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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)

(OJ L 253, 20.9.2008, p. 1)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Directive 2009/10/EC of 13 February 2009	L 44	62	14.2.2009
►M2	Commission Directive 2010/67/EU of 20 October 2010	L 277	17	21.10.2010

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

(Text with EEA relevance)

(Codified version)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption ([1]), 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 ([2]) has been substantially amended several times ([3]). 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 ([4]).

(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:

([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.

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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.

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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 ([1]).

E 200 SORBIC ACID

Definition	
Chemical name	Sorbic acid
	Trans, trans-2,4-hexadienoic acid
Einecs	203-768-7
Chemical formula	$C_6H_8O_2$
Molecular weight	112,12
Assay	Content not less than 99 % on the anhydrous basis
Description	Colourless needles or white free flowing powder, having a slight characteristic odour and showing no change in colour after heating for 90 minutes at 105 °C
Identification	
A. Melting range	Between 133 °C and 135 °C, after vacuum drying for four hours in a sulphuric acid desiccator
B. Spectrometry	An isopropanol solution (1 in 4 000 000) shows absorbance maximum at 254 ± 2 nm
C. Positive test for double bonds	
D. Sublimation point	80 °C
Purity	
Water content	Not more than 0,5 % (Karl Fischer method)
Sulphated ash	Not more than 0,2 %
Aldehydes	Not more than 0,1 % (as formaldehyde)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 202 POTASSIUM SORBATE

Definition	
Chemical name	Potassium sorbate
	Potassium (E, E)-2,4-hexadienoate
	Potassium salt of trans, trans 2,4-hexadienoic acid

([1]) OJ L 226, 22.9.1995, p. 1.

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Einecs	246-376-1
Chemical formula	$C_6H_7O_2K$
Molecular weight	150,22
Assay	Content not less than 99 % on the dried basis
Description	White crystalline powder showing no change in colour after heating for 90 minutes at 105 °C
Identification	
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	
Purity	
Loss on drying	Not more than 1,0 % (105 °C, 3h)
Acidity or alkalinity	Not more than about 1,0 % (as sorbic acid or K_2CO_3)
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

Definition	
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
Description	Fine white crystalline powder not showing any change in colour after heating at 105 °C for 90 minutes
Identification	
A. Melting range of sorbic acid isolated by acidification and not recrystallised 133 °C to 135 °C after vacuum drying in a sulphuric acid desiccator	

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B. Positive tests for calcium and for double bonds	
Purity	
Loss on drying	Not more than 2,0 %, determined by vacuum drying for four hours in a sulphuric acid desiccator
Aldehydes	Not more than 0,1 % (as formaldehyde)
Fluoride	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 210 BENZOIC ACID

Definition	
Chemical name	Benzoic acid
	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
Description	White crystalline powder
Identification	
A. Melting range	121,5 °C to 123,5 °C
B. Positive sublimation test and test for benzoate	
Purity	
Loss on drying	Not more than 0,5 % after drying for three hours over sulphuric acid
pH	About 4 (solution in water)
Sulphated ash	Not more than 0,05 %
Chlorinated organic compounds	Not more than 0,07 % expressed as chloride corresponding to 0,3 % expressed as monochlorobenzoic acid

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Readily oxidisable substances	Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N $KMnO_4$ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N $KMnO_4$ to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required
Readily carbonisable substances	A cold solution of 0,5 g of benzoic acid in 5 ml of 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC ([2]), 0,3 ml of ferric chloride TSC ([3]), 0,1 ml of copper sulphate TSC ([4]) 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

E 211 SODIUM BENZOATE

Definition	
Chemical name	Sodium benzoate Sodium salt of benzenecarboxylic acid Sodium salt of phenylcarboxylic acid
Einecs	208-534-8
Chemical formula	$C_7H_5O_2Na$

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

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

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

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

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Molecular weight	144,11
Assay	Not less than 99 % of $C_7H_5O_2Na$, after drying at 105 °C for four hours
Description	A white, almost odourless, crystalline powder or granules
Identification	
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	
Purity	
Loss on drying	Not more than 1,5 % after drying at 105 °C for four hours
Readily oxidisable substances	Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N $KMnO_4$ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N $KMnO_4$ to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required
Polycyclic acids	On fractional acidification of a (neutralised) solution of sodium benzoate, the first precipitate must not have a different melting range from that of benzoic acid
Chlorinated organic compounds	Not more than 0,06 % expressed as chloride, corresponding to 0,25 % expressed as monochlorobenzoic acid
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

Definition	
Chemical name	Potassium benzoate
	Potassium salt of benzenecarboxylic acid
	Potassium salt of phenylcarboxylic acid
Einecs	209-481-3
Chemical formula	$C_7H_5KO_2 \cdot 3H_2O$

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Molecular weight	214,27
Assay	Content not less than 99 % $C_7H_5KO_2$ after drying at 105 °C to constant weight
Description	White crystalline powder
Identification	
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	
Purity	
Loss on drying	Not more than 26,5 %, determined by drying at 105 °C
Chlorinated organic compounds	Not more than 0,06 % expressed as chloride, corresponding to 0,25 % expressed as monochlorobenzoic acid
Readily oxidisable substances	Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N $KMnO_4$ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N $KMnO_4$ to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required
Readily carbonisable substances	A cold solution of 0,5 g of benzoic acid in 5 ml 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC, 0,3 ml of ferric chloride TSC, 0,1 ml of copper sulphate TSC and 4,4 ml of water
Polycyclic acids	On fractional acidification of a (neutralised) solution of potassium benzoate, the first precipitate must not have a different melting range from that of benzoic acid
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

Synonyms	Monocalcium benzoate
Definition	
Chemical name	Calcium benzoate
	Calcium dibenzoate

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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	
Description	White or colourless crystals, or white powder	
Identification		
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		
Purity		
Loss on drying	Not more than 17,5 % determined by drying at 105 °C to constant weight	
Water insoluble matter	Not more than 0,3 %	
Chlorinated organic compounds	Not more than 0,06 % expressed as chloride, corresponding to 0,25 % expressed as monochlorobenzoic acids	
Readily 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	

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

E 214 ETHYL *p*-HYDROXYBENZOATE

Synonyms	Ethylparaben
	Ethyl *p*-oxybenzoate
Definition	
Chemical name	Ethyl-*p*-hydroxybenzoate
	Ethyl ester of *p*-hydroxybenzoic acid
Einecs	204-399-4
Chemical formula	$C_9H_{10}O_3$
Molecular weight	166,8
Assay	Content not less than 99,5 % after drying for two hours at 80 °C
Description	Almost odourless, small, colourless crystals or a white, crystalline powder
Identification	
A. Melting range	115 °C to 118 °C
B. Positive test for *p*-hydroxybenzoate	Melting range of *p*-hydroxybenzoic acid isolated by acidification and not recrystallised: 213 °C to 217 °C, after vacuum drying in a sulphuric acid desiccator
C. Positive test for alcohol	
Purity	
Loss on drying	Not more than 0,5 % after drying for two hours at 80 °C
Sulphated ash	Not more than 0,05 %
p-Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as *p*-hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 215 SODIUM ETHYL *p*-HYDROXYBENZOATE

Definition	
Chemical name	Sodium ethyl *p*-hydroxybenzoate
	Sodium compound of the ethyl ester of *p*-hydroxybenzoic acid
Einecs	252-487-6

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Chemical formula	$C_9H_9O_3Na$
Molecular weight	188,8
Assay	Content of ethylester of *p*-hydroxybenzoic acid not less than 83 % on the anhydrous basis
Description	White, crystalline hygroscopic powder
Identification	
A. Melting range	115 °C to 118 °C, after vacuum drying in a sulphuric acid desiccator
B. Positive test for *p*-hydroxybenzoate	Melting range of *p*-hydroxybenzoic acid derived from the sample is 213 °C to 217 °C
C. Positive test for sodium	
D. pH of a 0,1 % aqueous solution must be between 9,9 and 10,3	
Purity	
Loss on drying	Not more than 5 %, determined by vacuum drying in a sulphuric acid desiccator
Sulphated ash	37 to 39 %
p-Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as *p*-hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 218 METHYL *p*-HYDROXYBENZOATE

Synonyms	Methylparaben
	Methyl-*p*-oxybenzoate
Definition	
Chemical name	Methyl *p*-hydroxybenzoate
	Methyl ester of *p*-hydroxybenzoic acid
Einecs	243-171-5
Chemical formula	$C_8H_8O_3$
Molecular weight	152,15
Assay	Content not less than 99 % after drying for two hours at 80 °C
Description	Almost odourless, small colourless crystals or white crystalline powder
Identification	
A. Melting range	125 °C to 128 °C
B. Positive test for *p*-hydroxybenzoate	Melting range of *p*-hydroxybenzoic acid derived from the sample is 213 °C to 217 °C after drying for two hours at 80 °C

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Purity	
Loss on drying	Not more than 0,5 %, after drying for two hours at 80 °C
Sulphated ash	Not more than 0,05 %
p-Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as *p*-hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 219 SODIUM METHYL *p*-HYDROXYBENZOATE

Definition	
Chemical name	Sodium methyl *p*-hydroxybenzoate
	Sodium compound of the methylester of *p*-hydroxybenzoic acid
Chemical formula	$C_8H_7O_3Na$
Molecular weight	174,15
Assay	Content not less than 99,5 % on the anhydrous basis
Description	White, hygroscopic powder
Identification	
A. The white precipitate formed by acidifying with hydrochloric acid a 10 % (w/v) aqueous solution of the sodium derivative of methyl *p*-hydroxybenzoate (using litmus paper as indicator) shall, when washed with water and dried at 80 °C for two hours, have a melting range of 125 °C to 128 °C	
B. Positive test for sodium	
C. pH of a 0,1 % solution in carbon dioxide free water, not less than 9,7 and not more than 10,3	
Purity	
Water content	Not more than 5 % (Karl Fischer method)
Sulphated ash	40 % to 44,5 % on the anhydrous basis
p-Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as *p*-hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

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E 220 SULPHUR DIOXIDE

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

E 221 SODIUM SULPHITE

Definition		
Chemical name	Sodium sulphite (anhydrous or heptahydrate)	
Einecs	231-821-4	
Chemical formula	Anhydrous:	Na_2SO_3
	Heptahydrate:	$Na_2SO_3 7H_2O$
Molecular weight	Anhydrous:	126,04
	Heptahydrate:	252,16
Assay	Anhydrous:	Not less than 95 % of Na_2SO_3 and not less than 48 % of SO_2
	Heptahydrate:	Not less than 48 % of Na_2SO_3 and not less than 24 % of SO_2
Description	White crystalline powder or colourless crystals	

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Identification	
A. Positive tests for sulphite and for sodium	
B. pH of a 10 % solution (anhydrous) or a 20 % solution (heptahydrate) between 8,5 and 11,5	
Purity	
Thiosulphate	Not more than 0,1 % based on the SO_2 content
Iron	Not more than 50 mg/kg based on the SO_2 content
Selenium	Not more than 10 mg/kg based on the SO_2 content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 222 SODIUM BISULPHITE

Definition	
Chemical name	Sodium bisulphite
	Sodium hydrogen sulphite
Einecs	231-921-4
Chemical formula	$NaHSO_3$ in aqueous solution
Molecular weight	104,06
Assay	Content not less than 32 % w/w $NaHSO_3$
Description	A clear, colourless to yellow solution
Identification	
A. Positive tests for sulphite and for sodium	
B. pH of a 10 % aqueous solution between 2,5 and 5,5	
Purity	
Iron	Not more than 50 mg/kg of Na_2SO_3 based on the SO_2 content
Selenium	Not more than 10 mg/kg based on the SO_2 content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

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E 223 SODIUM METABISULPHITE

Synonyms	Pyrosulphite
	Sodium pyrosulphite
Definition	
Chemical name	Sodium disulphite
	Disodium pentaoxodisulphate
Einecs	231-673-0
Chemical formula	$Na_2S_2O_5$
Molecular weight	190,11
Assay	Content not less than 95 % $Na_2S_2O_5$ and not less than 64 % of SO_2
Description	White crystals or crystalline powder
Identification	
A. Positive tests for sulphite and for sodium	
B. pH of a 10 % aqueous solution between 4,0 and 5,5	
Purity	
Thiosulphate	Not more than 0,1 % based on the SO_2 content
Iron	Not more than 50 mg/kg based on the SO_2 content
Selenium	Not more than 10 mg/kg based on the SO_2 content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 224 POTASSIUM METABISULPHITE

Synonyms	Potassium pyrosulphite
Definition	
Chemical name	Potassium disulphite
	Potassium pentaoxo disulphate
Einecs	240-795-3
Chemical formula	$K_2S_2O_5$
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
Description	Colourless crystals or white crystalline powder

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Identification	
A. Positive tests for sulphite and for potassium	
Purity	
Thiosulphate	Not more than 0,1 % based on the SO_2 content
Iron	Not more than 50 mg/kg based on the SO_2 content
Selenium	Not more than 10 mg/kg based on the SO_2 content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 226 CALCIUM SULPHITE

Definition	
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 $CaSO_3 \cdot 2H_2O$ and not less than 39 % of SO_2
Description	White crystals or white crystalline powder
Identification	
A. Positive tests for sulphite and for calcium	
Purity	
Iron	Not more than 50 mg/kg based on the SO_2 content
Selenium	Not more than 10 mg/kg based on the SO_2 content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 227 CALCIUM BISULPHITE

Definition	
Chemical name	Calcium bisulphite
	Calcium hydrogen sulphite

▼B

Einecs	237-423-7
Chemical formula	$Ca(HSO_3)_2$
Molecular weight	202,22
Assay	6 to 8 % (w/v) of sulphur dioxide and 2,5 to 3,5 % (w/v) of calcium dioxide corresponding to 10 to 14 % (w/v) of calcium bisulphite $[Ca(HSO_3)_2]$
Description	Clear greenish-yellow aqueous solution having a distinct odour of sulphur dioxide
Identification	
A. Positive tests for sulphite and for calcium	
Purity	
Iron	Not more than 50 mg/kg based on the SO_2 content
Selenium	Not more than 10 mg/kg based on the SO_2 content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 228 POTASSIUM BISULPHITE

Definition	
Chemical name	Potassium bisulphite
	Potassium hydrogen sulphite
Einecs	231-870-1
Chemical formula	$KHSO_3$ in aqueous solution
Molecular weight	120,17
Assay	Content not less than 280 g $KHSO_3$ per litre (or 150 g SO_2 per litre)
Description	Clear colourless aqueous solution
Identification	
A. Positive tests for sulphite and for potassium	
Purity	
Iron	Not more than 50 mg/kg based on the SO_2 content
Selenium	Not more than 10 mg/kg based on the SO_2 content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

▼M1

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▼B

E 231 ORTHOPHENYLPHENOL

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

E 232 SODIUM ORTHOPHENYLPHENOL

Synonyms	Sodium orthophenylphenate
	Sodium salt of°-phenylphenol
Definition	
Chemical name	Sodium orthophenylphenol
Einecs	205-055-6
Chemical formula	$C_{12}H_9ONa \cdot 4H_2O$
Molecular weight	264,26
Assay	Content not less than 97 % of $C_{12}H_9ONa \cdot 4H_2O$
Description	White or slightly yellowish crystalline powder

▼B

Identification	
A. Positive tests for phenolate and for sodium	
B. Melting range of orthophenylphenol isolated by acidification and not recrystallised derived from the sample 56 ºC to 58 ºC after drying in a sulphuric acid desiccator	
C. pH of a 2 % aqueous solution must be between 11,1 and 11,8	
Purity	
Diphenylether	Not more than 0,3 %
p-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

▼M1

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E 234 NISIN

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

▼B

E 235 NATAMYCIN

Synonyms	Pimaricin
Definition	Natamycin is a fungicide of the polyene macrolide group, and is produced by natural strains of *Streptomyces natalensis* or of *Streptococcus lactis*
Einecs	231-683-5
Chemical formula	$C_{33}H_{47}O_{13}N$
Molecular weight	665,74
Assay	Content not less than 95 % on the anhydrous basis
Description	White to creamy-white crystalline powder
Identification	
A. Colour reactions	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° to + 295° (a 1 % w/v solution in glacial acetic acid, at 20 °C and calculated with reference to the dried material)
Purity	
Loss on drying	Not more than 8 % (over P_2O_5, in vacuum at 60 °C to constant weight)
Sulphated ash	Not more than 0,5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Microbiological criteria: total viable count	Not more than 100/g

E 239 HEXAMETHYLENE TETRAMINE

Synonyms	Hexamine
	Methenamine

▼B

Definition	
Chemical name	1,3,5,7-Tetraazatricyclo [3.3.1.1^{3,7}]-decane, hexamethylenetetramine
Einecs	202-905-8
Chemical formula	$C_6H_{12}N_4$
Molecular weight	140,19
Assay	Content not less than 99 % on the anhydrous basis
Description	Colourless or white crystalline powder
Identification	
A. Positive tests for formaldehyde and for ammonia	
B. Sublimation point approximately 260 °C	
Purity	
Loss on drying	Not more than 0,5 % after drying at 105 °C in vacuum over P_2O_5 for two hours
Sulphated ash	Not more than 0,05 %
Sulphates	Not more than 0,005 % expressed as SO_4
Chlorides	Not more than 0,005 % expressed as Cl
Ammonium salts	Not detectable
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 242 DIMETHYL DICARBONATE

Synonyms	DMDC
	Dimethyl pyrocarbonate
Definition	
Chemical name	Dimethyl dicarbonate
	Pyrocarbonic acid dimethyl ester
Einecs	224-859-8
Chemical formula	$C_4H_6O_5$
Molecular weight	134,09
Assay	Content not less than 99,8 %

▼B

Description	Colourless liquid, decomposes in aqueous solution. It is corrosive to skin and eyes and toxic by inhalation and ingestion
Identification	
A. Decomposition	After dilution positive tests for CO_2 and methanol
B. Melting point	17 °C
Boiling point	172 °C with decomposition
C. Density 20 °C	Approximately 1,25 g/cm^3
D. Infrared spectrum	Maxima at 1 156 and 1 832 cm^{-1}
Purity	
Dimethyl carbonate	Not more than 0,2 %
Chlorine, total	Not more than 3 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 249 POTASSIUM NITRITE

Definition	
Chemical name	Potassium nitrite
Einecs	231-832-4
Chemical formula	KNO_2
Molecular weight	85,11
Assay	Content not less than 95 % on the anhydrous basis ([5])
Description	White or slightly yellow, deliquescent granules
Identification	
A. Positive tests for nitrite and for potassium	
B. pH of a 5 % solution:	Not less than 6,0 and not more than 9,0
Purity	
Loss on drying	Not more than 3 % after drying for four hours over silica gel
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

([5]) When labelled ‘for food use’, nitrite may only be sold in a mixture with salt or a salt substitute.

▼B

E 250 SODIUM NITRITE

Definition	
Chemical name	Sodium nitrite
Einecs	231-555-9
Chemical formula	$NaNO_2$
Molecular weight	69,00
Assay	Content not less than 97 % on the anhydrous basis (6)
Description	White crystalline powder or yellowish lumps
Identification	
A. Positive tests for nitrite and for sodium	
Purity	
Loss on drying	Not more than 0,25 % after drying over silica gel for four hours
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 251 SODIUM NITRATE

1. SOLID SODIUM NITRATE

Synonyms	Chile saltpetre
	Cubic or soda nitre
Definition	
Chemical name	Sodium nitrate
Einecs	231-554-3
Chemical formula	$NaNO_3$
Molecular weight	85,00
Assay	Content not less than 99 % after drying
Description	White crystalline, slightly hygroscopic powder
Identification	
A. Positive tests for nitrate and for sodium	
B. pH of a 5 % solution	Not less than 5,5 and more than 8,3
Purity	
Loss on drying	Not more than 2 % after drying at 105 °C for four hours
Nitrites	Not more than 30 mg/kg expressed as $NaNO_2$

(6) When labelled 'for food use', nitrite may only be sold in a mixture with salt or a salt substitute.

▼B

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

Definition	Liquid sodium nitrate is an aqueous solution of sodium nitrate as the direct result of the chemical reaction between sodium hydroxide and nitric acid in stoechiometric amounts, without subsequent crystallisation. Standardised forms prepared from liquid sodium nitrate meeting these specifications may contain nitric acid in excessive amounts, if clearly stated or labelled.
Chemical name	Sodium nitrate
Einecs	231-554-3
Chemical formula	$NaNO_3$
Molecular weight	85,00
Assay	Content between 33,5 % and 40,0 % of $NaNO_3$
Description	Clear colourless liquid
Identification	
A. Positive tests for nitrate and for sodium	
B. pH	Not less than 1,5 and not more than 3,5
Purity	
Free nitric acid	Not more than 0,01 %
Nitrites	Not more than 10 mg/kg expressed as $NaNO_2$
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 0,3 mg/kg
This specification refers to a 35 % aqueous solution	

E 252 POTASSIUM NITRATE

Synonyms	Chile saltpetre Cubic or soda nitre
Definition	
Chemical name	Potassium nitrate
Einecs	231-818-8
Chemical formula	KNO_3
Molecular weight	101,11

▼B

Assay	Content not less than 99 % on the anhydrous basis
Description	White crystalline powder or transparent prisms having a cooling, saline, pungent taste
Identification	
A. Positive tests for nitrate and for potassium	
B. pH of a 5 % solution	Not less than 4,5 and not more than 8,5
Purity	
Loss on drying	Not more than 1 % after drying at 105 °C for four hours
Nitrites	Not more than 20 mg/kg expressed as KNO_2
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 260 ACETIC ACID

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

▼B

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

E 261 POTASSIUM ACETATE

Definition	
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
Description	Colourless, deliquescent crystals or a white crystalline powder, odourless or with a faint acetic odour
Identification	
A. pH of a 5 % aqueous solution	Not less than 7,5 and not more than 9,0
B. Positive tests for acetate and for potassium	
Purity	
Loss on drying	Not more than 8 % after drying at 150 °C for two hours
Formic acid, formates and other 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

Definition	
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	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
Identification		
A. pH of a 1 % aqueous solution	Not less than 8,0 and not more than 9,5	
B. Positive tests for acetate and for sodium		
Purity		
Loss on drying	Anhydrous:	Not more than 2 % (120 °C, 4 hours)
	Trihydrate:	Between 36 and 42 % (120 °C, 4 hours)
Formic acid, formates and other 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

Definition	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
Description	White, hygroscopic crystalline solid with an acetic odour
Identification	
A. pH of a 10 % aqueous solution	Not less than 4,5 and not more than 5,0
B. Positive tests for acetate and for sodium	
Purity	
Water content	Not more than 2 % (Karl Fischer method)
Formic acid, formates and other oxidisable substances	Not more than 1 000 mg/kg expressed as formic acid

▼B

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

E 263 CALCIUM ACETATE

Definition		
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	
Description	Anhydrous calcium acetate is a white, hygroscopic, bulky, crystalline solid with a slightly bitter taste. A slight odour of acetic acid may be present. The monohydrate may be needles, granules or powder	
Identification		
A. pH of a 10 % aqueous solution	Not less than 6,0 and not more than 9,0	
B. Positive tests for acetate and for calcium		
Purity		
Loss on drying	Not more than 11 % after drying (155 °C to constant weight, for the monohydrate)	
Water insoluble matter	Not more than 0,3 %	
Formic acid, formates and other 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 270 LACTIC ACID

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

▼B

Einecs	200-018-0
Chemical formula	$C_3H_6O_3$
Molecular weight	90,08
Assay	Content not less than 76 % and not more than 84 %
Description	Colourless or yellowish, nearly odourless, syrupy liquid with an acid taste, consisting of a mixture of lactic acid ($C_3H_6O_3$) and lactic acid lactate ($C_6H_{10}O_5$). It is obtained by the lactic fermentation of sugars or is prepared synthetically
Note:	
Lactic acid is hygroscopic and when concentrated by boiling, it condenses to form lactic acid lactate, which on dilution and heating hydrolyzes to lactic acid	
Identification	
A. Positive test for lactate	
Purity	
Sulphated ash	Not more than 0,1 %
Chloride	Not more than 0,2 %
Sulphate	Not more than 0,25 %
Iron	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Note:	
This specification refers to a 80 % aqueous solution; for weaker aqueous solutions, calculate values corresponding to their lactic acid content	

E 280 PROPIONIC ACID

Definition	
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	Colourless or slightly yellowish, oily liquid with a slightly pungent odour
Indentification	
A. Melting point	- 22 °C
B. Distillation range	138,5 °C to 142,5 °C
Purity	
Non-volatile residue	Not more than 0,01 % when dried at 140 °C to constant weight
Aldehydes	Not more than 0,1 % expressed as formaldehyde
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 281 SODIUM PROPIONATE

Definition	
Chemical name	Sodium propionate
	Sodium propanoate
Einecs	205-290-4
Chemical formula	$C_3H_5O_2Na$
Molecular weight	96,06
Assay	Content not less than 99 % after drying for two hours at 105 °C
Description	White crystalline hygroscopic powder, or a fine white powder
Identification	
A. Positive tests for propionate and for sodium	
B. pH of a 10 % aqueous solution	Not less than 7,5 and not more than 10,5
Purity	
Loss on drying	Not more than 4 % determined by drying for two hours at 105 °C
Water insolubles	Not more than 0,1 %
Iron	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

▼B

E 282 CALCIUM PROPIONATE

Definition	
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
Description	White crystalline powder
Identification	
A. Positive tests for propionate and for calcium	
B. pH of a 10 % aqueous solution	Between 6,0 and 9,0
Purity	
Loss on drying	Not more than 4 %, determined by drying for two hours at 105 °C
Water insolubles	Not more than 0,3 %
Iron	Not more than 50 mg/kg
Fluoride	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 283 POTASSIUM PROPIONATE

Definition	
Chemical name	Potassium propionate Potassium propanoate
Einecs	206-323-5
Chemical formula	$C_3H_5KO_2$
Molecular weight	112,17
Assay	Content not less than 99 % after drying for two hours at 105 °C
Description	White crystalline powder
Identification	
A. Positive tests for propionate and for potassium	
Purity	
Loss on drying	Not more than 4 %, determined by drying for two hours at 105 °C

▼B

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

Synonyms	Boracic acid
	Orthoboric acid
	Borofax
Definition	
Einecs	233-139-2
Chemical formula	H_3BO_3
Molecular weight	61,84
Assay	Content not less than 99,5 %
Description	Colourless, odourless, transparent crystals or white granules or powder; slightly unctuous to the touch; occurs in nature as the mineral sassolite
Identification	
A. Melting point	At approximately 171 °C
B. Burns with a nice green flame	
C. pH of a 3,3 % aqueous solution	Between 3,8 and 4,8
Purity	
Peroxides	No colour develops with added KI-solution
Arsenic	Not more than 1 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 285 SODIUM TETRABORATE (BORAX)

Synonyms	Sodium borate
Definition	
Chemical name	Sodium tetraborate
	Sodium biborate
	Sodium pyroborate
	Anhydrous tetraborate

▼B

Einecs	215-540-4
Chemical formula	$Na_2B_4O_7$
	$Na_2B_4O_7 \cdot 10H_2O$
Molecular weight	201,27
Description	Powder or glass-like plates becoming opaque on exposure to air; slowly soluble in water
Identification	
A. Melting range	Between 171 °C and 175 °C with decomposition
Purity	
Peroxides	No colour develops with added KI-solution
Arsenic	Not more than 1 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 290 CARBON DIOXIDE

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

▼B

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

▼M2

Oil content	Not more than 5 mg/kg

▼B

E 296 MALIC ACID

Synonyms	DL-Malic acid, pomalous acid
Definition	
Chemical name	DL-Malic acid, hydroxybutanedioic acid, hydroxy-succinic acid
Einecs	230-022-8
Chemical formula	$C_4H_6O_5$
Molecular weight	134,09
Assay	Content not less than 99,0 %
Description	White or nearly white crystalline powder or granules
Identification	
A. Melting range between 127 °C and 132 °C	
B. Positive test for malate	
C. Solutions of this substance are optically inactive in all concentrations	
Purity	
Sulphated ash	Not more than 0,1 %
Fumaric acid	Not more than 1,0 %
Maleic acid	Not more than 0,05 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 297 FUMARIC ACID

Definition	
Chemical name	Trans-butenedioic acid, trans-1,2-ethylene-dicarboxylic acid
Einecs	203-743-0
Chemical formula	$C_4H_4O_4$
Molecular weight	116,07

▼B

Assay	Content not less than 99,0 % on the anhydrous basis
Description	White crystalline powder or granules
Identification	
A. Melting range	286 °C-302 °C (closed capillary, rapid heating)
B. Positive tests for double bonds and for 1,2-dicarboxylic acid	
C. pH of a 0,05 % solution at 25 °C	3,0-3,2
Purity	
Loss on drying	Not more than 0,5 % (120 °C, 4h)
Sulphated ash	Not more than 0,1 %
Maleic acid	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 300 ASCORBIC ACID

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

▼B

pH of a 2 % aqueous solution	Between 2,4 and 2,8
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 301 SODIUM ASCORBATE

