less than 90 % on the anhydrous basis	
P <sub>2</sub> O <sub>5</sub> content	Not less than 61 % and not more than 64 %	
<b>Description</b>	White crystals or powder	
<b>Identification</b>		
A.	Positive tests for calcium and for phosphate	
<b>Purity</b>		
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

<b>Synonyms</b>	Pentasodium tripolyphosphate
	Sodium tripolyphosphate
<b>Definition</b>	
Chemical name	Pentasodium triphosphate
Einecs	231-838-7
Chemical formula	$\text{Na}_5\text{O}_{10}\text{P}_3 \cdot n\text{H}_2\text{O}$ (n = 0 or 6)
Molecular weight	367,86
Assay	Content not less than 85,0 % (anhydrous) or 65,0 % (hexahydrate)
P <sub>2</sub> O <sub>5</sub> content	Not less than 56 % and not more than 59 % (anhydrous) or not less than 43 % and not more than 45 % (hexahydrate)
<b>Description</b>	White, slightly hygroscopic granules or powder
<b>Identification</b>	
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
<b>Purity</b>	
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

*Status: This is the original version (as it was originally adopted).*

Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

#### E 451 (ii) PENTAPOTASSIUM TRIPHOSPHATE

<b>Synonyms</b>	Pentapotassium tripolyphosphate
	Potassium triphosphate
	Potassium tripolyphosphate
<b>Definition</b>	
Chemical name	Pentapotassium triphosphate
	Pentapotassium tripolyphosphate
Einecs	237-574-9
Chemical formula	$K_5O_{10}P_3$
Molecular weight	448,42
Assay	Content not less than 85 % on the anhydrous basis
P <sub>2</sub> O <sub>5</sub> content	Not less than 46,5 % and not more than 48 %
<b>Description</b>	White, very hygroscopic powder or granules
<b>Identification</b>	
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
<b>Purity</b>	
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

<b>Synonyms</b>	Sodium hexametaphosphate
	Sodium tetrapolyphosphate
	Graham's salt
	Sodium polyphosphates, glassy
	Sodium polymetaphosphate
	Sodium metaphosphate
<b>Definition</b>	Soluble sodium polyphosphates are obtained by fusion and subsequent chilling of sodium orthophosphates. These compounds are a class consisting of several amorphous, water-soluble polyphosphates composed of linear chains of metaphosphate units, $(\text{NaPO}_3)_x$ where $x \geq 2$ , terminated by $\text{Na}_2\text{PO}_4$ groups. These substances are usually identified by their $\text{Na}_2\text{O}/\text{P}_2\text{O}_5$ ratio or their $\text{P}_2\text{O}_5$ content. The $\text{Na}_2\text{O}/\text{P}_2\text{O}_5$ ratios vary from about 1,3 for sodium tetrapolyphosphate, where $x =$ approximately 4; to about 1,1 for Graham's salt, commonly called sodium hexametaphosphate, where $x = 13$ to 18; and to about 1,0 for the higher molecular weight sodium polyphosphates, where $x = 20$ to 100 or more. The pH of their solutions varies from 3,0 to 9,0
Chemical name	Sodium polyphosphate
Einecs	272-808-3
Chemical formula	Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula $\text{H}_{(n+2)}\text{P}_n\text{O}_{(3n+1)}$ where 'n' is not less than 2
Molecular weight	$(102)_n$
Assay $\text{P}_2\text{O}_5$ content	Not less than 60 % and not more than 71 % on the ignited basis
<b>Description</b>	Colourless or white, transparent platelets, granules, or powders
<b>Identification</b>	
A. Solubility	Very soluble in water
B. Positive tests for sodium and for phosphate	

*Status: This is the original version (as it was originally adopted).*

C. pH of a 1 % solution	Between 3,0 and 9,0
<b>Purity</b>	
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

<b>Synonyms</b>	Insoluble sodium metaphosphate
	Maddrell's salt
	Insoluble sodium polyphosphate, IMP
<b>Definition</b>	Insoluble sodium metaphosphate is a high molecular weight sodium polyphosphate composed of two long metaphosphate chains (NaPO <sub>3</sub> ) <sub>x</sub> that spiral in opposite directions about a common axis. The Na <sub>2</sub> O/P <sub>2</sub> O <sub>5</sub> 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 <sub>(n+2)</sub> P <sub>n</sub> O <sub>(3n+1)</sub> where 'n' is not less than 2
Molecular weight	(102) <sub>n</sub>
P <sub>2</sub> O <sub>5</sub> content	Not less than 68,7 % and not more than 70,0 %
<b>Description</b>	White crystalline powder
<b>Identification</b>	
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
<b>Purity</b>	
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

<b>Synonyms</b>	Potassium metaphosphate Potassium polymetaphosphate Kurrol salt
<b>Definition</b>	
Chemical name	Potassium polyphosphate
Einecs	232-212-6
Chemical formula	(KPO <sub>3</sub> ) <sub>n</sub> Heterogenous mixtures of potassium salts of linear condensed polyphosphoric acids of general formula H <sub>(n+2)</sub> P <sub>n</sub> O <sub>(3n+1)</sub> where 'n' is not less than 2
Molecular weight	(118) <sub>n</sub>
P <sub>2</sub> O <sub>5</sub> content	Not less than 53,5 % and not more than 61,5 % on the ignited basis
<b>Description</b>	Fine white powder or crystals or colourless glassy platelets
<b>Identification</b>	
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
<b>Purity</b>	
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 <sub>2</sub> O <sub>5</sub> content

*Status: This is the original version (as it was originally adopted).*

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(iii) SODIUM CALCIUM POLYPHOSPHATE

<b>Synonym</b>	Sodium calcium polyphosphate, glassy
<b>Definition</b>	
Chemical name	Sodium calcium polyphosphate
Einecs	233-782-9
Chemical formula	$(\text{NaPO}_3)_n \text{CaO}$ where n is typically 5
Assay	Not less than 61 % and not more than 69 % as $\text{P}_2\text{O}_5$
<b>Description</b>	White glassy crystals, spheres
<b>Identification</b>	
A. pH of a 1 % m/m slurry	Approximately 5 to 7
B. CaO content	7 %-15 % m/m
<b>Purity</b>	
Fluoride	Not more than 10 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 452 (iv) CALCIUM POLYPHOSPHATE

<b>Synonyms</b>	Calcium metaphosphate
	Calcium polymetaphosphate
<b>Definition</b>	
Chemical name	Calcium polyphosphate
Einecs	236-769-6
Chemical formula	$(\text{CaP}_2\text{O}_6)_n$



	Heterogenous mixtures of calcium salts of condensed polyphosphoric acids of general formula $H_{(n+2)}P_nO_{(n+1)}$ where 'n' is not less than 2
Molecular weight	$(198)_n$
P <sub>2</sub> O <sub>5</sub> content	Not less than 71 % and not more than 73 % on the ignited basis
<b>Description</b>	Odourless, colourless crystals or white powder
<b>Identification</b>	
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 %
<b>Purity</b>	
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 <sub>2</sub> O <sub>5</sub> content
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

## E 459 BETA-CYCLODEXTRIN

<b>Definition</b>	Beta-cyclodextrin is a non-reducing cyclic saccharide consisting of seven $\alpha$ -1,4-linked D-glucofuranosyl units. The product is manufactured by the action of the enzyme cycloglycosyltransferase (CGTase) obtained from <i>Bacillus circulans</i> , <i>Paenibacillus macerans</i> or recombinant <i>Bacillus licheniformis</i> strain SJ1608 on partially hydrolysed starch
Chemical name	Cycloheptaamylose
Einecs	231-493-2
Chemical formula	$(C_6H_{10}O_5)_7$

*Status: This is the original version (as it was originally adopted).*

Molecular weight	1 135
Assay	Content not less than 98,0 % of (C <sub>6</sub> H <sub>10</sub> O <sub>5</sub> ) <sub>7</sub> on an anhydrous basis
<b>Description</b>	Virtually odourless white or almost white crystalline solid
<b>Identification</b>	
A. Solubility	Sparingly soluble in water; freely soluble in hot water; slightly soluble in ethanol
B. Specific rotation	[α] <sup>25</sup> <sub>D</sub> : + 160° to + 164° (1 % solution)
<b>Purity</b>	
Water	Not more than 14 % (Karl Fischer method)
Other cyclodextrins	Not more than 2 % on an anhydrous basis
Residual solvents (toluene and trichloroethylene)	Not more than 1 mg/kg for each solvent
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg

#### E 460 (i) MICROCRISTALLINE CELLULOSE

<b>Synonyms</b>	Cellulose gel
<b>Definition</b>	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 <sub>6</sub> H <sub>10</sub> O <sub>5</sub> ) <sub>n</sub>
Molecular weight	About 36 000
Assay	Not less than 97 % calculated as cellulose on the anhydrous basis
<b>Description</b>	A fine white or almost white odourless powder
<b>Identification</b>	
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
<b>Purity</b>		
	Loss on drying	Not more than 7 % (105 °C, 3 hours)
	Water-soluble matter	Not more than 0,24 %
	Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
	pH of a 10 % suspension in water	The pH of the supernatant liquid is between 5,0 and 7,5
	Starch	Not detectable To 20 ml of the dispersion obtained in identification, test D, add a few drops of iodine solution and mix. No purplish to blue or blue colour should be produced
	Particle size	Not less than 5 µm (not more than 10 % of particles of less than 5 µm)
	Carboxyl groups	Not more than 1 %
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 5 mg/kg
	Mercury	Not more than 1 mg/kg
	Cadmium	Not more than 1 mg/kg
	Heavy metals (as Pb)	Not more than 10 mg/kg

## E 460 (ii) POWDERED CELLULOSE

<b>Definition</b>	Purified, mechanically disintegrated cellulose prepared by processing alpha-
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*Status: This is the original version (as it was originally adopted).*

	cellulose obtained as a pulp from natural strains of fibrous plant materials
Chemical name	Cellulose
	Linear polymer of 1:4 linked glucose residues
Einecs	232-674-9
Chemical formula	(C <sub>6</sub> H <sub>10</sub> O <sub>5</sub> ) <sub>n</sub>
Molecular weight	(162) <sub>n</sub> (n is predominantly 1 000 and greater)
Assay	Content not less than 92 %
<b>Description</b>	A white, odourless powder
<b>Identification</b>	
A. Solubility	Insoluble in water, ethanol, ether and dilute mineral acids. Slightly soluble in sodium hydroxide solution
B. Suspension test	Mix 30 g of the sample with 270 ml of water in a high-speed (12 000 rpm) power blender for 5 minutes. The resultant mixture will be either a free-flowing suspension or a heavy, lumpy suspension which flows poorly, if at all, settles only slightly and contains many trapped air bubbles. If a free-flowing suspension is obtained, transfer 100 ml into a 100-ml graduated cylinder and allow to stand for 1 hour. The solids settle and a supernatant liquid appears
<b>Purity</b>	
Loss on drying	Not more than 7 % (105 °C, 3 hours)
Water-soluble matter	Not more than 1,0 %
Sulphated ash	Not more than 0,3 % determined at 800 ± 25 °C
pH of a 10 % suspension in water	The pH of the supernatant liquid is between 5,0 and 7,5
Starch	Not detectable
	To 20 ml of the dispersion obtained in identification, test B, add a few drops of iodine solution and mix. No purplish to blue or blue colour should be produced
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

Heavy metals (as Pb)	Not more than 10 mg/kg
Particle size	Not less than 5 $\mu\text{m}$ (not more than 10 % of particles of less than 5 $\mu\text{m}$ )

## E 461 METHYL CELLULOSE

<b>Synonyms</b>	Cellulose methyl ether
<b>Definition</b>	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: $\text{C}_6\text{H}_7\text{O}_2(\text{OR}_1)(\text{OR}_2)(\text{OR}_3)$ where $\text{R}_1$ , $\text{R}_2$ , $\text{R}_3$ each may be one of the following: — H — $\text{CH}_3$ — or $\text{CH}_2\text{CH}_3$
Molecular weight	From about 20 000 to 380 000
Assay	Content not less than 25 % and not more than 33 % of methoxyl groups ( $-\text{OCH}_3$ ) and not more than 5 % of hydroxyethoxyl groups ( $-\text{OCH}_2\text{CH}_2\text{OH}$ )
<b>Description</b>	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
<b>Identification</b>	
A. Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol, ether and chloroform. Soluble in glacial acetic acid
<b>Purity</b>	
Loss on drying	Not more than 10 % (105 °C, 3 hours)
Sulphated ash	Not more than 1,5 % determined at 800 $\pm$ 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

*Status: This is the original version (as it was originally adopted).*

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

#### E 462 ETHYL CELLULOSE

<b>Synonyms</b>	Cellulose ethyl ether
<b>Definition</b>	Ethyl cellulose is cellulose obtained directly from fibrous plant material and partially etherified with ethyl groups
Chemical name	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 $R_1$ and $R_2$ may be any of the following: — H — $CH_2CH_3$
Assay	Content not less than 44 % and not more than 50 % of ethoxyl groups ( $-OC_2H_5$ ) on the dried basis (equivalent to not more than 2,6 ethoxyl groups per anhydroglucose unit)
<b>Description</b>	Slightly hygroscopic white to off-white, odourless and tasteless powder
<b>Identification</b>	
A. Solubility	Practically insoluble in water, in glycerol and in propane-1,2-diol but soluble in varying proportions in certain organic solvents depending upon the ethoxyl content. Ethyl cellulose containing less than 46 to 48 % of ethoxyl groups is freely soluble in tetrahydrofuran, in methyl acetate, in chloroform and in aromatic hydrocarbon ethanol mixtures. Ethyl cellulose containing 46 to 48 % or more of ethoxyl groups is freely soluble in ethanol, in methanol, in toluene, in chloroform and in ethyl acetate
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
<b>Purity</b>	
Loss on drying	Not more than 3 % (105 °C, 2 hours)

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

## E 463 HYDROXYPROPYL CELLULOSE

<b>Synonyms</b>	Cellulose hydroxypropyl ether
<b>Definition</b>	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:  $C_6H_7O_2(OR_1)(OR_2)(OR_3)$ , where $R_1, R_2, R_3$ each may be one of the following: — H — $CH_2CHOHCH_3$ — $CH_2CHO(CH_2CHOHCH_3)CH_3$ — $CH_2CHO[CH_2CHO(CH_2CHOHCH_3)CH_3]CH_3$
Molecular weight	From about 30 000 to 1 000 000
Assay	Content not less than 80,5 % of hydroxypropoxyl groups ( $-OCH_2CHOHCH_3$ ) equivalent to not more than 4,6 hydroxypropyl groups per anhydroglucose unit on the anhydrous basis
<b>Description</b>	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
<b>Identification</b>	
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
<b>Purity</b>	
Loss on drying	Not more than 10 % (105 °C, 3 hours)

*Status: This is the original version (as it was originally adopted).*

Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
pH of a 1 % colloidal solution	Not less than 5,0 and not more than 8,0
Propylene chlorohydrins	Not more than 0,1 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

#### E 464 HYDROXYPROPYL METHYL CELLULOSE

<b>Definition</b>	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: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$ , where $R_1, R_2, R_3$ each may be one of the following: — H — $CH_3$ — $CH_2CHOHCH_3$ — $CH_2CHO(CH_2CHOHCH_3)CH_3$ — $CH_2CHO[CH_2CHO(CH_2CHOHCH_3)CH_3]CH_3$
Molecular weight	From about 13 000 to 200 000
Assay	Content not less than 19 % and not more than 30 % methoxyl groups ( $-OCH_3$ ) and not less than 3 % and not more than 12 % hydroxypropoxyl groups ( $-OCH_2CHOHCH_3$ ), on the anhydrous basis
<b>Description</b>	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
<b>Identification</b>	
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
<b>Purity</b>	
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

