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(Acts whose publication is obligatory)

COMMISSION DIRECTIVE 96/77/EC

of 2 December 1996

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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

After consulting the Scientific Committee for Food,

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

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

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

Whereas Directives 65/66/EEC and 78/664/EEC should be repealed accordingly;

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

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

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

Article 2

Directives 65/66/EEC and 78/664/EEC are hereby repealed.

(1) OJ No L 40, 11. 2. 1989, p. 27.
(2) OJ No L 237, 10. 9. 1994, p. 1.
(3) OJ No L 61, 18. 3. 1995, p. 1.
(4) OJ No 22, 9. 2. 1965, p. 373.
(5) OJ No L 352, 13. 12. 1986, p. 45.
(6) OJ No L 223, 14. 8. 1978, p. 30.
(7) OJ No L 297, 23. 10. 1982, p. 31.

Article 3

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

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

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

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 2 December 1996.

For the Commission

Martin BANGEMANN

Member of the Commission

ANNEX

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
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 re-crystallized 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 re-crystallized 133 °C to 135 °C after vacuum drying in a sulphuric acid desiccator	
B. Positive tests for calcium and for double bonds	
Purity	
Loss on drying	Not more than 2,0 %, determined by vacuum drying for four hours in a sulphuric acid desiccator
Aldehydes	Not more than 0,1 % (as formaldehyde)
Fluoride	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 210 BENZOIC ACID

Definition	
Chemical name	Benzoic acid 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
Readily oxidizable substances	Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N $KMnO_4$ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N $KMnO_4$ to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required
Readily carbonizable substances	A cold solution of 0,5 g of benzoic acid in 5 ml of 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC([1]), 0,3 ml of ferric chloride TSC([2]), 0,1 ml of copper sulphate TSC([3]) and 4,4 ml of water
Polycyclic acids	On fractional acidification of a neutralized solution of benzoic acid, the first precipitate must not have a different melting point from that of the benzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

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

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

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

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

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	$C_7H_5O_2Na$
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 recrystallized 121,5 °C to 123,5 °C, after drying in a sulphuric acid desiccator
C. Positive tests for benzoate and for sodium	
Purity	
Loss on drying	Not more than 1,5 % after drying at 105 °C for four hours
Readily oxidizable substances	Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N $KMnO_4$ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N $KMnO_4$ to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required
Polycyclic acids	On fractional acidification of a (neutralized) solution of sodium benzoate, the first precipitate must not have a different melting range from that of benzoic acid
Chlorinated organic compounds	Not more than 0,06 % expressed as chloride, corresponding to 0,25 % expressed as monochlorobenzoic acid
Degree of acidity or alkalinity	Neutralization of 1 g of sodium benzoate, in the presence of phenolphthalein, must not require more than 0,25 ml of 0,1 N NaOH or 0,1 N HCl
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 212 POTASSIUM BENZOATE

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

Molecular weight	214,27
Assay	Content not less than 99 % $C_7H_5O_2K$ after drying at 105 °C to constant weight
Description	White crystalline powder
Identification	
A. Melting range of benzoic acid isolated by acidification and not recrystallized 121,5 °C to 123,5 °C, after vacuum drying in a sulphuric acid desiccator	
B. Positive tests for benzoate and for potassium	
Purity	
Loss on drying	Not more than 26,5 %, determined by drying at 105 °C
Chlorinated organic compounds	Not more than 0,06 % expressed as chloride, corresponding to 0,25 % expressed as monochlorobenzoic acid
Readily oxidizable substances	Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N $KMnO_4$ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N $KMnO_4$ to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required
Readily carbonizable substances	A cold solution of 0,5 g of benzoic acid in 5 ml 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC, 0,3 ml of ferric chloride TSC, 0,1 ml of copper sulphate TSC and 4,4 ml of water
Polycyclic acids	On fractional acidification of a (neutralized) solution of potassium benzoate, the first precipitate must not have a different melting range from that of benzoic acid
Degree of acidity or alkalinity	Neutralization of 1 g of potassium benzoate, in the presence of phenolphthalein, must not require more than 0,25 ml of 0,1 N NaOH or 0,1 N HCl
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

