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COMMISSION REGULATION (EU) No 231/2012

of 9 March 2012

laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council

(Text with EEA relevance)

(OJ L 83, 22.3.2012, p. 1)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Regulation (EU) No 1050/2012 of 8 November 2012	L 310	45	9.11.2012
►M2	Commission Regulation (EU) No 25/2013 of 16 January 2013	L 13	1	17.1.2013
►M3	Commission Regulation (EU) No 497/2013 of 29 May 2013	L 143	20	30.5.2013
►M4	Commission Regulation (EU) No 724/2013 of 26 July 2013	L 202	11	27.7.2013
►M5	Commission Regulation (EU) No 739/2013 of 30 July 2013	L 204	35	31.7.2013
►M6	Commission Regulation (EU) No 816/2013 of 28 August 2013	L 230	1	29.8.2013
►M7	Commission Regulation (EU) No 817/2013 of 28 August 2013	L 230	7	29.8.2013
►M8	Commission Regulation (EU) No 1274/2013 of 6 December 2013	L 328	79	7.12.2013
►M9	Commission Regulation (EU) No 264/2014 of 14 March 2014	L 76	22	15.3.2014
►M10	Commission Regulation (EU) No 298/2014 of 21 March 2014	L 89	36	25.3.2014
►M11	Commission Regulation (EU) No 497/2014 of 14 May 2014	L 143	6	15.5.2014
►M12	Commission Regulation (EU) No 506/2014 of 15 May 2014	L 145	35	16.5.2014
►M13	Commission Regulation (EU) No 685/2014 of 20 June 2014	L 182	23	21.6.2014
►M14	Commission Regulation (EU) No 923/2014 of 25 August 2014	L 252	11	26.8.2014
►M15	Commission Regulation (EU) No 957/2014 of 10 September 2014	L 270	1	11.9.2014
►M16	Commission Regulation (EU) No 966/2014 of 12 September 2014	L 272	1	13.9.2014
►M17	Commission Regulation (EU) 2015/463 of 19 March 2015	L 76	42	20.3.2015
►M18	Commission Regulation (EU) 2015/649 of 24 April 2015	L 107	17	25.4.2015
►M19	Commission Regulation (EU) 2015/1725 of 28 September 2015	L 252	12	29.9.2015
►M20	Commission Regulation (EU) 2015/1739 of 28 September 2015	L 253	3	30.9.2015
►M21	Commission Regulation (EU) 2016/1814 of 13 October 2016	L 278	37	14.10.2016
►M22	Commission Regulation (EU) 2017/324 of 24 February 2017	L 49	4	25.2.2017
►M23	Commission Regulation (EU) 2017/1399 of 28 July 2017	L 199	8	29.7.2017
►M24	Commission Regulation (EU) 2018/75 of 17 January 2018	L 13	24	18.1.2018

►**M25**	Commission Regulation (EU) 2018/98 of 22 January 2018	L 17	14	23.1.2018
►**M26**	Commission Regulation (EU) 2018/681 of 4 May 2018	L 116	1	7.5.2018
►**M27**	Commission Regulation (EU) 2018/1461 of 28 September 2018	L 245	1	1.10.2018
►**M28**	Commission Regulation (EU) 2018/1462 of 28 September 2018	L 245	6	1.10.2018
►**M29**	Commission Regulation (EU) 2018/1472 of 28 September 2018	L 247	1	3.10.2018
►**M30**	Commission Regulation (EU) 2018/1481 of 4 October 2018	L 251	13	5.10.2018
►**M31**	Commission Regulation (EU) 2020/763 of 9 June 2020	L 182	8	10.6.2020
►**M32**	Commission Regulation (EU) 2020/771 of 11 June 2020	L 184	25	12.6.2020
►**M33**	Commission Regulation (EU) 2021/1156 of 13 July 2021	L 249	87	14.7.2021
►**M34**	Commission Regulation (EU) 2022/650 of 20 April 2022	L 119	65	21.4.2022
►**M35**	Commission Regulation (EU) 2022/1023 of 28 June 2022	L 172	5	29.6.2022
►**M36**	Commission Regulation (EU) 2022/1037 of 29 June 2022	L 173	52	30.6.2022
►**M37**	Commission Regulation (EU) 2022/1396 of 11 August 2022	L 211	182	12.8.2022
►**M38**	Commission Regulation (EU) 2022/1922 of 10 October 2022	L 264	1	11.10.2022
►**M39**	Commission Regulation (EU) 2023/440 of 28 February 2023	L 64	4	1.3.2023
►**M40**	Commission Regulation (EU) 2023/447 of 1 March 2023	L 65	16	2.3.2023
►**M41**	Commission Regulation (EU) 2023/1329 of 29 June 2023	L 166	66	30.6.2023
►**M42**	Commission Regulation (EU) 2023/1428 of 7 July 2023	L 175	6	10.7.2023
►**M43**	Commission Regulation (EU) 2023/2086 of 28 September 2023	L 241	73	29.9.2023
►**M44**	Commission Regulation (EU) 2023/2379 of 29 September 2023	L 2379	1	3.10.2023
►**M45**	Commission Regulation (EU) 2023/2108 of 6 October 2023	L 2108	1	9.10.2023
►**M46**	Commission Regulation (EU) 2024/346 of 22 January 2024	L 346	1	23.1.2024

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COMMISSION REGULATION (EU) No 231/2012

of 9 March 2012

laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council

(Text with EEA relevance)

Article 1

Specifications for food additives

Specifications for food additives including colours and sweeteners listed in Annex II and III to Regulation (EC) No 1333/2008 are laid down in the Annex to this Regulation.

Article 2

Repeals

Directives 2008/60/EC, 2008/84/EC and 2008/128/EC are repealed with effect from 1 December 2012.

Article 3

Transitional measures

Foodstuffs containing food additives that have been lawfully placed on the market before 1 December 2012, but do not comply with this Regulation, may continue to be marketed until stocks are exhausted.

Article 4

Entry into force

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

It shall apply from 1 December 2012.

However, the specifications laid down in the Annex for additives steviol glycosides (E 960) and basic methacrylate copolymer (E 1205) shall apply from the date of entry into force of this Regulation.

This Regulation shall be binding in its entirety and directly applicable in the Member States.

▼B

ANNEX

▼M37

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

No residue above 0,1 mg/kg, irrespective of its origin, of ethylene oxide (sum of ethylene oxide and 2-chloro-ethanol expressed as ethylene oxide [1]) shall be present in food additives listed in Annexes II and III to Regulation (EC) No 1333/2008, including mixtures of food additives.

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Aluminium lakes for use in colours only where explicitly stated.

Definition:	Aluminium lakes are prepared by reacting colours complying with the purity criteria set out in the appropriate specification monograph with alumina under aqueous conditions. The alumina is usually freshly prepared undried material made by reacting aluminium sulphate or chloride with sodium or calcium carbonate or bicarbonate or ammonia. Following lake formation, the product is filtered, washed with water and dried. Unreacted alumina may also be present in the finished product.
HCl insoluble matter	Not more than 0,5 %
NaOH insoluble matter	Not more than 0,5 %, for E 127 erythrosine only
Ether extractable matter	Not more than 0,2 % (under neutral conditions)
	Specific purity criteria for the corresponding colours are applicable.

E 100 CURCUMIN

Synonyms	CI Natural Yellow 3; Turmeric Yellow; Diferoyl Methane
Definition	Curcumin is obtained by solvent extraction of turmeric i.e. the ground rhizomes of strains of *Curcuma longa* L. In order to obtain a concentrated curcumin powder, the extract is purified by crystallization. The product consists essentially of curcumins; i.e. the colouring principle (1,7-bis(4-hydroxy-3-methoxyphenyl)hepta-1,6-dien-3,5-dione) and its two desmethoxy derivatives in varying proportions. Minor amounts of oils and resins naturally occurring in turmeric may be present. Curcumin is also used as the aluminium lake; the aluminium content is less than 30 %. Only the following solvents may be used in the extraction: ethylacetate, acetone, carbon dioxide, dichloromethane, n-butanol, methanol, ethanol, hexane, propan-2-ol.
Colour Index No	75300
Einecs	207-280-5
Chemical name	I 1,7-Bis(4-hydroxy-3-methoxyphenyl)hepta-1,6-diene-3,5-dione II 1-(4-Hydroxyphenyl)-7-(4-hydroxy-3-methoxy-phenyl-)hepta-1,6-diene-3,5-dione III 1,7-Bis(4-hydroxyphenyl)hepta-1,6-diene-3,5-dione
Chemical formula	I $C_{21}H_{20}O_6$ II $C_{20}H_{18}O_5$ III $C_{19}H_{16}O_4$
Molecular weight	I. 368,39 II. 338,39 III. 308,39
Assay	Content not less than 90 % total colouring matters $E^{1\%}_{1cm}$ 1 607 at ca. 426 nm in ethanol

[1] i.e. ethylene oxide + 0,55* 2-chloroethanol.

▼B

Description	Orange-yellow crystalline powder
Identification	
Spectrometry	Maximum in ethanol at ca. 426 nm
Melting range	179 °C-182 °C
Purity	
Solvent residues	Ethylacetate, Acetone, n-butanol, Methanol, Ethanol, Hexane, Propan-2-ol: Not more than 50 mg/kg, singly or in combination
	Dichloromethane: not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

Aluminium lakes of this colour may be used.

E 101 (i) RIBOFLAVIN

Synonyms	Lactoflavin;
Definition	
Colour Index No	
Einecs	201-507-1
Chemical name	7,8-Dimethyl-10-(D-ribo-2,3,4,5-tetrahydroxy-pentyl)benzo(g)pteridine-2,4(3H,10H)-dione; 7,8-dimethyl-10-(1′-D-ribityl)isoalloxazine
Chemical formula	$C_{17}H_{20}N_4O_6$
Molecular weight	376,37
Assay	Content not less than 98 % on the anhydrous basis
	$E^{1\%}_{1cm}$ 328 at ca. 444 nm in aqueous solution
Description	Yellow to orange-yellow crystalline powder, with slight odour
Identification	
Spectrometry	The ratio A_{375}/A_{267} is between 0,31 and 0,33; The ratio A_{444}/A_{267} is between 0,36 and 0,39: in aqueous solution
	Maximum in water at ca. 375 nm
Specific rotation	$[\alpha]_D^{20}$ between – 115° and – 140° in a 0,05 N sodium hydroxide solution
Purity	
Loss on drying	Not more than 1,5 % (105 °C, 4 hours)

▼B

Sulphated ash	Not more than 0,1 %
Primary aromatic amines	Not more than 100 mg/kg (calculated as aniline)
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

▼M14

Aluminium lakes of this colour may be used.

▼B

E 101 (ii) RIBOFLAVIN-5′-PHOSPHATE

Synonyms	Riboflavin-5′-phosphate sodium
Definition	These specifications apply to riboflavin 5′-phosphate together with minor amounts of free riboflavin and riboflavin diphosphate.
Colour Index No	
Einecs	204-988-6
Chemical name	Monosodium(2R,3R,4S)-5-(3′)10′-dihydro-7′,8′-dimethyl-2′,4′-dioxo-10′-benzo[γ]pteridinyl)-2,3,4-trihydroxypentyl phosphate; monosodium salt of 5′-monophosphate ester of riboflavin
Chemical formula	For the dihydrate form: $C_{17}H_{20}N_4NaO_9P \cdot 2H_2O$ For the anhydrous form: $C_{17}H_{20}N_4NaO_9P$
Molecular weight	514,36
Assay	Content not less than 95 % total colouring matters calculated as $C_{17}H_{20}N_4NaO_9P.2H_2O$ $E^{1\%}_{1cm}$ 250 at ca. 375 nm in aqueous solution
Description	Yellow to orange crystalline hygroscopic powder, with slight odour
Identification	
Spectrometry	The ratio A_{375}/A_{267} is between 0,30 and 0,34 The ratio A_{444}/A_{267} is between 0,35 and 0,40 } in aqueous solution Maximum in water at ca. 375 nm
Specific rotation	$[\alpha]_D^{20}$ between + 38° and + 42° in a 5 molar HCl solution
Purity	
Loss on drying	Not more than 8 % (100 °C, 5 hours in vacuum over P_2O_5) for the dihydrate form
Sulphated ash	Not more than 25 %
Inorganic phosphate	Not more than 1,0 % (calculated as PO_4 on the anhydrous basis)
Subsidiary colouring matters	Riboflavin (free): Not more than 6 % Riboflavine diphosphate: Not more than 6 %
Primary aromatic amines	Not more than 70 mg/kg (calculated as aniline)

▼B

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

▼M14

Aluminium lakes of this colour may be used.

▼B

E 102 TARTRAZINE

Synonyms	CI Food Yellow 4
Definition	Tartrazine is prepared from 4-amino-benzenesulphonic acid, which is diazotized using hydrochloric acid and sodium nitrite. The diazo compound is then coupled with 4,5-dihydro-5-oxo-1-(4sulphophenyl)-1H-pyrazole-3-carboxylic acid or with the methyl ester, the ethyl ester, or a salt of this carboxylic acid. The resulting dye is purified and isolated as the sodium salt. Tartrazine consists essentially of trisodium 5-hydroxy-1-(4-sulfonatophenyl)-4-(4-sulfonatophenylazo)-H-pyrazole-3-carboxylate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Tartrazine is described as the sodium salt. The calcium and the potassium salt are also permitted.
Colour Index No	19140
Einecs	217-699-5
Chemical name	Trisodium-5-hydroxy-1-(4-sulfonatophenyl)-4-(4-sulfonatophenylazo)-H-pyrazole-3-carboxylate
Chemical formula	$C_{16}H_9N_4Na_3O_9S_2$
Molecular weight	534,37
Assay	Content not less than 85 % total colouring matters calculated as the sodium salt $E^{1\%}_{1cm}$ 530 at ca. 426 nm in aqueous solution
Description	Light orange powder or granules
Appearance of the aqueous solution	Yellow
Identification	
Spectrometry	Maximum in water at ca. 426 nm
Purity	
Water insoluble matter	Not more than 0,2 %
Subsidiary colouring matters	Not more than 1,0 %
Organic compounds other than colouring matters:	
4-hydrazinobenzene sulfonic acid	Total not more than 0,5 %
4-aminobenzene-1-sulfonic acid	
5-oxo-1-(4-sulfophenyl)-2-pyrazoline-3-carboxylic acid	
4,4′-diazoaminodi(benzene sulfonic acid)	
Tetrahydroxysuccinic acid	

▼B

Unsulfonated primary aromatic amines	Not more than 0,01 % (calculated as aniline)
Ether extractable matter	Not more than 0,2 % under neutral conditions
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

Aluminium lakes of this colour may be used.

