

This document is meant purely as a documentation tool and the institutions do not assume any liability for its contents

► **B**

COMMISSION DIRECTIVE 96/77/EC

of 2 December 1996

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

(Text with EEA relevance)

(OJ L 339, 30.12.1996, p. 1)

Amended by:

	Official Journal		
	No	page	date
► <u>M1</u> Commission Directive 98/86/EC of 11 November 1998	L 334	1	9.12.1998
► <u>M2</u> Commission Directive 2000/63/EC of 5 October 2000	L 277	1	30.10.2000
► <u>M3</u> Commission Directive 2001/30/EC of 2 May 2001	L 146	1	31.5.2001
► <u>M4</u> Commission Directive 2002/82/EC of 15 October 2002	L 292	1	28.10.2002
► <u>M5</u> Commission Directive 2003/95/EC of 27 October 2003	L 283	71	31.10.2003

▼B

COMMISSION DIRECTIVE 96/77/EC
of 2 December 1996

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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

After consulting the Scientific Committee for Food,

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

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

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

Whereas Directives 65/66/EEC and 78/664/EEC should be repealed accordingly;

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

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

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

⁽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.

▼M1*Article 2*

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

▼B*Article 3*

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

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

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

Article 4

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

Article 5

This Directive is addressed to the Member States.

▼ **B**

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 recrystallized 133 °C to 135 °C after vacuum drying in a sulphuric acid desiccator

B. Positive tests for potassium and for double bonds

▼ **B****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 ₂ CO 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**

<i>Chemical name</i>	Calcium sorbate Calcium salts of trans, trans-2,4-hexadienoic acid
Einecs	231-321-6
<i>Chemical formula</i>	C ₁₂ H ₁₄ O ₄ Ca
<i>Molecular weight</i>	262,32
<i>Assay</i>	Content not less than 98 % on the dried basis
<i>Description</i>	Fine white crystalline powder not showing any change in colour after heating at 105 °C for 90 minutes

Identification

- A. Melting range of sorbic acid isolated by acidification and not recrystallized 133 °C to 135 °C after vacuum drying in a sulphuric acid desiccator
- B. Positive tests for calcium and for double bonds

Purity

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

E 210 BENZOIC ACID**Definition**

<i>Chemical name</i>	Benzoic acid Benzenecarboxylic acid Phenylcarboxylic acid
Einecs	200-618-2
<i>Chemical formula</i>	C ₇ H ₆ O ₂
<i>Molecular weight</i>	122,12
<i>Assay</i>	Content not less than 99,5 % on the anhydrous basis
<i>Description</i>	White crystalline powder

▼ **B****Identification**

A. Melting range 121,5 °C to 123,5 °C

B. Positive sublimation test and test for benzoate

Purity

Loss on drying Not more than 0,5 % after drying for three hours over sulphuric acid

pH About 4 (solution in water)

Sulphated ash Not more than 0,05 %

Chlorinated organic compounds Not more than 0,07 % expressed as chloride corresponding to 0,3 % expressed as monochlorobenzoic acid

Readily oxidizable substances Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N KMnO_4 in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N KMnO_4 to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required

Readily carbonizable substances A cold solution of 0,5 g of benzoic acid in 5 ml of 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC (1), 0,3 ml of ferric chloride TSC (2), 0,1 ml of copper sulphate TSC (3) and 4,4 ml of water

Polycyclic acids On fractional acidification of a neutralized solution of benzoic acid, the first precipitate must not have a different melting point from that of the benzoic acid

Arsenic Not more than 3 mg/kg

Lead Not more than 5 mg/kg

Mercury Not more than 1 mg/kg

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

E 211 SODIUM BENZOATE**Definition**

Chemical name Sodium benzoate
Sodium salt of benzenecarboxylic acid
Sodium salt of phenylcarboxylic acid

Einecs 208-534-8

Chemical formula $\text{C}_7\text{H}_5\text{O}_2\text{Na}$

Molecular weight 144,11

Assay Not less than 99 % of $\text{C}_7\text{H}_5\text{O}_2\text{Na}$, after drying at 105 °C for four hours

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

▼B

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**

<i>Chemical name</i>	Potassium benzoate Potassium salt of benzenecarboxylic acid Potassium salt of phenylcarboxylic acid
Einecs	209-481-3
<i>Chemical formula</i>	$\text{C}_7\text{H}_5\text{KO}_2 \cdot 3\text{H}_2\text{O}$
<i>Molecular weight</i>	214,27
<i>Assay</i>	Content not less than 99 % $\text{C}_7\text{H}_5\text{O}_2\text{K}$ after drying at 105 °C to constant weight
<i>Description</i>	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

▼B

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

▼B

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

▼B

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

<i>Chemical name</i>	Sodium ethyl <i>p</i> -hydroxybenzoate Sodium compound of the ethyl ester of <i>p</i> -hydroxybenzoic acid
Einecs	252-487-6
<i>Chemical formula</i>	C ₉ H ₉ O ₃ Na
<i>Molecular weight</i>	188,8
<i>Assay</i>	Content of ethylester of <i>p</i> -hydroxybenzoic acid not less than 83 % on the anhydrous basis
<i>Description</i>	White, crystalline hygroscopic powder

Identification

A. Melting range	115 °C to 118 °C, after vacuum drying in a sulphuric acid desiccator
B. Positive test for <i>p</i> -hydroxybenzoate	Melting range of <i>p</i> -hydroxybenzoic acid derived from the sample is 213 °C to 217 °C
C. Positive test for sodium	
D. pH of a 0,1 % aqueous solution must be between 9,9 and 10,3	

Purity

Loss on drying	Not more than 5 %, determined by vacuum drying in a sulphuric acid desiccator
Sulphated ash	37 to 39 %
<i>p</i> -Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 216 PROPYL *p*-HYDROXYBENZOATE**Synonyms**

Propylparaben
Propyl *p*-oxybenzoate

Definition

<i>Chemical name</i>	Propyl <i>p</i> -hydroxybenzoate n-Propyl <i>p</i> -hydroxybenzoic acid
Einecs	202-307-7
<i>Chemical formula</i>	C ₁₀ H ₁₂ O ₃
<i>Molecular weight</i>	180,21
<i>Assay</i>	Content not less than 99,5 % after drying for two hours at 80 °C
<i>Description</i>	Almost odourless, small, colourless crystals or a white, crystalline powder

Identification

A. Melting range	95 °C to 97 °C after drying for two hours at 80 °C
B. Positive test for <i>p</i> -hydroxybenzoate	Melting range of <i>p</i> -hydroxybenzoic acid derived from the sample is 213 °C to 217 °C

▼B

Purity

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

E 217 SODIUM PROPYL *p*-HYDROXYBENZOATE**Definition**

<i>Chemical name</i>	Sodium n-propyl <i>p</i> -hydroxybenzoate Sodium compound of the n-propylester of <i>p</i> -hydroxybenzoic acid
Einecs	252-488-1
<i>Chemical formula</i>	C ₁₀ H ₁₁ O ₃ Na
<i>Molecular weight</i>	202,21
<i>Assay</i>	Content of the propyl ester of <i>p</i> -hydroxybenzoic acid not less than 85 % on the anhydrous basis
<i>Description</i>	White, or almost white, crystalline hygroscopic powder

Identification

- A. Melting range of ester isolated by acidification and not recrystallized: 94 °C to 97 °C, after vacuum drying in a sulphuric acid desiccator
- B. Positive test for sodium
- C. pH of a 0,1 % aqueous solution must be between 9,8 and 10,2

Purity

Loss on drying	Not more than 5 %, determined by vacuum drying in a sulphuric acid desiccator
Sulphated ash	34 to 36 %
<i>p</i> -Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 218 METHYL *p*-HYDROXYBENZOATE**Synonyms**

Methylparaben
Methyl-*p*-oxybenzoate

Definition

<i>Chemical name</i>	Methyl <i>p</i> -hydroxybenzoate Methyl ester of <i>p</i> -hydroxybenzoic acid
Einecs	243-171-5

▼ **B**

<i>Chemical formula</i>	$C_8H_8O_3$
<i>Molecular weight</i>	152,15
<i>Assay</i>	Content not less than 99 % after drying for two hours at 80 °C
<i>Description</i>	Almost odourless, small colourless crystals or white crystalline powder
Identification	
A. Melting range	125 °C to 128 °C
B. Positive test for <i>p</i> -hydroxybenzoate	Melting range of <i>p</i> -hydroxybenzoic acid derived from the sample is 213 °C to 217 °C after drying for two hours at 80 °C
Purity	
Loss on drying	Not more than 0,5 %, after drying for two hours at 80 °C
Sulphated ash	Not more than 0,05 %
<i>p</i> -Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as <i>p</i> -hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 219 SODIUM METHYL *p*-HYDROXYBENZOATE

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

▼B

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

E 220 SULPHUR DIOXIDE**Definition**

<i>Chemical name</i>	Sulphur dioxide Sulphurous acid anhydride
Einecs	231-195-2
<i>Chemical formula</i>	SO ₂
<i>Molecular weight</i>	64,07
<i>Assay</i>	Content not less than 99 %
<i>Description</i>	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**

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

Identification

A. Positive tests for sulphite and for sodium

B. pH of a 10 % solution (anhydrous) or a 20 % solution (heptahydrate) between 8,5 and 11,5

▼B**Purity**

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

E 222 SODIUM BISULPHITE**Definition**

<i>Chemical name</i>	Sodium bisulphite Sodium hydrogen sulphite
Einecs	231-921-4
<i>Chemical formula</i>	NaHSO ₃ in aqueous solution
<i>Molecular weight</i>	104,06
<i>Assay</i>	Content not less than 32 % w/w NaHSO ₃
<i>Description</i>	A clear, colourless to yellow solution

Identification

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

Purity

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

E 223 SODIUM METABISULPHITE**Synonyms**

Pyrosulphite
Sodium pyrosulphite

Definition

<i>Chemical name</i>	Sodium disulphite Disodium pentaoxodisulphate
Einecs	231-673-0
<i>Chemical formula</i>	Na ₂ S ₂ O ₅
<i>Molecular weight</i>	190,11
<i>Assay</i>	Content not less than 95 % Na ₂ S ₂ O ₅ and not less than 64 % of SO ₂
<i>Description</i>	White crystals or crystalline powder

▼ **B****Identification**

A. Positive tests for sulphite and for sodium

B. pH of a 10 % aqueous solution between 4,0 and 5,5

Purity

Thiosulphate

Not more than 0,1 % based on the SO₂ content

Iron

Not more than 50 mg/kg based on the SO₂ content

Selenium

Not more than 10 mg/kg based on the SO₂ content

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 mg/kg

E 224 POTASSIUM METABISULPHITE**Synonyms**

Potassium pyrosulphite

Definition

Chemical name

Potassium disulphite

Potassium pentaoxo disulphate

Einecs

240-795-3

Chemical formula

K₂S₂O₅

Molecular weight

222,33

Assay

Content not less than 90 % of K₂S₂O₅ and not less than 51,8 % of SO₂, the remainder being composed almost entirely of potassium sulphate

Description

Colourless crystals or white crystalline powder

Identification

A. Positive tests for sulphite and for potassium

Purity

Thiosulphate

Not more than 0,1 % based on the SO₂ content

Iron

Not more than 50 mg/kg based on the SO₂ content

Selenium

Not more than 10 mg/kg based on the SO₂ content

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 mg/kg

E 226 CALCIUM SULPHITE**Definition**

Chemical name

Calcium sulphite

Einecs

218-235-4

Chemical formula

CaSO₃·2H₂O

Molecular weight

156,17

Assay

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

▼**B**

<i>Description</i>	White crystals or white crystalline powder
Identification	
A. Positive tests for sulphite and for calcium	
Purity	
Iron	Not more than 50 mg/kg based on the SO ₂ content
Selenium	Not more than 10 mg/kg based on the SO ₂ content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 227 CALCIUM BISULPHITE

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

E 228 POTASSIUM BISULPHITE

Definition	
<i>Chemical name</i>	Potassium bisulphite Potassium hydrogen sulphite
Einecs	231-870-1
<i>Chemical formula</i>	KHSO ₃ in aqueous solution
<i>Molecular weight</i>	120,17
<i>Assay</i>	Content not less than 280 g KHSO ₃ per litre (or 150 g SO ₂ per litre)
<i>Description</i>	Clear colourless aqueous solution

▼ **B****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

C₁₂H₁₀

Molecular weight

154,20

Assay

Content not less than 99,8 %

Description

White or pale yellow to amber crystalline solid having a characteristic odour

Identification

A. Melting range

68,5 °C to 70,5 °C

B. Distillation range

It distils completely within a 2,5 °C range between 252,5 °C and 257,5 °C

Purity

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

▼ **B****Definition**

<i>Chemical name</i>	(1,1'-Biphenyl)-2-ol 2-Hydroxydiphenyl <i>o</i> -Hydroxydiphenyl
Einecs	201-993-5
<i>Chemical formula</i>	C ₁₂ H ₁₀ O
<i>Molecular weight</i>	170,20
<i>Assay</i>	Content not less than 99 %
<i>Description</i>	White or slightly yellowish crystalline powder

Identification

A. Melting range	56 °C to 58 °C
B. Positive test for phenolate	An ethanolic solution (1 g in 10 ml) produces a green colour on addition of 10 % ferric chloride solution

Purity

Sulphated ash	Not more than 0,05 %
Diphenyl ether	Not more than 0,3 %
<i>p</i> -Phenylphenol	Not more than 0,1 %
1-Naphthol	Not more than 0,01 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 232 SODIUM ORTHOPHENYLPHENOL**Synonyms**

Sodium orthophenylphenate
Sodium salt of *o*-phenylphenol

Definition

<i>Chemical name</i>	Sodium orthophenylphenol
Einecs	205-055-6
<i>Chemical formula</i>	C ₁₂ H ₉ ONa·4H ₂ O
<i>Molecular weight</i>	264,26
<i>Assay</i>	Content not less than 97 % of C ₁₂ H ₉ ONa·4H ₂ O
<i>Description</i>	White or slightly yellowish crystalline powder

Identification

- A. Positive tests for phenolate and for sodium
- B. Melting range of orthophenylphenol isolated by acidification and not recrystallized derived from the sample 56 °C to 58 °C after drying in a sulphuric acid desiccator
- C. pH of a 2 % aqueous solution must be between 11,1 and 11,8

Purity

Diphenylether	Not more than 0,3 %
<i>p</i> -phenylphenol	Not more than 0,1 %
1-naphthol	Not more than 0,01 %

▼ **B**

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

E 233 THIABENDAZOLE**Definition**

<i>Chemical name</i>	4-(2-benzimidazolyl)thiazole 2-(4-thiazolyl)-1H-benzimidazole
----------------------	--

Einecs 1205-725-8

Chemical formula C₁₀H₇N₃S

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 cm} ^{1 %} at 302 nm ± 2 nm: approximately 1 230 E _{1 cm} ^{1 %} at 258 nm ± 2 nm: approximately 200 E _{1 cm} ^{1 %} at 243 nm ± 2 nm: approximately 620 Ratio of absorption 243 nm/302 nm = 0,47 to 0,53 Ratio of absorption 258 nm/302 nm = 0,14 to 0,18

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 C₁₄₃H₂₃₀N₄₂O₃₇S₇

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

▼ **B**

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*C₃₃H₄₇O₁₃N*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

$[\alpha]_D^{20} = + 250^\circ$ to $+ 295^\circ$ (a 1 % w/v solution in glacial acetic acid, at 20 °C and calculated with reference to the dried material)

Purity

Loss on drying

Not more than 8 % (over P₂O₅, 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*C₆H₁₂N₄*Molecular weight*

140,19

▼B

<i>Assay</i>	Content not less than 99 % on the anhydrous basis
<i>Description</i>	Colourless or white crystalline powder
Identification	
A. Positive tests for formaldehyde and for ammonia	
B. Sublimation point approximately 260 °C	
Purity	
Loss on drying	Not more than 0,5 % after drying at 105 °C in vacuum over P ₂ O ₅ for two hours
Sulphated ash	Not more than 0,05 %
Sulphates	Not more than 0,005 % expressed as SO ₄
Chlorides	Not more than 0,005 % expressed as Cl
Ammonium salts	Not detectable
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
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
<i>Chemical name</i>	Dimethyl dicarbonate Pyrocarbonic acid dimethyl ester
<i>Chemical formula</i>	C ₄ H ₆ O ₅
<i>Molecular weight</i>	134,09
<i>Assay</i>	Content not less than 99,8 %
<i>Description</i>	Colourless liquid, decomposes in aqueous solution. It is corrosive to skin and eyes and toxic by inhalation and ingestion
Identification	
A. Decomposition	After dilution positive tests for CO ₂ and methanol
B. Melting point	17 °C
Boiling point	172 °C with decomposition
C. Density 20 °C	Approximately 1,25 g/cm ³
D. Infrared spectrum	Maxima at 1 156 and 1 832 cm ⁻¹
Purity	
Dimethyl carbonate	Not more than 0,2 %
Chlorine, total	Not more than 3 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

▼B**E 249 POTASSIUM NITRITE****Definition**

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

Identification

- A. Positive tests for nitrite and for potassium
- B. pH of a 5 % solution: not less than 6,0 and not more than 9,0

Purity

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

E 250 SODIUM NITRITE**Definition**

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

Identification

- A. Positive tests for nitrite and for sodium

Purity

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

▼M5**E 251 SODIUM NITRATE****1. SOLID SODIUM NITRATE****Synonyms**

Chile saltpetre
Cubic or soda nitre

▼ M5**Definition***Chemical name*

Sodium nitrate

EINECS

231-554-3

*Chemical formula*NaNO₃*Molecular weight*

85,00

Assay

Content not less than 99 % after drying

Description

White crystalline, slightly hygroscopic powder

Identification

A. Positive tests for nitrate and for sodium

B. pH of a 5 % solution

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

Purity

Loss on drying

Not more than 2 % after drying at 105 °C for four hours

Nitrites

Not more than 30 mg/kg expressed as NaNO₂

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 251 SODIUM NITRATE**2. LIQUID SODIUM NITRATE****Definition**

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

Chemical name

Sodium nitrate

EINECS

231-554-3

*Chemical formula*NaNO₃*Molecular weight*

85,00

*Assay*Content between 33,5 % and 40,0 % of NaNO₃*Description*

Clear colourless liquid

Identification

A. Positive tests for nitrate and for sodium

B. pH

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

Purity

Free nitric acid

Not more than 0,01 %

Nitrites

Not more than 10 mg/kg expressed as NaNO₂

Arsenic

Not more than 1 mg/kg

Lead

Not more than 1 mg/kg

Mercury

Not more than 0,3 mg/kg

This specification refers to a 35 % aqueous solution.

▼ B**E 252 POTASSIUM NITRATE****Synonyms**

Chile saltpetre

Cubic or soda nitre

▼B**Definition***Chemical name*

Potassium nitrate

Einecs

231-818-8

*Chemical formula*KNO₃*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 KNO₂

Arsenic

Not more than 3 mg/kg

Lead

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*C₂H₄O₂*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

▼**B**

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

E 261 POTASSIUM ACETATE**Definition**

<i>Chemical name</i>	Potassium acetate
Einecs	204-822-2
<i>Chemical formula</i>	$C_2H_3O_2K$
<i>Molecular weight</i>	98,14
<i>Assay</i>	Content not less than 99 % on the anhydrous basis
<i>Description</i>	Colourless, deliquescent crystals or a white crystalline powder, odourless or with a faint acetic odour

Identification

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

Purity

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

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

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

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	

▼ **B****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
B. Positive tests for acetate and for sodium

Not less than 4,5 and not more than 5,0

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

▼ **B****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**

<i>Chemical name</i>	Lactic acid 2-Hydroxypropionic acid 1-Hydroxyethane-1-carboxylic acid
----------------------	---

Einecs	200-018-0
---------------	-----------

<i>Chemical formula</i>	$C_3H_6O_3$
-------------------------	-------------

<i>Molecular weight</i>	90,08
-------------------------	-------

<i>Assay</i>	Content not less than 76 % and not more than 84 %
--------------	---

<i>Description</i>	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

▼ **B***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

Identification

A. Melting point

– 22 °C

B. Distillation range

138,5 °C to 142,5 °C

Purity

Non-volatile residue

Not more than 0,01 % when dried at 140 °C to constant weight

Aldehydes

Not more than 0,1 % expressed as formaldehyde

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 mg/kg

E 281 SODIUM PROPIONATE**Definition***Chemical name*

Sodium propionate
Sodium propanoate

Einecs

205-290-4

Chemical formula $C_3H_5O_2Na$ *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

▼B

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

E 282 CALCIUM PROPIONATE**Definition**

<i>Chemical name</i>	Calcium propionate
Einecs	223-795-8
<i>Chemical formula</i>	$C_6H_{10}O_4Ca$
<i>Molecular weight</i>	186,22
<i>Assay</i>	Content not less than 99 %, after drying for two hours at 105 °C
<i>Description</i>	White crystalline powder

Identification

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

Purity

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

E 283 POTASSIUM PROPIONATE**Definition**

<i>Chemical name</i>	Potassium propionate Potassium propanoate
Einecs	206-323-5
<i>Chemical formula</i>	$C_3H_5KO_2$
<i>Molecular weight</i>	112,17
<i>Assay</i>	Content not less than 99 % after drying for two hours at 105 °C
<i>Description</i>	White crystalline powder

Identification

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

Purity

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

▼ **B**

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 baborate
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

▼ **B****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

CO₂

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

C₆H₈O₆

Molecular weight

176,13

▼B

<i>Assay</i>	Ascorbic acid, after drying in a vacuum desiccator over sulphuric acid for 24 hours, contains not less than 99 % of C ₆ H ₈ O ₆
<i>Description</i>	White to pale yellow, odourless crystalline solid
Identification	
A. Melting range	Between 189 °C and 193 °C with decomposition
B. Positive tests for ascorbic acid	
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	[α] _D ²⁰ between + 20,5 ° and + 21,5 ° (10 % w/v aqueous solution)
pH of a 2 % aqueous solution	Between 2,4 and 2,8
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 301 SODIUM ASCORBATE**Definition**

<i>Chemical name</i>	Sodium ascorbate Sodium L-ascorbate 2,3-Didehydro-L-threo-hexono-1,4-lactone sodium enolate 3-Keto-L-gulofurano-lactone sodium enolate
----------------------	---

Einecs

205-126-1

*Chemical formula*C₆H₇O₆Na*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 C₆H₇O₆Na*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	[α] _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

▼B

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)

▼**B**

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

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

<i>Chemical name</i>	Ascorbyl stearate L-ascorbyl stearate 2,3-didehydro-L-threo-hexono-1,4-lactone-6-stearate 6-stearoyl-3-keto-L-gulofuranolactone
Einecs	246-944-9
<i>Chemical formula</i>	$C_{24}H_{42}O_7$
<i>Molecular weight</i>	442,6
<i>Assay</i>	Content not less than 98 %
<i>Description</i>	White or yellowish, white solid with a citrus-like odour

Identification

A. Melting point	About 116 °C
------------------	--------------

Purity

Loss on drying	Not more than 2,0 % after drying in a vacuum oven at 56 °C to 60 °C for one hour
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 306 TOCOPHEROL-RICH EXTRACT**Definition**

	Product obtained by the vacuum steam distillation of edible vegetable oil products, comprising concentrated tocopherols and tocotrienols
	Contains tocopherols such as d- α -, d- β -, d- γ - and d- ζ -tocopherols
<i>Molecular weight</i>	430,71 (d- α -tocopherol)
<i>Assay</i>	Content not less than 34 % of total tocopherols
<i>Description</i>	Brownish red to red, clear, viscous oil having a mild, characteristic odour and taste. May show a slight separation of wax-like constituents in microcrystalline form

Identification

A. By suitable gas liquid chromatographic method	
B. Solubility tests	Insoluble in water. Soluble in ethanol. Miscible in ether

Purity

Sulphated ash	Not more than 0,1 %
Specific rotation	$[\alpha]_D^{20}$ not less than + 20 °
Arsenic	Not more than 3 mg/kg

▼B

Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
E 307 ALPHA-TOCOPHEROL	
Synonyms	dl- α -Tocopherol
Definition	
<i>Chemical name</i>	dl-5,7,8-Trimethyltolcol dl-2,5,7,8-tetramethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol
Einecs	200-412-2
<i>Chemical formula</i>	C ₂₉ H ₅₀ O ₂
<i>Molecular weight</i>	430,71
<i>Assay</i>	Content not less than 96 %
<i>Description</i>	Slightly yellow to amber, nearly odourless, clear, viscous oil which oxidizes and darkens on exposure to air or light
Identification	
A. Solubility tests	Insoluble in water, freely soluble in ethanol, miscible in ether
B. Spectrophotometry	In absolute ethanol the maximum absorption is about 292 nm
Purity	
Refractive index	n _D ²⁰ 1,503 — 1,507
Specific absorption E _{1 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	[α] _D ²⁰ 0 ° ± 0,05 ° (1 in 10 solution in chloroform)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 308 GAMMA-TOCOPHEROL

Synonyms	dl- γ -Tocopherol
Definition	
<i>Chemical name</i>	2,7,8-trimethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol
Einecs	231-523-4
<i>Chemical formula</i>	C ₂₈ H ₄₈ O ₂
<i>Molecular weight</i>	416,69
<i>Assay</i>	Content not less than 97 %
<i>Description</i>	Clear, viscous, pale yellow oil which oxidizes and darkens on exposure to air or light
Identification	
A. Spectrometry	Maximum absorptions in absolute ethanol at about 298 nm and 257 nm

▼B

Purity

Specific absorption $E_{1\text{ cm}}^{1\%}$ in ethanol	$E_{1\text{ cm}}^{1\%}$ (298 nm) between 91 and 97 $E_{1\text{ cm}}^{1\%}$ (257 nm) between 5,0 and 8,0
Refractive index	n_D^{20} 1,503—1,507
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 309 DELTA-TOCOPHEROL**Definition**

<i>Chemical name</i>	2,8-dimethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol
Einecs	204-299-0
<i>Chemical formula</i>	$C_{27}H_{46}O_2$
<i>Molecular weight</i>	402,7
<i>Assay</i>	Content not less than 97 %
<i>Description</i>	Clear, viscous, pale yellowish or orange oil which oxidizes and darkens on exposure to air or light

Identification

A. Spectrometry	Maximum absorptions in absolute ethanol at about 298 nm and 257 nm
-----------------	--

Purity

Specific absorption $E_{1\text{ cm}}^{1\%}$ in ethanol	$E_{1\text{ cm}}^{1\%}$ (298 nm) between 89 and 95 $E_{1\text{ cm}}^{1\%}$ (257 nm) between 3,0 and 6,0
Refractive index	n_D^{20} 1,500—1,504
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 310 PROPYL GALLATE**Definition**

<i>Chemical name</i>	Propyl gallate Propyl ester of gallic acid n-propyl ester of 3,4,5-trihydroxybenzoic acid
Einecs	204-498-2
<i>Chemical formula</i>	$C_{10}H_{12}O_5$
<i>Molecular weight</i>	212,20
<i>Assay</i>	Content not less than 98 % on the anhydrous basis
<i>Description</i>	White to creamy-white, crystalline, odourless solid

Identification

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

▼B

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

E 311 OCTYL GALLATE**Definition***Chemical name*

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

Einecs

213-853-0

Chemical formula $C_{15}H_{22}O_5$ *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 $E_{1\text{ cm}}^{1\%}$ in ethanol $E_{1\text{ cm}}^{1\%}$ (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

▼ **B****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 $E_{1\text{ cm}}^{1\%}$ in ethanol $E_{1\text{ cm}}^{1\%}$ (275 nm) not less than 300 and not more than 325

Arsenic

Not more than 3 mg/kg

Lead

Not more than 10 mg/kg

Mercury

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 30 mg/kg

E 315 ERYTHORBIC ACID**Synonyms**

Isoascorbic acid
D-araboascorbic acid

Definition*Chemical name*D-Erythro-hex-2-enoic acid γ -lactone

Isoascorbic acid

D-isoascorbic acid

Einecs

201-928-0

Chemical formula $C_6H_8O_6$ *Molecular weight*

176,13

Assay

Content not less than 98 % on the anhydrous basis

Description

White to slightly yellow crystalline solid which darkens gradually on exposure to light