Definition	
Chemical name	Sodium ascorbate Sodium L-ascorbate 2,3-Didehydro-L-threo-hexono-1,4-lactone sodium 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 $C_6H_7O_6Na$
Description	White or almost white, odourless crystalline solid which darkens on exposure to light
Identification	
A. Positive tests for ascorbate and for sodium	
Purity	
Loss on drying	Not more than 0,25 % after drying in a vacuum desiccator over sulphuric acid for 24 hours
Specific rotation	$[\alpha]_D^{20}$ between + 103° and + 106° (10 % w/v aqueous solution)
pH of 10 % aqueous solution	Between 6,5 and 8,0
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 302 CALCIUM ASCORBATE

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

▼B

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
Description	White to slightly pale greyish-yellow odourless crystalline powder
Identification	
A. Positive tests for ascorbate and for calcium	
Purity	
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Specific rotation	$[\alpha]_D^{20}$ between + 95° and + 97° (5 % w/v aqueous solution)
pH of 10 % aqueous solution	Between 6,0 and 7,5
Volatile matter	Not more than 0,3 % determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 304 (i) ASCORBYL PALMITATE

Definition	
Chemical name	Ascorbyl palmitate
	L-ascorbyl palmitate
	2,3-didehydro-L-threo-hexono-1,4-lactone-6-palmitate
	6-palmitoyl-3-keto-L-gulofuranolactone
Einecs	205-305-4
Chemical formula	$C_{22}H_{38}O_7$
Molecular weight	414,55
Assay	Content not less than 98 % on the dried basis
Description	White or yellowish-white solid with a citrus-like odour
Identification	
A. Melting range	Between 107 °C and 117 °C
Purity	
Loss on drying	Not more than 2,0 % after drying in a vacuum oven at 56 °C and 60 °C for one hour

▼B

Sulphated ash	Not more than 0,1 %
Specific rotation	$[\alpha]_D^{20}$ between + 21° and + 24° (5 % w/v in methanol solution)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 304 (ii) ASCORBYL STEARATE

Definition	
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	$C_{24}H_{42}O_7$
Molecular weight	442,6
Assay	Content not less than 98 %
Description	White or yellowish, white solid with a citrus-like odour
Identification	
A. Melting point	About 116 °C
Purity	
Loss on drying	Not more than 2,0 % after drying in a vacuum oven at 56 °C to 60 °C for one hour
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 306 TOCOPHEROL-RICH EXTRACT

Definition	Product obtained by the vacuum steam distillation of edible vegetable oil products, comprising concentrated tocopherols and tocotrienols
	Contains tocopherols such as d-α-, d-β-, d-γ- and d-ς-tocopherols
Molecular weight	430,71 (d-α-tocopherol)
Assay	Content not less than 34 % of total tocopherols

▼B

Description	Brownish red to red, clear, viscous oil having a mild, characteristic odour and taste. May show a slight separation of wax-like constituents in microcrystalline form
Identification	
A. By suitable gas liquid chromatographic method	
B. Solubility tests	Insoluble in water. Soluble in ethanol. Miscible in ether
Purity	
Sulphated ash	Not more than 0,1 %
Specific rotation	$[\alpha]_D^{20}$ not less than + 20°
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 307 ALPHA-TOCOPHEROL

Synonyms	DL-α-Tocopherol
Definition	
Chemical name	DL-5,7,8-Trimethyltocol
	DL-2,5,7,8-tetramethyl-2-(4′,8′,12′-trimethyltridecyl)-6-chromanol
Einecs	233-466-0
Chemical formula	$C_{29}H_{50}O_2$
Molecular weight	430,71
Assay	Content not less than 96 %
Description	Slightly yellow to amber, nearly odourless, clear, viscous oil which oxidises and darkens on exposure to air or light
Identification	
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
Purity	
Refractive index	n_D^{20} 1,503-1,507
Specific absorption $E_{1cm}^{1\%}$ in ethanol	$E_{1cm}^{1\%}$ (292 nm) 72-76 (0,01 g in 200 ml of absolute ethanol)
Sulphated ash	Not more than 0,1 %
Specific rotation	$[\alpha]_D^{25}$ 0° ± 0,05° (1 in 10 solution in chloroform)
Lead	Not more than 2 mg/kg

▼B

E 308 GAMMA-TOCOPHEROL

Synonyms	dl-γ-Tocopherol
Definition	
Chemical name	2,7,8-trimethyl-2-(4′,8′,12′-trimethyltridecyl)-6-chromanol
Einecs	231-523-4
Chemical formula	$C_{28}H_{48}O_2$
Molecular weight	416,69
Assay	Content not less than 97 %
Description	Clear, viscous, pale yellow oil which oxidises and darkens on exposure to air or light
Identification	
A. Spectrometry	Maximum absorptions in absolute ethanol at about 298 nm and 257 nm
Purity	
Specific absorption $E^{1\%}_{1cm}$ in ethanol	$E^{1\%}_{1cm}$ (298 nm) between 91 and 97 $E^{1\%}_{1cm}$ (257 nm) between 5,0 and 8,0
Refractive index	$[n]_D^{20}$ 1,503-1,507
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 309 DELTA-TOCOPHEROL

Definition	
Chemical name	2,8-dimethyl-2-(4′,8′,12′-trimethyltridecyl)-6-chromanol
Einecs	204-299-0
Chemical formula	$C_{27}H_{46}O_2$
Molecular weight	402,7
Assay	Content not less than 97 %
Description	Clear, viscous, pale yellowish or orange oil which oxidises and darkens on exposure to air or light
Identification	
A. Spectrometry	Maximum absorptions in absolute ethanol at about 298 nm and 257 nm

▼B

Purity	
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} 1,500-1,504
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 310 PROPYL GALLATE

Definition	
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	212,20
Assay	Content not less than 98 % on the anhydrous basis
Description	White to creamy-white, crystalline, odourless solid
Identification	
A. Solubility tests	Slightly soluble in water, freely soluble in ethanol, ether and propane-1,2-diol
B. Melting range	Between 146 °C and 150 °C after drying at 110 °C for four hours
Purity	
Loss on drying	Not more than 1,0 % (110 °C, four hours)
Sulphated ash	Not more than 0,1 %
Free acid	Not more than 0,5 % (as gallic acid)
Chlorinated organic compound	Not more than 100 mg/kg (as C1)
Specific absorption $E^{1\%}_{1cm}$ in ethanol	$E^{1\%}_{1cm}$ (275 nm) not less than 485 and not more than 520
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

▼B

E 311 OCTYL GALLATE

Definition	
Chemical name	Octyl gallate
	Octyl ester of gallic acid
	n-octyl ester of 3,4,5-trihydroxybenzoic acid
Einecs	213-853-0
Chemical formula	$C_{15}H_{22}O_5$
Molecular weight	282,34
Assay	Content not less than 98 % after drying at 90 °C for six hours
Description	White to creamy-white odourless solid
Identification	
A. Solubility tests	Insoluble in water, freely soluble in ethanol, ether and propane-1,2-diol
B. Melting range	Between 99 °C and 102 °C after drying at 90 °C for six hours
Purity	
Loss on drying	Not more than 0,5 % (90 °C, six hours)
Sulphated ash	Not more than 0,05 %
Free acid	Not more than 0,5 % (as gallic acid)
Chlorinated organic compound	Not more than 100 mg/kg (as C1)
Specific absorption $E^{1\%}_{1cm}$ 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

Synonyms	Lauryl gallate
Definition	
Chemical name	Dodecyl gallate
	n-dodecyl (or lauryl) ester of 3,4,5-trihydroxybenzoic acid
	Dodecyl ester of gallic acid
Einecs	214-620-6
Chemical formula	$C_{19}H_{30}O_5$
Molecular weight	338,45
Assay	Content not less than 98 % after drying at 90 °C for six hours

▼B

Description	White or creamy-white odourless solid
Identification	
A. Solubility tests	Insoluble in water, freely soluble in ethanol and ether
B. Melting range	Between 95 °C and 98 °C after drying at 90 °C for six hours
Purity	
Loss on drying	Not more than 0,5 % (90 °C, six hours)
Sulphated ash	Not more than 0,05 %
Free acid	Not more than 0,5 % (as gallic acid)
Chlorinated organic compound	Not more than 100 mg/kg (as Cl)
Specific absorption $E^{1\%}_{1cm}$ in ethanol	$E^{1\%}_{1cm}$ (275 nm) not less than 300 and not more than 325
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 30 mg/kg

E 315 ERYTHORBIC ACID

Synonyms	Isoascorbic acid
	D-Araboascorbic acid
Definition	
Chemical name	D-Erythro-hex-2-enoic acid γ-lactone
	Isoascorbic acid
	D-Isoascorbic acid
Einecs	201-928-0
Chemical formula	$C_6H_8O_6$
Molecular weight	176,13
Assay	Content not less than 98 % on the anhydrous basis
Description	White to slightly yellow crystalline solid which darkens gradually on exposure to light
Identification	
A. Melting range	About 164 °C to 172 °C with decomposition
B. Positive test for ascorbic acid/colour reaction	
Purity	
Loss on drying	Not more than 0,4 % after drying under reduced pressure on silica gel for 3 hours
Sulphated ash	Not more than 0,3 %
Specific rotation	[α]10 % (w/v) aqueous solution between - 16,5° to - 18,0°

▼B

Oxalate	To a solution of 1 g in 10 ml of water add 2 drops of glacial acetic acid and 5 ml of 10 % calcium acetate solution. The solution should remain clear
Lead	Not more than 2 mg/kg

E 316 SODIUM ERYTHORBATE

Synonyms	Sodium isoascorbate
Definition	
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 mono-hydrate
Einecs	228-973-9
Chemical formula	$C_6H_7O_6Na \cdot H_2O$
Molecular weight	216,13
Assay	Content not less than 98 % after drying in a vacuum desiccator over sulphuric acid for 24 hours expressed on the monohydrate basis
Description	White crystalline solid
Identification	
A. Solubility tests	Freely soluble in water, very slightly soluble in ethanol
B. Positive test for ascorbic acid/colour reaction	
C. Positive test for sodium	
Purity	
Loss on drying	Not more than 0,25 % after drying in a vacuum desiccator over sulphuric acid for 24 hours
Specific rotation	[α]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

▼B

E 319 TERTIARY-BUTYLHYDROQUINONE (TBHQ)

Synonyms	TBHQ
Definition	
Chemical names	Tert-butyl-1,4-benzenediol
	2-(1,1-Dimethylethyl)-1,4-benzenediol
Einecs	217-752-2
Chemical formula	$C_{10}H_{14}O_2$
Molecular weight	166,22
Assay	Content not less than 99 % of $C_{10}H_{14}O_2$
Description	White crystalline solid having a characteristic odour
Identification	
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
Purity	
Tertiary-Butyl-p-benzoquinone	Not more than 0,2 %
2,5-Di-tertiary-butyl hydroquinone	Not more than 0,2 %
Hydroxyquinone	Not more than 0,1 %
Toluene	Not more than 25 mg/kg
Lead	Not more than 2 mg/kg

E 320 BUTYLATED HYDROXYANISOLE (BHA)

Synonyms	BHA
Definition	
Chemical names	3-Tertiary-butyl-4-hydroxyanisole
	A mixture of 2-tertiary-butyl-4-hydroxyanisole and 3-tertiary-butyl-4-hydroxyanisole
Einecs	246-563-8
Chemical formula	$C_{11}H_{16}O_2$
Formula weight	180,25
Assay	Content not less than 98,5 % of $C_{11}H_{16}O_2$ and not less than 85 % of 3-tertiary-butyl-4-hydroxyanisole isomer
Description	White or slightly yellow crystals or waxy solid with a slight aromatic smell
Identification	
A. Solubility	Insoluble in water, freely soluble in ethanol
B. Melting range	Between 48 °C and 63 °C

▼B

C. Colour reaction	Passes test for phenol groups
Purity	
Sulphated ash	Not more than 0,05 % after calcination at 800 ± 25 °C
Phenolic impurities	Not more than 0,5 %
Specific absorption $E^{1\%}_{1cm}$	$E^{1\%}_{1cm}$ (290 nm) not less than 190 and not more than 210
Specific absorption $E^{1\%}_{1cm}$	$E^{1\%}_{1cm}$ (228 nm) not less than 326 and not more than 345
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 321 BUTYLATED HYDROXYTOLUENE (BHT)

Synonyms	BHT
Definition	
Chemical name	2,6-Ditertiary-butyl-*p*-cresol
	4-Methyl-2,6-ditertiarybutylphenol
Einecs	204-881-4
Chemical formula	$C_{15}H_{24}O$
Molecular weight	220,36
Assay	Content not less than 99 %
Description	White, crystalline or flaked solid, odourless or having a characteristic faint aromatic odour
Identification	
A. Solubility tests	Insoluble in water and propane- 1,2-diol
	Freely soluble in ethanol
B. Melting point	At 70 ºC
C. Absorbance maximum	The absorption in the range 230 to 320 nm of a 2 cm layer of a 1 in 100 000 solution in dehydrated ethanol exhibits a maximum only at 278 nm
Purity	
Sulphated ash	Not more than 0,005 %
Phenolic impurities	Not more than 0,5 %
Specific absorption $E^{1\%}_{1cm}$ 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

▼B

E 322 LECITHINS

Synonyms	Phosphatides Phospholipids
Definition	Lecithins are mixtures or fractions of phosphatides obtained by physical procedures from animal or vegetable foodstuffs; they also include hydrolysed products obtained through the use of harmless and appropriate enzymes. The final product must not show any signs of residual enzyme activity The lecithins may be slightly bleached in aqueous medium by means of hydrogen peroxide. This oxidation must not chemically modify the lecithin phosphatides
Einecs	232-307-2
Assay	— Lecithins: not less than 60,0 % of substances insoluble in acetone — Hydrolysed lecithins: not less than 56,0 % of substances insoluble in acetone
Description	— Lecithins: brown liquid or viscous semi-liquid or powder — Hydrolysed lecithins: light brown to brown viscous liquid or paste
Identification	
A. Positive tests for choline, for phosphorus and fatty acids	
B. Test for hydrolysed lecithin	To a 800 ml beaker add 500 ml of water (30 °C-35 °C). Then slowly add 50 ml of the sample with constant stirring. Hydrolysed lecithin will form a homogeneous emulsion. Non-hydrolysed lecithin will form a distinct mass of about 50 g
Purity	
Loss on drying	Not more than 2,0 % determined by drying at 105 °C for one hour
Toluene-insoluble matter	Not more than 0,3 %
Acid value	— Lecithins: not more than 35 mg of potassium hydroxide per gram — Hydrolysed lecithins: not more than 45 mg of potassium hydroxide per gram
Peroxide value	Equal to or less than 10
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 325 SODIUM LACTATE

Definition	
Chemical name	Sodium lactate Sodium 2-hydroxypropanoate

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Einecs	200-772-0
Chemical formula	$C_3H_5NaO_3$
Molecular weight	112,06 (anhydrous)
Assay	Content not less than 57 % and not more than 66 %
Description	Colourless, transparent, liquid. Odourless, or with a slight, characteristic odour
Identification	
A. Positive test for lactate	
B. Positive test for sodium	
Purity	
Acidity	Not more than 0,5 % after drying expressed as lactic acid
pH of a 20 % aqueous solution	6,5 to 7,5
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Reducing substances	No reduction of Fehling's solution
Note:	
This specification refers to a 60 % aqueous solution	

E 326 POTASSIUM LACTATE

Definition	
Cheminal name	Potassium lactate
	Potassium 2-hydroxypropanoate
Einecs	213-631-3
Chemical formula	$C_3H_5O_3K$
Molecular weight	128,17 (anhydrous)
Assay	Content not less than 57 % and not more than 66 %
Description	Slightly viscous, almost odourless clear liquid. Odourless, or with a slight, characteristic odour
Identification	
A. Ignition	Ignite potassium lactate solution to an ash. The ash is alkaline, and an effervescence occurs when acid is added
B. Colour reaction	Overlay 2 ml of potassium lactate solution on 5 ml of a 1 in 100 solution of catechol in sulphuric acid. A deep red colour is produced at the zone of contact

▼B

C. Positive tests for potassium and for lactate	
Purity	
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Acidity	Dissolve 1 g of potassium lactate solution in 20 ml of water, add 3 drops of phenolphthalein TS and titrate with 0,1 N sodium hydroxide. Not more than 0,2 ml should be required
Reducing substances	Potassium lactate solution shall not cause any reduction of Fehling's solution
Note:	
This specification refers to a 60 % aqueous solution	

E 327 CALCIUM LACTATE

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

▼B

Fluoride	Not more than 30 mg/kg (expressed as fluorine)
pH of a 5 % solution	Between 6,0 and 8,0
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Reducing substances	No reduction of Fehling's solution

E 330 CITRIC ACID

Definition	
Chemical name	Citric acid
	2-Hydroxy-1,2,3-propanetricarboxylic acid
	β-Hydroxytricarballytic 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
Description	Citric acid is a white or colourless, odourless, crystalline solid, having a strongly acid taste. The monohydrate effloresces in dry air
Identification	
A. Solubility tests	Very soluble in water; freely soluble in ethanol; soluble in ether
Purity	
Water content	Anhydrous citric acid contains not more than 0,5 % water; citric acid monohydrate contains not more than 8,8 % water (Karl Fischer method)
Sulphated ash	Not more than 0,05 % after calcination at 800 ± 25 °C
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg
Oxalates	Not more than 100 mg/kg, expressed as oxalic acid, after drying

▼B

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

E 331 (i) MONOSODIUM CITRATE

Synonyms	Monosodium citrate
	Monobasic sodium citrate
Definition	
Chemical name	Monosodium citrate
	Monosodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid
Chemical formula	(a) $C_6H_7O_7Na$ (anhydrous)
	(b) $C_6H_7O_7Na \cdot H_2O$ (monohydrate)
Molecular weight	(a) 214,11 (anhydrous)
	(b) 232,23 (monohydrate)
Assay	Content not less than 99 % on the anhydrous basis
Description	Crystalline white powder or colourless crystals
Identification	
A. Positive tests for citrate and for sodium	
Purity	
Loss on drying	Determined by drying at 180 ºC for four hours:
	— anhydrous: not more than 1,0 %
	— monohydrate: not more than 8,8 %
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 1 % aqueous solution	Between 3,5 and 3,8
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

E 331 (ii) DISODIUM CITRATE

Synonyms	Disodium citrate
	Dibasic sodium citrate
Definition	
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

▼B

Assay	Content not less than 99 % on the anhydrous basis
Description	Crystalline white powder or colourless crystals
Identification	
A. Positive tests for citrate and for sodium	
Purity	
Loss on drying	Not more than 13,0 % by drying at 180 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 1 % aqueous solution	Between 4,9 and 5,2
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

E 331 (iii) TRISODIUM CITRATE

Synonyms	Trisodium citrate Tribasic sodium citrate
Definition	
Chemical name	Trisodium citrate Trisodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Trisodium salt of citric acid, in anhydrous, dihydrate or pentahydrate form
Einecs	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
Description	Crystalline white powder or colourless crystals
Identification	
A. Positive tests for citrate and for sodium	
Purity	
Loss on drying	Determined by drying at 180 °C for four hours: — anhydrous: not more than 1,0 % — dihydrate: not more than 13,5 % — pentahydrate: not more than 30,3 %

▼B

Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 5 % aqueous solution	Between 7,5 and 9,0
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

E 332 (i) MONOPOTASSIUM CITRATE

Synonyms	Monopotassium citrate
	Monobasic potassium citrate
Definition	
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	$C_6H_7O_7K$
Molecular weight	230,21
Assay	Content not less than 99 % on the anhydrous basis
Description	White, hygroscopic, granular powder or transparent crystals
Identification	
A. Positive tests for citrate and for potassium	
Purity	
Loss on drying	Not more than 1,0 % determined by drying at 180 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 1 % aqueous solution	Between 3,5 and 3,8
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

E 332 (ii) TRIPOTASSIUM CITRATE

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

▼B

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
Description	White, hygroscopic, granular powder or transparent crystals
Identification	
A. Positive tests for citrate and for potassium	
Purity	
Loss on drying	Not more than 6,0 % determined by drying at 180 ºC for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 5 % aqueous solution	Between 7,5 and 9,0
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

E 333 (i) MONOCALCIUM CITRATE

Synonyms	Monocalcium citrate
	Monobasic calcium citrate
Definition	
Chemical name	Monocalcium citrate
	Monocalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid
	Monohydrate monocalcium salt of citric acid
Chemical formula	$(C_6H_7O_7)_2Ca \cdot H_2O$
Molecular weight	440,32
Assay	Content not less than 97,5 % on the anhydrous basis
Description	Fine white powder
Identification	
A. Positive tests for citrate and for calcium	
Purity	
Loss on drying	Not more than 7,0 % determined by drying at 180 ºC 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)

▼B

Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg
Carbonates	Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles

E 333 (ii) DICALCIUM CITRATE

Synonyms	Dicalcium citrate
	Dibasic calcium citrate
Definition	
Chemical name	Dicalcium citrate
	Dicalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid
	Trihydrated dicalcium salt of citric acid
Chemical formula	$(C_6H_7O_7)_2Ca_2 \cdot 3H_2O$
Molecular weight	530,42
Assay	Not less than 97,5 % on the anhydrous basis
Description	Fine white powder
Identification	
A. Positive tests for citrate and for calcium	
Purity	
Loss on drying	Not more than 20,0 % determined by drying at 180 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg
Carbonates	Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles

E 333 (iii) TRICALCIUM CITRATE

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

▼B

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
Description	Fine white powder
Identification	
A. Positive tests for citrate and for calcium	
Purity	
Loss on drying	Not more than 14,0 % determined by drying at 180 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg
Carbonates	Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles

E 334 L(+)-TARTARIC ACID

Definition	
Chemical name	L-tartaric acid
	L-2,3-dihydroxybutanedioic acid
	d-α, β-dihydroxysuccinic acid
Einecs	201-766-0
Chemical formula	$C_4H_6O_6$
Molecular weight	150,09
Assay	Content not less than 99,5 % on the anhydrous basis
Description	Colourless or translucent crystalline solid or white crystalline powder
Identification	
A. Melting range	Between 168 °C and 170 °C
B. Positive test for tartrate	
Purity	
Loss on drying	Not more than 0,5 % (over P_2O_5, three hours)
Sulphated ash	Not more than 1 000 mg/kg after calcination at 800 ± 25 °C

▼B

Specific optical rotation of a 20 % w/v aqueous solution	$[\alpha]\ ^{20}_{D}$ 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

Synonyms	Monosodium salt of L-(+)-tartaric acid
Definition	
Chemical name	Monosodium salt of L-2,3-dihydroxybutanedioic acid
	Monohydrated monosodium salt of L-(+)-tartaric acid
Chemical formula	$C_4H_5O_6Na\cdot H_2O$
Molecular weight	194,05
Assay	Content not less than 99 % on the anhydrous basis
Description	Transparent colourless crystals
Identification	
A. Positive tests for tartrate and for sodium	
Purity	
Loss on drying	Not more than 10,0 % determined by drying at 105 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 335 (ii) DISODIUM TARTRATE

Definition	
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	$C_4H_4O_6Na_2\cdot 2H_2O$

▼B

Molecular weight	230,8
Assay	Content not less than 99 % on the anhydrous basis
Description	Transparent, colourless crystals
Identification	
A. Positive tests for tartrate and for sodium	
B. Solubility tests	1 gram is insoluble in 3 ml of water. Insoluble in ethanol
Purity	
Loss on drying	Not more than 17,0 % determined by drying at 150 ºC 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

Synonyms	Monobasic potassium tartrate
Definition	
Chemical name	Anhydrous monopotassium salt of L-(+)-tartaric acid
	Monopotassium salt of L-2,3-dihydroxybutanedioic acid
Chemical formula	$C_4H_5O_6K$
Molecular weight	188,16
Assay	Content not less than 98 % on the anhydrous basis
Description	White crystalline or granulated powder
Identification	
A. Positive tests for tartrate and for potassium	
B. Melting point	230 ºC
Purity	
pH of a 1 % aqueous solution	3,4
Loss on drying	Not more than 1,0 % determined by drying at 105 ºC for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
Arsenic	Not more than 3 mg/kg

▼B

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

E 336 (ii) DIPOTASSIUM TARTRATE

Synonyms	Dibasic potassium tartrate
Definition	
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
Description	White crystalline or granulated powder
Identification	
A. Positive tests for tartrate and for potassium	
Purity	
pH of a 1 % aqueous solution	Between 7,0 and 9,0
Loss on drying	Not more than 4,0 % determined by drying at 150 ºC for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 337 POTASSIUM SODIUM TARTRATE

Synonyms	Potassium sodium L-(+)-tartrate
	Rochelle salt
	Seignette salt
Definition	
Chemical name	Potassium sodium salt of L-2,3-dihydroxybutanedioic acid
	Potassium sodium L-(+)-tartrate
Einecs	206-156-8
Chemical formula	$C_4H_4O_6KNa \cdot 4H_2O$
Molecular weight	282,23

▼B

Assay	Content not less than 99 % on the anhydrous basis
Description	Colourless crystals or white crystalline powder
Identification	
A. Positive tests for tartrate, for potassium and for sodium	
B. Solubility tests	1 gram is soluble in 1 ml of water, insoluble in ethanol
C. Melting range	Between 70 and 80 °C
Purity	
Loss on drying	Not more than 26,0 % and not less than 21,0 % determined by drying at 150 °C for three hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of 1 % aqueous solution	Between 6,5 and 8,5
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 338 PHOSPHORIC ACID

Synonyms	Orthophosphoric acid
	Monophosphoric acid
Definition	
Chemical name	Phosphoric acid
Einecs	231-633-2
Chemical formula	H_3PO_4
Molecular weight	98,00
Assay	Phosphoric acid is commercially available as an aqueous solution at variable concentrations. Content not less than 67,0 % and not more than 85,7 %.
Description	Clear, colourless, viscous liquid
Identification	
A. Positive tests for acid and for phosphate	
Purity	
Volatile acids	Not more than 10 mg/kg (as acetic acid)
Chlorides	Not more than 200 mg/kg (expressed as chlorine)
Nitrates	Not more than 5 mg/kg (as $NaNO_3$)
Sulphates	Not more than 1 500 mg/kg (as $CaSO_4$)
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg

▼B

Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg
Note:	
This specification refers to a 75 % aqueous solution	

E 339 (i) MONOSODIUM PHOSPHATE

Synonyms	Monosodium monophosphate
	Acid monosodium monophosphate
	Monosodium orthophosphate
	Monobasic sodium phosphate
	Sodium dihydrogen monophosphate
Definition	
Chemical name	Sodium dihydrogen monophosphate
Einecs	231-449-2
Chemical formula	Anhydrous: NaH_2PO_4
	Monohydrate: $NaH_2PO_4 \cdot H_2O$
	Dihydrate: $NaH_2PO_4 \cdot 2H_2O$
Molecular weight	Anhydrous: 119,98
	Monohydrate: 138,00
	Dihydrate: 156,01
Assay	After drying at 60 °C for one hour and then at 105 °C for four hours, contains not less than 97 % of NaH_2PO_4
P_2O_5 content	Between 58,0 % and 60,0 % on the anhydrous basis
Description	A white odourless, slightly deliquescent powder, crystals or granules
Identification	
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
Purity	
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)

▼B

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

Synonyms	Disodium monophosphate
	Secondary sodium phosphate
	Disodium orthophosphate
	Acid disodium phosphate
Definition	
Chemical name	Disodium hydrogen monophosphate
	Disodium hydrogen orthophosphate
Einecs	231-448-7
Chemical formula	Anhydrous: Na_2HPO_4
	Hydrat: $Na_2HPO_4 \cdot nH_2O$ (n = 2,7 or 12)
Molecular weight	141,98 (anhydrous)
Assay	After drying at 40 °C for three hours and subsequently at 105 °C for five hours, contains not less than 98 % of Na_2HPO_4
P_2O_5 content	Between 49 % and 51 % on the anhydrous basis
Description	Anhydrous disodium hydrogen phosphate is a white, hygroscopic, odourless powder. Hydrated forms available include the dihydrate: a white crystalline, odourless solid; the heptahydrate: white, odourless, efflorescent crystals or granular powder; and the dodecahydrate: white, efflorescent, odourless powder or crystals
Identification	
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
Purity	
Loss on drying	When dried at 40 °C for three hours and then at 105 °C for five hours, the losses in weight are as follows: anhydrous not more than 5,0 %, dihydrate not more than 22,0 %, heptahydrate not more than 50,0 %, dodecahydrate not more than 61,0 %
Water-insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg

▼B

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

E 339 (iii) TRISODIUM PHOSPHATE

Synonyms	Sodium phosphate
	Tribasic sodium phosphate
	Trisodium orthophosphate
Definition	Trisodium phosphate is obtained from aqueous solutions and crystallises in the anhydrous form and with 1/2, 1, 6, 8 or 12 H_2O. 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_3PO_4
	Hydrated: $Na_3PO_4 \cdot nH_2O$ (n = 1/2, 1, 6, 8, or 12)
Molecular weight	163,94 (anhydrous)
Assay	Sodium phosphate anhydrous and the hydrated forms, with the exception of the dodecahydrate, contain not less than 97,0 % of Na_3PO_4 calculated on the dried basis. Sodium phosphate dodecahydrate contains not less than 92,0 % of Na_3PO_4 calculated on the ignited basis
P_2O_5 content	Between 40,5 % and 43,5 % on the anhydrous basis
Description	White odourless crystals, granules or crystalline powder
Identification	
A. Positive tests for sodium and for phosphate	
B. Solubility	Freely soluble in water. Insoluble in ethanol
C. pH of a 1 % solution	Between 11,5 and 12,5
Purity	
Loss on ignition	When dried at 120 °C for two hours and then ignited at about 800 °C for 30 minutes, the losses in weight are as follows: anhydrous not more than 2,0 %, monohydrate not more than 11,0 %, dodecahydrate: between 45,0 % and 58,0 %
Water insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 340 (i) MONOPOTASSIUM PHOSPHATE