E 104 QUINOLINE YELLOW

Synonyms	CI Food Yellow 13
Definition	Quinoline Yellow is prepared by sulfonating 2-(2-quinolyl) indan-1,3-dione or a mixture containing about two thirds 2-(2-quinolyl)indane-1,3-dione and one third 2-(2-(6-methylquinolyl))indane-1,3-dione. Quinoline Yellow consists essentially of sodium salts of a mixture of disulfonates (principally), monosulfonates and trisulfonates of the above compound and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Quinoline Yellow is described as the sodium salt. The calcium and the potassium salt are also permitted.
Colour Index No	47005
Einecs	305-897-5
Chemical name	The disodium salts of the disulfonates of 2-(2-quinolyl) indan-1,3-dione (principal component)
Chemical formula	$C_{18}H_9N\ Na_2O_8S_2$ (principal component)
Molecular weight	477,38 (principal component)
Assay	Content not less than 70 % total colouring matters calculated as the sodium salt Quinoline Yellow shall have the following composition: Of the total colouring matters present: — not less than 80 % shall be disodium 2-(2-quinolyl) indan-1,3-dione-disulfonates — not more than 15 % shall be sodium 2-(2-quinolyl) indan-1,3-dione-monosulfonates — not more than 7,0 % shall be trisodium 2-(2-quinolyl) indan-1,3-dione-trisulfonate $E^{1\%}_{1cm}$ 865 (principal component) at ca. 411 nm in aqueous acetic acid solution
Description	Yellow powder or granules
Appearance of the aqueous solution	Yellow
Identification	
Spectrometry	Maximum in aqueous acetic acid solution of pH 5 at ca. 411 nm

▼B

Purity	
Water insoluble matter	Not more than 0,2 %
Subsidiary colouring matters	Not more than 4,0 %
Organic compounds other than colouring matters:	
2-methylquinoline	Total not more than 0,5 %
2-methylquinoline-sulfonic acid	
Phthalic acid	
2,6-dimethyl quinoline	
2,6-dimethyl quinoline sulfonic acid	
2-(2-quinolyl)indan-1,3-dione	Not more than 4 mg/kg
Unsulfonated primary aromatic amines	Not more than 0,01 % (calculated as aniline)
Ether extractable matter	Not more than 0,2 % under neutral conditions
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

Aluminium lakes of this colour may be used.

E 110 SUNSET YELLOW FCF

Synonyms	CI Food Yellow 3; Orange Yellow S
Definition	Sunset Yellow FCF consists essentially of disodium 2-hydroxy-1-(4-sulfonatophenylazo) naphthalene-6-sulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Sunset Yellow FCF is manufactured by diazotizing 4-aminobenzenesulphonic acid using hydrochloric acid and sodium nitrite or sulphuric acid and sodium nitrite. The diazo compound is coupled with 6-hydroxy-2-naphthalene-sulphonic acid. The dye is isolated as the sodium salt and dried. Sunset Yellow FCF is described as the sodium salt. The calcium and the potassium salt are also permitted.
Colour Index No	15985
Einecs	220-491-7
Chemical name	Disodium 2-hydroxy-1-(4-sulfonatophenylazo)naphthalene-6-sulfonate
Chemical formula	$C_{16}H_{10}N_2Na_2O_7S_2$
Molecular weight	452,37
Assay	Content not less than 85 % total colouring matters calculated as the sodium salt $E^{1\%}_{1cm}$ 555 at ca. 485 nm in aqueous solution at pH 7

▼B

Description	Orange-red powder or granules
Appearance of the aqueous solution	Orange
Identification	
Spectrometry	Maximum in water at ca. 485 nm at pH 7
Purity	
Water insoluble matter	Not more than 0,2 %
Subsidiary colouring matters	Not more than 5,0 %
1-(Phenylazo)-2-naphthalenol (Sudan I)	Not more than 0,5 mg/kg
Organic compounds other than colouring matters:	
4-aminobenzene-1-sulfonic acid	Total not more than 0,5 %
3-hydroxynaphthalene-2,7-disulfonic acid	
6-hydroxynaphthalene-2-sulfonic acid	
7-hydroxynaphthalene-1,3-disulfonic acid	
4,4′-diazoaminodi(benzene sulfonic acid)	
6,6′-oxydi(naphthalene-2-sulfonic acid)	
Unsulfonated primary aromatic amines	Not more than 0,01 % (calculated as aniline)
Ether extractable matter	Not more than 0,2 % under neutral conditions
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

Aluminium lakes of this colour may be used.

▼M29

E 120 CARMINIC ACID, CARMINE

Synonyms	CI Natural Red 4
Definition	Carminic acid is obtained from aqueous, aqueous alcoholic or alcoholic extracts from Cochineal, which consists of the dried bodies of the female insect Dactylopius coccus Costa. Carmines are aluminium lakes of carminic acid in which aluminium and carminic acid are thought to be present in the molar ratio 1:2. The colouring principle is carminic acid. Minor amounts of its aminated form 4-aminocarminic acid may also be present. In commercial products the colouring principle carminic acid may be present in association with ammonium, calcium, potassium or sodium cations, singly or in combination, and these cations may also be present in excess. Commercial products may also contain proteinaceous material derived from the source insect.
Colour Index No	75470
Einecs	Carminic acid: 215-023-3; carmines: 215-724-4
Chemical name	7-β-D-glucopyranosyl-3,5,6,8-tetrahydroxy-1-methyl-9,10-dioxoanthracene-2-carboxylic acid (carminic acid); carmine is the hydrated aluminium chelate of this acid
Chemical formula	$C_{22}H_{20}O_{13}$ (carminic acid)
Molecular weight	492,39 (carminic acid)

▼M29

Assay	Content not less than 90 % carminic acid; not less than 50 % carminic acid in the chelates.	
Description	Red to dark red, friable, solid or powder	
Identification		
Spectrometry	Carminic acid:	
	Maximum in aqueous ammonia solution at ca. 518 nm	
	Maximum in dilute hydrochloric solution at ca. 494 nm	
	E 1 %/1 cm 139 at peak around 494 nm in dilute hydrochloric acid	
	4-aminocarminic acid:	
	Maximum in aqueous ammonia solution at 535 nm	
	Maximum in dilute hydrochloric solution at 530 nm	
	E 1 %/1 cm 260 at peak around 535 nm in aqueous ammonia solution, pH 9,5	
	In commercial products carminic acid may be differentiated from its amine by HPLC	
Purity		
Solvent residues	Ethanol:	Not more than 150 mg/kg
	Methanol:	Not more than 50 mg/kg
Total ash	Carminic acid:	Not more than 5 %
	Carmine:	Not more than 12 %
Protein (N × 6,25)	Carminic acid:	Not more than 2,2 %
	Carmine:	Not more than 25 %
4-aminocarminic acid	Not more than 3 % relative to carminic acid	
Matter insoluble in dilute ammonia	Carmine: Not more than 1 %	
Arsenic	Not more than 1 mg/kg	
Lead	Not more than 1,5 mg/kg	
Mercury	Not more than 0,5 mg/kg	
Cadmium	Not more than 0,1 mg/kg	
Microbiological criteria		
Salmonella spp.	Absent in 10 g	

Aluminium lakes of this colour may be used.

▼B

E 122 AZORUBINE, CARMOISINE

Synonyms	CI Food Red 3
Definition	Azorubine consists essentially of disodium 4-hydroxy-3-(4-sulfonato-1-naphthylazo) naphthalene-1-sulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components.
	Azorubine is described as the sodium salt. The calcium and the potassium salt are also permitted.
Colour Index No	14720
Einecs	222-657-4
Chemical name	Disodium 4-hydroxy-3-(4-sulfonato-1-naphthylazo) naphthalene-1-sulfonate
Chemical formula	$C_{20}H_{12}N_2Na_2O_7S_2$
Molecular weight	502,44
Assay	Content not less than 85 % total colouring matters, calculated as the sodium salt
	$E^{1\%}_{1cm}$ 510 at ca. 516 nm in aqueous solution

▼B

Description	Red to maroon powder or granules
Appearance of the aqueous solution	Red
Identification	
Spectrometry	Maximum in water at ca. 516 nm
Purity	
Water insoluble matter	Not more than 0,2 %
Subsidiary colouring matters	Not more than 1 %
Organic compounds other than colouring matters:	
4-aminonaphthalene-1-sulfonic acid 4-hydroxynaphthalene-1-sulfonic acid	Total not more than 0,5 %
Unsulfonated primary aromatic amines	Not more than 0,01 % (calculated as aniline)
Ether extractable matter	Not more than 0,2 % under neutral conditions
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

Aluminium lakes of this colour may be used.

E 123 AMARANTH

Synonyms	CI Food Red 9
Definition	Amaranth consists essentially of trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-3,6-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Amaranth is manufactured by coupling 4-amino-1-naphthalenesulphonic acid with 3-hydroxy-2,7-naphthalenedisulphonic acid. Amaranth is described as the sodium salt. The calcium and the potassium salt are also permitted.
Colour Index No	16185
Einecs	213-022-2
Chemical name	Trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-3,6-disulfonate
Chemical formula	$C_{20}H_{11}N_2Na_3O_{10}S_3$
Molecular weight	604,48
Assay	Content not less than 85 % total colouring matters, calculated as the sodium salt $E^{1\%}_{1cm}$ 440 at ca. 520 nm in aqueous solution

▼B

Description	Reddish-brown powder or granules
Appearance of the aqueous solution	Red
Identification	
Spectrometry	Maximum in water at ca. 520 nm
Purity	
Water insoluble matter	Not more than 0,2 %
Subsidiary colouring matters	Not more than 3,0 %
Organic compounds other than colouring matters:	
4-aminonaphthalene-1-sulfonic acid	Total not more than 0,5 %
3-hydroxynaphthalene-2,7-disulfonic acid	
6-hydroxynaphthalene-2-sulfonic acid	
7-hydroxynaphthalene-1,3-disulfonic acid	
7-hydroxynaphthalene-1,3-6-trisulfonic acid	
Unsulfonated primary aromatic amines	Not more than 0,01 % (calculated as aniline)
Ether extractable matter	Not more than 0,2 % under neutral conditions
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

Aluminium lakes of this colour may be used.

E 124 PONCEAU 4R, COCHINEAL RED A

Synonyms	CI Food Red 7; New Coccine
Definition	Ponceau 4R consists essentially of trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-6,8-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Ponceau 4R is manufactured by coupling diazotized naphthionic acid to G acid (2-naphthol-6,8- disulphonic acid) and converting the coupling product to the trisodium salt. Ponceau 4R is described as the sodium salt. The calcium and the potassium salt are also permitted.
Colour Index No	16255
Einecs	220-036-2
Chemical name	Trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-6,8-disulfonate
Chemical formula	$C_{20}H_{11}N_2Na_3O_{10}S_3$
Molecular weight	604,48

▼B

Assay	Content not less than 80 % total colouring matters, calculated as the sodium salt. $E^{1\%}_{1cm}$ 430 at ca. 505 nm in aqueous solution
Description	Reddish powder or granules
Appearance of the aqueous solution	Red
Identification	
Spectrometry	Maximum in water at ca. 505 nm
Purity	
Water insoluble matter	Not more than 0,2 %
Subsidiary colouring matters	Not more than 1,0 %
Organic compounds other than colouring matters:	
4-aminonaphthalene-1-sulfonic acid	Total not more than 0,5 %
7-hydroxynaphthalene-1,3-disulfonic acid	
3-hydroxynaphthalene-2,7-disulfonic acid	
6-hydroxynaphthalene-2-sulfonic acid	
7-hydroxynaphthalene-1,3-6-trisulfonic acid	
Unsulfonated primary aromatic amines	Not more than 0,01 % (calculated as aniline)
Ether extractable matter	Not more than 0,2 % under neutral conditions
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

Aluminium lakes of this colour may be used.

E 127 ERYTHROSINE

Synonyms	CI Food Red 14
Definition	Erythrosine consists essentially of disodium 2-(2,4,5,7-tetraiodo-3-oxido-6-oxoxanthen-9-yl) benzoate monohydrate and subsidiary colouring matters together with water, sodium chloride and/or sodium sulphate as the principal uncoloured components. Erythrosine is manufactured by iodination of fluorescein, the condensation product of resorcinol and phthalic anhydride Erythrosine is described as the sodium salt. The calcium and the potassium salt are also permitted.
Colour Index No	45430
Einecs	240-474-8
Chemical name	Disodium 2-(2,4,5,7-tetraiodo-3-oxido-6-oxoxanthen-9-yl)benzoate monohydrate
Chemical formula	$C_{20}H_6I_4Na_2O_5\ H_2O$

▼B

Molecular weight	897,88
Assay	Content not less than 87 % total colouring matters, calculated as the anhydrous sodium salt $E_{1cm}^{1\%}$ 1 100 at ca. 526 nm in aqueous solution at pH 7
Description	Red powder or granules.
Appearance of the aqueous solution	Red
Identification	
Spectrometry	Maximum in water at ca. 526 nm at pH 7
Purity	
Inorganic iodides	Not more than 0,1 % (calculated as sodium iodide)
Water insoluble matter	Not more than 0,2 %
Subsidiary colouring matters (except fluorescein)	Not more than 4,0 %
Fluorescein	Not more than 20 mg/kg
Organic compounds other than colouring matters:	
Tri-iodoresorcinol	Not more than 0,2 %
2-(2,4-dihydroxy-3,5-diiodobenzoyl) benzoic acid	Not more than 0,2 %
Ether extractable matter	From a solution of pH from 7 through 8, not more than 0,2 %
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

Aluminium Lakes of this colour may be used.

E 129 ALLURA RED AC

Synonyms	CI Food Red 17
Definition	Allura Red AC consists essentially of disodium 2-hydroxy-1-(2-methoxy-5-methyl-4-sulfonato-phenylazo) naphthalene-6-sulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Allura Red AC is manufactured by coupling diazotized 5-amino-4-methoxy-2-toluenesulphonic acid with 6-hydroxy-2-naphthalene sulphonic acid Allura Red AC is described as the sodium salt. The calcium and the potassium salt are also permitted.
Colour Index No	16035
Einecs	247-368-0
Chemical name	Disodium 2-hydroxy-1-(2-methoxy-5-methyl-4-sulfonatophenylazo) naphthalene-6-sulfonate
Chemical formula	$C_{18}H_{14}N_2Na_2O_8S_2$
Molecular weight	496,42

▼B

Assay	Content not less than 85 % total colouring matters, calculated as the sodium salt $E^{1\%}_{1cm}$ 540 at ca. 504 nm in aqueous solution at pH 7
Description	Dark red powder or granules
Appearance of the aqueous solution	Red
Identification	
Spectrometry	Maximum in water at ca. 504 nm
Purity	
Water insoluble matter	Not more than 0,2 %
Subsidiary colouring matters	Not more than 3,0 %
Organic compounds other than colouring matters:	
6-hydroxy-2-naphthalene sulfonic acid, sodium salt	Not more than 0,3 %
4-amino-5-methoxy-2-methyl-benezene sulfonic acid	Not more than 0,2 %
6,6-oxybis (2-naphthalene sulfonic acid) disodium salt	Not more than 1,0 %
Unsulfonated primary aromatic amines	Not more than 0,01 % (calculated as aniline)
Ether extractable matter	From a solution of pH 7, not more than 0,2 %
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

Aluminium lakes of this colour may be used.

E 131 PATENT BLUE V

Synonyms	CI Food Blue 5
Definition	Patent Blue V consists essentially of the calcium or sodium compound of [4-(α-(4-diethylaminophenyl)-5-hydroxy-2,4-disulfophenyl-methylidene)-2,5-cyclohexadien-1-ylidene] diethylammonium hydroxide inner salt and subsidiary colouring matters together with sodium chloride and/or sodium sulphate and/or calcium sulphate as the principal uncoloured components. The potassium salt is also permitted.
Colour Index No	42051
Einecs	222-573-8
Chemical name	The calcium or sodium compound of [4-(α-(4-diethylaminophenyl)-5-hydroxy-2,4-disulfophenyl-methylidene) 2,5-cyclohexadien-1-ylidene] diethyl-ammonium hydroxide inner salt

▼B

Chemical formula	Calcium compound: $C_{27}H_{31}N_2O_7S_2Ca_{1/2}$ Sodium compound: $C_{27}H_{31}N_2O_7S_2Na$
Molecular weight	Calcium compound: 579,72 Sodium compound: 582,67
Assay	Content not less than 85 % total colouring matters, calculated as the sodium salt $E^{1\%}_{1cm}$ 2 000 at ca. 638 nm in aqueous solution at pH 5
Description	Dark blue powder or granules
Appearance of the aqueous solution	Blue
Identification	
Spectrometry	Maximum in water at 638 nm at pH 5
Purity	
Water insoluble matter	Not more than 0,2 %
Subsidiary colouring matters	Not more than 2,0 %
Organic compounds other than colouring matters:	
3-hydroxy benzaldehyde 3-hydroxy benzoic acid 3-hydroxy-4-sulfobenzoic acid N,N-diethylamino benzene sulfonic acid	Total not more than 0,5 %
Leuco base	Not more than 4,0 %
Unsulfonated primary aromatic amines	Not more than 0,01 % (calculated as aniline)
Ether extractable matter	From a solution of pH 5 not more than 0,2 %
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

Aluminium lakes of this colour may be used.