<b>Synonyms</b>	Methylethylcellulose
<b>Definition</b>	Ethyl methyl cellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with methyl and ethyl groups
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: <ul style="list-style-type: none"> <li>— H</li> <li>— CH<sub>3</sub></li> <li>— CH<sub>2</sub>CH<sub>3</sub></li> </ul>
Molecular weight	From about 30 000 to 40 000
Assay	Content on the anhydrous basis not less than 3,5 % and not more than 6,5 % of methoxyl groups (-OCH <sub>3</sub> ) and not less than 14,5 % and not more than 19 % of ethoxyl groups (-OCH <sub>2</sub> CH <sub>3</sub> ), and not less than 13,2 % and not more than 19,6 % of total alkoxy groups, calculated as methoxyl

*Status: This is the original version (as it was originally adopted).*

<b>Description</b>	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
<b>Identification</b>	
A. Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Soluble in ethanol. Insoluble in ether
<b>Purity</b>	
Loss on drying	Not more than 15 % for the fibrous form, and not more than 10 % for the powdered form (105 °C to constant weight)
Sulphated ash	Not more than 0,6 %
pH of a 1 % colloidal solution	Not less than 5,0 and not more than 8,0
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

#### E 466 SODIUM CARBOXY METHYL CELLULOSE

<b>Synonyms</b>	Carboxy methyl cellulose
	CMC
	NaCMC
	Sodium CMC
	Cellulose gum
<b>Definition</b>	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: — H — CH <sub>2</sub> COONa — CH <sub>2</sub> COOH

Molecular weight	Higher than approximately 17 000 (degree of polymerisation approximately 100)
Assay	Content on the anhydrous basis not less than 99,5 %
<b>Description</b>	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
<b>Identification</b>	
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
<b>Purity</b>	
Degree of substitution	Not less than 0,2 and not more than 1,5 carboxymethyl groups (-CH <sub>2</sub> COOH) per anhydroglucose unit
Loss on drying	Not more than 12 % (105 °C to constant weight)
pH of a 1 % colloidal solution	Not less than 5,0 and not more than 8,5
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

*Status: This is the original version (as it was originally adopted).*

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 468 CROSS-LINKED SODIUM CARBOXYMETHYLCELLULOSE

<b>Synonyms</b>	Cross-linked carboxymethyl cellulose
	Cross-linked CMC
	Cross-linked sodium CMC
	Cross-linked cellulose gum
<b>Definition</b>	Cross-linked sodium carboxymethyl cellulose is the sodium salt of thermally cross-linked partly O-carboxymethylated cellulose
<b>Chemical name</b>	Sodium salt of the cross-linked carboxymethyl ether cellulose
<b>Chemical formula</b>	The polymers containing substituted anhydroglucose units with the general formula:
	$C_6H_7O_2(OR_1)(OR_2)(OR_3)$
	where R <sub>1</sub> , R <sub>2</sub> and R <sub>3</sub> may be any of the following: — H — CH <sub>2</sub> COONa — CH <sub>2</sub> COOH
<b>Description</b>	Slightly hygroscopic, white to off white, odourless powder
<b>Identification</b>	
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
<b>Purity</b>	
Loss on drying	Not more than 6 % (105 °C, 3h)
Water solubles	Not more than 10 %
Degree of substitution	Not less than 0,2 and not more than 1,5 carboxymethyl groups per anhydroglucose unit
pH of 1 %	Not less than 5,0 and not more than 7,0
Sodium content	Not more than 12,4 % on anhydrous basis
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

## E 469 ENZYMATICALLY HYDROLYSED CARBOXYMETHYLCELLULOSE

<b>Synonyms</b>	Sodium carboxymethyl cellulose, enzymatically hydrolysed
<b>Definition</b>	Enzymatically hydrolysed carboxymethylcellulose is obtained from carboxymethylcellulose by enzymatic digestion with a cellulase produced by <i>Trichoderma longibrachiatum</i> (formerly <i>T. reesei</i> )
Chemical name	Carboxymethyl cellulose, sodium, partially enzymatically hydrolysed
Chemical formula	Sodium salts of polymers containing substituted anhydroglucose units with the general formula: $[C_6H_7O_2(OH)_x(OCH_2COONa)_y]_n$ where n is the degree of polymerisation x = 1,5 to 2,8 y = 0,2 to 1,5 x + y = 3,0 (y = degree of substitution)
Formula weight	178,14 where y = 0,2 282,18 where y = 1,5

*Status: This is the original version (as it was originally adopted).*

	Macromolecules: Not less than 800 (n about 4)
Assay	Not less than 99,5 %, including mono- and disaccharides, on the dried basis
<b>Description</b>	White or slightly yellowish or greyish, odourless, slightly hygroscopic granular or fibrous powder
<b>Identification</b>	
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 $2,5 \text{ kgm}^{-1}\text{s}^{-1}$ at 25 °C corresponding to an average molecule weight of 5 000 D
<b>Purity</b>	
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 470a SODIUM, POTASSIUM AND CALCIUM SALTS OF FATTY ACIDS

<b>Definition</b>	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 %
<b>Description</b>	White or creamy white light powders, flakes or semi-solids
<b>Identification</b>	
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	
<b>Purity</b>	
Sodium	Not less than 9 % and not more than 14 % expressed as Na <sub>2</sub> O
Potassium	Not less than 13 % and not more than 21,5 % expressed as K <sub>2</sub> O
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

*Status: This is the original version (as it was originally adopted).*

<b>Definition</b>	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 %
<b>Description</b>	White or creamy-white light powders, flakes or semi-solids
<b>Identification</b>	
A. Solubility	Insoluble in water, partially soluble in ethanol and ether
B. Positive tests for magnesium and for fatty acids	
<b>Purity</b>	
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

<b>Synonyms</b>	Glyceryl monostearate
	Glyceryl monopalmitate
	Glyceryl monooleate, etc.
	Monostearin, monopalmitin, monoolein, etc.
	GMS (for glyceryl monostearate)
<b>Definition</b>	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

*Note: 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).*



Assay	Content of mono- and diesters: not less than 70 %
<b>Description</b>	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
<b>Identification</b>	
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
<b>Purity</b>	
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

*Note: 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

<b>Synonyms</b>	Acetic acid esters of mono- and diglycerides
	Acetoglycerides
	Acetylated mono- and diglycerides
	Acetic and fatty acid esters of glycerol

*Note: 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).*

*Status: This is the original version (as it was originally adopted).*

<b>Definition</b>	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
<b>Description</b>	Clear, mobile liquids to solids, from white to pale yellow in colour
<b>Identification</b>	
A. Positive tests for glycerol, for fatty acids and for acetic acid	
B. Solubility	Insoluble in water. Soluble in ethanol
<b>Purity</b>	
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

*Note: 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

<b>Synonyms</b>	Lactic acid esters of mono- and diglycerides
	Lactoglycerides
	Mono- and diglycerides of fatty acids esterified with lactic acid
<b>Definition</b>	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

*Note: 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).*

<b>Description</b>	Clear, mobile liquids to waxy solids of variable consistency, from white to pale yellow in colour
<b>Identification</b>	
A. Positive tests for glycerol, for fatty acids and for lactic acid	
B. Solubility	Insoluble in cold water but dispersible in hot water
<b>Purity</b>	
Acids other than lactic and fatty acids	Not detectable
Free glycerol	Not more than 2 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Total lactic acid	Not less than 13 % and not more than 45 %
Free fatty acids (and lactic acid)	Not more than 3 % estimated as oleic acid
Total glycerol	Not less than 13 % and not more than 30 %
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C

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

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

<b>Synonyms</b>	Citrem
	Citric acid esters of mono- and diglycerides
	Citroglycerides
	Mono- and diglycerides of fatty acids esterified with citric acid
<b>Definition</b>	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

*Note: 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).*

*Status: This is the original version (as it was originally adopted).*

<b>Description</b>	Yellowish or light brown liquids to waxy solids or semi-solids
<b>Identification</b>	
A. Positive tests for glycerol, for fatty acids and for citric acid	
B. Solubility	Insoluble in cold water
	Dispersible in hot water
	Soluble in oils and fats
	Insoluble in cold ethanol
<b>Purity</b>	
Acids other than citric and fatty acids	Not detectable
Free glycerol	Not more than 2 %
Total glycerol	Not less than 8 % and not more than 33 %
Total citric acid	Not less than 13 % and not more than 50 %
Sulphated ash (determined at 800 ± 25 °C)	Non-neutralised products: not more than 0,5 %
	Partially or wholly neutralised products: not more than 10 %
Lead	Not more than 2 mg/kg
Free fatty acids	Not more than 3 % estimated as oleic acid

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

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

<b>Synonyms</b>	Tartaric acid esters of mono- and diglycerides
	Mono- and diglycerides of fatty acids esterified with tartaric acid
<b>Definition</b>	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
<b>Description</b>	Sticky viscous yellowish liquids to hard yellow waxes
<b>Identification</b>	

*Note: 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).*

A.	Positive tests for glycerol, for fatty acids and for tartaric acid	
<b>Purity</b>		
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

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

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

<b>Synonyms</b>	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
<b>Definition</b>	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
<b>Description</b>	Sticky viscous liquids through a fat-like consistency to yellow waxes which hydrolyse in moist air to liberate acetic acid
<b>Identification</b>	

*Note: 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).*

*Status: This is the original version (as it was originally adopted).*

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

*Note: 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

<b>Synonyms</b>	Mono- and diglycerides of fatty acids esterified with acetic acid and tartaric acid
<b>Definition</b>	Esters of glycerol with acetic and tartaric acids and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free tartaric and acetic acids, and free glycerides. May contain mono- and diacetyltartaric esters of mono- and diglycerides of fatty acids
<b>Description</b>	Sticky liquids to solids, from white to pale-yellow in colour
<b>Identification</b>	
A.	Positive tests for glycerol, for fatty acids, for tartaric acid and for acetic acid

*Note: 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).*

*Status: This is the original version (as it was originally adopted).*

<b>Purity</b>	
Acids other than acetic, tartaric and fatty acids	Not detectable
Free glycerol	Not more than 2 %
Total glycerol	Not less than 12 % and not more than 27 %
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Total acetic acid	Not less than 10 % and not more than 20 %
Total tartaric acid	Not less than 20 % and not more than 40 %
Free fatty acids	Not more than 3 % estimated as oleic acid

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

#### E 473 SUCROSE ESTERS OF FATTY ACIDS

<b>Synonyms</b>	Sucroesters
	Sugar esters
<b>Definition</b>	Essentially the mono-, di- and triesters of sucrose with fatty acids occurring in food fats and oils. They may be prepared from sucrose and the methyl and ethyl esters of food fatty acids or by extraction from sucroglycerides. No organic solvent other than dimethylsulphoxide, dimethylformamide, ethyl acetate, propane-2-ol, 2-methyl-1-propanol, propylene glycol and methyl ethyl ketone may be used for their preparation
<b>Assay</b>	Content not less than 80 %

*Note: 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).*

*Status: This is the original version (as it was originally adopted).*

<b>Description</b>	Stiff gels, soft solids or white to slightly greyish-white powders
<b>Identification</b>	
A. Positive tests for sugar for fatty acids	
B. Solubility	Sparingly soluble in water Soluble in ethanol
<b>Purity</b>	
Sulphated ash	Not more than 2 % determined at $800 \pm 25$ °C
Free sugar	Not more than 5 %
Free fatty acids	Not more than 3 % estimated as oleic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Methanol	Not more than 10 mg/kg
Dimethylsulphoxide	Not more than 2 mg/kg
Dimethylformamide	Not more than 1 mg/kg
2-methyl-1-propanol	Not more than 10 mg/kg
Ethylacetate	Not more than 350 mg/kg, singly or in combination
Propane-2-ol	
Prolyleneglycol	
Methyl ethyl ketone	Not more than 10 mg/kg

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

#### E 474 SUCROGLYCERIDES

<b>Synonyms</b>	Sugar glycerides
<b>Definition</b>	Sucroglycerides are produced by reacting sucrose with an edible fat or oil to produce a mixture of essentially mono-, di- and triesters of sucrose

*Note: 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).*



		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
<b>Description</b>		Soft solid masses, stiff gels or white to off-white powders
<b>Identification</b>		
A. Positive tests for sugar and for fatty acids		
B. Solubility		Insoluble in cold water Soluble in ethanol
<b>Purity</b>		
Sulphated ash		Not more than 2 % determined at 800 ± 25 °C
Free sugar		Not more than 5 %
Free fatty acids		Not more than 3 % estimated as oleic acid
Arsenic		Not more than 3 mg/kg
Lead		Not more than 5 mg/kg
Mercury		Not more than 1 mg/kg
Cadmium		Not more than 1 mg/kg
Heavy metals (as Pb)		Not more than 10 mg/kg
Methanol		Not more than 10 mg/kg
Dimethylformamide		Not more than 1 mg/kg
2-methyl-1-propanol		Not more than 10 mg/kg, single or in combination
Cyclohexane		
Ethylacetate		Not more than 350 mg/kg, single or in combination
Propane-2-ol		

*Note: 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

*Status: This is the original version (as it was originally adopted).*

<b>Synonyms</b>	Polyglycerol fatty acid esters
	Polyglycerin esters of fatty acid esters
<b>Definition</b>	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 %
<b>Description</b>	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
<b>Identification</b>	
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
<b>Purity</b>	
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
Acids other than fatty acids	Not detectable
Free fatty acids	Not more than 6 % estimated as oleic acid
Total glycerol and polyglycerol	Not less than 18 % and not more than 60 %
Free glycerol and polyglycerol	Not more than 7 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

*Note: 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

<b>Synonyms</b>	Glycerol esters of condensed castor oil fatty acids
	Polyglycerol esters of polycondensed fatty acids from castor oil
	Polyglycerol esters of interesterified ricinoleic acid
	PGPR
<b>Definition</b>	Polyglycerol polyricinoleate is prepared by the esterification of polyglycerol with condensed castor oil fatty acids
<b>Description</b>	Clear, highly viscous liquid
<b>Identification</b>	
A. Solubility	Insoluble in water and in ethanol.
	Soluble in ether, hydrocarbons and halogenated hydrocarbons
B. Positive tests for glycerol, polyglycerol and for ricinoleic acid	
C. Refractive index $[n]^{65}$	Between 1,463 and 1,4665
<b>Purity</b>	
Polyglycerols	The polyglycerol moiety shall be composed of not less than 75 % of di-, tri- and tetraglycerols and shall contain not more than 10 % of polyglycerols equal to or higher than heptaglycerol
Hydroxyl value	Not less than 80 and not more than 100
Acid value	Not more than 6
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

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

<b>Synonyms</b>	Propylene glycol esters of fatty acids
<b>Definition</b>	Consists of mixtures of propane-1,2-diol mono- and diesters of fatty acids occurring in food fats and oils. The alcohol moiety is

*Note: 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).*

*Status: This is the original version (as it was originally adopted).*

	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 %
<b>Description</b>	Clear liquids or waxy white flakes, beads or solids having a bland odour
<b>Identification</b>	
A. Positive tests for propylene glycol and for fatty acids	
<b>Purity</b>	
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
Acids other than fatty acids	Not detectable
Free fatty acids	Not more than 6 % estimated as oleic acid
Total propane-1,2-diol	Not less than 11 % and not more than 31 %
Free propane-1,2-diol	Not more than 5 %
Dimer and trimer of propylene glycol	Not more than 0,5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

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

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

<b>Synonyms</b>	TOSOM
<b>Definition</b>	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

<b>Description</b>	Pale yellow to light brown a waxy or solid consistency
<b>Identification</b>	
A. Solubility	Insoluble in water. Soluble in hot oil or fat
<b>Purity</b>	
Melting range	55-65 °C
Free fatty acids	Not more than 1,5 % estimated as oleic acid
Free glycerol	Not more than 2 %
Total fatty acids	83-90 %
Total glycerol	16-22 %
Fatty acid methyl esters, not forming adduct with urea	Not more than 9 % of total fatty acid methyl esters
Fatty acids, insoluble in petroleum ether	Not more than 2 % of total fatty acids
Peroxide value	Not more than 3
Epoxides	Not more than 0,03 % oxirane oxygen
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 481 SODIUM STEAROYL-2-LACTYLATE