Synonyms	Monobasic potassium phosphate
	Monopotassium monophosphate
	Potassium orthophosphate
Definition	
Chemical name	Potassium dihydrogen phosphate
	Monopotassium dihydrogen orthophosphate
	Monopotassium dihydrogen monophosphate
Einecs	231-913-4
Chemical formula	KH_2PO_4
Molecular weight	136,09
Assay	Content not less than 98,0 % after drying at 105 ºC for four hours
P_2O_5 content	Between 51,0 % and 53,0 % on the anhydrous basis
Description	Odourless, colourless crystals or white granular or crystalline powder, hygroscopic
Identification	
A. Positive tests for potassium and for phosphate	
B. Solubility	Freely soluble in water. Insoluble in ethanol
C. pH of a 1 % solution	Between 4,2 and 4,8
Purity	
Loss on drying	Not more than 2,0 % determined by drying at 105 ºC for four hours
Water-insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 340 (ii) DIPOTASSIUM PHOSPHATE

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

▼B

Definition	
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 ºC for four hours
P_2O_5 content	Between 40,3 % and 41,5 % on the anhydrous basis
Description	Colourless or white granular powder, crystals or masses; deliquescent substance
Identification	
A. Positive tests for potassium and for phosphate	
B. Solubility	Freely soluble in water. Insoluble in ethanol
C. pH of a 1 % solution	Between 8,7 and 9,4
Purity	
Loss on drying	Not more than 2,0 % determined by drying at 105 ºC for four hours
Water-insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 340 (iii) TRIPOTASSIUM PHOSPHATE

Synonyms	Potassium phosphate
	Tribasic potassium phosphate
	Tripotassium orthophosphate
Definition	
Chemical name	Tripotassium monophosphate
	Tripotassium phosphate
	Tripotassium orthophosphate
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)

▼B

Assay	Content not less than 97 % calculated on the ignited basis
P_2O_5 content	Between 30,5 % and 33,0 % on the ignited basis
Description	Colourless or white, odourless hygroscopic crystals or granules. Hydrated forms available include the mono-hydrate and trihydrate
Identification	
A. Positive tests for potassium and for phosphate	
B. Solubility	Freely soluble in water. Insoluble in ethanol
C. pH of a 1 % solution	Between 11,5 and 12,3
Purity	
Loss on ignition	Anhydrous: not more than 3,0 %; hydrated: not more than 23,0 %. Determined by drying at 105 ºC for one hour and then ignite at about 800 ºC ± 25 ºC for 30 minutes
Water insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 341 (i) MONOCALCIUM PHOSPHATE

Synonyms	Monobasic calcium phosphate
	Monocalcium orthophosphate
Definition	
Chemical name	Calcium dihydrogen phosphate
Einecs	231-837-1
Chemical formula	Anhydrous: $Ca(H_2PO_4)_2$
	Monohydrate: $Ca(H_2PO_4)_2 \cdot H_2O$
Molecular weight	234,05 (anhydrous)
	252,08 (monohydrate)
Assay	Content not less than 95 % on the dried basis
P_2O_5 content	Between 55,5 % and 61,1 % on the anhydrous basis
Description	Granular powder or white, deliquescent crystals or granules
Identification	
A. Positive tests for calcium and for phosphate	
B. CaO content	Between 23,0 % and 27,5 % (anhydrous)
	Between 19,0 % and 24,8 % (monohydrate)

▼B

Purity	
Loss on drying	Not more than 14 % determined by drying at 105 °C for four hours (anhydrous) Not more than 17,5 % determined by drying at 60 °C for one hour, then at 105 °C for four hours (monohydrate)
Loss on ignition	Not more than 17,5 % after ignition at 800 °C ± 25 °C for 30 minutes (anhydrous) Not more than 25,0 % determined by drying at 105 °C for one hour, then ignite at 800 °C ± 25 °C for 30 minutes (monohydrate)
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 341 (ii) DICALCIUM PHOSPHATE

Synonyms	Dibasic calcium phosphate Dicalcium orthophosphate
Definition	
Chemical name	Calcium monohydrogen phosphate Calcium hydrogen orthophosphate Secondary calcium phosphate
Einecs	231-826-1
Chemical formula	Anhydrous: $CaHPO_4$ Dihydrate: $CaHPO_4 \cdot 2H_2O$
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 $CaHPO_4$
P_2O_5 content	Between 50,0 % and 52,5 % on the anhydrous basis
Description	White crystals or granules, granular powder or powder
Identification	
A. Positive tests for calcium and for phosphate	
B. Solubility tests	Sparingly soluble in water. Insoluble in ethanol
Purity	
Loss on ignition	Not more than 8,5 % (anhydrous), or 26,5 % (dihydrate) after ignition at 800 °C ± 25 °C for 30 minutes

▼B

Fluoride	Not more than 50 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 341 (iii) TRICALCIUM PHOSPHATE

Synonyms	Calcium phosphate, tribasic
	Calcium orthophosphate
	Pentacalcium hydroxy monophosphate
	Calcium hydroxyapatite
Definition	Tricalcium phosphate consists of a variable mixture of calcium phosphates obtained from neutralisation of phosphoric acid with calcium hydroxide and having the approximate composition of $10CaO \cdot 3P_2O_5 \cdot H_2O$
Chemical name	Pentacalcium hydroxy monophosphate
	Tricalcium monophosphate
Einecs	235-330-6 (Pentacalcium hydroxy monophosphate)
	231-840-8 (Calcium orthophosphate)
Chemical formula	$Ca_5(PO_4)_3 \cdot OH$ or $Ca_3(PO_4)_2$
Molecular weight	502 or 310
Assay	Content not less than 90 % calculated on the ignited basis
P2O5 content	Between 38,5 % and 48,0 % on the anhydrous basis
Description	A white, odourless powder which is stable in air
Identification	
A. Positive tests for calcium and for phosphate	
B. Solubility	Practically insoluble in water; insoluble in ethanol soluble in dilute hydrochloric and nitric acid
Purity	
Loss on ignition	Not more than 8 % after ignition at 800 °C ± 25 °C, 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

▼B

E 343(i) MONOMAGNESIUM PHOSPHATE

Synonyms	Magnesiumdihydrogenphosphate
	Magnesiumphosphate, monobasic
	Monomagnesium orthophosphate
Definition	
Chemical name	Monomagnesiumdihydrogenmonophosphate
Einecs	236-004-6
Chemical formula	$Mg(H_2PO_4)_2 \cdot nH_2O$ (where n = 0 to 4)
Molecular weight	218,30 (anhydrous)
Assay	Not less than 51,0 % after ignition
Description	White, odourless, crystalline powder, slightly soluble in water
Identification	
A. Positive test for magnesium and for phosphate	
B. MgO content	Not less than 21,5 % after ignition
Purity	
Fluoride	Not more than 10 mg/kg (as fluorine)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 4 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 343(ii) DIMAGNESIUM PHOSPHATE

Synonyms	Magnesiumhydrogenphosphate
	Magnesiumphosphate, dibasic
	Dimagnesium orthophosphate
	Secondary magnesiumphosphate
Definition	
Chemical name	Dimagnesiummonohydrogenmonophosphate
Einecs	231-823-5
Chemical formula	$MgHPO_4 \cdot nH_2O$ (where n = 0-3)
Molecular weight	120,30 (anhydrous)
Assay	Not less than 96 % after ignition
Description	White, odourless, crystalline powder, slightly soluble in water
Identification	
A. Positive test for magnesium and for phosphate	
B. MgO content:	Not less than 33,0 % calculated on an anhydrous basis

▼B

Purity	
Fluoride	Not more than 10 mg/kg (as fluorine)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 4 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 350 (i) SODIUM MALATE

Synonyms	Sodium salt of malic acid
Definition	
Chemical name	Disodium DL-malate, disodium salt of hydroxybutanedioic acid
Chemical formula	Hemihydrate: $C_4H_4Na_2O_5 \cdot 1/2\ H_2O$
	Trihydrate: $C_4H_4Na_2O_5 \cdot 3H_2O$
Molecular weight	Hemihydrate: 187,05
	Trihydrate: 232,10
Assay	Content not less than 98,0 % on the anhydrous basis
Description	White crystalline powder or lumps
Identification	
A. Positive tests for 1,2-dicarboxylic acid and for sodium	
B. Azo dye formation	Positive
C. Solubility	Freely soluble in water
Purity	
Loss on drying	Not more than 7,0 % (130 °C, 4h) for the hemihydrate, or 20,5 %-23,5 % (130 °C, 4h) for the trihydrate
Alkalinity	Not more than 0,2 % as Na_2CO_3
Fumaric acid	Not more than 1,0 %
Maleic acid	Not more than 0,05 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 350 (ii) SODIUM HYDROGEN MALATE

Synonyms	Monosodium salt of DL-malic acid
Definition	
Chemical name	Monosodium DL-malate, monosodium 2-DL-hydroxy succinate
Chemical formula	$C_4H_5NaO_5$

▼B

Molecular weight	156,07
Assay	Content not less than 99,0 % on the anhydrous basis
Description	White powder
Identification	
A. Positive tests for 1,2-dicarboxylic acid and for sodium	
B. Azo dye formation	Positive
Purity	
Loss on drying	Not more than 2,0 % (110 °C, 3h)
Maleic acid	Not more than 0,05 %
Fumaric acid	Not more than 1,0 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 351 POTASSIUM MALATE

Synonyms	Potassium salt of malic acid
Definition	
Chemical name	Dipotassium DL-malate, dipotassium salt of hydroxybutanedioic acid
Chemical formula	$C_4H_4K_2O_5$
Molecular weight	210,27
Assay	Content not less than 59,5 %
Description	Colourless or almost colourless aqueous solution
Identification	
A. Positive tests for 1,2-dicarboxylic acid and for potassium	
B. Azo dye formation	Positive
Purity	
Alkalinity	Not more than 0,2 % as K_2CO_3
Fumaric acid	Not more than 1,0 %
Maleic acid	Not more than 0,05 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 352 (i) CALCIUM MALATE

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

E 352 (ii) CALCIUM HYDROGEN MALATE

Synonyms	Monocalcium salt of DL-malic acid
Definition	
Chemical name	Monocalcium DL-malate, monocalcium 2-DL-hydroxysuccinate
Chemical formula	$(C_4H_5O_5)_2Ca$
Assay	Content not less than 97,5 % on the anhydrous basis
Description	White powder
Identification	
A. Positive tests for 1,2-dicarboxylic acid and for calcium	
B. Azo dye formation	Positive
Purity	
Loss on drying	Not more than 2,0 % (110 °C, 3h)
Maleic acid	Not more than 0,05 %

▼B

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

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

E 354 CALCIUM TARTRATE

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

▼B

Purity	
Sulphates (as H_2SO_4)	Not more than 1 g/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 355 ADIPIC ACID

Definition	
Chemical name	Hexanedioic acid, 1,4-butanedicarboxylic acid
Einecs	204-673-3
Chemical formula	$C_6H_{10}O_4$
Molecular weight	146,14
Assay	Content not less than 99,6 %
Description	White odourless crystals or crystalline powder
Identification	
A. Melting range	151,5 °C-154,0 °C
B. Solubility	Slightly soluble in water. Freely soluble in ethanol
Purity	
Water	Not more than 0,2 % (Karl Fischer method)
Sulphated ash	Not more than 20 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 356 SODIUM ADIPATE

Definition	
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)
Description	White odourless crystals or crystalline powder
Identification	
A. Melting range	151 °C-152 °C (for adipic acid)
B. Solubility	Approximately 50 g/100 ml water (20 °C)
C. Positive test for sodium	

▼B

Purity	
Water	Not more than 3 % (Karl Fischer)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 357 POTASSIUM ADIPATE

Definition	
Chemical name	Potassium adipate
Einecs	242-838-1
Chemical formula	$C_6H_8K_2O_4$
Molecular weight	222,32
Assay	Content not less than 99,0 % (on anhydrous basis)
Description	White odourless crystals or crystalline powder
Identification	
A. Melting range	151 °C-152 °C (for adipic acid)
B. Solubility	Approximately 60 g/100 ml water (20 °C)
C. Positive test for potassium	
Purity	
Water	Not more than 3 % (Karl Fischer)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 363 SUCCINIC ACID

Definition	
Chemical name	Butanedioic acid
Einecs	203-740-4
Chemical formula	$C_4H_6O_4$
Molecular weight	118,09
Assay	Content no less than 99,0 %
Description	Colourless or white, odourless crystals
Identification	
A. Melting range	Between 185,0 °C and 190,0 °C
Purity	
Residue on ignition	Not more than 0,025 % (800 °C, 15 min)
Arsenic	Not more than 3 mg/kg

▼B

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

E 380 TRIAMMONIUM CITRATE

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

E 385 CALCIUM DISODIUM ETHYLENEDIAMINETETRAACETATE

Synonyms	Calcium disodium EDTA
	Calcium disodium edetate
Definition	
Chemical name	N, N′-1,2-Ethanediylbis [N-(carboxymethyl)-glycinate] [(4-)-O,O′,O^N,O^N]calciate(2)-disodium
	Calcium disodium ethylenediaminetetra acetate Calcium disodium (ethylenedinitrilo)tetra acetate
Einecs	200-529-9
Chemical formula	$C_{10}H_{12}O_8CaN_2Na_2 \cdot 2H_2O$
Molecular weight	410,31
Assay	Content not less than 97 % on the anhydrous basis
Description	White, odourless crystalline granules or white to nearly white powder, slightly hygroscopic
Identification	
A. Positive tests for sodium and for calcium	

▼B

B. Chelating activity to metal ions positive	
C. pH of a 1 % solution between 6,5 and 7,5	
Purity	
Water content	5 to 13 % (Karl Fischer method)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

▼M2

E 392 EXTRACTS OF ROSEMARY

GENERAL SPECIFICATION

Synonym	Extract of rosemary leaf (antioxidant)
Definition	Extracts of rosemary contain several components, which have been proven to exert antioxidative functions. These components belong mainly to the classes of phenolic acids, flavonoids, diterpenoids. Besides the antioxidant compounds, the extracts can also contain triterpenes and organic solvent extractable material specifically defined in the following specification
EINECS	283-291-9
Chemical name	Rosemary extract (*Rosmarinus officinalis*)
Description	Rosemary leaf extract antioxidant is prepared by extraction of the leaves of *Rosmarinus officinalis* using a food approved solvent system. Extracts may then be deodorised and decolourised. Extracts may be standardised
Identification	
Reference antioxidative compounds: phenolic diterpenes	Carnosic acid ($C_{20}H_{28}O_4$) and Carnosol ($C_{20}H_{26}O_4$) (which comprise not less than 90 % of the total phenolic diterpenes)
Reference key volatiles	Borneol, Bornyl Acetate, Camphor, 1,8-Cineol, Verbenone
Density	> 0,25 g/ml
Solubility	Insoluble in water
Purity	
Loss on Drying	< 5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg

▼M2

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

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

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

Extracts of rosemary produced from dried rosemary leaves extracted by means of supercritical carbon dioxide with a small amount of ethanol as entrainer.

Identification	
Content of reference antioxidative compounds	≥ 13 % w/w, expressed as the total of carnosic acid and carnosol
Antioxidant/Volatiles — Ratio	(Total % w/w of carnosic acid and carnosol) ≥ 15 (% w/w of reference key volatiles)* (* as a percentage of total volatiles in the extract, measured by Gas Chromatography — Mass Spectrometry Detection, 'GC-MSD')
Residual Solvents	Ethanol: not more than 2 %

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

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

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

▼M2

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

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

Identification	
Content of reference antioxidative compounds	≥ 5 % w/w, expressed as the total of carnosic acid and carnosol
Antioxidant/Volatiles — Ratio	(Total % w/w of carnosic acid and carnosol) ≥ 15 (% w/w of reference key volatiles)* (* as a percentage of total volatiles in the extract, measured by Gas Chromatography — Mass Spectrometry Detection, 'GC-MSD')
Residual solvents	Hexane: not more than 25 mg/kg Ethanol: not more than 500 mg/kg

▼M1

E 400 ALGINIC ACID

Definition	Linear glycuronoglycan consisting mainly of β-(1-4) linked D-mannuronic and α-(1-4) linked L-guluronic acid units in pyranose ring form. Hydrophilic colloidal carbohydrate extracted by the use of dilute alkali from natural strains of various species of brown seaweeds (*Phaeophyceae*)
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_2), 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)
Description	Alginic acid occurs in filamentous, grainy, granular and powdered forms. It is a white to yellowish brown and nearly odourless
Identification	
A. Solubility	Insoluble in water and organic solvents, slowly soluble in solutions of sodium carbonate, sodium hydroxide and trisodium phosphate
B. Calcium chloride precipitation test	To a 0,5 % solution of the sample in 1 M sodium hydroxide solution, add one fifth of its volume of a 2,5 % solution of calcium chloride. A voluminous, gelatinous precipitate is formed. This test distinguishes alginic acid from acacia gum, sodium carboxymethyl cellulose, carboxymethyl starch, carrageenan, gelatin, gum ghatti, karaya gum, locust bean gum, methyl cellulose and tragacanth gum

▼M1

C. Ammonium sulphate precipitation test	To a 0,5 % solution of the sample in 1 M sodium hydroxide solution, add one half of its volume of a saturated solution of ammonium sulphate. No precipitate is formed. This test distinguishes alginic acid from agar, sodium carboxymethyl cellulose, carrageenan, de-esterified pectin, gelatin, locust bean gum, methyl cellulose and starch
D. Colour reaction	Dissolve as completely as possible 0,01 g of the sample by shaking with 0,15 ml of 0,1 N sodium hydroxide and add 1 ml of acid ferric sulphate solution. Within 5 minutes, a cherry-red colour develops that finally becomes deep purple
Purity	
pH of a 3 % suspension	Between 2,0 and 3,5
Loss on drying	Not more than 15 % (105 °C, 4 hours)
Sulphated ash	Not more than 8 % on the anhydrous basis
Sodium hydroxide (1 M solution)	Not more than 2 % on the anhydrous basis insoluble matter
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
E. coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

E 401 SODIUM ALGINATE

Definition	
Chemical name	Sodium salt of alginic acid
Chemical formula	$(C_6H_7NaO_6)_n$
Molecular weight	10 000-600 000 (typical average)
Assay	Yields, on the anhydrous basis, not less than 18 % and not more than 21 % of carbon dioxide corresponding to not less than 90,8 % and not more than 106,0 % of sodium alginate (calculated on equivalent weight basis of 222)
Description	Nearly odourless, white to yellowish fibrous or granular powder

▼M1

Identification	
Positive test for sodium and alginic acid	
Purity	
Loss on drying	Not more than 15 % (105 °C, 4 hours)
Water-insoluble matter	Not more than 2 % on the anhydrous basis
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
E. coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

E 402 POTASSIUM ALGINATE

Definition	
Chemical name	Potassium salt of alginic acid
Chemical formula	$(C_6H_7KO_6)_n$
Molecular weight	10 000-600 000 (typical average)
Assay	Yields, on the anhydrous basis, not less than 16,5 % and not more than 19,5 % of carbon dioxide corresponding to not less than 89,2 % and not more than 105,5 % of potassium alginate (calculated on an equivalent weight basis of 238)
Description	Nearly odourless, white to yellowish fibrous or granular powder
Identification	
Positive test for potassium and for alginic acid	
Purity	
Loss on drying	Not more than 15 % (105 °C, 4 hours)
Water-insoluble matter	Not more than 2 % on the anhydrous basis
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

▼M1

Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
E. coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

E 403 AMMONIUM ALGINATE

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

▼M1

E 404 CALCIUM ALGINATE

Synonyms	Calcium salt of alginate
Definition	
Chemical name	Calcium salt of alginic acid
Chemical formula	$(C_6H_7Ca_{1/2}O_6)_n$
Molecular weight	10 000-600 000 (typical average)
Assay	Yields, on the anhydrous basis, not less than 18 % and not more than 21 % carbon dioxide corresponding to not less than 89,6 % and not more than 104,5 % of calcium alginate (calculated on an equivalent weight basis of 219)
Description	Nearly odourless, white to yellowish fibrous or granular powder
Identification	
Positive test for calcium and alginic acid	
Purity	
Loss on drying	Not more than 15,0 % (105 °C, 4 hours)
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
E. coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

E 405 PROPANE-1,2-DIOL ALGINATE

Synonyms	Hydroxypropyl alginate 1,2-propanediol ester of alginic acid Propylene glycol alginate
Definition	
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	$(C_9H_{14}O_7)_n$ (esterified)
Molecular weight	10 000-600 000 (typical average)

▼M1

Assay	Yields, on the anhydrous basis, not less than 16 % and not more than 20 % of CO_2 of carbon dioxide
Description	Nearly odourless, white to yellowish brown fibrous or granular powder
Identification	
Positive test for 1,2-propanediol and alginic acid after hydrolysis	
Purity	
Loss on drying	Not more than 20 % (105 °C, 4 hours)
Total propane-1,2-diol content	Not less than 15 % and not more than 45 %
Free propane-1,2-diol content	Not more than 15 %
Water-insoluble matter	Not more than 2 % on the anhydrous basis
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
E. coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

▼B

E 406 AGAR

Synonyms	Gelose
	Japan agar
	Bengal, Ceylon, Chinese or Japanese isinglass
	Layor Carang
Definition	
Chemical name	Agar is a hydrophilic colloidal polysaccharide consisting mainly of D-galactose units. On about every tenth D-galactopyranose unit one of the hydroxyl groups is esterified with sulphuric acid which is neutralised by calcium, magnesium, potassium or sodium. It is extracted from certain natural strains of marine algae of the families *Gelidiaceae* and *Sphaerococcaceae* and related red algae of the class *Rhodophyceae*
Einecs	232-658-1

▼B

Assay	The threshold gel concentration should not be higher than 0,25 %
Description	Agar is odourless or has a slight characteristic odour. Unground agar usually occurs in bundles consisting of thin, membranous, agglutinated strips, or in cut, flaked or granulated forms. It may be light yellowish-orange, yellowish-grey to pale yellow, or colourless. It is tough when damp, brittle when dry. Powdered agar is white to yellowish-white or pale yellow. When examined in water under a microscope, the agar appears granular and somewhat filamentous. A few fragments of the spicules of sponges and a few frustules of diatoms may be present. In chloral hydrate solution, the powdered agar appears more transparent than in water, more or less granular, striated, angular and occasionally contains frustules of diatoms. Gel strength may be standardised by the addition of dextrose and maltodextrines or sucrose
Identification	
A. Solubility	Insoluble in cold water; soluble in boiling water
Purity	
Loss on drying	Not more than 22 % (105 °C, 5 hours)
Ash	Not more than 6,5 % on the anhydrous basis determined at 550 °C
Acid-insoluble ash (insoluble in approximately 3N Hydrochloric acid)	Not more than 0,5 % determined at 550 °C on the anhydrous basis
Insoluble matter (in hot water)	Not more than 1,0 %
Starch	Not detectable by the following method: to a 1 in 10 solution of the sample add a few drops of iodine solution. No blue colour is produced
Gelatin and other proteins	Dissolve about 1 g of agar in 100 ml of boiling water and allow to cool of about 50 °C. To 5 ml of the solution add 5 ml of trinitrophenol solution (1 g of anhydrous trinitrophenol/100 ml of hot water). No turbidity appears within 10 minutes
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

▼M1

E 407 CARRAGEENAN

Synonyms	Products of commerce are sold under different names such as: Irish moss gelose Eucheuman (from *Eucheuma* spp.) Iridophycan (from *Iridaea* spp.) Hypnean (from *Hypnea* spp.) Furcellaran or Danish agar (from *Furcellaria fastigiata*) Carrageenan (from *Chondrus* and *Gigartina* spp.)
Definition	Carrageenan is obtained by aqueous extraction of natural strains of seaweeds of *Gigartinaceae, Solieriaceae, Hypneaeceae* and *Furcellariaceae*, families of the class *Rhodophyceae* (red seaweeds). No organic precipitant shall be used other than methanol, ethanol and propane-2-ol. Carrageenan consists chiefly of the potassium, sodium, magnesium and calcium salts of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3,6-anhydrogalactose. Carrageenan shall not be hydrolysed or otherwise chemically degraded. Formaldehyde may be present as an adventitious impurity up to a maximum level of 5 mg/kg
Einecs	232-524-2
Description	Yellowish to colourless, coarse to fine powder which is practically odourless
Identification	
Positive tests for galactose, for anhydrogalactose and for sulphate	
Purity	
Methanol, ethanol, propane-2-ol content	Not more than 0,1 % singly or in combination
Viscosity of a 1,5 % solution at 75 °C	Not less than 5 mPa.s
Loss on drying	Not more than 12 % (105 °C, four hours)
Sulphate	Not less than 15 % and not more than 40 % on the dried basis (as SO_4)
Ash	Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C
Acid-insoluble ash	Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)
Acid-insoluble matter	Not 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

▼M1

Mercury	Not more than 1 mg/kg
Cadmium	Not more than 2 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
E. coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

E 407a PROCESSED EUCHEUMA SEAWEED

Synonyms	PES (acronym for processed eucheuma seaweed)
Definition	Processed eucheuma seaweed is obtained by aqueous alkaline (KOH) treatment of the natural strains of seaweeds *Eucheuma cottonii* and *Eucheuma spinosum*, of the class *Rhodophyceae* (red seaweeds) to remove impurities and by fresh water washing and drying to obtain the product. Further purification may be achieved by washing with methanol, ethanol or propane-2-ol and drying. The product consist chiefly of the potassium salt of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3,6-anhydrogalactose. Sodium, calcium and magnesium salts of the polysaccharide sulphate esters are present in lesser amounts. Up to 15 % algal cellulose is also present in the product. The carrageenan in processed eucheuma seaweed shall not be hydrolysed or otherwise chemically degraded. Formaldehyde may be present as an adventitious impurity up to a maximum level of 5 mg/kg.
Description	Tan to yellowish, coarse to fine powder which is practically odourless
Identification	
A. Positive tests for galactose, for anhydrogalactose and for sulphate	
B. Solubility	Forms cloudy viscous suspensions in water. Insoluble in ethanol
Purity	
Methanol, ethanol, propane-2-ol content	Not more than 0,1 % singly or in combination
Viscosity of a 1,5 % solution at 75 °C	Not less than 5 mPa.s
Loss on drying	Not more than 12 % (105 °C, four hours)
Sulphate	Not less than 15 % and not more than 40 % on the dried basis (as SO_4)
Ash	Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C

▼M1

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 2 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
E. coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

▼B

E 410 LOCUST BEAN GUM

Synonyms	Carob bean gum Algaroba gum
Definition	Locust bean gum is the ground endosperm of the seeds of the natural strains of carob tree, *Ceratonia siliqua* (L.) Taub. (family *Leguminosae*). Consists mainly of a high molecular weight hydrocolloidal polysaccharide, composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as galactomannan
Molecular weight	50 000-3 000 000
Einecs	232-541-5
Assay	Galactomannan content not less than 75 %
Description	White to yellowish-white, nearly odourless powder
Identification	
A. Positive tests for galactose mannose	
B. Microscopic examination	Place some ground sample in an aqueous solution containing 0,5 % iodine and 1 % potassium iodide on a glass slide and examine under microscope. Locust bean gum contains long stretched tubiform cells, separated or slightly interspaced. Their brown contents are much less regularly formed in guar gum. Guar gum shows close groups of round to pear shaped cells. Their contents are yellow to brown
C. Solubility	Soluble in hot water, insoluble in ethanol

▼B

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

▼M1

E 412 GUAR GUM

Synonyms	Gum cyamopsis Guar flour
Definition	Guar gum is the ground endosperm of the seeds of natural strains of the guar plant, *Cyamopsis tetragonolobur* (L.) Taub. (family *Leguminosae*). Consists mainly of a high molecular weight hydrocolloidal polysaccharide composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as a galactomannan. The gum may be partially hydrolysed by either heat treatment, mild acid or alkaline oxidative treatment for viscosity adjustment.
Einecs	232-536-0
Molecular weight	Consists mainly of a high molecular weight hydrocolloidal polysaccharide (50 000-8 000 000)
Assay	Galactomannan content not less than 75 %
Description	A white to yellowish-white, nearly odourless powder
Identification	
A. Positive tests for galactose and for mannose	
B. Solubility	Soluble in cold water
Purity	
Loss on drying	Not more than 15 % (105 °C, 5 hours)
Ash	Not more than 5,5 % determined at 800 °C

▼M1

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)
Organic peroxides	Not more than 0,7 meq active oxygen/kg sample
Furfural	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Arsenic	Not more than 3 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