E 132 INDIGOTINE, INDIGO CARMINE

Synonyms	CI Food Blue 1
Definition	Indigotine consists essentially of a mixture of disodium 3,3′dioxo-2,2′-bi-indolylidene-5,5′-disulfonate, and disodium 3,3′-dioxo-2,2′-bi-indolylidene-5,7′-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Indigotine is described as the sodium salt. The calcium and the potassium salt are also permitted. Indigo carmine is obtained by sulphonation of indigo. This is accomplished by heating indigo (or indigo paste) in the presence of sulphuric acid. The dye is isolated and subjected to purification procedures.

▼B

Colour Index No	73015
Einecs	212-728-8
Chemical name	Disodium 3,3′-dioxo-2,2′-bi-indolylidene-5,5′-disulfonate
Chemical formula	$C_{16}H_8N_2Na_2O_8S_2$
Molecular weight	466,36
Assay	Content not less than 85 % total colouring matters, calculated as the sodium salt; disodium 3,3′-dioxo-2,2′-bi-indolylidene-5,7′-disulfonate: not more than 18 % $E^{1\%}_{1cm}$ 480 at ca. 610 nm in aqueous solution
Description	Dark-blue powder or granules
Appearance of the aqueous solution	Blue
Identification	
Spectrometry	Maximum in water at ca. 610 nm
Purity	
Water insoluble matter	Not more than 0,2 %
Subsidiary colouring matters	Excluding disodium 3,3′-dioxo-2,2′-bi-indolylidene-5,7′-disulfonate: not more than 1,0 %
Organic compounds other than colouring matters:	
Isatin-5-sulfonic acid 5-sulfoanthranilic acid Anthranilic acid	Total not more than 0,5 %
Unsulfonated primary aromatic amines	Not more than 0,01 % (calculated as aniline)
Ether extractable matter	Not more than 0,2 % under neutral conditions
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

Aluminium lakes of this colour may be used.

E 133 BRILLIANT BLUE FCF

Synonyms	CI Food Blue 2
Definition	Brilliant Blue FCF consists essentially of disodium α-(4-(N-ethyl-3-sulfonatobenzylamino) phenyl)-α-(4-N-ethyl-3-sulfonatobenzylamino) cyclohexa-2,5-dienylidene) toluene-2-sulfonate and its isomers and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Brilliant Blue FCF is described as the sodium salt. The calcium and the potassium salt are also permitted.
Colour Index No	42090
Einecs	223-339-8

▼B

Chemical name	Disodium α-(4-(N-ethyl-3-sulfonatobenzylamino) phenyl)-α-(4-N-ethyl-3-sulfonatobenzylamino) cyclohexa-2,5-dienylidene) toluene-2-sulfonate
Chemical formula	$C_{37}H_{34}N_2Na_2O_9S_3$
Molecular weight	792,84
Assay	Content not less than 85 % total colouring matters, calculated as the sodium salt $E^{1\%}_{1cm}$ 1 630 at ca. 630 nm in aqueous solution
Description	Reddish-blue powder or granules
Appearance of the aqueous solution	Blue
Identification	
Spectrometry	Maximum in water at ca. 630 nm
Purity	
Water insoluble matter	Not more than 0,2 %
Subsidiary colouring matters	Not more than 6,0 %
Organic compounds other than colouring matters:	
Sum of 2-, 3- and 4-formyl benzene sulfonic acids	Not more than 1,5 %
3-((ethyl)(4-sulfophenyl) amino) methyl benzene sulfonic acid	Not more than 0,3 %
Leuco base	Not more than 5,0 %
Unsulfonated primary aromatic amines	Not more than 0,01 % (calculated as aniline)
Ether extractable matter	Not more than 0,2 % at pH 7
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

Aluminium lakes of this colour may be used.

E 140 (i) CHLOROPHYLLS

Synonyms	CI Natural Green 3; Magnesium Chlorophyll; Magnesium Phaeophytin
Definition	Chlorophylls are obtained by solvent extraction of strains of edible plant material, grass, lucerne and nettle. During the subsequent removal of solvent, the naturally present coordinated magnesium may be wholly or partly removed from the chlorophylls to give the corresponding phaeophytins. The principal colouring matters are the phaeophytins and magnesium chlorophylls. The extracted product, from which the solvent has been removed, contains other pigments such as carotenoids as well as oils, fats and waxes derived from the source material. Only the following solvents may be used for the extraction: acetone, methyl ethyl ketone, dichloromethane, carbon dioxide, methanol, ethanol, propan-2-ol and hexane.

▼B

Colour Index No	75810
Einecs	Chlorophylls: 215-800-7, chlorophyll a: 207-536-6, Chlorophyll b: 208-272-4
Chemical name	The major colouring principles are: Phytyl (13^2R,17S,18S)-3-(8-ethyl-13^2-methoxycarbonyl-2,7,12,18-tetramethyl-13′-oxo-3-vinyl-13^1-13^2-17,18-tetrahydrocyclopenta[at]-porphyrin-17-yl)propionate, (Phaeophytin a), or as the magnesium complex (Chlorophyll a) Phytyl (13^2R,17S,18S)-3-(8-ethyl-7-formyl-13^2-methoxycarbonyl-2,12,18-trimethyl-13′-oxo-3-vinyl-13^1-13^2-17,18-tetrahydro-cyclopenta[at]-porphyrin-17-yl)propionate, (Pheophytin b), or as the magnesium complex (Chlorophyll b)
Chemical formula	Chlorophyll a (magnesium complex): $C_{55}H_{72}MgN_4O_5$ Chlorophyll a: $C_{55}H_{74}N_4O_5$ Chlorophyll b (magnesium complex): $C_{55}H_{70}MgN_4O_6$ Chlorophyll b: $C_{55}H_{72}N_4O_6$
Molecular weight	Chlorophyll a (magnesium complex): 893,51 Chlorophyll a: 871,22 Chlorophyll b (magnesium complex): 907,49 Chlorophyll b: 885,20
Assay	Content of total combined Chlorophylls and their magnesium complexes is not less than 10 % $E^{1\%}_{1cm}$ 700 at ca. 409 nm in chloroform
Description	Waxy solid ranging in colour from olive green to dark green depending on the content of coordinated magnesium
Identification	
Spectrometry	Maximum in chloroform at ca. 409 nm
Purity	
Solvent residues	Acetone; Methyl Ethyl ketone; Methanol; Ethanol; Propan-2-ol; Hexane: Not more than 50 mg/kg, singly or in combination Dichloromethane: 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
Cadmium	Not more than 1 mg/kg

▼B

E 140 (ii) CHLOROPHYLLINS

Synonyms	CI Natural Green 5; Sodium Chlorophyllin; Potassium Chlorophyllin
Definition	The alkali salts of chlorophyllins are obtained by the saponification of a solvent extract of strains of edible plant material, grass, lucerne and nettle. The saponification removes the methyl and phytol ester groups and may partially cleave the cyclopentenyl ring. The acid groups are neutralised to form the salts of potassium and/or sodium. Only the following solvents may be used for the extraction: acetone, methyl ethyl ketone, dichloromethane, carbon dioxide, methanol, ethanol, propan-2-ol and hexane.
Colour Index No	75815
Einecs	287-483-3
Chemical name	The major colouring principles in their acid forms are: — 3-(10-carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-oxo-2-vinylphorbin-7-yl)propionate (chlorophyllin a) and — 3-(10-carboxylato-4-ethyl-3-formyl-1,5,8-trimethyl-9-oxo-2-vinylphorbin-7-yl)propionate (chlorophyllin b) Depending on the degree of hydrolysis the cyclopentenyl ring may be cleaved with the resultant production of a third carboxyl function. Magnesium complexes may also be present.
Chemical formula	Chlorophyllin a (acid form): $C_{34}H_{34}N_4O_5$ Chlorophyllin b (acid form): $C_{34}H_{32}N_4O_6$
Molecular weight	Chlorophyllin a: 578,68 Chlorophyllin b: 592,66 Each may be increased by 18 daltons if the cyclopentenyl ring is cleaved.
Assay	Content of total chlorophyllins is not less than 95 % of the sample dried at ca. 100 °C for 1 hour. $E^{1\%}_{1cm}$ 700 at ca. 405 nm in aqueous solution at pH 9 $E^{1\%}_{1cm}$ 140 at ca. 653 nm in aqueous solution at pH 9
Description	Dark green to blue/black powder
Identification	
Spectrometry	Maximum in aqueous phosphate buffer at pH 9 at ca. 405 nm and at ca. 653 nm
Purity	
Solvent residues	Acetone, Methyl ethyl ketone, Methanol, Ethanol, Propan-2-ol, Hexane: Not more than 50 mg/kg, singly or in combination Dichloromethane: not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

▼B

E 141 (i) COPPER COMPLEXES OF CHLOROPHYLLS

Synonyms	CI Natural Green 3; Copper Chlorophyll; Copper Phaeophytin
Definition	Copper chlorophylls are obtained by addition of a salt of copper to the substance obtained by solvent extraction of strains of edible plant material, grass, lucerne, and nettle. The product, from which the solvent has been removed, contains other pigments such as carotenoids as well as fats and waxes derived from the source material. The principal colouring matters are the copper phaeophytins. Only the following solvents may be used for the extraction: acetone, methyl ethyl ketone, dichloromethane, carbon dioxide, methanol, ethanol, propan-2-ol and hexane.
Colour Index No	75810
Einecs	Copper chlorophyll a: 239-830-5; copper chlorophyll b: 246-020-5
Chemical name	[Phytyl (13^2R,17S,18S)-3-(8-ethyl-13^2-methoxycarbonyl-2,7,12,18-tetramethyl-13′-oxo-3-vinyl-13^1-13^2-17,18-tetrahydrocyclopenta[at]-porphyrin-17-yl)propionate] copper (II) (Copper Chlorophyll a) [Phytyl (13^2R,17S,18S)-3-(8-ethyl-7-formyl-13^2-methoxycarbonyl-2,12,18-trimethyl-13′-oxo-3-vinyl-13^1-13^2-17,18-tetrahydro-cyclopenta[at]-porphyrin-17-yl)propionate] copper (II) (Copper chlorophyll b)
Chemical formula	Copper chlorophyll a: $C_{55}H_{72}Cu\ N_4O_5$ Copper chlorophyll b: $C_{55}H_{70}Cu\ N_4O_6$
Molecular weight	Copper chlorophyll a: 932,75 Copper chlorophyll b: 946,73
Assay	Content of total copper chlorophylls is not less than 10 %. $E^{1\%}_{1cm}$ 540 at ca. 422 nm in chloroform $E^{1\%}_{1cm}$ 300 at ca. 652 nm in chloroform
Description	Waxy solid ranging in colour from blue green to dark green depending on the source material
Identification	
Spectrometry	Maximum in chloroform at ca. 422 nm and at ca. 652 nm
Purity	
Solvent residues	Acetone; Methyl ethyl ketone; Methanol; Ethanol; Propan-2-ol; Hexane: Not more than 50 mg/kg, singly or in combination Dichloromethane: not more than 10 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

▼B

Copper ions	Not more than 200 mg/kg
Total copper	Not more than 8,0 % of the total copper phaeophytins

Aluminium lakes of this colour may be used.

E 141 (ii) COPPER COMPLEXES OF CHLOROPHYLLINS

Synonyms	Sodium Copper Chlorophyllin; Potassium Copper Chlorophyllin; CI Natural Green 5
Definition	The alkali salts of copper chlorophyllins are obtained by the addition of copper to the product obtained by the saponification of a solvent extraction of strains of edible plant material, grass, lucerne, and nettle; the saponification removes the methyl and phytol ester groups and may partially cleave the cyclopentenyl ring. After addition of copper to the purified chlorophyllins, the acid groups are neutralised to form the salts of potassium and/or sodium. Only the following solvents may be used for the extraction: acetone, methyl ethyl ketone, dichloromethane, carbon dioxide methanol, ethanol, propan-2-ol and hexane.
Colour Index No	75815
Einecs	
Chemical name	The major colouring principles in their acid forms are 3-(10-Carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-oxo-2-vinylphorbin-7-yl)propionate, copper complex (Copper chlorophyllin a) and 3-(10-Carboxylato-4-ethyl-3-formyl-1,5,8-trimethyl-9-oxo-2-vinylphorbin-7-yl) propionate, copper complex (Copper chlorophyllin b)
Chemical formula	Copper chlorophyllin a (acid form): $C_{34}H_{32}Cu\ N_4O_5$ Copper chlorophyllin b (acid form): $C_{34}H_{30}Cu\ N_4O_6$
Molecular weight	Copper chlorophyllin a: 640,20 Copper chlorophyllin b: 654,18 Each may be increased by 18 daltons if the cyclopentenyl ring is cleaved.
Assay	Content of total copper chlorophyllins is not less than 95 % of the sample dried at 100 °C for 1 h. $E^{1\%}_{1cm}$ 565 at ca. 405 nm in aqueous phosphate buffer at pH 7,5 $E^{1\%}_{1cm}$ 145 at ca. 630 nm in aqueous phosphate buffer at pH 7,5
Description	Dark green to blue/black powder
Identification	
Spectrometry	Maximum in aqueous phosphate buffer at pH 7,5 at ca. 405 nm and at 630 nm
Purity	
Solvent residues	Acetone Methyl ethyl ketone Methanol Ethanol Propan-2-ol Hexane — Not more than 50 mg/kg, singly or in combination

▼B

	Dichloromethane: 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
Cadmium	Not more than 1 mg/kg
Copper ions	Not more than 200 mg/kg
Total copper	Not more than 8,0 % of the total copper chlorophyllins

Aluminium lakes of this colour may be used.

E 142 GREEN S

Synonyms	CI Food Green 4, Brilliant Green BS
Definition	Green S consists essentially of sodium N-[4-[[4-(dimethylamino)phenyl] 2-hydroxy-3,6-disulfo-1-naphthalenyl)methylene]-2,5-cyclohexadien-1-ylidene]-N-methylmethanaminium and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured compounds. Green S is described as the sodium salt. The calcium and the potassium salt are also permitted.
Colour Index No	44090
Einecs	221-409-2
Chemical name	Sodium N-[4-[[4-(dimethylamino)phenyl](2-hydroxy-3,6-disulfo-1-naphthalenyl)-methylene]2,5-cyclohexadien-1-ylidene]-N-methylmethanaminium; Sodium 5-[4-dimethylamino-α-(4-dimethyliminocyclohexa-2,5-dienylidene) benzyl]-6-hydroxy-7-sulfonato-naphthalene-2-sulfonate (alternative chemical name).
Chemical formula	$C_{27}H_{25}N_2NaO_7S_2$
Molecular weight	576,63
Assay	Content not less than 80 % total colouring matters calculated as the sodium salt $E^{1\%}_{1cm}$ 1 720 at ca. 632 nm in aqueous solution
Description	Dark blue or dark green powder or granules
Appearance of the aqueous solution	Blue or green
Identification	
Spectrometry	Maximum in water at ca. 632 nm
Purity	
Water insoluble matter	Not more than 0,2 %
Subsidiary colouring matters	Not more than 1,0 %
Organic compounds other than colouring matters:	
4,4′-bis(dimethylamino)-benzhydryl alcohol	Not more than 0,1 %
4,4′-bis(dimethylamino)-benzophenone	Not more than 0,1 %
3-hydroxynaphthalene-2,7-disulfonic acid	Not more than 0,2 %

▼B

Leuco base	Not more than 5,0 %
Unsulfonated primary aromatic amines	Not more than 0,01 % (calculated as aniline)
Ether extractable matter	Not more than 0,2 % under neutral conditions
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

Aluminium lakes of this colour may be used.