Identification

A. Melting range

About 164 °C to 172 °C with decomposition

B. Positive test for ascorbic acid/colour reaction

Purity

Loss on drying

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

▼B

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

E 316 SODIUM ERYTHORBATE

Synonyms	Sodium isoascorbate
Definition	
<i>Chemical name</i>	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
<i>Chemical formula</i>	$C_6H_7O_6Na \cdot H_2O$
<i>Molecular weight</i>	216,13
<i>Assay</i>	Content not less than 98 % after drying in a vacuum desiccator over sulphuric acid for 24 hours expressed on the monohydrate basis
<i>Description</i>	White crystalline solid
Identification	
A. Solubility tests	Freely soluble in water, very slightly soluble in ethanol
B. Positive test for ascorbic acid/colour reaction	
C. Positive test for sodium	
Purity	
Loss on drying	Not more than 0,25 % after drying in a vacuum desiccator over sulphuric acid for 24 hours
Specific rotation	$[\alpha]_D^{25}$ 10 % (w/v) aqueous solution between $+95^\circ$ and $+98^\circ$
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

▼M2**E 320 BUTYLATED HYDROXYANISOLE (BHA)**

Synonyms	BHA
-----------------	-----

▼ **M2****Definition***Chemical names*

3-Tertiary-butyl-4-hydroxyanisole

A mixture of 2-tertiary-butyl-4-hydroxyanisole and 3-tertiary-butyl-4-hydroxyanisole

EINECS

246-563-8

Chemical formula $C_{11}H_{16}O_2$ *Formula weight*

180,25

*Assay*Content not less than 98,5 % of $C_{11}H_{16}O_2$ and not less than 85 % of 3-tertiary-butyl-4-hydroxyanisole isomer*Description*

White or slightly yellow crystals or waxy solid with a slight aromatic smell

Identification

A. Solubility

Insoluble in water, freely soluble in ethanol

B. Melting range

Between 48 °C and 63 °C

C. Colour reaction

Passes test for phenol groups

Purity

Sulphated ash

Not more than 0,05 % after calcination at 800 ± 25 °C

Phenolic impurities

Not more than 0,5 %

Specific absorption $E_{1cm}^{1\%}$ $E_{1cm}^{1\%}$ (290 nm) not less than 190 and not more than 210Specific absorption $E_{1cm}^{1\%}$ $E_{1cm}^{1\%}$ (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

▼ **B****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 %

▼B

Phenolic impurities	Not more than 0,5 %
Specific absorption $E_{1\text{ cm}}^{1\%}$ in ethanol	$E_{1\text{ cm}}^{1\%}$ (278 nm) not less than 81 and not more than 88
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 322 LECITHINS**Synonyms**

Phosphatides
Phospholipids

Definition

Lecithins are mixtures or fractions of phosphatides obtained by physical procedures from animal or vegetable foodstuffs; they also include hydrolysed products obtained through the use of harmless and appropriate enzymes. The final product must not show any signs of residual enzyme activity

The lecithins may be slightly bleached in aqueous medium by means of hydrogen peroxide. This oxidation must not chemically modify the lecithin phosphatides

Einecs

232-307-2

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

▼B**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***Chemical 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

▼B

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

E 327 CALCIUM LACTATE

Definition*Chemical name*

Calcium dilactate
 Calcium dilactate hydrate
 2-Hydroxypropanoic acid calcium salt

Einecs

212-406-7

Chemical formula $(C_3H_5O_2)_2 Ca \cdot nH_2O$ (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 -Hydroxytricarballic acid

Einecs

201-069-1

▼**B**

<i>Chemical formula</i>	(a) $C_6H_8O_7$ (anhydrous) (b) $C_6H_8O_7 \cdot H_2O$ (monohydrate)
<i>Molecular weight</i>	(a) 192,13 (anhydrous) (b) 210,15 (monohydrate)
<i>Assay</i>	Citric acid may be anhydrous or it may contain 1 molecule of water. Citric acid contains not less than 99,5 % of $C_6H_8O_7$, calculated on the anhydrous basis
<i>Description</i>	Citric acid is a white or colourless, odourless, crystalline solid, having a strongly acid taste. The monohydrate effloresces in dry air
Identification	
A. Solubility tests	Very soluble in water; freely soluble in ethanol; soluble in ether
Purity	
Water content	Anhydrous citric acid contains not more than 0,5 % water; citric acid monohydrate contains not more than 8,8 % water (Karl Fischer method)
Sulphated ash	Not more than 0,05 % after calcination at 800 ± 25 °C
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg
Oxalates	Not more than 100 mg/kg, expressed as oxalic acid, after drying
Readily carbonizable substances	Heat 1 g of powdered sample with 10 ml of 98 % minimum sulphuric acid in a water bath at 90 °C in the dark for one hour. Not more than a pale brown colour should be produced (Matching Fluid K)

E 331 (i) MONOSODIUM CITRATE

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

▼B

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

E 331 (ii) DISODIUM CITRATE

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

E 331 (iii) TRISODIUM CITRATE

Synonyms	Trisodium citrate Tribasic sodium citrate
Definition	
<i>Chemical name</i>	Trisodium citrate Trisodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Trisodium salt of citric acid, in anhydrous, dihydrate or pentahydrate form
Einecs	200-675-3
<i>Chemical formula</i>	Anhydrous: $C_6H_5O_7Na_3$ Hydrated: $C_6H_5O_7Na_3 \cdot nH_2O$ (n = 2 or 5)
<i>Molecular weight</i>	258,07 (anhydrous)
<i>Assay</i>	Not less than 99 % on the anhydrous basis

▼B

<i>Description</i>	Crystalline white powder or colourless crystals
Identification	
A. Positive tests for citrate and for sodium	
Purity	
Loss on drying	Determined by drying at 180 °C for four hours: — anhydrous: not more than 1,0 % — dihydrate: not more than 13,5 % — pentahydrate: not more than 30,3 %
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 5 % aqueous solution	Between 7,5 and 9,0
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

E 332 (i) MONOPOTASSIUM CITRATE

Synonyms	Monopotassium citrate Monobasic potassium citrate
Definition	
<i>Chemical name</i>	Monopotassium citrate Monopotassium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid Anhydrous monopotassium salt of citric acid
Einecs	212-753-4
<i>Chemical formula</i>	$C_6H_7O_7K$
<i>Molecular weight</i>	230,21
<i>Assay</i>	Content not less than 99 % on the anhydrous basis
<i>Description</i>	White, hygroscopic, granular powder or transparent crystals
Identification	
A. Positive tests for citrate and for potassium	
Purity	
Loss on drying	Not more than 1,0 % determined by drying at 180 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 1 % aqueous solution	Between 3,5 and 3,8
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

E 332 (ii) TRIPOTASSIUM CITRATE

Synonyms	Tripotassium citrate Tribasic potassium citrate
-----------------	--

▼ **B****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

▼**B**

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

▼ **B****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

C₄H₆O₆

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
B. Positive test for tartrate

Between 168 °C and 170 °C

Purity

Loss on drying	Not more than 0,5 % (over P ₂ O ₅ , three hours)
Sulphated ash	Not more than 1 000 mg/kg after calcination at 800 ± 25 °C
Specific optical rotation of a 20 % w/v aqueous solution	$[\alpha]_D^{20}$ between + 11,5 ° and + 13,5 °
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

▼B

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

E 335 (ii) DISODIUM TARTRATE

Definition	
<i>Chemical name</i>	Disodium L-tartrate Disodium (+)-tartrate Disodium (+)-2,3-dihydroxybutanedioic acid Dihydrated disodium salt of L-(+)-tartaric acid
Einecs	212-773-3
<i>Chemical formula</i>	$C_4H_4O_6Na_2 \cdot 2H_2O$
<i>Molecular weight</i>	230,8
<i>Assay</i>	Content not less than 99 % on the anhydrous basis
<i>Description</i>	Transparent, colourless crystals
Identification	
A. Positive tests for tartrate and for sodium	
B. Solubility tests	1 gram is insoluble in 3 ml of water. Insoluble in ethanol
Purity	
Loss on drying	Not more than 17,0 % determined by drying at 150 °C for four hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of a 1 % aqueous solution	Between 7,0 and 7,5
Arsenic	Not more than 3 mg/kg
Lead	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
-----------------	------------------------------

▼ **B****Definition**

<i>Chemical name</i>	Anhydrous monopotassium salt of L-(+)-tartaric acid Monopotassium salt of L-2,3-dihydroxybutanedioic acid
<i>Chemical formula</i>	$C_4H_5O_6K$
<i>Molecular weight</i>	188,16
<i>Assay</i>	Content not less than 98 % on the anhydrous basis
<i>Description</i>	White crystalline or granulated powder

Identification

A. Positive tests for tartrate and for potassium	
B. Melting point	230 °C

Purity

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

E 336 (ii) DIPOTASSIUM TARTRATE**Synonyms**

Dibasic potassium tartrate

Definition

<i>Chemical name</i>	Dipotassium salt of L-2,3-dihydroxybutanedioic acid Dipotassium salt with half a molecule of water of L-(+)-tartaric acid
----------------------	--

Einecs

213-067-8

Chemical formula $C_4H_4O_6K_2 \cdot \frac{1}{2}H_2O$ *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

▼ **B****E 337 POTASSIUM SODIUM TARTRATE**

Synonyms	Potassium sodium L-(+)-tartrate Rochelle salt Seignette salt
Definition	
<i>Chemical name</i>	Potassium sodium salt of L-2,3-dihydroxybutanedioic acid Potassium sodium L-(+)-tartrate
Einecs	206-156-8
<i>Chemical formula</i>	$C_4H_4O_6KNa \cdot 4H_2O$
<i>Molecular weight</i>	282,23
<i>Assay</i>	Content not less than 99 % on the anhydrous basis
<i>Description</i>	Colourless crystals or white crystalline powder
Identification	
A. Positive tests for tartrate, for potassium and for sodium	
B. Solubility tests	1 gram is soluble in 1 ml of water, insoluble in ethanol
C. Melting range	Between 70 and 80 °C
Purity	
Loss on drying	Not more than 26,0 % and not less than 21,0 % determined by drying at 150 °C for three hours
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
pH of 1 % aqueous solution	Between 6,5 and 8,5
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

▼ **M4****E 338 PHOSPHORIC ACID**

Synonyms	Orthophosphoric acid Monophosphoric acid
Definition	
<i>Chemical name</i>	Phosphoric acid
Einecs	231-633-2
<i>Chemical formula</i>	H_3PO_4
<i>Molecular weight</i>	98,00
<i>Assay</i>	Phosphoric acid is commercially available as an aqueous solution at variable concentrations. Content not less than 67,0 % and not more than 85,7 %.
<i>Description</i>	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)

▼ **M4**

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

Note:

This specification refers to a 75 % aqueous solution.

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

Monosodium monophosphate
Acid monosodium monophosphate
Monosodium orthophosphate
Monobasic sodium phosphate
Sodium dihydrogen monophosphate

Definition*Chemical name*

Sodium dihydrogen monophosphate

Einecs

231-449-2

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

Anhydrous: 119,98

Monohydrate: 138,00

Dihydrate: 156,01

Assay

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

P₂O₅ content

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

Description

A white odourless, slightly deliquescent powder, crystals or granules

Identification

A. Positive tests for sodium and for phosphate

B. Solubility

Freely soluble in water. Insoluble in ethanol or ether

C. pH of a 1 % solution

Between 4,1 and 5,0

Purity

Loss on drying

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

Water-insoluble substances

Not more than 0,2 % on the anhydrous basis

Fluoride

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

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

▼ **M4****E 339 (ii) DISODIUM PHOSPHATE**

Synonyms	Disodium monophosphate Secondary sodium phosphate Disodium orthophosphate Acid disodium phosphate
Definition	
<i>Chemical name</i>	Disodium hydrogen monophosphate Disodium hydrogen orthophosphate
Einecs	231-448-7
<i>Chemical formula</i>	Anhydrous: Na ₂ HPO ₄ Hydrat: Na ₂ HPO ₄ · nH ₂ O (n = 2, 7 or 12)
<i>Molecular weight</i>	141,98 (anhydrous)
<i>Assay</i>	After drying at 40 °C for three hours and subsequently at 105 °C for five hours, contains not less than 98 % of Na ₂ HPO ₄
<i>P₂O₅ content</i>	Between 49 % and 51 % on the anhydrous basis
<i>Description</i>	Anhydrous disodium hydrogen phosphate is a white, hygroscopic, odourless powder. Hydrated forms available include the dihydrate: a white crystalline, odourless solid; the heptahydrate: white, odourless, efflorescent crystals or granular powder; and the dodecahydrate: white, efflorescent, odourless powder or crystals
Identification	
A. Positive tests for sodium and for phosphate	
B. Solubility	Freely soluble in water. Insoluble in ethanol
C. pH of a 1 % solution	Between 8,4 and 9,6
Purity	
Loss on drying	When dried at 40 °C for three hours and then at 105°C for five hours, the losses in weight are as follows: anhydrous not more than 5,0 %, dihydrate not more than 22,0 %, heptahydrate not more than 50,0 %, dodecahydrate not more than 61,0 %
Water-insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 339 (iii) TRISODIUM PHOSPHATE

Synonyms	Sodium phosphate Tribasic sodium phosphate Trisodium orthophosphate
Definition	
	Trisodium phosphate is obtained from aqueous solutions and crystallises in the anhydrous form and with 1/2, 1, 6, 8 or 12 H ₂ O. The dodecahydrate always crystallises from aqueous solutions with an excess of sodium hydroxide. It contains ¼ molecule of NaOH

▼ **M4**

<i>Chemical name</i>	Trisodium monophosphate Trisodium phosphate Trisodium orthophosphate
Einecs	231-509-8
<i>Chemical formula</i>	Anhydrous: Na_3PO_4 Hydrated: $\text{Na}_3\text{PO}_4 \cdot n\text{H}_2\text{O}$ (n = 1/2, 1, 6, 8, or 12)
<i>Molecular weight</i>	163,94 (anhydrous)
<i>Assay</i>	Sodium phosphate anhydrous and the hydrated forms, with the exception of the dodecahydrate, contain not less than 97,0 % of Na_3PO_4 calculated on the dried basis. Sodium phosphate dodecahydrate contains not less than 92,0 % of Na_3PO_4 calculated on the ignited basis
<i>P₂O₅ content</i>	Between 40,5 % and 43,5 % on the anhydrous basis
<i>Description</i>	White odourless crystals, granules or crystalline powder
Identification	
A. Positive tests for sodium and for phosphate	
B. Solubility	Freely soluble in water. Insoluble in ethanol
C. pH of a 1 % solution	Between 11,5 and 12,5
Purity	
Loss on ignition	When dried at 120 °C for two hours and then ignited at about 800 °C for 30 minutes, the losses in weight are as follows: anhydrous not more than 2,0 %, monohydrate not more than 11,0 %, dodecahydrate: between 45,0 % and 58,0 %
Water insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 340 (i) MONOPOTASSIUM PHOSPHATE

Synonyms	Monobasic potassium phosphate Monopotassium monophosphate Potassium orthophosphate
Definition	
<i>Chemical name</i>	Potassium dihydrogen phosphate Monopotassium dihydrogen orthophosphate Monopotassium dihydrogen monophosphate
Einecs	231-913-4
<i>Chemical formula</i>	KH_2PO_4
<i>Molecular weight</i>	136,09
<i>Assay</i>	Content not less than 98,0 % after drying at 105 °C for four hours
<i>P₂O₅ content</i>	Between 51,0 % and 53,0 % on the anhydrous basis
<i>Description</i>	Odourless, colourless crystals or white granular or crystalline powder, hygroscopic

▼ **M4****Identification**

- A. Positive tests for potassium and for phosphate
- B. Solubility
- C. pH of a 1 % solution

Freely soluble in water. Insoluble in ethanol

Between 4,2 and 4,8

Purity

- Loss on drying
- Water-insoluble substances
- Fluoride
- Arsenic
- Cadmium
- Lead
- Mercury

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

Not more than 0,2 % on the anhydrous basis

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

Not more than 3 mg/kg

Not more than 1 mg/kg

Not more than 4 mg/kg

Not more than 1 mg/kg

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

P₂O₅ content

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

Description

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

Identification

- A. Positive tests for potassium and for phosphate
- B. Solubility
- C. pH of a 1 % solution

Freely soluble in water. Insoluble in ethanol

Between 8,7 and 9,4

Purity

- Loss on drying
- Water-insoluble substances
- Fluoride
- Arsenic
- Cadmium
- Lead
- Mercury

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

Not more than 0,2 % on the anhydrous basis

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

Not more than 3 mg/kg

Not more than 1 mg/kg

Not more than 4 mg/kg

Not more than 1 mg/kg

▼ **M4****E 340 (iii) TRIPOTASSIUM PHOSPHATE**

Synonyms	Potassium phosphate Tribasic potassium phosphate Tripotassium orthophosphate
Definition	
<i>Chemical name</i>	Tripotassium monophosphate Tripotassium phosphate Tripotassium orthophosphate
Einecs	231-907-1
<i>Chemical formula</i>	Anhydrous: K_3PO_4 Hydrated: $K_3PO_4 \cdot nH_2O$ (n = 1 or 3)
<i>Molecular weight</i>	212,27 (anhydrous)
<i>Assay</i>	Content not less than 97 % calculated on the ignited basis
<i>P₂O₅ content</i>	Between 30,5 % and 33,0 % on the ignited basis
<i>Description</i>	Colourless or white, odourless hygroscopic crystals or granules. Hydrated forms available include the monohydrate and trihydrate
Identification	
A. Positive tests for potassium and for phosphate	
B. Solubility	Freely soluble in water. Insoluble in ethanol
C. pH of a 1 % solution	Between 11,5 and 12,3
Purity	
Loss on ignition	Anhydrous: not more than 3,0 %; hydrated: not more than 23,0 %. Determined by drying at 105 °C for one hour and then ignite at about 800 °C ± 25 °C for 30 minutes
Water insoluble substances	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 341 (i) MONOCALCIUM PHOSPHATE

Synonyms	Monobasic calcium phosphate Monocalcium orthophosphate
Definition	
<i>Chemical name</i>	Calcium dihydrogen phosphate
Einecs	231-837-1
<i>Chemical formula</i>	Anhydrous: $Ca(H_2PO_4)_2$ Monohydrate: $Ca(H_2PO_4)_2 \cdot H_2O$
<i>Molecular weight</i>	234,05 (anhydrous) 252,08 (monohydrate)
<i>Assay</i>	Content not less than 95 % on the dried basis
<i>P₂O₅ content</i>	Between 55,5 % and 61,1 % on the anhydrous basis

▼ **M4**

<i>Description</i>	Granular powder or white, deliquescent crystals or granules
Identification	
A. Positive tests for calcium and for phosphate	
B. CaO content	Between 23,0 % and 27,5 % (anhydrous) Between 19,0 % and 24,8 % (monohydrate)
Purity	
Loss on drying	Not more than 14 % determined by drying at 105 °C for four hours (anhydrous) Not more than 17,5 % determined by drying at 60 °C for one hour, then at 105 °C for four hours (monohydrate)
Loss on ignition	Not more than 17,5 % after ignition at 800 °C ± 25 °C for 30 minutes (anhydrous) Not more than 25,0 % determined by drying at 105 °C for one hour, then ignite at 800 °C ± 25 °C for 30 minutes (monohydrate)
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 341 (ii) DICALCIUM PHOSPHATE

Synonyms	Dibasic calcium phosphate Dicalcium orthophosphate
Definition	
<i>Chemical name</i>	Calcium monohydrogen phosphate Calcium hydrogen orthophosphate Secondary calcium phosphate
Einecs	231-826-1
<i>Chemical formula</i>	Anhydrous: CaHPO_4 Dihydrate: $\text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$
<i>Molecular weight</i>	136,06 (anhydrous) 172,09 (dihydrate)
<i>Assay</i>	Dicalcium phosphate, after drying at 200 °C for three hours, contains not less than 98 % and not more than the equivalent of 102 % of CaHPO_4
<i>P₂O₅ content</i>	Between 50,0 % and 52,5 % on the anhydrous basis
<i>Description</i>	White crystals or granules, granular powder or powder
Identification	
A. Positive tests for calcium and for phosphate	
B. Solubility tests	Sparingly soluble in water. Insoluble in ethanol
Purity	
Loss on ignition	Not more than 8,5 % (anhydrous), or 26,5 % (dihydrate) after ignition at 800 °C ± 25 °C for 30 minutes
Fluoride	Not more than 50 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg

▼ **M4**

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

E 341 (iii) TRICALCIUM PHOSPHATE

Synonyms	Calcium phosphate, tribasic Calcium orthophosphate Pentacalcium hydroxy monophosphate Calcium hydroxyapatite
Definition	Tricalcium phosphate consists of a variable mixture of calcium phosphates obtained from neutralisation of phosphoric acid with calcium hydroxide and having the approximate composition of $10\text{CaO} \cdot 3\text{P}_2\text{O}_5 \cdot \text{H}_2\text{O}$
<i>Chemical name</i>	Pentacalcium hydroxy monophosphate Tricalcium monophosphate
Einecs	235-330-6 (<i>Pentacalcium hydroxy monophosphate</i>) 231-840-8 (<i>Calcium orthophosphate</i>)
<i>Chemical formula</i>	$\text{Ca}_3(\text{PO}_4)_3 \cdot \text{OH}$ or $\text{Ca}_3(\text{PO}_4)_2$
<i>Molecular weight</i>	502 or 310
<i>Assay</i>	Content not less than 90 % calculated on the ignited basis
<i>P₂O₅ content</i>	Between 38,5 % and 48,0 % on the anhydrous basis
<i>Description</i>	A white, odourless powder which is stable in air
Identification	
A. Positive tests for calcium and for phosphate	
B. Solubility	Practically insoluble in water; insoluble in ethanol, soluble in dilute hydrochloric and nitric acid
Purity	
Loss on ignition	Not more than 8 % after ignition at $800\text{ °C} \pm 25\text{ °C}$, to constant weight
Fluoride	Not more than 50 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

▼ **B****E 385 CALCIUM DISODIUM ETHYLENEDIAMINETETRAACETATE**

Synonyms	Calcium disodium EDTA Calcium disodium edetate
Definition	
<i>Chemical name</i>	$\text{N}_2\text{N}'\text{-1,2-Ethanediybis [N-(carboxymethyl)-glycinate]}$ [(4-)-O,O',O ^N ,O ^N]calciate(2)-disodium Calcium disodium ethylenediaminetetra acetate Calcium disodium (ethylenedinitrilo)tetra acetate
Einecs	200-529-9
<i>Chemical formula</i>	$\text{C}_{10}\text{H}_{12}\text{O}_8\text{CaN}_2\text{Na}_2 \cdot 2\text{H}_2\text{O}$
<i>Molecular weight</i>	410,31
<i>Assay</i>	Content not less than 97 % on the anhydrous basis

▼B

<i>Description</i>	White, odourless crystalline granules or white to nearly white powder, slightly hygroscopic
Identification	
A. Positive tests for sodium and for calcium	
B. Chelating activity to metal ions positive	
C. pH of a 1 % solution between 6,5 and 7,5	
Purity	
Water content	5 to 13 % (Karl Fischer method)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

▼M1

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

E 400 ALGINIC ACID

Definition	Linear glycuronoglycan consisting mainly of β -(1-4) linked D-mannuronic and α -(1-4) linked L-guluronic acid units in pyranose ring form. Hydrophilic colloidal carbohydrate extracted by the use of dilute alkali from natural strains of various species of brown seaweeds (<i>Phaeophyceae</i>)
Einecs	232-680-1
<i>Chemical formula</i>	$(C_6H_8O_6)_n$
<i>Molecular weight</i>	10 000—600 000 (typical average)
<i>Assay</i>	Alginic acid yields, on the anhydrous basis, not less than 20 % and not more than 23 % of carbon dioxide (CO ₂), equivalent to not less than 91 % and not more than 104,5 % of alginic acid $(C_6H_8O_6)_n$ (calculated on equivalent weight basis of 200)
<i>Description</i>	Alginic acid occurs in filamentous, grainy, granular and powdered forms. It is a white to yellowish brown and nearly odourless
Identification	
A. Solubility	Insoluble in water and organic solvents, slowly soluble in solutions of sodium carbonate, sodium hydroxide and trisodium phosphate
B. Calcium chloride precipitation test	To a 0,5 % solution of the sample in 1 M sodium hydroxide solution, add one fifth of its volume of a 2,5 % solution of calcium chloride. A voluminous, gelatinous precipitate is formed. This test distinguishes alginic acid from acacia gum, sodium carboxymethyl cellulose, carboxymethyl starch, carrageenan, gelatin, gum ghatti, karaya gum, locust bean gum, methyl cellulose and tragacanth gum
C. Ammonium sulphate precipitation test	To a 0,5 % solution of the sample in 1 M sodium hydroxide solution, add one half of its volume of a saturated solution of ammonium sulphate. No precipitate is formed. This test distinguishes alginic acid from agar, sodium carboxymethyl cellulose, carrageenan, de-esterified pectin, gelatin, locust bean gum, methyl cellulose and starch

▼ **M1**

D. Colour reaction	Dissolve as completely as possible 0,01 g of the sample by shaking with 0,15 ml of 0,1 N sodium hydroxide and add 1 ml of acid ferric sulphate solution. Within 5 minutes, a cherry-red colour develops that finally becomes deep purple
Purity	
pH of a 3 % suspension	Between 2,0 and 3,5
Loss on drying	Not more than 15 % (105 °C, 4 hours)
Sulphated ash	Not more than 8 % on the anhydrous basis
Sodium hydroxide (1 M solution)	Not more than 2 % on the anhydrous basis insoluble matter
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

E 401 SODIUM ALGINATE**Definition**

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

Identification

A. Positive test for sodium and alginic acid

Purity

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

▼ **M1****E 402 POTASSIUM ALGINATE****Definition***Chemical name*

Potassium salt of alginic acid

Chemical formula $(C_6H_7KO)_n$ *Molecular weight*

10 000-600 000 (typical average)

Assay

Yields, on the anhydrous basis, not less than 16,5 % and not more than 19,5 % of carbon dioxide corresponding to not less than 89,2 % and not more than 105,5 % of potassium alginate (calculated on an equivalent weight basis of 238)

Description

Nearly odourless, white to yellowish fibrous or granular powder

Identification

A. Positive test for potassium and for alginic acid

Purity

Loss on drying

Not more than 15 % (105 °C, 4 hours)

Water-insoluble matter

Not more than 2 % on the anhydrous basis

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 20 mg/kg

Total plate count

Not more than 5 000 colonies per gram

Yeast and moulds

Not more than 500 colonies per gram

E. coli

Negative in 5 g

Salmonella spp.