▼B

E 413 TRAGACANTH

Synonyms	Tragacanth gum
	Tragant
Definition	Tragacanth is a dried exudation obtained from the stems and branches of natural strains of *Astragalus gummifer* Labillardiere and other Asiatic species of *Astragalus* (family *Leguminosae*). It consists mainly of high molecular weight polysaccharides (galactoarabans and acidic polysaccharides) which, on hydrolysis, yield galacturonic acid, galactose, arabinose, xylose and fucose. Small amounts of rhamnose and of glucose (derived from traces of starch and/or cellulose) may also be present
Molecular weight	Approximately 800 000
Einecs	232-252-5
Description	Unground Tragacanth gum occurs as flattened, lamellated, straight or curved fragments or as spirally twisted pieces 0,5-2,5 mm thick and up to 3 cm in length. It is white to pale yellow in colour but some pieces may have a red tinge. The pieces are horny in texture, with a short fracture. It is odourless and solutions have an insipid mucilaginous taste. Powdered tragacanth is white to pale yellow or pinkish brown (pale tan) in colour
Identification	
A. Solubility	1 g of the sample in 50 ml of water swells to form a smooth, stiff, opalescent mucilage; insoluble in ethanol and does not swell in 60 % (w/v) aqueous ethanol
Purity	
Negative test for Karaya gum	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

▼B

Loss on drying	Not more than 16 % (105 ºC, 5 hours)
Total ash	Not more than 4 %
Acid insoluble ash	Not more than 0,5 %
Acid insoluble matter	Not more than 2 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Salmonella spp.	Negative in 10 g
E. coli	Negative in 5 g

E 414 ACACIA GUM

Synonyms	Gum arabic
Definition	Acacia gum is a dried exudation obtained from the stems and branches of natural strains of *Acacia senegal* (L) Willdenow or closely related species of Acacia (family *Leguminosae*). It consists mainly of high molecular weight polysaccharides and their calcium, magnesium and potassium salts, which on hydrolysis yield arabinose, galactose, rhamnose and glucuronic acid
Molecular weight	Approximately 350 000
Einecs	232-519-5
Description	Unground acacia gum occurs as white or yellowish-white spheroidal tears of varying sizes or as angular fragments and is sometimes mixed with darker fragments. It is also available in the form of white to yellowish-white flakes, granules, powder or spray-dried material.
Identification	
A. Solubility	1 g dissolves in 2 ml of cold water forming a solution which flows readily and is acid to litmus, insoluble in ethanol
Purity	
Loss on drying	Not more than 17 % (105 ºC, 5 hours) for granular and not more than 10 % (105 ºC, 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

▼B

Tannin	To 10 ml of a 1 in 50 solution add about 0,1 ml of ferric chloride solution (9 g $FeCl_3.6H_2O$ made up to 100 ml with water). No blackish colouration or blackish precipitate is formed
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Hydrolysis products	Mannose, xylose and galacturonic acid are absent (determined by chromatography)
Salmonella spp.	Negative in 10 g
E. coli	Negative in 5 g

E 415 XANTHAN GUM

Definition	Xanthan gum is a high molecular weight polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with natural strains of *Xanthomonas campestris*, purified by recovery with ethanol or propane-2-ol, dried and milled. It contains D-glucose and D-mannose as the dominant hexose units, along with D-glucuronic acid and pyruvic acid, and is prepared as the sodium, potassium or calcium salt. Its solutions are neutral
Molecular weight	Approximately 1 000 000
Einecs	234-394-2
Assay	Yields, on dried basis, not less than 4,2 % and not more than 5 % of CO_2 corresponding to between 91 % and 108 % of xanthan gum
Description	Cream-coloured powder
Identification	
A. Solubility	Soluble in water. Insoluble in ethanol
Purity	
Loss on drying	Not more than 15 % (105 °C, 21/2 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

▼B

Total plate count	Not more than 5 000 colonies per gram
Yeast and mould	Not more than 300 colonies per gram
E. coli	Absent in 5 g
Salmonella spp.	Absent in 10 g
Xanthomonas campestris	Viable cells absent in 1 g

E 416 KARAYA-GUM

Synonyms	Katilo
	Kadaya
	Gum *sterculia*
	Sterculia
	Karaya, gum karaya
	Kullo
	Kuterra
Definition	Karaya gum is a dried exudation from the stems and branches of natural strains of: *Sterculia urens* Roxburgh and other species of *Sterculia* (family *Sterculiaceae*) or from *Cochlospermum gossypium* A.P. De Candolle or other species of *Cochlospermum* (family *Bixaceae*). It consists mainly of high molecular weight acetylated polysaccharides, which on hydrolysis yield galactose, rhamnose, and galacturonic acid, together with minor amounts of glucuronic acid
Einecs	232-539-4
Description	Karaya gum occurs in tears of variable size and in broken irregular pieces having a characteristic semi-crystalline appearance. It is pale yellow to pinkish brown in colour, translucent and horny. Powdered karaya gum is a pale grey to pinkish brown. The gum has a distinctive odour of acetic acid
Identification	
A. Solubility	Insoluble in ethanol
B. Swelling in ethanol solution	Karaya gum swells in 60 % ethanol distinguishing it from other gums
Purity	
Loss on drying	Not more than 20 % (105 °C, 5 hours)
Total ash	Not more than 8 %
Acid insoluble ash	Not more than 1 %
Acid insoluble matter	Not more than 3 %

▼B

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

E 417 TARA GUM

Definition	Tara gum is obtained by grinding the endosperm of the seeds of natural strains of *Caesalpinia spinosa* (family *Leguminosae*). It consists chiefly of polysaccharides of high molecular weight composed mainly of galacto-mannans. The principal component consists of a linear chain of (1-4)-β-D-mannopyranose units with α-D-galac-topyranose 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
Description	A white to white-yellow odourless powder
Identification	
A. Solubility	Soluble in water
	Insoluble in ethanol
B. Gel formation	To an aqueous solution of the sample add small amounts of sodium borate. A gel is formed
Purity	
Loss on drying	Not more than 15 %
Ash	Not more than 1,5 %
Acid insoluble matter	Not more than 2 %
Protein	Not more than 3,5 % (factor N × 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

▼B

E 418 GELLAN GUM

Definition	Gellan gum is a high molecular weight polysaccharide gum produced by a pure culture fermentation of a carbohydrate by natural strains of *Pseudomonas elodea*, purified by recovery with isopropyl alcohol, dried, and milled. The high molecular weight polysaccharide is principally composed of a tetrasaccharide repeating unit of one rhamnose, one glucuronic acid, and two glucoses, and substituted with acyl (glyceryl and acetyl) groups as the O-glycosidically linked esters. The glucuronic acid is neutralised to a mixed potassium, sodium, calcium, and magnesium salt
Einecs	275-117-5
Molecular weight	Approximately 500 000
Assay	Yields, on the dried basis, not less than 3,3 % and not more than 6,8 % of CO_2
Description	An off-white powder
Identification	
A. Solubility	Soluble in water, forming a viscous solution.
	Insoluble in ethanol
Purity	
Loss on drying	Not more than 15 % after drying (105 °C, 21/2 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
E. coli	Negative in 5 g
Salmonella 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 ([1]).

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.

([1]) OJ L 158, 18.6.2008, p. 17.

▼B

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

Synonyms	Glycerin
	Glycerine
Definition	
Chemical names	1,2,3-propanetriol
	Glycerol
	Trihydroxypropane
Einecs	200-289-5
Chemical formula	$C_3H_8O_3$
Molecular weight	92,10
Assay	Content not less than 98 % of glycerol on the anhydrous basis
Description	Clear, colourless hygroscopic syrupy liquid with not more than a slight characteristic odour, which is neither harsh nor disagreeable
Identification	
A. Acrolein formation on heating	Heat a few drops of the sample in a test tube with about 0,5 g of potassium bisulphate. The characteristic pungent vapours of acrolein are evolved
B. Specific gravity (25/25 °C)	Not less than 1,257
C. Refractive index $[n]D^{20}$	Between 1,471 and 1,474
Purity	
Water	Not more than 5 % (Karl Fischer method)
Sulphated ash	Not more than 0,01 % determined at 800 ± 25 °C
Butanetriols	Not more than 0,2 %
Acrolein, glucose and ammonium compounds	Heat a mixture of 5 ml of glycerol and 5 ml of potassium hydroxide solution (1 in 10) at 60 °C for five minutes. It neither becomes yellow nor emits an odour of ammonia
Fatty acids and esters	Not more than 0,1 % calculated as butyric acid
Chlorinated compounds	Not more than 30 mg/kg (as chlorine)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

▼B

E 425(i) KONJAC GUM

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

▼B

E 425(ii) KONJAC GLUCOMANNAN

Definition	Konjac glucomannan is a water-soluble hydrocolloid obtained from Konjac flour by washing with water-containing ethanol. Konjac flour is the unpurified raw product from the tuber of the perennial plant *Amorphophallus konjac*. The main component is the water-soluble high-molecular-weight polysaccharide glucomannan, which consists of D-mannose and D-glucose units at a molar ratio of 1,6:1,0, connected by β(1-4)-glycosidic bonds with a branch at about each 50th or 60th unit. About each 19th sugar residue is acetylated
Molecular weight	500 000 to 2 000 000
Assay	Total dietary fibre: not less than 95 % on a dry weight basis
Description	White to slightly brownish fine particle size, free flowing and odourless powder
Identification	
A. Solubility	Dispersible in hot or cold water forming a highly viscous solution with a pH between 5,0 and 7,0. Solubility is increased by heat and mechanical agitation
B. Formation of heat-stable gel	Prepare a 2 % solution of the sample by heating it in a boiling water bath for 30 min, with continuous agitation and then cooling the solution to room temperature. For each g of the sample used to prepare 30 g of the 2 % solution, add 1 ml of 10 % potassium carbonate solution to the fully hydrated sample at ambient temperature. Heat the mixture in a water bath to 85 ºC, and maintain for 2 h without agitation. Under these conditions a thermally stable gel is formed
C. Viscosity (1 % solution)	Not less than 20 $kgm^{-1}s^{-1}$ at 25 ºC
Purity	
Loss on drying	Not more than 8 % (105 ºC, 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_2)	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 ºC, 3 to 4h)
Lead	Not more than 1 mg/kg

▼B

Salmonella spp.	Absent in 12,5 g
E. coli	Absent in 5 g

E 426 SOYBEAN HEMICELLULOSE

▼M2

Definition	Soybean Hemicellulose is a refined water-soluble polysaccharide obtained from natural strain soybean fibre by hot water extraction. No organic precipitant shall be used other than ethanol

▼B

Chemical names	Water soluble soybean polysaccharides
	Water soluble soybean fibre
Assay	Not less than 74 % carbohydrate

▼M2

Description	Free flowing white or yellowish white powder

▼B

Identification	
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
Purity	
Loss on drying	Not more than 7 % (105 ºC, 4h)
Protein	Not more than 14 %
Total ash	Not more than 9,5 % (600 ºC, 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
E. coli	Negative in 10 g

▼M2

Ethanol	Not more than 2 %

▼M2

E 427 CASSIA GUM

Synonyms	
Definition	Cassia gum is the ground purified endosperm of the seeds of *Cassia tora* and *Cassia obtusifoli* (*Leguminosae*) containing less than 0,05 % of *Cassia occidentalis*. It consists mainly of high molecular weight polysaccharides composed primarily of a linear chain of 1,4-β-D-mannopyranose units linked with 1,6-α-D-galactopyranose units. The ratio of mannose to galactose is about 5:1 In the manufacture the seeds are dehusked and degermed by thermal mechanical treatment followed by milling and screening of the endosperm. The ground endosperm is further purified by extraction with isopropanol
Assay	Not less than 75 % of Galactomannan
Description	Pale yellow to off-white, odourless powder
Identification	
Solubility	Insoluble in ethanol. Disperses well in cold water forming a colloidal solution
Gel formation with borate	To an aqueous dispersion of the sample add sufficient sodium borate test solution (TS) to raise the pH to above 9; a gel is formed
Gel formation with xanthan gum	Weigh 1,5 g of the sample and 1,5 g of xanthan gum and blend them. Add this blend (with rapid stirring) into 300 ml water at 80 °C in a 400 ml beaker. Stir until the mixture is dissolved and continue stirring for an extra 30 min after dissolution (maintain the temperature above 60 °C during the stirring process). Discontinue stirring and allow the mixture to cool at room temperature for at least 2 h A firm, viscoelastic gel forms after the temperature drops below 40 °C, but no such gel forms in a 1 % control solution of cassia gum or xanthan gum alone prepared in a similar manner
Viscosity	Less than 500 mPa.s (25 °C, 2h, 1 % solution) corresponding to an average molecular weight of 200 000-300 000 D
Purity	
Acid insoluble matter	Not more than 2,0 %
pH	5,5-8 (1 % aqueous solution)
Crude fat	Not more than 1 %
Proteins	Not more than 7 %
Total ash	Not more than 1,2 %
Loss on drying	Not more than 12 % (5 h, 105 °C)
Total Anthraquinones	Not more than 0,5 mg/kg (detection limit)
Solvent residues	Not more than 750 mg/kg Isopropyl alcohol

▼M2

Lead	Not more than 1 mg/kg
Microbiological criteria	
Total plate count	Not more than 5 000 colony forming units per gram
Yeast and mould	Not more than 100 colony forming units per gram
Salmonella spp.	Absent in 25 g
E. Coli	Absent in 1 g

▼B

E 431 POLYOXYETHYLENE (40) STEARATE

Synonyms	Polyoxyl (40) stearate
	polyoxyethylene (40) monostearate
Definition	A mixture of the mono- and diesters of edible commercial stearic acid and mixed polyoxyethylene diols (having an average polymer length of about 40 oxyethylene units) together with free polyol
Assay	Content not less than 97,5 % on the anhydrous basis
Description	Cream-coloured flakes or waxy solid at 25 °C with a faint odour
Identification	
A. Solubility	Soluble in water, ethanol, methanol and ethyl acetate. Insoluble in mineral oil
B. Congealing range	39 °C-44 °C
C. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
Purity	
Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 1
Saponification value	Not less than 25 and not more than 35
Hydroxyl value	Not less than 27 and not more than 40
1,4-Dioxane	Not more than 5 mg/kg
Ethylene oxide	Not more than 0,2 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

▼B

E 432 POLYOXYETHYLENE SORBITAN MONOLAURATE (POLYSORBATE 20)

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

Synonyms	Polysorbate 80
	Polyoxyethylene (20) sorbitan monooleate
Definition	A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial oleic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides
Assay	Content not less than 65 % of oxyethylene groups, equivalent to not less than 96,5 % of polyoxyethylene (20) sorbitan monooleate on the anhydrous basis
Description	A lemon to amber-coloured oily liquid at 25 ºC with a faint characteristic odour

▼B

Identification	
A. Solubility	Soluble in water, ethanol, methanol, ethyl acetate and toluene. Insoluble in mineral oil and petroleum ether
B. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
Purity	
Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 45 and not more than 55
Hydroxyl value	Not less than 65 and not more than 80
1,4-dioxane	Not more than 5 mg/kg
Ethylene oxide	Not more than 0,2 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 434 POLYOXYETHYLENE SORBITAN MONOPALMITATE (POLYSORBATE 40)

Synonyms	Polysorbate 40
	Polyoxyethylene (20) sorbitan monopalmitate
Definition	A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial palmitic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides
Assay	Content not less than 66 % of oxyethylene groups, equivalent to not less than 97 % of polyoxyethylene (20) sorbitan monopalmitate on the anhydrous basis
Description	A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour
Identification	
A. Solubility	Soluble in water, ethanol, methanol, ethyl acetate and acetone. Insoluble in mineral oil
B. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
Purity	
Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 41 and not more than 52
Hydroxyl value	Not less than 90 and not more than 107

▼B

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)

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

▼B

E 436 POLYOXYETHYLENE SORBITAN TRISTEARATE (POLYSORBATE 65)

Synonyms	Polysorbate 65
	Polyoxyethylene (20) sorbitan tristearate
Definition	A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial stearic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides
Assay	Content not less than 46 % of oxyethylene groups, equivalent to not less than 96 % of polyoxyethylene (20) sorbitan tristearate on the anhydrous basis
Description	A tan-coloured, waxy solid at 25 °C with a faint characteristic odour
Identification	
A. Solubility	Dispersible in water. Soluble in mineral oil, vegetal oils, petroleum ether, acetone, ether, dioxane, ethanol and methanol
B. Congealing range	29-33 °C
C. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
Purity	
Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 88 and not more than 98
Hydroxyl value	Not less than 40 and not more than 60
1,4-dioxane	Not more than 5 mg/kg
Ethylene oxide	Not more than 0,2 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 440 (i) PECTIN

Definition	Pectin consists mainly of the partial methyl esters of polygalacturonic acid and their ammonium, sodium, potassium and calcium salts. It is obtained by extraction in an aqueous medium of natural strains of appropriate edible plant material, usually citrus fruits or apples. No organic precipitant shall be used other than methanol, ethanol and propane-2-ol
Einecs	232-553-0
Assay	Content not less than 65 % of galacturonic acid on the ash-free and anhydrous basis after washing with acid and alcohol

▼B

Description	White, light yellow, light grey or light brown powder
Identification	
A. Solubility	Soluble in water forming a colloidal, opalescent solution. Insoluble in ethanol
Purity	
Loss on drying	Not more than 12 % (105 °C, 2 hours)
Acid insoluble ash	Not more than 1 % (insoluble in approximately 3N hydrochloric acid)
Sulphur dioxide	Not more than 50 mg/kg on the anhydrous basis
Nitrogen content	Not more than 1,0 % after washing with acid and ethanol
Free methanol, ethanol and propane-2-ol	Not more than 1 %, singly or in combination, on the anhydrous basis
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 440 (ii) AMIDATED PECTIN

Definition	Amidated pectin consists mainly of the partial methyl esters and amides of polygalacturonic acid and their ammonium, sodium, potassium and calcium salts. It is obtained by extraction in an aqueous medium of appropriate natural strains of edible plant material, usually citrus fruits or apples and treatment with ammonia under alkaline conditions. No organic precipitant shall be used other than methanol, ethanol and propane-2-ol
Assay	Content not less than 65 % of galacturonic acid on the ash-free and anhydrous basis after washing with acid and alcohol
Description	White, light yellow, light greyish or light brownish powder
Identification	
A. Solubility	Soluble in water forming a colloidal, opalescent solution. Insoluble in ethanol
Purity	
Loss on drying	Not more than 12 % (105 °C, 2 hours)
Acid-insoluble ash	Not more than 1 % (insoluble in approximately 3N hydrochloric acid)
Degree of amidation	Not more than 25 % of total carboxyl groups
Sulphur dioxide residue	Not more than 50 mg/kg on the anhydrous basis
Nitrogen content	Not more than 2,5 % after washing with acid and ethanol

▼B

Free methanol, ethanol and propane-2-ol	Not more than 1 % single or in combination, on a volatile matter-free basis
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 442 AMMONIUM PHOSPHATIDES

Synonyms	Ammonium salts of phosphatidic acid, mixed ammonium salts of phoshorylated glycerides
Definition	A mixture of the ammonium compounds of phosphatidic acids derived from edible fat and oil (usually partially hardened rapeseed oil). One or two or three glyceride moieties may be attached to phosphorus. Moreover, two phosphorus esters may be linked together as phosphatidyl phosphatides
Assay	The phosphorus content is not less than 3 % and not more than 3,4 % by weight; the ammonium content is not less than 1,2 % and not more than 1,5 % (calculated as N)
Description	Unctuous semi-solid
Identification	
A. Solubility	Soluble in fats. Insoluble in water. Partially soluble in ethanol and in acetone
B. Positive tests for glycerol, for fatty acid and for phosphate	
Purity	
Petroleum ether insoluble matter	Not more than 2,5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 444 SUCROSE ACETATE ISOBUTYRATE

Synonyms	SAIB
Definition	Sucrose acetate isobutyrate is a mixture of the reaction products formed by the esterification of food grade sucrose with acetic acid anhydride and isobutyric anhydride, followed by distillation. The mixture contains all possible combinations of esters in which the molar ratio of acetate to butyrate is about 2:6

▼B

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 $C_{40}H_{62}O_{19}$
Description	A pale straw-coloured liquid, clear and free of sediment and having a bland odour
Identification	
A. Solubility	Insoluble in water. Soluble in most organic solvents
B. Refractive index	$[n]^{40}_{D}$: 1,4492-1,4504
C. Specific gravity	$[d]^{25}_{D}$: 1,141-1,151
Purity	
Triacetin	Not more than 0,1 %
Acid value	Not more than 0,2
Saponification value	Not less than 524 and not more than 540
Arsenic	Not more than 3 mg/kg
Lead	Not more than 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

Synonyms	Ester gum
Definition	A complex mixture of tri- and diglycerol esters of resin acids from wood rosin. The rosin is obtained by the solvent extraction of aged pine stumps followed by a liquid-liquid solvent refining process. Excluded from these specifications are substances derived from gum rosin, and exudate of living pine trees, and substances derived from tall oil rosin, a by-product of kraft (paper) pulp processing. The final product is composed of approximately 90 % resin acids and 10 % neutrals (non-acidic compounds). The resin acid fraction is a complex mixture of isomeric diterpenoid monocarboxylic acids having the empirical molecular formula of $C_{20}H_{30}O_2$, chiefly abietic acid. The substance is purified by steam stripping or by countercurrent steam distillation
Description	Hard, yellow to pale amber-coloured solid
Identification	
A. Solubility	Insoluble in water, soluble in acetone
B. Infrared absorption spectrum	Characteristic of the compound

▼B

Purity	
Specific gravity of solution	$[d]^{20}_{25}$ not less than 0,935 when determined in a 50 % solution in d-limonene (97 %, boilding point 175,5-176 °C, d^{20}_4: 0,84)
Ring and ball softening range	Between 82 °C and 90 °C
Acid value	Not less than 3 and not more than 9
Hydroxyl value	Not less than 15 and not more than 45
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
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

Synonyms	Disodium dihydrogen diphosphate
	Disodium dihydrogen pyrophosphate
	Sodium acid pyrophosphate
	Disodium pyrophosphate
Definition	
Chemical name	Disodium dihydrogen diphosphate
Einecs	231-835-0
Chemical formula	$Na_2H_2P_2O_7$
Molecular weight	221,94
Assay	Content not less than 95 % of disodium diphosphate
P_2O_5 Content	Not less than 63,0 % and not more than 64,5 %
Description	White powder or grains
Identification	
A. Positive tests for sodium and for phosphate	
B. Solubility	Soluble in water
C. pH of a 1 % solution	Between 3,7 and 5,0
Purity	
Loss on drying	Not more than 0,5 % (105 °C, four hours)
Water-insoluble matter	Not more than 1 %

▼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 450 (ii) TRISODIUM DIPHOSPHATE

Synonyms	Acid trisodium pyrophosphate
	Trisodium monohydrogen diphosphate
Definition	
Einecs	238-735-6
Chemical formula	Monohydrate: $Na_3HP_2O_7 \cdot H_2O$
	Anhydrous: $Na_3HP_2O_7$
Molecular weight	Monohydrate: 261,95
	Anhydrous: 243,93
Assay	Content not less than 95 % on the anhydrous basis
P_2O_5 content	Not less than 57 % and not more than 59 %
Description	White powder or grains, occurs anhydrous or as a monohydrate
Identification	
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
Purity	
Loss on ignition	Not more than 4,5 % on the anhydrous compound
	Not more than 11,5 % on the monohydrous basis
Loss on drying	Not more than 0,5 % (105 °C, four hours)
Water-insoluble matter	Not more than 0,2 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 450 (iii) TETRASODIUM DIPHOSPHATE

Synonyms	Tetrasodium pyrophosphate
	Sodium pyrophosphate
Definition	
Chemical name	Tetrasodium diphosphate

▼B

Einecs	231-767-1
Chemical formula	Anhydrous: $Na_4P_2O_7$
	Decahydrate: $Na_4P_2O_7 \cdot 10H_2O$
Molecular weight	Anhydrous: 265,94
	Decahydrate: 446,09
Assay	Content not less than 95 % of $Na_4P_2O_7$ on the ignited basis
P_2O_5 content	Not less than 52,5 % and not more than 54,0 %
Description	Colourless or white crystals, or a white crystalline or granular powder. The decahydrate effloresces slightly in dry air
Identification	
A. Positive tests for sodium and for phosphate	
B. Solubility	Soluble in water. Insoluble in ethanol
C. pH of a 1 % solution	Between 9,8 and 10,8
Purity	
Loss on ignition	Not more than 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

Synonyms	Potassium pyrophosphate
	Tetrapotassium pyrophosphate
Definition	
Chemical name	Tetrapotassium diphosphate
Einecs	230-785-7
Chemical formula	$K_4P_2O_7$
Molecular weight	330,34 (anhydrous)
Assay	Content not less than 95 % on the ignited basis
P_2O_5 content	Not less than 42,0 % and not more than 43,7 % on the anhydrous basis
Description	Colourless crystals or white, very hygroscopic powder

▼B

Identification	
A. Positive tests for potassium and for phosphate	
B. Solubility	Soluble in water, insoluble in ethanol
C. pH of a 1 % solution	Between 10,0 and 10,8
Purity	
Loss on ignition	Not more than 2 % after drying at 105 ºC for four hours and then ignition at 550 ºC for 30 minutes
Water-insoluble substances	Not more than 0,2 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 450 (vi) DICALCIUM DIPHOSPHATE

Synonyms	Calcium pyrophosphate
Definition	
Chemical name	Dicalcium diphosphate
	Dicalcium pyrophosphate
Einecs	232-221-5
Chemical formula	$Ca_2P_2O_7$
Molecular weight	254,12
Assay	Content not less than 96 %
P_2O_5 content	Not less than 55 % and not more than 56 %
Description	A fine, white, odourless powder
Identification	
A. Positive tests for calcium and for phosphate	
B. Solubility	Insoluble in water. Soluble in dilute hydrochloric and nitric acids
C. pH of a 10 % suspension in water	Between 5,5 and 7,0
Purity	
Loss on ignition	Not more than 1,5 % at 800 ºC ± 25 ºC 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

▼B

E 450 (vii) CALCIUM DIHYDROGEN DIPHOSPHATE

Synonyms	Acid calcium pyrophosphate
	Monocalcium dihydrogen pyrophosphate
Definition	
Chemical name	Calcium dihydrogen diphosphate
Einecs	238-933-2
Chemical formula	$CaH_2P_2O_7$
Molecular weight	215,97
Assay	Content not less than 90 % on the anhydrous basis
P_2O_5 content	Not less than 61 % and not more than 64 %
Description	White crystals or powder
Identification	
A. Positive tests for calcium and for phosphate	
Purity	
Acid-insoluble matter	Not more than 0,4 %
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 451 (i) PENTASODIUM TRIPHOSPHATE

Synonyms	Pentasodium tripolyphosphate
	Sodium tripolyphosphate
Definition	
Chemical name	Pentasodium triphosphate
Einecs	231-838-7
Chemical formula	$Na_5O_{10}P_3 \cdot nH_2O$ (n = 0 or 6)
Molecular weight	367,86
Assay	Content not less than 85,0 % (anhydrous) or 65,0 % (hexahydrate)
P_2O_5 content	Not less than 56 % and not more than 59 % (anhydrous) or not less than 43 % and not more than 45 % (hexahydrate)
Description	White, slightly hygroscopic granules or powder
Identification	
A. Solubility	Freely soluble in water. Insoluble in ethanol

▼B

B. Positive tests for sodium and for phosphate	
C. pH of a 1 % solution	Between 9,1 and 10,2
Purity	
Loss on drying	Anhydrous: Not more than 0,7 % (105 ºC, one hour)
	Hexahydrate: Not more than 23,5 % (60 ºC, one hour, followed by drying at 105 ºC, four hours)
Water-insoluble substances	Not more than 0,1 %
Higher polyphosphates	Not more than 1 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 451 (ii) PENTAPOTASSIUM TRIPHOSPHATE

Synonyms	Pentapotassium tripolyphosphate
	Potassium triphosphate
	Potassium tripolyphosphate
Definition	
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_2O_5 content	Not less than 46,5 % and not more than 48 %
Description	White, very hygroscopic powder or granules
Identification	
A. Solubility	Very soluble in water
B. Positive tests for potassium and for phosphate	
C. pH of a 1 % solution	Between 9,2 and 10,5
Purity	
Loss on ignition	Not more than 0,4 % (after drying at 105 ºC, four hours, followed by ignition at 550 ºC, 30 minutes)
Water-insoluble matter	Not more than 2 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)

▼B

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

E 452 (i) SODIUM POLYPHOSPHATE

1. SOLUBLE POLYPHOSPHATE

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

▼B

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

Synonyms	Insoluble sodium metaphosphate
	Maddrell's salt
	Insoluble sodium polyphosphate, IMP
Definition	Insoluble sodium metaphosphate is a high molecular weight sodium polyphosphate composed of two long metaphosphate chains $(NaPO_3)_x$ that spiral in opposite directions about a common axis. The Na_2O/P_2O_5 ratio is about 1,0. The pH of 1 in 3 suspension in water is about 6,5
Chemical name	Sodium polyphosphate
Einecs	272-808-3
Chemical formula	Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula $H_{(n + 2)}P_nO_{(3n + 1)}$ where 'n' is not less than 2
Molecular weight	$(102)_n$
P_2O_5 content	Not less than 68,7 % and not more than 70,0 %
Description	White crystalline powder
Identification	
A. Solubility	Insoluble in water, soluble in mineral acids and in solutions of potassium and ammonium (but not sodium) chlorides
B. Positive tests for sodium and for phosphate	
C. pH of 1 in 3 suspension in water	About 6,5
Purity	
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 452 (ii) POTASSIUM POLYPHOSPHATE