E 150a PLAIN CARAMEL

Synonyms	Caustic caramel
Definition	Plain caramel is prepared by the controlled heat treatment of carbohydrates (commercially available food grade nutritive sweeteners which are the monomers glucose and fructose and/or polymers thereof, e.g. glucose syrups, sucrose, and/or invert syrups, and dextrose). To promote caramelisation, acids, alkalis and salts may be employed, with the exception of ammonium compounds and sulphites.
Colour Index No	
Einecs	232-435-9
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	Dark brown to black liquids or solids
Identification	
Purity	
Colour bound by DEAE cellulose	Not more than 50 %
Colour bound by phosphoryl cellulose	Not more than 50 %
Colour intensity ([1])	0,01-0,12
Total nitrogen	Not more than 0,1 %
Total sulphur	Not more than 0,2 %
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

([1]) Colour intensity is defined as the absorbance of a 0,1 % (w/v) solution of caramel colour solids in water in a 1 cm cell at 610 nm.

▼B

E 150b CAUSTIC SULPHITE CARAMEL

Synonyms	
Definition	Caustic sulphite caramel is prepared by the controlled heat treatment of carbohydrates (commercially available food grade nutritive sweeteners which are the monomers glucose and fructose and/or polymers thereof, e.g. glucose syrups, sucrose, and/or invert syrups, and dextrose) with or without acids or alkalis, in the presence of sulphite compounds (sulphurous acid, potassium sulphite, potassium bisulphite, sodium sulphite and sodium bisulphite); no ammonium compounds are used.
Colour Index No	
Einecs	232-435-9
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	Dark brown to black liquids or solids
Identification	
Purity	
Colour bound by DEAE cellulose	More than 50 %
Colour intensity ([1])	0,05-0,13
Total nitrogen	Not more than 0,3 % ([2])
Sulphur dioxide	Not more than 0,2 % ([2])
Total sulphur	0,3-3,5 % ([2])
Sulphur bound by DEAE cellulose	More than 40 %
Absorbance ratio of colour bound by DEAE cellulose	19-34
Absorbance ratio ($A_{280/560}$)	Greater than 50
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 150c AMMONIA CARAMEL

Synonyms	
Definition	Ammonia caramel is prepared by the controlled heat treatment of carbohydrates (commercially available food grade nutritive sweeteners which are the monomers glucose and fructose and/or polymers thereof, e.g. glucose syrups, sucrose, and/or invert syrups, and dextrose) with or without acids or alkalis, in the presence of ammonium compounds (ammonium hydroxide, ammonium carbonate, ammonium hydrogen carbonate and ammonium phosphate); no sulphite compounds are used.

([1]) Colour intensity is defined as the absorbance of a 0,1 % (w/v) solution of caramel colour solids in water in a 1 cm cell at 610 nm.
([2]) Expressed on equivalent colour basis i.e. is expressed in terms of a product having a colour intensity of 0,1 absorbance units.

▼B

Colour Index No	
Einecs	232-435-9
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	Dark brown to black liquids or solids
Identification	
Purity	
Colour bound by DEAE cellulose	Not more than 50 %
Colour bound by phosphoryl cellulose	More than 50 %
Colour intensity ([1])	0,08-0,36
Ammoniacal nitrogen	Not more than 0,3 % ([2])
4-methylimidazole	Not more than 200 mg/kg ([2])
2-acetyl-4-tetrahydroxy-butylimidazole	Not more than 10 mg/kg ([2])
Total sulphur	Not more than 0,2 % ([2])
Total nitrogen	0,7-3,3 % ([2])
Absorbance ratio of colour bound by phosphoryl cellulose	13-35
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 150d SULPHITE AMMONIA CARAMEL

Synonyms	
Definition	Sulphite ammonia caramel is prepared by the controlled heat treatment of carbohydrates (commercially available food grade nutritive sweeteners which are the monomers glucose and fructose and/or polymers thereof (e.g. glucose syrups, sucrose, and/or invert syrups, and dextrose) with or without acids or alkalis in the presence of both sulphite and ammonium compounds (sulphurous acid, potassium sulphite, potassium bisulphite, sodium sulphite, sodium bisulphite, ammonium hydroxide, ammonium carbonate, ammonium hydrogen carbonate, ammonium phosphate, ammonium sulphate, ammonium sulphite and ammonium hydrogen sulphite).
Colour Index No	
Einecs	232-435-9
Chemical name	
Chemical formula	

([1]) Colour intensity is defined as the absorbance of a 0,1 % (w/v) solution of caramel colour solids in water in a 1 cm cell at 610 nm.
([2]) Expressed on equivalent colour basis i.e. is expressed in terms of a product having a colour intensity of 0,1 absorbance units.

▼B

Molecular weight	
Assay	
Description	Dark brown to black liquids or solids
Identification	
Purity	
Colour bound by DEAE cellulose	More than 50 %
Colour intensity (1)	0,10-0,60
Ammoniacal nitrogen	Not more than 0,6 % (2)
Sulphur dioxide	Not more than 0,2 % (2)
4-methylimidazole	Not more than 250 mg/kg (2)
Total nitrogen	0,3-1,7 % (2)
Total sulphur	0,8-2,5 % (2)
Nitrogen/sulphur ratio of alcohol precipitate	0,7-2,7
Absorbance ratio of alcohol precipitate (3)	8-14
Absorbance ratio ($A_{280/560}$)	Not more than 50
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

▼M8

E 151 BRILLIANT BLACK PN

▼B

Synonyms	CI Food Black 1

▼M8

Definition	Brilliant Black PN consists essentially of tetrasodium-4-acetamido-5-hydroxy-6-[7-sulfonato-4-(4-sulfonatophenylazo)-1-naphthylazo] naphthalene-1,7-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Brilliant Black PN is described as the sodium salt. The calcium and the potassium salt are also permitted.

▼B

Colour Index No	28440
Einecs	219-746-5
Chemical name	Tetrasodium 4-acetamido-5-hydroxy-6-[7-sulfonato-4-(4-sulfonatophenylazo)-1-naphthylazo] naphthalene-1,7-disulfonate
Chemical formula	$C_{28}H_{17}N_5Na_4O_{14}S_4$
Molecular weight	867,69

(1) Colour intensity is defined as the absorbance of a 0,1 % (w/v) solution of caramel colour solids in water in a 1 cm cell at 610 nm.
(2) Expressed on equivalent colour basis i.e. is expressed in terms of a product having a colour intensity of 0,1 absorbance units.
(3) Absorbance ratio of alcohol precipitate is defined as the absorbance of the precipitate at 280 nm divided by the absorbance at 560 nm (1 cm cell).

▼B

Assay	Content not less than 80 % total colouring matters calculated as the sodium salt $E^{1\%}_{1cm}$ 530 at ca. 570 nm in solution
Description	Black powder or granules
Appearance of the aqueous solution	Black-bluish
Identification	
Spectrometry	Maximum in water at ca. 570 nm
Purity	
Water insoluble matter	Not more than 0,2 %
Subsidiary colouring matters	Not more than 4 % (expressed on the dye content)
Organic compounds other than colouring matters:	
4-acetamido-5-hydroxynaphthalene-1,7-disulfonic acid	Total not more than 0,8 %
4-amino-5-hydroxynaphthalene-1,7-disulfonic acid	
8-aminonaphthalene-2-sulfonic acid-	
4,4′-diazoaminodi-(benzenesulfonic acid)	
Unsulfonated primary aromatic amines	Not more than 0,01 % (calculated as aniline)
Ether extractable matter	Not more than 0,2 % under neutral conditions
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

Aluminium lakes of this colour may be used.

E 153 VEGETABLE CARBON

Synonyms	Vegetable black
Definition	Vegetable activated carbon is produced by the carbonisation of vegetable material such as wood, cellulose residues, peat and coconut and other shells. The activated carbon thus produced is milled by a roller mill and the resulting highly activated powdered carbon is treated by a cyclone. The fine fractio40800n from the cyclone is purified by hydrochloric acid washing, neutralised and then dried. The resulting product is what is known traditionally as vegetable black. Products with a higher colouring power are produced from the fine fraction by a further cyclone treatment or by extra milling, followed by acid washing, neutralising and drying. It consists essentially of finely divided carbon. It may contain minor amounts of nitrogen, hydrogen and oxygen. Some moisture may be absorbed on the product after manufacture.

▼B

Colour Index No	77266
Einecs	231-153-3
Chemical name	Carbon
Chemical formula	C
Atomic weight	12,01
Assay	Content not less than 95 % of carbon calculated on an anhydrous and ash-free basis
Loss on drying	Not more than 12 % (120 °C 4 h)
Description	Black, odourless powder
Identification	
Solubility	Insoluble in water and organic solvents
Burning	When heated to redness it burns slowly without a flame
Purity	
Ash (Total)	Not more than 4,0 % (ignition temperature: 625 °C)
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
Polycyclic aromatic hydrocarbons	Benzo(a)pyrene less than 50 µg/kg in the extract obtained by extraction of 1 g of the product with 10 g pure cyclohexane in a continuous extraction.
Alkali soluble matter	The filtrate obtained by boiling 2 g of the sample with 20 ml N sodium hydroxide and filtering shall be colourless

E 155 BROWN HT

Synonyms	CI Food Brown 3
Definition	Brown HT consists essentially of disodium 4,4′-(2,4-dihydroxy-5-hydroxymethyl-1,3-phenylene bisazo) di (naphthalene-1-sulfonate) and subsidiary colouring matters together with sodium chloride and/or sulphate as the principal uncoloured components. Brown HT is described as the sodium salt. The calcium and potassium salt are also permitted.
Colour Index No	20285
Einecs	224-924-0
Chemical name	Disodium 4,4′-(2,4-dihydroxy-5-hydroxymethyl-1,3-phenylene bisazo)di (naphthalene-1-sulfonate)
Chemical formula	$C_{27}H_{18}N_4Na_2O_9S_2$
Molecular weight	652,57
Assay	Content not less than 70 % total colouring matters calculated as the sodium salt. $E^{1\%}_{1cm}$ 403 at ca. 460 nm in aqueous solution at pH 7
Description	Reddish-brown powder or granules
Appearance of the aqueous solution	Brown

▼B

Identification	
Spectrometry	Maximum in water of pH 7 at ca. 460 nm
Purity	
Water insoluble matter	Not more than 0,2 %
Subsidiary colouring matters	Not more than 10 % (TLC method)
Organic compounds other than colouring matters:	
4-aminonaphthalene- 1-sulfonic acid	Not more than 0,7 %
Unsulfonated primary aromatic amines	Not more than 0,01 % (calculated as aniline)
Ether extractable matter	Not more than 0,2 % in a solution of pH 7
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

Aluminium lakes of this colour may be used.

E 160 a (i) BETA-CAROTENE

Synonyms	CI Food Orange 5
Definition	These specifications apply predominantly to all trans isomer of beta-carotene together with minor amounts of other carotenoids. Diluted and stabilised preparations may have different trans-cis isomer ratios.
Colour Index No	40800
Einecs	230-636-6
Chemical name	Beta-carotene; beta, beta-carotene
Chemical formula	$C_{40}H_{56}$
Molecular weight	536,88
Assay	Not less than 96 % total colouring matters (expressed as beta-carotene) $E^{1\%}_{1cm}$ 2 500 at approximately by 440 nm to 457 nm in cyclohexane
Description	Red to brownish-red crystals or crystalline powder
Identification	
Spectrometry	Maximum in cyclohexane at 453 nm to 456 nm
Purity	
Sulphated ash	Not more than 0,1 %
Subsidiary colouring matters	Carotenoids other than beta-carotene: not more than 3,0 % of total colouring matters
Lead	Not more than 2 mg/kg

▼B

E 160 a (ii) PLANT CAROTENES

Synonyms	CI Food Orange 5	
Definition	Plant carotenes are obtained by solvent extraction of strains of edible plants, carrots, vegetable oils, grass, alfalfa (lucerne) and nettle. The main colouring principle consists of carotenoids of which beta-carotene accounts for the major part. Alpha, gamma-carotene and other pigments may be present. Besides the colour pigments, this substance may contain oils, fats and waxes naturally occurring in the source material. Only the following solvents may be used in the extraction: acetone, methyl ethyl ketone, methanol, ethanol, propan-2-ol, hexane (1), dichloromethane and carbon dioxide.	
Colour Index No	75130	
Einecs	230-636-6	
Chemical name		
Chemical formula	Beta-carotene: $C_{40}H_{56}$	
Molecular weight	Beta-carotene: 536,88	
Assay	Content of carotenes (calculated as beta-carotene) is not less than 5 %. For products obtained by extraction of vegetables oils: not less than 0,2 % in edible fats $E^{1\%}_{1cm}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane	
Description		
Identification		
Spectrometry	Maximum in cyclohexane at 440 nm to 457 nm and 470 nm to 486 nm	
Purity		
Solvent residues	Acetone Methyl ethyl ketone Methanol Propan-2-ol Hexane Ethanol	Not more than 50 mg/kg, singly or in combination
	Dichloromethane	Not more than 10 mg/kg
Lead	Not more than 2 mg/kg	

E 160 a (iii) BETA-CAROTENE FROM *Blakeslea trispora*

Synonyms	CI Food Orange 5
Definition	Obtained by a fermentation process using a mixed culture of the two sexual mating types (+) and (–) of strains of the fungus *Blakeslea trispora*. The beta-carotene is extracted from the biomass with ethyl acetate or isobutyl acetate followed by propan-2-ol and crystallised. The crystallised product consists mainly of trans beta-carotene. Because of the natural process approximately 3 % of the product consists of mixed carotenoids, which is specific for the product.

(1) Benzene not more than 0,05 % v/v.

▼B

Colour Index No	40800
Einecs	230-636-6
Chemical name	Beta-carotene; beta, beta-carotene
Chemical formula	$C_{40}H_{56}$
Molecular weight	536,88
Assay	Not less than 96 % total colouring matters (expressed as beta-carotene) $E^{1\%}_{1cm}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane
Description	Red, brownish-red or purple-violet crystals or crystalline powder (colour varies according to extraction solvent used and conditions of crystallisation)
Identification	
Spectrometry	Maximum in cyclohexane at 453 nm to 456 nm
Purity	
Solvent residues	Ethyl acetate, Ethanol: Not more than 0,8 %, singly or in combination Isobutyl acetate: Not more than 1,0 % Propan-2-ol: Not more than 0,1 %
Sulphated ash	Not more than 0,2 %
Subsidiary colouring matters	Carotenoids other than beta-carotene: not more than 3,0 % of total colouring matters
Lead	Not more than 2 mg/kg
Microbiological criteria	
Moulds	Not more than 100 colonies per gram
Yeasts	Not more than 100 colonies per gram
Salmonella spp.	Absent in 25 g
Escherichia coli	Absent in 5 g

E 160 a (iv) ALGAL CAROTENES

Synonyms	CI Food Orange 5

▼M8

Definition	Mixed carotenes may also be produced from strains of the algae *Dunaliella salina*. Beta-carotene is extracted using an essential oil. The preparation is a 20 to 30 % suspension in edible oil. The ratio of trans-cis isomers is in the range of 50/50 to 71/29. The main colouring principle consists of carotenoids of which beta-carotene accounts for the major part. Alpha-carotene, lutein, zeaxanthin and beta-cryptoxanthin may be present. Besides the colour pigments, this substance may contain oils, fats and waxes naturally occurring in the source material.