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 recrystallized 121,5 °C to 123,5 °C, after vacuum drying in a sulphuric acid desiccator	
B. Positive tests for benzoate and for calcium	
Purity	
Loss on drying	Not more than 17,5 % determined by drying at 105 °C to constant weight
Water insoluble matter	Not more than 0,3 %
Chlorinated organic compounds	Not more than 0,06 % expressed as chloride, corresponding to 0,25 % expressed as monochlorobenzoic acids
Readily oxidizable substances	Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N $KMnO_4$ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N $KMnO_4$ to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required
Readily carbonizable substances	Cold solution of 0,5 g of benzoic acid in 5 ml of 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC, 0,3 ml of ferric chloride TSC, 0,1 ml of copper sulphate TSC and 4,4 ml of water
Polycyclic acids	On fractional acidification of a (neutralized) solution of calcium benzoate, the first precipitate must not be a different melting range from that of benzoic acid
Degree of acidity or alkalinity	Neutralization of 1 g of calcium benzoate, in the presence of phenolphthalein, must not require more than 0,25 ml of 0,1 N NaOH or 0,1 N HCl
Fluoride	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
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 recrystallized: 213 °C to 217 °C, after vacuum drying in a sulphuric acid desiccator
C. Positive test for alcohol	
Purity	
Loss on drying	Not more than 0,5 % after drying for two hours at 80 °C
Sulphated ash	Not more than 0,05 %
p-Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as *p*-hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

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
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 216 PROPYL *p*-HYDROXYBENZOATE

Synonyms	Propylparaben Propyl *p*-oxybenzoate
Definition	
Chemical name	Propyl *p*-hydroxybenzoate n-Propyl *p*-hydroxybenzoic acid
Einecs	202-307-7
Chemical formula	$C_{10}H_{12}O_3$
Molecular weight	180,21
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	95 °C to 97 °C after drying for two hours at 80 °C
B. Positive test for *p*-hydroxybenzoate	Melting range of *p*-hydroxybenzoic acid derived from the sample is 213 °C to 217 °C
Purity	
Loss on drying	Not more than 0,5 % after drying for two hours at 80 °C
Sulphated ash	Not more than 0,05 %
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 217 SODIUM PROPYL *p*-HYDROXYBENZOATE

Definition	
Chemical name	Sodium n-propyl *p*-hydroxybenzoate Sodium compound of the n-propylester of *p*-hydroxybenzoic acid
Einecs	252-488-1
Chemical formula	$C_{10}H_{11}O_3Na$
Molecular weight	202,21
Assay	Content of the propyl ester of *p*-hydroxybenzoic acid not less than 85 % on the anhydrous basis
Description	White, or almost white, crystalline hygroscopic powder
Identification	
A. Melting range of ester isolated by acidification and not recrystallized: 94 °C to 97 °C, after vacuum drying in a sulphuric acid desiccator	
B. Positive test for sodium	
C. pH of a 0,1 % aqueous solution must be between 9,8 and 10,2	
Purity	
Loss on drying	Not more than 5 %, determined by vacuum drying in a sulphuric acid desiccator
Sulphated ash	34 to 36 %
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
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

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
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

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
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
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

E 230 BIPHENYL

Synonyms	Diphenyl
Definition	
Chemical name	1,1'-biphenyl Phenylbenzene
Einecs	202-163-5
Chemical formula	$C_{12}H_{10}$
Molecular weight	154,20
Assay	Content not less than 99,8 %
Description	White or pale yellow to amber crystalline solid having a characteristic odour
Identification	
A. Melting range	68,5 °C to 70,5 °C
B. Distillation range	It distils completely within a 2,5 °C range between 252,5 °C and 257,5 °C
Purity	
Benzene	Not more than 10 mg/kg
Aromatic amines	Not more than 2 mg/kg (as aniline)
Phenol derivatives	Not more than 5 mg/kg (as phenol)

Readily carbonizable substances	Cold solution of 0,5 g of biphenyl in 5 ml of 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC, 0,3 ml of ferric chloride TSC, 0,1 ml of copper sulphate TSC and 4,4 ml of water
Terphenyl and higher polyphenyl derivatives	Not more than 0,2 %
Polycyclic aromatic hydrocarbons	Absent
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 231 ORTHOPHENYLPHENOL