Negative in 10 g

E 403 AMMONIUM ALGINATE**Definition***Chemical name*

Ammonium salt of alginic acid

Chemical formula $(C_6H_{11}NO)_n$ *Molecular weight*

10 000-600 000 (typical average)

Assay

Yields, on the anhydrous basis, not less than 18 % and not more than 21 % of carbon dioxide corresponding to not less than 88,7 % and not more than 103,6 % ammonium alginate (calculated on an equivalent weight basis of 217)

Description

White to yellowish fibrous or granular powder

Identification

A. Positive test for ammonium and alginic acid

Purity

Loss on drying

Not more than 15 % (105 °C, 4 hours)

Sulphated ash

Not more than 7 % on the dried basis

Water-insoluble matter

Not more than 2 % on the anhydrous basis

Arsenic

Not more than 3 mg/kg

▼ **M1**

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

E 404 CALCIUM ALGINATE**Synonyms**

Calcium salt of alginate

Definition*Chemical name*

Calcium salt of alginic acid

Chemical formula $(C_6H_7Ca_{1/2}O_6)_n$ *Molecular weight*

10 000-600 000 (typical average)

Assay

Yields, on the anhydrous basis, not less than 18 % and not more than 21 % carbon dioxide corresponding to not less than 89,6 % and not more than 104,5 % of calcium alginate (calculated on an equivalent weight basis of 219)

Description

Nearly odourless, white to yellowish fibrous or granular powder

Identification

A. Positive test for calcium and alginic acid

Purity

Loss on drying	Not more than 15,0 % (105 °C, 4 hours)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

E 405 PROPANE-1,2-DIOL ALGINATE**Synonyms**

Hydroxypropyl alginate
1,2-propanediol ester of alginic acid
Propylene glycol alginate

Definition*Chemical name*

Propane-1,2-diol ester of alginic acid; varies in composition according to its degree of esterification and the percentage of free and neutralised carboxyl groups in the molecule

Chemical formula

$(C_9H_{14}O_7)_n$
(esterified)

Molecular weight

10 000—600 000 (typical average)

▼ **M1**

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

E 406 AGAR**Synonyms**

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

Definition*Chemical name*

Agar is a hydrophilic colloidal polysaccharide consisting mainly of D-galactose units. On about every tenth D-galactopyranose unit one of the hydroxyl groups is esterified with sulphuric acid which is neutralised by calcium, magnesium, potassium or sodium. It is extracted from certain natural strains of marine algae of the families *Gelidiaceae* and *Sphaerococcaceae* and related red algae of the class *Rhodophyceae*

Einecs

232-658-1

Assay

The threshold gel concentration should not be higher than 0,25 %

Description

Agar is odourless or has a slight characteristic odour. Underground agar usually occurs in bundles consisting of thin, membranous, agglutinated strips, or in cut, flaked or granulated forms. It may be light yellowish-orange, yellowish-grey to pale yellow, or colourless. It is tough when damp, brittle when dry. Powdered agar is white to yellowish-white or pale yellow. When examined in water under a microscope, the agar appears granular and somewhat filamentous. A few fragments of the spicules of sponges and a few frustules of diatoms may be present. In chloral hydrate solution, the powdered agar appears more transparent than in water, more or less granular, striated, angular and occasionally contains frustules of diatoms. Gel strength may be standardised by the addition of dextrose and maltodextrines or sucrose

▼ **M1****Identification**

A. Solubility

Insoluble in cold water; soluble in boiling water

Purity

Loss on drying

Not more than 22 % (105 °C, 5 hours)

Ash

Not more than 6,5 % on the anhydrous basis determined at 550 °C

Acid-insoluble ash (insoluble in approximately 3N Hydrochloric acid)

Not more than 0,5 % determined at 550 °C on the anhydrous basis

Insoluble matter (in hot water)

Not more than 1,0 %

Starch

Not detectable by the following method: to a 1 in 10 solution of the sample add a few drops of iodine solution. No blue colour is produced

Gelatin and other proteins

Dissolve about 1 g of agar in 100 ml of boiling water and allow to cool of about 50 °C. To 5 ml of the solution add 5 ml of trinitrophenol solution (1 g of anhydrous trinitrophenol/100 ml of hot water). No turbidity appears within 10 minutes

Water absorption

Place 5 g to agar in a 100 ml graduated cylinder, fill to the mark with water, mix and allow to stand at about 25 °C for 24 hours. Pour the contents of the cylinder through moistened glass wool, allowing the water to drain into a second 100 ml graduated cylinder. Not more than 75 ml of water is obtained

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 20 mg/kg

E 407 CARRAGEENAN**Synonyms**

Products of commerce are sold under different names such as:

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

Definition

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

Einecs

232-524-2

Description

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

Identification

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

▼ **M1****Purity**

Methanol, ethanol propane-2-ol content	Not more than 0,1 % singly or in combination
Viscosity of a 1,5 % solution at 75 °C	Not less than 5 mPa.s
Loss on drying	Not more than 12 % (105 °C, 4 hours)
Sulphate	Not less than 15 % and not more than 40 % on the anhydrous basis (as SO ₄)
Ash	Not less than 15 % and not more than 40 % determined on the anhydrous basis at 550 °C
Acid-insoluble ash	Not more than 1 % on the anhydrous basis (insoluble in 10 % hydrochloric acid)
Acid-insoluble matter	Not more than 2 % on the anhydrous basis (insoluble in 1 % v/v sulphuric acid)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

E 407a PROCESSED EUCHEUMA SEAWEED**Synonyms**

PES (acronym for processed eucheuma seaweed)

Definition

Processed eucheuma seaweed is obtained by aqueous alkaline (KOH) treatment of the natural strains of seaweeds *Eucheuma cottonii* und *Eucheuma spinosum*, of the class *Rhodophyceae* (red seaweeds) to remove impurities and by fresh water washing and drying to obtain the product. Further purification may be achieved by washing with methanol, ethanol or propane-2-ol and drying. The product consists chiefly of the potassium salts of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3,6-anhydrogalactose. Sodium, calcium and magnesium salts of the polysaccharide sulphate esters are present in lesser amounts. Up to 15 % algal cellulose is also present in the product. The carrageenan in processed eucheuma seaweed shall not be hydrolysed or otherwise chemically degraded

Description

Tan to yellowish, coarse to fine powder which is practically odourless

Identification

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

Forms cloudy viscous suspensions in water. Insoluble in ethanol

Purity

Methanol, ethanol, propane-2-ol content	Not more than 0,1 % singly or in combination
Viscosity of a 1,5 % solution at 75 °C	Not less than 5 mPa.s
Loss on drying	Not more than 12 % (105 °C, 4 hours)
Sulphate	Not less than 15 % and not more than 40 % on the dried basis (as SO ₄)

▼ **M1**

Ash	Not less than 1 % and not more than 40 % determined on the dried basis at 550 °C
Acid-insoluble ash	Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)
Acid-insoluble matter	Not less than 8 % and not more than 15 % on the dried basis (insoluble in 1 % v/v sulphuric acid)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and mould	Not more than 300 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

E 410 LOCUST BEAN GUM**Synonyms**

Carob bean gum
Algaroba gum

Definition

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

Molecular weight

50 000—3 000 000

Einecs

232-541-5

Assay

Galactomannan content not less than 75 %

Description

White to yellowish-white, nearly odourless powder

Identification

- A. Positive tests for galactose mannose
B. Microscopic examination

Place some ground sample in an aqueous solution containing 0,5 % iodine and 1 % potassium iodide on a glass slide and examine under microscope. Locust bean gum contains long stretched tubiform cells, separated or slightly interspaced. Their brown contents are much less regularly formed in guar gum. Guar gum shows close groups of round to pear shaped cells. Their contents are yellow to brown

- C. Solubility

Soluble in hot water, insoluble in ethanol

Purity

- Loss on drying

Not more than 15 % (105 °C, 5 hours)

- Ash

Not more than 1,2 % determined at 800 °C

- Protein (N × 6,25)

Not more than 7 %

- Acid-insoluble matter

Not more than 4 %

- Starch

Not detectable by the following method: to a 1 in 10 solution of the sample add a few drops of iodine solution. No blue colour is produced

- Arsenic

Not more than 3 mg/kg

- Lead

Not more than 5 mg/kg

- Mercury

Not more than 1 mg/kg

- Cadmium

Not more than 1 mg/kg

▼ **M1**

Heavy metals (as Pb)	Not more than 20 mg/kg
Ethanol and propane-2-ol	Not more than 1 %, single or in combination
E 412 GUAR GUM	
Synonyms	Gum cyamopsis Guar flour
Definition	Guar gum is the ground endosperm of the seeds of natural strains of the guar plant, <i>Cyamopsis tetragonolobus</i> (L.) Taub. (family <i>Leguminosae</i>). Consists mainly of a high molecular weight hydrocolloidal polysaccharide composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as galactomannan
Einecs	232-536-0
<i>Molecular weight</i>	50 000—8 000 000
<i>Assay</i>	Galactomannan content not less than 75 %
<i>Description</i>	A white to yellowish-white, nearly odourless powder
Identification	
A. Positive tests for galactose and for mannose	
B. Solubility	Soluble in cold water
Purity	
Loss on drying	Not more than 15 % (105 °C, 5 hours)
Ash	Not more than 1,5 % determined at 800 °C
Acid-insoluble matter	Not more than 7 %
Protein (N × 6,25)	Not more than 10 %
Starch	Not detectable by the following method: to a 1 in 10 solution of the sample add a few drops of iodine solution. (No blue colour is produced)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 413 TRAGACANTH

Synonyms	Tragacanth gum Tragant
Definition	Tragacanth is a dried exudation obtained from the stems and branches of natural strains of <i>Astragalus gummifer</i> Labillardiere and other Asiatic species of <i>Astragalus</i> (family <i>Leguminosae</i>). It consists mainly of high molecular weight polysaccharides (galactoarabans and acidic polysaccharides) which, on hydrolysis, yield galacturonic acid, galactose, arabinose, xylose and fucose. Small amounts of rhamnose and of glucose (derived from traces of starch and/or cellulose) may also be present
<i>Molecular weight</i>	Approximately 8 000 000
Einecs	232-252-5

▼ **M1**

<i>Description</i>	Unground Tragacanth gum occurs as flattened, lamellated, straight or curved fragments or as spirally twisted pieces 0,5-2,5 mm thick and up to 3 cm in length. It is white to pale yellow in colour but some pieces may have a red tinge. The pieces are horny in texture, with a short fracture. It is odourless and solutions have an insipid mucilaginous taste. Powdered tragacanth is white to pale yellow or pinkish brown (pale tan) in colour
Identification	
A. Solubility	1 g of the sample in 50 ml of water swells to form a smooth, stiff, opalescent mucilage; insoluble in ethanol and does not swell in 60 % (w/v) aqueous ethanol
Purity	
Negative test for Karaya gum	Boil 1 g with 20 ml of water until a mucilage is formed. Add 5 ml of hydrochloric acid and again boil the mixture for five minutes. No permanent pink or red colour develops
Loss on drying	Not more than 16 % (105 °C, 5 hours)
Total ash	Not more than 4 %
Acid insoluble ash	Not more than 0,5 %
Acid insoluble matter	Not more than 2 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
<i>Salmonella</i> spp.	Negative in 10 g
<i>E. coli</i>	Negative in 5 g

E 414 ACACIA GUM

Synonyms	Gum arabic
Definition	Acacia gum is a dried exudation obtained from the stems and branches of natural strains of <i>Acacia senegal</i> (L) Willdenow or closely related species of <i>Acacia</i> (family <i>Leguminosae</i>). It consists mainly of high molecular weight polysaccharides and their calcium, magnesium and potassium salts, which on hydrolysis yield arabinose, galactose, rhamnose and glucuronic acid
<i>Molecular weight</i>	Approximately 350 000
Einecs	232-519-5
<i>Description</i>	Unground acacia gum occurs as white or yellowish-white spheroidal tears of varying sizes or as angular fragments and is sometimes mixed with darker fragments. It is also available in the form of white to yellowish-white flakes, granules, powder or spray-dried material.
Identification	
A. Solubility	1 g dissolves in 2 ml of cold water forming a solution which flows readily and is acid to litmus, insoluble in ethanol
Purity	
Loss on drying	Not more than 17 % (105 °C, 5 hours) for granular and not more than 10 % (105 °C, 4 hours) for spray-dried material

▼ **M1**

Total ash	Not more than 4 %
Acid insoluble ash	Not more than 0,5 %
Acid insoluble matter	Not more than 1 %
Starch or dextrin	Boil a 1 in 50 solution of the gum and cool. To 5 ml add 1 drop of iodine solution. No bluish or reddish colours are produced
Tannin	To 10 ml of a 1 in 50 solution add about 0,1 ml of ferric chloride solution (9 g FeCl ₃ .6H ₂ O made up to 100 ml with water). No blackish colouration or blackish precipitate is formed
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Hydrolysis products	Mannose, xylose and galacturonic acid are absent (determined by chromatography)
<i>Salmonella</i> spp.	Negative in 10 g
<i>E. coli</i>	Negative in 5 g

E 415 XANTHAN GUM**Definition**

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

Molecular weight

Approximately 1 000 000

Einecs

234-394-2

Assay

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

Description

Cream-coloured powder

Identification

A. Solubility

Soluble in water. Insoluble in ethanol

Purity

Loss on drying

Not more than 15 % (105 °C, 2½ hours)

Total ash

Not more than 16 % on the anhydrous basis determined at 650 °C after drying at 105 °C for four hours

Pyruvic acid

Not less than 1,5 %

Nitrogen

Not more than 1,5 %

Propane-2-ol

Not more than 500 mg/kg

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 20 mg/kg

Total plate count

Not more than 10 000 colonies per gram

Yeast and mould

Not more than 300 colonies per gram

▼ **M1**

<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g
<i>Xanthomonas campestris</i>	Viable cells absent

E 416 KARAYA-GUM**Synonyms**

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

Definition

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

Einecs

232-539-4

Description

Karaya gum occurs in tears of variable size and in broken irregular pieces having a characteristic semi-crystalline appearance. It is pale yellow to pinkish brown in colour, translucent and horny. Powdered karaya gum is a pale grey to pinkish brown. The gum has a distinctive odour of acetic acid

Identification

A. Solubility

Insoluble in ethanol

B. Swelling in ethanol solution

Karaya gum swells in 60 % ethanol distinguishing it from other gums

Purity

Loss on drying

Not more than 20 % (105 °C, 5 hours)

Total ash

Not more than 8 %

Acid insoluble ash

Not more than 1 %

Acid insoluble matter

Not more than 3 %

Volatile acid

Not less than 10 % (as acetic acid)

Starch

Not detectable

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 20 mg/kg

Salmonella spp.

Negative in 10 g

E. coli

Negative in 5 g

▼ **M1****E 417 TARA GUM****Definition**

Tara gum is obtained by grinding the endosperm of the seeds of natural strains of *Caesalpinia spinosa* (family *Leguminosae*). It consists chiefly of polysaccharides of high molecular weight composed mainly of galactomannans. The principal component consists of a linear chain of (1-4)- β -D-mannopyranose units with α -D-galactopyranose units attached by (1-6) linkages. The ratio of mannose to galactose in tara gum is 3:1. (In locust bean gum this ratio is 4:1 and in guar gum 2:1)

Einecs

254-409-6

Description

A white to white-yellow odourless powder

Identification

A. Solubility

Soluble in water

Insoluble in ethanol

B. Gel formation

To an aqueous solution of the sample add small amounts of sodium borate. A gel is formed

Purity

Loss on drying

Not more than 15 %

Ash

Not more than 1,5 %

Acid insoluble matter

Not more than 2 %

Protein

Not more than 3,5 % (factor N x 5,7)

Starch

Not detectable

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 20 mg/kg

E 418 GELLAN GUM**Definition**

Gellan gum is a high molecular weight polysaccharide gum produced by a pure culture fermentation of a carbohydrate by natural strains of *Pseudomonas elodea*, purified by recovery with isopropyl alcohol, dried, and milled. The high molecular weight polysaccharide is principally composed of a tetrasaccharide repeating unit of one rhamnose, one glucuronic acid, and two glucoses, and substituted with acyl (glyceryl and acetyl) groups as the O-glycosidically linked esters. The glucuronic acid is neutralised to a mixed potassium, sodium, calcium, and magnesium salt

Einecs

275-117-5

Molecular weight

Approximately 500 000

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

An off-white powder

Identification

A. Solubility

Soluble in water, forming a viscous solution.

Insoluble in ethanol

Purity

Loss on drying

Not more than 15 % after drying (105 °C, 2½ hours)

▼ **M1**

Nitrogen	Not more than 3 %
Propane-2-ol	Not more than 750 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Total plate count	Not more than 10 000 colonies per gram
Yeast and mould	Not more than 400 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

E 422 GLYCEROL**Synonyms**

Glycerin
Glycerine

Definition*Chemical names*

1,2,3-propanetriol
Glycerol
Trihydroxypropane

Einecs

200-289-5

Chemical formula

$C_3H_8O_3$

Molecular weight

92,10

Assay

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

Description

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

Identification

A. Acrolein formation on heating

Heat a few drops of the sample in a test tube with about 0,5 g of potassium bisulphate. The characteristic pungent vapours of acrolein are evolved

B. Specific gravity (25/25 °C)

Not less than 1,257

C. Refractive index $[n]_D^{20}$

Between 1,471 and 1,474

Purity

Water

Not more than 5 % (Karl Fischer method)

Sulphated ash

Not more than 0,01 % determined at 800 ± 25 °C

Butanetriols

Not more than 0,2 %

Acrolein, glucose and ammonium compounds

Heat a mixture of 5 ml of glycerol and 5 ml of potassium hydroxide solution (1 in 10) at 60 °C for five minutes. It neither becomes yellow nor emits an odour of ammonia

Fatty acids and esters

Not more than 0,1 % calculated as butyric acid

Chlorinated compounds

Not more than 30 mg/kg (as chlorine)

Arsenic

Not more than 3 mg/kg

Lead

Not more than 2 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 5 mg/kg

▼ **M5****E 431 POLYOXYETHYLENE (40) STEARATE**

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

E 432 POLYOXYETHYLENE SORBITAN MONOLAURATE (POLYSORBATE 20)

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

▼ **M5**

Saponification value	Not less than 40 and not more than 50
Hydroxyl value	Not less than 96 and not more than 108
1,4-Dioxane	Not more than 5 mg/kg
Free ethylene oxide	Not more than 1 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 433 POLYOXYETHYLENE SORBITAN MONOOLEATE (POLYSORBATE 80)

Synonyms	Polysorbate 80 Polyoxyethylene (20) sorbitan monooleate
Definition	A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial oleic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides
<i>Assay</i>	Content not less than 65 % of oxyethylene groups, equivalent to not less than 96,5 % of polyoxyethylene (20) sorbitan monooleate on the anhydrous basis
<i>Description</i>	A lemon to amber-coloured oily liquid at 25 °C with a faint characteristic odour
Identification	
A. Solubility	Soluble in water, ethanol, methanol, ethyl acetate and toluene. Insoluble in mineral oil and petroleum ether
B. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
Purity	
Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 45 and not more than 55
Hydroxyl value	Not less than 65 and not more than 80
1,4-dioxane	Not more than 5 mg/kg
Ethylene oxide	Not more than 0,2 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 434 POLYOXYETHYLENE SORBITAN MONOPALMITATE (POLYSORBATE 40)

Synonyms	Polysorbate 40 Polyoxyethylene (20) sorbitan monopalmitate
Definition	A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial palmitic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides

▼ **M5**

<i>Assay</i>	Content not less than 66 % of oxyethylene groups, equivalent to not less than 97 % of polyoxyethylene (20) sorbitan monopalmitate on the anhydrous basis
<i>Description</i>	A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour
Identification	
A. Solubility	Soluble in water, ethanol, methanol, ethyl acetate and acetone. Insoluble in mineral oil
B. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
Purity	
Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 41 and not more than 52
Hydroxyl value	Not less than 90 and not more than 107
1,4-dioxane	Not more than 5 mg/kg
Ethylene oxide	Not more than 0,2 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 435 POLYOXYETHYLENE SORBITAN MONOSTEARATE (POLYSORBATE 60)

Synonyms	Polysorbate 60 Polyoxyethylene (20) sorbitan monostearate
Definition	A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial stearic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides
<i>Assay</i>	Content not less than 65 % of oxyethylene groups, equivalent to not less than 97 % of polyoxyethylene (20) sorbitan monostearate on the anhydrous basis
<i>Description</i>	A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour
Identification	
A. Solubility	Soluble in water, ethyl acetate and toluene. Insoluble in mineral oil and vegetable oils
B. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
Purity	
Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 45 and not more than 55
Hydroxyl value	Not less than 81 and not more than 96
1,4-Dioxane	Not more than 5 mg/kg
Free ethylene oxide	Not more than 1 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg

▼ **M5**

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

E 436 POLYOXYETHYLENE SORBITAN TRISTEARATE (POLYSORBATE 65)

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

▼ **M1****E 440 (i) PECTIN**

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

▼ **M1****Identification**

A. Solubility

Soluble in water forming a colloidal, opalescent solution. Insoluble in ethanol

Purity

Loss on drying

Not more than 12 % (105 °C, 2 hours)

Acid insoluble ash

Not more than 1 % (insoluble in approximately 3N hydrochloric acid)

Sulphur dioxide

Not more than 50 mg/kg on the anhydrous basis

Nitrogen content

Not more than 1,0 % after washing with acid and ethanol

Free methanol, ethanol and propane-2-ol

Not more than 1 %, singly or in combination, on the anhydrous basis

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 20 mg/kg

E 440 (ii) AMIDATED PECTIN**Definition**

Amidated pectin consists mainly of the partial methyl esters and amides of polygalacturonic acid and their ammonium, sodium, potassium and calcium salts. It is obtained by extraction in an aqueous medium of appropriate natural strains of edible plant material, usually citrus fruits or apples and treatment with ammonia under alkaline conditions. No organic precipitant shall be used other than methanol, ethanol and propane-2-ol

Assay

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

Description

White, light yellow, light greyish or light brownish powder

Identification

A. Solubility

Soluble in water forming a colloidal, opalescent solution. Insoluble in ethanol

Purity

Loss on drying

Not more than 12 % (105 °C, 2 hours)

Acid-insoluble ash

Not more than 1 % (insoluble in approximately 3N hydrochloric acid)

Degree of amidation

Not more than 25 % of total carboxyl groups

Sulphur dioxide residue

Not more than 50 mg/kg on the anhydrous basis

Nitrogen content

Not more than 2,5 % after washing with acid and ethanol

Free methanol, ethanol and propane-2-ol

Not more than 1 % single or in combination, on a volatile matter-free basis

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 20 mg/kg

▼ **M1****E 442 AMMONIUM PHOSPHATIDES**

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

E 444 SUCROSE ACETATE ISOBUTYRATE

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

▼ **M1**

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

E 445 GLYCEROL ESTERS OF WOOD ROSIN

Synonyms	Ester gum
Definition	A complex mixture of tri- and diglycerol esters of resin acids from wood rosin. The rosin is obtained by the solvent extraction of aged pine stumps followed by a liquid-liquid solvent refining process. Excluded from these specifications are substances derived from gum rosin, and exudate of living pine trees, and substances derived from tall oil rosin, a by-product of kraft (paper) pulp processing. The final product is composed of approximately 90 % resin acids and 10 % neutrals (non-acidic compounds). The resin acid fraction is a complex mixture of isomeric diterpenoid monocarboxylic acids having the empirical molecular formula of $C_{20}H_{30}O_2$, chiefly abietic acid. The substance is purified by steam stripping or by countercurrent steam distillation
<i>Description</i>	Hard, yellow to pale amber-coloured solid
Identification	
A. Solubility	Insoluble in water, soluble in acetone
B. Infrared absorption spectrum	Characteristic of the compound
Purity	
Specific gravity of solution	$[d]_{25}^{20}$ not less than 0,935 when determined in a 50 % solution in d-limonene (97 %, boiling point 175,5-176 °C, d_{4}^{20} : 0,84)
Ring and ball softening range	Between 82 °C and 90 °C
Acid value	Not less than 3 and not more than 9
Hydroxyl value	Not less than 15 and not more than 45
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Test for absence of tall oil rosin (sulphur test)	When sulphur-containing organic compounds are heated in the presence of sodium formate, the sulphur is converted to hydrogen sulphide which can readily be detected by the use of lead acetate paper. A positive test indicates the use of tall oil rosin instead of wood rosin

▼ **M4****E 450 (i) DISODIUM DIPHOSPHATE**

Synonyms	Disodium dihydrogen diphosphate Disodium dihydrogen pyrophosphate Sodium acid pyrophosphate Disodium pyrophosphate
Definition	
<i>Chemical name</i>	Disodium dihydrogen diphosphate

▼ **M4**

Einecs	231-835-0
<i>Chemical formula</i>	$\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$
<i>Molecular weight</i>	221,94
<i>Assay</i>	Content not less than 95 % of disodium diphosphate.
<i>P₂O₅ Content</i>	Not less than 63,0 % and not more than 64,5 %
<i>Description</i>	White powder or grains
Identification	
A. Positive tests for sodium and for phosphate	
B. Solubility	Soluble in water
C. pH of a 1 % solution	Between 3,7 and 5,0
Purity	
Loss on drying	Not more than 0,5 % (105 °C, four hours)
Water-insoluble matter	Not more than 1 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 450 (ii) TRISODIUM DIPHOSPHATE

Synonyms	Acid trisodium pyrophosphate Trisodium monohydrogen diphosphate
Definition	
Einecs	238-735-6
<i>Chemical formula</i>	Monohydrate: $\text{Na}_3\text{HP}_2\text{O}_7 \cdot \text{H}_2\text{O}$ Anhydrous: $\text{Na}_3\text{HP}_2\text{O}_7$
<i>Molecular weight</i>	Monohydrate: 261,95 Anhydrous: 243,93
<i>Assay</i>	Content not less than 95 % on the anhydrous basis
<i>P₂O₅ content</i>	Not less than 57 % and not more than 59 %
<i>Description</i>	White powder or grains, occurs anhydrous or as a monohydrate
Identification	
A. Positive tests for sodium and for phosphate	
B. Soluble in water	
C. pH of a 1 % solution	Between 6,7 and 7,5
Purity	
Loss on ignition	Not more than 4,5 % on the anhydrous compound Not more than 11,5 % on the monohydrated basis
Loss on drying	Not more than 0,5 % (105 °C, four hours)
Water-insoluble matter	Not more than 0,2 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg

▼ **M4**

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

E 450 (iii) TETRASODIUM DIPHOSPHATE

Synonyms	Tetrasodium pyrophosphate Sodium pyrophosphate
Definition	
<i>Chemical name</i>	Tetrasodium diphosphate
Einecs	231-767-1
<i>Chemical formula</i>	Anhydrous: $\text{Na}_4\text{P}_2\text{O}_7$ Decahydrate: $\text{Na}_4\text{P}_2\text{O}_7 \cdot 10\text{H}_2\text{O}$
<i>Molecular weight</i>	Anhydrous: 265,94 Decahydrate: 446,09
<i>Assay</i>	Content not less than 95 % of $\text{Na}_4\text{P}_2\text{O}_7$ on the ignited basis
<i>P₂O₅ content</i>	Not less than 52,5 % and not more than 54,0 %
<i>Description</i>	Colourless or white crystals, or a white crystalline or granular powder. The decahydrate effloresces slightly in dry air
Identification	
A. Positive tests for sodium and for phosphate	
B. Solubility	Soluble in water. Insoluble in ethanol
C. pH of a 1 % solution	Between 9,8 and 10,8
Purity	
Loss on ignition	Not more than 0,5 % for the anhydrous salt, not less than 38 % and not more than 42 % for the decahydrate, in both cases determined after drying at 105 °C for four hours, followed by ignition at 550 °C for 30 minutes
Water-insoluble matter	Not more than 0,2 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 450 (v) TETRAPOTASSIUM DIPHOSPHATE

Synonyms	Potassium pyrophosphate Tetrapotassium pyrophosphate
Definition	
<i>Chemical name</i>	Tetrapotassium diphosphate
Einecs	230-785-7
<i>Chemical formula</i>	$\text{K}_4\text{P}_2\text{O}_7$
<i>Molecular weight</i>	330,34 (anhydrous)
<i>Assay</i>	Content not less than 95 % on the ignited basis
<i>P₂O₅ content</i>	Not less than 42,0 % and not more than 43,7 % on the anhydrous basis
<i>Description</i>	Colourless crystals or white, very hygroscopic powder

▼ **M4****Identification**

- A. Positive tests for potassium and for phosphate
- B. Solubility
- C. pH of a 1 % solution

Soluble in water, insoluble in ethanol

Between 10,0 and 10,8

Purity

Loss on ignition

Not more than 2 % after drying at 105 °C for four hours and then ignition at 550 °C for 30 minutes

Water-insoluble substances

Not more than 0,2 %

Fluoride

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

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

E 450 (vi) DICALCIUM DIPHOSPHATE**Synonyms**

Calcium pyrophosphate

Definition

Chemical name

Dicalcium diphosphate
Dicalcium pyrophosphate

Einecs

232-221-5

Chemical formula

$\text{Ca}_2\text{P}_2\text{O}_7$

Molecular weight

254,12

Assay

Content not less than 96 %

P₂O₅ content

Not less than 55 % and not more than 56 %

Description

A fine, white, odourless powder

Identification

- A. Positive tests for calcium and for phosphate
- B. Solubility
- C. pH of a 10 % suspension in water

Insoluble in water. Soluble in dilute hydrochloric and nitric acids

Between 5,5 and 7,0

Purity

Loss on ignition

Not more than 1,5 % at 800 °C ± 25 °C for 30 minutes

Fluoride

Not more than 50 mg/kg (expressed as fluorine)