▼B

Colour Index No	75130
Einecs	
Chemical name	
Chemical formula	Beta-Carotene: $C_{40}H_{56}$
Molecular weight	Beta-Carotene: 536,88

▼B

Assay	Content of carotenes (calculated as beta-carotene) is not less than 20 % $E^{1\%}_{1cm}$ 2 500 at approximately by 440 nm to 457 nm in cyclohexane
Description	
Identification	
Spectrometry	Maximum in cyclohexane at 440 nm to 457 nm and 474 nm to 486 nm
Purity	
Natural tocopherols in edible oil	Not more than 0,3 %
Lead	Not more than 2 mg/kg

▼M32

E 160 b (i) ANNATTO BIXIN

(I) SOLVENT-EXTRACTED BIXIN

Synonyms	Annatto B, Orlean, Terre orellana, L. Orange, CI Natural Orange 4
Definition	Solvent-extracted bixin is obtained by the extraction of the outer coating of the seeds of the annatto tree (*Bixa orellana* L.) with one or more of the following food grade solvents: acetone, methanol, hexane, ethanol, isopropyl alcohol, ethyl acetate, alkaline alcohol or supercritical carbon dioxide. The resulting preparation may be acidified, followed by the removal of the solvent, drying and milling. Solvent-extracted bixin contains several coloured components; the major colouring principle is cis-bixin, a minor colouring principle is trans-bixin; thermal degradation products of bixin may also be present as a result of processing.
Colour Index No	75120
Einecs	230-248-7
Chemical name	cis-Bixin: Methyl (9-cis)-hydrogen-6,6'-diapo-Ψ,Ψ-carotenedioate
Chemical formula	cis-Bixin: $C_{25}H_{30}O_4$
Molecular weight	394,5
Assay	Not less than 85 % colouring matter (expressed as bixin) $E^{1\%}_{1cm}$ 3090 at ca. 487 nm in tetrahydrofuran and acetone
Description	Dark red-brown to red-purple powder
Identification	
Solubility	Insoluble in water, slightly soluble in ethanol
Spectrometry	The sample in acetone shows absorbance maxima at about 425, 457 and 487 nm
Purity	
Norbixin	Not more than 5 % of total colouring matters
Residual Solvents	Acetone: Not more than 30 mg/kg Methanol: Not more than 50 mg/kg Hexane: Not more than 25 mg/kg Ethanol: Isopropyl alcohol: not more than 50 mg/kg, singly or in combination Ethyl acetate:
Arsenic	Not more than 2 mg/kg

▼M32

Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 0,5 mg/kg

(II) AQUEOUS-PROCESSED BIXIN

Synonyms	Annatto E, Orlean, Terre orellana, L. Orange, CI Natural Orange 4
Definition	Aqueous-processed bixin is prepared by the extraction of the outer coating of the seeds of the annatto tree (*Bixa orellana* L.) by abrading the seeds in the presence of cold, mildly-alkaline water. The resultant preparation is acidified to precipitate bixin which is then filtered, dried and milled. Aqueous-processed bixin contains several coloured components; the major colouring principle is cis-bixin, a minor colouring principle is trans-bixin; thermal degradation products of bixin may also be present as a result of processing.
Colour Index No	75120
Einecs	230-248-7
Chemical name	cis-Bixin: Methyl (9-cis)-hydrogen-6,6'-diapo-Ψ,Ψ-carotenedioate
Chemical formula	cis-Bixin: $C_{25}H_{30}O_4$
Molecular weight	394,5
Assay	Not less than 25 % colouring matter (expressed as bixin) $E^{1\ \%}_{1cm}$ 3090 at ca. 487 nm in tetrahydrofuran and acetone
Description	Dark red-brown to red-purple powder
Identification	
Solubility	Insoluble in water, slightly soluble in ethanol
Spectrometry	The sample in acetone shows absorbance maxima at about 425, 457 and 487 nm
Purity	
Norbixin	Not more than 7 % of total colouring matters
Arsenic	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 0,5 mg/kg

E 160 b (ii) ANNATTO NORBIXIN

(I) SOLVENT-EXTRACTED NORBIXIN

Synonyms	Annatto C, Orlean, Terre orellana, L. Orange, CI Natural Orange 4
Definition	Solvent-extracted norbixin is obtained from the outer coating of the seeds of the annatto tree (*Bixa orellana* L.) by washing with one or more of the following food grade solvents: acetone, methanol, hexane, ethanol, isopropyl alcohol, ethyl acetate, alkaline alcohol or supercritical carbon dioxide followed by solvent removal, crystallization and drying. Aqueous alkali is added to the resultant powder, which is then heated to hydrolyse the colouring matter and cooled. The aqueous solution is filtered, and acidified to precipitate the norbixin. The precipitate is filtered, washed, dried and milled, to give a granular powder.

▼M32

	Solvent-extracted norbixin contains several coloured components; the major colouring principle is *cis*-norbixin, a minor colouring principle is *trans*-norbixin; thermal degradation products of norbixin may also be present as a result of processing.
Colour Index No	75120
Einecs	208-810-8
Chemical name	cis-Norbixin: 6,6'-Diapo-Ψ,Ψ-carotenedioic acid cis-Norbixin dipotassium salt: Dipotassium 6,6'-diapo-Ψ,Ψ-carotenedioate cis-Norbixin disodium salt: Disodium 6,6'-diapo-Ψ,Ψ-carotenedioate
Chemical formula	*cis*-Norbixin: $C_{24}H_{28}O_4$ *cis*-Norbixin dipotassium salt: $C_{24}H_{26}K_2O_4$ *cis*-Norbixin disodium salt: $C_{24}H_{26}Na_2O_4$
Molecular weight	380,5 (acid), 456,7 (dipotassium salt), 424,5 (disodium salt)
Assay	Not less than 85 % colouring matter (expressed as norbixin) $E^{1\ \%}_{1cm}$ 2870 at ca. 482 nm in 0,5 % potassium hydroxide solution
Description	Dark red-brown to red-purple powder
Identification	
Solubility	Soluble in alkaline water, slightly soluble in ethanol
Spectrometry	The sample in 0,5 % potassium hydroxide solution shows absorbance maxima at about 453 nm and 482 nm
Purity	
Residual Solvents	Acetone: Not more than 30 mg/kg Methanol: Not more than 50 mg/kg Hexane: Not more than 25 mg/kg Ethanol: Isopropyl alcohol: Ethyl acetate: not more than 50 mg/kg, singly or in combination
Arsenic	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 0,5 mg/kg

(II) ALKALI-PROCESSED NORBIXIN, ACID-PRECIPITATED

Synonyms	Annatto F, Orlean, Terre orellana, L. Orange, CI Natural Orange 4
Definition	Alkali-processed norbixin (acid-precipitated) is prepared by the extraction of the outer coating of the seeds of the annatto tree (*Bixa orellana* L.) with aqueous alkali. The bixin is hydrolysed to norbixin in hot alkaline solution and is acidified to precipitate the norbixin. The precipitate is filtered, dried and milled to give a granular powder. Alkali-processed norbixin contains several coloured components; the major colouring principle is *cis*-norbixin, a minor colouring principle is *trans*-norbixin; thermal degradation products of norbixin may also be present as a result of processing.
Colour Index No	75120

▼**M32**

Einecs	208-810-8
Chemical name	cis-Norbixin: 6,6'-Diapo-Ψ,Ψ-carotenedioic acid cis-Norbixin dipotassium salt: Dipotassium 6,6'-diapo-Ψ,Ψ-carotenedioate cis-Norbixin disodium salt: Disodium 6,6'-diapo-Ψ,Ψ-carotenedioate
Chemical formula	*cis*-Norbixin: $C_{24}H_{28}O_4$ *cis*-Norbixin dipotassium salt: $C_{24}H_{26}K_2O_4$ *cis*-Norbixin disodium salt: $C_{24}H_{26}Na_2O_4$
Molecular weight	380,5 (acid), 456,7 (dipotassium salt), 424,5 (disodium salt)
Assay	Not less than 35 % colouring matter (expressed as norbixin) $E^{1\ \%}_{1cm}$ 2870 at ca. 482 nm in 0,5 % potassium hydroxide solution
Description	Dark red-brown to red-purple powder
Identification	
Solubility	Soluble in alkaline water, slightly soluble in ethanol
Spectrometry	The sample in 0,5 % potassium hydroxide solution shows absorbance maxima at about 453 nm and 482 nm
Purity	
Arsenic	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 0,5 mg/kg

(III) ALKALI-PROCESSED NORBIXIN, NOT ACID-PRECIPITATED

Synonyms	Annatto G, Orlean, Terre orellana, L. Orange, CI Natural Orange 4
Definition	Alkali-processed norbixin (not acid-precipitated) is prepared by the extraction of the outer coating of the seeds of the annatto tree (*Bixa orellana* L.) with aqueous alkali. The bixin is hydrolysed to norbixin in hot alkaline solution. The precipitate is filtered, dried and milled to give a granular powder. Extracts contain mainly the potassium or sodium salt of norbixin as the major colouring matter. Alkali-processed norbixin (not acid-precipitated) contains several coloured components; the major colouring principle is *cis*-norbixin, a minor colouring principle is *trans*-norbixin; thermal degradation products of norbixin may also be present as a result of processing.
Colour Index No	75120
Einecs	208-810-8
Chemical name	cis-Norbixin: 6,6'-Diapo-Ψ,Ψ-carotenedioic acid cis-Norbixin dipotassium salt: Dipotassium 6,6'-diapo-Ψ,Ψ-carotenedioate cis-Norbixin disodium salt: Disodium 6,6'-diapo-Ψ,Ψ-carotenedioate
Chemical formula	*cis*-Norbixin: $C_{24}H_{28}O_4$ *cis*-Norbixin dipotassium salt: $C_{24}H_{26}K_2O_4$ *cis*-Norbixin disodium salt: $C_{24}H_{26}Na_2O_4$

▼M32

Molecular weight	380,5 (acid), 456,7 (dipotassium salt), 424,5 (disodium salt)
Assay	Not less than 15 % colouring matter (expressed as norbixin) $E^{1\ \%}_{1cm}$ 2870 at ca. 482 nm in 0,5 % potassium hydroxide solution
Description	Dark red-brown to red-purple powder
Identification	
Solubility	Soluble in alkaline water, slightly soluble in ethanol
Spectrometry	The sample in 0,5 % potassium hydroxide solution shows absorbance maxima at about 453 nm and 482 nm
Purity	
Arsenic	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 0,5 mg/kg

▼B

E 160 c PAPRIKA EXTRACT, CAPSANTHIN, CAPSORUBIN

Synonyms	Paprika Oleoresin
Definition	Paprika extract is obtained by solvent extraction of the strains of paprika, which consists of the ground fruits pods, with or without seeds, of *Capsicum annuum* L., and contains the major colouring principles of this spice. The major colouring principles are capsanthin and capsorubin. A wide variety of other coloured compounds is known to be present. Only the following solvents may be used in the extraction: methanol, ethanol, acetone, hexane, dichloromethane, ethyl acetate, propan-2-ol and carbon dioxide.
Colour Index No	
Einecs	Capsanthin: 207-364-1, capsorubin: 207-425-2
Chemical name	Capsanthin: (3R, 3′S, 5′R)-3,3′-dihydroxy-β,κ-carotene-6-one Capsorubin: (3S, 3′S, 5R, 5R′)-3,3′-dihydroxy-κ,κ-carotene-6,6′-dione
Chemical formula	Capsanthin: $C_{40}H_{56}O_3$ Capsorubin: $C_{40}H_{56}O_4$
Molecular weight	Capsanthin: 584,85 Capsorubin: 600,85
Assay	Paprika extract: content not less than 7,0 % carotenoids Capsanthin/capsorubin: not less than 30 % of total carotenoids $E^{1\%}_{1cm}$ 2 100 at ca. 462 nm in acetone

▼B

Description	Dark-red viscous liquid
Identification	
Spectrometry	Maximum in acetone at ca. 462 nm
Colour reaction	A deep blue colour is produced by adding one drop of sulphuric acid to one drop of sample in 2-3 drops of chloroform
Purity	
Solvent residues	Ethyl acetate, Methanol, Ethanol, Acetone, Hexane, Propan-2-ol: Not more than 50 mg/kg, singly or in combination Dichloromethane: not more than 10 mg/kg
Capsaicin	Not more than 250 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

E 160 d LYCOPENE

(i) SYNTHETIC LYCOPENE

Synonyms	Lycopene from chemical synthesis
Definition	Synthetic lycopene is a mixture of geometric isomeres of lycopenes and is produced by the Wittig condensation of synthetic intermediates commonly used in the production of other carotenoids used in food. Synthetic lycopene consists predominantly of all-*trans*-lycopene together with 5-*cis*-lycopene and minor quantities of other isomers. Commercial lycopene preparations intended for use in food are formulated as suspensions in edible oils or water-dispersible or water-soluble powder.
Colour Index No	75125
Einecs	207-949-1
Chemical name	ψ,ψ-carotene, all-*trans*-lycopene, (all-E)-lycopene, (all-E)-2,6,10,14,19,23,27,31-octamethyl-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriacontatridecaene
Chemical formula	$C_{40}H_{56}$
Molecular weight	536,85
Assay	Not less than 96 % total lycopenes (not less than 70 % all-*trans*-lycopene) $E^{1\%}_{1cm}$ at 465-475 nm in hexane (for 100 % pure all-*trans*-lycopene) is 3 450
Description	Red crystalline powder

▼B

Identification	
Spectrophotometry	A solution in hexane shows an absorption maximum at approximately 470 nm
Test for carotenoids	The colour of the solution of the sample in acetone disappears after successive additions of a 5 % solution of sodium nitrite and 1N sulphuric acid
Solubility	Insoluble in water, freely soluble in chloroform
Properties of 1 % solution in chloroform	Is clear and has intensive red-orange colour
Purity	
Loss on drying	Not more than 0,5 % (40 °C, 4 h at 20 mm Hg)
Apo-12'-lycopenal	Not more than 0,15 %
Triphenyl phosphine oxide	Not more than 0,01 %
Solvent residues	Methanol not more than 200 mg/kg, Hexane, Propan-2-ol: Not more than 10 mg/kg each. Dichloromethane: Not more than 10 mg/kg (in commercial preparations only)
Lead	Not more than 1 mg/kg

(ii) LYCOPENE FROM RED TOMATOES

Synonyms	Natural Yellow 27
Definition	Lycopene is obtained by solvent extraction of red tomatoes (*Lycopersicon esculentum* L.) with subsequent removal of the solvent. Only the following solvent may be used: carbon dioxide, ethyl acetate, acetone, propan-2-ol, methanol, ethanol and hexane. The major colouring principle of tomatoes is lycopene; minor amounts of other carotenoid pigments may be present. Besides the colour pigments the product may contain oil, fats, waxes and flavour components naturally occurring in tomatoes.
Colour Index No	75125
Einecs	207-949-1
Chemical name	Ψ,Ψ-carotene, all-*trans*-lycopene, (all-E)-lycopene, (all-E)-2,6,10,14,19,23,27,31-octamethyl-2,6,8,10,12,14,16,18,2 0,22,24,26,30-dotriacontatridecaene
Chemical formula	$C_{40}H_{56}$
Molecular weight	536,85
Assay	$E^{1\%}_{1cm}$ at 465-475 nm in hexane (for 100 % pure all-*trans*-lycopene) is 3 450. Content not less than 5 % total colouring matters
Description	Dark red viscous liquid
Identification	
Spectrophotometry	Maximum in hexane at ca. 472 nm