<b>Synonyms</b>	Sodium stearoyl lactylate Sodium stearoyl lactate
<b>Definition</b>	A mixture of the sodium salts of stearoyl lactic acids and its polymers and minor amounts of sodium salts of other related acids, manufactured by the reaction of stearic acid and lactic acid. Other food fatty acids may also be present, free or esterified, due to their presence in the stearic acid used
<b>Chemical names</b>	Sodium di-2-stearoyl lactate Sodium di(2-stearoyloxy)propionate
<b>Einecs</b>	246-929-7
<b>Chemical formula (major components)</b>	C <sub>21</sub> H <sub>39</sub> O <sub>4</sub> Na C <sub>19</sub> H <sub>35</sub> O <sub>4</sub> Na

*Status: This is the original version (as it was originally adopted).*

<b>Description</b>	White or slightly yellowish powder or brittle solid with a characteristic odour
<b>Identification</b>	
A. Positive tests for sodium, for fatty acids and for lactic acid	
B. Solubility	Insoluble in water. Soluble in ethanol
<b>Purity</b>	
Sodium	Not less than 2,5 % and not more than 5 %
Ester value	Not less than 90 and not more than 190
Acid value	Not less than 60 and not more than 130
Total lactic acid	Not less than 15 % and not more than 40 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

#### E 482 CALCIUM STEAROYL-2-LACTYLATE

<b>Synonyms</b>	Calcium stearoyl lactate
<b>Definition</b>	A mixture of the calcium salts of stearoyl lactic acids and its polymers and minor amounts of calcium salts of other related acids, manufactured by the reaction of stearic acid and lactic acid. Other food fatty acids may also be present, free or esterified, due to their presence in the stearic acid used
<b>Chemical name</b>	Calcium di-2-stearoyl lactate Calcium di(2-stearoyloxy)propionate
Einecs	227-335-7
<b>Chemical formula</b>	$C_{42}H_{78}O_8Ca$ $C_{38}H_{70}O_8Ca$
<b>Description</b>	White or slightly yellowish powder or brittle solid with a characteristic odour
<b>Identification</b>	
A. Positive tests for calcium, for fatty acids and for lactic acid	

B. Solubility	Slightly soluble in hot water
<b>Purity</b>	
Calcium	Not less than 1 % and not more than 5,2 %
Ester value	Not less than 125 and not more than 190
Total lactic acid	Not less than 15 % and not more than 40 %
Acid value	Not less than 50 and not more than 130
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 483 STEARYL TARTRATE

<b>Synonyms</b>	Stearyl palmityl tartrate
<b>Definition</b>	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
Chemical formula	C <sub>38</sub> H <sub>74</sub> O <sub>6</sub> to C <sub>40</sub> H <sub>78</sub> O <sub>6</sub>
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
<b>Description</b>	Cream-coloured unctuous solid (at 25 °C)
<b>Identification</b>	
A. Positive tests for tartare	
B. Melting range	Between 67 °C and 77 °C. After saponification the saturated long chain fatty alcohols have a melting range of 49 °C to 55 °C
<b>Purity</b>	
Hydroxyl value	Not less than 200 and not more than 220

*Status: This is the original version (as it was originally adopted).*

Acid value	Not more than 5,6
Total tartaric acid content	Not less than 18 % and not more than 35 %
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Unsatifiable matter	Not less than 77 % and not more than 83 %
Iodine value	Not more than 4 (Wijs method)

#### E 491 SORBITAN MONOSTEARATE

<b>Definition</b>	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
<b>Description</b>	Light, cream- to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour
<b>Identification</b>	
A. Solubility	Soluble at temperatures above its melting point in toluene, dioxane, carbon tetrachloride, ether, methanol, ethanol and aniline; insoluble in petroleum ether and acetone; insoluble in cold water but dispersible in warm water; soluble with haze at temperatures above 50 °C in mineral oil and ethyl acetate
B. Congealing range	50-52 °C
C. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyol
<b>Purity</b>	
Water	Not more than 2 % (Karl Fischer method)
Sulphated ash	Not more than 0,5 %
Acid value	Not more than 10



Saponification value	Not less than 147 and not more than 157
Hydroxyl value	Not less than 235 and not more than 260
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 492 SORBITAN TRISTEARATE

<b>Definition</b>	A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial stearic acid
Einecs	247-891-4
Assay	Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters
<b>Description</b>	Light, cream- to tan-coloured beads or flakes or hard, waxy solid with a slight odour
<b>Identification</b>	
A. Solubility	Slightly soluble in toluene, ether, carbon tetrachloride and ethyl acetate; dispersible in petroleum ether, mineral oil, vegetable oils, acetone and dioxane; insoluble in water, methanol and ethanol
B. Congealing range	47-50 °C
C. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyol
<b>Purity</b>	
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

<b>Definition</b>	A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial lauric acid
Einecs	215-663-3
Assay	Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters
<b>Description</b>	Amber-coloured oily viscous liquid, light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight odour
<b>Identification</b>	
A. Solubility	Dispersible in hot and cold water
B. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyol
<b>Purity</b>	
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

<b>Definition</b>	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

<b>Description</b>	Amber-coloured viscous liquid, light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour
<b>Identification</b>	
A. Solubility	Soluble at temperatures above its melting point in ethanol, ether, ethyl acetate, aniline, toluene, dioxane, petroleum ether and carbon tetrachloride. Insoluble in cold water, dispersible in warm water
B. Iodine value	The residue of oleic acid, obtained from the saponification of the sorbitan monooleate in assay, has a iodine value between 80 and 100
<b>Purity</b>	
Water	Not more than 2 % (Karl Fischer method)
Sulphated ash	Not more than 0,5 %
Acid value	Not more than 8
Saponification value	Not less than 145 and not more than 160
Hydroxyl value	Not less than 193 and not more than 210
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

## E 495 SORBITAN MONOPALMITATE

<b>Synonyms</b>	Sorbitan palmitate
<b>Definition</b>	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
<b>Description</b>	Light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour
<b>Identification</b>	
A. Solubility	Soluble at temperatures above its melting point in ethanol, methanol, ether, ethyl acetate, aniline, toluene, dioxane, petroleum

*Status: This is the original version (as it was originally adopted).*

	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
<b>Purity</b>	
Water	Not more than 2 % (Karl Fischer method)
Sulphate ash	Not more than 0,5 %
Acid value	Not more than 7,5
Saponification value	Not less than 140 and not more than 150
Hydroxyl value	Not less than 270 and not more than 305
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

#### E 500(i) SODIUM CARBONATE

<b>Synonyms</b>	Soda ash
<b>Definition</b>	
Chemical name	Sodium carbonate
Einecs	207-838-8
Chemical formula	$\text{Na}_2\text{CO}_3 \cdot n\text{H}_2\text{O}$ (n = 0, 1 or 10)
Molecular weight	106,0 (anhydrous)
Assay	Content not less than 99 % of $\text{Na}_2\text{CO}_3$ on the anhydrous basis
<b>Description</b>	Colourless crystals or white, granular or crystalline powder The anhydrous form is hygroscopic, the decahydrate efflorescent
<b>Identification</b>	
A. Positive tests for sodium and for carbonate	
B. Solubility	Freely soluble in water. Insoluble in ethanol
<b>Purity</b>	

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

<b>Synonyms</b>	Sodium bicarbonate, sodium acid carbonate, bicarbonate of soda, baking soda
<b>Definition</b>	
Chemical name	Sodium hydrogen carbonate
Einecs	205-633-8
Chemical formula	NaHCO <sub>3</sub>
Molecular weight	84,01
Assay	Content not less than 99 % on the anhydrous basis
<b>Description</b>	Colourless or white crystalline masses or crystalline powder
<b>Identification</b>	
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
<b>Purity</b>	
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

<b>Definition</b>	
Chemical name	Sodium monohydrogen dicarbonate

*Status: This is the original version (as it was originally adopted).*

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 $\text{Na}_2\text{CO}_3$
<b>Description</b>	White flakes, crystals or crystalline powder
<b>Identification</b>	
A. Positive tests for sodium and for carbonate	
B. Solubility	Freely soluble in water
<b>Purity</b>	
Sodium chloride	Not more than 0,5 %
Iron	Not more than 20 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

#### E 501(i) POTASSIUM CARBONATE

<b>Definition</b>	
Chemical name	Potassium carbonate
Einecs	209-529-3
Chemical formula	$\text{K}_2\text{CO}_3 \cdot n\text{H}_2\text{O}$ (n = 0 or 1,5)
Molecular weight	138,21 (anhydrous)
Assay	Content not less than 99,0 % on the anhydrous basis
<b>Description</b>	White, very deliquescent powder. The hydrate occurs as small, white, translucent crystals or granules
<b>Identification</b>	
A. Positive tests for potassium and for carbonate	
B. Solubility	Very soluble in water. Insoluble in ethanol
<b>Purity</b>	

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

## E 501(ii) POTASSIUM HYDROGEN CARBONATE

<b>Synonyms</b>	Potassium bicarbonate, acid potassium carbonate
<b>Definition</b>	
Chemical name	Potassium hydrogen carbonate
Einecs	206-059-0
Chemical formula	KHCO <sub>3</sub>
Molecular weight	100,11
Assay	Content not less than 99,0 % and not more than 101,0 % KHCO <sub>3</sub> on the anhydrous basis
<b>Description</b>	Colourless crystals or white powder or granules
<b>Identification</b>	
A. Positive tests for potassium and for carbonate	
B. Solubility	Freely soluble in water. Insoluble in ethanol
<b>Purity</b>	
Loss on drying	Not more than 0,25 % (over silica gel, 4h)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

## E 503(i) AMMONIUM CARBONATE

<b>Definition</b>	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	CH <sub>6</sub> N <sub>2</sub> O <sub>2</sub> , CH <sub>8</sub> N <sub>2</sub> O <sub>3</sub> and CH <sub>5</sub> NO <sub>3</sub>

*Status: This is the original version (as it was originally adopted).*

Molecular weight	Ammonium carbamate 78,06; ammonium carbonate 98,73; ammonium hydrogen carbonate 79,06
Assay	Content not less than 30,0 % and not more than 34,0 % of NH <sub>3</sub>
<b>Description</b>	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
<b>Identification</b>	
A. Positive tests for ammonium and for carbonate	
B. pH of a 5 % solution	about 8,6
C. Solubility	Soluble in water
<b>Purity</b>	
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

<b>Synonyms</b>	Ammonium bicarbonate
<b>Definition</b>	
Chemical name	Ammonium hydrogen carbonate
Einecs	213-911-5
Chemical formula	CH <sub>5</sub> NO <sub>3</sub>
Molecular weight	79,06
Assay	Content not less than 99,0 %
<b>Description</b>	White crystals or crystalline powder
<b>Identification</b>	
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
<b>Purity</b>		
	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 504(ii) MAGNESIUM HYDROXIDE CARBONATE

<b>Synonyms</b>	Magnesium hydrogen carbonate, magnesium subcarbonate (light or heavy), hydrated basic magnesium carbonate, magnesium carbonate hydroxide	
<b>Definition</b>		
Chemical name	Magnesium carbonate hydroxide hydrated	
Einecs	235-192-7	
Chemical formula	$4\text{MgCO}_3\text{Mg}(\text{OH})_2\cdot 5\text{H}_2\text{O}$	
Molecular weight	485	
Assay	Mg content not less than 40,0 % and not more than 45,0 % calculated as MgO	
<b>Description</b>	Light, white friable mass or bulky white powder	
<b>Identification</b>		
A.	Positive tests for magnesium and for carbonate	
B.	Solubility	Practically insoluble in water. Insoluble in ethanol
<b>Purity</b>		
	Acid insoluble matter	Not more than 0,05 %
	Water soluble matter	Not more than 1,0 %
	Calcium	Not more than 1,0 %
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 10 mg/kg

*Status: This is the original version (as it was originally adopted).*

Mercury	Not more than 1 mg/kg
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#### E 507 HYDROCHLORIC ACID

<b>Synonyms</b>	Hydrogen chloride, muriatic acid
<b>Definition</b>	
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
<b>Description</b>	Clear, colourless or slightly yellowish, corrosive liquid having a pungent odour
<b>Identification</b>	
A. Positive tests for acid and for chloride	
B. Solubility	Soluble in water and in ethanol
<b>Purity</b>	
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 SO <sub>2</sub> )
Oxidising substances	Not more than 30 mg/kg (as Cl <sub>2</sub> )
Sulphate	Not more than 0,5 %
Iron	Not more than 5 mg/kg
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

#### E 508 POTASSIUM CHLORIDE

<b>Synonyms</b>	Sylvine
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	Sylvite
<b>Definition</b>	
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
<b>Description</b>	Colourless, elongated, prismatic or cubital crystals or white granular powder. Odourless
<b>Identification</b>	
A. Solubility	Freely soluble in water. Insoluble in ethanol
B. Positive tests for potassium and for chloride	
<b>Purity</b>	
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 509 CALCIUM CHLORIDE

<b>Definition</b>	
Chemical name	Calcium chloride
Einecs	233-140-8
Chemical formula	$\text{CaCl}_2 \cdot n\text{H}_2\text{O}$ (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
<b>Description</b>	White, odourless, hygroscopic powder or deliquescent crystals
<b>Identification</b>	

*Status: This is the original version (as it was originally adopted).*

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
<b>Purity</b>		
	Magnesium and alkali salts	Not more than 5 % on the anhydrous basis
	Fluoride	Not more than 40 mg/kg
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 10 mg/kg
	Mercury	Not more than 1 mg/kg

#### E 511 MAGNESIUM CHLORIDE

<b>Definition</b>		
	Chemical name	Magnesium chloride
	Einecs	232-094-6
	Chemical formula	$\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$
	Molecular weight	203,3
	Assay	Content not less than 99,0 %
<b>Description</b>		Colourless, odourless, very deliquescent flakes or crystals
<b>Identification</b>		
A.	Positive tests for magnesium and for chloride	
B.	Solubility	Very soluble in water, freely soluble in ethanol
<b>Purity</b>		
	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

<b>Synonyms</b>	Tin chloride, tin dichloride
<b>Definition</b>	
Chemical name	Stannous chloride dihydrate
Einecs	231-868-0
Chemical formula	$\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$
Molecular weight	225,63
Assay	Content not less than 98,0 %
<b>Description</b>	Colourless or white crystals May have a slight odour of hydrochloric acid
<b>Identification</b>	
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
<b>Purity</b>	
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

<b>Synonyms</b>	Oil of vitriol, dihydrogen sulphate
<b>Definition</b>	
Chemical name	Sulphuric acid
Einecs	231-639-5
Chemical formula	$\text{H}_2\text{SO}_4$
Molecular weight	98,07
Assay	Sulphuric acid is commercially available in varying concentrations. The concentrated form contains not less than 96,0 %
<b>Description</b>	Clear, colourless or slightly brown, very corrosive oily liquid
<b>Identification</b>	

*Status: This is the original version (as it was originally adopted).*

A.	Positive tests for acid and for sulphate	
B.	Solubility	Miscible with water, with generation of much heat, also with ethanol
<b>Purity</b>		
Ash		Not more than 0,02 %
Reducing matter		Not more than 40 mg/kg (as SO <sub>2</sub> )
Nitrate		Not more than 10 mg/kg (on H <sub>2</sub> SO <sub>4</sub> basis)
Chloride		Not more than 50 mg/kg
Iron		Not more than 20 mg/kg
Selenium		Not more than 20 mg/kg
Arsenic		Not more than 3 mg/kg
Lead		Not more than 5 mg/kg
Mercury		Not more than 1 mg/kg