Synonyms	Potassium metaphosphate
	Potassium polymetaphosphate
	Kurrol salt
Definition	
Chemical name	Potassium polyphosphate
Einecs	232-212-6
Chemical formula	$(KPO_3)n$
	Heterogenous mixtures of potassium salts of linear condensed polyphosphoric acids of general formula $H_{(n + 2)}P_nO_{(3n + 1)}$ where 'n' is not less than 2
Molecular weight	$(118)_n$
P_2O_5 content	Not less than 53,5 % and not more than 61,5 % on the ignited basis
Description	Fine white powder or crystals or colourless glassy platelets
Identification	
A. Solubility	1 g dissolves in 100 ml of a 1 in 25 solution of sodium acetate
B. Positive tests for potassium and for phosphate	
C. pH of a 1 % suspension	Not more than 7,8
Purity	
Loss on ignition	Not more than 2 % (105 °C, four hours followed by ignition at 550 °C, 30 minutes)
Cyclic phosphate	Not more than 8 % on P_2O_5 content
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 452(iii) SODIUM CALCIUM POLYPHOSPHATE

Synonym	Sodium calcium polyphosphate, glassy
Definition	
Chemical name	Sodium calcium polyphosphate
Einecs	233-782-9
Chemical formula	$(NaPO_3)_n$ CaO where n is typically 5
Assay	Not less than 61 % and not more than 69 % as P_2O_5
Description	White glassy crystals, spheres

▼B

Identification	
A. pH of a 1 % m/m slurry	Approximately 5 to 7
B. CaO content	7 %-15 % m/m
Purity	
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

Synonyms	Calcium metaphosphate
	Calcium polymetaphosphate
Definition	
Chemical name	Calcium polyphosphate
Einecs	236-769-6
Chemical formula	$(CaP_2O_6)n$
	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_2O_5 content	Not less than 71 % and not more than 73 % on the ignited basis
Description	Odourless, colourless crystals or white powder
Identification	
A. Solubility	Usually sparingly soluble in water. Soluble in acid medium
B. Positive tests for calcium and for phosphate	
C. CaO content	27 to 29,5 %
Purity	
Loss on ignition	Not more than 2 % (105 °C, four hours followed by ignition at 550 °C, 30 minutes)
Cyclic phosphate	Not more than 8 % on P_2O_5 content
Fluoride	Not more than 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

▼B

E 459 BETA-CYCLODEXTRIN

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

Synonyms	Cellulose gel
Definition	Microcrystalline cellulose is purified, partally depolymerised cellulose prepared by treating alpha-cellulose, obtained as a pulp from natural strains of fibrous plant material, with mineral acids. The degree of polymerisation is typically less than 400
Chemical name	Cellulose
Einecs	232-674-9
Chemical formula	$(C_6H_{10}O_5)_n$
Molecular weight	About 36 000
Assay	Not less than 97 % calculated as cellulose on the anhydrous basis
Description	A fine white or almost white odourless powder

▼B

Identification	
A. Solubility	Insoluble in water, ethanol, ether and dilute mineral acids. Slightly soluble in sodium hydroxide solution
B. Colour reaction	To 1 mg of the sample, add 1 ml of phosphoric acid and heat on a water bath for 30 minutes. Add 4 ml of a 1 in 4 solution of pyrocatechol in phosphoric acid and heat for 30 minutes. A red colour is produced
C. To be identified by IR spectroscopy	
D. Suspension test	Mix 30 g of the sample with 270 ml of water in a high-speed (12 000 rpm) power blender for 5 minutes. The resultant mixture will be either a free-following suspension or a heavy, lumpy suspension which flows poorly, if at all, settles only slightly and contains many trapped air bubbles. If a free-flowing suspension is obtained, transfer 100 ml into a 100-ml graduated cylinder and allow to stand for 1 hour. The solids settles and a supernatant liquid appears
Purity	
Loss on drying	Not more than 7 % (105 ºC, 3 hours)
Water-soluble matter	Not more than 0,24 %
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 ºC
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

Definition	Purified, mechanically disintegrated celluslose prepared by processing alpha-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

▼B

Chemical formula	$(C_6H_{10}O_5)_n$
Molecular weight	$(162)_n$ (n is predominantly 1 000 and greater)
Assay	Content not less than 92 %
Description	A white, odourless powder
Identification	
A. Solubility	Insoluble in water, ethanol, ether and dilute mineral acids. Slightly soluble in sodium hydroxide solution
B. Suspension test	Mix 30 g of the sample with 270 ml of water in a high-speed (12 000 rpm) power blender for 5 minutes. The resultant mixture will be either a free-flowing suspension or a heavy, lumpy suspension which flows poorly, if at all, settles only slightly and contains many trapped air bubbles. If a free-flowing suspension is obtained, transfer 100 ml into a 100-ml graduated cylinder and allow to stand for 1 hour. The solids settle and a supernatant liquid appears
Purity	
Loss on drying	Not more than 7 % (105 °C, 3 hours)
Water-soluble matter	Not more than 1,0 %
Sulphated ash	Not more than 0,3 % determined at 800 ± 25 °C
pH of a 10 % suspension in water	The pH of the supernatant liquid is between 5,0 and 7,5
Starch	Not detectable
	To 20 ml of the dispersion obtained in identification, test B, add a few drops of iodine solution and mix. No purplish to blue or blue colour should be produced
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Particle size	Not less than 5 μm (not more than 10 % of particles of less than 5 μm)

E 461 METHYL CELLULOSE

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

▼B

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 — or CH_2CH_3
Molecular weight	From about 20 000 to 380 000
Assay	Content not less than 25 % and not more than 33 % of methoxyl groups ($-OCH_3$) and not more than 5 % of hydroxyethoxyl groups ($-OCH_2CH_2OH$)
Description	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	
A. Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol, ether and chloroform. Soluble in glacial acetic acid
Purity	
Loss on drying	Not more than 10 % (105 °C, 3 hours)
Sulphated ash	Not more than 1,5 % determined at 800 ± 25 °C
pH of a 1 % colloidal solution	Not less than 5,0 and not more than 8,0
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 462 ETHYL CELLULOSE

Synonyms	Cellulose ethyl ether
Definition	Ethyl cellulose is cellulose obtained directly from fibrous plant material and partially etherified with ethyl groups
Chemical 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

▼B

Assay	Content not less than 44 % and not more than 50 % of ethoxyl groups ($-OC_2H_5$) on the dried basis (equivalent to not more than 2,6 ethoxyl groups per anhydroglucose unit)
Description	Slightly hygroscopic white to off-white, odourless and tasteless powder
Identification	
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
Purity	
Loss on drying	Not more than 3 % (105 ºC, 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

Synonyms	Cellulose hydroxypropyl ether
Definition	Hydroxypropylcellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with hydroxypropyl groups
Chemical name	Hydroxypropyl ether of cellulose
Chemical formula	The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$, where R_1, R_2, R_3 each may be one of the following: — H — $CH_2CHOHCH_3$ — $CH_2CHO(CH_2CHOHCH_3)CH_3$ — $CH_2CHO[CH_2CHO(CH_2CHOHCH_3)CH_3]CH_3$

▼B

Molecular weight	From about 30 000 to 1 000 000

▼M2

Assay	Content not more than 80,5 % of hydroxypropoxyl groups (-$OCH_2CHOHCH_3$) equivalent to not more than 4,6 hydroxypropyl groups per anhydroglucose unit on the anhydrous basis

▼B

Description	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	
A. Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Soluble in ethanol. Insoluble in ether
B. Gas chromatography	Determine the substituents by gas chromotography
Purity	
Loss on drying	Not more than 10 % (105 °C, 3 hours)
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
pH of a 1 % colloidal solution	Not less than 5,0 and not more than 8,0
Propylene chlorohydrins	Not more than 0,1 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 464 HYDROXYPROPYL METHYL CELLULOSE

Definition	Hydroxypropyl methyl cellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with methyl groups and containing a small degree of hydroxypropyl substitution
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 — $CH_2CHO[CH_2CHO$ ($CH_2CHOHCH_3$) $CH_3]CH_3$

▼B

Molecular weight	From about 13 000 to 200 000
Assay	Content not less than 19 % and not more than 30 % methoxyl groups (-OCH_3) and not less than 3 % and not more than 12 % hydroxypropoxyl groups (-$OCH_2CHOHCH_3$), on the anhydrous basis
Description	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	
A. Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol
B. Gas chromatography	Determine the substituents by gas chromatography
Purity	
Loss on drying	Not more than 10 % (105 ºC, 3 hours)
Sulphated ash	Not more than 1,5 % for products with viscosities of 50 mPa.s or above Not more than 3 % for products with viscosities below 50 mPa.s
pH of a 1 % colloidal solution	Not less than 5,0 and not more than 8,0
Propylene chlorohydrins	Not more than 0,1 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 465 ETHYL METHYL CELLULOSE

Synonyms	Methylethylcellulose
Definition	Ethyl methyl cellulose 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: — H — CH_3 — CH_2CH_3
Molecular weight	From about 30 000 to 40 000

▼B

Assay	Content on the anhydrous basis not less than 3,5 % and not more than 6,5 % of methoxyl groups ($-OCH_3$) and not less than 14,5 % and not more than 19 % of ethoxyl groups ($-OCH_2CH_3$), and not less than 13,2 % and not more than 19,6 % of total alkoxyl groups, calculated as methoxyl
Description	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	
A. Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Soluble in ethanol. Insoluble in ether
Purity	
Loss on drying	Not more than 15 % for the fibrous form, and not more than 10 % for the powdered form (105 ºC to constant weight)
Sulphated ash	Not more than 0,6 %
pH of a 1 % colloidal solution	Not less than 5,0 and not more than 8,0
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 466 SODIUM CARBOXY METHYL CELLULOSE

Synonyms	Carboxy methyl cellulose CMC NaCMC Sodium CMC Cellulose gum
Definition	Carboxy methyl cellulose is the partial sodium salt of a carboxymethyl ether of cellulose, the cellulose being obtained directly from natural strains of fibrous plant material
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_2COONa — CH_2COOH
Molecular weight	Higher than approximately 17 000 (degree of polymerisation approximately 100)

▼B

Assay	Content on the anhydrous basis not less than 99,5 %
Description	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	
A. Solubility	Yields a viscous colloidal solution with water. Insoluble in ethanol
B. Foam test	A 0,1 % solution of the sample is shaken vigorously. No layer of foam appears. (This test permits the distinction of sodium carboxymethyl cellulose from other cellulose ethers)
C. Precipitate formation	To 5 ml of a 0,5 % solution of the sample, add 5 ml of 5 % solution of copper sulphate or of aluminium sulphate. A precipitate appears. (This test permits the distinction of sodium carboxymethyl cellulose from other cellulose ethers and from gelatine, locust bean gum and tragacanth)
D. Colour reaction	Add 0,5 g powdered carboxy methyl cellulose sodium to 50 ml of water, while stirring to produce an uniform dispersion. Continue the stirring until a clear solution is produced, and use the solution for the following test: To 1 mg of the sample, diluted with an equal volume of water, in a small test tube, add 5 drops of 1-naphthol solution. Incline the test tube, and carefully introduce down the side of the tube 2 ml of sulphuric acid so that it forms a lower layer. A red-purple colour develops at the interface
Purity	
Degree of substitution	Not less than 0,2 and not more than 1,5 carboxymethyl groups ($-CH_2COOH$) per anhydroglucose unit
Loss on drying	Not more than 12 % (105 °C to constant weight)
pH of a 1 % colloidal solution	Not less than 5,0 and not more than 8,5
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Total glycolate	Not more than 0,4 %, calculated as sodium glycolate on the anhydrous basis
Sodium	Not more than 12,4 % on the anhydrous basis

E 468 CROSS-LINKED SODIUM CARBOXYMETHYLCELLULOSE

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

▼B

Definition	Cross-linked sodium carboxymethyl cellulose is the sodium salt of thermally cross-linked partly O-carboxymethylated cellulose
Chemical name	Sodium salt of the cross-linked carboxymethyl ether cellulose
Chemical formula	The polymers containing substituted anhydroglucose units with the general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$ where R_1, R_2 and R_3 may be any of the following: — H — CH_2COONa — CH_2COOH
Description	Slightly hygroscopic, white to off white, odourless powder
Identification	
A.	Shake 1 g with 100 ml of a solution containing 4 mg/kg methylene blue and allow to settle. The substance to be examined absorbs the methylene blue and settles as a blue, fibrous mass
B.	Shake 1 g with 50 ml of water. Transfer 1 ml of the mixture to a test tube, add 1 ml water and 0,05 ml of freshly prepared 40 g/l solution of alpha-naphthol in methanol. Incline the test tube and add carefully 2 ml of sulphuric acid down the side so that it forms a lower layer. A reddish-violet colour develops at the interface
C.	It gives the reaction of sodium
Purity	
Loss on drying	Not more than 6 % (105 °C, 3h)
Water solubles	Not more than 10 %
Degree of substitution	Not less than 0,2 and not more than 1,5 carboxymethyl groups per anhydroglucose unit
pH of 1 %	Not less than 5,0 and not more than 7,0
Sodium content	Not more than 12,4 % on anhydrous basis
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

▼B

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

E 469 ENZYMATICALLY HYDROLYSED CARBOXYMETHYLCELLULOSE

Synonyms	Sodium carboxymethyl cellulose, enzymatically hydrolysed
Definition	Enzymatically hydrolysed carboxymethylcellulose is obtained from carboxymethylcellulose by enzymatic digestion with a cellulase produced by *Trichoderma longibrachiatum* (formerly *T. reesei*)
Chemical name	Carboxymethyl cellulose, sodium, partially enzymatically hydrolysed
Chemical formula	Sodium salts of polymers containing substituted anhydroglucose units with the general formula: $[C_6H_7O_2(OH)_x(OCH_2COONa)_y]_n$ where n is the degree of polymerisation x = 1,50 to 2,80 y = 0,2 to 1,50 x + y = 3,0 (y = degree of substitution)
Formula weight	178,14 where y = 0,20 282,18 where y = 1,50 Macromolecules: Not less than 800 (n about 4)
Assay	Not less than 99,5 %, including mono- and disaccharides, on the dried basis
Description	White or slightly yellowish or greyish, odourless, slightly hygroscopic granular or fibrous powder
Identification	
A. Solubility	Soluble in water, insoluble in ethanol
B. Foam test	Vigorously shake a 0,1 % solution of the sample. No layer of foam appears. This test distinguishes sodium carboxymethyl cellulose, whether hydrolysed or not, from other cellulose ethers and from alginates and natural gums
C. Precipitate formation	To 5 ml of a 0,5 % solution of the sample add 5 ml of a 5 % solution of copper or aluminium sulphate. A precipitate appears. This test distinguishes sodium carboxymethyl cellulose, whether hydrolysed or not, from other cellulose ethers and from gelatine, carob bean gum and tragacanth gum

▼B

D. Colour reaction	Add 0,5 g of the powdered sample to 50 ml of water, while stirring to produce a uniform dispersion. Continue the stirring until a clear solution is produced. Dilute 1 ml of the solution with 1 ml of water in a small test tube. Add 5 drops of 1-naphthol TS. Incline the tube, and carefully introduce down the side of the tube 2 ml of sulphuric acid so that it forms a lower layer. A red-purple colour develops at the interface
E. Viscosity (60 % solids)	Not less than 2,500 $kgm^{-1}s^{-1}$ at 25 °C corresponding to an average molecule weight of 5 000 D
Purity	
Loss on drying	Not more than 12 % (105 °C to constant weight)
Degree of substitution	Not less than 0,2 and not more than 1,5 carboxymethyl groups per anhydroglucose unit on the dried basis
pH of a 1 % colloidal solution	Not less than 6,0 and not more than 8,5
Sodium chloride and sodium glycolate	Not more than 0,5 % singly or in combination
Residual enzyme activity	Passes test. No change in viscosity of test solution occurs, which indicates hydrolysis of the sodium carboxymethyl cellulose
Lead	Not more than 3 mg/kg

E 470a SODIUM, POTASSIUM AND CALCIUM SALTS OF FATTY ACIDS

Definition	Sodium, potassium and calcium salts of fatty acids occurring in food oils and fats, these salts being obtained either from edible fats and oils or from distilled food fatty acids
Assay	Content on the anhydrous basis not less than 95 %
Description	White or creamy white light powders, flakes or semi-solids
Identification	
A. Solubility	Sodium and potassium salts: soluble in water and ethanol calcium salts: insoluble in water, ethanol and ether
B. Positive tests for cations and for fatty acids	
Purity	
Sodium	Not less than 9 % and not more than 14 % expressed as Na_2O
Potassium	Not less than 13 % and not more than 21,5 % expressed as K_2O
Calcium	Not less than 8,5 % and not more than 13 % expressed as CaO
Unsaponifiable matter	Not more than 2 %

▼B

Free fatty acids	Not more than 3 % estimated as oleic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Free alkali	Not more than 0,1 % expressed as NaOH
Matter insoluble in alcohol	Not more than 0,2 % (sodium and potassium salts only)

E 470b MAGNESIUM SALTS OF FATTY ACIDS

Definition	Magnesium salts of fatty acids occurring in foods oils and fats, these salts being obtained either from edible fats and oils or from distilled food fatty acids
Assay	Content on the anhydrous basis not less than 95 %
Description	White or creamy-white light powders, flakes or semi-solids
Identification	
A. Solubility	Insoluble in water, partially soluble in ethanol and ether
B. Positive tests for magnesium and for fatty acids	
Purity	
Magnesium	Not less than 6,5 % and not more than 11 % expressed as MgO
Free alkali	Not more than 0,1 % expressed as MgO
Unsaponifiable matter	Not more than 2 %
Free fatty acids	Not more than 3 % estimated as oleic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 471 MONO- AND DIGLYCERIDES OF FATTY ACIDS

Synonyms	Glyceryl monostearate
	Glyceryl monopalmitate
	Glyceryl monooleate, etc.
	Monostearin, monopalmitin, monoolein, etc.
	GMS (for glyceryl monostearate)

▼B

Definition	Mono- and diglycerides of fatty acids consist of mixtures of glycerol mono-, di- and triesters of fatty acids occurring in food oils and fats. They may contain small amounts of free fatty acids and glycerol
Assay	Content of mono- and diesters: not less than 70 %
Description	The product varies from a pale yellow to pale brown oily liquid to a white or slightly off-white hard waxy solid. The solids may be in the form of flakes, powders or small beads
Identification	
A. Infrared spectrum	Characteristic of a partial fatty acid ester of a polyol
B. Positive tests for glycerol and for fatty acids	
C. Solubility	Insoluble in water, soluble in ethanol and toluene
Purity	
Water content	Not more than 2 % (Karl Fischer method)
Acid value	Not more than 6
Free glycerol	Not more than 7 %
Polyglycerols	Not more than 4 % diglycerol and not more than 1 % higher polyglycerols both based on total glycerol content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Total glycerol	Not less than 16 % and not more than 33 %
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C

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

Synonyms	Acetic acid esters of mono- and diglycerides
	Acetoglycerides
	Acetylated mono- and diglycerides
	Acetic and fatty acid esters of glycerol

▼B

Definition	Esters of glycerol with acetic and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free acetic acid and free glycerides
Description	Clear, mobile liquids to solids, from white to pale yellow in colour
Identification	
A. Positive tests for glycerol, for fatty acids and for acetic acid	
B. Solubility	Insoluble in water. Soluble in ethanol
Purity	
Acids other than acetic and fatty acids	Not detectable
Free glycerol	Not more than 2 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Total acetic acid	Not less than 9 % and not more than 32 %
Free fatty acids (and acetic acid)	Not more than 3 % estimated as oleic acid
Total glycerol	Not less than 14 % and not more than 31 %
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C

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

Synonyms	Lactic acid esters of mono- and diglycerides
	Lactoglycerides
	Mono- and diglycerides of fatty acids esterified with lactic acid
Definition	Esters of glycerol with lactic acid and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free lactic acid and free glycerides
Description	Clear, mobile liquids to waxy solids of variable consistency, from white to pale yellow in colour
Identification	
A. Positive tests for glycerol, for fatty acids and for lactic acid	

▼B

B. Solubility	Insoluble in cold water but dispersible in hot water
Purity	
Acids other than lactic and fatty acids	Not detectable
Free glycerol	Not more than 2 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Total lactic acid	Not less than 13 % and not more than 45 %
Free fatty acids (and lactic acid)	Not more than 3 % estimated as oleic acid
Total glycerol	Not less than 13 % and not more than 30 %
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C

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

Synonyms	Citrem
	Citric acid esters of mono- and diglycerides
	Citroglycerides
	Mono- and diglycerides of fatty acids esterified with citric acid
Definition	Esters of glycerol with citric acid and fatty acids occurring in food oils and fats. They may contain small amounts of free glycerol, free fatty acids, free citric acid and free glycerides. They may be partially or wholly neutralised with sodium hydroxide or with potassium hydroxide
Description	Yellowish or light brown liquids to waxy solids or semi-solids
Identification	
A. Positive 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	
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 ºC)	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

Synonyms	Tartaric acid esters of mono- and diglycerides Mono- and diglycerides of fatty acids esterified with tartaric acid
Definition	Esters of glycerol with tartaric acid and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free tartaric acid and free glycerides
Description	Sticky viscous yellowish liquids to hard yellow waxes
Identification	
A. Positive tests for glycerol, for fatty acids and for tartaric acid	
Purity	
Acids other than tartaric and fatty acids	Not detectable
Free glycerol	Not more than 2 %
Total glycerol	Not less than 12 % and not more than 29 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Total tartaric acid	Not less than 15 % and not more than 50 %
Free fatty acids	Not more than 3 % estimated as oleic acid
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 ºC

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).

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

Synonyms	Diacetyltartaric acid esters of mono- and diglycerides Mono-and diglycerides of fatty acids esterified with mono- and diacetyltartaric acid Diacetyltartaric and fatty acid esters of glycerol
Definition	Mixted esters of glycerol with mono- and diacetyltartaric acids (obtained from tartaric acid) and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free tartaric and acetic acids and their combinations, and free glycerides. Contains also tartaric and acetic esters of fatty acids
Description	Sticky viscous liquids through a fat-like consistency to yellow waxes which hydrolyse in moist air to liberate acetic acid
Identification	
A. Positive tests for glycerol, for fatty acids, for tartaric acid and for acetic acid	
Purity	
Acids other than acetic, tartaric and fatty acids	Not detectable
Free glycerol	Not more than 2 %
Total glycerol	Not less than 11 % and not more than 28 %
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 ºC
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).

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

Synonyms	Mono- and diglycerides of fatty acids esterified with acetic acid and tartaric acid
Definition	Esters of glycerol with acetic and tartaric acids and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free tartaric and ecetic acids, and free glycerides. May contain mono- and diacetyltartaric esters of mono- and diglycerides of fatty acids
Description	Sticky liquids to solids, from white to pale-yellow in colour
Identification	
A. Positive tests for glycerol, for fatty acids, for tartaric acid and for acetic acid	
Purity	
Acids other than acetic, tartaric and fatty acids	Not detectable
Free glycerol	Not more than 2 %
Total glycerol	Not less than 12 % and not more than 27 %
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
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

Synonyms	Sucroesters
	Sugar esters
Definition	Essentially the mono-, di- and triesters of sucrose with fatty acids occurring in food fats and oils. They may be prepared from sucrose and the methyl and ethyl esters of food fatty acids or by extraction from sucroglycerides. No organic solvent other than dimethylsulphoxide, dimethylformamide, ethyl acetate, propane-2-ol, 2-methyl-1-propanol, propylene glycol and methyl ethyl ketone may be used for their preparation

▼B

Assay	Content not less than 80 %
Description	Stiff gels, soft solids or white to slightly greyish-white powders
Identification	
A. Positive tests for sugar for fatty acids	
B. Solubility	Sparingly soluble in water
	Soluble in ethanol
Purity	
Sulphated ash	Not more than 2 % determined at 800 ± 25 °C
Free sugar	Not more than 5 %
Free fatty acids	Not more than 3 % estimated as oleic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Methanol	Not more than 10 mg/kg
Dimethylsulphoxide	Not more than 2 mg/kg
Dimethylformamide	Not more than 1 mg/kg
2-methyl-1-propanol	Not more than 10 mg/kg
Ethylacetate Propane-2-ol Prolyleneglycol	Not more than 350 mg/kg, singly or in combination
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

Synonyms	Sugar glycerides
Definition	Sucroglycerides are produced by reacting sucrose with an edible fat or oil to produce a mixture of essentially mono-, di- and triesters of sucrose and fatty acids together with residual mono-, di- and triglycerides from fat or oil. No organic solvents shall be used in their preparation other than cyclohexane, dimethylformamide, ethyl acetate, 2-methyl-1-propanol and propane-2-ol
Assay	Content not less than 40 % and not more than 60 % of sucrose fatty acid esters

▼B

Description	Soft solid masses, stiff gels or white to off-white powders
Identification	
A. Positive tests for sugar and for fatty acids	
B. Solubility	Insoluble in cold water
	Soluble in ethanol
Purity	
Sulphated ash	Not more than 2 % determined at 800 ± 25 ºC
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 Cyclohexane	Not more than 10 mg/kg, single or in combination
Ethylacetate Propane-2-ol	Not more than 350 mg/kg, single or in combination

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

Synonyms	Polyglycerol fatty acid esters
	Polyglycerin esters of fatty acid esters
Definition	Polyglycerol esters of fatty acids are produced by the esterification of polyglycerol with food fats and oils or with fatty acids occurring in foods fats and oils. The polyglycerol moiety is predominantly di-, tri- and tetraglycerol and contains not more than 10 % of polyglycerols equal to or higher than heptaglycerol
Assay	Content of total fatty acid ester not less than 90 %
Description	Light yellow to amber, oily to very viscous liquids; light tan to medium brown, plastic or soft solids; and light tan to brown, hard, waxy solids

▼B

Identification	
A. Positive tests for glycerol, for polyglycerols and for fatty acids	
B. Solubility	The esters range from very hydrophilic to very lipophilic, but as a class tend to be dispersible in water and soluble in organic solvents and oils
Purity	
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

Synonyms	Glycerol esters of condensed castor oil fatty acids
	Polyglycerol esters of polycondensed fatty acids from castor oil
	Polyglycerol esters of interesterified ricinoleic acid
	PGPR
Definition	Polyglycerol polyricinoleate is prepared by the esterification of polyglycerol with condensed castor oil fatty acids
Description	Clear, highly viscous liquid
Identification	
A. Solubility	Insoluble in water and in ethanol.
	Soluble in ether, hydrocarbons and halogenated hydrocarbons
B. Positive tests for glycerol, polyglycerol and for ricinoleic acid	
C. Refractive index $[n]^{65}$	Between 1,4630 and 1,4665

▼B

Purity	
Polyglycerols	The polyglycerol moiety shall be composed of not less than 75 % of di-, tri- and tetraglycerols and shall contain not more than 10 % of polyglycerols equal to or higher than heptaglycerol
Hydroxyl value	Not less than 80 and not more than 100
Acid value	Not more than 6
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

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

Synonyms	Propylene glycol esters of fatty acids
Definition	Consists of mixtures of propane-1,2-diol mono- and diesters of fatty acids occurring in food fats and oils. The alcohol moiety is exclusively propane-1,2-diol together with dimer and traces of trimer. Organic acids other than food fatty acids are absent
Assay	Content of total fatty acid ester not less than 85 %
Description	Clear liquids or waxy white flakes, beads or solids having a bland odour
Identification	
A. Positive tests for propylene glycol and for fatty acids	
Purity	
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 ºC
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).