▼B

Purity		
Solvent residues	Propan-2-ol	Not more than 50 mg/kg, singly or in combination
	Hexane	
	Acetone	
	Ethanol	
	Methanol	
	Ethylacetate	
Sulphated ash	Not more than 1 %	
Mercury	Not more than 1 mg/kg	
Cadmium	Not more than 1 mg/kg	
Arsenic	Not more than 3 mg/kg	
Lead	Not more than 2 mg/kg	

(iii) LYCOPENE FROM *BLAKESLEA TRISPORA*

Synonyms	Natural Yellow 27
Definition	Lycopene from *Blakeslea trispora* is extracted from the fungal biomass and purified by crystallisation and filtration. It consists predominantly of all-*trans*-lycopene. It also contains minor quantities of other carotenoids. Propan-2-ol and isobutyl acetate are the only solvents used in the manufacture. Commercial lycopene preparations intended for use in food are formulated as suspensions in edible oils or water-dispersible or water-soluble powder.
Colour Index No	75125
Einecs	207-949-1
Chemical name	Ψ,Ψ-carotene, all-*trans*-lycopene, (all-E)-lycopene, ((all-E)-2,6,10,14,19,23,27,31-octamethyl-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriacontatridecaene
Chemical formula	$C_{40}H_{56}$
Molecular weight	536,85
Assay	Not less than 95 % total lycopenes and not less than 90 % all-*trans*-lycopene of all colouring matters $E^{1\%}_{1cm}$ at 465-475 nm in hexane (for 100 % pure all-*trans*-lycopene) is 3 450
Description	Red crystalline powder
Identification	
Spectrophotometry	A solution in hexane shows an absorption maximum at approximately 470 nm
Test of carotenoids	The colour of the solution of the sample in acetone disappears after successive additions of a 5 % solution of sodium nitrite and 1N sulphuric acid
Solubility	Insoluble in water, freely soluble in chloroform
Properties of 1 % solution in chloroform	Is clear and has intensive red-orange colour

▼B

Purity	
Loss on drying	Not more than 0,5 % (40 °C, 4 h at 20 mm Hg)
Other carotenoids	Not more than 5 %
Solvent residues	Propan-2-ol: not more than 0,1 % Isobutyl acetate: not more than 1,0 % Dichloromethane: not more than 10 mg/kg (in commercial preparations only)
Sulphated ash	Not more than 0,3 %
Lead	Not more than 1 mg/kg

E 160 e BETA-APO-8′-CAROTENAL (C30)

Synonyms	CI Food Orange 6
Definition	These specifications apply predominantly to the all-*trans* isomer of β-apo-8′-carotenal together with minor amounts of other carotenoids. Diluted and stabilised forms are prepared from β-apo-8′-carotenal meeting these specifications and include solutions or suspensions of ß-apo-8′carotenal in edible fats or oils, emulsions and water dispersible powders. These preparations may have different cis/trans isomer ratios.
Colour Index No	40820
Einecs	214-171-6
Chemical name	β-Apo-8′-carotenal; *trans*-β-Apo-8′carotene-aldehyde
Chemical formula	$C_{30}H_{40}O$
Molecular weight	416,65
Assay	Not less than 96 % of total colouring matters $E^{1\%}_{1cm}$ 2 640 at 460-462 nm in cyclohexane
Description	Dark violet crystals with metallic lustre or crystalline powder
Identification	
Spectrometry	Maximum in cyclohexane at 460-462 nm
Purity	
Sulphated ash	Not more than 0,1 %
Subsidiary colouring matters	Carotenoids other than β-apo-8′-carotenal: not more than 3,0 % of total colouring matters
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 161 b LUTEIN

Synonyms	Mixed Carotenoids; Xanthophylls
Definition	Lutein is obtained by solvent extraction of the strains of edible fruits and plants, grass, lucerne (alfalfa) and *Tagetes erecta*. The main colouring principle consists of carotenoids of which lutein

▼B

	and its fatty acid esters account for the major part. Variable amounts of carotenes will also be present. Lutein may contain fats, oils and waxes naturally occurring in the plant material. Only the following solvents may be used for the extraction: methanol, ethanol, propan-2-ol, hexane, acetone, methyl ethyl ketone and carbon dioxide	
Colour Index No		
Einecs	204-840-0	
Chemical name	3,3′-dihydroxy-d-carotene	
Chemical formula	$C_{40}H_{56}O_2$	
Molecular weight	568,88	
Assay	Content of total colouring matter not less than 4 % calculated as lutein $E^{1\%}_{1cm}$ 2 550 at ca. 445 nm in chloroform/ethanol (10 + 90) or in hexane/ethanol/acetone (80 + 10 + 10)	
Description	Dark, yellowish brown liquid	
Identification		
Spectrometry	Maximum in chloroform/ethanol (1:9) at ca. 445 nm	
Purity		
Solvent residues	Acetone Methyl ethyl ketone Methanol Ethanol Propan-2-ol Hexane	Not more than 50 mg/kg, singly or in combination
Arsenic	Not more than 3 mg/kg	
Lead	Not more than 3 mg/kg	
Mercury	Not more than 1 mg/kg	
Cadmium	Not more than 1 mg/kg	

E 161g CANTHAXANTHIN

Synonyms	CI Food Orange 8
Definition	These specifications apply to predominantly all-*trans* isomers of canthaxanthin together with minor amounts of other carotenoids. Diluted and stabilised forms are prepared from canthaxanthin meeting these specifications and include solutions or suspensions of canthaxanthin in edible fats or oils, emulsions and water dispersible powders. These preparations may have different cis/trans isomer ratios.
Colour Index No	40850

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Einecs	208-187-2
Chemical name	β-Carotene-4,4′-dione; canthaxanthin; 4,4′-dioxo-β-carotene
Chemical formula	$C_{40}H_{52}O_2$
Molecular weight	564,86
Assay	Not less than 96 % of total colouring matters (expressed as canthaxanthin)
	$E^{1\%}_{1cm}$ 2 200 at ca. 485 nm in chloroform; at 468-472 nm in cyclohexane; at 464-467 nm in petroleum ether
Description	Deep violet crystals or crystalline powder
Identification	
Spectrometry	Maximum in chloroform at ca. 485 nm Maximum in cyclohexane at 468-472 nm Maximum in petroleum ether at 464-467 nm
Purity	
Sulphated ash	Not more than 0,1 %
Subsidiary colouring matters	Carotenoids other than canthaxanthin: not more than 5,0 % of total colouring matters
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 162 BEETROOT RED, BETANIN

Synonyms	Beet Red
Definition	Beet red is obtained from the roots of strains of red beets (*Beta vulgaris* L. var. *rubra*) by pressing crushed beet as press juice or by aqueous extraction of shredded beet roots and subsequent enrichment in the active principle. The colour is composed of different pigments all belonging to the class betalaine. The main colouring principle consists of betacyanins (red) of which betanin accounts for 75-95 %. Minor amounts of betaxanthin (yellow) and degradation products of betalaines (light brown) may be present. Besides the colour pigments the juice or extract consists of sugars, salts, and/or proteins naturally occurring in red beets. The solution may be concentrated and some products may be refined in order to remove most of the sugars, salts and proteins.
Colour Index No	
Einecs	231-628-5
Chemical name	(S-(R′,R′)-4-(2-(2-Carboxy-5(β-D-glucopyranosyloxy)-2,3-dihydro-6-hydroxy-1H-indol-1-yl)ethenyl)-2,3-dihydro-2,6-pyridine-dicarboxylic acid; 1-(2-(2,6-dicarboxy-1,2,3,4-tetrahydro-4-pyridylidene)ethylidene)-5-β-D-glucopyranosyloxy)-6-hydroxyindolium-2-carboxylate

▼B

Chemical formula	Betanin: $C_{24}H_{26}N_2O_{13}$
Molecular weight	550,48
Assay	Content of red colour (expressed as betanine) is not less than 0,4 % $E^{1\%}_{1cm}$ 1 120 at ca. 535 nm in aqueous solution at pH 5
Description	Red or dark red liquid, paste, powder or solid
Identification	
Spectrometry	Maximum in water of pH 5 at ca. 535 nm
Purity	
Nitrate	Not more than 2 g nitrate anion/g of red colour (as calculated from assay).
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 163 ANTHOCYANINS

Synonyms	
Definition	Anthocyanins are obtained by maceration or extraction with sulphited water, acidified water, carbon dioxide, methanol or ethanol from the strains of vegetables and edible fruits, with subsequent concentration and/or purification if necessary. The resulting product can be transformed into powder by an industrial drying process. Anthocyanins contain common components of the source material, namely anthocyanine, organic acids, tannins, sugars, minerals etc., but not necessarily in the same proportions as found in the source material. Ethanol may naturally be present as a result of the maceration process. The colouring principle is anthocyanin. Products are marketed according to their colour strength as determined by the assay. Colour content is not expressed using quantitative units.
Colour Index No	
Einecs	208-438-6 (cyanidin); 205-125-6 (peonidin); 208-437-0 (delphinidin); 211-403-8 (malvidin); 205-127-7 (pelargonidin); 215-849-4 (petunidin)
Chemical name	3,3′,4′,5,7-Pentahydroxy-flavylium chloride (cyanidin) 3,4′,5,7-Tetrahydroxy-3′-methoxyflavylium chloride (peonidin) 3,4′,5,7-Tetrahydroxy-3′,5′-dimethoxyflavylium chloride (malvidin) 3,5,7-Trihydroxy-2-(3,4,5,trihydroxyphenyl)-1-benzopyrylium chloride (delphinidin) 3,3′4′,5,7-Pentahydroxy-5′-methoxyflavylium chloride (petunidin) 3,5,7-Trihydroxy-2-(4-hydroxyphenyl)-1-benzopyrilium chloride (pelargonidin)

▼B

Chemical formula	Cyanidin: $C_{15}H_{11}O_6Cl$ Peonidin: $C_{16}H_{13}O_6Cl$ Malvidin: $C_{17}H_{15}O_7Cl$ Delphinidin: $C_{15}H_{11}O_7Cl$ Petunidin: $C_{16}H_{13}O_7Cl$ Pelargonidin: $C_{15}H_{11}O_5Cl$
Molecular weight	Cyanidin: 322,6 Peonidin: 336,7 Malvidin: 366,7 Delphinidin: 340,6 Petunidin: 352,7 Pelargonidin: 306,7
Assay	$E^{1\%}_{1cm}$ 300 for the pure pigment at 515-535 nm at pH 3,0
Description	Purplish-red liquid, powder or paste, having a slight characteristic odour
Identification	
Spectrometry	Maximum in methanol with 0,01 % conc. HCl Cyanidin: 535 nm Peonidin: 532 nm Malvidin: 542 nm Delphinidin: 546 nm Petunidin: 543 nm Pelargonidin: 530 nm
Purity	
Solvent residues	Methanol: Not more than 50 mg/kg Ethanol: Not more than 200 mg/kg
Sulfur dioxide	Not more than 1 000 mg/kg per percent pigment
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

Aluminium lakes of this colour may be used.

E 170 CALCIUM CARBONATE

Synonyms	CI Pigment White 18; Chalk
Definition	Calcium carbonate is the product obtained from ground limestone or by the precipitation of calcium ions with carbonate ions.
Colour Index No	77220
Einecs	Calcium carbonate: 207-439-9 Limestone: 215-279-6
Chemical name	Calcium carbonate
Chemical formula	$CaCO_3$

▼B

Molecular weight	100,1
Assay	Content not less than 98 % on the anhydrous basis
Description	White crystalline or amorphous, odourless and tasteless powder
Identification	
Solubility	Practically insoluble in water and in alcohol. Dissolves with effervescence in diluted acetic acid, in diluted hydrochloric acid and in diluted nitric acid, and the resulting solutions, after boiling, give positive tests for calcium.
Purity	
Loss on drying	Not more than 2,0 % (200 °C, 4 hours)
Acid-insoluble substances	Not more than 0,2 %
Magnesium and alkali salts	Not more than 1 %
Fluoride	Not more than 50 mg/kg
Antimony (as Sb) Copper (as Cu) Chromium (as Cr) Zinc (as Zn) Barium (as Ba)	Not more than 100 mg/kg, singly or in combination
Arsenic	Not more than 3 mg/kg
Lead	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg

E 171 TITANIUM DIOXIDE

Synonyms	CI Pigment White 6
Definition	Titanium dioxide consists essentially of pure anatase and/or rutile titanium dioxide which may be coated with small amounts of alumina and/or silica to improve the technological properties of the product. The anatase grades of pigmentary titanium dioxide can only be made by the sulphate process which creates a large amount of sulphuric acid as a by-product. The rutile grades of titanium dioxide are typically made by the chloride process. Certain rutile grades of titanium dioxide are produced using mica (also known as potassium aluminum silicate) as a template to form the basic platelet structure. The surface of the mica is coated with titanium dioxide using a specialised patented process. Rutile titanium dioxide, platelet form is manufactured by subjecting titanium dioxide (rutile) coated mica nacreous pigment to an extractive dissolution in acid followed by an extractive dissolution in alkali. All of the mica is removed during this process and the resulting product is a platelet form of rutile titanium dioxide.
Colour Index No	77891
Einecs	236-675-5

▼B

Chemical name	Titanium dioxide
Chemical formula	TiO_2
Molecular weight	79,88
Assay	Content not less than 99 % on an alumina and silica-free basis
Description	White to slightly coloured powder
Identification	
Solubility	Insoluble in water and organic solvents. Dissolves slowly in hydrofluoric acid and in hot concentrated sulphuric acid.
Purity	
Loss on drying	Not more than 0,5 % (105 °C, 3 hours)
Loss on ignition	Not more than 1,0 % on a volatile matter free basis (800 °C)
Aluminium oxide and/or silicon dioxide	Total not more than 2,0 %
Matter soluble in 0,5 N HCl	Not more than 0,5 % on an alumina and silica-free basis and, in addition, for products containing alumina and/or silica, not more than 1,5 % on the basis of the product as sold.
Water soluble matter	Not more than 0,5 %
Cadmium	Not more than 1 mg/kg after an extraction with 0,5 N HCl.
Antimony	Not more than 2 mg/kg after an extraction with 0,5 N HCl.
Arsenic	Not more than 1 mg/kg after an extraction with 0,5 N HCl.
Lead	Not more than 10 mg/kg after an extraction with 0,5 N HCl.
Mercury	Not more than 1 mg/kg after an extraction with 0,5 N HCl.