#### E 514(i) SODIUM SULPHATE

<b>Definition</b>		
Chemical name		Sodium sulphate
Chemical formula		Na <sub>2</sub> SO <sub>4</sub> · nH <sub>2</sub> O (n = 0 or 10)
Molecular weight		142,04 (anhydrous) 322,04 (decahydrate)
Assay		Content not less than 99,0 % on the anhydrous basis
<b>Description</b>		Colourless crystals or a fine, white, crystalline powder The decahydrate is efflorescent
<b>Identification</b>		
A.	Positive tests for sodium and for sulphate	
B.	Acidity of a 5 % solution: neutral or slightly alkaline to litmus paper	
<b>Purity</b>		
Loss on drying		Not more than 1,0 % (anhydrous) or not more than 57 % (decahydrate) at 130 °C
Selenium		Not more than 30 mg/kg

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

## E 514(ii) SODIUM HYDROGEN SULPHATE

<b>Synonyms</b>	Acid sodium sulphate, sodium bisulphate, nitre cake
<b>Definition</b>	
Chemical name	Sodium hydrogen sulphate
Chemical formula	NaHSO <sub>4</sub>
Molecular weight	120,06
Assay	Content not less than 95,2 %
<b>Description</b>	White, odourless crystals or granules
<b>Identification</b>	
A. Positive tests for sodium and for sulphate	
B. Solutions are strongly acidic	
<b>Purity</b>	
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

<b>Definition</b>	
Chemical name	Potassium sulphate
Chemical formula	K <sub>2</sub> SO <sub>4</sub>
Molecular weight	174,25
Assay	Content not less than 99,0 %
<b>Description</b>	Colourless or white crystals or crystalline powder
<b>Identification</b>	

*Status: This is the original version (as it was originally adopted).*

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
<b>Purity</b>		
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

<b>Definition</b>		
<b>Synonyms</b>		Potassium bisulphate, potassium acid sulphate
Chemical name		Potassium hydrogen sulphate
Chemical formula		KHSO <sub>4</sub>
Molecular weight		136,17
Assay		Content not less than 99 %
Melting point		197 °C
<b>Description</b>		White deliquescent crystals, pieces or granules
<b>Identification</b>		
A.	Positive test for potassium	
B.	Solubility	Freely soluble in water, insoluble in ethanol
<b>Purity</b>		
Selenium		Not more than 30 mg/kg
Arsenic		Not more than 3 mg/kg
Lead		Not more than 5 mg/kg
Mercury		Not more than 1 mg/kg

#### E 516 CALCIUM SULPHATE

<b>Synonyms</b>		Gypsum, selenite, anhydrite
<b>Definition</b>		



Chemical name	Calcium sulphate
Einecs	231-900-3
Chemical formula	CaSO <sub>4</sub> · nH <sub>2</sub> O (n = 0 or 2)
Molecular weight	136,14 (anhydrous), 172,18 (dihydrate)
Assay	Content not less than 99,0 % on the anhydrous basis
<b>Description</b>	Fine, white to slightly yellowish-white odourless powder
<b>Identification</b>	
A. Positive tests for calcium and for sulphate	
B. Solubility	Slightly soluble in water, insoluble in ethanol
<b>Purity</b>	
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

<b>Definition</b>	
Chemical name	Ammonium sulphate
Einecs	231-984-1
Chemical formula	(NH <sub>4</sub> ) <sub>2</sub> SO <sub>4</sub>
Molecular weight	132,14
Assay	Content not less than 99,0 % and not more than 100,5 %
<b>Description</b>	White powder, shining plates or crystalline fragments
<b>Identification</b>	
A. Positive tests for ammonium and for sulphate	

*Status: This is the original version (as it was originally adopted).*

B. Solubility	Freely soluble in water, insoluble in ethanol
<b>Purity</b>	
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

<b>Synonyms</b>	Alum
<b>Definition</b>	
Chemical name	Aluminium sulphate
Einecs	233-135-0
Chemical formula	$Al_2(SO_4)_3$
Molecular weight	342,13
Assay	Content not less than 99,5 % on the ignited basis
<b>Description</b>	White powder, shining plates or crystalline fragments
<b>Identification</b>	
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
<b>Purity</b>	
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

<b>Synonyms</b>	Soda alum, sodium alum
<b>Definition</b>	

Chemical name	Aluminium sodium sulphate
Einecs	233-277-3
Chemical formula	$\text{AlNa}(\text{SO}_4)_2 \cdot n\text{H}_2\text{O}$ (n = 0 or 12)
Molecular weight	242,09 (anhydrous)
Assay	Content on the anhydrous basis not less than 96,5 % (anhydrous) and 99,5 % (dodecahydrate)
<b>Description</b>	Transparent crystals or white crystalline powder
<b>Identification</b>	
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
<b>Purity</b>	
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

<b>Synonyms</b>	Potassium alum, potash alum
<b>Definition</b>	
Chemical name	Aluminium potassium sulphate dodecahydrate
Einecs	233-141-3
Chemical formula	$\text{AlK}(\text{SO}_4)_2 \cdot 12 \text{H}_2\text{O}$
Molecular weight	474,38
Assay	Content not less than 99,5 %

*Status: This is the original version (as it was originally adopted).*

<b>Description</b>	Large, transparent crystals or white crystalline powder
<b>Identification</b>	
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
<b>Purity</b>	
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

<b>Synonyms</b>	Ammonium alum
<b>Definition</b>	
Chemical name	Aluminium ammonium sulphate
Einecs	232-055-3
Chemical formula	$\text{AlNH}_4(\text{SO}_4)_2 \cdot 12 \text{H}_2\text{O}$
Molecular weight	453,32
Assay	Content not less than 99,5 %
<b>Description</b>	Large, colourless crystals or white powder
<b>Identification</b>	
A. Positive tests for aluminium, for ammonium and for sulphate	
B. Solubility	Freely soluble in water, soluble in ethanol
<b>Purity</b>	
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

<b>Synonyms</b>	Caustic soda, lye
<b>Definition</b>	
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
<b>Description</b>	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
<b>Identification</b>	
A. Positive tests for sodium	
B. A 1 % solution is strongly alkaline	
C. Solubility	Very soluble in water. Freely soluble in ethanol
<b>Purity</b>	
Water insoluble and organic matter	A 5 % solution is completely clear and colourless to slightly coloured
Carbonate	Not more than 0,5 % (as Na <sub>2</sub> CO <sub>3</sub> )
Arsenic	Not more than 3 mg/kg
Lead	Not more than 0,5 mg/kg
Mercury	Not more than 1 mg/kg

## E 525 POTASSIUM HYDROXIDE

<b>Synonyms</b>	Caustic potash
<b>Definition</b>	

*Status: This is the original version (as it was originally adopted).*

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
<b>Description</b>	White or nearly white pellets, flakes, sticks, fused masses or other forms
<b>Identification</b>	
A. Positive tests for potassium	
B. A 1 % solution is strongly alkaline	
C. Solubility	Very soluble in water. Freely soluble in ethanol
<b>Purity</b>	
Water insoluble matter	A 5 % solution is completely clear and colourless
Carbonate	Not more than 3,5 % (as K <sub>2</sub> CO <sub>3</sub> )
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg

#### E 526 CALCIUM HYDROXIDE

<b>Synonyms</b>	Slaked lime, hydrated lime
<b>Definition</b>	
Chemical name	Calcium hydroxide
Einecs	215-137-3
Chemical formula	Ca(OH) <sub>2</sub>
Molecular weight	74,09
Assay	Content not less than 92,0 %
<b>Description</b>	White powder
<b>Identification</b>	
A. Positive tests for alkali and for calcium	
B. Solubility	Slightly soluble in water. Insoluble in ethanol. Soluble in glycerol

<b>Purity</b>	
Acid insoluble ash	Not more than 1,0 %
Magnesium and alkali salts	Not more than 1,0 %
Barium	Not more than 300 mg/kg
Fluoride	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg

## E 527 AMMONIUM HYDROXIDE

<b>Synonyms</b>	Aqua ammonia, strong ammonia solution
<b>Definition</b>	
Chemical name	Ammonium hydroxide
Chemical formula	NH <sub>4</sub> OH
Molecular weight	35,05
Assay	Content not less than 27 % of NH <sub>3</sub>
<b>Description</b>	Clear, colourless solution, having an exceedingly pungent, characteristic odour
<b>Identification</b>	
A. Positive tests for ammonia	
<b>Purity</b>	
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

<b>Definition</b>	
Chemical name	Magnesium hydroxide
Einecs	215-170-3
Chemical formula	Mg(OH) <sub>2</sub>
Molecular weight	58,32
Assay	Content not less than 95,0 % on the anhydrous basis
<b>Description</b>	Odourless, white bulky powder
<b>Identification</b>	

*Status: This is the original version (as it was originally adopted).*

A.	Positive test for magnesium and for alkali	
B.	Solubility	Practically insoluble in water and in ethanol
<b>Purity</b>		
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

<b>Synonyms</b>		Burnt lime
<b>Definition</b>		
Chemical name		Calcium oxide
Einecs		215-138-9
Chemical formula		CaO
Molecular weight		56,08
Assay		Content not less than 95,0 % on the ignited basis
<b>Description</b>		Odourless, hard, white or greyish white masses of granules, or white to greyish powder
<b>Identification</b>		
A.	Positive test for alkali and for calcium	
B.	Heat is generated on moistening the sample with water	
C.	Solubility	Slightly soluble in water. Insoluble in ethanol. Soluble in glycerol
<b>Purity</b>		
Loss on ignition		Not more than 10,0 % (ca 800 °C to constant weight)
Acid insoluble matter		Not more than 1,0 %
Barium		Not more than 300 mg/kg



Magnesium and alkali salts	Not more than 1,5 %
Fluoride	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg

## E 530 MAGNESIUM OXIDE

<b>Definition</b>	
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
<b>Description</b>	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
<b>Identification</b>	
A. Positive test for alkali and for magnesium	
B. Solubility	Practically insoluble in water. Insoluble in ethanol
<b>Purity</b>	
Loss on ignition	Not more than 5,0 % (ca 800 °C to constant weight)
Calcium oxide	Not more than 1,5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg

## E 535 SODIUM FERROCYANIDE

<b>Synonyms</b>	Yellow prussiate of soda, sodium hexacyanoferrate
<b>Definition</b>	
Chemical name	Sodium ferrocyanide

*Status: This is the original version (as it was originally adopted).*

Einecs	237-081-9
Chemical formula	$\text{Na}_4\text{Fe}(\text{CN})_6 \cdot 10 \text{H}_2\text{O}$
Molecular weight	484,1
Assay	Content not less than 99,0 %
<b>Description</b>	Yellow crystals or crystalline powder
<b>Identification</b>	
A. Positive test for sodium and for ferrocyanide	
<b>Purity</b>	
Free moisture	Not more than 1,0 %
Water insoluble matter	Not more than 0,03 %
Chloride	Not more than 0,2 %
Sulphate	Not more than 0,1 %
Free cyanide	Not detectable
Ferricyanide	Not detectable
Lead	Not more than 5 mg/kg

#### E 536 POTASSIUM FERROCYANIDE

<b>Synonyms</b>	Yellow prussiate of potash, potassium hexacyanoferrate
<b>Definition</b>	
Chemical name	Potassium ferrocyanide
Einecs	237-722-2
Chemical formula	$\text{K}_4\text{Fe}(\text{CN})_6 \cdot 3 \text{H}_2\text{O}$
Molecular weight	422,4
Assay	Content not less than 99,0 %
<b>Description</b>	Lemon yellow crystals
<b>Identification</b>	
A. Positive test for potassium and for ferrocyanide	
<b>Purity</b>	
Free moisture	Not more than 1,0 %
Water insoluble matter	Not more than 0,03 %
Chloride	Not more than 0,2 %

Sulphate	Not more than 0,1 %
Free cyanide	Not detectable
Ferricyanide	Not detectable
Lead	Not more than 5 mg/kg

## E 538 CALCIUM FERROCYANIDE

<b>Synonyms</b>	Yellow prussiate of lime, calcium hexacyanoferrate
<b>Definition</b>	
Chemical name	Calcium ferrocyanide
Einecs	215-476-7
Chemical formula	$\text{Ca}_2\text{Fe}(\text{CN})_6 \cdot 12\text{H}_2\text{O}$
Molecular weight	508,3
Assay	Content not less than 99,0 %
<b>Description</b>	Yellow crystals or crystalline powder
<b>Identification</b>	
A. Positive test for calcium and for ferrocyanide	
<b>Purity</b>	
Free moisture	Not more than 1,0 %
Water insoluble matter	Not more than 0,03 %
Chloride	Not more than 0,2 %
Sulphate	Not more than 0,1 %
Free cyanide	Not detectable
Ferricyanide	Not detectable
Lead	Not more than 5 mg/kg

## E 541 SODIUM ALUMINIUM PHOSPHATE, ACIDIC

<b>Synonyms</b>	SALP
<b>Definition</b>	
Chemical name	Sodium trialuminium tetradecahydrogen octaphosphate tetrahydrate (A) or Trisodium dialuminium pentadecahydrogen octaphosphate (B)
Einecs	232-090-4

*Status: This is the original version (as it was originally adopted).*

Chemical formula	NaAl <sub>3</sub> H <sub>14</sub> (PO <sub>4</sub> ) <sub>8</sub> · 4H <sub>2</sub> O (A)
	Na <sub>3</sub> Al <sub>2</sub> H <sub>15</sub> (PO <sub>4</sub> ) <sub>8</sub> (B)
Molecular weight	949,88 (A)
	897,82 (B)
Assay	Content not less than 95,0 % (both forms)
<b>Description</b>	White odourless powder
<b>Identification</b>	
A. Positive test for sodium, for aluminium and for phosphate	
B. pH	Acid to litmus
C. Solubility	Insoluble in water. Soluble in hydrochloric acid
<b>Purity</b>	
Loss on ignition	19,5 %-21,0 % (A) } (750 °C-800 °C, 2h)
	15 %-16 % (B) } (750 °C-800 °C, 2h)
Fluoride	Not more than 25 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 4 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

#### E 551 SILICON DIOXIDE

<b>Synonyms</b>	Silica, silicium dioxide
<b>Definition</b>	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	(SiO <sub>2</sub> ) <sub>n</sub>
Molecular weight	60,08 (SiO <sub>2</sub> )

Assay	Content after ignition not less than 99,0 % (fumed silica) or 94,0 % (hydrated forms)
<b>Description</b>	White, fluffy powder or granules
	Hygroscopic
<b>Identification</b>	
A. Positive test for silica	
<b>Purity</b>	
Loss on drying	Not more than 2,5 % (fumed silica, 105 °C, 2h)
	Not more than 8,0 % (precipitated silica and silica gel, 105 °C, 2h)
	Not more than 70 % (hydrous silica, 105 °C, 2h)
Loss on ignition	Not more than 2,5 % after drying (1 000 °C, fumed silica)
	Not more than 8,5 % after drying (1 000 °C, hydrated forms)
Soluble ionisable salts	Not more than 5,0 % (as Na <sub>2</sub> SO <sub>4</sub> )
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

<b>Definition</b>	Calcium silicate is a hydrous or anhydrous silicate with varying proportions of CaO and SiO <sub>2</sub>
Chemical name	Calcium silicate
Einecs	215-710-8
Assay	Content on the anhydrous basis: — as SiO <sub>2</sub> not less than 50 % and not more than 95 % — as CaO not less than 3 % and not more than 35 %
<b>Description</b>	White to off-white free-flowing powder that remains so after absorbing relatively large amounts of water or other liquids
<b>Identification</b>	

*Status: This is the original version (as it was originally adopted).*

A.	Positive test for silicate and for calcium	
B.	Forms a gel with mineral acids	
<b>Purity</b>		
Loss on drying		Not more than 10 % (105 °C, 2h)
Loss on ignition		Not less than 5 % and not more than 14 % (1 000 °C, constant weight)
Sodium		Not more than 3 %
Fluoride		Not more than 50 mg/kg
Arsenic		Not more than 3 mg/kg
Lead		Not more than 5 mg/kg
Mercury		Not more than 1 mg/kg