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

Definition	
Chemical name	4-(2-benzimidazolyl)thiazole 2-(4-thiazolyl)-1H-benzimidazole
Einecs	1205-725-8
Chemical formula	$C_{10}H_7N_3S$

Molecular weight	201,26
Assay	Content not less than 98 % on the anhydrous basis
Description	White, or almost white, odourless powder
Identification	
A. Melting range	296 °C to 303 °C
B. Spectrometry	Absorption maxima in 0,1 N HCl (0,0005 % w/v) at 302 nm, 258 nm and 243 nm $E^{1\%}_{1\,cm}$ at 302 nm ±2 nm: approximately 1 230 $E^{1\%}_{1\,cm}$ at 258 nm ±2 nm: approximately 200 $E^{1\%}_{1\,cm}$ at 243 nm ±2 nm: approximately 620 Ratio of absorption 243 nm/302 nm = 0,47 to 0,53 Ratio of absorption 258 nm/302 nm = 0,14 to 0,18
Purity	
Water content	Not more than 0,5 % (Karl Fischer method)
Sulphated ash	Not more than 0,2 %
Selenium	Not more than 3 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 234 NISIN

Definition	Nisin consists of several closely related polypeptides produced by natural strains of *Streptococcus lactis*, Lancefield group N
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 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 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 235 NATAMYCIN

Synonyms	Pimaricin
Definition	Natamycin is a fungicide of the polyene macrolide group, and is produced by natural strains of *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 neutralized 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
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	
Einecs	224-859-8
Chemical name	Dimethyl dicarbonate Pyrocarbonic acid dimethyl ester
Chemical formula	$C_4H_6O_5$
Molecular weight	134,09
Assay	Content not less than 99,8 %
Description	Colourless liquid, decomposes in aqueous solution. It is corrosive to skin and eyes and toxic by inhalation and ingestion

Identification	
A. Decomposition	After dilution positive tests for CO_2 and methanol
B. Melting point Boiling point	17 °C 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 [1]
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

[1] When labelled 'for food use', nitrite may only be sold in a mixture with salt or a salt substitute.

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 [1]
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

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 at 105 °C for four hours
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
C. Melting point: ± 308 °C	

[1] When labelled 'for food use', nitrite may only be sold in a mixture with salt or a salt substitute.

Purity	
Loss on drying	Not more than 2 % after drying at 105 °C for four hours
Nitrites	Not more than 30 mg/kg expressed as $NaNO_2$
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 252 POTASSIUM NITRATE

Synonyms	Chile saltpetre Cubic or soda nitre
Definition	
Chemical name	Potassium nitrate
Einecs	231-818-8
Chemical formula	KNO_3
Molecular weight	101,11
Assay	Content not less than 99 % on the anhydrous basis
Description	White crystalline powder or transparent prisms having a cooling, saline, pungent taste
Identification	
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 oxidizable substances	Not more than 1 000 mg/kg expressed as formic acid
Readily oxidizable substances	Dilute 2 ml of the sample in a glass-stoppered container with 10 ml of water and add 0,1 ml of 0,1 N potassium permanganate. The pink colour does not change to brown within 30 minutes
Arsenic	Not more than 1 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 261 POTASSIUM ACETATE

Definition	
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 oxidizable substances	Not more than 1 000 mg/kg expressed as formic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 262 (i) SODIUM ACETATE

Definition	
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
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 oxidizable substances	Not more than 1 000 mg/kg expressed as formic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 262 (ii) SODIUM DIACETATE

Definition	Sodium diacetate is a molecular compound of sodium acetate and acetic acid
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 oxidizable substances	Not more than 1 000 mg/kg expressed as formic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 263 CALCIUM ACETATE

Definition	
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 oxidizable substances	Not more than 1 000 mg/kg expressed as formic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 270 LACTIC ACID

Definition	
Chemical name	Lactic acid 2-Hydroxypropionic acid 1-Hydroxyethane-1-carboxylic acid
Einecs	200-018-0
Chemical formula	$C_3H_6O_3$
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 %
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