E 172 IRON OXIDES AND IRON HYDROXIDES

Synonyms	Iron Oxide Yellow: CI Pigment Yellow 42 and 43	
	Iron Oxide Red: CI Pigment Red 101 and 102	
	Iron Oxide Black: CI Pigment Black 11	
Definition	Iron oxides and iron hydroxides are produced synthetically and consist essentially of anhydrous and/or hydrated iron oxides. The range of hues includes yellows, reds, browns and blacks. Food quality iron oxides are primarily distinguished from technical grades by the comparatively low levels of contamination by other metals. This is achieved by the selection and control of the source of the iron and/or by the extent of chemical purification during the manufacturing process.	
Colour Index No	Iron Oxide Yellow:	77492
	Iron Oxide Red:	77491
	Iron Oxide Black:	77499

▼B

Einecs	Iron Oxide Yellow:	257-098-5
	Iron Oxide Red:	215-168-2
	Iron Oxide Black:	235-442-5
Chemical name	Iron Oxide Yellow: hydrated ferric oxide, hydrated iron (III) oxide	
	Iron Oxide Red: anhydrous ferric oxide, anhydrous iron (III) oxide	
	Iron Oxide Black: ferroso ferric oxide, iron (II, III) oxide	
Chemical formula	Iron Oxide Yellow:	$FeO(OH) \cdot H_2O$
	Iron Oxide Red:	Fe_2O_3
	Iron Oxide Black:	$FeO.Fe_2O_3$
Molecular weight	88,85:	FeO(OH)
	159,70:	Fe_2O_3
	231,55:	$FeO.Fe_2O_3$
Assay	Yellow not less than 60 %, red and black not less than 68 % total iron, expressed as iron	
Description	Powder; yellow, red, brown or black in hue	
Identification		
Solubility	Insoluble in water and in organic solvents Soluble in concentrated mineral acids	
Purity		
Water soluble matter	Not more than 1,0 %	
Arsenic	Not more than 3 mg/kg	
Cadmium	Not more than 1 mg/kg	
Chromium	Not more than 100 mg/kg	
Copper	Not more than 50 mg/kg	By total dissolution
Lead	Not more than 10 mg/kg	
Mercury	Not more than 1 mg/kg	
Nickel	Not more than 200 mg/kg	
Zinc	Not more than 100 mg/kg	

E 173 ALUMINIUM

Synonyms	CI Pigment Metal
Definition	Aluminium powder is composed of finely divided particles of aluminium. The grinding may or may not be carried out in the presence of edible vegetable oils and/or food additive quality fatty acids. It is free from admixture with substances other than edible vegetable oils and/or food additive quality fatty acids.

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Colour Index No	77000
Einecs	231-072-3
Chemical name	Aluminium
Chemical formula	Al
Atomic weight	26,98
Assay	Not less than 99 % calculated as Al on an oil-free basis
Description	A silvery-grey powder or tiny sheets
Identification	
Solubility	Insoluble in water and in organic solvents. Soluble in dilute hydrochloric acid.
Test for aluminium	A sample dissolved in dilute hydrochloric acid passes test
Purity	
Loss on drying	Not more than 0,5 % (105 °C, to constant weight)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 174 SILVER

Synonyms	Argentum
Definition	
Colour Index No	77820
Einecs	231-131-3
Chemical name	Silver
Chemical formula	Ag
Atomic weight	107,87
Assay	Content not less than 99,5 % Ag
Description	Silver-coloured powder or tiny sheets
Identification	
Purity	

E 175 GOLD

Synonyms	Pigment Metal 3; Aurum
Definition	
Colour Index No	77480
Einecs	231-165-9
Chemical name	Gold

▼B

Chemical formula	Au	
Atomic weight	197,0	
Assay	Content not less than 90 % Au	
Description	Gold-coloured powder or tiny sheets	
Identification		
Purity		
Silver	Not more than 7 %	After complete dissolution
Copper	Not more than 4 %	

E 180 LITHOLRUBINE BK

Synonyms	CI Pigment Red 57; Rubinpigment; Carmine 6B
Definition	Lithol Rubine BK consists essentially of calcium 3-hydroxy-4-(4-methyl-2-sulfonatophenylazo)-2-naphthalenecarboxylate and subsidiary colouring matters together with water, calcium chloride and/or calcium sulphate as the principal uncoloured components.
Colour Index No	15850:1
Einecs	226-109-5
Chemical name	Calcium 3-hydroxy-4-(4-methyl-2-sulfonatophenylazo)-2-naphthalenecarboxylate
Chemical formula	$C_{18}H_{12}CaN_2O_6S$
Molecular weight	424,45
Assay	Content not less than 90 % total colouring matters $E^{1\%}_{1cm}$ 200 at ca. 442 nm in dimethylformamide
Description	Red powder
Identification	
Spectrometry	Maximum in dimethylformamide at ca. 442 nm
Purity	
Subsidiary colouring matters	Not more than 0,5 %
Organic compounds other than colouring matters:	
2-Amino-5-methylbenzenesulfonic acid, calcium salt	Not more than 0,2 %
3-hydroxy-2-naphthalenecarboxylic acid, calcium salt	Not more than 0,4 %
Unsulfonated primary aromatic amines	Not more than 0,01 % (expressed as aniline)

▼B

Ether extractable matter	From a solution of pH 7, not more than 0,2 %
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

Aluminium lakes of this colour may be used.

E 200 SORBIC ACID

Synonyms	
Definition	
Einecs	203-768-7
Chemical name	Sorbic acid; *trans*, *trans*-2,4-Hexadienoic acid
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	
Melting range	Between 133 °C and 135 °C, after vacuum drying for four hours in a sulphuric acid desiccator
Spectrometry	A propan-2-ol solution (1 in 4 000 000) shows absorbance maximum at 254 ± 2 nm
Test for double bonds	Passes test
Solubility	Slightly soluble in water, soluble in ethanol.
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 2 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 202 POTASSIUM SORBATE

Synonyms	
Definition	
Einecs	246-376-1
Chemical name	Potassium sorbate; Potassium (E,E)-2,4-hexadienoate; Potassium salt of *trans*, *trans* 2,4-hexadienoic acid
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	
Melting range for sorbic acid	Melting range of sorbic acid isolated by acidification and not recrystallised 133 °C to 135 °C after vacuum drying in a sulphuric acid desiccator
Test for potassium	Passes test
Test for double bonds	Passes test
Purity	
Loss on drying	Not more than 1,0 % (105 °C, 3 hours)
Acidity or alkalinity	Not more than about 1,0 % (as sorbic acid or K_2CO_3)
Aldehydes	Not more than 0,1 %, calculated as formaldehyde
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

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E 210 BENZOIC ACID

Synonyms	
Definition	
Einecs	200-618-2
Chemical name	Benzoic acid; Benzenecarboxylic acid; Phenylcarboxylic acid
Chemical formula	$C_7H_6O_2$
Molecular weight	122,12
Assay	Content not less than 99,5 % on the anhydrous basis

▼B

Description	White crystalline powder
Identification	
Melting range	121,5 °C -123,5 °C
Sublimation test	Passes test
Test for benzoate	Passes test
pH	About 4 (solution in water)
Purity	
Loss on drying	Not more than 0,5 % (3 hours, over sulphuric acid)
Sulphated ash	Not more than 0,05 %
Chlorinated organic compounds	Not more than 0,07 % expressed as chloride corresponding to 0,3 % expressed as monochlorobenzoic acid
Readily oxidisable substances	Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N $KMnO_4$ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N $KMnO_4$ to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required
Readily carbonisable substances	A cold solution of 0,5 g of benzoic acid in 5 ml of 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC ([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 neutralised solution of benzoic acid, the first precipitate must not have a different melting point from that of the benzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

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

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

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

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

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E 211 SODIUM BENZOATE

Synonyms	
Definition	
Einecs	208-534-8
Chemical name	Sodium benzoate; Sodium salt of benzenecarboxylic acid; Sodium salt of phenylcarboxylic acid
Chemical formula	$C_7H_5O_2Na$
Molecular weight	144,11
Assay	Not less than 99 % of $C_7H_5O_2Na$, after drying at 105 °C for four hours
Description	A white, almost odourless, crystalline powder or granules
Identification	
Solubility	Freely soluble in water, sparingly soluble in ethanol
Melting range for benzoic acid	Melting range of benzoic acid isolated by acidification and not recrystallised 121,5 °C to 123,5 °C, after drying in a sulphuric acid desiccator
Test for benzoate	Passes test
Test for sodium	Passes test
Purity	
Loss on drying	Not more than 1,5 % (105 °C, 4 hours)
Readily oxidisable substances	Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N $KMnO_4$ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N $KMnO_4$ to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required
Polycyclic acids	On fractional acidification of a (neutralised) solution of sodium benzoate, the first precipitate must not have a different melting range from that of benzoic acid
Chlorinated organic compounds	Not more than 0,06 % expressed as chloride, corresponding to 0,25 % expressed as monochlorobenzoic acid
Acidity or alkalinity	Neutralisation of 1 g of sodium benzoate, in the presence of phenolphthalein, must not require more than 0,25 ml of 0,1 N NaOH or 0,1 N HCl
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 212 POTASSIUM BENZOATE

Synonyms	
Definition	
Einecs	209-481-3
Chemical name	Potassium benzoate; Potassium salt of benzenecarboxylic acid; Potassium salt of phenylcarboxylic acid

▼B

Chemical formula	$C_7H_5KO_2 \cdot 3H_2O$
Molecular weight	214,27
Assay	Content not less than 99 % $C_7H_5KO_2$ after drying at 105 °C to constant weight
Description	White crystalline powder
Identification	
Melting range for benzoic acid	Melting range of benzoic acid isolated by acidification and not recrystallised 121,5 °C to 123,5 °C, after vacuum drying in a sulphuric acid desiccator
Test for benzoate	Passes test
Test for potassium	Passes test
Purity	
Loss on drying	Not more than 26,5 % (105 °C, 4 hours)
Chlorinated organic compounds	Not more than 0,06 % expressed as chloride, corresponding to 0,25 % expressed as monochlorobenzoic acid
Readily oxidisable substances	Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N $KMnO_4$ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N $KMnO_4$ to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required
Readily carbonisable substances	A cold solution of 0,5 g of benzoic acid in 5 ml 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC, 0,3 ml of ferric chloride TSC, 0,1 ml of copper sulphate TSC and 4,4 ml of water
Polycyclic acids	On fractional acidification of a (neutralised) solution of potassium benzoate, the first precipitate must not have a different melting range from that of benzoic acid
Acidity or alkalinity	Neutralisation of 1 g of potassium benzoate, in the presence of phenolphthalein, must not require more than 0,25 ml of 0,1 N NaOH or 0,1 N HCl
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 213 CALCIUM BENZOATE

Synonyms	Monocalcium benzoate	
Definition		
Einecs	218-235-4	
Chemical name	Calcium benzoate; Calcium dibenzoate	
Chemical formula	Anhydrous:	$C_{14}H_{10}O_4Ca$
	Monohydrate:	$C_{14}H_{10}O_4Ca \cdot H_2O$
	Trihydrate:	$C_{14}H_{10}O_4Ca \cdot 3H_2O$

▼B

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		
Melting range for benzoic acid	Melting range of benzoic acid isolated by acidification and not recrystallised 121,5 °C to 123,5 °C, after vacuum drying in a sulphuric acid desiccator	
Test for benzoate	Passes test	
Test for calcium	Passes test	
Purity		
Loss on drying	Not more than 17,5 % (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 acid	
Readily oxidisable substances	Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N $KMnO_4$ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N $KMnO_4$ to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required	
Readily carbonisable substances	Cold solution of 0,5 g of benzoic acid in 5 ml of 94,5 to 95,5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0,2 ml of cobalt chloride TSC, 0,3 ml of ferric chloride TSC, 0,1 ml of copper sulphate TSC and 4,4 ml of water	
Polycyclic acids	On fractional acidification of a (neutralised) solution of calcium benzoate, the first precipitate must not be a different melting range from that of benzoic acid	
Acidity or alkalinity	Neutralisation of 1 g of calcium benzoate, in the presence of phenolphthalein, must not require more than 0,25 ml of 0,1 N NaOH or 0,1 N HCl	
Fluoride	Not more than 10 mg/kg	
Arsenic	Not more than 3 mg/kg	
Lead	Not more than 2 mg/kg	
Mercury	Not more than 1 mg/kg	

E 214 ETHYL p-HYDROXYBENZOATE

Synonyms	Ethylparaben; Ethyl *p*-oxybenzoate
Definition	
Einecs	204-399-4
Chemical name	Ethyl-*p*-hydroxybenzoate; Ethyl ester of *p*-hydroxybenzoic acid

▼B

Chemical formula	$C_9H_{10}O_3$
Molecular weight	166,8
Assay	Content not less than 99,5 % after drying for two hours at 80 °C
Description	Almost odourless, small, colourless crystals or a white, crystalline powder
Identification	
Melting range	115-118 °C
Test for *p*-hydroxybenzoate	Melting range of *p*-hydroxybenzoic acid isolated by acidification and not recrystallised: 213 °C to 217 °C, after vacuum drying in a sulphuric acid desiccator
Test for alcohol	Passes test
Purity	
Loss on drying	Not more than 0,5 % (80 °C, 2 hours)
Sulphated ash	Not more than 0,05 %
p-Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as *p*-hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 215 SODIUM ETHYL p-HYDROXYBENZOATE

Synonyms	
Definition	
Einecs	252-487-6
Chemical name	Sodium ethyl *p*-hydroxybenzoate; Sodium compound of the ethyl ester of *p*-hydroxybenzoic acid
Chemical formula	$C_9H_9O_3Na$
Molecular weight	188,8
Assay	Content of ethylester of *p*-hydroxybenzoic acid not less than 83 % on the anhydrous basis
Description	White, crystalline hygroscopic powder
Identification	
Melting range	115 °C to 118 °C, after vacuum drying in a sulphuric acid desiccator
Test for *p*-hydroxybenzoate	Melting range of *p*-hydroxybenzoic acid derived from the sample is 213 °C to 217 °C
Test for sodium	Passes test
pH	9,9-10,3 (0,1 % aqueous solution)
Purity	
Loss on drying	Not more than 5 %, (by vacuum drying in a sulphuric acid desiccator)
Sulphated ash	37 to 39 %

▼B

p-Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as *p*-hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 218 METHYL p-HYDROXYBENZOATE

Synonyms	Methylparaben; Methyl-*p*-oxybenzoate
Definition	
Einecs	243-171-5
Chemical name	Methyl *p*-hydroxybenzoate; Methyl ester of *p*-hydroxybenzoic acid
Chemical formula	$C_8H_8O_3$
Molecular weight	152,15
Assay	Content not less than 99 % after drying for two hours at 80 °C
Description	Almost odourless, small colourless crystals or white crystalline powder
Identification	
Melting range	125 °C - 128 °C
Test for *p*-hydroxybenzoate	Melting range of *p*-hydroxybenzoic acid derived from the sample is 213 °C to 217 °C after drying for two hours at 80 °C
Purity	
Loss on drying	Not more than 0,5 % (80 °C, 2 hours)
Sulphated ash	Not more than 0,05 %
p-Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as *p*-hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 219 SODIUM METHYL p-HYDROXYBENZOATE

Synonyms	
Definition	
Einecs	
Chemical name	Sodium methyl *p*-hydroxybenzoate; Sodium compound of the methylester of *p*-hydroxybenzoic acid
Chemical formula	$C_8H_7O_3Na$
Molecular weight	174,15
Assay	Content not less than 99,5 % on the anhydrous basis
Description	White, hygroscopic powder

▼B

Identification	
Melting range	The white precipitate formed by acidifying with hydrochloric acid a 10 % (w/v) aqueous solution of the sodium derivative of methyl *p*-hydroxybenzoate (using litmus paper as indicator) shall, when washed with water and dried at 80 °C for two hours, have a melting range of 125 °C to 128 °C
Test for sodium	Passes test
pH	9,7-10,3 (0,1 % solution in carbon dioxide free water)
Purity	
Water content	Not more than 5 % (Karl Fischer method)
Sulphated ash	40 % to 44,5 % on the anhydrous basis
p-Hydroxybenzoic acid and salicylic acid	Not more than 0,35 % expressed as *p*-hydroxybenzoic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 220 SULPHUR DIOXIDE