Arsenic

Not more than 3 mg/kg

Cadmium

Not more than 1 mg/kg

Lead

Not more than 4 mg/kg

Mercury

Not more than 1 mg/kg

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

Acid calcium pyrophosphate
Monocalcium dihydrogen pyrophosphate

Definition

Chemical name

Calcium dihydrogen diphosphate

Einecs

238-933-2

▼ **M4**

<i>Chemical formula</i>	CaH ₂ P ₂ O ₇
<i>Molecular weight</i>	215,97
<i>Assay</i>	Content not less than 90 % on the anhydrous basis
<i>P₂O₅ content</i>	Not less than 61 % and not more than 64 %
<i>Description</i>	White crystals or powder
Identification	
A. Positive tests for calcium and for phosphate	
Purity	
Acid-insoluble matter	Not more than 0,4 %
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 451 (i) PENTASODIUM TRIPHOSPHATE

Synonyms	Pentasodium tripolyphosphate Sodium tripolyphosphate
Definition	
<i>Chemical name</i>	Pentasodium triphosphate
Einecs	231-838-7
<i>Chemical formula</i>	Na ₅ O ₁₀ P ₃ · nH ₂ O (n = 0 or 6)
<i>Molecular weight</i>	367,86
<i>Assay</i>	Content not less than 85,0 % (anhydrous) or 65,0 % (hexahydrate)
<i>P₂O₅ content</i>	Not less than 56 % and not more than 59 % (anhydrous) or not less than 43 % and not more than 45 % (hexahydrate)
<i>Description</i>	White, slightly hygroscopic granules or powder
Identification	
A. Solubility	Freely soluble in water. Insoluble in ethanol
B. Positive tests for sodium and for phosphate	
C. pH of a 1 % solution	Between 9,1 and 10,2
Purity	
Loss on drying	Anhydrous: Not more than 0,7 % (105 °C, one hour) Hexahydrate: Not more than 23,5 % (60 °C, one hour, followed by drying at 105 °C, four hours)
Water-insoluble substances	Not more than 0,1 %
Higher polyphosphates	Not more than 1 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

▼ **M4****E 451 (ii) PENTAPOTASSIUM TRIPHOSPHATE**

Synonyms	Pentapotassium tripolyphosphate Potassium triphosphate Potassium tripolyphosphate
Definition	
<i>Chemical name</i>	Pentapotassium triphosphate Pentapotassium tripolyphosphate
Einecs	237-574-9
<i>Chemical formula</i>	$K_5O_{10}P_3$
<i>Molecular weight</i>	448,42
<i>Assay</i>	Content not less than 85 % on the anhydrous basis
<i>P₂O₅ content</i>	Not less than 46,5 % and not more than 48 %
<i>Description</i>	White, very hygroscopic powder or granules
Identification	
A. Solubility	Very soluble in water
B. Positive tests for potassium and for phosphate	
C. pH of a 1 % solution	Between 9,2 and 10,5
Purity	
Loss on ignition	Not more than 0,4 % (after drying at 105 °C, four hours, followed by ignition at 550 °C, 30 minutes)
Water-insoluble matter	Not more than 2 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 452 (i) SODIUM POLYPHOSPHATE

1. SOLUBLE POLYPHOSPHATE

Synonyms	Sodium hexametaphosphate Sodium tetrapolyphosphate Graham's salt Sodium polyphosphates, glassy Sodium polymetaphosphate Sodium metaphosphate
Definition	
Soluble sodium polyphosphates are obtained by fusion and subsequent chilling of sodium orthophosphates. These compounds are a class consisting of several amorphous, water-soluble polyphosphates composed of linear chains of metaphosphate units, (NaPO ₃) _x where x ≥ 2, terminated by Na ₂ PO ₄ groups. These substances are usually identified by their Na ₂ O/P ₂ O ₅ ratio or their P ₂ O ₅ content. The Na ₂ O/P ₂ O ₅ ratios vary from about 1,3 for sodium tetrapolyphosphate, where x = approximately 4; to about 1,1 for Graham's salt, commonly called sodium hexametaphosphate, where x = 13 to 18; and to about 1,0 for the higher molecular weight sodium polyphosphates, where x = 20 to 100 or more. The pH of their solutions varies from 3,0 to 9,0	

▼ **M4**

<i>Chemical name</i>	Sodium polyphosphate
Einecs	272-808-3
<i>Chemical formula</i>	Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula $H_{(n+2)}P_nO_{(3n+1)}$ where 'n' is not less than 2
<i>Molecular weight</i>	$(102)_n$
<i>Assay P_2O_5 content</i>	Not less than 60 % and not more than 71 % on the ignited basis
<i>Description</i>	Colourless or white, transparent platelets, granules, or powders
Identification	
A. Solubility	Very soluble in water
B. Positive tests for sodium and for phosphate	
C. pH of a 1 % solution	Between 3,0 and 9,0
Purity	
Loss on ignition	Not more than 1 %
Water-insoluble matter	Not more than 0,1 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

2. INSOLUBLE POLYPHOSPHATE

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

▼ **M4**

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

E 452 (ii) POTASSIUM POLYPHOSPHATE

Synonyms	Potassium metaphosphate Potassium polymetaphosphate Kurrol salt
Definition	
<i>Chemical name</i>	Potassium polyphosphate
Einecs	232-212-6
<i>Chemical formula</i>	(KPO ₃) _n Heterogenous mixtures of potassium salts of linear condensed polyphosphoric acids of general formula H _(n+2) P _n O _(3n+1) where 'n' is not less than 2
<i>Molecular weight</i>	(118) _n
<i>P₂O₅ content</i>	Not less than 53,5 % and not more than 61,5 % on the ignited basis
<i>Description</i>	Fine white powder or crystals or colourless glassy platelets
Identification	
A. Solubility	1 g dissolves in 100 ml of a 1 in 25 solution of sodium acetate
B. Positive tests for potassium and for phosphate	
C. pH of a 1 % suspension	Not more than 7,8
Purity	
Loss on ignition	Not more than 2 % (105 °C, four hours followed by ignition at 550 °C, 30 minutes)
Cyclic phosphate	Not more than 8 % on P ₂ O ₅ content
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

E 452 (iv) CALCIUM POLYPHOSPHATE

Synonyms	Calcium metaphosphate Calcium polymetaphosphate
Definition	
<i>Chemical name</i>	Calcium polyphosphate
Einecs	236-769-6
<i>Chemical formula</i>	(CaP ₂ O ₆) _n Heterogenous mixtures of calcium salts of condensed polyphosphoric acids of general formula H _(n+2) P _n O _(n+1) where 'n' is not less than 2
<i>Molecular weight</i>	(198) _n
<i>P₂O₅ content</i>	Not less than 71 % and not more than 73 % on the ignited basis

▼ **M4**

<i>Description</i>	Odourless, colourless crystals or white powder
Identification	
A. Solubility	Usually sparingly soluble in water. Soluble in acid medium
B. Positive tests for calcium and for phosphate	
C. CaO content	27 to 29,5 %
Purity	
Loss on ignition	Not more than 2 % (105 °C, four hours followed by ignition at 550 °C, 30 minutes)
Cyclic phosphate	Not more than 8 % on P ₂ O ₅ content
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 4 mg/kg
Mercury	Not more than 1 mg/kg

▼ **M1****E 460 (i) MICROCRISTALLINE CELLULOSE**

Synonyms	Cellulose gel
Definition	Microcrystalline cellulose is purified, partially depolymerised cellulose prepared by treating alpha-cellulose, obtained as a pulp from natural strains of fibrous plant material, with mineral acids. The degree of polymerisation is typically less than 400
<i>Chemical name</i>	Cellulose
Einecs	232-674-9
<i>Chemical formula</i>	(C ₆ H ₁₀ O ₅) _n
<i>Molecular weight</i>	About 36 000
<i>Assay</i>	Not less than 97 % calculated as cellulose on the anhydrous basis
<i>Description</i>	A fine white or almost white odourless powder
Identification	
A. Solubility	Insoluble in water, ethanol, ether and dilute mineral acids. Slightly soluble in sodium hydroxide solution
B. Colour reaction	To 1 mg of the sample, add 1 ml of phosphoric acid and heat on a water bath for 30 minutes. Add 4 ml of a 1 in 4 solution of pyrocatechol in phosphoric acid and heat for 30 minutes, A red colour is produced
C. To be identified by IR spectroscopy	
D. Suspension test	Mix 30 g of the sample with 270 ml of water in a high-speed (12 000 rpm) power blender for 5 minutes. The resultant mixture will be either a free-following suspension or a heavy, lumpy suspension which flows poorly, if at all, settles only slightly and contains many trapped air bubbles. If a free-flowing suspension is obtained, transfer 100 ml into a 100-ml graduated cylinder and allow to stand for 1 hour. The solids settles and a supernatant liquid appears
Purity	
Loss on drying	Not more than 7 % (105 °C, 3 hours)
Water-soluble matter	Not more than 0,24%
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C

▼ **M1**

pH of a 10 % suspension in water	The pH of the supernatant liquid is between 5,0 and 7,5
Starch	Not detectable
	To 20 ml of the dispersion obtained in identification, test D, add a few drops of iodine solution and mix. No purplish to blue or blue colour should be produced
Particle size	Not less than 5 μm (not more than 10 % of particles of less than 5 μm)
Carboxyl groups	Not more than 1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 460 (ii) POWDERED CELLULOSE**Definition**

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

Chemical name

Cellulose

Linear polymer of 1:4 linked glucose residues

Einecs

232-674-9

Chemical formula

$(\text{C}_6\text{H}_{10}\text{O}_5)_n$

Molecular weight

$(162)_n$ (n is predominantly 1 000 and greater)

Assay

Content not less than 92 %

Description

A white, odourless powder

Identification

A. Solubility

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

B. Suspension test

Mix 30 g of the sample with 270 ml of water in a high-speed (12 000 rpm) power blender for 5 minutes. The resultant mixture will be either a free-flowing suspension or a heavy, lumpy suspension which flows poorly, if at all, settles only slightly and contains many trapped air bubbles. If a free-flowing suspension is obtained, transfer 100 ml into a 100-ml graduated cylinder and allow to stand for 1 hour. The solids settles and a supernatant liquid appears

Purity

Loss on drying

Not more than 7 % (105 °C, 3 hours)

Water-soluble matter

Not more than 1,0 %

Sulphated ash

Not more than 0,3 % determined at 800 ± 25 °C

pH of a 10 % suspension in water

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

Starch

Not detectable

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

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 mg/kg

▼ **M1**

Particle size	Not less than 5 μm (not more than 10 % of particles of less than 5 μm)
E 461 METHYL CELLULOSE	
Synonyms	Cellulose methyl ether
Definition	Methyl cellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with methyl groups
<i>Chemical name</i>	Methyl ether of cellulose
<i>Chemical formula</i>	The polymers contain substituted anhydroglucose units with the following general formula: $\text{C}_6\text{H}_7\text{O}_2(\text{OR}_1)(\text{OR}_2)(\text{OR}_3)$ where $\text{R}_1, \text{R}_2, \text{R}_3$ each may be one of the following: — H — CH_3 or — CH_2CH_3
<i>Molecular weight</i>	From about 20 000 to 380 000
<i>Assay</i>	Content not less than 25 % and not more than 33 % of methoxyl groups ($-\text{OCH}_3$) and not more than 5 % of hydroxyethoxyl groups ($-\text{OCH}_2\text{CH}_2\text{OH}$)
<i>Description</i>	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	
A. Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol, ether and chloroform. Soluble in glacial acetic acid
Purity	
Loss on drying	Not more than 10 % (105 °C, 3 hours)
Sulphated ash	Not more than 1,5 % determined at 800 ± 25 °C
pH of a 1 % colloidal solution	Not less than 5,0 and not more than 8,0
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 463 HYDROXYPROPYL CELLULOSE

Synonyms	Cellulose hydroxypropyl ether
Definition	Hydroxypropylcellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with hydroxypropyl groups
<i>Chemical name</i>	Hydroxypropyl ether of cellulose
<i>Chemical formula</i>	The polymers contain substituted anhydroglucose units with the following general formula: $\text{C}_6\text{H}_7\text{O}_2(\text{OR}_1)(\text{OR}_2)(\text{OR}_3)$, where $\text{R}_1, \text{R}_2, \text{R}_3$ each may be one of the following: — H — $\text{CH}_2\text{CHOHCH}_3$ — $\text{CH}_2\text{CHO}(\text{CH}_2\text{CHOHCH}_3)\text{CH}_3$ — $\text{CH}_2\text{CHO}[\text{CH}_2\text{CHO}(\text{CH}_2\text{CHOHCH}_3)\text{CH}_3]\text{CH}_3$
<i>Molecular weight</i>	From about 30 000 to 1 000 000

▼ **M1**

<i>Assay</i>	Content not less than 80,5 % of hydroxypropoxyl groups (-OCH ₂ CHOHCH ₃) equivalent to not more than 4,6 hydroxypropyl groups per anhydroglucose unit on the anhydrous basis
<i>Description</i>	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	
A. Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Soluble in ethanol. Insoluble in ether
B. Gas chromatography	Determine the substituents by gas chromatography
Purity	
Loss on drying	Not more than 10 % (105 °C, 3 hours)
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
pH of a 1 % colloidal solution	Not less than 5,0 and not more than 8,0
Propylene chlorohydrins	Not more than 0,1 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 464 HYDROXYPROPYL METHYL CELLULOSE

Definition	Hydroxypropyl methyl cellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with methyl groups and containing a small degree of hydroxypropyl substitution
<i>Chemical name</i>	2-Hydroxypropyl ether of methylcellulose
<i>Chemical formula</i>	The polymers contain substituted anhydroglucose units with the following general formula: C ₆ H ₇ O ₂ (OR ₁)(OR ₂)(OR ₃), where R ₁ , R ₂ , R ₃ each may be one of the following: — H — CH ₃ — CH ₂ CHOHCH ₃ — CH ₂ CHO (CH ₂ CHOHCH ₃) CH ₃ — CH ₂ CHO[CH ₂ CHO (CH ₂ CHOHCH ₃) CH ₃]CH ₃
<i>Molecular weight</i>	From about 13 000 to 200 000
<i>Assay</i>	Content not less than 19 % and not more than 30 % methoxyl groups (-OCH ₃) and not less than 3 % and not more than 12 % hydroxypropoxyl groups (-OCH ₂ CHOHCH ₃), on the anhydrous basis
<i>Description</i>	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	
A. Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol
B. Gas chromatography	Determine the substituents by gas chromatography
Purity	
Loss on drying	Not more than 10 % (105 °C, 3 hours)

▼ **M1**

Sulphated ash	Not more than 1,5 % for products with viscosities of 50 mPa.s or above Not more than 3 % for products with viscosities below 50 mPa.s
pH of a 1 % colloidal solution	Not less than 5,0 and not more than 8,0
Propylene chlorohydrins	Not more than 0,1 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 465 ETHYL METHYL CELLULOSE**Synonyms**

Methylethylcellulose

Definition

Ethyl methyl cellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with methyl and ethyl groups

Chemical name

Ethyl methyl ether of cellulose

Chemical formula

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

$$C_6H_7O_2(OR_1)(OR_2)(OR_3)$$
 where R_1, R_2, R_3 each may be one of the following:

- H
- CH_3
- CH_2CH_3

Molecular weight

From about 30 000 to 40 000

*Assay*Content on the anhydrous basis not less than 3,5 % and not more than 6,5 % of methoxyl groups ($-OCH_3$) and not less than 14,5 % and not more than 19 % of ethoxyl groups ($-OCH_2CH_3$), and not less than 13,2 % and not more than 19,6 % of total alkoxy groups, calculated as methoxyl*Description*

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

Identification

A. Solubility

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

Purity

Loss on drying

Not more than 15 % for the fibrous form, and not more than 10 % for the powdered form (105 °C to constant weight)

Sulphated ash

Not more than 0,6 %

pH of a 1 % colloidal solution

Not less than 5,0 and not more than 8,0

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 20 mg/kg

▼ **M1****E 466 SODIUM CARBOXY METHYL CELLULOSE**

Synonyms	Carboxy methyl cellulose CMC NaCMC Sodium CMC Cellulose gum
Definition	Carboxy methyl cellulose is the partial sodium salt of a carboxymethyl ether of cellulose, the cellulose being obtained directly from natural strains of fibrous plant material
<i>Chemical name</i>	Sodium salt of the carboxymethyl ether of cellulose
<i>Chemical formula</i>	The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$, where R_1, R_2, R_3 each may be one of the following: — H — CH_2COONa — CH_2COOH
<i>Molecular weight</i>	Higher than approximately 17 000 (degree of polymerisation approximately 100)
<i>Assay</i>	Content on the anhydrous basis not less than 99,5 %
<i>Description</i>	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	
A. Solubility	Yields a viscous colloidal solution with water. Insoluble in ethanol
B. Foam test	A 0,1 % solution of the sample is shaken vigorously. No layer of foam appears. (This test permits the distinction of sodium carboxymethyl cellulose from other cellulose ethers)
C. Precipitate formation	To 5 ml of a 0,5 % solution of the sample, add 5 ml of 5 % solution of copper sulphate or of aluminium sulphate. A precipitate appears. (This test permits the distinction of sodium carboxymethyl cellulose from other cellulose ethers and from gelatine, locust bean gum and tragacanth)
D. Colour reaction	Add 0,5 g powdered carboxy methyl cellulose sodium to 50 ml of water, while stirring to produce an uniform dispersion. Continue the stirring until a clear solution is produced, and use the solution for the following test: To 1 mg of the sample, diluted with an equal volume of water, in a small test tube, add 5 drops of 1-naphthol solution. Incline the test tube, and carefully introduce down the side of the tube 2 ml of sulphuric acid so that it forms a lower layer. A red-purple colour develops at the interface
Purity	
Degree of substitution	Not less than 0,2 and not more than 1,5 carboxymethyl groups ($-CH_2COOH$) per anhydroglucose unit
Loss on drying	Not more than 12 % (105 °C to constant weight)
pH of a 1 % colloidal solution	Not less than 5,0 and not more than 8,5
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

▼ **M1**

Heavy metals (as Pb)	Not more than 20 mg/kg
Total glycolate	Not more than 0,4 %, calculated as sodium glycolate on the anhydrous basis
Sodium	Not more than 12,4 % on the anhydrous basis

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

Definition	Sodium, potassium and calcium salts of fatty acids occurring in food oils and fats, these salts being obtained either from edible fats and oils or from distilled food fatty acids
<i>Assay</i>	Content on the anhydrous basis not less than 95 %
<i>Description</i>	White or creamy white light powders, flakes or semi-solids
Identification	
A. Solubility	Sodium and potassium salts: soluble in water and ethanol calcium salts: insoluble in water, ethanol and ether
B. Positive tests for cations and for fatty acids	
Purity	
Sodium	Not less than 9 % and not more than 14 % expressed as Na ₂ O
Potassium	Not less than 13 % and not more than 21,5 % expressed as K ₂ O
Calcium	Not less than 8,5 % and not more than 13 % expressed as CaO
Unsaponifiable matter	Not more than 2 %
Free fatty acids	Not more than 3 % estimated as oleic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Free alkali	Not more than 0,1 % expressed as NaOH
Matter insoluble in alcohol	Not more than 0,2 % (sodium and potassium salts only)

E 470b MAGNESIUM SALTS OF FATTY ACIDS

Definition	Magnesium salts of fatty acids occurring in foods oils and fats, these salts being obtained either from edible fats and oils or from distilled food fatty acids
<i>Assay</i>	Content on the anhydrous basis not less than 95 %
<i>Description</i>	White or creamy-white light powders, flakes or semi-solids
Identification	
A. Solubility	Insoluble in water, partially soluble in ethanol and ether
B. Positive tests for magnesium and for fatty acids	
Purity	
Magnesium	Not less than 6,5 % and not more than 11 % expressed as MgO

▼ **M1**

Free alkali	Not more than 0,1 % expressed as MgO
Unsaponifiable matter	Not more than 2 %
Free fatty acids	Not more than 3 % estimated as oleic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 471 MONO- AND DIGLYCERIDES OF FATTY ACIDS

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

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

▼ **M1****E 472 a ACETIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS**

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

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

E 472 b LACTIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS

Synonyms	Lactic acid esters of mono- and diglycerides Lactoglycerides Mono- and diglycerides of fatty acids esterified with lactic acid
Definition	Esters of glycerol with lactic acid and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free lactic acid and free glycerides
<i>Description</i>	Clear, mobile liquids to waxy solids of variable consistency, from white to pale yellow in colour
Identification	
A. Positive tests for glycerol, for fatty acids and for lactic acid	
B. Solubility	Insoluble in cold water but dispersible in hot water
Purity	
Acids other than lactic and fatty acids	Not detectable
Free glycerol	Not more than 2 %
Arsenic	Not more than 3 mg/kg

▼ **M1**

Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Total lactic acid	Not less than 13 % and not more than 45 %
Free fatty acids (and lactic acid)	Not more than 3 % estimated as oleic acid
Total glycerol	Not less than 13 % and not more than 30 %
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C

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

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

Synonyms	Citric acid esters of mono- and diglycerides Citroglycerides Mono- and diglycerides of fatty acids esterified with citric acid
Definition	Esters of glycerol with citric acid and fatty acids occurring in food oils and fats. They may contain small amounts of free glycerol, free fatty acids, free citric acid and free glycerides. They may be partially or wholly neutralised with sodium hydroxide or with potassium hydroxide
<i>Description</i>	Yellowish or light brown liquids to waxy solids or semi-solids
Identification	
A. Positive tests for glycerol, for fatty acids and for citric acid	
B. Solubility	Insoluble in cold water Dispersible in hot water Soluble in oils and fats Insoluble in cold ethanol
Purity	
Acids other than citric and fatty acids	Not detectable
Free glycerol	Not more than 2 %
Total glycerol	Not less than 8 % and not more than 33 %
Total citric acid	Not less than 13 % and not more than 50 %
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Free fatty acids	Not more than 3 % estimated as oleic acid

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

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

Synonyms	Tartaric acid esters of mono- and diglycerides Mono- and diglycerides of fatty acids esterified with tartaric acid
-----------------	---

▼ **M1**

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

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

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

Synonyms	Diacetyltartaric acid esters of mono- and diglycerides Mono- and diglycerides of fatty acids esterified with mono- and diacetyltartaric acid Diacetyltartaric and fatty acid esters of glycerol
Definition	Mixed esters of glycerol with mono- and diacetyltartaric acids (obtained from tartaric acid) and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free tartaric and acetic acids and their combinations, and free glycerides. Contains also tartaric and acetic esters of fatty acids
<i>Description</i>	Sticky viscous liquids through a fat-like consistency to yellow waxes which hydrolyse in moist air to liberate acetic acid
Identification	
A. Positive tests for glycerol, for fatty acids, for tartaric acid and for acetic acid	
Purity	
Acids other than acetic, tartaric and fatty acids	Not detectable
Free glycerol	Not more than 2 %
Total glycerol	Not less than 11 % and not more than 28 %
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

▼ **M1**

Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Total tartaric acid	Not less than 10 % and not more than 40 %
Total acetic acid	Not less than 8 % and not more than 32 %
Free fatty acids	Not more than 3 % estimated as oleic acid

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

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

Synonyms	Mono- and diglycerides of fatty acids esterified with acetic acid and tartaric acid
Definition	Esters of glycerol with acetic and tartaric acids and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free tartaric and acetic acids, and free glycerides. May contain mono- and diacetyltartaric esters of mono- and diglycerides of fatty acids
<i>Description</i>	Sticky liquids to solids, from white to pale-yellow in colour
Identification	
A. Positive tests for glycerol, for fatty acids, for tartaric acid and for acetic acid	
Purity	
Acids other than acetic, tartaric and fatty acids	Not detectable
Free glycerol	Not more than 2 %
Total glycerol	Not less than 12 % and not more than 27 %
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Total acetic acid	Not less than 10 % and not more than 20 %
Total tartaric acid	Not less than 20 % and not more than 40 %
Free fatty acids	Not more than 3 % estimated as oleic acid

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

E 473 SUCROSE ESTERS OF FATTY ACIDS

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

▼ **M1**

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

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

E 474 SUCROGLYCERIDES

Synonyms	Sugar glycerides
Definition	Sucroglycerides are produced by reacting sucrose with an edible fat or oil to produce a mixture of essentially mono-, di- and triesters of sucrose and fatty acids together with residual mono-, di- and triglycerides from fat or oil. No organic solvents shall be used in their preparation other than cyclohexane, dimethylformamide, ethyl acetate, 2-methyl-1-propanol and propane-2-ol
<i>Assay</i>	Content not less than 40 % and not more than 60 % of sucrose fatty acid esters
<i>Description</i>	Soft solid masses, stiff gels or white to off-white powders
Identification	
A. Positive tests for sugar and for fatty acids	
B. Solubility	Insoluble in cold water Soluble in ethanol
Purity	
Sulphated ash	Not more than 2 % determined at 800 ± 25 °C
Free sugar	Not more than 5 %
Free fatty acids	Not more than 3 % estimated as oleic acid
Arsenic	Not more than 3 mg/kg

▼ **M1**

Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Methanol	Not more than 10 mg/kg
Dimethylformamide	Not more than 1 mg/kg
2-methyl-1-propanol } Cyclohexane } Ethyl acetate } Propane-2-ol }	Not more than 10 mg/kg, single or in combination
	Not more than 350 mg/kg, single or in combination

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

E 475 POLYGLYCEROL ESTERS OF FATTY ACIDS

Synonyms	Polyglycerol fatty acid esters Polyglycerin esters of fatty acid esters
Definition	Polyglycerol esters of fatty acids are produced by the esterification of polyglycerol with food fats and oils or with fatty acids occurring in foods fats and oils. The polyglycerol moiety is predominantly di-, tri- and tetraglycerol and contains not more than 10 % of polyglycerols equal to or higher than heptaglycerol
<i>Assay</i>	Content of total fatty acid ester not less than 90 %
<i>Description</i>	Light yellow to amber, oily to very viscous liquids; light tan to medium brown, plastic or soft solids; and light tan to brown, hard, waxy solids
Identification	
A. Positive tests for glycerol, for polyglycerols and for fatty acids	
B. Solubility	The esters range from very hydrophilic to very lipophilic, but as a class tend to be dispersible in water and soluble in organic solvents and oils
Purity	
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
Acids other than fatty acids	Not detectable
Free fatty acids	Not more than 6 % estimated as oleic acid
Total glycerol and polyglycerol	Not less than 18 % and not more than 60 %
Free glycerol and polyglycerol	Not more than 7 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

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

E 476 POLYGLYCEROL POLYRICINOLEATE

Synonyms	Glycerol esters of condensed castor oil fatty acids Polyglycerol esters of polycondensed fatty acids from castor oil Polyglycerol esters of interesterified ricinoleic acid PGPR
-----------------	---

▼ **M1**

Definition	Polyglycerol polyricinoleate is prepared by the esterification of polyglycerol with condensed castor oil fatty acids
<i>Description</i>	Clear, highly viscous liquid
Identification	
A. Solubility	Insoluble in water and in ethanol. Soluble in ether, hydrocarbons and halogenated hydrocarbons
B. Positive tests for glycerol, polyglycerol and for ricinoleic acid	
C. Refractive index [n] ⁶⁵	Between 1,4630 and 1,4665
Purity	
Polyglycerols	The polyglycerol moiety shall be composed of not less than 75 % of di-, tri- and tetraglycerols and shall contain not more than 10 % of polyglycerols equal to or higher than heptaglycerol
Hydroxyl value	Not less than 80 and not more than 100
Acid value	Not more than 6
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

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

Synonyms	Propylene glycol esters of fatty acids
Definition	Consists of mixtures of propane-1,2-diol mono- and diesters of fatty acids occurring in food fats and oils. The alcohol moiety is exclusively propane-1,2-diol together with dimer and traces of trimer. Organic acids other than food fatty acids are absent.
<i>Assay</i>	Content of total fatty acid ester not less than 85 %
<i>Description</i>	Clear liquids or waxy white flakes, beads or solids having a bland odour
Identification	
A. Positive tests for propylene glycol and for fatty acids	
Purity	
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
Acids other than fatty acids	Not detectable
Free fatty acids	Not more than 6 % estimated as oleic acid
Total propane-1,2-diol	Not less than 11 % and not more than 31 %
Free propane-1,2-diol	Not more than 5 %
Dimer and trimer of propylene glycol	Not more than 0,5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