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
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
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 pressurized cylinders or bulk storage systems, or in compressed solid blocks of 'dry ice'. Solid (dry ice) forms usually contain added substances, such as propylene glycol or mineral oil, as binders
Identification	
A. Precipitation (Precipitate formation)	When a stream of the sample is passed through a solution of barium hydroxide, a white precipitate is produced which dissolves with effervescence in dilute acetic acid
Purity	
Acidity	915 ml of gas bubbled through 50 ml of freshly boiled water must not render the latter more acid to methylorange than is 50 ml freshly boiled water to which has been added 1 ml of hydrochloric acid (0,01 N)
Reducing substances, hydrogen phosphide and sulphide	915 ml of gas bubbled through 25 ml of ammoniacal silver nitrate reagent to which has been added 3 ml of ammonia must not cause clouding or blackening of this solution
Carbon monoxide	Not more than 10 µl/l
Oil content	Not more than 0,1 mg/l

E 300 ASCORBIC ACID

Definition	
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)
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

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
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
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	200-412-2
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 oxidizes and darkens on exposure to air or light
Identification	
A. Solubility tests	Insoluble in water, freely soluble in ethanol, miscible in ether
B. Spectrophotometry	In absolute ethanol the maximum absorption is about 292 nm
Purity	
Refractive index	n_D^{20} 1,503 — 1,507
Specific absorption $E_{1\,cm}^{1\%}$ in ethanol	$E_{1\,cm}^{1\%}$ (292 nm) 72—76 (0,01 g in 200 ml of absolute ethanol)
Sulphated ash	Not more than 0,1 %
Specific rotation	$[\alpha]_D^{20}$ 0°±0,05° (1 in 10 solution in chloroform)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 308 GAMMA-TOCOPHEROL

Synonyms	dl-γ-Tocopherol
Definition	
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 oxidizes and darkens on exposure to air or light
Identification	
A. Spectrometry	Maximum absorptions in absolute ethanol at about 298 nm and 257 nm
Purity	
Specific absorption $E\,^{1\%}_{1\,cm}$ in ethanol	$E\,^{1\%}_{1\,cm}$ (298 nm) between 91 and 97 $E\,^{1\%}_{1\,cm}$ (257 nm) between 5,0 and 8,0
Refractive index	$n\,^{20}_{D}$ 1,503—1,507
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 309 DELTA-TOCOPHEROL

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

Purity	
Specific absorption $E^{1\%}_{1\,cm}$ in ethanol	$E^{1\%}_{1\,cm}$ (298 nm) between 89 and 95 $E^{1\%}_{1\,cm}$ (257 nm) between 3,0 and 6,0
Refractive index	n^{20}_{D} 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 $E^{1\%}_{1\,cm}$ in ethanol	$E^{1\%}_{1\,cm}$ (275 nm) not less than 485 and not more than 520
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 311 OCTYL GALLATE

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 Cl)
Specific absorption $E^{1\%}_{1\,cm}$ in ethanol	$E^{1\%}_{1\,cm}$ (275 nm) not less than 375 and not more than 390
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 312 DODECYL GALLATE

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

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

E 315 ERYTHORBIC ACID

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

Specific rotation	$[\alpha]_D^{25}$ 10 % (w/v) aqueous solution between – 16,5° to – 18,0°
Oxalate	To a solution of 1 g in 10 ml of water add 2 drops of glacial acetic acid and 5 ml of 10 % calcium acetate solution. The solution should remain clear
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 316 SODIUM ERYTHORBATE

Synonyms	Sodium isoascorbate
Definition	
Chemical name	Sodium isoascorbate Sodium D-isoascorbic acid Sodium salt of 2,3-didehydro-D-erythro-hexono-1,4-lactone 3-keto-D-gulofurano-lactone sodium enolate monohydrate
Einecs	228-973-9
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	$[\alpha]_D^{25}$ 10 % (w/v) aqueous solution between + 95° and + 98°
pH of a 10 % aqueous solution	5,5 to 8,0
Oxalate	To a solution of 1 g in 10 ml of water add 2 drops of glacial acetic acid and 5 ml of 10 % calcium acetate solution. The solution should remain clear
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 320 BUTYLATED HYDROXYANISOLE (BHA)