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

<b>Definition</b>	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 SiO <sub>2</sub> on the ignited basis	
<b>Description</b>	Very fine, white, odourless powder, free from grittiness	
<b>Identification</b>		
A.	Positive test for magnesium and for silicate	
B.	pH of a 10 % slurry	Between 7,0 and 10,8
<b>Purity</b>		
Loss on drying		Not more than 15 % (105 °C, 2h)
Loss on ignition		Not more than 15 % after drying (1 000 °C, 20 min)
Water soluble salts		Not more than 3 %
Free alkali		Not more than 1 % (as NaOH)
Fluoride		Not more than 10 mg/kg
Arsenic		Not more than 3 mg/kg
Lead		Not more than 5 mg/kg
Mercury		Not more than 1 mg/kg

## E 553a(ii) MAGNESIUM TRISILICATE

<b>Definition</b>	
Chemical name	Magnesium trisilicate
Chemical formula	$Mg_2Si_3O_8 \cdot xH_2O$ (approximate composition)
Einecs	239-076-7
Assay	Content not less than 29,0 % of MgO and not less than 65,0 % of SiO <sub>2</sub> both on the ignited basis
<b>Description</b>	Fine, white powder, free from grittiness
<b>Identification</b>	
A. Positive test for magnesium and for silicate	
B. pH of a 5 % slurry	Between 6,3 and 9,5
<b>Purity</b>	
Loss on ignition	Not less than 17 % and not more than 34 % (1 000 °C)
Water soluble salts	Not more than 2 %
Free alkali	Not more than 1 % (as NaOH)
Fluoride	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

## E 553b TALC

<b>Synonyms</b>	Talcum
<b>Definition</b>	Naturally occurring form of hydrous magnesium silicate containing varying proportions of such associated minerals as alpha-quartz, calcite, chlorite, dolomite, magnesite, and phlogopite
Chemical name	Magnesium hydrogen metasilicate
Einecs	238-877-9
Chemical formula	$Mg_3(Si_4O_{10})(OH)_2$
Molecular weight	379,22
<b>Description</b>	Light, homogeneous, white or almost white powder, greasy to the touch

*Status: This is the original version (as it was originally adopted).*

<b>Identification</b>	
A. IR absorption	Characteristic peaks at 3 677, 1 018 and 669 $\text{cm}^{-1}$
B. X-ray diffraction	Peaks at 9,34/4,66/3,12 Å
C. Solubility	Insoluble in water and ethanol
<b>Purity</b>	
Loss on drying	Not more than 0,5 % (105 °C, 1h)
Acid-soluble matter	Not more than 6 %
Water-soluble matter	Not more than 0,2 %
Acid-soluble iron	Not detectable
Arsenic	Not more than 10 mg/kg
Lead	Not more than 5 mg/kg

#### E 554 SODIUM ALUMINIUM SILICATE

<b>Synonyms</b>	Sodium silicoaluminate, sodium aluminosilicate, aluminium sodium silicate
<b>Definition</b>	
Chemical name	Sodium aluminium silicate
Assay	Content on the anhydrous basis: — as $\text{SiO}_2$ not less than 66,0 % and not more than 88,0 % — as $\text{Al}_2\text{O}_3$ not less than 5,0 % and not more than 15,0 %
<b>Description</b>	Fine white amorphous powder or beads
<b>Identification</b>	
A. Positive tests for sodium, for aluminium and for silicate	
B. pH of a 5 % slurry	Between 6,5 and 11,5
<b>Purity</b>	
Loss on drying	Not more than 8,0 % (105 °C, 2h)
Loss on ignition	Not less than 5,0 % and not more than 11,0 % on the anhydrous basis (1 000 °C, constant weight)
Sodium	Not less than 5 % and not more than 8,5 % (as $\text{Na}_2\text{O}$ ) on the anhydrous basis



*Status: This is the original version (as it was originally adopted).*

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

#### E 555 POTASSIUM ALUMINIUM SILICATE

<b>Synonyms</b>	Mica
<b>Definition</b>	Natural mica consists of mainly potassium aluminium silicate (muscovite)
Einecs	310-127-6
Chemical name	Potassium aluminium silicate
Chemical formulae	$KAl_2[AlSi_3O_{10}](OH)_2$
Molecular weight	398
Assay	Content not less than 98 %
<b>Description</b>	Light grey to white crystalline platelets or powder
<b>Identification</b>	
A. Solubility	Insoluble in water, diluted acids and alkali and organic solvents
<b>Purity</b>	
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

<b>Synonyms</b>	Calcium aluminosilicate, calcium silicoaluminate, aluminium calcium silicate
<b>Definition</b>	

*Status: This is the original version (as it was originally adopted).*

Chemical name	Calcium aluminium silicate
Assay	Content on the anhydrous basis: — as SiO <sub>2</sub> not less than 44,0 % and not more than 50,0 % — as Al <sub>2</sub> O <sub>3</sub> not less than 3,0 % and not more than 5,0 % — as CaO not less than 32,0 % and not more than 38,0 %
<b>Description</b>	Fine white, free-flowing powder
<b>Identification</b>	
A. Positive tests for calcium, for aluminium and for silicate	
<b>Purity</b>	
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

<b>Definition</b>	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) <sub>8</sub> (Si <sub>4</sub> O <sub>10</sub> ) <sub>4</sub> (OH) <sub>8</sub> · 12H <sub>2</sub> O
Molecular weight	819
Assay	Montmorillonite content not less than 80 %
<b>Description</b>	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)
<b>Identification</b>	
A. Methylene blue test	
B. X-Ray diffraction	Characteristic peaks at 12,5/15 Å
C. IR absorption	Peaks at 428/470/530/1 110-1 020/3 750 — 3 400 cm <sup>-1</sup>
<b>Purity</b>	
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

## E 559 ALUMINIUM SILICATE (KAOLIN)

<b>Synonyms</b>	Kaolin, light or heavy	
<b>Definition</b>	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	Al <sub>2</sub> Si <sub>2</sub> O <sub>5</sub> (OH) <sub>4</sub> (kaolinite)	
Molecular weight	264	
Assay	Content not less than 90 % (sum of silica and alumina, after ignition)	
	Silica (SiO <sub>2</sub> )	Between 45 % and 55 %
	Alumina (Al <sub>2</sub> O <sub>3</sub> )	Between 30 % and 39 %
<b>Description</b>	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	
<b>Identification</b>		
A. Positive tests for alumina and for silicate		
B. X-ray diffraction:	Characteristic peaks at 7,18/3,58/2,38/1,78 Å	

*Status: This is the original version (as it was originally adopted).*

C. IR absorption:	Peaks at 3 700 and 3 620 cm <sup>-1</sup>
<b>Purity</b>	
Loss on ignition	Between 10 and 14 % (1 000 °C, constant weight)
Water soluble matter	Not more than 0,3 %
Acid soluble matter	Not more than 2 %
Iron	Not more than 5 %
Potassium oxide (K <sub>2</sub> O)	Not more than 5 %
Carbon	Not more than 0,5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

#### E 570 FATTY ACIDS

<b>Definition</b>	Linear fatty acids, caprylic acid (C <sub>8</sub> ), capric acid (C <sub>10</sub> ), lauric acid (C <sub>12</sub> ), myristic acid (C <sub>14</sub> ), palmitic acid (C <sub>16</sub> ), stearic acid (C <sub>18</sub> ), oleic acid (C <sub>18:1</sub> )
Chemical name	octanoic acid (C <sub>8</sub> ), decanoic acid (C <sub>10</sub> ), dodecanoic acid (C <sub>12</sub> ), tetradecanoic acid (C <sub>14</sub> ), hexadecanoic acid (C <sub>16</sub> ), octadecanoic acid (C <sub>18</sub> ), 9-octadecenoic acid (C <sub>18:1</sub> )
Assay	Not less than 98 % by chromatography
<b>Description</b>	A colourless liquid or white solid obtained from oils and fats
<b>Identification</b>	
A. Individual fatty acids can be identified by acid value, iodine value, gas chromatography and molecular weight	
<b>Purity</b>	
Residue on ignition	Not more than 0,1 %
Unsaponifiable matter	Not more than 1,5 %
Water	Not more than 0,2 % (Karl Fischer method)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

## E 574 GLUCONIC ACID

<b>Synonyms</b>	D-gluconic acid, dextronic acid
<b>Definition</b>	Gluconic acid is an aqueous solution of gluconic acid and glucono-delta-lactone
Chemical name	Gluconic acid
Chemical formula	C <sub>6</sub> H <sub>12</sub> O <sub>7</sub> (gluconic acid)
Molecular weight	196,2
Assay	Content not less than 50,0 % (as gluconic acid)
<b>Description</b>	Colourless to light yellow, clear syrupy liquid
<b>Identification</b>	
A. Formation of phenylhydrazine derivative positive	Compound formed melts between 196 °C and 202 °C with decomposition
<b>Purity</b>	
Residue on ignition	Not more than 1,0 %
Reducing matter	Not more than 0,75 % (as D-glucose)
Chloride	Not more than 350 mg/kg
Sulphate	Not more than 240 mg/kg
Sulphite	Not more than 20 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

## E 575 GLUCONO-DELTA-LACTONE

<b>Synonyms</b>	Gluconolactone, GDL, D-gluconic acid delta-lactone, delta-gluconolactone
<b>Definition</b>	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	C <sub>6</sub> H <sub>10</sub> O <sub>6</sub>
Molecular weight	178,14

*Status: This is the original version (as it was originally adopted).*

Assay	Content not less than 99,0 % on the anhydrous basis
<b>Description</b>	Fine, white, nearly odourless, crystalline powder
<b>Identification</b>	
A. Formation of phenylhydrazine derivative of gluconic acid positive	Compound formed melts between 196 °C and 202 °C with decomposition
B. Solubility	Freely soluble in water. Sparingly soluble in ethanol
C. Melting point	152 °C ± 2 °C
<b>Purity</b>	
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

<b>Synonyms</b>	Sodium salt of D-gluconic acid
<b>Definition</b>	
Chemical name	Sodium D-gluconate
Einecs	208-407-7
Chemical formula	C <sub>6</sub> H <sub>11</sub> NaO <sub>7</sub> (anhydrous)
Molecular weight	218,14
Assay	Content not less than 98,0 %
<b>Description</b>	White to tan, granular to fine, crystalline powder
<b>Identification</b>	
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
<b>Purity</b>	
Reducing matter	Not more than 1,0 % (as D-glucose)
Lead	Not more than 2 mg/kg

#### E 577 POTASSIUM GLUCONATE

<b>Synonyms</b>	Potassium salt of D-gluconic acid
<b>Definition</b>	
Chemical name	Potassium D-gluconate
Einecs	206-074-2
Chemical formula	C <sub>6</sub> H <sub>11</sub> KO <sub>7</sub> (anhydrous)
	C <sub>6</sub> H <sub>11</sub> KO <sub>7</sub> · H <sub>2</sub> O (monohydrate)
Molecular weight	234,25 (anhydrous)
	252,26 (monohydrate)
Assay	Content not less than 97,0 % and not more than 103,0 % on dried basis
<b>Description</b>	Odourless, free flowing white to yellowish white, crystalline powder or granules
<b>Identification</b>	
A. Positive test for potassium and for gluconate	
B. pH of a 10 % solution	Between 7,0 and 8,3
<b>Purity</b>	
Loss on drying	Anhydrous: not more than 3,0 % (105 °C, 4h, vacuum) Monohydrate: not less than 6 % and not more than 7,5 % (105 °C, 4h, vacuum)
Reducing substances	Not more than 1,0 % (as D-glucose)
Lead	Not more than 2 mg/kg

## E 578 CALCIUM GLUCONATE

<b>Synonyms</b>	Calcium salt of D-gluconic acid
<b>Definition</b>	
Chemical name	Calcium di-D-gluconate
Einecs	206-075-8
Chemical formula	C <sub>12</sub> H <sub>22</sub> CaO <sub>14</sub> (anhydrous)
	C <sub>12</sub> H <sub>22</sub> CaO <sub>14</sub> · H <sub>2</sub> O (monohydrate)
Molecular weight	430,38 (anhydrous form)
	448,39 (monohydrate)
Assay	Content not less than 98,0 % and not more than 102 % on the anhydrous and monohydrate basis

*Status: This is the original version (as it was originally adopted).*

<b>Description</b>	Odourless, white crystalline granules or powder, stable in air
<b>Identification</b>	
A. Positive test for calcium and for gluconate	
B. Solubility	Soluble in water, insoluble in ethanol
C. pH of a 5 % solution	Between 6,0 and 8,0
<b>Purity</b>	
Loss on drying	Not more than 3,0 % (105 °C, 16h) (anhydrous)
	Not more than 2,0 % (105 °C, 16h) (monohydrate)
Reducing substances	Not more than 1,0 % (as D-glucose)
Lead	Not more than 2 mg/kg

#### E 579 FERROUS GLUCONATE

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



Loss on drying	Not more than 10 % (105 °C, 16 hours)
Oxalic acid	Not detectable
Iron (Fe III)	Not more than 2 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Reducing substances	Not more than 0,5 % expressed as glucose

## E 585 FERROUS LACTATE

<b>Synonyms</b>	Iron(II) lactate
	Iron(II) 2-hydroxy propanoate
	Propanoic acid, 2-hydroxy-iron(2 +) salt (2:1)
<b>Definition</b>	
Chemical name	Ferrous 2-hydroxy propanoate
Einecs	227-608-0
Chemical formulae	$C_6H_{10}FeO_6 \cdot xH_2O$ (x = 2 or 3)
Molecular weight	270,02 (dihydrate) 288,03 (trihydrate)
Assay	Content not less than 96 % on the dried basis
<b>Description</b>	Greenish-white crystals or light green powder having a characteristic smell
<b>Identification</b>	
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
<b>Purity</b>	
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

*Status: This is the original version (as it was originally adopted).*

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

#### E 586 4-HEXYLRESORCINOL

<b>Synonyms</b>	4-Hexyl-1,3-benzenediol Hexylresorcinol
<b>Definition</b>	
Chemical name	4-Hexylresorcinol
Einecs	205-257-4
Chemical formula	C <sub>12</sub> H <sub>18</sub> O <sub>2</sub>
Molecular weight	197,24
Assay	Not less than 98 % on the dried basis
<b>Description</b>	White powder
<b>Identification</b>	
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
<b>Purity</b>	
Acidity	Not more than 0,05 %
Sulphated ash	Not more than 0,1 %
Resorcinol and other phenols	Shake about 1 g of the sample with 50 ml of water for a few minutes, filter, and to the filtrate add 3 drops of ferric chloride TS. No red or blue colour is produced
Nickel	Not more than 2 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 3 mg/kg

#### E 620 GLUTAMIC ACID

<b>Synonyms</b>	L-Glutamic acid, L- $\alpha$ -aminoglutaric acid
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<b>Definition</b>	
Chemical name	L-Glutamic acid, L-2-amino-pentanedioic acid
Einecs	200-293-7
Chemical formula	C <sub>5</sub> H <sub>9</sub> NO <sub>4</sub>
Molecular weight	147,13
Assay	Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis
<b>Description</b>	
White crystals or crystalline powder	
<b>Identification</b>	
A.	Positive test for glutamic acid by thin layer chromatography
B.	Specific rotation $[\alpha]_D^{20}$
	Between 31,5° and 32,2° (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
C.	pH of a saturated solution
	Between 3,0 and 3,5
<b>Purity</b>	
Loss on drying	Not more than 0,2 % (80 °C, 3h)
Sulphated ash	Not more than 0,2 %
Chloride	Not more than 0,2 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Lead	Not more than 2 mg/kg

## E 621 MONOSODIUM GLUTAMATE

<b>Synonyms</b>	
Sodium glutamate, MSG	
<b>Definition</b>	
Chemical name	Monosodium L-glutamate monohydrate
Einecs	205-538-1
Chemical formula	C <sub>5</sub> H <sub>8</sub> NaNO <sub>4</sub> · H <sub>2</sub> O
Molecular weight	187,13
Assay	Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis
<b>Description</b>	
White, practically odourless crystals or crystalline powder	
<b>Identification</b>	