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

Synonyms	TOSOM
Definition	Thermally oxidised soya bean oil interacted with mono- and diglycerides of fatty acids is a complex mixture of esters of glycerol and fatty acids found in edible fat and fatty acids from thermally oxidised soya bean oil. It is produced by interaction and desodorisation under vacuum at 130 ºC of 10 % of thermally oxidised soya bean oil and 90 % mono- and diglycerides of food fatty acids. Soya bean oil is exclusively made from natural strains of soya beans
Description	Pale yellow to light brown a waxy or solid consistency
Identification	
A. Solubility	Insoluble in water. Soluble in hot oil or fat
Purity	
Melting range	55-65 ºC
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

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

▼B

Chemical names	Sodium di-2-stearoyl lactate
	Sodium di(2-stearoyloxy)propionate
Einecs	246-929-7
Chemical formula (major components)	$C_{21}H_{39}O_4Na$
	$C_{19}H_{35}O_4Na$
Description	White or slightly yellowish powder or brittle solid with a characteristic odour
Identification	
A. Positive tests for sodium, for fatty acids and for lactic acid	
B. Solubility	Insoluble in water. Soluble in ethanol
Purity	
Sodium	Not less than 2,5 % and not more than 5 %
Ester value	Not less than 90 and not more than 190
Acid value	Not less than 60 and not more than 130
Total lactic acid	Not less than 15 % and not more than 40 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 482 CALCIUM STEAROYL-2-LACTYLATE

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

▼B

Purity	
Calcium	Not less than 1 % and not more than 5,2 %
Ester value	Not less than 125 and not more than 190
Total lactic acid	Not less than 15 % and not more than 40 %
Acid value	Not less than 50 and not more than 130
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 483 STEARYL TARTRATE

Synonyms	Stearyl palmityl tartrate
Definition	Product of the esterification of tartaric acid with commercial stearyl alcohol, which consists essentially of stearyl and palmityl alcohols. It consists mainly of diester, with minor amounts of monoester and of unchanged starting materials
Chemical name	Distearyl tartrate Dipalmityl tartrate
Chemical formula	$C_{38}H_{74}O_6$ to $C_{40}H_{78}O_6$
Molecular weight	627 to 655
Assay	Content of total ester not less than 90 % corresponding to an ester value of not less than 163 and not more than 180
Description	Cream-coloured unctuous solid (at 25 °C)
Identification	
A. Positive tests for tartare	
B. Melting range	Between 67 °C and 77 °C. After saponification the saturated long chain fatty alcohols have a melting range of 49 °C to 55 °C
Purity	
Hydroxyl value	Not less than 200 and not more than 220
Acid value	Not more than 5,6
Total tartaric acid content	Not less than 18 % and not more than 35 %
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

▼B

Heavy metals (as Pb)	Not more than 10 mg/kg
Unsaponifiable matter	Not less than 77 % and not more than 83 %
Iodine value	Not more than 4 (Wijs method)

E 491 SORBITAN MONOSTEARATE

Definition	A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial stearic acid
Einecs	215-664-9
Assay	Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters
Description	Light, cream- to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour
Identification	
A. Solubility	Soluble at temperatures above its melting point in toluene, dioxane, carbon tetrachloride, ether, methanol, ethanol and aniline; insoluble in petroleum ether and acetone; insoluble in cold water but dispersible in warm water; soluble with haze at temperatures above 50 °C in mineral oil and ethyl acetate
B. Congealing range	50-52 °C
C. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyol
Purity	
Water	Not more than 2 % (Karl Fischer method)
Sulphated ash	Not more than 0,5 %
Acid value	Not more than 10
Saponification value	Not less than 147 and not more than 157
Hydroxyl value	Not less than 235 and not more than 260
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 492 SORBITAN TRISTEARATE

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

▼B

Einecs	247-891-4
Assay	Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters
Description	Light, cream- to tan-coloured beads or flakes or hard, waxy solid with a slight odour
Identification	
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
Purity	
Water	Not more than 2 % (Karl Fischer method)
Sulphated ash	Not more than 0,5 %
Acid value	Not more than 15
Saponification value	Not less than 176 and not more than 188
Hydroxyl value	Not less than 66 and not more than 80
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 493 SORBITAN MONOLAURATE

Definition	A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial lauric acid
Einecs	215-663-3
Assay	Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters
Description	Amber-coloured oily viscous liquid, light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight odour
Identification	
A. Solubility	Dispersible in hot and cold water
B. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyol
Purity	
Water	Not more than 2 % (Karl Fischer method)
Sulphated ash	Not more than 0,5 %

▼B

Acid value	Not more than 7
Saponification value	Not less than 155 and not more than 170
Hydroxyl value	Not less than 330 and not more than 358
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 494 SORBITAN MONOOLEATE

Definition	A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial oleic acid. Major constituent is 1,4-sorbitan monooleate. Other constituents include isosorbide monooleate, sorbitan dioleate and sorbitan trioleate
Einecs	215-665-4
Assay	Content not less than 95 % of a mixture of sorbitol, sorbitan and isosorbide esters
Description	Amber-coloured viscous liquid, light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour
Identification	
A. Solubility	Soluble at temperatures above its melting point in ethanol, ether, ethyl acetate, aniline, toluene, dioxane, petroleum ether and carbon tetrachloride. Insoluble in cold water, dispersible in warm water
B. Iodine value	The residue of oleic acid, obtained from the saponification of the sorbitan monoleate in assay, has a iodine value between 80 and 100
Purity	
Water	Not more than 2 % (Karl Fischer method)
Sulphated ash	Not more than 0,5 %
Acid value	Not more than 8
Saponification value	Not less than 145 and not more than 160
Hydroxyl value	Not less than 193 and not more than 210
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

▼B

E 495 SORBITAN MONOPALMITATE

Synonyms	Sorbitan palmitate
Definition	A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial palmitic acid
Einecs	247-568-8
Assay	Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters
Description	Light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour
Identification	
A. Solubility	Soluble at temperatures above its melting point in ethanol, methanol, ether, ethyl acetate, aniline, toluene, dioxane, petroleum ether and carbon tetrachloride. Insoluble in cold water but dispersible in warm water
B. Congealing range	45-47 °C
C. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of polyol
Purity	
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

Synonyms	Soda ash
Definition	
Chemical name	Sodium carbonate
Einecs	207-838-8
Chemical formula	$Na_2CO_3 \cdot nH_2O$ (n = 0, 1 or 10)
Molecular weight	106,00 (anhydrous)
Assay	Content not less than 99 % of Na_2CO_3 on the anhydrous basis

▼B

Description	Colourless crystals or white, granular or crystalline powder The anhydrous form is hygroscopic, the decahydrate efflorescent
Identification	
A. Positive tests for sodium and for carbonate	
B. Solubility	Freely soluble in water. Insoluble in ethanol
Purity	
Loss on drying	Not more than 2 % (anhydrous), 15 % (monohydrate) or 55 %-65 % (decahydrate) (70 °C raising gradually to 300 °C, to constant weight)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 500(ii) SODIUM HYDROGEN CARBONATE

Synonyms	Sodium bicarbonate, sodium acid carbonate, bicarbonate of soda, baking soda
Definition	
Chemical name	Sodium hydrogen carbonate
Einecs	205-633-8
Chemical formula	$NaHCO_3$
Molecular weight	84,01
Assay	Content not less than 99 % on the anhydrous basis
Description	Colourless or white crystalline masses or crystalline powder
Identification	
A. Positive tests for sodium and for carbonate	
B. pH of a 1 % solution	Between 8,0 and 8,6
C. Solubility	Soluble in water. Insoluble in ethanol
Purity	
Loss on drying	Not more than 0,25 % (over silica gel, 4h)
Ammonium salts	No odour of ammonia detectable after heating
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 500(iii) SODIUM SESQUICARBONATE

Definition	
Chemical name	Sodium monohydrogen dicarbonate
Einecs	208-580-9
Chemical formula	$Na_2(CO)_3 \cdot NaHCO_3 \cdot 2H_2O$
Molecular weight	226,03
Assay	Content between 35,0 % and 38,6 % of $NaHCO_3$ and between 46,4 % and 50,0 % of Na_2CO_3
Description	White flakes, crystals or crystalline powder
Identification	
A. Positive tests for sodium and for carbonate	
B. Solubility	Freely soluble in water
Purity	
Sodium chloride	Not more than 0,5 %
Iron	Not more than 20 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 501(i) POTASSIUM CARBONATE

Definition	
Chemical name	Potassium carbonate
Einecs	209-529-3
Chemical formula	$K_2CO_3 \cdot nH_2O$ (n = 0 or 1,5)
Molecular weight	138,21 (anhydrous)
Assay	Content not less than 99,0 % on the anhydrous basis
Description	White, very deliquescent powder.
	The hydrate occurs as small, white, translucent crystals or granules
Identification	
A. Positive tests for potassium and for carbonate	
B. Solubility	Very soluble in water. Insoluble in ethanol
Purity	
Loss on drying	Not more than 5 % (anhydrous) or 18 % (hydrate) (180 °C, 4h)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 501(ii) POTASSIUM HYDROGEN CARBONATE

Synonyms	Potassium bicarbonate, acid potassium carbonate
Definition	
Chemical name	Potassium hydrogen carbonate
Einecs	206-059-0
Chemical formula	$KHCO_3$
Molecular weight	100,11
Assay	Content not less than 99,0 % and not more than 101,0 % $KHCO_3$ on the anhydrous basis
Description	Colourless crystals or white powder or granules
Identification	
A. Positive tests for potassium and for carbonate	
B. Solubility	Freely soluble in water. Insoluble in ethanol
Purity	
Loss on drying	Not more than 0,25 % (over silica gel, 4h)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 503(i) AMMONIUM CARBONATE

Definition	Ammonium carbonate consists of ammonium carbamate, ammonium carbonate and ammonium hydrogen carbonate in varying proportions
Chemical name	Ammonium carbonate
Einecs	233-786-0
Chemical formula	$CH_6N_2O_2$, $CH_8N_2O_3$ and CH_5NO_3
Molecular weight	Ammonium carbamate 78,06; ammonium carbonate 98,73; ammonium hydrogen carbonate 79,06
Assay	Content not less than 30,0 % and not more than 34,0 % of NH_3
Description	White powder or hard, white or translucent masses or crystals. Becomes opaque on exposure to air and is finally converted into white porous lumps or powder (of ammonium bicarbonate) due to loss of ammonia and carbon dioxide
Identification	
A. Positive tests for ammonium and for carbonate	
B. pH of a 5 % solution	about 8,6
C. Solubility	Soluble in water

▼B

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

E 503(ii) AMMONIUM HYDROGEN CARBONATE

Synonyms	Ammonium bicarbonate
Definition	
Chemical name	Ammonium hydrogen carbonate
Einecs	213-911-5
Chemical formula	CH_5NO_3
Molecular weight	79,06
Assay	Content not less than 99,0 %
Description	White crystals or crystalline powder
Identification	
A. Positive tests for ammonium and for carbonate	
B. pH of a 5 % solution	about 8,0
C. Solubility	Freely soluble in water. Insoluble in ethanol
Purity	
Non-volatile matter	Not more than 500 mg/kg
Chlorides	Not more than 30 mg/kg
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

▼M1

E 504(i) MAGNESIUM CARBONATE

Synonyms	Hydromagnesite
Definition	Magnesium carbonate is a basic hydrated or a monohydrated magnesium carbonate or a mixture of the two
Chemical name	Magnesium carbonate
Chemical formula	$MgCO_3.nH_2O$

▼M1

Einecs	208-915-9
Assay	Not less than 24 % and not more than 26,4 % of Mg
Description	Odourless, light, white friable masses or as a bulky white powder
Identification	
A. Solubility	Practically insoluble both in water or ethanol
B. Positive tests for magnesium and for carbonate	
Purity	
Acid insoluble matter	Not more than 0,05 %
Water soluble matter	Not more than 1 %
Calcium	Not more than 0,4 %
Arsenic	Not more than 4 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 504(ii) MAGNESIUM HYDROXIDE CARBONATE

Synonyms	Magnesium hydrogen carbonate, magnesium subcarbonate (light or heavy), hydrated basic magnesium carbonate, magnesium carbonate hydroxide
Definition	
Chemical name	Magnesium carbonate hydroxide hydrated
Einecs	235-192-7
Chemical formula	$4MgCO_3Mg(OH)_25H_2O$
Molecular weight	485
Assay	Mg content not less than 40,0 % and not more than 45,0 % calculated as MgO
Description	Light, white friable mass or bulky white powder
Identification	
A. Positive tests for magnesium and for carbonate	
B. Solubility	Practically insoluble in water. Insoluble in ethanol
Purity	
Acid insoluble matter	Not more than 0,05 %
Water soluble matter	Not more than 1,0 %
Calcium	Not more than 1,0 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 507 HYDROCHLORIC ACID

Synonyms	Hydrogen chloride, muriatic acid
Definition	
Chemical name	Hydrochloric acid
Einecs	231-595-7
Chemical formula	HCl
Molecular weight	36,46
Assay	Hydrochloric acid is commercially available in varying concentrations. Concentrated hydrochloric acid contains not less than 35,0 % HCl
Description	Clear, colourless or slightly yellowish, corrosive liquid having a pungent odour
Identification	
A. Positive tests for acid and for chloride	
B. Solubility	Soluble in water and in ethanol
Purity	
Total organic compounds	Total organic compounds (non-fluorine containing): not more than 5 mg/kg
	Benzene: not more than 0,05 mg/kg
	Fluorinated compounds (total): not more than 25 mg/kg
Non-volatile matter	Not more than 0,5 %
Reducing substances	Not more than 70 mg/kg (as SO_2)
Oxidising substances	Not more than 30 mg/kg (as Cl_2)
Sulphate	Not more than 0,5 %
Iron	Not more than 5 mg/kg
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 508 POTASSIUM CHLORIDE

Synonyms	Sylvine
	Sylvite
Definition	
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	Colourless, elongated, prismatic or cubital crystals or white granular powder. Odourless
Identification	
A. Solubility	Freely soluble in water. Insoluble in ethanol
B. Positive tests for potassium and for chloride	
Purity	
Loss on drying	Not more than 1 % (105 ºC, 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

Definition	
Chemical name	Calcium chloride
Einecs	233-140-8
Chemical formula	$CaCl_2 \cdot nH_2O$ (n = 0,2 or 6)
Molecular weight	110,99 (anhydrous), 147,02 (dihydrate), 219,08 (hexahydrate)
Assay	Content not less than 93,0 % on the anhydrous basis
Description	White, odourless, hygroscopic powder or deliquescent crystals
Identification	
A. Positive tests for calcium and for chloride	
B. Solubility	Anhydrous calcium chloride: freely soluble in water and ethanol Dihydrate: freely soluble in water, soluble in ethanol Hexahydrate: very soluble in water and ethanol
Purity	
Magnesium and alkali salts	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

▼B

E 511 MAGNESIUM CHLORIDE

Definition	
Chemical name	Magnesium chloride
Einecs	232-094-6
Chemical formula	$MgCl_2 \cdot 6H_2O$
Molecular weight	203,30
Assay	Content not less than 99,0 %
Description	Colourless, odourless, very deliquescent flakes or crystals
Identification	
A. Positive tests for magnesium and for chloride	
B. Solubility	Very soluble in water, freely soluble in ethanol
Purity	
Ammonium	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg

E 512 STANNOUS CHLORIDE

Synonyms	Tin chloride, tin dichloride
Definition	
Chemical name	Stannous chloride dihydrate
Einecs	231-868-0
Chemical formula	$SnCl_2 \cdot 2H_2O$
Molecular weight	225,63
Assay	Content not less than 98,0 %
Description	Colourless or white crystals
	May have a slight odour of hydrochloric acid
Identification	
A. Positive tests for tin (II) and for chloride	
B. Solubility	Water: soluble in less than its own weight of water, but it forms an insoluble basic salt with excess water
	Ethanol: soluble
Purity	
Sulphate	Not more than 30 mg/kg

▼B

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

E 513 SULPHURIC ACID

Synonyms	Oil of vitriol, dihydrogen sulphate
Definition	
Chemical name	Sulphuric acid
Einecs	231-639-5
Chemical formula	H_2SO_4
Molecular weight	98,07
Assay	Sulphuric acid is commercially available in varying concentrations. The concentrated form contains not less than 96,0 %
Description	Clear, colourless or slightly brown, very corrosive oily liquid
Identification	
A. Positive tests for acid and for sulphate	
B. Solubility	Miscible with water, with generation of much heat, also with ethanol
Purity	
Ash	Not more than 0,02 %
Reducing matter	Not more than 40 mg/kg (as SO_2)
Nitrate	Not more than 10 mg/kg (on H_2SO_4 basis)
Chloride	Not more than 50 mg/kg
Iron	Not more than 20 mg/kg
Selenium	Not more than 20 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 514(i) SODIUM SULPHATE

Definition	
Chemical name	Sodium sulphate
Chemical formula	$Na_2SO_4 \cdot nH_2O$ (n = 0 or 10)
Molecular weight	142,04 (anhydrous)
	322,04 (decahydrate)

▼B

Assay	Content not less than 99,0 % on the anhydrous basis
Description	Colourless crystals or a fine, white, crystalline powder The decahydrate is efflorescent
Identification	
A. Positive tests for sodium and for sulphate	
B. Acidity of a 5 % solution: neutral or slightly alkaline to litmus paper	
Purity	
Loss on drying	Not more than 1,0 % (anhydrous) or not more than 57 % (decahydrate) at 130 °C
Selenium	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 514(ii) SODIUM HYDROGEN SULPHATE

Synonyms	Acid sodium sulphate, sodium bisulphate, nitre cake
Definition	
Chemical name	Sodium hydrogen sulphate
Chemical formula	$NaHSO_4$
Molecular weight	120,06
Assay	Content not less than 95,2 %
Description	White, odourless crystals or granules
Identification	
A. Positive tests for sodium and for sulphate	
B. Solutions are strongly acidic	
Purity	
Loss on drying	Not more than 0,8 %
Water insoluble	Not more than 0,05 %
Selenium	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 515(i) POTASSIUM SULPHATE

Definition	
Chemical name	Potassium sulphate
Chemical formula	K_2SO_4
Molecular weight	174,25
Assay	Content not less than 99,0 %
Description	Colourless or white crystals or crystalline powder
Identification	
A. Positive tests for potassium and for sulphate	
B. pH of a 5 % solution	Between 5,5 and 8,5
C. Solubility	Freely soluble in water, insoluble in ethanol
Purity	
Selenium	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 515(ii) POTASSIUM HYDROGEN SULPHATE

Definition	
Synonyms	Potassium bisulphate, potassium acid sulphate
Chemical name	Potassium hydrogen sulphate
Chemical formula	$KHSO_4$
Molecular weight	136,17
Assay	Content not less than 99 %
Melting point	197 °C
Description	White deliquescent crystals, pieces or granules
Identification	
A. Positive test for potassium	
B. Solubility	Freely soluble in water, insoluble in ethanol
Purity	
Selenium	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 516 CALCIUM SULPHATE

Synonyms	Gypsum, selenite, anhydrite
Definition	
Chemical name	Calcium sulphate
Einecs	231-900-3
Chemical formula	$CaSO_4 \cdot nH_2O$ (n = 0 or 2)
Molecular weight	136,14 (anhydrous), 172,18 (dihydrate)
Assay	Content not less than 99,0 % on the anhydrous basis
Description	Fine, white to slightly yellowish-white odourless powder
Identification	
A. Positive tests for calcium and for sulphate	
B. Solubility	Slightly soluble in water, insoluble in ethanol
Purity	
Loss on drying	Anhydrous: not more than 1,5 % (250 °C, constant weight)
	Dihydrate: not more than 23 % (ibid.)
Fluoride	Not more than 30 mg/kg
Selenium	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 517 AMMONIUM SULPHATE

Definition	
Chemical name	Ammonium sulphate
Einecs	231-984-1
Chemical formula	$(NH_4)_2SO_4$
Molecular weight	132,14
Assay	Content not less than 99,0 % and not more than 100,5 %
Description	White powder, shining plates or crystalline fragments
Identification	
A. Positive tests for ammonium and for sulphate	
B. Solubility	Freely soluble in water, insoluble in ethanol
Purity	
Loss on ignition	Not more than 0,25 %
Selenium	Not more than 30 mg/kg
Lead	Not more than 5 mg/kg

▼B

E 520 ALUMINIUM SULPHATE

Synonyms	Alum
Definition	
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
Description	White powder, shining plates or crystalline fragments
Identification	
A. Positive tests for aluminium and for sulphate	
B. pH of a 5 % solution	2,9 or above
C. Solubility	Freely soluble in water, insoluble in ethanol
Purity	
Loss on ignition	Not more than 5 % (500 °C, 3h)
Alkalies and alkaline earths	Not more than 0,4 %
Selenium	Not more than 30 mg/kg
Fluoride	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg

E 521 ALUMINIUM SODIUM SULPHATE

Synonyms	Soda alum, sodium alum
Definition	
Chemical name	Aluminium sodium sulphate
Einecs	233-277-3
Chemical formula	$AlNa(SO_4)_2 \cdot nH_2O$ (n = 0 or 12)
Molecular weight	242,09 (anhydrous)
Assay	Content on the anhydrous basis not less than 96,5 % (anhydrous) and 99,5 % (dodecahydrate)
Description	Transparent crystals or white crystalline powder
Identification	
A. Positive tests for aluminium, for sodium and for sulphate	
B. Solubility	Dodecahydrate is freely soluble in water. The anhydrous form is slowly soluble in water. Both forms are insoluble in ethanol
Purity	
Loss on drying	Anhydrous form: not more than 10,0 % (220 °C, 16h)
	Dodecahydrate: not more than 47,2 % (50 °C-55 °C, 1h then 200 °C, 16h)

▼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 522 ALUMINIUM POTASSIUM SULPHATE

Synonyms	Potassium alum, potash alum
Definition	
Chemical name	Aluminium potassium sulphate dodecahydrate
Einecs	233-141-3
Chemical formula	$AlK(SO_4)_2 \cdot 12\ H_2O$
Molecular weight	474,38
Assay	Content not less than 99,5 %
Description	Large, transparent crystals or white crystalline powder
Identification	
A. Positive tests for aluminium, for potassium and for sulphate	
B. pH of a 10 % solution between 3,0 and 4,0	
C. Solubility	Freely soluble in water, insoluble in ethanol
Purity	
Ammonium salts	No odour of ammonia detectable after heating
Selenium	Not more than 30 mg/kg
Fluoride	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 523 ALUMINIUM AMMONIUM SULPHATE

Synonyms	Ammonium alum
Definition	
Chemical name	Aluminium ammonium sulphate
Einecs	232-055-3
Chemical formula	$AlNH_4(SO_4)_2 \cdot 12\ H_2O$
Molecular weight	453,32
Assay	Content not less than 99,5 %
Description	Large, colourless crystals or white powder

▼B

Identification	
A. Positive tests for aluminium, for ammonium and for sulphate	
B. Solubility	Freely soluble in water, soluble in ethanol
Purity	
Alkali metals and alkaline earths	Not more than 0,5 %
Selenium	Not more than 30 mg/kg
Fluoride	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 524 SODIUM HYDROXIDE

Synonyms	Caustic soda, lye
Definition	
Chemical name	Sodium hydroxide
Einecs	215-185-5
Chemical formula	NaOH
Molecular weight	40,0
Assay	Content of solid forms not less than 98,0 % of total alkali (as NaOH). Content of solutions accordingly, based on the stated or labelled percentage of NaOH
Description	White or nearly white pellets, flakes, sticks, fused masses or other forms. Solutions are clear or slightly turbid, colourless or slightly coloured, strongly caustic and hygroscopic and when exposed to the air they absorb carbon dioxide, forming sodium carbonate
Identification	
A. Positive tests for sodium	
B. A 1 % solution is strongly alkaline	
C. Solubility	Very soluble in water. Freely soluble in ethanol
Purity	
Water insoluble and organic matter	A 5 % solution is completely clear and colourless to slightly coloured
Carbonate	Not more than 0,5 % (as Na_2CO_3)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 0,5 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 525 POTASSIUM HYDROXIDE

Synonyms	Caustic potash
Definition	
Chemical name	Potassium hydroxide
Einecs	215-181-3
Chemical formula	KOH
Molecular weight	56,11
Assay	Content not less than 85,0 % of alkali calculated as KOH
Description	White or nearly white pellets, flakes, sticks, fused masses or other forms
Identification	
A. Positive tests for potassium	
B. A 1 % solution is strongly alkaline	
C. Solubility	Very soluble in water. Freely soluble in ethanol
Purity	
Water insoluble matter	A 5 % solution is completely clear and colourless
Carbonate	Not more than 3,5 % (as K_2CO_3)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg

▼M1

E 526 CALCIUM HYDROXIDE

Synonyms	Slaked lime, hydrated lime
Definition	
Chemical name	Calcium hydroxide
Einecs	215-137-3
Chemical formula	$Ca(OH)_2$
Molecular weight	74,09
Assay	Content not less than 92 %
Description	White powder
Identification	
A. Positive tests for alkali and for calcium	
B. Solubility	Slightly soluble in water. Insoluble in ethanol. Soluble in glycerol
Purity	
Acid insoluble ash	Not more than 1,0 %

▼M1

Magnesium and alkali salts	Not more than 2,7 %
Barium	Not more than 300 mg/kg
Fluoride	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 6 mg/kg

▼B

E 527 AMMONIUM HYDROXIDE

Synonyms	Aqua ammonia, strong ammonia solution
Definition	
Chemical name	Ammonium hydroxide
Chemical formula	NH_4OH
Molecular weight	35,05
Assay	Content not less than 27 % of NH_3
Description	Clear, colourless solution, having an exceedingly pungent, characteristic odour
Identification	
A. Positive tests for ammonia	
Purity	
Non-volatile matter	Not more than 0,02 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

E 528 MAGNESIUM HYDROXIDE

Definition	
Chemical name	Magnesium hydroxide
Einecs	215-170-3
Chemical formula	$Mg(OH)_2$
Molecular weight	58,32
Assay	Content not less than 95,0 % on the anhydrous basis
Description	Odourless, white bulky powder
Identification	
A. Positive test for magnesium and for alkali	
B. Solubility	Practically insoluble in water and in ethanol
Purity	
Loss on drying	Not more than 2,0 % (105 °C, 2h)
Loss on ignition	Not more than 33 % (800 °C to constant weight)

▼B

Calcium oxide	Not more than 1,5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg

▼M1

E 529 CALCIUM OXIDE

Synonyms	Burnt lime
Definition	
Chemical name	Calcium oxide
Einecs	215-138-9
Chemical formula	CaO
Molecular weight	56,08
Assay	Content not less than 95 % on the ignited basis
Description	Odourless, hard, white or greyish white masses of granules, or white to greyish powder
Identification	
A. Positive test for alkali and for calcium	
B. Heat is generated on moistening the sample in water	
C. Solubility	Slightly soluble in water. Insoluble in ethanol. Soluble in glycerol
Purity	
Loss on ignition	Not more than 10 % (ca. 800 °C to constant weight)
Acid insoluble matter	Not more than 1 %
Barium	Not more than 300 mg/kg
Magnesium and alkali salts	Not more than 3,6 %
Fluoride	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 7 mg/kg

▼B

E 530 MAGNESIUM OXIDE

Definition	
Chemical name	Magnesium oxide
Einecs	215-171-9
Chemical formula	MgO
Molecular weight	40,31

▼B

Assay	Content not less than 98,0 % on the ignited basis
Description	A very bulky, white powder known as light magnesium oxide or a relative dense, white powder known as heavy magnesium oxide. 5 g of light magnesium oxide occupy a volume of 40 to 50 ml, while 5 g of heavy magnesium oxide occupy a volume of 10 to 20 ml
Identification	
A. Positive test for alkali and for magnesium	
B. Solubility	Practically insoluble in water. Insoluble in ethanol
Purity	
Loss on ignition	Not more than 5,0 % (ca 800 ºC to constant weight)
Calcium oxide	Not more than 1,5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg

E 535 SODIUM FERROCYANIDE

Synonyms	Yellow prussiate of soda, sodium hexacyanoferrate
Definition	
Chemical name	Sodium ferrocyanide
Einecs	237-081-9
Chemical formula	$Na_4Fe(CN)_6 \cdot 10\ H_2O$
Molecular weight	484,1
Assay	Content not less than 99,0 %
Description	Yellow crystals or crystalline powder
Identification	
A. Positive test for sodium and for ferrocyanide	
Purity	
Free moisture	Not more than 1,0 %
Water insoluble matter	Not more than 0,03 %
Chloride	Not more than 0,2 %
Sulphate	Not more than 0,1 %
Free cyanide	Not detectable
Ferricyanide	Not detectable
Lead	Not more than 5 mg/kg

▼B

E 536 POTASSIUM FERROCYANIDE

Synonyms	Yellow prussiate of potash, potassium hexacyanoferrate
Definition	
Chemical name	Potassium ferrocyanide
Einecs	237-722-2
Chemical formula	$K_4Fe(CN)6 \cdot 3\ H_2O$
Molecular weight	422,4
Assay	Content not less than 99,0 %
Description	Lemon yellow crystals
Identification	
A. Positive test for potassium and for ferrocyanide	
Purity	
Free moisture	Not more than 1,0 %
Water insoluble matter	Not more than 0,03 %
Chloride	Not more than 0,2 %
Sulphate	Not more than 0,1 %
Free cyanide	Not detectable
Ferricyanide	Not detectable
Lead	Not more than 5 mg/kg

E 538 CALCIUM FERROCYANIDE

Synonyms	Yellow prussiate of lime, calcium hexacyanoferrate
Definition	
Chemical name	Calcium ferrocyanide
Einecs	215-476-7
Chemical formula	$Ca_2Fe(CN)_6 \cdot 12H_2O$
Molecular weight	508,3
Assay	Content not less than 99,0 %
Description	Yellow crystals or crystalline powder
Identification	
A. Positive test for calcium and for ferrocyanide	
Purity	
Free moisture	Not more than 1,0 %
Water insoluble matter	Not more than 0,03 %
Chloride	Not more than 0,2 %
Sulphate	Not more than 0,1 %

▼B

Free cyanide	Not detectable
Ferricyanide	Not detectable
Lead	Not more than 5 mg/kg