Synonyms	BHA
Definition	
Chemical name	3-Tertiary-butyl-4-hydroxyanisole A mixture of 2-tertiarybutyl-4-hydroxyanisole and 3-tertiarybutyl-4-hydroxyanisole
Einecs	246-563-8
Chemical formula	$C_{11}H_{16}O_2$
Molecular weight	180,25
Assay	Content not less than 98,5 % of $C_{11}H_{16}O_2$ and not less than 85 % of 3-tertiary-butyl-4-hydroxyanisole isomer
Description	White or slightly yellow crystals or waxy solid with a slight aromatic smell
Identification	
A. Solubility tests	Insoluble in water
B. Melting range	Between 48 °C and 55 °C
Purity	
Sulphated ash	Not more than 0,05 % after calcination at 800 ±25 °C
Phenolic impurities	Not more than 0,5 %
Specific absorption $E\,^{1\%}_{1\,cm}$ in ethanol	$E\,^{1\%}_{1\,cm}$ (290 nm) not less than 190 and not more than 210 $E\,^{1\%}_{1\,cm}$ (228 nm) not less than 326 and not more than 345
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 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 °C
C. Absorbance maximum	The absorption in the range 230 to 320 nm of a 2 cm layer of a 1 in 100 000 solution in dehydrated ethanol exhibits a maximum only at 278 nm
Purity	
Sulphated ash	Not more than 0,005 %
Phenolic impurities	Not more than 0,5 %
Specific absorption $E^{1\%}_{1cm}$ in ethanol	$E^{1\%}_{1cm}$ (278 nm) not less than 81 and not more than 88
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 322 LECITHINS

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
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 potassium	
Purity	
Acidity	Not more than 0,5 % after drying expressed as lactic acid
pH of a 20 % aqueous solution	6,5 to 7,5
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Reducing substances	No reduction of Fehling's solution
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
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
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
Readily carbonizable substances	Heat 1 g of powdered sample with 10 ml of 98 % minimum sulphuric acid in a water bath at 90 °C in the dark for one hour. Not more than a pale brown colour should be produced (Matching Fluid K)

E 331 (i) MONOSODIUM CITRATE

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

E 331 (ii) DISODIUM CITRATE

Synonyms	Disodium citrate Dibasic sodium citrate
Definition	
Chemical name	Disodium citrate Disodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Disodium salt of citric acid with 1,5 molecules of water

Einecs	205-623-3
Chemical formula	$C_6H_6O_7Na_2 \cdot 1,5H_2O$
Molecular weight	263,11
Assay	Content not less than 99 % on the anhydrous basis
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 %
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
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 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 5 % aqueous solution	Between 7,5 and 9,0
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

E 333 (i) MONOCALCIUM CITRATE

Synonyms	Monocalcium citrate Monobasic calcium citrate
Definition	
Chemical name	Monocalcium citrate Monocalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Monohydrate monocalcium salt of citric acid
Chemical formula	$(C_6H_7O_7)_2Ca \cdot H_2O$
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 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 1 % aqueous solution	Between 3,2 and 3,5
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg
Carbonates	Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles

E 333 (ii) DICALCIUM CITRATE

Synonyms	Dicalcium citrate Dibasic calcium citrate
Definition	
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
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
Specific optical rotation of a 20 % w/v aqueous solution	$[\alpha]_D^{20}$ 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	$C_4H_4O_6Na_2 \cdot 2H_2O$
Molecular weight	230,8
Assay	Content not less than 99 % on the anhydrous basis
Description	Transparent, colourless crystals
Identification	
A. Positive tests for tartrate and for sodium	
B. Solubility tests	1 gram is insoluble in 3 ml of water. Insoluble in ethanol
Purity	
Loss on drying	Not more than 17,0 % determined by drying at 150 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 1 % aqueous solution	Between 7,0 and 7,5
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

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 °C
Purity	
pH of a 1 % aqueous solution	3,4
Loss on drying	Not more than 1,0 % determined by drying at 105 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 336 (ii) DIPOTASSIUM TARTRATE