*Status: This is the original version (as it was originally adopted).*

A.	Positive test for sodium	
B.	Positive test for glutamic acid by thin-layer chromatography	
C.	Specific rotation $[\alpha]_D^{20}$	Between 24,8° and 25,3° (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
D.	pH of a 5 % solution	Between 6,7 and 7,2
<b>Purity</b>		
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

<b>Synonyms</b>	Potassium glutamate, MPG	
<b>Definition</b>		
Chemical name	Monopotassium L-glutamate monohydrate	
Einecs	243-094-0	
Chemical formula	$C_5H_8KNO_4 \cdot H_2O$	
Molecular weight	203,24	
Assay	Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis	
<b>Description</b>	White, practically odourless crystals or crystalline powder	
<b>Identification</b>		
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
<b>Purity</b>		

*Status: This is the original version (as it was originally adopted).*

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

<b>Synonyms</b>	Calcium glutamate
<b>Definition</b>	
Chemical name	Monocalcium di-L-glutamate
Einecs	242-905-5
Chemical formula	$C_{10}H_{16}CaN_2O_8 \cdot x H_2O$ (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
<b>Description</b>	White, practically odourless crystals or crystalline powder
<b>Identification</b>	
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)
<b>Purity</b>	
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

<b>Synonyms</b>	Ammonium glutamate
<b>Definition</b>	
Chemical name	Monoammonium L-glutamate monohydrate
Einecs	231-447-1

*Status: This is the original version (as it was originally adopted).*

Chemical formula	$C_5H_{12}N_2O_4 \cdot H_2O$
Molecular weight	182,18
Assay	Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis
<b>Description</b>	White, practically odourless crystals or crystalline powder
<b>Identification</b>	
A. Positive test for ammonium	
B. Positive test for glutamic acid by thin-layer chromatography	
C. Specific rotation $[\alpha]_D^{20}$	Between 25,4° and 26,4° (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
D. pH of a 5 % solution	Between 6,0 and 7,0
<b>Purity</b>	
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

<b>Synonyms</b>	Magnesium glutamate
<b>Definition</b>	
Chemical name	Monomagnesium di-L-glutamate tetrahydrate
Einecs	242-413-0
Chemical formula	$C_{10}H_{16}MgN_2O_8 \cdot 4H_2O$
Molecular weight	388,62
Assay	Content not less than 95,0 % and not more than 105,0 % on the anhydrous basis
<b>Description</b>	Odourless, white or off-white crystals or powder
<b>Identification</b>	
A. Positive test for magnesium	

B.	Positive test for glutamic acid by thin-layer chromatography	
C.	Specific rotation $[\alpha]_D^{20}$	Between 23,8° and 24,4° (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
D.	pH of a 10 % solution	Between 6,4 and 7,5
<b>Purity</b>		
	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

<b>Synonyms</b>	Guanylic acid	
<b>Definition</b>		
Chemical name	Guanosine-5'-monophosphoric acid	
Einecs	201-598-8	
Chemical formula	C <sub>10</sub> H <sub>14</sub> N <sub>5</sub> O <sub>8</sub> P	
Molecular weight	363,22	
Assay	Content not less than 97,0 % on the anhydrous basis	
<b>Description</b>	Odourless, colourless or white crystals or white crystalline powder	
<b>Identification</b>		
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
<b>Purity</b>		
	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

*Status: This is the original version (as it was originally adopted).*

<b>Synonyms</b>	Sodium guanylate, sodium 5'-guanylate
<b>Definition</b>	
Chemical name	Disodium guanosine-5'-monophosphate
Einecs	221-849-5
Chemical formula	$C_{10}H_{12}N_5Na_2O_8P \cdot x H_2O$ (x = ca. 7)
Molecular weight	407,19 (anhydrous)
Assay	Content not less than 97,0 % on the anhydrous basis
<b>Description</b>	Odourless, colourless or white crystals or white crystalline powder
<b>Identification</b>	
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
<b>Purity</b>	
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

<b>Synonyms</b>	Potassium guanylate, potassium 5'-guanylate
<b>Definition</b>	
Chemical name	Dipotassium guanosine-5'-monophosphate
Einecs	226-914-1
Chemical formula	$C_{10}H_{12}K_2N_5O_8P$
Molecular weight	439,4
Assay	Content not less than 97,0 % on the anhydrous basis
<b>Description</b>	Odourless, colourless or white crystals or white crystalline powder
<b>Identification</b>	
A. Positive test for ribose, for organic phosphate, and for potassium	



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
<b>Purity</b>		
	Loss on drying	Not more than 5 % (120 °C, 4h)
	Other nucleotides	Not detectable by thin-layer chromatography
	Lead	Not more than 2 mg/kg

## E 629 CALCIUM GUANYLATE

<b>Synonyms</b>		Calcium 5'-guanylate
<b>Definition</b>		
Chemical name		Calcium guanosine-5'-monophosphate
Chemical formula		C <sub>10</sub> H <sub>12</sub> CaN <sub>5</sub> O <sub>8</sub> P · nH <sub>2</sub> O
Molecular weight		401,2 (anhydrous)
Assay		Content not less than 97,0 % on the anhydrous basis
<b>Description</b>		Odourless, white or off-white crystals or powder
<b>Identification</b>		
A.	Positive test for ribose, 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 256 nm
<b>Purity</b>		
	Loss on drying	Not more than 23,0 % (120 °C, 4h)
	Other nucleotides	Not detectable by thin-layer chromatography
	Lead	Not more than 2 mg/kg

## E 630 INOSINIC ACID

<b>Synonyms</b>		5'-Inosinic acid
<b>Definition</b>		
Chemical name		Inosine-5'-monophosphoric acid
Einecs		205-045-1

*Status: This is the original version (as it was originally adopted).*

Chemical formula	$C_{10}H_{13}N_4O_8P$
Molecular weight	348,21
Assay	Content not less than 97,0 % on the anhydrous basis
<b>Description</b>	Odourless, colourless or white crystals or powder
<b>Identification</b>	
A. Positive test for ribose, and for organic phosphate	
B. pH of a 5 % solution	Between 1,0 and 2,0
C. Spectrometry:	maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm
<b>Purity</b>	
Loss on drying	Not more than 3,0 % (120 °C, 4h)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

#### E 631 DISODIUM INOSINATE

<b>Synonyms</b>	Sodium inosinate, sodium 5'-inosinate
<b>Definition</b>	
Chemical name	Disodium inosine-5'-monophosphate
Einecs	225-146-4
Chemical formula	$C_{10}H_{11}N_4Na_2O_8P \cdot H_2O$
Molecular weight	392,17 (anhydrous)
Assay	Content not less than 97,0 % on the anhydrous basis
<b>Description</b>	Odourless, colourless or white crystals or powder
<b>Identification</b>	
A. Positive test for ribose, and 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 250 nm
<b>Purity</b>	

*Status: This is the original version (as it was originally adopted).*

Water	Not more than 28,5 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

#### E 632 DIPOTASSIUM INOSINATE

<b>Synonyms</b>	Potassium inosinate, potassium 5'-inosinate
<b>Definition</b>	
Chemical name	Dipotassium inosine-5'-monophosphate
Einecs	243-652-3
Chemical formula	C <sub>10</sub> H <sub>11</sub> K <sub>2</sub> N <sub>4</sub> O <sub>8</sub> P
Molecular weight	424,39
Assay	Content not less than 97,0 % on the anhydrous basis
<b>Description</b>	Odourless, colourless or white crystals or powder
<b>Identification</b>	
A. Positive test for ribose, and for organic phosphate and for potassium	
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 250 nm
<b>Purity</b>	
Water	Not more than 10,0 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

#### E 633 CALCIUM INOSINATE

<b>Synonyms</b>	Calcium 5'-inosinate
<b>Definition</b>	
Chemical name	Calcium inosine-5'-monophosphate
Chemical formula	C <sub>10</sub> H <sub>11</sub> CaN <sub>4</sub> O <sub>8</sub> P · nH <sub>2</sub> O
Molecular weight	386,19 (anhydrous)
Assay	Content not less than 97,0 % on the anhydrous basis

*Status: This is the original version (as it was originally adopted).*

<b>Description</b>	Odourless, colourless or white crystals or powder
<b>Identification</b>	
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
<b>Purity</b>	
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

<b>Definition</b>	
Chemical name	Calcium 5'-ribonucleotide is essentially a mixture of calcium inosine-5'-monophosphate and calcium guanosine-5'-monophosphate
Chemical formula	$C_{10}H_{11}N_4CaO_8P \cdot nH_2O$ $C_{10}H_{12}N_5CaO_8P \cdot nH_2O$
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
<b>Description</b>	Odourless, white or nearly white crystals or powder
<b>Identification</b>	
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
<b>Purity</b>	
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

<b>Synonyms</b>	Sodium 5'-ribonucleotide
<b>Definition</b>	
Chemical name	Disodium 5'-ribonucleotide is essentially a mixture of disodium inosine-5'-monophosphate and disodium guanosine-5'-monophosphate
Chemical formula	C <sub>10</sub> H <sub>11</sub> N <sub>4</sub> Na <sub>2</sub> O <sub>8</sub> P · nH <sub>2</sub> O and C <sub>10</sub> H <sub>12</sub> N <sub>5</sub> Na <sub>2</sub> O <sub>8</sub> P · nH <sub>2</sub> 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
<b>Description</b>	Odourless, white or nearly white crystals or powder
<b>Identification</b>	
A. Positive test for ribose, and for organic phosphate and for sodium	
B. pH of a 5 % solution	Between 7,0 and 8,5
<b>Purity</b>	
Water	Not more than 26,0 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

## E 640 GLYCINE AND ITS SODIUM SALT

<b>Synonyms(gly)</b>	Aminoacetic acid, glycocoll
<b>(Na salt)</b>	Sodium glycinate
<b>Definition</b>	
Chemical name (gly)	Aminoacetic acid
(Na salt)	Sodium glycinate
Chemical formula (gly)	C <sub>2</sub> H <sub>5</sub> NO <sub>2</sub>
(Na salt)	C <sub>2</sub> H <sub>5</sub> NO <sub>2</sub> Na
Einecs (gly)	200-272-2
(Na salt)	227-842-3
Molecular weight (gly)	75,07
(Na salt)	98

*Status: This is the original version (as it was originally adopted).*

Assay	Content not less than 98,5 % on the anhydrous basis
<b>Description</b>	White crystals or crystalline powder
<b>Identification</b>	
A. Positive test for amino acid (gly and Na salt)	
B. Positive test for sodium (Na salt)	
<b>Purity</b>	
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 650 ZINC ACETATE

<b>Synonyms</b>	Acetic acid, zinc salt, dihydrate
<b>Definition</b>	
Chemical name	Zinc acetate dihydrate
Chemical formula	$C_4H_6O_4 Zn \cdot 2H_2O$
Molecular weight	219,51
Assay	Content not less than 98 % and not more than 102 % of $C_4H_6O_4 Zn \cdot 2H_2O$
<b>Description</b>	Colourless crystals or fine, off-white powder
<b>Identification</b>	
A. Positive tests for acetate and for zinc	
B. pH of a 5 % solution	Between 6,0 and 8,0
<b>Purity</b>	
Insoluble matter	Not more than 0,005 %
Chlorides	Not more than 50 mg/kg
Sulphates	Not more than 100 mg/kg

Alkalines and alkaline earths	Not more than 0,2 %
Organic volatile impurities	Passes test
Iron	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 20 mg/kg
Cadmium	Not more than 5 mg/kg

## E 900 DIMETHYL POLYSILOXANE

<b>Synonyms</b>	Polydimethyl siloxane, silicone fluid, silicone oil, dimethyl silicone
<b>Definition</b>	Dimethylpolysiloxane is a mixture of fully methylated linear siloxane polymers containing repeating units of the formula $(\text{CH}_3)_2\text{SiO}$ and stabilised with trimethylsiloxy end-blocking units of the formula $(\text{CH}_3)_3\text{SiO}$
Chemical name	Siloxanes and silicones, di-methyl
Chemical formula	$(\text{CH}_3)_3\text{-Si-[O-Si(CH}_3)_2]_n\text{-O-Si(CH}_3)_3$
Assay	Content of total silicon not less than 37,3 % and not more than 38,5 %
<b>Description</b>	Clear, colourless, viscous liquid
<b>Identification</b>	
A. Specific gravity (25°/25 °C)	Between 0,964 and 0,977
B. Refractive index $[n]_D^{25}$	Between 1,4 and 1,405
C. Infrared spectrum characteristic of the compound	
<b>Purity</b>	
Loss on drying	Not more than 0,5 % (150 °C, 4h)
Viscosity	Not less than $1,0 \cdot 10^{-4} \text{ m}^2\text{s}^{-1}$ at 25 °C
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

## E 901 BEESWAX

<b>Synonyms</b>	White wax, yellow wax
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*Status: This is the original version (as it was originally adopted).*

<b>Definition</b>	Yellow bees wax is the wax obtained by melting the walls of the honeycomb made by the honey bee, <i>Apis mellifera</i> L., with hot water and removing foreign matter
	White beeswax is obtained by bleaching yellow beeswax
Einecs	232-383-7 (beeswax)
<b>Description</b>	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
<b>Identification</b>	
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
<b>Purity</b>	
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

<b>Definition</b>	Candelilla wax is a purified wax obtained from the leaves of the candelilla plant, <i>Euphorbia antisyphilitica</i>
Einecs	232-347-0
<b>Description</b>	Hard, yellowish brown, opaque to translucent wax
<b>Identification</b>	



A.	Specific gravity	About 0,983
B.	Melting range	Between 68,5 °C and 72,5 °C
C.	Solubility	Insoluble in water
		Soluble in chloroform and toluene
<b>Purity</b>		
	Acid value	Not less than 12 and not more than 22
	Saponification value	Not less than 43 and not more than 65
	Glycerol and other polyols	Not more than 0,5 % (as glycerol)
	Ceresin, paraffins and certain other waxes	Absent
	Fats, Japan wax, rosin and soaps	Absent
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 5 mg/kg
	Mercury	Not more than 1 mg/kg

## E 903 CARNAUBA WAX

<b>Definition</b>	Carnauba wax is a purified wax obtained from the leaf buds and leaves of the Brazilian Mart wax palm, <i>Copernicia cerifera</i>	
Einecs	232-399-4	
<b>Description</b>	Light brown to pale yellow powder or flakes or hard and brittle solid with a resinous fracture	
<b>Identification</b>		
A.	Specific gravity	About 0,997
B.	Melting range	Between 82 °C and 86 °C
C.	Solubility	Insoluble in water
		Partly soluble in boiling ethanol
		Soluble in chloroform and diethyl ether
<b>Purity</b>		
	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

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*Status: This is the original version (as it was originally adopted).*

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

## E 904 SHELLAC

<b>Synonyms</b>	Bleached shellac, white shellac
<b>Definition</b>	Shellac is the purified and bleached lac, the resinous secretion of the insect <i>Laccifer (Tachardia) lacca</i> Kerr (Fam. <i>Coccidae</i> )
Einecs	232-549-9
<b>Description</b>	Bleached shellac — off-white, amorphous, granular resin Wax-free bleached shellac — light yellow, amorphous, granular resin
<b>Identification</b>	
A. Solubility	Insoluble in water; freely (though very slowly) soluble in alcohol; slightly soluble in acetone
B. Acid value	Between 60 and 89
<b>Purity</b>	
Loss on drying	Not more than 6,0 % (40 °C, over silica gel, 15h)
Rosin	Absent
Wax	Bleached shellac: not more than 5,5 % Wax-free bleached shellac: not more than 0,2 %
Lead	Not more than 2 mg/kg

## E 905 MICROCRYSTALLINE WAX

<b>Synonyms</b>	Petroleum wax
<b>Definition</b>	Microcrystalline wax is a refined mixture of solid, saturated hydrocarbons, mainly branched paraffin, obtained from petroleum
<b>Description</b>	White to amber, odourless wax
<b>Identification</b>	
A. Solubility	Insoluble in water, very slightly soluble in ethanol
B. Refractive Index	$n_D^{100}$ 1,434-1,448