▼ **M1**

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

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

Synonyms	TOSOM
Definition	Thermally oxidised soya bean oil interacted with mono- and diglycerides of fatty acids is a complex mixture of esters of glycerol and fatty acids found in edible fat and fatty acids from thermally oxidised soya bean oil. It is produced by interaction and desodorisation under vacuum at 130 °C of 10 % of thermally oxidised soya bean oil and 90 % mono- and diglycerides of food fatty acids. Soya bean oil is exclusively made from natural strains of soya beans
<i>Description</i>	Pale yellow to light brown a waxy or solid consistency
Identification	
A. Solubility	Insoluble in water. Soluble in hot oil or fat
Purity	
Melting range	55—65 °C
Free fatty acids	Not more than 1,5 % estimated as oleic acid
Free glycerol	Not more than 2 %
Total fatty acids	83—90 %
Total glycerol	16—22 %
Fatty acid methyl esters, not forming adduct with urea	Not more than 9 % of total fatty acid methyl esters
Fatty acids, insoluble in petroleum ether	Not more than 2 % of total fatty acids
Peroxide value	Not more than 3
Epoxides	Not more than 0,03 % oxirane oxygen
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 481 SODIUM STEAROYL-2-LACTYLATE

Synonyms	Sodium stearoyl lactylate Sodium stearoyl lactate
Definition	A mixture of the sodium salts of stearoyl lactic acids and its polymers and minor amounts of sodium salts of other related acids, manufactured by the reaction of stearic acid and lactic acid. Other food fatty acids may also be present, free or esterified, due to their presence in the stearic acid used
<i>Chemical names</i>	Sodium di-2-stearoyl lactate Sodium di(2-stearoyloxy)propionate
Einecs	246-929-7
<i>Chemical formula</i> (major components)	$C_{21}H_{39}O_4Na$ $C_{19}H_{35}O_4Na$
<i>Description</i>	White or slightly yellowish powder or brittle solid with a characteristic odour

▼ **M1****Identification**

A. Positive tests for sodium, for fatty acids and for lactic acid

B. Solubility

Insoluble in water. Soluble in ethanol

Purity

Sodium

Not less than 2,5 % and not more than 5 %

Ester value

Not less than 90 and not more than 190

Acid value

Not less than 60 and not more than 130

Total lactic acid

Not less than 15 % and not more than 40 %

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 mg/kg

E 482 CALCIUM STEAROYL-2-LACTYLATE**Synonyms**

Calcium stearoyl lactate

Definition

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

Chemical name

Calcium di-2-stearoyl lactate

Calcium di(2-stearoyloxy)propionate

Einecs

227-335-7

Chemical formula

$C_{42}H_{78}O_8Ca$

$C_{38}H_{70}O_8Ca$

Description

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

Identification

A. Positive tests for calcium, for fatty acids and for lactic acid

B. Solubility

Slightly soluble in hot water

Purity

Calcium

Not less than 1 % and not more than 5,2 %

Ester value

Not less than 125 and not more than 190

Total lactic acid

Not less than 15 % and not more than 40 %

Acid value

Not less than 50 and not more than 130

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 mg/kg

E 483 STEARYL TARTRATE**Synonyms**

Stearyl palmityl tartrate

▼ **M1**

Definition	Product of the esterification of tartaric acid with commercial stearyl alcohol, which consists essentially of stearyl and palmityl alcohols. It consists mainly of diester, with minor amounts of monoester and of unchanged starting materials
<i>Chemical name</i>	Distearyl tartrate Dipalmityl tartrate
<i>Chemical formula</i>	$C_{38}H_{74}O_6$ to $C_{40}H_{78}O_6$
<i>Molecular weight</i>	627 to 655
<i>Assay</i>	Content of total ester not less than 90 % corresponding to an ester value of not less than 163 and not more than 180
<i>Description</i>	Cream-coloured unctuous solid (at 25 °C)
Identification	
A. Positive tests for tartare	
B. Melting range	Between 67 °C and 77 °C. After saponification the saturated long chain fatty alcohols have a melting range of 49 °C to 55 °C
Purity	
Hydroxyl value	Not less than 200 and not more than 220
Acid value	Not more than 5,6
Total tartaric acid content	Not less than 18 % and not more than 35 %
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Unsaponifiable matter	Not less than 77 % and not more than 83 %
Iodine value	Not more than 4 (Wijs)

E 491 SORBITAN MONOSTEARATE

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

▼ **M1**

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

E 492 SORBITAN TRISTEARATE

Definition	A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial stearic acid
Einecs	247-891-4
<i>Assay</i>	Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters
<i>Description</i>	Light, cream- to tan-coloured beads or flakes or hard, waxy solid with a slight odour
Identification	
A. Solubility	Slightly soluble in toluene, ether, carbon tetrachloride and ethyl acetate; dispersible in petroleum ether, mineral oil, vegetable oils, acetone and dioxane; insoluble in water, methanol and ethanol
B. Congealing range	47—50 °C
C. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyol
Purity	
Water	Not more than 2 % (Karl Fischer method)
Sulphated ash	Not more than 0,5 %
Acid value	Not more than 15
Saponification value	Not less than 176 and not more than 188
Hydroxyl value	Not less than 66 and not more than 80
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 493 SORBITAN MONOLAURATE

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

▼ **M1****Purity**

Water	Not more than 2 % (Karl Fischer method)
Sulphated ash	Not more than 0,5 %
Acid value	Not more than 7
Saponification value	Not less than 155 and not more than 170
Hydroxyl value	Not less than 330 and not more than 358
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 494 SORBITAN MONOOLEATE**Definition**

A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial oleic acid. Major constituent is 1,4-sorbitan monooleate. Other constituents include isosorbide monooleate, sorbitan dioleate and sorbitan trioleate

Einecs

215-665-4

Assay

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

Description

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

Identification

A. Solubility

Soluble at temperatures above its melting point in ethanol, ether, ethyl acetate, aniline, toluene, dioxane, petroleum ether and carbon tetrachloride. Insoluble in cold water, dispersible in warm water

B. Iodine value

The residue of oleic acid, obtained from the saponification of the sorbitan monooleate in assay, has a iodine value between 80 and 100

Purity

Water	Not more than 2 % (Karl Fischer method)
Sulphated ash	Not more than 0,5 %
Acid value	Not more than 8
Saponification value	Not less than 145 and not more than 160
Hydroxyl value	Not less than 193 and not more than 210
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 495 SORBITAN MONOPALMITATE**Synonyms**

Sorbitan palmitate

Definition

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

Einecs

247-568-8

Assay

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

▼ **M1**

<i>Description</i>	Light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour
Identification	
A. Solubility	Soluble at temperatures above its melting point in ethanol, methanol, ether, ethyl acetate, aniline, toluene, dioxane, petroleum ether and carbon tetrachloride. Insoluble in cold water but dispersible in warm water
B. Congealing range	45—47 °C
C. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of polyol
Purity	
Water	Not more than 2 % (Karl Fischer method)
Sulphate ash	Not more than 0,5 %
Acid value	Not more than 7,5
Saponification value	Not less than 140 and not more than 150
Hydroxyl value	Not less than 270 and not more than 305
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 508 POTASSIUM CHLORIDE

Synonyms	Sylvine Sylvite
Definition	
<i>Chemical name</i>	Potassium chloride
Einecs	231-211-8
<i>Chemical formulae</i>	KCl
<i>Molecular weight</i>	74,56
<i>Assay</i>	Content not less than 99 % on the dried basis
<i>Description</i>	Colourless, elongated, prismatic or cubital crystals or white granular powder. Odourless
Identification	
A. Solubility	Freely soluble in water. Insoluble in ethanol
B. Positive tests for potassium and for chloride	
Purity	
Loss on drying	Not more than 1 % (105 °C, 2 hours)
Sodium	Negative test
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

▼ **M1****E 579 FERROUS GLUCONATE****Definition***Chemical name*Ferrous di-D-gluconate dihydrate
Iron(II) di-gluconate dihydrate**Einecs**

206-076-3

Chemical formulae $C_{12}H_{22}FeO_{14} \cdot 2H_2O$ *Molecular weight*

482,17

Assay

Content not less than 95 % on the dried basis

Description

Pale greenish-yellow to yellowish-grey powder or granules, which may have a faint odour of burnt sugar

Identification

A. Solubility

Soluble with slight heating in water. Practically insoluble in ethanol

B. Positive test for ferrous ion

C. Formation of phenylhydrazine derivative of gluconic acid positive

D. pH of a 10 % solution

Between 4 and 5,5

Purity

Loss on drying

Not more than 10 % (105 °C, 16 hours)

Oxalic acid

Not detectable

Iron (Fe III)

Not more than 2 %

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Reducing substances

Not more than 0,5 % expressed as glucose

E 585 FERROUS LACTATE**Synonyms**Iron(II) lactate
Iron(II) 2-hydroxy propanoate
Propanoic acid, 2-hydroxy-iron(2 +) salt (2:1)**Definition***Chemical name*

Ferrous 2-hydroxy propanoate

Einecs

227-608-0

Chemical formulae $C_6H_{10}FeO_6 \cdot xH_2O$ (x = 2 or 3)*Molecular weight*

270,02 (dihydrate)

288,03 (trihydrate)

Assay

Content not less than 96 % on the dried basis

Description

Greenish-white crystals or light green powder having a characteristic smell

Identification

A. Solubility

Soluble in water. Practically insoluble in ethanol

B. Positive test for ferrous ion and for lactate

C. pH of a 2 % solution

Between 4 and 6

▼ **M1****Purity**

Loss on drying	Not more than 18 % (100 °C, under vacuum, approximately 700 mm Hg)
Iron (Fe III)	Not more than 0,6 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

▼ **M4****E 650 ZINC ACETATE****Synonyms**

Acetic acid, zinc salt, dihydrate

Definition*Chemical name*

Zinc acetate dihydrate

Chemical formula $C_4H_6O_4 Zn \cdot 2H_2O$ *Molecular weight*

219,51

*Assay*Content not less than 98 % and not more than 102 % of $C_4H_6O_4 Zn \cdot 2H_2O$ *Description*

Colourless crystals or fine, off-white powder

Identification

A. Positive tests for acetate and for zinc

B. pH of a 5 % solution

Between 6,0 and 8,0

Purity

Insoluble matter

Not more than 0,005 %

Chlorides

Not more than 50 mg/kg

Sulphates

Not more than 100 mg/kg

Alkalines and alkaline earths

Not more than 0,2 %

Organic volatile impurities

Passes test

Iron

Not more than 50 mg/kg

Arsenic

Not more than 3 mg/kg

Lead

Not more than 20 mg/kg

Cadmium

Not more than 5 mg/kg

E 943a BUTANE**Synonyms**

n-Butane

Definition*Chemical name*

Butane

Chemical formula $CH_3CH_2CH_2CH_3$ *Molecular weight*

58,12

Assay

Content not less than 96 %

Description

Colourless gas or liquid with mild, characteristic odour

Identification

A. Vapour pressure

108,935 kPa at 20 °C

▼ **M4****Purity**

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

E 943b ISOBUTANE**Synonyms**

2-methyl propane

Definition*Chemical name*

2-methyl propane

Chemical formula $(\text{CH}_3)_2\text{CH CH}_3$ *Molecular weight*

58,12

Assay

Content not less than 94 %

Description

Colourless gas or liquid with mild, characteristic odour

Identification

A. Vapour pressure

205,465 kPa at 20 °C

Purity

Methane	Not more than 0,15 % v/v
Ethane	Not more than 0,5 % v/v
Propane	Not more than 2,0 % v/v
n-Butane	Not more than 4,0 % v/v
1,3-butadiene	Not more than 0,1 % v/v
Moisture	Not more than 0,005 %

E 944 PROPANE**Definition***Chemical name*

Propane

Chemical formula $\text{CH}_3\text{CH}_2\text{CH}_3$ *Molecular weight*

44,09

Assay

Content not less than 95 %

Description

Colourless gas or liquid with mild, characteristic odour

Identification

A. Vapour pressure

732,910 kPa at 20 °C

Purity

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

▼ M4**E 949 HYDROGEN****Definition**

<i>Chemical name</i>	Hydrogen
Einecs	215-605-7
<i>Chemical formula</i>	H ₂
<i>Molecular weight</i>	2
<i>Assay</i>	Content not less than 99,9 %
<i>Description</i>	Colourless, odourless, highly flammable gas

Purity

Water	Not more than 0,005 % v/v
Oxygen	Not more than 0,001 % v/v
Nitrogen	Not more than 0,75 % v/v

▼ B**E 1105 LYSOZYME****Synonyms**

Lysozyme hydrochloride
Muramidase

Definition

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

<i>Chemical name</i>	Enzyme Commission (EC) No: 3.2.1.17
Einecs	232-620-4
<i>Molecular weight</i>	About 14 000
<i>Assay</i>	Content not less than 950 mg/g on the anhydrous basis
<i>Description</i>	White, odourless powder having a slightly sweet taste

Identification

- A. Isoelectric point 10,7
- B. pH of a 2 % aqueous solution between 3,0 and 3,6
- C. Absorption maximum of an aqueous solution (25 mg/100 ml) at 281 nm, a minimum at 252 nm

Purity

Water content	Not more than 6,0 % (Karl Fischer method) (powder form only)
Residue on ignition	Not more than 1,5 %
Nitrogen	Not less than 16,8 % and not more than 17,8 %
Arsenic	Not more than 1 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

Microbiological criteria

Total bacterial count	Not more than 5×10^4 col/g
<i>Salmonellae</i>	Absent in 25 g

▼ **B**

<i>Staphylococcus aureus</i>	Absent in 1 g
<i>Escherichia coli</i>	Absent in 1 g

▼ **M4****E 1201 POLYVINYLPIRROLIDONE**

Synonyms	Povidone PVP Soluble polyvinylpyrrolidone
Definition	
<i>Chemical name</i>	Polyvinylpyrrolidone, poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene]
<i>Chemical formula</i>	(C ₆ H ₉ NO) _n
<i>Molecular weight</i>	Not less than 25 000
<i>Assay</i>	Content not less than 11,5 % and not more than 12,8 % of nitrogen (N) on the anhydrous basis
<i>Description</i>	White or nearly white powder
Identification	
A. Solubility	Soluble in water and in ethanol. Insoluble in ether
B. pH of a 5 % solution	Between 3,0 and 7,0
Purity	
Water	Not more than 5 % (Karl Fischer)
Total ash	Not more than 0,1 %
Aldehyde	Not more than 500 mg/kg (as acetaldehyde)
Free-N-vinylpyrrolidone	Not more than 10 mg/kg
Hydrazine	Not more than 1 mg/kg
Lead	Not more than 5 mg/kg

E 1202 POLYVINYL POLYPYRROLIDONE

Synonyms	Crospovidone Cross linked polyvidone Insoluble polyvinylpyrrolidone
Definition	Polyvinylpolypyrrolidone is a poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene], cross linked in a random fashion. It is produced by the polymerisation of N-vinyl-2-pyrrolidone in the presence of either caustic catalyst or N, N'-divinyl-imidazolidone. Due to its insolubility in all common solvents the molecular weight range is not amenable to analytical determination
<i>Chemical name</i>	Polyvinylpyrrolidone, poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene]
<i>Chemical formula</i>	(C ₆ H ₉ NO) _n
<i>Assay</i>	Content not less than 11 % and not more than 12,8 % nitrogen (N) on the anhydrous basis
<i>Description</i>	A white hygroscopic powder with a faint, non-objectionable odour
Identification	
A. Solubility	Insoluble in water, ethanol and ether
B. pH of a 1 % suspension in water	Between 5,0 and 8,0
Purity	
Water	Not more than 6 % (Karl Fischer)

▼ **M4**

Sulphated ash	Not more than 0,4 %
Water-soluble matter	Not more than 1 %
Free-N-vinylpyrrolidone	Not more than 10 mg/kg
Free-N,N'-divinyl-imidazolidone	Not more than 2 mg/kg
Lead	Not more than 5 mg/kg

▼ **M5****POLYETHYLENE GLYCOL 6000**

Synonyms	PEG 6000 Macrogol 6000
Definition	Polyethylene glycol 6000 is a mixture of polymers with the general formula $\text{H} - (\text{OCH}_2 - \text{CH}) - \text{OH}$ corresponding to an average relative molecular mass of approximately 6 000
<i>Chemical formula</i>	$(\text{C}_2\text{H}_4\text{O})_n \text{H}_2\text{O}$ (n = number of ethylene oxide units corresponding to a molecular weight of 6 000, about 140)
<i>Molecular weight</i>	5 600 — 7 000
<i>Assay</i>	Not less than 90,0 % and not more than 110,0 %
<i>Description</i>	A white or almost white solid with a waxy or paraffin-like appearance
Identification	
A. Solubility	Very soluble in water and in methylene chloride. Practically insoluble in alcohol, in ether and in fatty and mineral oils
B. Melting range	Between 55 °C and 61 °C
Purity	
Viscosity	Between 0,220 and 0,275 $\text{kgm}^{-1}\text{s}^{-1}$ at 20 °C
Hydroxyl value	Between 16 and 22
Sulphated ash	Not more than 0,2 %
Ethylene oxide	Not more than 0,2 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

▼ **M2****E 296 MALIC ACID**

Synonyms	DL-Malic acid, pomalous acid
Definition	
<i>Chemical name</i>	DL-Malic acid, hydroxybutanedioic acid, hydroxysuccinic acid
EINECS	230-022-8
<i>Chemical formula</i>	$\text{C}_4\text{H}_6\text{O}_5$
<i>Molecular weight</i>	134,09
<i>Assay</i>	Content not less than 99,0 %
<i>Description</i>	White or nearly white crystalline powder or granules

▼ **M2****Identification**

- A. Melting range between 127 °C and 132 °C
 B. Positive test for malate
 C. Solutions of this substance are optically inactive in all concentrations

Purity

Sulphated ash	Not more than 0,1 %
Fumaric acid	Not more than 1,0 %
Maleic acid	Not more than 0,05 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 297 FUMARIC ACID**Definition**

<i>Chemical name</i>	Trans-butenedioic acid, trans-1,2-ethylene-dicarboxylic acid
EINECS	203-743-0
<i>Chemical formula</i>	C ₄ H ₄ O ₄
<i>Molecular weight</i>	116,07
<i>Assay</i>	Content not less than 99,0 % on the anhydrous basis
<i>Description</i>	White crystalline powder or granules

Identification

- | | |
|--|---|
| A. Melting range | 286 °C - 302 °C (closed capillary, rapid heating) |
| B. Positive tests for double bonds and for 1,2-dicarboxylic acid | |
| C. pH of a 0,05 % solution at 25 °C | 3,0 - 3,2 |

Purity

Loss on drying	Not more than 0,5 % (120 °C, 4h)
Sulphated ash	Not more than 0,1 %
Maleic acid	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 343(i) MONOMAGNESIUM PHOSPHATE**Synonyms**

Magnesiumdihydrogenphosphate
 Magnesiumphosphate, monobasic
 Monomagnesium orthophosphate

Definition

<i>Chemical name</i>	Monomagnesiumdihydrogenmonophosphate
EINECS	236-004-6
<i>Chemical formula</i>	Mg(H ₂ PO ₄) ₂ ·nH ₂ O (where n = 0 to 4)
<i>Molecular weight</i>	218,30 (anhydrous)
<i>Assay</i>	Not less than 51,0 % after ignition

▼ **M2**

<i>Description</i>	White, odourless, crystalline powder, slightly soluble in water
Identification	
A. Positive test for magnesium and for phosphate	
B. MgO content	Not less than 21,5 % after ignition
Purity	
Fluoride	Not more than 10 mg/kg (as fluorine)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 4 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 343(ii) DIMAGNESIUM PHOSPHATE

Synonyms	Magnesiumhydrogenphosphate Magnesiumphosphate, dibasic Dimagnesium orthophosphate Secondary magnesiumphosphate
Definition	
<i>Chemical name</i>	Dimagnesiummonohydrogenmonophosphate
EINECS	231-823-5
<i>Chemical formula</i>	MgHPO ₄ · nH ₂ O (where n = 0 - 3)
<i>Molecular weight</i>	120,30 (anhydrous)
<i>Assay</i>	Not less than 96 % after ignition
<i>Description</i>	White, odourless, crystalline powder, slightly soluble in water
Identification	
A. Positive test for magnesium and for phosphate	
B. MgO content:	Not less than 33,0 % calculated on an anhydrous basis
Purity	
Fluoride	Not more than 10 mg/kg (as fluorine)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 4 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 350 (i) SODIUM MALATE

Synonyms	Sodium salt of malic acid
Definition	
<i>Chemical name</i>	Disodium DL-malate, disodium salt of hydroxybutanedioic acid
<i>Chemical formula</i>	Hemihydrate: C ₄ H ₄ Na ₂ O ₅ · ½ H ₂ O Trihydrate: C ₄ H ₄ Na ₂ O ₅ · 3H ₂ O
<i>Molecular weight</i>	Hemihydrate: 187,05 Trihydrate: 232,10
<i>Assay</i>	Content not less than 98,0 % on the anhydrous basis

▼ **M2**

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

E 350 (ii) SODIUM HYDROGEN MALATE

Synonyms	Monosodium salt of DL-malic acid
Definition	
<i>Chemical name</i>	Monosodium DL-malate, monosodium 2-DL-hydroxy succinate
<i>Chemical formula</i>	C ₄ H ₅ NaO ₅
<i>Molecular weight</i>	156,07
<i>Assay</i>	Content not less than 99,0 % on the anhydrous basis
<i>Description</i>	White powder
Identification	
A. Positive tests for 1,2-dicarboxylic acid and for sodium	
B. Azo dye formation	Positive
Purity	
Loss on drying	Not more than 2,0 % (110 °C, 3h)
Maleic acid	Not more than 0,05 %
Fumaric acid	Not more than 1,0 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 351 POTASSIUM MALATE

Synonyms	Potassium salt of malic acid
Definition	
<i>Chemical name</i>	Dipotassium DL-malate, dipotassium salt of hydroxybutanedioic acid
<i>Chemical formula</i>	C ₄ H ₄ K ₂ O ₅
<i>Molecular weight</i>	210,27
<i>Assay</i>	Content not less than 59,5 %
<i>Description</i>	Colourless or almost colourless aqueous solution

▼ **M2****Identification**

- A. Positive tests for 1,2-dicarboxylic acid and for potassium
 B. Azo dye formation

Positive

Purity

- Alkalinity
 Fumaric acid
 Maleic acid
 Arsenic
 Lead
 Mercury

Not more than 0,2 % as K_2CO_3
 Not more than 1,0 %
 Not more than 0,05 %
 Not more than 3 mg/kg
 Not more than 5 mg/kg
 Not more than 1 mg/kg

E 352 (i) CALCIUM MALATE**Synonyms**

Calcium salt of malic acid

Definition*Chemical name*Calcium DL-malate, calcium- α -hydroxysuccinate, calcium salt of hydroxybutanedioic acid*Chemical formula* $C_4H_5CaO_5$ *Molecular weight*

172,14

Assay

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

Description

White powder

Identification

- A. Positive tests for malate, 1,2-dicarboxylic acid and for calcium
 B. Azo dye formation
 C. Solubility

Positive
 Slightly soluble in water

Purity

- Loss on drying
 Alkalinity
 Maleic acid
 Fumaric acid
 Fluoride
 Arsenic
 Lead
 Mercury

Not more than 2 % (100 °C, 3h)
 Not more than 0,2 % as $CaCO_3$
 Not more than 0,05 %
 Not more than 1,0 %
 Not more than 30 mg/kg
 Not more than 3 mg/kg
 Not more than 5 mg/kg
 Not more than 1 mg/kg

E 352 (ii) CALCIUM HYDROGEN MALATE**Synonyms**

Monocalcium salt of DL-malic acid

Definition*Chemical name*

Monocalcium DL-malate, monocalcium 2-DL-hydroxysuccinate

Chemical formula $(C_4H_5O_5)_2Ca$ *Assay*

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

Description

White powder

▼ **M2****Identification**

- A. Positive tests for 1,2-dicarboxylic acid and for calcium
 B. Azo dye formation

Positive

Purity

- Loss on drying
 Maleic acid
 Fumaric acid
 Fluoride
 Arsenic
 Lead
 Mercury

Not more than 2,0 % (110 °C, 3h)
 Not more than 0,05 %
 Not more than 1,0 %
 Not more than 30 mg/kg
 Not more than 3 mg/kg
 Not more than 5 mg/kg
 Not more than 1 mg/kg

E 355 ADIPIC ACID**Definition***Chemical name*

Hexanedioic acid, 1,4-butanedicarboxylic acid

EINECS

204-673-3

*Chemical formula*C₆H₁₀O₄*Molecular weight*

146,14

Assay

Content not less than 99,6 %

Description

White odourless crystals or crystalline powder

Identification

- A. Melting range
 B. Solubility

151,5-154,0 °C
 Slightly soluble in water. Freely soluble in ethanol

Purity

- Water
 Sulphated ash
 Arsenic
 Lead
 Mercury

Not more than 0,2 % (Karl Fischer method)
 Not more than 20 mg/kg
 Not more than 3 mg/kg
 Not more than 5 mg/kg
 Not more than 1 mg/kg

E 363 SUCCINIC ACID**Definition***Chemical name*

Butanedioic acid

EINECS

203-740-4

*Chemical formula*C₄H₆O₄*Molecular weight*

118,09

Assay

Content no less than 99,0 %

Description

Colourless or white, odourless crystals

Identification

- A. Melting range

Between 185,0 °C and 190,0 °C

Purity

- Residue on ignition

Not more than 0,025 % (800 °C, 15 min)

▼ **M2**

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

E 380 TRIAMMONIUM CITRATE

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

E 452(iii) SODIUM CALCIUM POLYPHOSPHATE

Synonym	Sodium calcium polyphosphate, glassy
Definition	
<i>Chemical name</i>	Sodium calcium polyphosphate
EINECS	233-782-9
<i>Chemical formula</i>	$(NaPO_3)_n CaO$ where n is typically 5
<i>Assay</i>	Not less than 61 % and not more than 69 % as P_2O_5
<i>Description</i>	White glassy crystals, spheres
Identification	
A. pH of a 1 % m/m slurry	Approximately 5 to 7
B. CaO content	7 %-15 % m/m
Purity	
Fluoride	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 4 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

▼ **M5****E 459 BETA-CYCLODEXTRIN**

Definition	Beta-cyclodextrin is a non-reducing cyclic saccharide consisting of seven α -1,4-linked D-glucopyranosyl units. The product is manufactured by the action of the enzyme cycloglycosyltransferase (CGTase) obtained from <i>Bacillus circulans</i> , <i>Paenibacillus macerans</i> or recombinant <i>Bacillus licheniformis</i> strain SJ1608 on partially hydrolysed starch.
<i>Chemical name</i>	Cycloheptaamylose
EINECS	231-493-2
<i>Chemical formula</i>	(C ₆ H ₁₀ O ₅) ₇
<i>Molecular weight</i>	1135
<i>Assay</i>	Content not less than 98,0 % of (C ₆ H ₁₀ O ₅) ₇ on an anhydrous basis
<i>Description</i>	Virtually odourless white or almost white crystalline solid
Identification	
A. Solubility	Sparingly soluble in water; freely soluble in hot water; slightly soluble in ethanol
B. Specific rotation	[α] _D ²⁵ : +160 ° to +164 ° (1 % solution)
Purity	
Water	Not more than 14 % (Karl Fischer method)
Other cyclodextrins	Not more than 2 % on an anhydrous basis
Residual solvents (toluene and trichloroethylene)	Not more than 1 mg/kg for each solvent
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg

▼ **M2****E 468 CROSS-LINKED SODIUM CARBOXYMETHYL-CELLULOSE**

Synonyms	Cross-linked carboxymethyl cellulose Cross-linked CMC Cross-linked sodium CMC Cross-linked cellulose gum
Definition	Cross-linked sodium carboxymethyl cellulose is the sodium salt of thermally cross-linked partly O-carboxymethylated cellulose
<i>Chemical name</i>	Sodium salt of the cross-linked carboxymethyl ether cellulose
<i>Chemical formula</i>	The polymers containing substituted anhydroglucose units with the general formula: C ₆ H ₇ O ₂ (OR ₁)(OR ₂)(OR ₃) where R ₁ , R ₂ and R ₃ may be any of the following: — H — CH ₂ COONa — CH ₂ COOH
<i>Description</i>	Slightly hygroscopic, white to off white, odourless powder