Synonyms	Dibasic potassium tartrate
Definition	
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	$C_4H_4O_6K_2 \cdot ½H_2O$
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 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 337 POTASSIUM SODIUM TARTRATE

Synonyms	Potassium sodium L-(+)-tartrate Rochelle salt Seignette salt
Definition	
Chemical name	Potassium sodium salt of L-2,3-dihydroxybutanedioic acid Potassium sodium L-(+)-tartrate
Einecs	206-156-8
Chemical formula	$C_4H_4O_6KNa \cdot 4H_2O$
Molecular weight	282,23
Assay	Content not less than 99 % on the anhydrous basis
Description	Colourless crystals or white crystalline powder
Identification	
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	Content not less than 71 % and not more than 83 %
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
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 75 % aqueous solution	

E 339 (i) MONOSODIUM PHOSPHATE

Synonyms	Monosodium monophosphate Acid monosodium monophosphate Monosodium orthophosphate Monobasic sodium phosphate
Definition	
Chemical name	Sodium dihydrogen monophosphate
Einecs	231-449-2
Chemical formula	Anhydrous: 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 6,0 °C for one hour and then at 105 °C for four hours, contains not less than 97 % of NaH_2PO_4
Description	A white odourless, slightly deliquescent powder, crystals or granules
Identification	
A. Positive tests for sodium and for phosphate	
B. Solubility tests	Freely soluble in water. Insoluble in ethanol, ether or chloroform
C. P_2O_5 content	Between 58,0% and 60,0%

Purity	
Loss on drying	The anhydrous salt loses no more than 2,0 %, the monohydrate no more than 15,0 %, and the dihydrate no more than 25 % when dried first at 60 °C for one hour, then at 105 °C for four hours
Water-insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
pH of a 1 % aqueous solution	Between 4,1 and 5,0
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 339 (ii) DISODIUM PHOSPHATE

Synonyms	Disodium monophosphate Secondary sodium phosphate Disodium orthophosphate Acid disodium phosphate
Definition	
Chemical name	Disodium hydrogen monophosphate Disodium hydrogen orthophosphate
Einecs	231-448-7
Chemical formula	Anhydrous: Na_2HPO_4 Hydrated: $Na_2HPO_4 \cdot nH_2O$ (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
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 tests	Freely soluble in water. Insoluble in ethanol
C. P_2O_5 content	Between 49 % and 51 % (anhydrous)
Purity	
Loss on drying	When dried at 40 °C for three hours and then at 105 °C for five hours, the losses in weight are as follows: anhydrous not more than 5,0 %, dihydrate not more than 22,0 %, heptahydrate not more than 50,0 %, dodecahydrate not more than 61,0 %

Water-insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
pH of a 1,0 % aqueous solution	Between 8,4 and 9,6
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 339 (iii) TRISODIUM PHOSPHATE

Synonyms	Sodium phosphate Tribasic sodium phosphate Trisodium orthophosphate
Definition	
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 = 0,5, 1 or 12)
Molecular weight	163,94 (anhydrous)
Assay	Sodium phosphate anhydrous, and also the hemi- and monohydrates, contains not less than 97,0 % of Na_3PO_4, calculated on the dried basis. Sodium phosphate dodecahydrate contains not less than 92,0 % of Na_3PO_4, calculated on the ignited basis
Description	White odourless crystals, granules or a crystalline powder. Hydrated forms available include hemi- and monohydrates, hexahydrate, octahydrate, decahydrate and dodecahydrate. The dodecahydrate contains ¼ molecule of sodium hydroxide
Identification	
A. Positive tests for sodium and for phosphate	
B. Solubility tests	Freely soluble in water. Insoluble in ethanol
C. P_2O_5 content	Between 40,5 % and 43,5 % (anhydrous)
Purity	
Loss on ignition	When dried at 120 °C for two hours and then ignited at about 800 °C for 30 minutes, the losses in weight are as follows: anhydrous not more than 2,0 %, monohydrate: not more than 11,0 %, dodecahydrate: between 45,0 % and 58,0 %
Water-insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)

pH of a 1,0 % aqueous solution	Between 11,5 and 12,5
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 340 (i) MONOPOTASSIUM PHOSPHATE