<b>Purity</b>		
Molecular weight	Average not less than 500	
Viscosity at 100 °C	Not less than $1,1 \cdot 10^{-5} \text{ m}^2\text{s}^{-1}$	
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:	
	nm	Maximum absorbance per cm path length
	280-289	0,15
	290-299	0,12
	300-359	0,08
	360-400	0,02

## E 907 HYDROGENATED POLY-1-DECENE

<b>Synonyms</b>	Hydrogenated polydec-1-ene
	Hydrogenated poly-alpha-olefin
<b>Definition</b>	
Chemical formula	$\text{C}_{10n}\text{H}_{20n+2}$ 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 <sub>30</sub> : 13-37 %
	C <sub>40</sub> : 35-70 %
	C <sub>50</sub> : 9-25 %
	C <sub>60</sub> : 1-7 %
<b>Description</b>	
<b>Identification</b>	

*Status: This is the original version (as it was originally adopted).*

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
<b>Purity</b>		
Viscosity		Between $5,7 \times 10^{-6}$ and $6,1 \times 10^{-6} \text{ m}^2\text{s}^{-1}$ 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 sulphuric acid with a 5 g sample of hydrogenated poly-1-decene is not darker than a very slight straw colour
Nickel		Not more than 1 mg/kg
Lead		Not more than 1 mg/kg

#### E 912 MONTAN ACID ESTERS

<b>Definition</b>		Montan acids and/or esters with ethylene glycol and/or 1,3-butanediol and/or glycerol
Chemical name		Montan acid esters
<b>Description</b>		Almost white to yellowish flakes, powder, granules or pellets
<b>Identification</b>		
A.	Density (20 °C)	Between 0,98 and 1,05
B.	Drop point	Greater than 77 °C
<b>Purity</b>		
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

*Status: This is the original version (as it was originally adopted).*

<b>Definition</b>	Polar reaction products from mild oxidation of polyethylene
Chemical name	Oxidised polyethylene
<b>Description</b>	Almost white flakes, powder, granules or pellets
<b>Identification</b>	
A. Density (20 °C)	Between 0,92 and 1,05
B. Drop point	Greater than 95 °C
<b>Purity</b>	
Acid value	Not more than 70
Viscosity at 120 °C	Not less than $8,1 \cdot 10^{-5} \text{ m}^2\text{s}^{-1}$
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 920 L-CYSTEINE

<b>Definition</b>	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	$\text{C}_3\text{H}_7\text{NO}_2\text{S} \cdot \text{HCl} \cdot n \text{H}_2\text{O}$ (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
<b>Description</b>	White powder or colourless crystals
<b>Identification</b>	
A. Solubility	Freely soluble in water and in ethanol
B. Melting range	Anhydrous form melts at about 175 °C
C. Specific rotation	$[\alpha]_{\text{D}}^{20}$ : between 5,0° and 8,0° or
	$[\alpha]_{\text{D}}^{25}$ : between 4,9° and 7,9°
<b>Purity</b>	
Loss on drying	Between 8,0 % and 12,0 %

*Status: This is the original version (as it was originally adopted).*

	Not more than 2,0 % (anhydrous form)
Residue on ignition	Not more than 0,1 %
Ammonium-ion	Not more than 200 mg/kg
Arsenic	Not more than 1,5 mg/kg
Lead	Not more than 5 mg/kg

## E 927b CARBAMIDE

<b>Synonyms</b>	Urea
<b>Definition</b>	
Einecs	200-315-5
Chemical formula	CH <sub>4</sub> N <sub>2</sub> O
Molecular weight	60,06
Assay	Content not less than 99,0 % on the anhydrous basis
<b>Description</b>	Colourless to white, prismatic, crystalline powder or small, white pellets
<b>Identification</b>	
A. Solubility	Very soluble in water Soluble in ethanol
B. Precipitation with nitric acid	To pass the test a white, crystalline precipitate is formed
C. Colour reaction	To pass the test a reddish-violet colour is produced
D. Melting range	132 °C to 135 °C
<b>Purity</b>	
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

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

## E 939 HELIUM

<b>Definition</b>	
Chemical name	Helium
Einecs	231-168-5
Chemical formula	He
Molecular weight	4
Assay	Not less than 99 %
<b>Description</b>	Colourless, odourless, non-flammable gas
<b>Purity</b>	
Water	Not more than 0,05 %
Methane and other hydrocarbons calculated as methane	Not more than 100 µl/l

## E 941 NITROGEN

<b>Definition</b>	
Chemical name	Nitrogen
Einecs	231-783-9
Chemical formula	N <sub>2</sub>
Molecular weight	28
Assay	Not less than 99 %
<b>Description</b>	Colourless, odourless, non-flammable gas
<b>Purity</b>	
Water	Not more than 0,05 %

*Status: This is the original version (as it was originally adopted).*

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

#### E 942 NITROUS OXIDE

<b>Definition</b>	
Chemical name	Nitrous oxide
Einecs	233-032-0
Chemical formula	N <sub>2</sub> O
Molecular weight	44
Assay	Not less than 99 %
<b>Description</b>	Colourless, non-flammable gas, sweetish odour
<b>Purity</b>	
Water	Not more than 0,05 %
Carbon monoxide	Not more than 30 µl/l
Nitrogen dioxide and nitrogen oxide	Not more than 10 µl/l

#### E 943a BUTANE

<b>Synonyms</b>	n-Butane
<b>Definition</b>	
Chemical name	Butane
Chemical formula	CH <sub>3</sub> CH <sub>2</sub> CH <sub>2</sub> CH <sub>3</sub>
Molecular weight	58,12
Assay	Content not less than 96 %
<b>Description</b>	Colourless gas or liquid with mild, characteristic odour
<b>Identification</b>	
A. Vapour pressure	108,935 kPa at 20 °C
<b>Purity</b>	
Methane	Not more than 0,15 % v/v
Ethane	Not more than 0,5 % v/v
Propane	Not more than 1,5 % v/v



Isobutane	Not more than 3,0 % v/v
1,3-butadiene	Not more than 0,1 % v/v
Moisture	Not more than 0,005 %

## E 943b ISOBUTANE

<b>Synonyms</b>	2-methyl propane
<b>Definition</b>	
Chemical name	2-methyl propane
Chemical formula	(CH <sub>3</sub> ) <sub>2</sub> CH CH <sub>3</sub>
Molecular weight	58,12
Assay	Content not less than 94 %
<b>Description</b>	Colourless gas or liquid with mild, characteristic odour
<b>Identification</b>	
A. Vapour pressure	205,465 kPa at 20 °C
<b>Purity</b>	
Methane	Not more than 0,15 % v/v
Ethane	Not more than 0,5 % v/v
Propane	Not more than 2,0 % v/v
n-Butane	Not more than 4,0 % v/v
1,3-butadiene	Not more than 0,1 % v/v
Moisture	Not more than 0,005 %

## E 944 PROPANE

<b>Definition</b>	
Chemical name	Propane
Chemical formula	CH <sub>3</sub> CH <sub>2</sub> CH <sub>3</sub>
Molecular weight	44,09
Assay	Content not less than 95 %
<b>Description</b>	Colourless gas or liquid with mild, characteristic odour
<b>Identification</b>	
A. Vapour pressure	732,91 kPa at 20 °C
<b>Purity</b>	

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*Status: This is the original version (as it was originally adopted).*

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

## E 948 OXYGEN

<b>Definition</b>	
Chemical name	Oxygen
Einecs	231-956-9
Chemical formula	O <sub>2</sub>
Molecular weight	32
Assay	Not less than 99 %
<b>Description</b>	Colourless, odourless, non-flammable gas
<b>Purity</b>	
Water	Not more than 0,05 %
Methane and other hydrocarbons calculated as methane	Not more than 100 µl/l

## E 949 HYDROGEN

<b>Definition</b>	
Chemical name	Hydrogen
Einecs	215-605-7
Chemical formula	H <sub>2</sub>
Molecular weight	2
Assay	Content not less than 99,9 %
<b>Description</b>	Colourless, odourless, highly flammable gas
<b>Purity</b>	
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 950 ACESULFAME K

Purity criteria for this additive are the same as set out for this additive in Annex I to Directive 2008/60/EC.

E 951 ASPARTAME

Purity criteria for this additive are the same as set out for this additive in Annex I to Directive 2008/60/EC.

E 953 ISOMALT

Purity criteria for this additive are the same as set out for this additive in Annex I to Directive 2008/60/EC.

E 957 THAUMATIN

Purity criteria for this additive are the same as set out for this additive in Annex I to Directive 2008/60/EC.

E 959 NEOHESPERIDINE DIHYDROCHALCONE

Purity criteria for this additive are the same as set out for this additive in Annex I to Directive 2008/60/EC.

E 965(i) MALTITOL

Purity criteria for this additive are the same as set out for this additive in Annex I to Directive 2008/60/EC.

E 965(ii) MALTITOL SYRUP

Purity criteria for this additive are the same as set out for this additive in Annex I to Directive 2008/60/EC.

E 966 LACTITOL

Purity criteria for this additive are the same as set out for this additive in Annex I to Directive 2008/60/EC.

E 967 XYLITOL

Purity criteria for this additive are the same as set out for this additive in Annex I to Directive 2008/60/EC.

E 999 QUILLAIA EXTRACT

<b>Synonyms</b>	Soapbark extract, Quillay bark extract, Panama bark extract, Quillai extract, Murillo bark extract, China bark extract
<b>Definition</b>	Quillaia extract is obtained by aqueous extraction of <i>Quillaia saponaria</i> Molina, or other <i>Quillaia</i> species, trees of the family <i>Rosaceae</i> . 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
<b>Description</b>	Quillaia extract in the powder form is light brown with a pink tinge. It is also available as an aqueous solution
<b>Identification</b>	

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*Status: This is the original version (as it was originally adopted).*

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A. pH of a 2,5 % solution	Between 4,5 and 5,5
<b>Purity</b>	
Water	Not more than 6,0 % (Karl Fischer method) (powder form only)
Arsenic	Not more than 2 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

## E 1103 INVERTASE

<b>Definition</b>	Invertase is produced from <i>Saccharomyces cerevisiae</i>
Systematic name	$\beta$ -D-Fructofuranoside fructohydrolase
Enzyme Commission No	EC 3.2.1.26
Einecs	232-615-7
<b>Purity</b>	
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Cadmium	Not more than 0,5 mg/kg
Total bacterial count	Not more than 50 000/g
<i>Salmonella</i> spp.	Absent by test in 25 g
Coliforms	Not more than 30/g
<i>E. coli</i>	Absent by test in 25 g

## E 1105 LYSOZYME

<b>Synonyms</b>	Lysozyme hydrochloride
	Muramidase
<b>Definition</b>	Lysozyme is a linear polypeptide obtained from hens' egg whites consisting of 129 amino acids. It possesses enzymatic activity in its ability to hydrolyse the $\beta$ (1-4) linkages between N-acetylmuramic acid and N-acetylglucosamine in the outer membranes of bacterial species, in particular gram-positive organisms. Is usually obtained as the hydrochloride
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
<b>Description</b>	White, odourless powder having a slightly sweet taste
<b>Identification</b>	
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	
<b>Purity</b>	
Water content	Not more than 6,0 % (Karl Fischer method) (powder form only)
Residue on ignition	Not more than 1,5 %
Nitrogen	Not less than 16,8 % and not more than 17,8 %
Arsenic	Not more than 1 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Microbiological criteria	
Total bacterial count	Not more than $5 \times 10^4$ col/g
<i>Salmonellae</i>	Absent in 25 g
<i>Staphylococcus aureus</i>	Absent in 1 g
<i>Escherichia coli</i>	Absent in 1 g

## E 1200 POLYDEXTROSE

<b>Synonyms</b>	Modified polydextroses
<b>Definition</b>	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.

*Status: This is the original version (as it was originally adopted).*

	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
<b>Description</b>	White to light tan-coloured solid. Polydextroses dissolve in water to give a clear, colourless to straw coloured solution
<b>Identification</b>	
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
<b>Purity</b>	
Water	Not more than 4,0 % (Karl Fischer method)
Sulphated ash	Not more than 0,3 % (polydextrose) Not more than 2,0 % (polydextrose N)
Nickel	Not more than 2 mg/kg for hydrogenated polydextroses
1,6-Anhydro-D-glucose	Not more than 4,0 % on the ash-free and the dried basis
Glucose and sorbitol	Not more than 6,0 % combined on the ash-free and the dried basis; glucose and sorbitol are determined separately
Molecular weight limit	Negative test for polymers of molecular weight greater than 22 000
5-Hydroxy-methylfurfural	Not more than 0,1 % (polydextrose) Not more than 0,05 % (polydextrose-N)
Lead	Not more than 0,5 mg/kg

#### E 1201 POLYVINYLPIRROLIDONE

<b>Synonyms</b>	Povidone
	PVP

	Soluble polyvinylpyrrolidone
<b>Definition</b>	
Chemical name	Polyvinylpyrrolidone, poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene]
Chemical formula	(C <sub>6</sub> H <sub>9</sub> NO) <sub>n</sub>
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
<b>Description</b>	White or nearly white powder
<b>Identification</b>	
A. Solubility	Soluble in water and in ethanol. Insoluble in ether
B. pH of a 5 % solution	Between 3,0 and 7,0
<b>Purity</b>	
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

<b>Synonyms</b>	Crospovidone
	Cross linked polyvidone
	Insoluble polyvinylpyrrolidone
<b>Definition</b>	Polyvinylpolypyrrolidone is a poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene], cross linked in a random fashion. It is produced by the polymerisation of N-vinyl-2-pyrrolidone in the presence of either caustic catalyst or N, N'-divinyl-imidazolidone. Due to its insolubility in all common solvents the molecular weight range is not amenable to analytical determination
Chemical name	Polyvinylpyrrolidone, poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene]
Chemical formula	(C <sub>6</sub> H <sub>9</sub> NO) <sub>n</sub>

*Status: This is the original version (as it was originally adopted).*

Assay	Content not less than 11 % and not more than 12,8 % nitrogen (N) on the anhydrous basis
<b>Description</b>	A white hygroscopic powder with a faint, non-objectionable odour
<b>Identification</b>	
A. Solubility	Insoluble in water, ethanol and ether
B. pH of a 1 % suspension in water	Between 5,0 and 8,0
<b>Purity</b>	
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

#### E 1204 PULLULAN

<b>Definition</b>	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 <i>Aureobasidium pullulans</i> . 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	$(C_6H_{10}O_5)_x$
Assay	Not less than 90 % of glucan on the dried basis
<b>Description</b>	White to off-white odourless powder
<b>Identification</b>	
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.	Depoly-merisation with pullulanase	Prepare two test tubes each with 10 ml of a 10 % pullulan solution. Add 0,1 ml pullulanase solution having activity 10 units/g to one test tube, and 0,1 ml water to the other. After incubation at about 25 °C for 20 minutes, the viscosity of the pullulanase-treated solution is visibly lower than that of the untreated solution
<b>Purity</b>		
Loss on drying		Not more than 6 % (90 °C, pressure not more than 50 mm Hg, 6 h)
Mono-, di- and oligosaccharides		Not more than 10 % expressed as glucose
Viscosity		100 to 180 mm <sup>2</sup> /s (10 % w/w aqueous solution at 30 °C)
Lead		Not more than 1 mg/kg
Yeast and moulds		Not more than 100 colonies per gram
Coliforms		Absent in 25 g
Salmonella		Absent in 25 g

## E 1404 OXIDISED STARCH

<b>Definition</b>		Oxidised starch is starch treated with sodium hypochlorite
<b>Description</b>		White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
<b>Identification</b>		
A.	If not pregelatinised: by microscopic observation	
B.	Iodine staining positive (dark blue to light red colour)	
<b>Purity</b> (all values expressed on an anhydrous basis except for loss on drying)		
Loss on drying		Not more than 15,0 % for cereal starch
		Not more than 21,0 % for potato starch
		Not more than 18,0 % for other starches
Carboxyl groups		Not more than 1,1 %