E 541 SODIUM ALUMINIUM PHOSPHATE, ACIDIC

Synonyms	SALP
Definition	
Chemical name	Sodium trialuminium tetradecahydrogen octaphosphate tetrahydrate (A) or Trisodium dialuminium pentadecahydrogen octaphosphate (B)
Einecs	232-090-4
Chemical formula	$NaAl_3H_{14}(PO_4)_8 \cdot 4H_2O$ (A) $Na_3Al_2H_{15}(PO_4)_8$ (B)
Molecular weight	949,88 (A) 897,82 (B)
Assay	Content not less than 95,0 % (both forms)
Description	White odourless powder
Identification	
A. Positive test for sodium, for aluminium and for phosphate	
B. pH	Acid to litmus
C. Solubility	Insoluble in water. Soluble in hydrochloric acid
Purity	
Loss on ignition	19,5 %-21,0 % (A) } (750 °C-800 °C, 2h) 15 %-16 % (B) } (750 °C-800 °C, 2h)
Fluoride	Not more than 25 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 4 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 551 SILICON DIOXIDE

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

▼B

Chemical name	Silicon dioxide
Einecs	231-545-4
Chemical formula	$(SiO_2)_n$
Molecular weight	60,08 (SiO_2)
Assay	Content after ignition not less than 99,0 % (fumed silica) or 94,0 % (hydrated forms)
Description	White, fluffy powder or granules
	Hygroscopic
Identification	
A. Positive test for silica	
Purity	
Loss on drying	Not more than 2,5 % (fumed silica, 105 °C, 2h)
	Not more than 8,0 % (precipitated silica and silica gel, 105 °C, 2h)
	Not more than 70 % (hydrous silica, 105 °C, 2h)
Loss on ignition	Not more than 2,5 % after drying (1 000 °C, fumed silica)
	Not more than 8,5 % after drying (1 000 °C, hydrated forms)
Soluble ionisable salts	Not more than 5,0 % (as Na_2SO_4)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 552 CALCIUM SILICATE

Definition	Calcium silicate is a hydrous or anhydrous silicate with varying proportions of CaO and SiO_2
Chemical name	Calcium silicate
Einecs	215-710-8
Assay	Content on the anhydrous basis:
	— as SiO_2 not less than 50 % and not more than 95 %
	— as CaO not less than 3 % and not more than 35 %
Description	White to off-white free-flowing powder that remains so after absorbing relatively large amounts of water or other liquids
Identification	
A. Positive test for silicate and for calcium	
B. Forms a gel with mineral acids	

▼B

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

E 553a(i) MAGNESIUM SILICATE

Definition	Magnesium silicate is a synthetic compound of which the molar ratio of magnesium oxide to silicon dioxide is approximately 2:5
Assay	Content not less than 15 % of MgO and not less than 67 % of SiO_2 on the ignited basis
Description	Very fine, white, odourless powder, free from grittiness
Identification	
A. Positive test for magnesium and for silicate	
B. pH of a 10 % slurry	Between 7,0 and 10,8
Purity	
Loss on drying	Not more than 15 % (105 °C, 2h)
Loss on ignition	Not more than 15 % after drying (1 000 °C, 20 min)
Water soluble salts	Not more than 3 %
Free alkali	Not more than 1 % (as NaOH)
Fluoride	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 553a(ii) MAGNESIUM TRISILICATE

Definition	
Chemical name	Magnesium trisilicate
Chemical formula	$Mg_2Si_3O_8 \cdot xH_2O$ (approximate composition)
Einecs	239-076-7
Assay	Content not less than 29,0 % of MgO and not less than 65,0 % of SiO_2 both on the ignited basis

▼B

Description	Fine, white powder, free from grittiness
Identification	
A. Positive test for magnesium and for silicate	
B. pH of a 5 % slurry	Between 6,3 and 9,5
Purity	
Loss on ignition	Not less than 17 % and not more than 34 % (1 000 °C)
Water soluble salts	Not more than 2 %
Free alkali	Not more than 1 % (as NaOH)
Fluoride	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 553b TALC

Synonyms	Talcum
Definition	Naturally occurring form of hydrous magnesium silicate containing varying proportions of such associated minerals as alpha-quartz, calcite, chlorite, dolomite, magnesite, and phlogopite
Chemical name	Magnesium hydrogen metasilicate
Einecs	238-877-9
Chemical formula	$Mg_3(Si_4O_{10})(OH)_2$
Molecular weight	379,22
Description	Light, homogeneous, white or almost white powder, greasy to the touch
Identification	
A. IR absorption	Characteristic peaks at 3 677, 1 018 and 669 cm^{-1}
B. X-ray diffraction	Peaks at 9,34/4,66/3,12 Å
C. Solubility	Insoluble in water and ethanol
Purity	
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

▼B

E 554 SODIUM ALUMINIUM SILICATE

Synonyms	Sodium silicoaluminate, sodium aluminosilicate, aluminium sodium silicate
Definition	
Chemical name	Sodium aluminium silicate
Assay	Content on the anhydrous basis: — as SiO_2 not less than 66,0 % and not more than 88,0 % — as Al_2O_3 not less than 5,0 % and not more than 15,0 %
Description	Fine white amorphous powder or beads
Identification	
A. Positive tests for sodium, for aluminium and for silicate	
B. pH of a 5 % slurry	Between 6,5 and 11,5
Purity	
Loss on drying	Not more than 8,0 % (105 ºC, 2h)
Loss on ignition	Not less than 5,0 % and not more than 11,0 % on the anhydrous basis (1 000 ºC, constant weight)
Sodium	Not less than 5 % and not more than 8,5 % (as Na_2O) on the anhydrous basis
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 555 POTASSIUM ALUMINIUM SILICATE

Synonyms	Mica
Definition	Natural mica consists of mainly potassium aluminium silicate (muscovite)
Einecs	310-127-6
Chemical name	Potassium aluminium silicate
Chemical formulae	$KAl_2[AlSi_3O_{10}](OH)_2$
Molecular weight	398
Assay	Content not less than 98 %
Description	Light grey to white crystalline platelets or powder
Identification	
A. Solubility	Insoluble in water, diluted acids and alkali and organic solvents
Purity	
Loss on drying	Not more than 0,5 % (105 ºC, 2h)
Antimony	Not more than 20 mg/kg
Zinc	Not more than 25 mg/kg

▼B

Barium	Not more than 25 mg/kg
Chromium	Not more than 100 mg/kg
Copper	Not more than 25 mg/kg
Nickel	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 2 mg/kg
Lead	Not more than 10 mg/kg

E 556 CALCIUM ALUMINIUM SILICATE

Synonyms	Calcium aluminosilicate, calcium silicoaluminate, aluminium calcium silicate
Definition	
Chemical name	Calcium aluminium silicate
Assay	Content on the anhydrous basis: — as SiO_2 not less than 44,0 % and not more than 50,0 % — as Al_2O_3 not less than 3,0 % and not more than 5,0 % — as CaO not less than 32,0 % and not more than 38,0 %
Description	Fine white, free-flowing powder
Identification	
A. Positive tests for calcium, for aluminium and for silicate	
Purity	
Loss on drying	Not more than 10,0 % (105 ºC, 2h)
Loss on ignition	Not less than 14,0 % and not more than 18,0 on the anhydrous basis (1 000 ºC, constant weight)
Fluoride	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg

E 558 BENTONITE

Definition	Bentonite is a natural clay containing a high proportion of montmorillonite, a native hydrated aluminium silicate in which some aluminium and silicon atoms were naturally replaced by other atoms such as magnesium and iron. Calcium and sodium ions are trapped between the mineral layers. There are four common types of bentonite: natural sodium bentonite, natural calcium bentonite, sodium-activated bentonite and acid-activated bentonite

▼B

Einecs	215-108-5
Chemical formula	$(Al, Mg)_8(Si_4O_{10})_4(OH)_8 \cdot 12H_2O$
Molecular weight	819
Assay	Montmorillonite content not less than 80 %
Description	Very fine, yellowish or greyish white powder or granules. The structure of bentonite allows it to absorb water in its structure and on its external surface (swelling properties)
Identification	
A. Methylene blue test	
B. X-Ray diffraction	Characteristic peaks at 12,5/15 A
C. IR absorption	Peaks at 428/470/530/1 110-1 020/3 750 — 3 400 cm^{-1}
Purity	
Loss on drying	Not more than 15,0 % (105 °C, 2h)
Arsenic	Not more than 2 mg/kg
Lead	Not more than 20 mg/kg

E 559 ALUMINIUM SILICATE (KAOLIN)

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

▼B

Purity	
Loss on ignition	Between 10 and 14 % (1 000 °C, constant weight)
Water soluble matter	Not more than 0,3 %
Acid soluble matter	Not more than 2 %
Iron	Not more than 5 %
Potassium oxide (K_2O)	Not more than 5 %
Carbon	Not more than 0,5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 570 FATTY ACIDS

Definition	Linear fatty acids, caprylic acid (C_8), capric acid (C_{10}), laurinc acid (C_{12}), myristic acid (C_{14}), palmitic acid (C_{16}), stearic acid (C_{18}), oleic acid ($C_{18:1}$)
Chemical name	octanoic acid (C_8), decanoic acid (C_{10}), dodecanoic acid (C_{12}), tetradecanoic acid (C_{14}), hexadecanoic acid (C_{16}), octadecanoic acid (C_{18}), 9-octadecenoic acid ($C_{18:1}$)
Assay	Not less than 98 % by chromatography
Description	A colourless liquid or white solid obtained from oils and fats
Identification	
A. Individual fatty acids can be identified by acid value, iodine value, gas chromatog-raphy and molecular weight	
Purity	
Residue on ignition	Not more than 0,1 %
Unsaponifiable matter	Not more than 1,5 %
Water	Not more than 0,2 % (Karl Fischer method)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 574 GLUCONIC ACID

Synonyms	D-gluconic acid, dextronic acid
Definition	Gluconic acid is an aqueous solution of gluconic acid and glucono-delta-lactone
Chemical name	Gluconic acid
Chemical formula	$C_6H_{12}O_7$ (gluconic acid)

▼B

Molecular weight	196,2
Assay	Content not less than 50,0 % (as gluconic acid)
Description	Colourless to light yellow, clear syrupy liquid
Identification	
A. Formation of phenylhydrazine derivative positive	Compound formed melts between 196 °C and 202 °C with decomposition
Purity	
Residue on ignition	Not more than 1,0 %
Reducing matter	Not more than 0,75 % (as D-glucose)
Chloride	Not more than 350 mg/kg
Sulphate	Not more than 240 mg/kg
Sulphite	Not more than 20 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 575 GLUCONO-DELTA-LACTONE

Synonyms	Gluconolactone, GDL, D-gluconic acid delta-lactone, delta-gluconolactone
Definition	Glucono-delta-lactone is the cyclic 1,5-intramolecular ester of D-gluconic acid. In aqueous media it is hydrolysed to an equilibrium mixture of D-gluconic acid (55 %-66 %) and the delta- and gamma-lactones
Chemical name	D-Glucono-1,5-lactone
Einecs	202-016-5
Chemical formula	$C_6H_{10}O_6$
Molecular weight	178,14
Assay	Content not less than 99,0 % on the anhydrous basis
Description	Fine, white, nearly odourless, crystalline powder
Identification	
A. Formation of phenylhydrazine derivative of gluconic acid positive	Compound formed melts between 196 °C and 202 °C with decomposition
B. Solubility	Freely soluble in water. Sparingly soluble in ethanol
C. Melting point	152 °C ± 2 °C
Purity	
Water	Not more than 1,0 % (Karl Fischer method)
Reducing substances	Not more than 0,75 % (as D-glucose)
Lead	Not more than 2 mg/kg

▼B

E 576 SODIUM GLUCONATE

Synonyms	Sodium salt of D-gluconic acid
Definition	
Chemical name	Sodium D-gluconate
Einecs	208-407-7
Chemical formula	$C_6H_{11}NaO_7$ (anhydrous)
Molecular weight	218,14
Assay	Content not less than 98,0 %
Description	White to tan, granular to fine, crystalline powder
Identification	
A. Positive test for sodium and for gluconate	
B. Solubility	Very soluble in water. Sparingly soluble in ethanol
C. pH of a 10 % solution	Between 6,5 and 7,5
Purity	
Reducing matter	Not more than 1,0 % (as D-glucose)
Lead	Not more than 2 mg/kg

E 577 POTASSIUM GLUCONATE

Synonyms	Potassium salt of D-gluconic acid
Definition	
Chemical name	Potassium D-gluconate
Einecs	206-074-2
Chemical formula	$C_6H_{11}KO_7$ (anhydrous)
	$C_6H_{11}KO_7 \cdot H_2O$ (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
Description	Odourless, free flowing white to yellowish white, crystalline powder or granules
Identification	
A. Positive test for potassium and for gluconate	
B. pH of a 10 % solution	Between 7,0 and 8,3
Purity	
Loss on drying	Anhydrous: not more than 3,0 % (105 °C, 4h, vacuum)
	Monohydrate: not less than 6 % and not more than 7,5 % (105 °C, 4h, vacuum)

▼B

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

E 578 CALCIUM GLUCONATE

Synonyms	Calcium salt of D-gluconic acid
Definition	
Chemical name	Calcium di-D-gluconate
Einecs	206-075-8
Chemical formula	$C_{12}H_{22}CaO_{14}$ (anhydrous)
	$C_{12}H_{22}CaO_{14} \cdot H_2O$ (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
Description	Odourless, white crystalline granules or powder, stable in air
Identification	
A. Positive test for calcium and for gluconate	
B. Solubility	Soluble in water, insoluble in ethanol
C. pH of a 5 % solution	Between 6,0 and 8,0
Purity	
Loss on drying	Not more than 3,0 % (105 °C, 16h) (anhydrous)
	Not more than 2,0 % (105 °C, 16h) (monohydrate)
Reducing substances	Not more than 1,0 % (as D-glucose)
Lead	Not more than 2 mg/kg

E 579 FERROUS GLUCONATE

Definition	
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
Description	Pale greenish-yellow to yellowish-grey powder or granules, which may have a faint odour of burnt sugar
Identification	
A. Solubility	Soluble with slight heating in water. Practically insoluble in ethanol

▼B

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

E 585 FERROUS LACTATE

Synonyms	Iron(II) lactate
	Iron(II) 2-hydroxy propanoate
	Propanoic acid, 2-hydroxy-iron(2 +) salt (2:1)
Definition	
Chemical name	Ferrous 2-hydroxy propanoate
Einecs	227-608-0
Chemical formulae	$C_6H_{10}FeO_6 \cdot xH_2O$ (x = 2 or 3)
Molecular weight	270,02 (dihydrate)
	288,03 (trihydrate)
Assay	Content not less than 96 % on the dried basis
Description	Greenish-white crystals or light green powder having a characteristic smell
Identification	
A. Solubility	Soluble in water. Practically insoluble in ethanol
B. Positive test for ferrous ion and for lactate	
C. pH of a 2 % solution	Between 4 and 6
Purity	
Loss on drying	Not more than 18 % (100 ºC, under vacuum, approximately 700 mm Hg)
Iron (Fe III)	Not more than 0,6 %

▼B

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 586 4-HEXYLRESORCINOL

Synonyms	4-Hexyl-1,3-benzenediol
	Hexylresorcinol
Definition	
Chemical name	4-Hexylresorcinol
Einecs	205-257-4
Chemical formula	$C_{12}H_{18}O_2$
Molecular weight	197,24
Assay	Not less than 98 % on the dried basis
Description	White powder
Identification	
A. Solubility	Freely soluble in ether and acetone; very slightly soluble in water
B. Nitric acid test	To 1 ml of a saturated solution of the sample, add 1 ml of nitric acid. A light red colour appears
C. Bromine test	To 1 ml of saturated solution of the sample, add 1 ml of bromine TS. A yellow, flocculent precipitate dissolves producing a yellow solution
D. Melting range	62 to 67 ºC
Purity	
Acidity	Not more than 0,05 %
Sulphated ash	Not more than 0,1 %
Resorcinol and other phenols	Shake about 1 g of the sample with 50 ml of water for a few minutes, filter, and to the filtrate add 3 drops of ferric chloride TS. No red or blue colour is produced
Nickel	Not more than 2 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 3 mg/kg

E 620 GLUTAMIC ACID

Synonyms	L-Glutamic acid, L-α-aminoglutaric acid
Definition	
Chemical name	L-Glutamic acid, L-2-amino-pentanedioic acid
Einecs	200-293-7

▼B

Chemical formula	$C_5H_9NO_4$
Molecular weight	147,13
Assay	Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis
Description	White crystals or crystalline powder
Identification	
A. Positive test for glutamic acid by thin layer chromatography	
B. Specific rotation $[\alpha]D^{20}$	Between + 31,5º and + 32,2º
	(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
C. pH of a saturated solution	Between 3,0 and 3,5
Purity	
Loss on drying	Not more than 0,2 % (80 ºC, 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

Synonyms	Sodium glutamate, MSG
Definition	
Chemical name	Monosodium L-glutamate monohydrate
Einecs	205-538-1
Chemical formula	$C_5H_8NaNO_4 \cdot H_2O$
Molecular weight	187,13
Assay	Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis
Description	White, practically odourless crystals or crystalline powder
Identification	
A. Positive test for sodium	
B. Positive test for glutamic acid by thin-layer chromatography	
C. Specific rotation $[\alpha]_D^{20}$	Between + 24,8º and + 25,3º
	(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
D. pH of a 5 % solution	Between 6,7 and 7,2
Purity	
Loss on drying	Not more than 0,5 % (98 ºC, 5h)

▼B

Chloride	Not more than 0,2 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Lead	Not more than 2 mg/kg

E 622 MONOPOTASSIUM GLUTAMATE

Synonyms	Potassium glutamate, MPG
Definition	
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
Description	White, practically odourless crystals or crystalline powder
Identification	
A. Positive test for potassium	
B. Positive test for glutamic acid by thin-layer chromatog-raphy	
C. Specific rotation $[\alpha]_D^{20}$	Between + 22,5° and + 24,0°
	(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
D. pH of a 2 % solution	Between 6,7 and 7,3
Purity	
Loss on drying	Not more than 0,2 % (80 °C, 5h)
Chloride	Not more than 0,2 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Lead	Not more than 2 mg/kg

E 623 CALCIUM DIGLUTAMATE

Synonyms	Calcium glutamate
Definition	
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	White, practically odourless crystals or crystalline powder
Identification	
A. Positive test for calcium	
B. Positive test for glutamic acid by thin-layer chromatog-raphy	
C. Specific rotation $[\alpha]_D^{20}$	Between + 27,4 and + 29,2 (for calcium diglutamate with x = 4) (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
Purity	
Water	Not more than 19,0 % (for calcium diglutamate with x = 4) (Karl Fischer)
Chloride	Not more than 0,2 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Lead	Not more than 2 mg/kg

E 624 MONOAMMONIUM GLUTAMATE

Synonyms	Ammonium glutamate
Definition	
Chemical name	Monoammonium L-glutamate monohydrate
Einecs	231-447-1
Chemical formula	$C_5H_{12}N_2O_4 \cdot H_2O$
Molecular weight	182,18
Assay	Content not less than 99,0 % and not more 101,0 % on the anhydrous basis
Description	White, practically odourless crystals or crystalline powder
Identification	
A. Positive test for ammonium	
B. Positive test for glutamic acid by thin-layer chromatog-raphy	
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
Purity	
Loss on drying	Not more than 0,5 % (50 °C, 4h)
Sulphated ash	Not more than 0,1 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Lead	Not more than 2 mg/kg

▼B

E 625 MAGNESIUM DIGLUTAMATE

Synonyms	Magnesium glutamate
Definition	
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
Description	Odourless, white or off-white crystals or powder
Identification	
A. Positive test for magnesium	
B. Positive test for glutamic acid by thin-layer chromatog-raphy	
C. Specific rotation $[\alpha]_D^{20}$	Between + 23,8º and + 24,4º
	(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
D. pH of a 10 % solution	Between 6,4 and 7,5
Purity	
Water	Not more than 24 % (Karl Fischer)
Chloride	Not more than 0,2 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Lead	Not more than 2 mg/kg

E 626 GUANYLIC ACID

Synonyms	Guanylic acid
Definition	
Chemical name	Guanosine-5'-monophosphoric acid
Einecs	201-598-8
Chemical formula	$C_{10}H_{14}N_5O_8P$
Molecular weight	363,22
Assay	Content not less than 97,0 % on the anhydrous basis
Description	Odourless, colourless or white crystals or white crys-talline powder
Identification	
A. Positive test for ribose and for organic phosphate	
B. pH of a 0,25 % solution	Between 1,5 and 2,5

▼B

C. Spectrometry:	maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm
Purity	
Loss on drying	Not more than 1,5 % (120 °C, 4h)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

E 627 DISODIUM GUANYLATE

Synonyms	Sodium guanylate, sodium 5'-guanylate
Definition	
Chemical name	Disodium guanosine-5'-monophosphate
Einecs	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
Description	Odourless, colourless or white crystals or white crystalline powder
Identification	
A. Positive test for ribose, for organic phosphate, and for sodium	
B. pH of a 5 % solution	Between 7,0 and 8,5
C. Spectrometry:	maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm
Purity	
Loss on drying	Not more than 25 % (120 °C, 4h)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

E 628 DIPOTASSIUM GUANYLATE

Synonyms	Potassium guanylate, potassium 5'-guanylate
Definition	
Chemical name	Dipotassium guanosine-5'-monophosphate
Einecs	226-914-1
Chemical formula	$C_{10}H_{12}K_2N_5O_8P$
Molecular weight	439,40
Assay	Content not less than 97,0 % on the anhydrous basis
Description	Odourless, colourless or white crystals or white crystalline powder

▼B

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

E 629 CALCIUM GUANYLATE

Synonyms	Calcium 5'-guanylate
Definition	
Chemical name	Calcium guanosine-5'-monophosphate
Chemical formula	$C_{10}H_{12}CaN_5O_8P \cdot nH_2O$
Molecular weight	401,20 (anhydrous)
Assay	Content not less than 97,0 % on the anhydrous basis
Description	Odourless, white or off-white crystals or powder
Identification	
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
Purity	
Loss on drying	Not more than 23,0 % (120 ºC, 4h)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

E 630 INOSINIC ACID

Synonyms	5'-Inosinic acid
Definition	
Chemical name	Inosine-5'-monophosphoric acid
Einecs	205-045-1
Chemical formula	$C_{10}H_{13}N_4O_8P$
Molecular weight	348,21

▼B

Assay	Content not less than 97,0 % on the anhydrous basis
Description	Odourless, colourless or white crystals or powder
Identification	
A. Positive test for ribose, and for organic phosphate	
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
Purity	
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

Synonyms	Sodium inosinate, sodium 5'-inosinate
Definition	
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
Description	Odourless, colourless or white crystals or powder
Identification	
A. Positive test for ribose, and for organic phosphate and for sodium	
B. pH of a 5 % solution	Between 7,0 and 8,5
C. Spectrometry:	maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm
Purity	
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

Synonyms	Potassium inosinate, potassium 5'-inosinate
Definition	
Chemical name	Dipotassium inosine-5'-monophosphate

▼B

Einecs	243-652-3
Chemical formula	$C_{10}H_{11}K_2N_4O_8P$
Molecular weight	424,39
Assay	Content not less than 97,0 % on the anhydrous basis
Description	Odourless, colourless or white crystals or powder
Identification	
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
Purity	
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

Synonyms	Calcium 5'-inosinate
Definition	
Chemical name	Calcium inosine-5'-monophosphate
Chemical formula	$C_{10}H_{11}CaN_4O_8P \cdot nH_2O$
Molecular weight	386,19 (anhydrous)
Assay	Content not less than 97,0 % on the anhydrous basis
Description	Odourless, colourless or white crystals or powder
Identification	
A. Positive test for ribose, and for organic phosphate and for calcium	
B. pH of a 0,05 % solution	Between 7,0 and 8,0
C. Spectrometry:	maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm
Purity	
Water	Not more than 23,0 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

▼B

E 634 CALCIUM 5'-RIBONUCLEOTIDE

Definition	
Chemical name	Calcium 5'-ribonucleotide is essentially a mixture of calcium inosine-5'-monophosphate and calcium guanosine-5'-monophosphate
Chemical formula	$C_{10}H_{11}N_4CaO_8P \cdot nH_2O$ y
	$C_{10}H_{12}N_5CaO_8P \cdot nH_2O$
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
Description	Odourless, white or nearly white crystals or powder
Identification	
A. Positive test for ribose, and for organic phosphate and for calcium	
B. pH of a 0,05 % solution	Between 7,0 and 8,0
Purity	
Water	Not more than 23,0 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

E 635 DISODIUM 5'-RIBONUCLEOTIDE

Synonyms	Sodium 5'-ribonucleotide
Definition	
Chemical name	Disodium 5'-ribonucleotide is essentially a mixture of disodium inosine-5'-monophosphate and disodium guanosine-5'-monophosphate
Chemical formula	$C_{10}H_{11}N_4Na_2O_8P \cdot nH_2O$ and
	$C_{10}H_{12}N_5Na_2O_8P \cdot nH_2O$
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
Description	Odourless, white or nearly white crystals or powder
Identification	
A. Positive test for ribose, and for organic phosphate and for sodium	
B. pH of a 5 % solution	Between 7,0 and 8,5
Purity	
Water	Not more than 26,0 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

▼B

E 640 GLYCINE AND ITS SODIUM SALT

Synonyms (gly)	Aminoacetic acid, glycocoll
(Na salt)	Sodium glycinate
Definition	
Chemical name (gly)	Aminoacetic acid
(Na salt)	Sodium glycinate
Chemical formula (gly)	$C_2H_5NO_2$
(Na salt)	$C_2H_5NO_2$ Na
Einecs (gly)	200-272-2
(Na salt)	227-842-3
Molecular weight (gly)	75,07
(Na salt)	98
Assay	Content not less than 98,5 % on the anhydrous basis
Description	White crystals or crystalline powder
Identification	
A. Positive test for amino acid (gly and Na salt)	
B. Positive test for sodium (Na salt)	
Purity	
Loss on drying (gly)	Not more than 0,2 % (105 °C, 3h)
(Na salt)	Not more than 0,2 % (105 °C, 3h)
Residue on ignition (gly)	Not more than 0,1 %
(Na salt)	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 650 ZINC ACETATE

Synonyms	Acetic acid, zinc salt, dihydrate
Definition	
Chemical name	Zinc acetate dihydrate
Chemical formula	$C_4H_6O_4$ Zn· $2H_2O$
Molecular weight	219,51
Assay	Content not less than 98 % and not more than 102 % of $C_4H_6O_4$ Zn · $2H_2O$

▼B

Description	Colourless crystals or fine, off-white powder
Identification	
A. Positive tests for acetate and for zinc	
B. pH of a 5 % solution	Between 6,0 and 8,0
Purity	
Insoluble matter	Not more than 0,005 %
Chlorides	Not more than 50 mg/kg
Sulphates	Not more than 100 mg/kg
Alkalines and alkaline earths	Not more than 0,2 %
Organic volatile impurities	Passes test
Iron	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 20 mg/kg
Cadmium	Not more than 5 mg/kg

E 900 DIMETHYL POLYSILOXANE

Synonyms	Polydimethyl siloxane, silicone fluid, silicone oil, dimethyl silicone
Definition	Dimethylpolysiloxane is a mixture of fully methylated linear siloxane polymers containing repeating units of the formula $(CH_3)_2$ SiO and stablised with trimethyl-siloxy end-blocking units of the formula $(CH_3)_3$ SiO
Chemical name	Siloxanes and silicones, di-methyl
Chemical formula	$(CH_3)_3$-Si-[O-Si$(CH_3)_2$]n-O-Si$(CH_3)_3$
Assay	Content of total silicon not less than 37,3 % and not more than 38,5 %
Description	Clear, colourless, viscous liquid
Identification	
A. Specific gravity (25º/25 ºC)	Between 0,964 and 0,977
B. Refractive index $[n]_D^{25}$	Between 1,400 and 1,405
C. Infrared spectrum characteristic of the compound	
Purity	
Loss on drying	Not more than 0,5 % (150 ºC, 4h)
Viscosity	Not less than $1{,}00 \cdot 10^{-4}$ m^2s^{-1} at 25 ºC
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

▼M1

E 901 BEESWAX

Synonyms	White wax, yellow wax
Definition	Yellow beeswax is the wax obtained by melting the walls of the honeycomb made by the honey bee, *Apis mellifera L.*, with hot water and removing foreign matter White beeswax is obtained by bleaching yellow beeswax
Einecs	232-383-7 (beeswax)
Description	Yellowish white (white form) or yellowish to greyish brown (yellow form) pieces or plates with a fine-grained and non-crystalline fracture, having an agreeable, honey-like odour
Identification	
A. Melting range	Between 62 °C and 65 °C
B. Specific gravity	About 0,96
C. Solubility	Insoluble in water Sparingly soluble in alcohol Very soluble in chloroform and ether
Purity	
Acid value	Not less than 17 and not more than 24
Saponification value	87-104
Peroxide value	Not more than 5
Glycerol and other polyols	Not more than 0,5 % (as glycerol)
Ceresin, paraffins and certain other waxes	Absent
Fats, Japan wax, rosin and soaps	Absent
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 902 CANDELILLA WAX

Definition	Candelilla wax is a purified wax obtained from the leaves of the candelilla plant, *Euphorbia antisyphilitica*
Einecs	232-347-0
Description	Hard, yellowish brown, opaque to translucent wax
Identification	
A. Specific gravity	About 0,983
B. Melting range	Between 68,5 °C and 72,5 °C