▼ **M2****Identification**

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

Purity

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

E 469 ENZYMATICALLY HYDROLYSED CARBOXY-METHYLCELLULOSE**Synonyms**

Sodium carboxymethyl cellulose, enzymatically hydrolysed

Definition

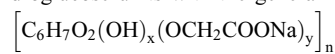
Enzymatically hydrolysed carboxymethylcellulose is obtained from carboxymethylcellulose by enzymatic digestion with a cellulase produced by *Trichoderma longibrachiatum* (formerly *T. reesei*)

Chemical name

Carboxymethyl cellulose, sodium, partially enzymatically hydrolysed

Chemical formula

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



where n is the degree of polymerisation

x = 1,50 to 2,80

y = 0,2 to 1,50

x + y = 3,0

(y = degree of substitution)

Formula weight

178,14 where y = 0,20

282,18 where y = 1,50

Macromolecules: Not less than 800 (n about 4)

Assay

Not less than 99,5 %, including mono- and disaccharides, on the dried basis

Description

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

Identification

- A. Solubility Soluble in water, insoluble in ethanol

▼ **M2**

B. Foam test	Vigorously shake a 0,1 % solution of the sample. No layer of foam appears. This test distinguishes sodium carboxymethyl cellulose, whether hydrolysed or not, from other cellulose ethers and from alginates and natural gums
C. Precipitate formation	To 5 ml of a 0,5 % solution of the sample add 5 ml of a 5 % solution of copper or aluminium sulphate. A precipitate appears. This test distinguishes sodium carboxymethyl cellulose, whether hydrolysed or not, from other cellulose ethers and from gelatine, carob bean gum and tragacanth gum
D. Colour reaction	Add 0,5 g of the powdered sample to 50 ml of water, while stirring to produce a uniform dispersion. Continue the stirring until a clear solution is produced. Dilute 1 ml of the solution with 1 ml of water in a small test tube. Add 5 drops of 1-naphthol TS. Incline the tube, and carefully introduce down the side of the tube 2 ml of sulphuric acid so that it forms a lower layer. A red-purple colour develops at the interface
E. Viscosity (60 % solids)	Not less than 2,500 kgm ⁻¹ s ⁻¹ at 25 °C corresponding to an average molecule weight of 5 000 D
Purity	
Loss on drying	Not more than 12 % (105 °C to constant weight)
Degree of substitution	Not less than 0,2 and not more than 1,5 carboxymethyl groups per anhydroglucose unit on the dried basis
pH of a 1 % colloidal solution	Not less than 6,0 and not more than 8,5
Sodium chloride and sodium glycolate	Not more than 0,5 % singly or in combination
Residual enzyme activity	Passes test. No change in viscosity of test solution occurs, which indicates hydrolysis of the sodium carboxymethyl cellulose
Lead	Not more than 3 mg/kg

E 500(i) SODIUM CARBONATE

Synonyms	Soda ash
Definition	
<i>Chemical name</i>	Sodium carbonate
EINECS	207-838-8
<i>Chemical formula</i>	Na ₂ CO ₃ · nH ₂ O (n = 0, 1 or 10)
<i>Molecular weight</i>	106,00 (anhydrous)
<i>Assay</i>	Content not less than 99 % of Na ₂ CO ₃ on the anhydrous basis
<i>Description</i>	Colourless crystals or white, granular or crystalline powder The anhydrous form is hygroscopic, the decahydrate efflorescent
Identification	
A. Positive tests for sodium and for carbonate	
B. Solubility	Freely soluble in water. Insoluble in ethanol
Purity	
Loss on drying	Not more than 2 % (anhydrous), 15 % (monohydrate) or 55 %-65 % (decahydrate) (70 °C raising gradually to 300 °C, to constant weight)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

▼ **M2**

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

E 500(ii) SODIUM HYDROGEN CARBONATE

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

E 500(iii) SODIUM SESQUICARBONATE

Definition	
<i>Chemical name</i>	Sodium monohydrogen dicarbonate
EINECS	208-580-9
<i>Chemical formula</i>	Na ₂ (CO ₃) ₃ · NaHCO ₃ · 2H ₂ O
<i>Molecular weight</i>	226,03
<i>Assay</i>	Content between 35,0 % and 38,6 % of NaHCO ₃ and between 46,4 % and 50,0 % of Na ₂ CO ₃
<i>Description</i>	White flakes, crystals or crystalline powder
Identification	
A. Positive tests for sodium and for carbonate	
B. Solubility	Freely soluble in water
Purity	
Sodium chloride	Not more than 0,5 %
Iron	Not more than 20 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

▼ **M2****E 501(i) POTASSIUM CARBONATE****Definition**

<i>Chemical name</i>	Potassium carbonate
EINECS	209-529-3
<i>Chemical formula</i>	$K_2CO_3 \cdot nH_2O$ (n = 0 or 1,5)
<i>Molecular weight</i>	138,21 (anhydrous)
<i>Assay</i>	Content not less than 99,0 % on the anhydrous basis
<i>Description</i>	White, very deliquescent powder. The hydrate occurs as small, white, translucent crystals or granules

Identification

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

Purity

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

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

Potassium bicarbonate, acid potassium carbonate

Definition

<i>Chemical name</i>	Potassium hydrogen carbonate
EINECS	206-059-0
<i>Chemical formula</i>	$KHCO_3$
<i>Molecular weight</i>	100,11
<i>Assay</i>	Content not less than 99,0 % and not more than 101,0 % $KHCO_3$ on the anhydrous basis
<i>Description</i>	Colourless crystals or white powder or granules

Identification

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

Purity

Loss on drying	Not more than 0,25 % (over silica gel, 4h)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 503(i) AMMONIUM CARBONATE**Definition**

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

<i>Chemical name</i>	Ammonium carbonate
----------------------	--------------------

▼ **M2**

EINECS	233-786-0
<i>Chemical formula</i>	CH ₆ N ₂ O ₂ , CH ₈ N ₂ O ₃ and CH ₅ NO ₃
<i>Molecular weight</i>	Ammonium carbamate 78,06; ammonium carbonate 98,73; ammonium hydrogen carbonate 79,06
<i>Assay</i>	Content not less than 30,0 % and not more than 34,0 % of NH ₃
<i>Description</i>	White powder or hard, white or translucent masses or crystals. Becomes opaque on exposure to air and is finally converted into white porous lumps or powder (of ammonium bicarbonate) due to loss of ammonia and carbon dioxide
Identification	
A. Positive tests for ammonium and for carbonate	
B. pH of a 5 % solution about 8,6	
C. Solubility	Soluble in water
Purity	
Non-volatile matter	Not more than 500 mg/kg
Chlorides	Not more than 30 mg/kg
Sulphate	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 503(ii) AMMONIUM HYDROGEN CARBONATE

Synonyms	Ammonium bicarbonate
Definition	
<i>Chemical name</i>	Ammonium hydrogen carbonate
EINECS	213-911-5
<i>Chemical formula</i>	CH ₅ NO ₃
<i>Molecular weight</i>	79,06
<i>Assay</i>	Content not less than 99,0 %
<i>Description</i>	White crystals or crystalline powder
Identification	
A. Positive tests for ammonium and for carbonate	
B. pH of a 5 % solution about 8,0	
C. Solubility	Freely soluble in water. Insoluble in ethanol
Purity	
Non-volatile matter	Not more than 500 mg/kg
Chlorides	Not more than 30 mg/kg
Sulphate	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 507 HYDROCHLORIC ACID

Synonyms	Hydrogen chloride, muriatic acid
-----------------	----------------------------------

▼ **M2****Definition***Chemical name*

Hydrochloric acid

EINECS

231-595-7

Chemical formula

HCl

Molecular weight

36,46

Assay

Hydrochloric acid is commercially available in varying concentrations. Concentrated hydrochloric acid contains not less than 35,0 % HCl

Description

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

Identification

A. Positive tests for acid and for chloride

B. Solubility

Soluble in water and in ethanol

Purity

Total organic compounds

Total organic compounds (non-fluorine containing): not more than 5 mg/kg

Benzene: not more than 0,05 mg/kg

Fluorinated compounds (total): not more than 25 mg/kg

Non-volatile matter

Not more than 0,5 %

Reducing substances

Not more than 70 mg/kg (as SO₂)

Oxidising substances

Not more than 30 mg/kg (as Cl₂)

Sulphate

Not more than 0,5 %

Iron

Not more than 5 mg/kg

Arsenic

Not more than 1 mg/kg

Lead

Not more than 1 mg/kg

Mercury

Not more than 1 mg/kg

E 509 CALCIUM CHLORIDE**Definition***Chemical name*

Calcium chloride

EINECS

233-140-8

*Chemical formula*CaCl₂ · nH₂O (n = 0,2 or 6)*Molecular weight*

110,99 (anhydrous), 147,02 (dihydrate), 219,08 (hexahydrate)

Assay

Content not less than 93,0 % on the anhydrous basis

Description

White, odourless, hygroscopic powder or deliquescent crystals

Identification

A. Positive tests for calcium and for chloride

B. Solubility

Anhydrous calcium chloride: freely soluble in water and ethanol

Dihydrate: freely soluble in water, soluble in ethanol

Hexahydrate: very soluble in water and ethanol

Purity

Magnesium and alkali salts

Not more than 5 % on the anhydrous basis

▼ **M2**

Fluoride	Not more than 40 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg

E 511 MAGNESIUM CHLORIDE**Definition**

<i>Chemical name</i>	Magnesium chloride
EINECS	232-094-6
<i>Chemical formula</i>	MgCl ₂ · 6H ₂ O
<i>Molecular weight</i>	203,30
<i>Assay</i>	Content not less than 99,0 %
<i>Description</i>	Colourless, odourless, very deliquescent flakes or crystals

Identification

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

Purity

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

E 512 STANNOUS CHLORIDE**Synonyms**

Tin chloride, tin dichloride

Definition

<i>Chemical name</i>	Stannous chloride dihydrate
EINECS	231-868-0
<i>Chemical formula</i>	SnCl ₂ · 2H ₂ O
<i>Molecular weight</i>	225,63
<i>Assay</i>	Content not less than 98,0 %
<i>Description</i>	Colourless or white crystals May have a slight odour of hydrochloric acid

Identification

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

Purity

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

▼ **M2****E 513 SULPHURIC ACID**

Synonyms	Oil of vitriol, dihydrogen sulphate
Definition	
<i>Chemical name</i>	Sulphuric acid
EINECS	231-639-5
<i>Chemical formula</i>	H ₂ SO ₄
<i>Molecular weight</i>	98,07
<i>Assay</i>	Sulphuric acid is commercially available in varying concentrations. The concentrated form contains not less than 96,0 %
<i>Description</i>	Clear, colourless or slightly brown, very corrosive oily liquid
Identification	
A. Positive tests for acid and for sulphate	
B. Solubility	Miscible with water, with generation of much heat, also with ethanol
Purity	
Ash	Not more than 0,02 %
Reducing matter	Not more than 40 mg/kg (as SO ₂)
Nitrate	Not more than 10 mg/kg (on H ₂ SO ₄ basis)
Chloride	Not more than 50 mg/kg
Iron	Not more than 20 mg/kg
Selenium	Not more than 20 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 514(i) SODIUM SULPHATE

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

▼ **M2**

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

E 514(ii) SODIUM HYDROGEN SULPHATE

Synonyms	Acid sodium sulphate, sodium bisulphate, nitre cake
Definition	
<i>Chemical name</i>	Sodium hydrogen sulphate
<i>Chemical formula</i>	NaHSO ₄
<i>Molecular weight</i>	120,06
<i>Assay</i>	Content not less than 95,2 %
<i>Description</i>	White, odourless crystals or granules
Identification	
A. Positive tests for sodium and for sulphate	
B. Solutions are strongly acidic	
Purity	
Loss on drying	Not more than 0,8 %
Water insoluble	Not more than 0,05 %
Selenium	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 515(i) POTASSIUM SULPHATE

Definition	
<i>Chemical name</i>	Potassium sulphate
<i>Chemical formula</i>	K ₂ SO ₄
<i>Molecular weight</i>	174,25
<i>Assay</i>	Content not less than 99,0 %
<i>Description</i>	Colourless or white crystals or crystalline powder
Identification	
A. Positive tests for potassium and for sulphate	
B. pH of a 5 % solution	Between 5,5 and 8,5
C. Solubility	Freely soluble in water, insoluble in ethanol
Purity	
Selenium	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 515(ii) POTASSIUM HYDROGEN SULPHATE

Definition	
<i>Synonyms</i>	Potassium bisulphate, potassium acid sulphate

▼ **M2**

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

E 516 CALCIUM SULPHATE

Synonyms	Gypsum, selenite, anhydrite
Definition	
<i>Chemical name</i>	Calcium sulphate
EINECS	231-900-3
<i>Chemical formula</i>	CaSO ₄ · nH ₂ O (n = 0 or 2)
<i>Molecular weight</i>	136,14 (anhydrous), 172,18 (dihydrate)
<i>Assay</i>	Content not less than 99,0 % on the anhydrous basis
<i>Description</i>	Fine, white to slightly yellowish-white odourless powder
Identification	
A. Positive tests for calcium and for sulphate	
B. Solubility	Slightly soluble in water, insoluble in ethanol
Purity	
Loss on drying	Anhydrous: not more than 1,5 % (250 °C, constant weight) Dihydrate: not more than 23 % (ibid.)
Fluoride	Not more than 30 mg/kg
Selenium	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 517 AMMONIUM SULPHATE

Definition	
<i>Chemical name</i>	Ammonium sulphate
EINECS	231-984-1
<i>Chemical formula</i>	(NH ₄) ₂ SO ₄
<i>Molecular weight</i>	132,14

▼ **M2**

<i>Assay</i>	Content not less than 99,0 % and not more than 100,5 %
<i>Description</i>	White powder, shining plates or crystalline fragments
Identification	
A. Positive tests for ammonium and for sulphate	
B. Solubility	Freely soluble in water, insoluble in ethanol
Purity	
Loss on ignition	Not more than 0,25 %
Selenium	Not more than 30 mg/kg
Lead	Not more than 5 mg/kg

E 520 ALUMINIUM SULPHATE

Synonyms	Alum
Definition	
<i>Chemical name</i>	Aluminium sulphate
EINECS	233-135-0
<i>Chemical formula</i>	$\text{Al}_2(\text{SO}_4)_3$
<i>Molecular weight</i>	342,13
<i>Assay</i>	Content not less than 99,5 % on the ignited basis
<i>Description</i>	White powder, shining plates or crystalline fragments
Identification	
A. Positive tests for aluminium and for sulphate	
B. pH of a 5 % solution 2,9 or above	
C. Solubility	Freely soluble in water, insoluble in ethanol
Purity	
Loss on ignition	Not more than 5 % (500 °C, 3h)
Alkalies and alkaline earths	Not more than 0,4 %
Selenium	Not more than 30 mg/kg
Fluoride	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg

E 521 ALUMINIUM SODIUM SULPHATE

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

▼ **M2****Identification**

- A. Positive tests for aluminium, for sodium and for sulphate
- B. Solubility

Dodecahydrate is freely soluble in water. The anhydrous form is slowly soluble in water. Both forms are insoluble in ethanol

Purity

Loss on drying

Anhydrous form: not more than 10,0 % (220 °C, 16h)

Dodecahydrate: not more than 47,2 % (50 °C-55 °C, 1h then 200 °C, 16h)

Ammonium salts

No odour of ammonia detectable after heating

Selenium

Not more than 30 mg/kg

Fluoride

Not more than 30 mg/kg

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 522 ALUMINIUM POTASSIUM SULPHATE**Synonyms**

Potassium alum, potash alum

Definition

Chemical name

Aluminium potassium sulphate dodecahydrate

EINECS

233-141-3

Chemical formula

$\text{AlK}(\text{SO}_4)_2 \cdot 12 \text{H}_2\text{O}$

Molecular weight

474,38

Assay

Content not less than 99,5 %

Description

Large, transparent crystals or white crystalline powder

Identification

- A. Positive tests for aluminium, for potassium and for sulphate
- B. pH of a 10 % solution between 3,0 and 4,0
- C. Solubility

Freely soluble in water, insoluble in ethanol

Purity

Ammonium salts

No odour of ammonia detectable after heating

Selenium

Not more than 30 mg/kg

Fluoride

Not more than 30 mg/kg

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

E 523 ALUMINIUM AMMONIUM SULPHATE**Synonyms**

Ammonium alum

Definition

Chemical name

Aluminium ammonium sulphate

EINECS

232-055-3

Chemical formula

$\text{AlNH}_4(\text{SO}_4)_2 \cdot 12 \text{H}_2\text{O}$

Molecular weight

453,32

▼ **M2**

<i>Assay</i>	Content not less than 99,5 %
<i>Description</i>	Large, colourless crystals or white powder
Identification	
A. Positive tests for aluminium, for ammonium and for sulphate	
B. Solubility	Freely soluble in water, soluble in ethanol
Purity	
Alkali metals and alkaline earths	Not more than 0,5 %
Selenium	Not more than 30 mg/kg
Fluoride	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 524 SODIUM HYDROXIDE

Synonyms	Caustic soda, lye
Definition	
<i>Chemical name</i>	Sodium hydroxide
EINECS	215-185-5
<i>Chemical formula</i>	NaOH
<i>Molecular weight</i>	40,0
<i>Assay</i>	Content of solid forms not less than 98,0 % of total alkali (as NaOH). Content of solutions accordingly, based on the stated or labelled percentage of NaOH
<i>Description</i>	White or nearly white pellets, flakes, sticks, fused masses or other forms. Solutions are clear or slightly turbid, colourless or slightly coloured, strongly caustic and hygroscopic and when exposed to the air they absorb carbon dioxide, forming sodium carbonate
Identification	
A. Positive tests for sodium	
B. A 1 % solution is strongly alkaline	
C. Solubility	Very soluble in water. Freely soluble in ethanol
Purity	
Water insoluble and organic matter	A 5 % solution is completely clear and colourless to slightly coloured
Carbonate	Not more than 0,5 % (as Na ₂ CO ₃)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 0,5 mg/kg
Mercury	Not more than 1 mg/kg

E 525 POTASSIUM HYDROXIDE

Synonyms	Caustic potash
Definition	
<i>Chemical name</i>	Potassium hydroxide
EINECS	215-181-3
<i>Chemical formula</i>	KOH

▼ **M2**

<i>Molecular weight</i>	56,11
<i>Assay</i>	Content not less than 85,0 % of alkali calculated as KOH
<i>Description</i>	White or nearly white pellets, flakes, sticks, fused masses or other forms
Identification	
A. Positive tests for potassium	
B. A 1 % solution is strongly alkaline	
C. Solubility	Very soluble in water. Freely soluble in ethanol
Purity	
Water insoluble matter	A 5 % solution is completely clear and colourless
Carbonate	Not more than 3,5 % (as K ₂ CO ₃)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg

E 526 CALCIUM HYDROXIDE

Synonyms	Slaked lime, hydrated lime
Definition	
<i>Chemical name</i>	Calcium hydroxide
EINECS	215-137-3
<i>Chemical formula</i>	Ca(OH) ₂
<i>Molecular weight</i>	74,09
<i>Assay</i>	Content not less than 92,0 %
<i>Description</i>	White powder
Identification	
A. Positive tests for alkali and for calcium	
B. Solubility	Slightly soluble in water. Insoluble in ethanol. Soluble in glycerol
Purity	
Acid insoluble ash	Not more than 1,0 %
Magnesium and alkali salts	Not more than 1,0 %
Barium	Not more than 300 mg/kg
Fluoride	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg

E 527 AMMONIUM HYDROXIDE

Synonyms	Aqua ammonia, strong ammonia solution
Definition	
<i>Chemical name</i>	Ammonium hydroxide
<i>Chemical formula</i>	NH ₄ OH
<i>Molecular weight</i>	35,05
<i>Assay</i>	Content not less than 27 % of NH ₃

▼ **M2**

<i>Description</i>	Clear, colourless solution, having an exceedingly pungent, characteristic odour
Identification	
A. Positive tests for ammonia	
Purity	
Non-volatile matter	Not more than 0,02 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

E 528 MAGNESIUM HYDROXIDE

Definition	
<i>Chemical name</i>	Magnesium hydroxide
EINECS	215-170-3
<i>Chemical formula</i>	Mg(OH) ₂
<i>Molecular weight</i>	58,32
<i>Assay</i>	Content not less than 95,0 % on the anhydrous basis
<i>Description</i>	Odourless, white bulky powder
Identification	
A. Positive test for magnesium and for alkali	
B. Solubility	Practically insoluble in water and in ethanol
Purity	
Loss on drying	Not more than 2,0 % (105 °C, 2h)
Loss on ignition	Not more than 33 % (800 °C to constant weight)
Calcium oxide	Not more than 1,5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg

E 529 CALCIUM OXIDE

Synonyms	Burnt lime
Definition	
<i>Chemical name</i>	Calcium oxide
EINECS	215-138-9
<i>Chemical formula</i>	CaO
<i>Molecular weight</i>	56,08
<i>Assay</i>	Content not less than 95,0 % on the ignited basis
<i>Description</i>	Odourless, hard, white or greyish white masses of granules, or white to greyish powder
Identification	
A. Positive test for alkali and for calcium	
B. Heat is generated on moistening the sample with water	
C. Solubility	Slightly soluble in water. Insoluble in ethanol. Soluble in glycerol

▼ **M2****Purity**

Loss on ignition	Not more than 10,0 % (ca 800 °C to constant weight)
Acid insoluble matter	Not more than 1,0 %
Barium	Not more than 300 mg/kg
Magnesium and alkali salts	Not more than 1,5 %
Fluoride	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg

E 530 MAGNESIUM OXIDE**Definition**

<i>Chemical name</i>	Magnesium oxide
EINECS	215-171-9
<i>Chemical formula</i>	MgO
<i>Molecular weight</i>	40,31
<i>Assay</i>	Content not less than 98,0 % on the ignited basis
<i>Description</i>	A very bulky, white powder known as light magnesium oxide or a relative dense, white powder known as heavy magnesium oxide. 5 g of light magnesium oxide occupy a volume of 40 to 50 ml, while 5 g of heavy magnesium oxide occupy a volume of 10 to 20 ml

Identification

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

Purity

Loss on ignition	Not more than 5,0 % (ca 800 °C to constant weight)
Calcium oxide	Not more than 1,5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg

E 535 SODIUM FERROCYANIDE**Synonyms**

Yellow prussiate of soda, sodium hexacyanoferrate

Definition

<i>Chemical name</i>	Sodium ferrocyanide
EINECS	237-081-9
<i>Chemical formula</i>	$\text{Na}_4\text{Fe}(\text{CN})_6 \cdot 10 \text{H}_2\text{O}$
<i>Molecular weight</i>	484,1
<i>Assay</i>	Content not less than 99,0 %
<i>Description</i>	Yellow crystals or crystalline powder

Identification

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

Purity

Free moisture	Not more than 1,0 %
---------------	---------------------

▼ **M2**

Water insoluble matter	Not more than 0,03 %
Chloride	Not more than 0,2 %
Sulphate	Not more than 0,1 %
Free cyanide	Not detectable
Ferricyanide	Not detectable
Lead	Not more than 5 mg/kg

E 536 POTASSIUM FERROCYANIDE

Synonyms	Yellow prussiate of potash, potassium hexacyanoferrate
Definition	
<i>Chemical name</i>	Potassium ferrocyanide
EINECS	237-722-2
<i>Chemical formula</i>	$K_4Fe(CN)_6 \cdot 3 H_2O$
<i>Molecular weight</i>	422,4
<i>Assay</i>	Content not less than 99,0 %
<i>Description</i>	Lemon yellow crystals
Identification	
A. Positive test for potassium and for ferrocyanide	
Purity	
Free moisture	Not more than 1,0 %
Water insoluble matter	Not more than 0,03 %
Chloride	Not more than 0,2 %
Sulphate	Not more than 0,1 %
Free cyanide	Not detectable
Ferricyanide	Not detectable
Lead	Not more than 5 mg/kg

E 538 CALCIUM FERROCYANIDE

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

▼ **M2**

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

E 541 SODIUM ALUMINIUM PHOSPHATE, ACIDIC

Synonyms	SALP
Definition	
<i>Chemical name</i>	Sodium trialuminium tetradecahydrogen octaphosphate tetrahydrate (A) or Trisodium dialuminium pentadecahydrogen octaphosphate (B)
EINECS	232-090-4
<i>Chemical formula</i>	$\text{NaAl}_3\text{H}_{14}(\text{PO}_4)_8 \cdot 4\text{H}_2\text{O}$ (A) $\text{Na}_3\text{Al}_2\text{H}_{15}(\text{PO}_4)_8$ (B)
<i>Molecular weight</i>	949,88 (A) 897,82 (B)
<i>Assay</i>	Content not less than 95,0 % (both forms)
<i>Description</i>	White odourless powder
Identification	
A. Positive test for sodium, for aluminium and for phosphate	
B. pH	Acid to litmus
C. Solubility	Insoluble in water. Soluble in hydrochloric acid
Purity	
Loss on ignition	19,5 % - 21,0 % (A) } (750 °C - 800 °C, 2h) 15 % - 16 % (B) } (750 °C - 800 °C, 2h)
Fluoride	Not more than 25 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 4 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 551 SILICON DIOXIDE

Synonyms	Silica, silicium dioxide
Definition	Silicon dioxide is an amorphous substance, which is produced synthetically by either a vapour-phase hydrolysis process, yielding fumed silica, or by a wet process, yielding precipitated silica, silica gel, or hydrous silica. Fumed silica is produced in essentially an anhydrous state, whereas the wet-process products are obtained as hydrates or contain surface absorbed water
<i>Chemical name</i>	Silicon dioxide
EINECS	231-545-4
<i>Chemical formula</i>	$(\text{SiO}_2)_n$
<i>Molecular weight</i>	60,08 (SiO_2)
<i>Assay</i>	Content after ignition not less than 99,0 % (fumed silica) or 94,0 % (hydrated forms)

▼ **M2**

<i>Description</i>	White, fluffy powder or granules Hygroscopic
Identification	
A. Positive test for silica	
Purity	
Loss on drying	Not more than 2,5 % (fumed silica, 105 °C, 2h) Not more than 8,0 % (precipitated silica and silica gel, 105 °C, 2h) Not more than 70 % (hydrous silica, 105 °C, 2h)
Loss on ignition	Not more than 2,5 % after drying (1 000 °C, fumed silica) Not more than 8,5 % after drying (1 000 °C, hydrated forms)
Soluble ionisable salts	Not more than 5,0 % (as Na ₂ SO ₄)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 552 CALCIUM SILICATE

Definition	Calcium silicate is a hydrous or anhydrous silicate with varying proportions of CaO and SiO ₂
<i>Chemical name</i>	Calcium silicate
EINECS	215-710-8
<i>Assay</i>	Content on the anhydrous basis: — as SiO ₂ not less than 50 % and not more than 95 % — as CaO not less than 3 % and not more than 35 %
<i>Description</i>	White to off-white free-flowing powder that remains so after absorbing relatively large amounts of water or other liquids
Identification	
A. Positive test for silicate and for calcium	
B. Forms a gel with mineral acids	
Purity	
Loss on drying	Not more than 10 % (105 °C, 2h)
Loss on ignition	Not less than 5 % and not more than 14 % (1 000 °C, constant weight)
Sodium	Not more than 3 %
Fluoride	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 553a(i) MAGNESIUM SILICATE

Definition	Magnesium silicate is a synthetic compound of which the molar ratio of magnesium oxide to silicon dioxide is approximately 2:5
<i>Assay</i>	Content not less than 15 % of MgO and not less than 67 % of SiO ₂ on the ignited basis