*Status: This is the original version (as it was originally adopted).*

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

#### E 1410 MONOSTARCH PHOSPHATE

<b>Definition</b>	Monostarch phosphate is starch esterified with ortho-phosphoric acid, or sodium or potassium ortho-phosphate or sodium tripolyphosphate
<b>Description</b>	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
<b>Identification</b>	
A. If not pregelatinised: by microscopic observation	
B. Iodine staining positive (dark blue to light red colour)	
<b>Purity</b> (all values expressed on an anhydrous basis except for loss on drying)	
Loss on drying	Not more than 15,0 % for cereal starch
	Not more than 21,0 % for potato starch
	Not more than 18,0 % for other starches
Residual phosphate	Not more than 0,5 % (as P) for wheat or potato starch
	Not more than 0,4 % (as P) for other starches
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches
	Not more than 10 mg/kg for other modified starches, unless otherwise specified
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 0,1 mg/kg

#### E 1412 DISTARCH PHOSPHATE

<b>Definition</b>	Distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride
<b>Description</b>	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
<b>Identification</b>	
A. If not pregelatinised: by microscopic observation	
B. Iodine staining positive (dark blue to light red colour)	
<b>Purity</b> (all values expressed on an anhydrous basis except for loss on drying)	
Loss on drying	Not more than 15,0 % for cereal starch
	Not more than 21,0 % for potato starch
	Not more than 18,0 % for other starches
Residual phosphate	Not more than 0,5 % (as P) for wheat or potato starch
	Not more than 0,4 % (as P) for other starches
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches
	Not more than 10 mg/kg for other modified starches, unless otherwise specified
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 0,1 mg/kg

## E 1413 PHOSPHATED DISTARCH PHOSPHATE

<b>Definition</b>	Phosphated distarch phosphate is starch having undergone a combination of treatments as described for monostarch phosphate and for distarch phosphate
<b>Description</b>	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
<b>Identification</b>	
A. If not pregelatinised: by microscopic observation	

*Status: This is the original version (as it was originally adopted).*

B. Iodine staining positive (dark blue to light red colour)	
<b>Purity</b> (all values expressed on an anhydrous basis except for loss on drying)	
Loss on drying	Not more than 15,0 % for cereal starch
	Not more than 21,0 % for potato starch
	Not more than 18,0 % for other starches
Residual phosphate	Not more than 0,5 % (as P) for wheat or potato starch
	Not more than 0,4 % (as P) for other starches
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches
	Not more than 10 mg/kg for other modified starches, unless otherwise specified
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 0,1 mg/kg

#### E 1414 ACETYLATED DISTARCH PHOSPHATE

<b>Definition</b>	Acetylated distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride and esterified by acetic anhydride or vinyl acetate
<b>Description</b>	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
<b>Identification</b>	
A. If not pregelatinised: by microscopic observation	
B. Iodine staining positive (dark blue to light red colour)	
<b>Purity</b> (all values expressed on an anhydrous basis except for loss on drying)	
Loss on drying	Not more than 15,0 % for cereal starch
	Not more than 21,0 % for potato starch
	Not more than 18,0 % for other starches
Acetyl groups	Not more than 2,5 %

Residual phosphate	Not more than 0,14 % (as P) for wheat or potato starch
	Not more than 0,04 % (as P) for other starches
Vinyl acetate	Not more than 0,1 mg/kg
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches
	Not more than 10 mg/kg for other modified starches, unless otherwise specified
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 0,1 mg/kg

## E 1420 ACETYLATED STARCH

<b>Synonyms</b>	Starch acetate
<b>Definition</b>	Acetylated starch is starch esterified with acetic anhydride or vinyl acetate
<b>Description</b>	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
<b>Identification</b>	
A. If not pregelatinised: by microscopic observation	
B. Iodine staining positive (dark blue to light red colour)	
<b>Purity</b> (all values expressed on an anhydrous basis except for loss on drying)	
Loss on drying	Not more than 15,0 % for cereal starch
	Not more than 21,0 % for potato starch
	Not more than 18,0 % for other starches
Acetyl groups	Not more than 2,5 %
Vinyl acetate	Not more than 0,1 mg/kg
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches
	Not more than 10 mg/kg for other modified starches, unless otherwise specified
Arsenic	Not more than 1 mg/kg

*Status: This is the original version (as it was originally adopted).*

Lead	Not more than 2 mg/kg
Mercury	Not more than 0,1 mg/kg

#### E 1422 ACETYLATED DISTARCH ADIPATE

<b>Definition</b>	Acetylated distarch adipate is starch cross-linked with adipic anhydride and esterified with acetic anhydride
<b>Description</b>	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
<b>Identification</b>	
A. If not pregelatinised: by microscopic observation	
B. Iodine staining positive (dark blue to light red colour)	
<b>Purity</b> (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

<b>Definition</b>	Hydroxypropyl starch is starch etherified with propylene oxide
<b>Description</b>	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
<b>Identification</b>	

A.	If not pregelatinised: by microscopic observation	
B.	Iodine staining positive (dark blue to light red colour)	
<b>Purity</b> (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

<b>Definition</b>	Hydroxypropyl distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride and etherified with propylene oxide	
<b>Description</b>	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles	
<b>Identification</b>		
A.	If not pregelatinised: by microscopic observation	
B.	Iodine staining positive (dark blue to light red colour)	
<b>Purity</b> (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

*Status: This is the original version (as it was originally adopted).*

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

<b>Synonyms</b>	SSOS
<b>Definition</b>	Starch sodium octenyl succinate is starch esterified with octenylsuccinic anhydride
<b>Description</b>	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
<b>Identification</b>	
A. If not pregelatinised: by microscopic observation	
B. Iodine staining positive (dark blue to light red colour)	
<b>Purity</b> (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



*Status: This is the original version (as it was originally adopted).*

Lead	Not more than 2 mg/kg
Mercury	Not more than 0,1 mg/kg

#### E 1451 ACETYLATED OXIDISED STARCH

<b>Definition</b>	Acetylated oxidised starch is starch treated with sodium hypochlorite followed by esterification with acetic anhydride
<b>Description</b>	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
<b>Identification</b>	
A. If not pregelatinised: by microscopic observation	
B. Iodine staining positive (dark blue to light red colour)	
<b>Purity</b> (all values expressed on an anhydrous basis except for loss on drying)	
Loss on drying	Not more than 15,0 % for cereal starch Not more than 21,0 % for potato starch Not more than 18,0 % for other starches
Carboxyl groups	Not more than 1,3 %
Acetyl groups	Not more than 2,5 %
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches Not more than 10 mg/kg for other modified starches, unless otherwise specified
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 0,1 mg/kg

#### E 1452 STARCH ALUMINIUM OCTENYL SUCCINATE

<b>Synonyms</b>	SAOS
<b>Definition</b>	Starch aluminium octenyl succinate is starch esterified with octenylsuccinic anhydride and treated with aluminium sulphate
<b>Description</b>	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

*Status: This is the original version (as it was originally adopted).*

<b>Identification</b>	
A. If not pregelatinised: by microscopic observation	
B. Iodine staining positive (dark blue to light red colour)	
<b>Purity</b> (all values expressed on an anhydrous basis except for loss on drying)	
Loss on drying	Not more than 21,0 %
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

<b>Synonyms</b>	Ethyl citrate
<b>Definition</b>	
Chemical name	Triethyl-2-hydroxypropan-1,2,3-tricarboxylate
Einecs	201-070-7
Chemical formula	C <sub>12</sub> H <sub>20</sub> O <sub>7</sub>
Molecular weight	276,29
Assay	Content not less than 99,0 %
<b>Description</b>	Odourless, practically colourless, oily liquid
<b>Identification</b>	
A. Specific gravity	d <sub>25</sub> <sup>25</sup> : 1,135-1,139
B. Refractive index	[n] <sub>D</sub> <sup>20</sup> : 1,439-1,441
<b>Purity</b>	
Water	Not more than 0,25 % (Karl Fischer method)

*Status: This is the original version (as it was originally adopted).*

Acidity	Not more than 0,02 % (as citric acid)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

#### E 1517 GLYCERYL DIACETATE

<b>Synonyms</b>	Diacetin
<b>Definition</b>	Glyceryl diacetate consist predominantly of a mixture of the 1,2- and 1,3-diacetates of glycerol, with minor amounts of the mono- and tri-esters
Chemical names	Glyceryl diacetate
	1, 2, 3-propanetriol diacetate
Chemical formula	C <sub>7</sub> H <sub>12</sub> O <sub>5</sub>
Molecular weight	176,17
Assay	Not less than 94,0 %
<b>Description</b>	Clear, colourless, hygroscopic, somewhat oily liquid with a slight, fatty odour
<b>Identification</b>	
A. Solubility	Soluble in water. Miscible with ethanol
B. Positive tests for glycerol and acetate	
C. Specific gravity	d <sub>20</sub> <sup>20</sup> : 1,175-1,195
D. Boiling range	Between 259 and 261 °C
<b>Purity</b>	
Total ash	Not more than 0,02 %
Acidity	Not more than 0,4 % (as ascetic acid)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

#### E 1518 GLYCERYL TRIACETATE

<b>Synonyms</b>	Triacetin
<b>Definition</b>	
Chemical name	Glyceryl triacetate
Einecs	203-051-9

*Status: This is the original version (as it was originally adopted).*

Chemical formula	C <sub>9</sub> H <sub>14</sub> O <sub>6</sub>
Molecular weight	218,21
Assay	Content not less than 98,0 %
<b>Description</b>	Colourless, somewhat oily liquid having a slightly fatty odour
<b>Identification</b>	
A. Positive tests for acetate and for glycerol	
B. Refractive index	Between 1,429 and 1,431 at 25 °C
C. Specific gravity (25 °C/25 °C)	Between 1,154 and 1,158
D. Boiling range	Between 258 and 270 °C
<b>Purity</b>	
Water	Not more than 0,2 % (Karl Fischer method)
Sulphated ash	Not more than 0,02 % (as citric acid)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

#### E 1519 BENZYL ALCOHOL

<b>Synonyms</b>	Phenylcarbinol
	Phenylmethyl alcohol
	Benzenemethanol
	Alpha-hydroxytoluene
<b>Definition</b>	
Chemical names	Benzyl alcohol
	Phenylmethanol
Chemical formula	C <sub>7</sub> H <sub>8</sub> O
Molecular weight	108,14
Assay	Not less than 98,0 %
<b>Description</b>	Colourless, clear liquid with a faint, aromatic odour
<b>Identification</b>	
A. Solubility	Soluble in water, ethanol and ether

B.	Refractive index	$[n]_D^{20}$ : 1,538-1,541
C.	Specific gravity	$d_{25}^{25}$ : 1,042-1,047
D.	Positive test for peroxides	
<b>Purity</b>		
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 bezaldehyde)
Lead		Not more than 5 mg/kg

## E 1520 PROPANE-1,2-DIOL

<b>Synonyms</b>		Propylene glycol
<b>Definition</b>		
Chemical names		1,2-dihydroxypropane
Einecs		200-338-0
Chemical formula		$C_3H_8O_2$
Molecular weight		76,1
Assay		Content not less than 99,5 % on the anhydrous basis
<b>Description</b>		Clear, colourless, hygroscopic, viscous liquid
<b>Identification</b>		
A.	Solubility	Soluble in water, ethanol and acetone
B.	Specific gravity	$d_{20}^{20}$ : 1,035-1,04
C.	Refractive index	$[n]_D^{20}$ : 1,431-1,433
<b>Purity</b>		
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

## POLYETHYLENE GLYCOL 6000

<b>Synonyms</b>		PEG 6000
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*Status: This is the original version (as it was originally adopted).*

	Macrogl 6000
<b>Definition</b>	Polyethylene glycol 6000 is a mixture of polymers with the general formula H-(OCH <sub>2</sub> -CH)-OH corresponding to an average relative molecular mass of approximately 6 000
Chemical formula	(C <sub>2</sub> H <sub>4</sub> O) <sub>n</sub> H <sub>2</sub> O (n = number of ethylene oxide units corresponding to a molecular weight of 6 000, about 140)
Molecular weight	5 600-7 000
Assay	Not less than 90,0 % and not more than 110,0 %
<b>Description</b>	A white or almost white solid with a waxy or paraffin-like appearance
<b>Identification</b>	
A. Solubility	Very soluble in water and in methylene chloride. Practically insoluble in alcohol, in ether and in fatty and mineral oils
B. Melting range	Between 55 °C and 61 °C
<b>Purity</b>	
Viscosity	Between 0,22 and 0,275 kgm <sup>-1</sup> s <sup>-1</sup> at 20 °C
Hydroxyl value	Between 16 and 22
Sulphated ash	Not more than 0,2 %
Ethylene oxide	Not more than 0,2 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

## ANNEX II

### PART A

#### Repealed Directive with list of its successive amendments

(referred to in Article 2)

Commission Directive 96/77/EC	(OJ L 339, 30.12.1996, p. 1)
Commission Directive 98/86/EC	(OJ L 334, 9.12.1998, p. 1)
Commission Directive 2000/63/EC	(OJ L 277, 30.10.2000, p. 1)
Commission Directive 2001/30/EC	(OJ L 146, 31.5.2001, p. 1)
Commission Directive 2002/82/EC	(OJ L 292, 28.10.2002, p. 1)
Commission Directive 2003/95/EC	(OJ L 283, 31.10.2003, p. 71)

Commission Directive 2004/45/EC Commission Directive 2006/129/ EC	(OJ L 113, 20.4.2004, p. 19) (OJ L 346, 9.12.2006, p. 15)
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## PART B

**List of time-limits for transposition into national law**

(referred to in Article 2)

<b>Directive</b>	<b>Time-limit for transposition</b>
96/77/EC	1 July 1997 <sup>a</sup>
98/86/EC	1 July 1999 <sup>b</sup>
2000/63/EC	31 March 2001 <sup>c</sup>
2001/30/EC	1 June 2002 <sup>d</sup>
2002/82/EC	31 August 2003
2003/95/EC	1 November 2004 <sup>e</sup>
2004/45/EC	1 April 2005 <sup>f</sup>
2006/129/EC	15 February 2008
<b>a</b>	According to Article 3(2) of Directive 96/77/EC, 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.
<b>b</b>	According to Article 2(2) of Directive 98/86/EC, products put on the market or labelled before 1 July 1999 which do not comply with this Directive may be marketed until stocks are exhausted.
<b>c</b>	According to Article 2(3) of Directive 2000/63/EC, products put on the market or labelled before 31 March 2001 which do not comply with this Directive may be marketed until stocks are exhausted.
<b>d</b>	According to Article 2(3) of Directive 2001/30/EC, products put on the market or labelled before 1 June 2002 which do not comply with this Directive may be marketed until stocks are exhausted.
<b>e</b>	According to Article 3 of Directive 2003/95/EC, products put on the market or labelled before 1 November 2004 which do not comply with this Directive may be marketed until stocks are exhausted.
<b>f</b>	According to Article 3 of Directive 2004/45/EC, products put on the market or labelled before 1 April 2005 which do not comply with this Directive may be marketed until stocks are exhausted.

## ANNEX III

## CORRELATION TABLE

<b>Directive 96/77/EC</b>	<b>This Directive</b>
Article 1	Article 1
Article 2	—
Article 3	—
—	Article 2

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*Status: This is the original version (as it was originally adopted).*

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Article 4	Article 3
Article 5	Article 4
Annex	Annex I
—	Annex II
—	Annex III



- (1) OJ L 40, 11.2.1989, p. 27.
- (2) OJ L 339, 30.12.1996, p. 1.
- (3) See Annex II, part A.
- (4) OJ L 61, 18.3.1995, p. 1.
- (5) OJ L 226, 22.9.1995, p. 1.
- (6) OJ L 158, 18.6.2008, p. 17.