▼B

C. Solubility	Insoluble in water
	Soluble in chloroform and toluene
Purity	
Acid value	Not less than 12 and not more than 22
Saponification value	Not less than 43 and not more than 65
Glycerol and other polyols	Not more than 0,5 % (as glycerol)
Ceresin, paraffins and certain other waxes	Absent
Fats, Japan wax, rosin and soaps	Absent
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 903 CARNAUBA WAX

Definition	Carnauba wax is a purified wax obtained from the leaf buds and leaves of the Brazilian Mart wax palm, *Copernicia cerifera*
Einecs	232-399-4
Description	Light brown to pale yellow powder or flakes or hard and brittle solid with a resinous fracture
Identification	
A. Specific gravity	About 0,997
B. Melting range	Between 82 °C and 86 °C
C. Solubility	Insoluble in water
	Partly soluble in boiling ethanol
	Soluble in chloroform and diethyl ether
Purity	
Sulphated ash	Not more than 0,25 %
Acid value	Not less than 2 and not more than 7
Ester value	Not less than 71 and not more than 88
Unsaponifiable matter	Not less than 50 % and not more than 55 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 904 SHELLAC

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

▼B

Einecs	232-549-9
Description	Bleached shellac — off-white, amorphous, granular resin
	Wax-free bleached shellac — light yellow, amorphous, granular resin
Identification	
A. Solubility	Insoluble in water; freely (though very slowly) soluble in alcohol; slightly soluble in acetone
B. Acid value	Between 60 and 89
Purity	
Loss on drying	Not more than 6,0 % (40 ºC, 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

▼M1

E 905 MICROCRYSTALLINE WAX

Synonyms	Petroleum wax, hydrocarbon wax, Fischer-Tropsch wax, synthetic wax, synthetic paraffin
Definition	Refined mixtures of solid, saturated hydrocarbons, obtained from petroleum or synthetic feedstocks
Description	White to amber, odourless wax
Identification	
A. Solubility	Insoluble in water, very slightly soluble in ethanol
B. Refractive Index	n_D^{100} 1,434-1,448
	Alternative: n_D^{120} 1,426-1,440
Purity	
Molecular weight	Average not less than 500
Viscosity	Not less than $1,1 \times 10^{-5}$ m^2 s^{-1} at 100 °C
	Alternative: Not less than $0,8 \times 10^{-5}$ m^2 s^{-1} at 120 °C, if solid at 100 °C
Residue on ignition	Not more than 0,1 wt %
Carbon number at 5 % distillation point	Not more than 5 % of molecules with carbon number less than 25
Colour	Passes test
Sulphur	Not more than 0,4 wt %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 3 mg/kg

▼M1

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

Alternative, if solid at 100 °C

PAC method as per 21 CFR& 175.250;

Absorbency at 290 nm in decahydronaphthalene at 88 °C: Not exceeding 0,01

▼B

E 907 HYDROGENATED POLY-1-DECENE

Synonyms	Hydrogenated polydec-1-ene
	Hydrogenated poly-alpha-olefin
Definition	
Chemical formula	$C_{10n}H_{20n+2}$ where n = 3-6
Molecular weight	560 (average)
Assay	Not less than 98,5 % of hydrogenated poly-1-decene, having the following oligomer distribution:
	C_{30}: 13-37 %
	C_{40}: 35-70 %
	C_{50}: 9-25 %
	C_{60}: 1-7 %
Description	
Identification	
A. Solubility	Insoluble in water; slightly soluble in ethanol; soluble in toluene
B. Burning	Burns with a bright flame and a paraffin-like characteristic smell
Purity	
Viscosity	Between $5,7 \times 10^{-6}$ and $6,1 \times 10^{-6}$ m^2s^{-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

▼B

Nickel	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg

E 912 MONTAN ACID ESTERS

Definition	Montan acids and/or esters with ethylene glycol and/or 1,3-butanediol and/or glycerol
Chemical name	Montan acid esters
Description	Almost white to yellowish flakes, powder, granules or pellets
Identification	
A. Density (20 °C)	Between 0,98 and 1,05
B. Drop point	Greater than 77 °C
Purity	
Acid value	Not more than 40
Glycerol	Not more than 1 % (by gas chromatography)
Other polyols	Not more than 1 % (by gas chromatography)
Other wax types	Not detectable (by differential scanning calorimetry and/or infrared spectroscopy)
Arsenic	Not more than 2 mg/kg
Chromium	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg

E 914 OXIDISED POLYETHYLENE WAX

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

▼B

E 920 L-CYSTEINE

Definition	L-cysteine hydrochloride or hydrochloride monohydrate. Human hair may not be used as a source for this substance
Einecs	200-157-7 (anhydrous)
Chemical formula	$C_3H_7NO_2S \cdot HCl \cdot n\ H_20$ (where n = 0 or 1)
Molecular weight	157,62 (anhydrous)
Assay	Content not less than 98,0 % and not more than 101,5 % on the anhydrous basis
Description	White powder or colourless crystals
Identification	
A. Solubility	Freely soluble in water and in ethanol
B. Melting range	Anhydrous form melts at about 175 °C
C. Specific rotation	$[\alpha]^{20}_D$: between + 5,0° and + 8,0° or
	$[\alpha]^{25}_D$: between + 4,9° and 7,9°
Purity	
Loss on drying	Between 8,0 % and 12,0 %
	Not more than 2,0 % (anhydrous form)
Residue on ignition	Not more than 0,1 %
Ammonium-ion	Not more than 200 mg/kg
Arsenic	Not more than 1,5 mg/kg
Lead	Not more than 5 mg/kg

E 927b **CARBAMIDE**

Synonyms	Urea
Definition	
Einecs	200-315-5
Chemical formula	CH_4N_2O
Molecular weight	60,06
Assay	Content not less than 99,0 % on the anhydrous basis
Description	Colourless to white, prismatic, crystalline powder or small, white pellets
Identification	
A. Solubility	Very soluble in water
	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	
Loss on drying	Not more than 1,0 % (105 ºC, 1h)
Sulphated ash	Not more than 0,1 %
Ethanol-insoluble matter	Not more than 0,04 %
Alkalinity	Passes test
Ammonium-ion	Not more than 500 mg/kg
Biuret	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

E 938 ARGON

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

E 939 HELIUM

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

▼B

E 941 NITROGEN

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

E 942 NITROUS OXIDE

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

E 943a BUTANE

Synonyms	n-Butane
Definition	
Chemical name	Butane
Chemical formula	$CH_3CH_2CH_2CH_3$
Molecular weight	58,12
Assay	Content not less than 96 %

▼B

Description	Colourless gas or liquid with mild, characteristic odour
Identification	
A. Vapour pressure	108,935 kPa at 20 °C
Purity	
Methane	Not more than 0,15 % v/v
Ethane	Not more than 0,5 % v/v
Propane	Not more than 1,5 % v/v
Isobutane	Not more than 3,0 % v/v
1,3-butadiene	Not more than 0,1 % v/v
Moisture	Not more than 0,005 %

E 943b **ISOBUTANE**

Synonyms	2-methyl propane
Definition	
Chemical name	2-methyl propane
Chemical formula	$(CH_3)_2CH\ CH_3$
Molecular weight	58,12
Assay	Content not less than 94 %
Description	Colourless gas or liquid with mild, characteristic odour
Identification	
A. Vapour pressure	205,465 kPa at 20 °C
Purity	
Methane	Not more than 0,15 % v/v
Ethane	Not more than 0,5 % v/v
Propane	Not more than 2,0 % v/v
n-Butane	Not more than 4,0 % v/v
1,3-butadiene	Not more than 0,1 % v/v
Moisture	Not more than 0,005 %

E 944 PROPANE

Definition	
Chemical name	Propane
Chemical formula	$CH_3CH_2CH_3$
Molecular weight	44,09
Assay	Content not less than 95 %
Description	Colourless gas or liquid with mild, characteristic odour

▼B

Identification	
A. Vapour pressure	732,910 kPa at 20 ºC
Purity	
Methane	Not more than 0,15 % v/v
Ethane	Not more than 1,5 % v/v
Isobutane	Not more than 2,0 % v/v
n-Butane	Not more than 1,0 % v/v
1,3-butadiene	Not more than 0,1 % v/v
Moisture	Not more than 0,005 %

E 948 OXYGEN

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

E 949 HYDROGEN

Definition	
Chemical name	Hydrogen
Einecs	215-605-7
Chemical formula	H_2
Molecular weight	2
Assay	Content not less than 99,9 %
Description	Colourless, odourless, highly flammable gas
Purity	
Water	Not more than 0,005 % v/v
Oxygen	Not more than 0,001 % v/v

▼M2

Nitrogen	Not more than 0,07 % v/v

▼B

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

Synonyms	Soapbark extract, Quillay bark extract, Panama bark extract, Quillai extract, Murillo bark extract, China bark extract
Definition	Quillaia extract is obtained by aqueous extraction of *Quillaia saponaria* Molina, or other *Quillaia* species, trees of the family *Rosaceae*. It contains a number of triterpenoid saponins consisting of glycosides of quillaic acid. Some sugars including glucose, galactose, arabinose, xylose, and rhamnose are also present, along with tannin, calcium oxalate and other minor components
Description	Quillaia extract in the powder form is light brown with a pink tinge. It is also available as an aqueous solution

▼B

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

E 1103 INVERTASE

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

E 1105 LYSOZYME

Synonyms	Lysozyme hydrochloride
	Muramidase
Definition	Lysozyme is a linear polypeptide obtained from hens' egg whites consisting of 129 amino acids. It possesses enzymatic activity in its ability to hydrolyse the β(1-4) linkages between N-acetylmuramic acid and N-acetylglucosamine in the outer membranes of bacterial species, in particular gram-positive organisms. Is usually obtained as the hydrochloride
Chemical name	Enzyme Commission (EC) No: 3.2.1.17
Einecs	232-620-4
Molecular weight	About 14 000
Assay	Content not less than 950 mg/g on the anhydrous basis
Description	White, odourless powder having a slightly sweet taste
Identification	
A. Isoelectric point 10,7	

▼B

B. pH of a 2 % aqueous solution between 3,0 and 3,6	
C. Absorption maximum of an aqueous solution (25 mg/100 ml) at 281 nm, a minimum at 252 nm	
Purity	
Water content	Not more than 6,0 % (Karl Fischer method) (powder form only)
Residue on ignition	Not more than 1,5 %
Nitrogen	Not less than 16,8 % and not more than 17,8 %
Arsenic	Not more than 1 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Microbiological criteria	
Total bacterial count	Not more than 5×10^4 col/g
Salmonellae	Absent in 25 g
Staphylococcus aureus	Absent in 1 g
Escherichia coli	Absent in 1 g

E 1200 POLYDEXTROSE

Synonyms	Modified polydextroses
Definition	Randomly bonded glucose polymers with some sorbitol end-groups, and with citric acid or phosphoric acid residues attached to the polymers by mono or diester bonds. They are obtained by melting and condensation of the ingredients and consist of approximately 90 parts D-glucose, 10 parts sorbitol and 1 part citric acid or 0,1 part phosphoric acid. The 1,6-glucosidic linkage predominates in the polymers but other linkages are present. The products contain small quantities of free glucose, sorbitol, levoglucosan (1,6-anhydro-D-glucose) and citric acid and may be neutralised with any food grade base and/or decolorised and deionised for further purification. The products may also be partially hydrogenated with Raney nickel catalyst to reduce residual glucose. Polydextrose-N is neutralised polydextrose
Assay	Content not less than 90 % of polymer on the ash free and anhydrous basis
Description	White to light tan-coloured solid. Polydextroses dissolve in water to give a clear, colourless to straw coloured solution

▼B

Identification	
A. Positive tests for sugar and for reducing sugar	
B. pH of a 10 % solution	Between 2,5 and 7,0 for polydextrose
	Between 5,0 and 6,0 for polydextrose-N
Purity	
Water	Not more than 4,0 % (Karl Fischer method)
Sulphated ash	Not more than 0,3 % (polydextrose)
	Not more than 2,0 % (polydextrose N)
Nickel	Not more than 2 mg/kg for hydrogenated polydextroses
1,6-Anhydro-D-glucose	Not more than 4,0 % on the ash-free and the dried basis
Glucose and sorbitol	Not more than 6,0 % combined on the ash-free and the dried basis; glucose and sorbitol are determined separately
Molecular weight limit	Negative test for polymers of molecular weight greater than 22 000
5-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 POLYVINYLPYRROLIDONE

Synonyms	Povidone
	PVP
	Soluble polyvinylpyrrolidone
Definition	
Chemical name	Polyvinylpyrrolidone, poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene]
Chemical formula	$(C_6H_9NO)_n$
Molecular weight	Not less than 25 000
Assay	Content not less than 11,5 % and not more than 12,8 % of nitrogen (N) on the anhydrous basis
Description	White or nearly white powder
Identification	
A. Solubility	Soluble in water and in ethanol. Insoluble in ether
B. pH of a 5 % solution	Between 3,0 and 7,0
Purity	
Water	Not more than 5 % (Karl Fischer)
Total ash	Not more than 0,1 %

▼B

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

▼M2

E 1203 POLYVINYL ALCOHOL

Synonyms	Vinyl alcohol polymer, PVOH
Definition	Polyvinyl alcohol is a synthetic resin prepared by the polymerisation of vinyl acetate, followed by partial hydrolysis of the ester in the presence of an alkaline catalyst. The physical characteristics of the product depend on the degree of polymerisation and the degree of hydrolysis
Chemical name	Ethenol homopolymer
Chemical formula	$(C_2H_3OR)_n$ where R = H or $COCH_3$
Description	Odourless, tasteless, translucent, white or cream-coloured granular powder
Identification	
Solubility	Soluble in water; sparingly soluble in ethanol
Precipitation reaction	Dissolve 0,25 g of the sample in 5 ml of water with warming and let the solution cool to room temperature. The addition of 10 ml of ethanol to this solution leads to a white, turbid or flocculent precipitate
Colour reaction	Dissolve 0,01 g of the sample in 100 ml of water with warming and let the solution cool to room temperature. A blue colour is produced when adding (to 5 ml solution) one drop of iodine test solution (TS) and a few drops of boric acid solution Dissolve 0,5 g of the sample in 10 ml of water with warming and let the solution cool to room temperature. A dark red to blue colour is produced after adding one drop of iodine TS to 5 ml of solution
Viscosity	4,8 to 5,8 mPa.s (4 % solution at 20 °C) corresponding to an average molecular weight of 26 000-30 000 D
Purity	
Water insoluble matter	Not more than 0,1 %
Ester value	Between 125 and 153 mg KOH/g
Degree of hydrolysis	86,5 to 89,0 %
Acid value	Not more than 3,0
Solvent residues	Not more than 1,0 % Methanol, 1,0 % Methyl acetate
pH	5,0 to 6,5 (4 % solution)

▼M2

Loss on drying	Not more than 5,0 % (105 °C, 3 H)
Residue in ignition	Not more than 1,0 %
Lead	Not more than 2,0 mg/kg

▼B

E 1202 POLYVINYLPOLYPYRROLIDONE

Synonyms	Crospovidone
	Cross linked polyvidone
	Insoluble polyvinylpyrrolidone
Definition	Polyvinylpolypyrrolidone is a poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene], cross linked in a random fashion. It is produced by the polymerisation of N-vinyl-2-pyrrolidone in the presence of either caustic catalyst or N, N'-divinyl-imidazolidone. Due to its insolubility in all common solvents the molecular weight range is not amenable to analytical determination
Chemical name	Polyvinylpyrrolidone, poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene]
Chemical formula	$(C_6H_9NO)_n$
Assay	Content not less than 11 % and not more than 12,8 % nitrogen (N) on the anhydrous basis
Description	A white hygroscopic powder with a faint, non-objectionable odour
Identification	
A. Solubility	Insoluble in water, ethanol and ether
B. pH of a 1 % suspension in water	Between 5,0 and 8,0
Purity	
Water	Not more than 6 % (Karl Fischer)
Sulphated ash	Not more than 0,4 %
Water-soluble matter	Not more than 1 %
Free-N-vinylpyrrolidone	Not more than 10 mg/kg
Free-N, N'-divinyl-imidazolidone	Not more than 2 mg/kg
Lead	Not more than 5 mg/kg

E 1204 PULLULAN

Definition	Linear, neutral glucan consisting mainly of maltotriose units connected by - 1,6 glycosidic bonds. It is produced by fermentation from a food-grade hydrolysed starch using a non-toxin-producing strain of *Aureobasidium pullulans*. After completion of the fermentation, the fungal cells are removed by microfiltration, the filtrate is heat-sterilised and pigments and other impurities are removed by adsorption and ion exchange chromatography

▼B

Einecs	232-945-1
Chemical formula	$(C_6H_{10}O_5)_x$
Assay	Not less than 90 % of glucan on the dried basis
Description	White to off-white odourless powder
Identification	
A. Solubility	Soluble in water, practically insoluble in ethanol
B. pH of 10 % solution	5,0 to 7,0
C. Precipitation with poly-ethylene 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 pull-ulanase	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
Purity	
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^2/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

Definition	Oxidised starch is starch treated with sodium hypochlorite
Description	White or nearly white powder or granules or (if prege-latinised) flakes, amorphous powder or coarse particles
Identification	
A. If not pregelatinised: by microscopic observation	
B. Iodine staining positive (dark blue to light red colour)	
Purity (all values expressed on an anhydrous basis except for loss on drying)	

▼B

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

E 1410 MONOSTARCH PHOSPHATE

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

▼B

E 1412 DISTARCH PHOSPHATE

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

E 1413 PHOSPHATED DISTARCH PHOSPHATE

Definition	Phosphated distarch phosphate is starch having undergone a combination of treatments as described for monostarch phosphate and for distarch phosphate
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification	
A. If not pregelatinised: by microscopic observation	
B. Iodine staining positive (dark blue to light red colour)	
Purity (all values expressed on an anhydrous basis except for loss on drying)	

▼B

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

E 1414 ACETYLATED DISTARCH PHOSPHATE

Definition	Acetylated distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride and esterified by acetic anhydride or vinyl acetate
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification	
A. If not pregelatinised: by microscopic observation	
B. Iodine staining positive (dark blue to light red colour)	
Purity (all values expressed on an anhydrous basis except for loss on drying)	
Loss on drying	Not more than 15,0 % for cereal starch
	Not more than 21,0 % for potato starch
	Not more than 18,0 % for other starches
Acetyl groups	Not more than 2,5 %
Residual phosphate	Not more than 0,14 % (as P) for wheat or potato starch
	Not more than 0,04 % (as P) for other starches
Vinyl acetate	Not more than 0,1 mg/kg

▼B

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

E 1420 ACETYLATED STARCH

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

E 1422 ACETYLATED DISTARCH ADIPATE

Definition	Acetylated distarch adipate is starch cross-linked with adipic anhydride and esterified with acetic anhydride
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

▼B

Identification	
A. If not pregelatinised: by microscopic observation	
B. Iodine staining positive (dark blue to light red colour)	
Purity (all values expressed on an anhydrous basis except for loss on drying)	
Loss on drying	Not more than 15,0 % for cereal starch
	Not more than 21,0 % for potato starch
	Not more than 18,0 % for other starches
Acetyl groups	Not more than 2,5 %
Adipate groups	Not more than 0,135 %
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches
	Not more than 10 mg/kg for other modified starches, unless otherwise specified
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 0,1 mg/kg

E 1440 HYDROXYPROPYL STARCH

Definition	Hydroxypropyl starch is starch etherified with propylene oxide
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification	
A. If not pregelatinised: by microscopic observation	
B. Iodine staining positive (dark blue to light red colour)	
Purity (all values expressed on an anhydrous basis except for loss on drying)	
Loss on drying	Not more than 15,0 % for cereal starch
	Not more than 21,0 % for potato starch
	Not more than 18,0 % for other starches
Hydroxypropyl groups	Not more than 7,0 %
Propylene chlorohydrin	Not more than 1 mg/kg

▼B

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

E 1442 HYDROXYPROPYL DISTARCH PHOSPHATE

Definition	Hydroxypropyl distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride and etherified with propylene oxide
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification	
A. If not pregelatinised: by microscopic observation	
B. Iodine staining positive (dark blue to light red colour)	
Purity (all values expressed on an anhydrous basis except for loss on drying)	
Loss on drying	Not more than 15,0 % for cereal starch Not more than 21,0 % for potato starch Not more than 18,0 % for other starches
Hydroxypropyl groups	Not more than 7,0 %
Residual phosphate	Not more than 0,14 % (as P) for wheat or potato starch Not more than 0,04 (as P) for other starches
Propylene chlorohydrin	Not more than 1 mg/kg
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches Not more than 10 mg/kg for other modified starches, unless otherwise specified
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 0,1 mg/kg

▼B

E 1450 STARCH SODIUM OCTENYL SUCCINATE

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

E 1451 ACETYLATED OXIDISED STARCH

Definition	Acetylated oxidised starch is starch treated with sodium hypochlorite followed by esterification with acetic anhydride
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification	
A. If not pregelatinised: by microscopic observation	
B. Iodine staining positive (dark blue to light red colour)	
Purity (all values expressed on an anhydrous basis except for loss on drying)	

▼B

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

Synonyms	SAOS
Definition	Starch aluminium octenyl succinate is starch esterified with octenylsuccinic anhydride and treated with aluminium sulphate
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification	
A. If not pregelatinised: by microscopic observation	
B. Iodine staining positive (dark blue to light red colour)	
Purity (all values expressed on an anhydrous basis except for loss on drying)	
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 %

▼B

E 1505 TRIETHYL CITRATE

Synonyms	Ethyl citrate
Definition	
Chemical name	Triethyl-2-hydroxypropan-1,2,3-tricarboxylate
Einecs	201-070-7
Chemical formula	$C_{12}H_{20}O_7$
Molecular weight	276,29
Assay	Content not less than 99,0 %
Description	Odourless, practically colourless, oily liquid
Identification	
A. Specific gravity	d_{25}^{25}: 1,135-1,139
B. Refractive index	$[n]_D^{20}$: 1,439-1,441
Purity	
Water	Not more than 0,25 % (Karl Fischer method)
Acidity	Not more than 0,02 % (as citric acid)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

E 1517 GLYCERYL DIACETATE

Synonyms	Diacetin
Definition	Glyceryl diacetate consist predominantly of a mixture of the 1,2- and 1,3-diacetates of glycerol, with minor amounts of the mono- and tri-esters
Chemical names	Glyceryl diacetate
	1, 2, 3-propanetriol diacetate
Chemical formula	$C_7H_{12}O_5$
Molecular weight	176,17
Assay	Not less than 94,0 %
Description	Clear, colourless, hygroscopic, somewhat oily liquid with a slight, fatty odour
Identification	
A. Solubility	Soluble in water. Miscible with ethanol
B. Positive tests for glycerol and acetate	
C. Specific gravity	d_{20}^{20}: 1,175-1,195
D. Boiling range	Between 259 and 261 °C
Purity	
Total ash	Not more than 0,02 %
Acidity	Not more than 0,4 % (as ascetic acid)

▼B

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

E 1518 GLYCERYL TRIACETATE

Synonyms	Triacetin
Definition	
Chemical name	Glyceryl triacetate
Einecs	203-051-9
Chemical formula	$C_9H_{14}O_6$
Molecular weight	218,21
Assay	Content not less than 98,0 %
Description	Colourless, somewhat oily liquid having a slightly fatty odour
Identification	
A. Positive tests for acetate and for glycerol	
B. Refractive index	Between 1,429 and 1,431 at 25 °C
C. Specific gravity (25 °C/25 °C)	Between 1,154 and 1,158
D. Boiling range	Between 258 and 270 °C
Purity	
Water	Not more than 0,2 % (Karl Fischer method)
Sulphated ash	Not more than 0,02 % (as citric acid)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

E 1519 BENZYL ALCOHOL

Synonyms	Phenylcarbinol
	Phenylmethyl alcohol
	Benzenemethanol
	Alpha-hydroxytoluene
Definition	
Chemical names	Benzyl alcohol
	Phenylmethanol
Chemical formula	C_7H_8O
Molecular weight	108,14
Assay	Not less than 98,0 %
Description	Colourless, clear liquid with a faint, aromatic odour

▼B

Identification	
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	
Purity	
Distillation range	Not less than 95 % v/v distils between 202 and 208 ºC
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

Synonyms	Propylene glycol
Definition	
Chemical names	1,2-dihydroxypropane
Einecs	200-338-0
Chemical formula	$C_3H_8O_2$
Molecular weight	76,10
Assay	Content not less than 99,5 % on the anhydrous basis
Description	Clear, colourless, hygroscopic, viscous liquid
Identification	
A. Solubility	Soluble in water, ethanol and acetone
B. Specific gravity	d_{20}^{20}: 1,035-1,040
C. Refractive index	$[n]^{20}_D$: 1,431-1,433
Purity	
Distillation range	99 % v/v distils between 185 ºC-189 ºC
Sulphated ash	Not more than 0,07 %
Water	Not more than 1,0 % (Karl Fischer method)
Lead	Not more than 5 mg/kg

▼M2

E 1521 POLYETHYLENE GLYCOLS

Synonyms	PEG, Macrogol, Polyethylene oxide
Definition	Addition polymers of ethylene oxide and water usually designated by a number roughly corresponding to the molecular weight
Chemical name	alpha-Hydro-omega-hydroxypoly (oxy-1,2-ethanediol)
Chemical formula	$HOCH_2 - (CH_2 - O - CH_2)_n - CH_2OH$

▼M2

Average molecular weight	380 to 9 000 D
Assay	PEG 400: Not less than 95 % and not more than 105 % PEG 3000: Not less than 90 % and not more than 110 % PEG 3350: Not less than 90 % and not more than 110 % PEG 4000: Not less than 90 % and not more than 110 % PEG 6000: Not less than 90 % and not more than 110 % PEG 8000: Not less than 87,5 % and not more than 112,5 %
Description	PEG 400 is a clear, viscous, colourless or almost colourless hygroscopic liquid PEG 3000, PEG 3350, PEG 4000, PEG 6000 and PEG 8000 are white or almost white solids with a waxy or paraffin-like appearance
Identification	
Melting point	PEG 400: 4-8 °C PEG 3000: 50-56 °C PEG 3350: 53-57 °C PEG 4000: 53-59 °C PEG 6000: 55-61 °C PEG 8000: 55-62 °C
Viscosity	PEG 400: 105 to 130 mPa.s at 20 °C PEG 3000: 75 to 100 mPa.s at 20 °C PEG 3350: 83 to 120 mPa.s at 20 °C PEG 4000: 110 to 170 mPa.s at 20 °C PEG 6000: 200 to 270 mPa.s at 20 °C PEG 8000: 260 to 510 mPa.s at 20 °C For polyethylene glycols having a average molecular weight greater than 400, the viscosity is determined on a 50 per cent m/m solution of the candidate substance in water
Solubility	PEG 400 is miscible with water, very soluble in acetone, in alcohol and in methylene chloride, practically insoluble in fatty oils and in mineral oils PEG 3000 and PEG 3350: very soluble in water and in methylene chloride, very slightly soluble in alcohol, practically insoluble in fatty oils and in mineral oils PEG 4000, PEG 6000 and PEG 8000: very soluble in water and in methylene chloride, practically insoluble in alcohol and in fatty oils and in mineral oils
Purity	
Acidity or alkalinity	Dissolve 5,0 g in 50 ml of carbon dioxide-free water and add 0,15 ml of bromothymol blue solution . The solution is yellow or green. Not more than 0,1 ml of 0,1 M sodium hydroxide is required to change the colour of the indicator to blue

▼**M2**

Hydroxyl value	PEG 400: 264-300 PEG 3000: 34-42 PEG 3350: 30-38 PEG 4000: 25-32 PEG 6000: 16-22 PEG 8000: 12-16
Sulphated ash	Not more than 0,2 %
1,4-Dioxane	Not more than 10 mg/kg
Ethylene oxide	Not more than 0,2 mg/kg
Ethylene glycol and diethylene glycol	Total not more than 0,25 % w/w individually or in combination
Lead	Not more than 1 mg/kg

▼B

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	(OJ L 113, 20.4.2004, p. 19)
Commission Directive 2006/129/EC	(OJ L 346, 9.12.2006, p. 15)

PART B

List of time-limits for transposition into national law

(referred to in Article 2)

Directive	Time-limit for transposition
96/77/EC	1 July 1997 ([1])
98/86/EC	1 July 1999 ([2])
2000/63/EC	31 March 2001 ([3])
2001/30/EC	1 June 2002 ([4])
2002/82/EC	31 August 2003
2003/95/EC	1 November 2004 ([5])
2004/45/EC	1 April 2005 ([6])
2006/129/EC	15 February 2008

([1]) 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.

([2]) 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.

([3]) 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.

([4]) 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.

([5]) 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.

([6]) 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.

▼B

ANNEX III

Correlation table

Directive 96/77/EC	This Directive
Article 1	Article 1
Article 2	—
Article 3	—
—	Article 2
Article 4	Article 3
Article 5	Article 4
Annex	Annex I
—	Annex II
—	Annex III