▼ **M2**

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

E 553a(ii) MAGNESIUM TRISILICATE

Definition	
<i>Chemical name</i>	Magnesium trisilicate
<i>Chemical formula</i>	Mg ₂ Si ₃ O ₈ · xH ₂ O (approximate composition)
EINECS	239-076-7
<i>Assay</i>	Content not less than 29,0 % of MgO and not less than 65,0 % of SiO ₂ both on the ignited basis
<i>Description</i>	Fine, white powder, free from grittiness
Identification	
A. Positive test for magnesium and for silicate	
B. pH of a 5 % slurry	Between 6,3 and 9,5
Purity	
Loss on ignition	Not less than 17 % and not more than 34 % (1 000 °C)
Water soluble salts	Not more than 2 %
Free alkali	Not more than 1 % (as NaOH)
Fluoride	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 570 FATTY ACIDS

Definition	Linear fatty acids, caprylic acid (C ₈), capric acid (C ₁₀), lauric acid (C ₁₂), myristic acid (C ₁₄), palmitic acid (C ₁₆), stearic acid (C ₁₈), oleic acid (C _{18:1})
<i>Chemical name</i>	octanoic acid (C ₈), decanoic acid (C ₁₀), dodecanoic acid (C ₁₂), tetradecanoic acid (C ₁₄), hexadecanoic acid (C ₁₆), octadecanoic acid (C ₁₈), 9-octadecenoic acid (C _{18:1})
<i>Assay</i>	Not less than 98 % by chromatography
<i>Description</i>	A colourless liquid or white solid obtained from oils and fats

▼ **M2****Identification**

- A. Individual fatty acids can be identified by acid value, iodine value, gas chromatography and molecular weight

Purity

Residue on ignition	Not more than 0,1 %
Unsaponifiable matter	Not more than 1,5 %
Water	Not more than 0,2 % (Karl Fischer method)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 574 GLUCONIC ACID**Synonyms**

D-gluconic acid, dextronic acid

Definition

Gluconic acid is an aqueous solution of gluconic acid and glucono-delta-lactone

Chemical name

Gluconic acid

*Chemical formula*C₆H₁₂O₇ (gluconic acid)*Molecular weight*

196,2

Assay

Content not less than 50,0 % (as gluconic acid)

Description

Colourless to light yellow, clear syrupy liquid

Identification

- A. Formation of phenylhydrazine derivative positive

Compound formed melts between 196 °C and 202 °C with decomposition

Purity

Residue on ignition	Not more than 1,0 %
Reducing matter	Not more than 0,75 % (as D-glucose)
Chloride	Not more than 350 mg/kg
Sulphate	Not more than 240 mg/kg
Sulphite	Not more than 20 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 575 GLUCONO-DELTA-LACTONE**Synonyms**

Gluconolactone, GDL, D-gluconic acid delta-lactone, delta-gluconolactone

Definition

Glucono-delta-lactone is the cyclic 1,5-intramolecular ester of D-gluconic acid. In aqueous media it is hydrolysed to an equilibrium mixture of D-gluconic acid (55 %-66 %) and the delta- and gamma-lactones

Chemical name

D-Glucono-1,5-lactone

EINECS

202-016-5

*Chemical formula*C₆H₁₀O₆*Molecular weight*

178,14

Assay

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

Description

Fine, white, nearly odourless, crystalline powder

▼ **M2****Identification**

- | | |
|--|--|
| A. Formation of phenylhydrazine derivative of gluconic acid positive | Compound formed melts between 196 °C and 202 °C with decomposition |
| B. Solubility | Freely soluble in water. Sparingly soluble in ethanol |
| C. Melting point | 152 °C ± 2 °C |

Purity

- | | |
|---------------------|---|
| Water | Not more than 1,0 % (Karl Fischer method) |
| Reducing substances | Not more than 0,75 % (as D-glucose) |
| Lead | Not more than 2 mg/kg |

E 576 SODIUM GLUCONATE**Synonyms**

Sodium salt of D-gluconic acid

Definition*Chemical name*

Sodium D-gluconate

EINECS

208-407-7

*Chemical formula*C₆H₁₁NaO₇ (anhydrous)*Molecular weight*

218,14

Assay

Content not less than 98,0 %

Description

White to tan, granular to fine, crystalline powder

Identification

- | | |
|---|---|
| A. Positive test for sodium and for gluconate | |
| B. Solubility | Very soluble in water. Sparingly soluble in ethanol |
| C. pH of a 10 % solution | Between 6,5 and 7,5 |

Purity

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

E 577 POTASSIUM GLUCONATE**Synonyms**

Potassium salt of D-gluconic acid

Definition*Chemical name*

Potassium D-gluconate

EINECS

206-074-2

*Chemical formula*C₆H₁₁KO₇ (anhydrous)C₆H₁₁KO₇ · H₂O (monohydrate)*Molecular weight*

234,25 (anhydrous)

252,26 (monohydrate)

Assay

Content not less than 97,0 % and not more than 103,0 % on dried basis

Description

Odourless, free flowing white to yellowish white, crystalline powder or granules

Identification

- | | |
|--|---------------------|
| A. Positive test for potassium and for gluconate | |
| B. pH of a 10 % solution | Between 7,0 and 8,3 |

▼ **M2****Purity**

Loss on drying	Anhydrous: not more than 3,0 % (105 °C, 4h, vacuum) Monohydrate: not less than 6 % and not more than 7,5 % (105 °C, 4h, vacuum)
Reducing substances	Not more than 1,0 % (as D-glucose)
Lead	Not more than 2 mg/kg

E 578 CALCIUM GLUCONATE**Synonyms**

Calcium salt of D-gluconic acid

Definition*Chemical name*

Calcium di-D-gluconate

EINECS

206-075-8

*Chemical formula*C₁₂H₂₂CaO₁₄ (anhydrous)C₁₂H₂₂CaO₁₄ · H₂O (monohydrate)*Molecular weight*

430,38 (anhydrous form)

448,39 (monohydrate)

Assay

Content not less than 98,0 % and not more than 102 % on the anhydrous and monohydrate basis

Description

Odourless, white crystalline granules or powder, stable in air

Identification

- A. Positive test for calcium and for gluconate
- B. Solubility
- C. pH of a 5 % solution

Soluble in water, insoluble in ethanol

Between 6,0 and 8,0

Purity

Loss on drying	Not more than 3,0 % (105 °C, 16h) (anhydrous) Not more than 2,0 % (105 °C, 16h) (monohydrate)
Reducing substances	Not more than 1,0 % (as D-glucose)
Lead	Not more than 2 mg/kg

E 640 GLYCINE AND ITS SODIUM SALT**Synonyms (gly)**

Aminoacetic acid, glycocoll

(Na salt)

Sodium glycinate

Definition**Chemical name (gly)**

Aminoacetic acid

(Na salt)

Sodium glycinate

*Chemical formula (gly)*C₂H₅NO₂*(Na salt)*C₂H₅NO₂ Na

EINECS (gly)

200-272-2

(Na salt)

227-842-3

Molecular weight (gly)

75,07

(Na salt)

98

Assay

Content not less than 98,5 % on the anhydrous basis

Description

White crystals or crystalline powder

▼ **M2****Identification**

- A. Positive test for aminoacid (gly and Na salt)
 B. Positive test for sodium (Na salt)

Purity

Loss on drying (gly)	Not more than 0,2 % (105 °C, 3h)
(Na salt)	Not more than 0,2 % (105 °C, 3h)
Residue on ignition (gly)	Not more than 0,1 %
(Na salt)	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 900 DIMETHYL POLYSILOXANE**Synonyms**

Polydimethyl siloxane, silicone fluid, silicone oil, dimethyl silicone

Definition

Dimethylpolysiloxane is a mixture of fully methylated linear siloxane polymers containing repeating units of the formula $(\text{CH}_3)_2\text{SiO}$ and stabilised with trimethylsiloxy end-blocking units of the formula $(\text{CH}_3)_3\text{SiO}$

Chemical name

Siloxanes and silicones, di-methyl

Chemical formula

$(\text{CH}_3)_3\text{-Si-[O-Si(CH}_3)_2]_n\text{-O-Si(CH}_3)_3$

Assay

Content of total silicon not less than 37,3 % and not more than 38,5 %

Description

Clear, colourless, viscous liquid

Identification

- A. Specific gravity (25°/25 °C) Between 0,964 and 0,977
 B. Refractive index $[n]_D^{25}$ Between 1,400 and 1,405
 C. Infrared spectrum characteristic of the compound

Purity

Loss on drying	Not more than 0,5 % (150 °C, 4h)
Viscosity	Not less than $1,00 \cdot 10^{-4} \text{ m}^2\text{s}^{-1}$ at 25 °C
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 901 BEESWAX**Synonyms**

White wax, yellow wax

Definition

Yellow bees wax is the wax obtained by melting the walls of the honeycomb made by the honey bee, *Apis mellifera* L., with hot water and removing foreign matter

White beeswax is obtained by bleaching yellow beeswax

EINECS

232-383-7 (beeswax)

Description

Yellowish white (white form) or yellowish to greyish brown (yellow form) pieces or plates with a fine-grained and non-crystalline fracture, having an agreeable, honey-like odour

▼ **M2****Identification**

A. Melting range	Between 62 °C and 65 °C
B. Specific gravity	About 0,96
C. Solubility	Insoluble in water Sparingly soluble in alcohol Very soluble in chloroform and ether

Purity

Acid value	Not less than 17 and not more than 24
Saponification value	87-104
Peroxide value	Not more than 5
Glycerol and other polyols	Not more than 0,5 % (as glycerol)
Ceresin, paraffins and certain other waxes	Absent
Fats, Japan wax, rosin and soaps	Absent
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 902 CANDELILLA WAX**Definition**

Candelilla wax is a purified wax obtained from the leaves of the candelilla plant, *Euphorbia antisyphilitica*

EINECS

232-347-0

Description

Hard, yellowish brown, opaque to translucent wax

Identification

A. Specific gravity	About 0,983
B. Melting range	Between 68,5 °C and 72,5 °C
C. Solubility	Insoluble in water Soluble in chloroform and toluene

Purity

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

E 903 CARNAUBA WAX**Definition**

Carnauba wax is a purified wax obtained from the leaf buds and leaves of the Brazilian Mart wax palm, *Copernicia cereferia*

EINECS

232-399-4

Description

Light brown to pale yellow powder or flakes or hard and brittle solid with a resinous fracture

▼ **M2****Identification**

A. Specific gravity	About 0,997
B. Melting range	Between 82 °C and 86 °C
C. Solubility	Insoluble in water Partly soluble in boiling ethanol Soluble in chloroform and diethyl ether

Purity

Sulphated ash	Not more than 0,25 %
Acid value	Not less than 2 and not more than 7
Ester value	Not less than 71 and not more than 88
Unsaponifiable matter	Not less than 50 % and not more than 55 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 904 SHELLAC**Synonyms**

Bleached shellac, white shellac

DefinitionShellac is the purified and bleached lac, the resinous secretion of the insect *Laccifer (Tachardia) lacca* Kerr (Fam. *Coccidae*)**EINECS**

232-549-9

*Description*Bleached shellac — off-white, amorphous, granular resin
Wax-free bleached shellac — light yellow, amorphous, granular resin**Identification**

A. Solubility	Insoluble in water; freely (though very slowly) soluble in alcohol; slightly soluble in acetone
B. Acid value	Between 60 and 89

Purity

Loss on drying	Not more than 6,0 % (40 °C, over silica gel, 15h)
Rosin	Absent
Wax	Bleached shellac: not more than 5,5 % Wax-free bleached shellac: not more than 0,2 %
Lead	Not more than 2 mg/kg

E 920 L-CYSTEINE**Definition**

L-cysteine hydrochloride or hydrochloride monohydrate. Human hair may not be used as a source for this substance

EINECS

200-157-7 (anhydrous)

Chemical formula $C_3H_7NO_2S \cdot HCl \cdot n H_2O$ (where $n = 0$ or 1)*Molecular weight*

157,62 (anhydrous)

Assay

Content not less than 98,0 % and not more than 101,5 % on the anhydrous basis

Description

White powder or colourless crystals

Identification

A. Solubility	Freely soluble in water and in ethanol
---------------	--

▼ **M2**

B. Melting range	Anhydrous form melts at about 175 °C
C. Specific rotation	$[\alpha]_D^{20}$: between + 5,0° and + 8,0° or $[\alpha]_D^{25}$: between + 4,9° and 7,9°
Purity	
Loss on drying	Between 8,0 % and 12,0 % Not more than 2,0 % (anhydrous form)
Residue on ignition	Not more than 0,1 %
Ammonium-ion	Not more than 200 mg/kg
Arsenic	Not more than 1,5 mg/kg
Lead	Not more than 5 mg/kg

E 927b CARBAMIDE

Synonyms	Urea
Definition	
EINECS	200-315-5
<i>Chemical formula</i>	CH ₄ N ₂ O
<i>Molecular weight</i>	60,06
<i>Assay</i>	Content not less than 99,0 % on the anhydrous basis
<i>Description</i>	Colourless to white, prismatic, crystalline powder or small, white pellets
Identification	
A. Solubility	Very soluble in water Soluble in ethanol
B. Precipitation with nitric acid	To pass the test a white, crystalline precipitate is formed
C. Colour reaction	To pass the test a reddish-violet colour is produced
D. Melting range	132 °C to 135 °C
Purity	
Loss on drying	Not more than 1,0 % (105 °C, 1h)
Sulphated ash	Not more than 0,1 %
Ethanol-insoluble matter	Not more than 0,04 %
Alkalinity	Passes test
Ammonium-ion	Not more than 500 mg/kg
Biuret	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

E 938 ARGON

Definition	
<i>Chemical name</i>	Argon
EINECS	231-147-0
<i>Chemical formula</i>	Ar
<i>Molecular weight</i>	40
<i>Assay</i>	Not less than 99 %
<i>Description</i>	Colourless, odourless, non-flammable gas

▼ **M2****Purity**

Water	Not more than 0,05 %
Methane and other hydrocarbons calculated as methane	Not more than 100 µl/l

E 939 HELIUM**Definition**

<i>Chemical name</i>	Helium
EINECS	231-168-5
<i>Chemical formula</i>	He
<i>Molecular weight</i>	4
<i>Assay</i>	Not less than 99 %
<i>Description</i>	Colourless, odourless, non-flammable gas

Purity

Water	Not more than 0,05 %
Methane and other hydrocarbons calculated as methane	Not more than 100 µl/l

E 941 NITROGEN**Definition**

<i>Chemical name</i>	Nitrogen
EINECS	231-783-9
<i>Chemical formula</i>	N ₂
<i>Molecular weight</i>	28
<i>Assay</i>	Not less than 99 %
<i>Description</i>	Colourless, odourless, non-flammable gas

Purity

Water	Not more than 0,05 %
Carbon monoxide	Not more than 10 µl/l
Methane and other hydrocarbons calculated as methane	Not more than 100 µl/l
Nitrogen dioxide and nitrogen oxide	Not more than 10 µl/l
Oxygen	Not more than 1 %

E 942 NITROUS OXIDE**Definition**

<i>Chemical name</i>	Nitrous oxide
EINECS	233-032-0
<i>Chemical formula</i>	N ₂ O
<i>Molecular weight</i>	44
<i>Assay</i>	Not less than 99 %
<i>Description</i>	Colourless, non-flammable gas, sweetish odour

Purity

Water	Not more than 0,05 %
Carbon monoxide	Not more than 30 µl/l

▼ **M2**

Nitrogen dioxide and nitrogen oxide	Not more than 10 µl/l
-------------------------------------	-----------------------

E 948 OXYGEN**Definition**

<i>Chemical name</i>	Oxygen
EINECS	231-956-9
<i>Chemical formula</i>	O ₂
<i>Molecular weight</i>	32
<i>Assay</i>	Not less than 99 %
<i>Description</i>	Colourless, odourless, non-flammable gas

Purity

Water	Not more than 0,05 %
Methane and other hydrocarbons calculated as methane	Not more than 100 µl/l

E 999 QUILLAIA EXTRACT**Synonyms**

	Soapbark extract, Quillay bark extract, Panama bark extract, Quillai extract, Murillo bark extract, China bark extract
--	--

Definition

	Quillaia extract is obtained by aqueous extraction of <i>Quillai saponaria</i> Molina, or other <i>Quillaia</i> species, trees of the family <i>Rosaceae</i> . It contains a number of triterpenoid saponins consisting of glycosides of quillaic acid. Some sugars including glucose, galactose, arabinose, xylose, and rhamnose are also present, along with tannin, calcium oxalate and other minor components
--	---

Description

	Quillaia extract in the powder form is light brown with a pink tinge. It is also available as an aqueous solution
--	---

Identification

A. pH of a 2,5 % solution	Between 4,5 and 5,5
---------------------------	---------------------

Purity

Water	Not more than 6,0 % (Karl Fischer method) (powder form only)
Arsenic	Not more than 2 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 1103 INVERTASE**Definition**

<i>Systematic name</i>	Invertase is produced from <i>Saccharomyces cerevisiae</i> β-D-Fructofuranoside fructohydrolase
<i>Enzyme Commission No</i>	EC 3.2.1.26
EINECS	232-615-7

Purity

Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Cadmium	Not more than 0,5 mg/kg
Total bacterial count	Not more than 50 000/g
<i>Salmonella</i> spp.	Absent by test in 25 g

▼ **M2**

Coliforms	Not more than 30/g
E. coli	Absent by test in 25 g
E 1200 POLYDEXTROSE	
Synonyms	Modified polydextroses
Definition	Randomly bonded glucose polymers with some sorbitol end-groups, and with citric acid or phosphoric acid residues attached to the polymers by mono or diester bonds. They are obtained by melting and condensation of the ingredients and consist of approximately 90 parts D-glucose, 10 parts sorbitol and 1 part citric acid or 0,1 part phosphoric acid. The 1,6-glycosidic linkage predominates in the polymers but other linkages are present. The products contain small quantities of free glucose, sorbitol, levoglucosan (1,6-anhydro-D-glucose) and citric acid and may be neutralised with any food grade base and/or decolorised and deionised for further purification. The products may also be partially hydrogenated with Raney nickel catalyst to reduce residual glucose. Polydextrose-N is neutralised polydextrose
<i>Assay</i>	Content not less than 90 % of polymer on the ash free and anhydrous basis
<i>Description</i>	White to light tan-coloured solid. Polydextroses dissolve in water to give a clear, colourless to straw coloured solution
Identification	
A. Positive tests for sugar and for reducing sugar	
B. pH of a 10 % solution	Between 2,5 and 7,0 for polydextrose Between 5,0 and 6,0 for polydextrose-N
Purity	
Water	Not more than 4,0 % (Karl Fischer method)
Sulphated ash	Not more than 0,3 % (polydextrose) Not more than 2,0 % (polydextrose N)
Nickel	Not more than 2 mg/kg for hydrogenated polydextroses
1,6-Anhydro-D-glucose	Not more than 4,0 % on the ash-free and the dried basis
Glucose and sorbitol	Not more than 6,0 % combined on the ash-free and the dried basis; glucose and sorbitol are determined separately
Molecular weight limit	Negative test for polymers of molecular weight greater than 22,000
5-Hydroxymethylfurfural	Not more than 0,1 % (polydextrose) Not more than 0,05 % (polydextrose-N)
Lead	Not more than 0,5 mg/kg

E 1404 OXIDISED STARCH

Definition	Oxidised starch is starch treated with sodium hypochlorite
<i>Description</i>	White or nearly white powder or granules or (if pre-gelatinised) flakes, amorphous powder or coarse particles

▼ **M2****Identification**

- A. If not pregelatinised: by microscopic observation
- B. Iodine staining positive (dark blue to light red colour)

Purity (all values expressed on an anhydrous basis except for loss on drying)

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

E 1410 MONOSTARCH PHOSPHATE**Definition**

Monostarch phosphate is starch esterified with orthophosphoric acid, or sodium or potassium ortho-phosphate or sodium tripolyphosphate

Description

White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

Identification

- A. If not pregelatinised: by microscopic observation
- B. Iodine staining positive (dark blue to light red colour)

Purity (all values expressed on an anhydrous basis except for loss on drying)

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

E 1412 DISTARCH PHOSPHATE**Definition**

Distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride

Description

White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

▼ **M2****Identification**

- A. If not pregelatinised: by microscopic observation
- B. Iodine staining positive (dark blue to light red colour)

Purity (all values expressed on an anhydrous basis except for loss on drying)

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

E 1413 PHOSPHATED DISTARCH PHOSPHATE**Definition**

Phosphated distarch phosphate is starch having undergone a combination of treatments as described for monostarch phosphate and for distarch phosphate

Description

White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

Identification

- A. If not pregelatinised: by microscopic observation
- B. Iodine staining positive (dark blue to light red colour)

Purity (all values expressed on an anhydrous basis except for loss on drying)

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

E 1414 ACETYLATED DISTARCH PHOSPHATE**Definition**

Acetylated distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride and esterified by acetic anhydride or vinyl acetate

Description

White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

▼ **M2****Identification**

- A. If not pregelatinised: by microscopic observation
- B. Iodine staining positive (dark blue to light red colour)

Purity (all values expressed on an anhydrous basis except for loss on drying)

Loss on drying	Not more than 15,0 % for cereal starch Not more than 21,0 % for potato starch Not more than 18,0 % for other starches
Acetyl groups	Not more than 2,5 %
Residual phosphate	Not more than 0,14 % (as P) for wheat or potato starch Not more than 0,04 % (as P) for other starches
Vinyl acetate	Not more than 0,1 mg/kg
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches Not more than 10 mg/kg for other modified starches, unless otherwise specified
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 0,1 mg/kg

E 1420 ACETYLATED STARCH**Synonyms**

Starch acetate

Definition

Acetylated starch is starch esterified with acetic anhydride or vinyl acetate

Description

White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

Identification

- A. If not pregelatinised: by microscopic observation
- B. Iodine staining positive (dark blue to light red colour)

Purity (all values expressed on an anhydrous basis except for loss on drying)

Loss on drying	Not more than 15,0 % for cereal starch Not more than 21,0 % for potato starch Not more than 18,0 % for other starches
Acetyl groups	Not more than 2,5 %
Vinyl acetate	Not more than 0,1 mg/kg
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches Not more than 10 mg/kg for other modified starches, unless otherwise specified
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 0,1 mg/kg

E 1422 ACETYLATED DISTARCH ADIPATE**Definition**

Acetylated distarch adipate is starch cross-linked with adipic anhydride and esterified with acetic anhydride

▼ **M2**

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

E 1440 HYDROXYPROPYL STARCH

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

E 1442 HYDROXYPROPYL DISTARCH PHOSPHATE

Definition	Hydroxypropyl distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride and etherified with propylene oxide
<i>Description</i>	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

▼ **M2****Identification**

- A. If not pregelatinised: by microscopic observation
- B. Iodine staining positive (dark blue to light red colour)

Purity (all values expressed on an anhydrous basis except for loss on drying)

Loss on drying	Not more than 15,0 % for cereal starch Not more than 21,0 % for potato starch Not more than 18,0 % for other starches
Hydroxypropyl groups	Not more than 7,0 %
Residual phosphate	Not more than 0,14 % (as P) for wheat or potato starch Not more than 0,04 (as P) for other starches
Propylene chlorohydrin	Not more than 1 mg/kg
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches Not more than 10 mg/kg for other modified starches, unless otherwise specified
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 0,1 mg/kg

E 1450 STARCH SODIUM OCTENYL SUCCINATE**Synonyms**

SSOS

Definition

Starch sodium octenyl succinate is starch esterified with octenylsuccinic anhydride

Description

White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

Identification

- A. If not pregelatinised: by microscopic observation
- B. Iodine staining positive (dark blue to light red colour)

Purity (all values expressed on an anhydrous basis except for loss on drying)

Loss on drying	Not more than 15,0 % for cereal starch Not more than 21,0 % for potato starch Not more than 18,0 % for other starches
Octenylsuccinyl groups	Not more than 3 %
Octenylsuccinic acid residue	Not more than 0,3 %
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches Not more than 10 mg/kg for other modified starches, unless otherwise specified
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 0,1 mg/kg

E 1451 ACETYLATED OXIDISED STARCH**Definition**

Acetylated oxidised starch is starch treated with sodium hypochlorite followed by esterification with acetic anhydride

▼ **M2**

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

E 1505 TRIETHYL CITRATE

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

E 1518 GLYCERYL TRIACETATE

Synonyms	Triacetin
Definition	
<i>Chemical name</i>	Glyceryl triacetate
EINECS	203-051-9
<i>Chemical formula</i>	$C_9H_{14}O_6$
<i>Molecular weight</i>	218,21

▼ **M2**

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

E 1520 PROPANE-1,2-DIOL

Synonyms	Propylene glycol
Definition	
<i>Chemical names</i>	1,2-dihydroxypropane
EINECS	200-338-0
<i>Chemical formula</i>	C ₃ H ₈ O ₂
<i>Molecular weight</i>	76,10
<i>Assay</i>	Content not less than 99,5 % on the anhydrous basis
<i>Description</i>	Clear, colourless, hygroscopic, viscous liquid
Identification	
A. Solubility	Soluble in water, ethanol and acetone
B. Specific gravity	d_{20}^{20} : 1,035-1,040
C. Refractive index	$[n]^{20}_D$: 1,431-1,433
Purity	
Distillation range	99 % v/v distills between 185 °C-189 °C
Sulphated ash	Not more than 0,07 %
Water	Not more than 1,0 % (Karl Fischer method)
Lead	Not more than 5 mg/kg

▼ **B**

- (1) Cobalt chloride TSC: dissolve approximately 65 g of cobalt chloride CoCl₂·6H₂O in a sufficient quantity of a mixture of 25 ml hydrochloric acid and 975 ml of water to give a total volume of 1 litre. Place exactly 5 ml of this solution in a round-bottomed flask containing 250 ml of iodine solution, add 5 ml of 3 % hydrogen peroxide, then 15 ml of a 20 % solution of sodium hydroxide. Boil for 10 minutes, allow to cool, add 2 g of potassium iodide and 20 ml of 25 % sulphuric acid. After the precipitate is completely dissolved, titrate the liberated iodine with sodium thiosulphate (0,1 N) in the presence of starch TS (*). 1 ml of sodium thiosulphate (0,1 N) corresponds to 23,80 mg of CoCl₂·6H₂O. Adjust final volume of solution by the addition of a sufficient quantity of the hydrochloric acid/water mixture to give a solution containing 59,5 mg of CoCl₂·6H₂O per ml.
- (2) Ferric chloride TSC: dissolve approximately 55 g of ferric chloride in a sufficient quantity of a mixture of 25 ml of hydrochloric acid and 975 ml of water to give a total volume of 1 litre. Place 10 ml of this solution in a round-bottomed flask containing 250 ml of iodine solution, add 15 ml of water and 3 g of potassium iodide; leave the mixture to stand for 15 minutes. Dilute with 100 ml of water then titrate the liberated iodine with sodium thiosulphate (0,1 N) in the presence of starch TS (*). 1 ml of sodium thiosulphate (0,1 N) corresponds to 27,03 mg of FeCl₃·6H₂O. Adjust final volume of solution by the addition of a sufficient quantity of the hydrochloric acid/water to give a solution containing 45,0 mg of FeCl₃·6H₂O per ml.
- (3) Copper sulphate TSC: dissolve approximately by 65 g of copper sulphate CuSO₄·5H₂O in a sufficient quantity of a mixture of 25 ml of hydrochloric acid and 975 ml of water to give a total volume of 1 litre. Place 10 ml of this solution in a round-bottomed flask containing 250 ml of iodine solution, add 40 ml of water, 4 ml of acetic acid and 3 g of potassium iodide. Titrate the liberated iodine with sodium thiosulphate (0,1 N) in the presence of starch TS (*). 1 ml of sodium thiosulphate (0,1 N) corresponds to 24,97 mg of CuSO₄·5H₂O. Adjust final volume of solution by the addition of a sufficient quantity of the hydrochloric acid/water mixture to give a solution containing 62,4 mg of CuSO₄·5H₂O per ml.

▼ **B**

- (*) Starch TS: triturate 0,5 g starch (potato starch, maize starch or soluble starch) with 5 ml of water; to the resulting paste add a sufficient quantity of water to give a total volume of 100 ml, stirring all the time. Boil for a few minutes, allow to cool, filter. The starch must be freshly prepared.
- (†) When labelled 'for food use', nitrite may only be sold in a mixture with salt or a salt substitute.

▼ **M3****E 170 (i) CALCIUM CARBONATE**

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/45/EC laying down specific purity criteria concerning colours for use in foodstuffs ⁽¹⁾.