Synonyms	Monobasic potassium phosphate Monopotassium monophosphate Potassium acid phosphate Potassium orthophosphate
Definition	
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 °C for four hours
Description	Odourless, colourless crystals or white granular or crystalline powder, hygroscopic
Identification	
A. Positive tests for potassium and for phosphate	
B. Solubility tests	Freely soluble in water. Insoluble in ethanol
C. P_2O_5 content	Between 51,0 % and 53,0 %
Purity	
Loss on drying	Not more than 2,0 % determined by drying at 105 °C for four hours
Water-insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
pH of a 1 % aqueous solution	Between 4,2 and 4,8
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 340 (ii) DIPOTASSIUM PHOSPHATE

Synonyms	Dipotassium monophosphate Secondary potassium phosphate Dipotassium acid phosphate Dipotassium orthophosphate Dibasic potassium phosphate
Definition	
Chemical name	Dipotassium hydrogen monophosphate Dipotassium hydrogen phosphate Dipotassium hydrogen orthophosphate
Einecs	231-834-5
Chemical formula	K_2HPO_4
Molecular weight	174,18
Assay	Content not less than 98 % after drying at 105 °C for four hours
Description	Colourless or white granular powder, crystals or masses; deliquescent substance
Identification	
A. Positive tests for potassium and for phosphate	
B. Solubility tests	Freely soluble in water. Insoluble in ethanol
C. P_2O_5 content	Between 40,3 % and 41,5 %
Purity	
Loss on drying	Not more than 2,0 % determined by drying at 105 °C for four hours
Water-insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
pH of a 1 % aqueous solution	Between 8,7 and 9,4
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

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

E 341 (i) MONOCALCIUM PHOSPHATE

Synonyms	Monobasic calcium phosphate Monocalcium orthophosphate
Definition	
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
Description	Granular powder or white, deliquescent crystals or granules

Identification	
A. Positive tests for calcium and for phosphate	
B. P_2O_5 content	Between 55,5 % and 61,1 % (anhydrous)
C. CaO content	Between 23,0 % and 27,5 % (anhydrous) Between 19,0 % and 24,8 % (monohydrate)
Purity	
Loss on drying	Not less than 14 % determined by drying at 105 °C for four hours (anhydrous)
	Not more than 17,5 % determined by drying at 60 °C for one hour, then at 105 °C for four hours (monohydrate)
Loss on ignition	Not more than 17,5 % after ignition at 800 °C±25 °C for 30 minutes (anhydrous)
	Not more than 25,0 % determined by drying at 105 °C for one hour, then ignite at 800 °C ±25 °C for 30 minutes (monohydrate)
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 341 (ii) DICALCIUM PHOSPHATE

Synonyms	Dibasic calcium phosphate Dicalcium orthophosphate
Definition	
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 $CaHPO_4$
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
C. P_2O_5 content	Between 50,0 % and 52,5 % (anhydrous)

Purity	
Loss on ignition	Not more than 8,5 % (anhydrous), or 26,5 % (dihydrate) after ignition at 800 °C ±25 °C for 30 minutes
Fluoride	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 341 (iii) TRICALCIUM PHOSPHATE

Synonyms	Calcium phosphate, tribasic Calcium orthophosphate
Definition	
Chemical name	Tricalcium monophosphate
Einecs	231-840-8
Chemical formula	$Ca_3(PO_4)_2$
Molecular weight	310,17
Assay	Not less than 90 % calculated on the ignited basis
Description	A white, odourless and tasteless powder which is stable in air
Identification	
A. Positive tests for calcium and for phosphate	
B. Solubility tests	Practically insoluble in water; insoluble in ethanol, soluble in dilute hydrochloric and nitric acid
C. P_2O_5 content	Between 38,5 % and 48,0 % (anhydrous)
Purity	
Loss on ignition	Not more than 8 % after ignition at 800 °C ±25 °C, to constant weight
Fluoride	Not more than 50 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 385 CALCIUM DISODIUM ETHYLENEDIAMINETETRAACETATE

Synonyms	Calcium disodium EDTA Calcium disodium edetate
Definition	
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. 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

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. 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