E 353 METATARTARIC ACID

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

E 354 CALCIUM TARTRATE

Synonyms	L-Calcium tartrate
Definition	
<i>Chemical name</i>	Calcium L(+)-2,3-dihydroxybutanedioate di-hydrate
<i>Chemical formula</i>	$C_4H_4CaO_6 \cdot 2H_2O$
<i>Molecular weight</i>	224,18
<i>Assay</i>	Not less than 98,0 %
<i>Description</i>	Fine crystalline powder with a white or off-white colour
Identification	
A. Slightly soluble in water. Solubility approximately 0,01 g/100 ml water (20 °C). Sparingly soluble in ethanol. Slightly soluble in diethyl ether. Soluble in acids	
B. Specific rotation $[\alpha]^{20}_D$	+7,0° to +7,4° (0,1 % in a 1N de HCl solution)
C. pH of a 5 % slurry	Between 6,0 and 9,0
Purity	
Sulphates (as H_2SO_4)	Not more than 1 g/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

⁽¹⁾ OJ L 226, 22.9.1995, p. 13.

▼ **M3**

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

E 356 SODIUM ADIPATE**Definition**

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

Identification

A. Melting range	151 °C-152 °C (for adipic acid)
B. Solubility	Approximately 50 g/100 ml water (20 °C)
C. Positive test for sodium	

Purity

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

E 357 POTASSIUM ADIPATE**Definition**

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

Identification

A. Melting range	151 °C-152 °C (for adipic acid)
B. Solubility	Approximately 60 g/100 ml water (20 °C)
C. Positive test for potassium	

Purity

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

E 420(i) SORBITOL

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs⁽¹⁾.

E 420(ii) SORBITOL SYRUP

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

⁽¹⁾ OJ L 178, 28.7.1995, p. 1.

▼ **M3****E 421 MANNITOL**

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 425(i) KONJAC GUM**Definition**

Konjac gum is a water-soluble hydrocolloid obtained from the Konjac flour by aqueous extraction. Konjac flour is the unpurified raw product from the root of the perennial plant *Amorphophallus konjac*. The main component of Konjac gum is the water-soluble high-molecular-weight polysaccharide glucomannan, which consists of *D*-mannose and *D*-glucose units at a molar ratio of 1,6:1,0, connected by $\beta(1-4)$ -glycosidic bonds. Shorter side chains are attached through $\beta(1-3)$ -glycosidic bonds, and acetyl groups occur at random at a ratio of about 1 group per 9 to 19 sugar units

Molecular weight

The main component, glucomannan, has an average molecular weight of 200 000 to 2 000 000

Assay

Not less than 75 % carbohydrate

Description

A white to cream to light tan powder

Identification

A. Solubility

Dispersible in hot or cold water forming a highly viscous solution with a pH between 4,0 and 7,0

B. Gel formation

Add 5 ml of a 4 % sodium borate solution to a 1 % solution of the sample in a test tube, and shake vigorously. A gel forms

C. Formation of heat-stable gel

Prepare a 2 % solution of the sample by heating it in a boiling water bath for 30 min, with continuous agitation and then cooling the solution to room temperature. For each g of the sample used to prepare 30 g of the 2 % solution, add 1 ml of 10 % potassium carbonate solution to the fully hydrated sample at ambient temperature. Heat the mixture in a water bath to 85 °C, and maintain for 2 h without agitation. Under these conditions a thermally stable gel is formed

D. Viscosity (1 % solution)

Not less than 3 kgm⁻¹s⁻¹ at 25 °C

Purity

Loss on drying

Not more than 12 % (105 °C, 5 h)

Starch

Not more than 3 %

Protein

Not more than 3 % (N × 5,7)

Determine nitrogen by Kjeldahl method. The percentage of nitrogen in the sample multiplied by 5,7 gives the percent of protein in the sample

Ether-soluble material

Not more than 0,1 %

Total ash

Not more than 5,0 % (800 °C, 3 to 4h)

Arsenic

Not more than 3 mg/kg

Lead

Not more than 2 mg/kg

Salmonella spp.

Absent in 12,5 g

E. coli

Absent in 5 g

E 425(ii) KONJAC GLUCOMANNAN**Definition**

Konjac glucomannan is a water-soluble hydrocolloid obtained from Konjac flour by washing with water-containing ethanol. Konjac flour is the unpurified raw product from the tuber of the perennial plant *Amorphophallus konjac*. The main component is the water-soluble high-molecular-weight polysaccharide glucomannan, which consists of *D*-mannose and *D*-glucose units at a molar ratio of 1,6:1,0, connected by $\beta(1-4)$ -glycosidic bonds with a branch at about each 50th or 60th unit. About each 19th sugar residue is acetylated

▼ **M3**

<i>Molecular weight</i>	500 000 to 2 000 000
<i>Assay</i>	Total dietary fibre: not less than 95 % on a dry weight basis
<i>Description</i>	White to slightly brownish fine particle size, free flowing and odourless powder
Identification	
A. Solubility	Dispersible in hot or cold water forming a highly viscous solution with a pH between 5,0 and 7,0. Solubility is increased by heat and mechanical agitation
B. Formation of heat-stable gel	Prepare a 2 % solution of the sample by heating it in a boiling water bath for 30 min, with continuous agitation and then cooling the solution to room temperature. For each g of the sample used to prepare 30 g of the 2 % solution, add 1 ml of 10 % potassium carbonate solution to the fully hydrated sample at ambient temperature. Heat the mixture in a water bath to 85 °C, and maintain for 2 h without agitation. Under these conditions a thermally stable gel is formed
C. Viscosity (1 % solution)	Not less than 20 kgm ⁻¹ s ⁻¹ at 25 °C
Purity	
Loss on drying	Not more than 8 % (105 °C, 3h)
Starch	Not more than 1 %
Protein	Not more than 1,5 % (N × 5,7) Determine nitrogen by Kjeldahl method. The percentage of nitrogen in the sample multiplied by 5,7 gives the percent of protein in the sample
Ether-soluble material	Not more than 0,5 %
Sulphite (as SO ₂)	Not more than 4 mg/kg
Chloride	Not more than 0,02 %
50 % Alcohol-soluble	Not more than 2,0 % material
Total ash	Not more than 2,0 % (800 °C, 3 to 4h)
Lead	Not more than 1 mg/kg
<i>Salmonella</i> spp.	Absent in 12,5 g
<i>E. coli</i>	Absent in 5 g

E 504(ii) MAGNESIUM HYDROXIDE CARBONATE

Synonyms	Magnesium hydrogen carbonate, magnesium subcarbonate (light or heavy), hydrated basic magnesium carbonate, magnesium carbonate hydroxide
Definition	
<i>Chemical name</i>	Magnesium carbonate hydroxide hydrated
EINECS	235-192-7
<i>Chemical formula</i>	4MgCO ₃ Mg(OH) ₂ 5H ₂ O
<i>Molecular weight</i>	485
<i>Assay</i>	Mg content not less than 40,0 % and not more than 45,0 % calculated as MgO
<i>Description</i>	Light, white friable mass or bulky white powder
Identification	
A. Positive tests for magnesium and for carbonate	
B. Solubility	Practically insoluble in water. Insoluble in ethanol
Purity	
Acid insoluble matter	Not more than 0,05 %

▼ **M3**

Water soluble matter	Not more than 1,0 %
Calcium	Not more than 1,0 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg

E 553b TALC**Synonyms**

Talcum

Definition

Naturally occurring form of hydrous magnesium silicate containing varying proportions of such associated minerals as alpha-quartz, calcite, chlorite, dolomite, magnesite, and phlogopite

Chemical name

Magnesium hydrogen metasilicate

EINECS

238-877-9

Chemical formula $Mg_3(Si_4O_{10})(OH)_2$ *Molecular weight*

379,22

Description

Light, homogeneous, white or almost white powder, greasy to the touch

Identification

- A. IR absorption
- B. X-ray diffraction
- C. Solubility

Characteristic peaks at 3 677, 1 018 and 669 cm^{-1}

Peaks at 9,34/4,66/3,12 Å

Insoluble in water and ethanol

Purity

- Loss on drying
- Acid-soluble matter
- Water-soluble matter
- Acid-soluble iron
- Arsenic
- Lead

Not more than 0,5 % (105 °C, 1h)

Not more than 6 %

Not more than 0,2 %

Not detectable

Not more than 10 mg/kg

Not more than 5 mg/kg

E 554 SODIUM ALUMINIUM SILICATE**Synonyms**

Sodium silicoaluminate, sodium aluminosilicate, aluminium sodium silicate

Definition*Chemical name*

Sodium aluminium silicate

Assay

Content on the anhydrous basis:

— as SiO_2 not less than 66,0 % and not more than 88,0 %— as Al_2O_3 not less than 5,0 % and not more than 15,0 %*Description*

Fine white amorphous powder or beads

Identification

- A. Positive tests for sodium, for aluminium and for silicate
- B. pH of a 5 % slurry

Between 6,5 and 11,5

Purity

- Loss on drying
- Loss on ignition

Not more than 8,0 % (105 °C, 2h)

Not less than 5,0 % and not more than 11,0 % on the anhydrous basis (1 000 °C, constant weight)

▼ **M3**

Sodium	Not less than 5 % and not more than 8,5 % (as Na ₂ O) on the anhydrous basis
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 555 POTASSIUM ALUMINIUM SILICATE

Synonyms	Mica
Definition	Natural mica consists of mainly potassium aluminium silicate (muscovite)
EINECS	310-127-6
<i>Chemical name</i>	Potassium aluminium silicate
<i>Chemical formulae</i>	$KAl_2[AlSi_3O_{10}](OH)_2$
<i>Molecular weight</i>	398
<i>Assay</i>	Content not less than 98 %
<i>Description</i>	Light grey to white crystalline platelets or powder
Identification	
A. Solubility	Insoluble in water, diluted acids and alkali and organic solvents
Purity	
Loss on drying	Not more than 0,5 % (105 °C, 2h)
Antimony	Not more than 20 mg/kg
Zinc	Not more than 25 mg/kg
Barium	Not more than 25 mg/kg
Chromium	Not more than 100 mg/kg
Copper	Not more than 25 mg/kg
Nickel	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 2 mg/kg
Lead	Not more than 10 mg/kg

E 556 CALCIUM ALUMINIUM SILICATE

Synonyms	Calcium aluminosilicate, calcium silicoaluminate, aluminium calcium silicate
Definition	
<i>Chemical name</i>	Calcium aluminium silicate
<i>Assay</i>	Content on the anhydrous basis: — as SiO ₂ not less than 44,0 % and not more than 50,0 % — as Al ₂ O ₃ not less than 3,0 % and not more than 5,0 % — as CaO not less than 32,0 % and not more than 38,0 %
<i>Description</i>	Fine white, free-flowing powder
Identification	
A. Positive tests for calcium, for aluminium and for silicate	
Purity	
Loss on drying	Not more than 10,0 % (105 °C, 2h)

▼ **M3**

Loss on ignition	Not less than 14,0 % and not more than 18,0 on the anhydrous basis (1 000 °C, constant weight)
Fluoride	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg

E 558 BENTONITE**Definition**

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

EINECS

215-108-5

Chemical formula $(\text{Al, Mg})_8(\text{Si}_4\text{O}_{10})_4(\text{OH})_8 \cdot 12\text{H}_2\text{O}$ *Molecular weight*

819

Assay

Montmorillonite content not less than 80 %

Description

Very fine, yellowish or greyish white powder or granules. The structure of bentonite allows it to absorb water in its structure and on its external surface (swelling properties)

Identification

- A. Methylene blue test
- B. X-Ray diffraction
- C. IR absorption

Characteristic peaks at 12,5/15 Å

Peaks at 428/470/530/1 110-1 020/3 750 — 3 400 cm^{-1} **Purity**

- Loss on drying
- Arsenic
- Lead

Not more than 15,0 % (105 °C, 2h)

Not more than 2 mg/kg

Not more than 20 mg/kg

E 559 ALUMINIUM SILICATE (KAOLIN)**Synonyms**

Kaolin, light or heavy

Definition

Aluminium silicate hydrous (kaolin) is a purified white plastic clay composed of kaolinite, potassium aluminium silicate, feldspar and quartz. Processing should not include calcination

EINECS

215-286-4 (kaolinite)

Chemical formula $\text{Al}_2\text{Si}_2\text{O}_5(\text{OH})_4$ (kaolinite)*Molecular weight*

264

Assay

Content not less than 90 % (sum of silica and alumina, after ignition)

Silica (SiO_2) Between 45 % and 55 %Alumina (Al_2O_3) Between 30 % and 39 %*Description*

Fine, white or greyish white, unctuous powder. Kaolin is made up of loose aggregations of randomly oriented stacks of kaolinite flakes or of individual hexagonal flakes

Identification

- A. Positive tests for alumina and for silicate

▼ **M3**

B. X-ray diffraction:	characteristic peaks at 7,18/3,58/2,38/1,78 Å
C. IR absorption:	peaks at 3 700 and 3 620 cm ⁻¹
Purity	
Loss on ignition	Between 10 and 14 % (1 000 °C, constant weight)
Water soluble matter	Not more than 0,3 %
Acid soluble matter	Not more than 2,0 %
Iron	Not more than 5 %
Potassium oxide (K ₂ O)	Not more than 5 %
Carbon	Not more than 0,5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 620 GLUTAMIC ACID

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

E 621 MONOSODIUM GLUTAMATE

Synonyms	Sodium glutamate, MSG
Definition	
<i>Chemical name</i>	Monosodium L-glutamate monohydrate
EINECS	205-538-1
<i>Chemical formula</i>	C ₅ H ₈ NaNO ₄ · H ₂ O
<i>Molecular weight</i>	187,13
<i>Assay</i>	Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis

▼ **M3**

<i>Description</i>	White, practically odourless crystals or crystalline powder
Identification	
A. Positive test for sodium	
B. Positive test for glutamic acid by thin-layer chromatography	
C. Specific rotation $[\alpha]_D^{20}$	Between + 24,8° and + 25,3° (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
D. pH of a 5 % solution	Between 6,7 and 7,2
Purity	
Loss on drying	Not more than 0,5 % (98 °C, 5h)
Chloride	Not more than 0,2 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Lead	Not more than 2 mg/kg

E 622 MONOPOTASSIUM GLUTAMATE

Synonyms	Potassium glutamate, MPG
Definition	
<i>Chemical name</i>	Monopotassium L-glutamate monohydrate
EINECS	243-094-0
<i>Chemical formula</i>	$C_5H_8KNO_4 \cdot H_2O$
<i>Molecular weight</i>	203,24
<i>Assay</i>	Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis
<i>Description</i>	White, practically odourless crystals or crystalline powder
Identification	
A. Positive test for potassium	
B. Positive test for glutamic acid by thin-layer chromatography	
C. Specific rotation $[\alpha]_D^{20}$	Between + 22,5° and + 24,0° (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
D. pH of a 2 % solution	Between 6,7 and 7,3
Purity	
Loss on drying	Not more than 0,2 % (80 °C, 5h)
Chloride	Not more than 0,2 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Lead	Not more than 2 mg/kg

E 623 CALCIUM DIGLUTAMATE

Synonyms	Calcium glutamate
Definition	
<i>Chemical name</i>	Monocalcium di-L-glutamate
EINECS	242-905-5
<i>Chemical formula</i>	$C_{10}H_{16}CaN_2O_8 \cdot x H_2O$ (x = 0, 1, 2 or 4)
<i>Molecular weight</i>	332,32 (anhydrous)

▼ **M3**

<i>Assay</i>	Content not less than 98,0 % and not more than 102,0 % on the anhydrous basis
<i>Description</i>	White, practically odourless crystals or crystalline powder
Identification	
A. Positive test for calcium	
B. Positive test for glutamic acid by thin-layer chromatography	
C. Specific rotation $[\alpha]_D^{20}$	Between + 27,4 and + 29,2 (for calcium diglutamate with $x = 4$) (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
Purity	
Water	Not more than 19,0 % (for calcium diglutamate with $x = 4$) (Karl Fischer)
Chloride	Not more than 0,2 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Lead	Not more than 2 mg/kg

E 624 MONOAMMONIUM GLUTAMATE

Synonyms	Ammonium glutamate
Definition	
<i>Chemical name</i>	Monoammonium L-glutamate monohydrate
EINECS	231-447-1
<i>Chemical formula</i>	$C_5H_{12}N_2O_4 \cdot H_2O$
<i>Molecular weight</i>	182,18
<i>Assay</i>	Content not less than 99,0 % and not more 101,0 % on the anhydrous basis
<i>Description</i>	White, practically odourless crystals or crystalline powder
Identification	
A. Positive test for ammonium	
B. Positive test for glutamic acid by thin-layer chromatography	
C. Specific rotation $[\alpha]_D^{20}$	Between + 25,4° and + 26,4° (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
D. pH of a 5 % solution	Between 6,0 and 7,0
Purity	
Loss on drying	Not more than 0,5 % (50 °C, 4h)
Sulphated ash	Not more than 0,1 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Lead	Not more than 2 mg/kg

E 625 MAGNESIUM DIGLUTAMATE

Synonyms	Magnesium glutamate
Definition	
<i>Chemical name</i>	Monomagnesium di-L-glutamate tetrahydrate
EINECS	242-413-0
<i>Chemical formula</i>	$C_{10}H_{16}MgN_2O_8 \cdot 4H_2O$

▼ **M3**

<i>Molecular weight</i>	388,62
<i>Assay</i>	Content not less than 95,0 % and not more than 105,0 % on the anhydrous basis
<i>Description</i>	Odourless, white or off-white crystals or powder
Identification	
A. Positive test for magnesium	
B. Positive test for glutamic acid by thin-layer chromatography	
C. Specific rotation $[\alpha]_D^{20}$	Between + 23,8° and + 24,4° (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
D. pH of a 10 % solution	Between 6,4 and 7,5
Purity	
Water	Not more than 24 % (Karl Fischer)
Chloride	Not more than 0,2 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Lead	Not more than 2 mg/kg

E 626 GUANYLIC ACID

Synonyms	Guanylic acid
Definition	
<i>Chemical name</i>	Guanosine-5'-monophosphoric acid
EINECS	201-598-8
<i>Chemical formula</i>	$C_{10}H_{14}N_5O_8P$
<i>Molecular weight</i>	363,22
<i>Assay</i>	Content not less than 97,0 % on the anhydrous basis
<i>Description</i>	Odourless, colourless or white crystals or white crystalline powder
Identification	
A. Positive test for ribose and for organic phosphate	
B. pH of a 0,25 % solution	Between 1,5 and 2,5
C. Spectrometry:	maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm
Purity	
Loss on drying	Not more than 1,5 % (120 °C, 4h)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

E 627 DISODIUM GUANYLATE

Synonyms	Sodium guanylate, sodium 5'-guanylate
Definition	
<i>Chemical name</i>	Disodium guanosine-5'-monophosphate
EINECS	221-849-5
<i>Chemical formula</i>	$C_{10}H_{12}N_5Na_2O_8P \cdot x H_2O$ (x = ca. 7)
<i>Molecular weight</i>	407,19 (anhydrous)
<i>Assay</i>	Content not less than 97,0 % on the anhydrous basis

▼ **M3**

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

E 628 DIPOTASSIUM GUANYLATE

Synonyms	Potassium guanylate, potassium 5'-guanylate
Definition	
<i>Chemical name</i>	Dipotassium guanosine-5'-monophosphate
EINECS	226-914-1
<i>Chemical formula</i>	$C_{10}H_{12}K_2N_5O_8P$
<i>Molecular weight</i>	439,40
<i>Assay</i>	Content not less than 97,0 % on the anhydrous basis
<i>Description</i>	Odourless, colourless or white crystals or white crystalline powder
Identification	
A. Positive test for ribose, for organic phosphate, and for potassium	
B. pH of a 5 % solution	Between 7,0 and 8,5
C. Spectrometry:	maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm
Purity	
Loss on drying	Not more than 5 % (120 °C, 4h)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

E 629 CALCIUM GUANYLATE

Synonyms	Calcium 5'-guanylate
Definition	
<i>Chemical name</i>	Calcium guanosine-5'-monophosphate
<i>Chemical formula</i>	$C_{10}H_{12}CaN_5O_8P \cdot nH_2O$
<i>Molecular weight</i>	401,20 (anhydrous)
<i>Assay</i>	Content not less than 97,0 % on the anhydrous basis
<i>Description</i>	Odourless, white or off-white crystals or powder
Identification	
A. Positive test for ribose, for organic phosphate, and for calcium	
B. pH of a 0,05 % solution	Between 7,0 and 8,0
C. Spectrometry:	maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm

▼ **M3**

Purity	
Loss on drying	Not more than 23,0 % (120 °C, 4h)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg
E 630 INOSINIC ACID	
Synonyms	5'-Inosinic acid
Definition	
<i>Chemical name</i>	Inosine-5'-monophosphoric acid
EINECS	205-045-1
<i>Chemical formula</i>	$C_{10}H_{13}N_4O_8P$
<i>Molecular weight</i>	348,21
<i>Assay</i>	Content not less than 97,0 % on the anhydrous basis
<i>Description</i>	Odourless, colourless or white crystals or powder
Identification	
A. Positive test for ribose, and for organic phosphate	
B. pH of a 5 % solution	Between 1,0 and 2,0
C. Spectrometry:	maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm
Purity	
Loss on drying	Not more than 3,0 % (120 °C, 4h)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg
E 631 DISODIUM INOSINATE	
Synonyms	Sodium inosinate, sodium 5'-inosinate
Definition	
<i>Chemical name</i>	Disodium inosine-5'-monophosphate
EINECS	225-146-4
<i>Chemical formula</i>	$C_{10}H_{11}N_4Na_2O_8P \cdot H_2O$
<i>Molecular weight</i>	392,17 (anhydrous)
<i>Assay</i>	Content not less than 97,0 % on the anhydrous basis
<i>Description</i>	Odourless, colourless or white crystals or powder
Identification	
A. Positive test for ribose, and for organic phosphate and for sodium	
B. pH of a 5 % solution	Between 7,0 and 8,5
C. Spectrometry:	maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm
Purity	
Water	Not more than 28,5 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg
E 632 DIPOTASSIUM INOSINATE	
Synonyms	Potassium inosinate, potassium 5'-inosinate

▼ **M3****Definition***Chemical name*

Dipotassium inosine-5'-monophosphate

EINECS

243-652-3

Chemical formula $C_{10}H_{11}K_2N_4O_8P$ *Molecular weight*

424,39

Assay

Content not less than 97,0 % on the anhydrous basis

Description

Odourless, colourless or white crystals or powder

Identification

A. Positive test for ribose, and for organic phosphate and for potassium

Between 7,0 and 8,5

B. pH of a 5 % solution

C. Spectrometry:

maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm

Purity

Water

Not more than 10,0 % (Karl Fischer)

Other nucleotides

Not detectable by thin-layer chromatography

Lead

Not more than 2 mg/kg

E 633 CALCIUM INOSINATE**Synonyms**

Calcium 5'-inosinate

Definition*Chemical name*

Calcium inosine-5'-monophosphate

Chemical formula $C_{10}H_{11}CaN_4O_8P \cdot nH_2O$ *Molecular weight*

386,19 (anhydrous)

Assay

Content not less than 97,0 % on the anhydrous basis

Description

Odourless, colourless or white crystals or powder

Identification

A. Positive test for ribose, and for organic phosphate and for calcium

Between 7,0 and 8,0

B. pH of a 0,05 % solution

C. Spectrometry:

maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm

Purity

Water

Not more than 23,0 % (Karl Fischer)

Other nucleotides

Not detectable by thin-layer chromatography

Lead

Not more than 2 mg/kg

E 634 CALCIUM 5'-RIBONUCLEOTIDE**Definition***Chemical name*

Calcium 5'-ribonucleotide is essentially a mixture of calcium inosine-5'-monophosphate and calcium guanosine-5'-monophosphate

Chemical formula $C_{10}H_{11}N_4CaO_8P \cdot nH_2O$ y $C_{10}H_{12}N_5CaO_8P \cdot nH_2O$ *Assay*

Content of both major components not less than 97,0 %, and of each component not less than 47,0 % and not more than 53 %, in every case on the anhydrous basis

Description

Odourless, white or nearly white crystals or powder

▼ **M3**

Identification	
A. Positive test for ribose, and for organic phosphate and for calcium	
B. pH of a 0,05 % solution	Between 7,0 and 8,0
Purity	
Water	Not more than 23,0 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

E 635 DISODIUM 5'-RIBONUCLEOTIDE

Synonyms	Sodium 5'-ribonucleotide
Definition	
<i>Chemical name</i>	Disodium 5'-ribonucleotide is essentially a mixture of disodium inosine-5'-monophosphate and disodium guanosine-5'-monophosphate
<i>Chemical formula</i>	$C_{10}H_{11}N_4O_8P \cdot nH_2O$ and $C_{10}H_{12}N_5Na_2O_8P \cdot nH_2O$
<i>Assay</i>	Content of both major components not less than 97,0 %, and of each component not less than 47,0 % and not more than 53 %, in every case on the anhydrous basis
<i>Description</i>	Odourless, white or nearly white crystals or powder
Identification	
A. Positive test for ribose, and for organic phosphate and for sodium	
B. pH of a 5 % solution	Between 7,0 and 8,5
Purity	
Water	Not more than 26,0 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

E 905 MICROCRYSTALLINE WAX

Synonyms	Petroleum wax
Definition	
<i>Description</i>	Microcrystalline wax is a refined mixture of solid, saturated hydrocarbons, mainly branched paraffin, obtained from petroleum
<i>Description</i>	White to amber, odourless wax
Identification	
A. Solubility	Insoluble in water, very slightly soluble in ethanol
B. Refractive Index	nD^{100} 1,434-1,448
Purity	
Molecular weight	Average not less than 500
Viscosity at 100 °C	Not less than $1,1 \cdot 10^{-5} \text{ m}^2\text{s}^{-1}$
Residue on ignition	Not more than 0,1 %
Carbon number at 5 % distillation point	Not more than 5 % of molecules with carbon number less than 25
Colour	Passes test
Sulphur	Not more than 0,4 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 3 mg/kg

▼ **M3**

Polycyclic aromatic compounds

The polycyclic aromatic hydrocarbons, obtained by extraction with dimethyl sulfoxide, shall meet the following ultraviolet absorbency limits:

nm	Maximum absorbance per cm path length
280-289	0,15
290-299	0,12
300-359	0,08
360-400	0,02

E 912 MONTAN ACID ESTERS**Definition**

Montan acids and/or esters with ethylene glycol and/or 1,3-butanediol and/or glycerol

Chemical name

Montan acid esters

Description

Almost white to yellowish flakes, powder, granules or pellets

Identification

A. Density (20 °C)

Between 0,98 and 1,05

B. Drop point

Greater than 77 °C

Purity

Acid value

Not more than 40

Glycerol

Not more than 1 % (by gas chromatography)

Other polyols

Not more than 1 % (by gas chromatography)

Other wax types

Not detectable (by differential scanning calorimetry and/or infrared spectroscopy)

Arsenic

Not more than 2 mg/kg

Chromium

Not more than 3 mg/kg

Lead

Not more than 2 mg/kg

E 914 OXIDISED POLYETHYLENE WAX**Definition**

Polar reaction products from mild oxidation of polyethylene

Chemical name

Oxidised polyethylene

Description

Almost white flakes, powder, granules or pellets

Identification

A. Density (20 °C)

Between 0,92 and 1,05

B. Drop point

Greater than 95 °C

Purity

Acid value

Not more than 70

Viscosity at 120 °C

Not less than $8,1 \cdot 10^{-5} \text{ m}^2\text{s}^{-1}$

Other wax types

Not detectable (by differential scanning calorimetry and/or infrared spectroscopy)

Oxygen

Not more than 9,5 %

Chromium

Not more than 5 mg/kg

Lead

Not more than 2 mg/kg

E 950 ACESULFAME K

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

▼M3**E 951 ASPARTAME**

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 953 ISOMALT

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC, as amended by Directive 98/66/EC, laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 957 THAUMATIN

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 959 NEOHESPERIDINE DIHYDROCHALCONE

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 965(i) MALTITOL

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 965(ii) MALTITOL SYRUP

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 966 LACTITOL

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 967 XYLITOL

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.