Synonyms	
Definition	
Einecs	231-195-2
Chemical name	Sulphur dioxide; Sulphurous acid anhydride
Chemical formula	SO_2
Molecular weight	64,07
Assay	Content not less than 99 %
Description	Colourless, non-flammable gas with strong pungent suffocating odour
Identification	
Test for sulphurous substances	Passes test
Purity	
Water content	Not more than 0,05 % (Karl Fischer method)
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

▼B

E 221 SODIUM SULPHITE

Synonyms			
Definition			
Einecs	231-821-4		
Chemical name	Sodium sulphite (anhydrous or heptahydrate)		
Chemical formula	Anhydrous:	Na_2SO_3	
	Heptahydrate:	$Na_2SO_3 7H_2O$	
Molecular weight	Anhydrous:	126,04	
	Heptahydrate:	252,16	
Assay	Anhydrous:	Not less than 95 % of Na_2SO_3 and not less than 48 % of SO_2	
	Heptahydrate:	Not less than 48 % of Na_2SO_3 and not less than 24 % of SO_2	
Description	White crystalline powder or colourless crystals		
Identification			
Test for sulphite	Passes test		
Test for sodium	Passes test		
pH	8,5-11,5 (anhydrous: 10 % solution; heptahydrate: 20 % solution)		
Purity			
Thiosulphate	Not more than 0,1 % based on the SO_2 content		
Iron	Not more than 10 mg/kg based on the SO_2 content		
Selenium	Not more than 5 mg/kg based on the SO_2 content		
Arsenic	Not more than 3 mg/kg		
Lead	Not more than 2 mg/kg		
Mercury	Not more than 1 mg/kg		

▼M3

E 222 SODIUM HYDROGEN SULPHITE

▼B

Synonyms		
Definition		
Einecs	231-921-4	
Chemical name	Sodium bisulphite; Sodium hydrogen sulphite	
Chemical formula	$NaHSO_3$ in aqueous solution	
Molecular weight	104,06	
Assay	Content not less than 32 % w/w $NaHSO_3$	
Description	A clear, colourless to yellow solution	
Identification		
Test for sulphite	Passes test	

▼B

Test for sodium	Passes test
pH	2,5-5,5 (10 % aqueous solution)
Purity	

▼M3

Iron	Not more than 10 mg/kg based on the SO_2 content

▼B

Selenium	Not more than 5 mg/kg based on the SO_2 content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 223 SODIUM METABISULPHITE

Synonyms	Pyrosulphite; Sodium pyrosulphite
Definition	
Einecs	231-673-0
Chemical name	Sodium disulphite; Disodium pentaoxodisulphate
Chemical formula	$Na_2S_2O_5$
Molecular weight	190,11
Assay	Content not less than 95 % $Na_2S_2O_5$ and not less than 64 % of SO_2
Description	White crystals or crystalline powder
Identification	
Test for sulphite	Passes test
Test for sodium	Passes test
pH	4,0-5,5 (10 % aqueous solution)
Purity	
Thiosulphate	Not more than 0,1 % based on the SO_2 content
Iron	Not more than 10 mg/kg based on the SO_2 content
Selenium	Not more than 5 mg/kg based on the SO_2 content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 224 POTASSIUM METABISULPHITE

Synonyms	Potassium pyrosulphite
Definition	
Einecs	240-795-3
Chemical name	Potassium disulphite; Potassium pentaoxo disulphate
Chemical formula	$K_2S_2O_5$
Molecular weight	222,33

▼B

Assay	Content not less than 90 % $K_2S_2O_5$ and not less than 51,8 % of SO_2, the remainder being composed almost entirely of potassium sulphate
Description	Colourless crystals or white crystalline powder
Identification	
Test for sulphite	Passes test
Test for potassium	Passes test
Purity	
Thiosulphate	Not more than 0,1 % based on the SO_2 content
Iron	Not more than 10 mg/kg based on the SO_2 content
Selenium	Not more than 5 mg/kg based on the SO_2 content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 226 CALCIUM SULPHITE

Synonyms	
Definition	
Einecs	218-235-4
Chemical name	Calcium sulphite
Chemical formula	$CaSO_3 \cdot 2H_2O$
Molecular weight	156,17
Assay	Content not less than 95 % of $CaSO_3 \cdot 2H_2O$ and not less than 39 % of SO_2
Description	White crystals or white crystalline powder
Identification	
Test for sulphite	Passes test
Test for calcium	Passes test
Purity	
Iron	Not more than 10 mg/kg based on the SO_2 content
Selenium	Not more than 5 mg/kg based on the SO_2 content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

▼M8

E 227 CALCIUM HYDROGEN SULPHITE

▼B

Synonyms	
Definition	
Einecs	237-423-7

▼B

Chemical name	Calcium bisulphite; Calcium hydrogen sulphite
Chemical formula	$Ca(HSO_3)_2$
Molecular weight	202,22
Assay	6 to 8 % (w/v) of sulphur dioxide and 2,5 to 3,5 % (w/v) of calcium dioxide corresponding to 10 to 14 % (w/v) of calcium bisulphite [$Ca(HSO_3)_2$]
Description	Clear greenish-yellow aqueous solution having a distinct odour of sulphur dioxide
Identification	
Test for sulphite	Passes test
Test for calcium	Passes test
Purity	
Iron	Not more than 10 mg/kg based on the SO_2 content
Selenium	Not more than 5 mg/kg based on the SO_2 content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

▼M8

E 228 POTASSIUM HYDROGEN SULPHITE

▼B

Synonyms	
Definition	
Einecs	231-870-1
Chemical name	Potassium bisulphite; Potassium hydrogen sulphite
Chemical formula	$KHSO_3$ in aqueous solution
Molecular weight	120,17
Assay	Content not less than 280 g $KHSO_3$ per litre (or 150 g SO_2 per litre)
Description	Clear colourless aqueous solution
Identification	
Test for sulphite	Passes test
Test for potassium	Passes test
Purity	
Iron	Not more than 10 mg/kg based on the SO_2 content
Selenium	Not more than 5 mg/kg based on the SO_2 content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 234 NISIN

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

E 235 NATAMYCIN

Synonyms	Pimaricin
Definition	Natamycin is a fungicide of the polyene macrolide group, and is produced by strains of *Streptomyces natalensis* and other relevant species
Einecs	231-683-5
Chemical name	A stereoisomer of 22-(3-Amino-3,6-dideoxy-β-D- mannopyranosyloxy)-1,3,26-trihydroxy-12-methyl-10-oxo-6,11,28-trioxatricyclo[22.3.1.$0^{5,7}$]octacosa-8,14,16,18,20-pentaene-25-carboxylic acid.
Chemical formula	$C_{33}H_{47}O_{13}N$
Molecular weight	665,74
Assay	Content not less than 95 % on the dried basis
Description	White to creamy-white crystalline powder
Identification	
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
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

▼B

pH	5,5-7,5 (1 % w/v solution in previously neutralised mixture of 20 parts dimethylformamide and 80 parts of water)
Specific rotation	$[\alpha]_D^{20}$ + 250° to + 295° (a 1 % w/v solution in glacial acetic acid, at 20 °C and calculated with reference to the dried material)
Purity	
Loss on drying	Not more than 8 % (over P_2O_5, in vacuum at 60 °C to constant weight)
Sulphated ash	Not more than 0,5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Microbiological criteria	
Total plate count	Not more than 100 colonies per gram

E 239 HEXAMETHYLENE TETRAMINE

Synonyms	Hexamine; Methenamine
Definition	
Einecs	202-905-8
Chemical name	1,3,5,7-Tetraazatricyclo [3.3.1.$1^{3,7}$]-decane, hexamethylenetetramine
Chemical formula	$C_6H_{12}N_4$
Molecular weight	140,19
Assay	Content not less than 99 % on the anhydrous basis
Description	Colourless or white crystalline powder
Identification	
Test for formaldehyde	Passes test
Test for ammonia	Passes test
Sublimation point:	Approximately 260 °C
Purity	
Loss on drying	Not more than 0,5 % (at 105 °C in vacuum over P_2O_5 for 2 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 2 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 242 DIMETHYL DICARBONATE

Synonyms	DMDC; Dimethyl pyrocarbonate
Definition	
Einecs	224-859-8
Chemical name	Dimethyl dicarbonate; Pyrocarbonic acid dimethyl ester
Chemical formula	$C_4H_6O_5$
Molecular weight	134,09
Assay	Content not less than 99,8 %
Description	Colourless liquid, decomposes in aqueous solution. It is corrosive to skin and eyes and toxic by inhalation and ingestion
Identification	
Decomposition	After dilution positive tests for CO_2 and methanol
Melting point	17 °C
Boiling point	172 °C with decomposition
Density 20 °C	Approximately 1,25 g/cm^3
Infrared absorption 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 2 mg/kg
Mercury	Not more than 1 mg/kg

▼M12

E 243 ETHYL LAUROYL ARGINATE

Synonyms	Lauric arginate ethyl ester; lauramide arginine ethyl ester; ethyl-Nα-lauroyl-L-arginate·HCl; LAE;

▼M19

Definition	Ethyl lauroyl arginate is synthesized by esterifying arginine with ethanol, followed by reacting the ester with lauroyl chloride, in aqueous media at a controlled temperature between 10 and 15 °C and at a pH between 6,7 and 6,9. The resultant ethyl lauroyl arginate is recovered as the hydrochloride salt, which is filtered and dried.

▼M12

ELINCS	434-630-6
Chemical name	Ethyl-Nα-dodecanoyl-L-arginate·HCl
Chemical formula	C20H41N4O3Cl
Molecular Weight	421,02
Assay	Not less than 85 % and not more than 95 %
Description	White powder

▼M12

Identification	
Solubility	Freely soluble in water, ethanol, propylene glycol and glycerol
Purity	
Nα-Lauroyl-L-arginine	Not more than 3 %
Lauric acid	Not more than 5 %
Ethyl laurate	Not more than 3 %
L-Arginine·HCl	Not more than 1 %
Ethyl arginate·2HCl	Not more than 1 %
Lead	Not more than 1 mg/kg
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

▼M36

E 246 GLYCOLIPIDS

Synonyms	
Definition	The naturally occurring glycolipids are obtained by a fermentation process using the wild type strain MUCL 53181 of the fungus *Dacryopinax spathularia* (edible sweet osmanthus ear mushroom). Glucose is used as a carbon source. The solvent-free downstream process includes filtration and microfiltration to remove microbial cells, precipitation and washing with buffered water to purify. The product is pasteurized and spray-dried. The production process does not chemically modify the glycolipids or change their innate composition.
CAS number	2205009-17-0
Chemical name	Glycolipids from *Dacryopinax spathularia*
Assay	Not less than 93 % total glycolipid content on the dried basis.
Description	Beige to light brown powder, weak characteristic odour
Identification	
Solubility	Complies (10 g/l in water)
pH	Between 5,0 and 7,0 (10 g/l in water)
Turbidity	Not more than 28 NTU (10 g/l in water)

▼M36

Purity	
Water content	Not more than 5 % (Karl Fischer Method)
Protein	Not more than 3 % (factor N x 6,25)
Fat	Not more than 2 % (gravimetric)
Sodium	Not more than 3,3 %
Arsenic	Not more than 1 mg/kg
Lead	Not more than 0,7 mg/kg
Cadmium	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Nickel	Not more than 2 mg/kg
Microbiological criteria	
Total aerobic count	Not more than 100 colonies per gram
Yeast and moulds	Not more than 10 colonies per gram
Coliforms	Not more than 3 MPN per gram
Salmonella spp.	Absent in 25 g’

▼B

E 249 POTASSIUM NITRITE

Synonyms	
Definition	
Einecs	231-832-4
Chemical name	Potassium nitrite
Chemical formula	KNO_2
Molecular weight	85,11
Assay	Content not less than 95 % on the anhydrous basis ([1])
Description	White or slightly yellow, deliquescent granules
Identification	
Test for nitrite	Passes test
Test for potassium	Passes test
pH	6,0-9,0 (5 % solution)

([1]) May only be sold in a mixture with salt or a salt substitute.

▼M45

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

▼B

E 250 SODIUM NITRITE

Synonyms	
Definition	
Einecs	231-555-9
Chemical name	Sodium nitrite
Chemical formula	$NaNO_2$
Molecular weight	69,00
Assay	Content not less than 97 % on the anhydrous basis [1]
Description	White crystalline powder or yellowish lumps
Identification	
Test for nitrite	Passes test
Test for sodium	Passes test

▼M45

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

▼B

E 251 SODIUM NITRATE

(i) SOLID SODIUM NITRATE

Synonyms	Chile saltpetre; Cubic or soda nitre
Definition	
Einecs	231-554-3
Chemical name	Sodium nitrate
Chemical formula	$NaNO_3$
Molecular weight	85,00
Assay	Content not less than 99 % on the anhydrous basis
Description	White crystalline, slightly hygroscopic powder

[1] May only be sold in a mixture with salt or a salt substitute.

▼B

Identification	
Test for nitrate	Passes test
Test for sodium	Passes test
pH	5,5-8,3 (5 % solution)

▼M45

Purity	
Loss on drying	Not more than 2 % (105 °C, 4 hours)
Nitrites	Not more than 30 mg/kg expressed as $NaNO_2$
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg

▼B

(ii) LIQUID SODIUM NITRATE

Synonyms	
Definition	Liquid sodium nitrate is an aqueous solution of sodium nitrate as the direct result of the chemical reaction between sodium hydroxide and nitric acid in stoechiometric amounts, without subsequent crystallisation. Standardised forms prepared from liquid sodium nitrate meeting these specifications may contain nitric acid in excessive amounts, if clearly stated or labelled.
Einecs	231-554-3
Chemical name	Sodium nitrate
Chemical formula	$NaNO_3$
Molecular weight	85,00
Assay	Content between 33,5 % and 40,0 % of $NaNO_3$
Description	Clear colourless liquid
Identification	
Test for nitrate	Passes test
Test for sodium	Passes test
pH	1,5-3,5

▼M45

Purity	
Free nitric acid	Not more than 0,01 %
Nitrites	Not more than 10 mg/kg expressed as $NaNO_2$
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg

▼B

This specification refers to a 35 % aqueous solution.

E 252 POTASSIUM NITRATE

Synonyms	Chile saltpetre; Cubic or soda nitre
Definition	
Einecs	231-818-8

▼B

Chemical name	Potassium nitrate
Chemical formula	KNO_3
Molecular weight	101,11
Assay	Content not less than 99 % on the anhydrous basis
Description	White crystalline powder or transparent prisms having a cooling, saline, pungent taste
Identification	
Test for nitrate	Passes test
Test for potassium	Passes test
pH	4,5-8,5 (5 % solution)

▼M45

Purity	
Loss on drying	Not more than 1 % (105 °C, 4 hours)
Nitrites	Not more than 20 mg/kg expressed as KNO_2
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg

▼B

E 260 ACETIC ACID

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

▼B

Arsenic	Not more than 1 mg/kg
Lead	Not more than 0,5 mg/kg
Mercury	Not more than 1 mg/kg

▼M2

E 261 (i) POTASSIUM ACETATE

▼B

Synonyms	
Definition	
Einecs	204-822-2
Chemical name	Potassium acetate
Chemical formula	$C_2H_3O_2K$
Molecular weight	98,14
Assay	Content not less than 99 % on the anhydrous basis
Description	Colourless, deliquescent crystals or a white crystalline powder, odourless or with a faint acetic odour
Identification	
pH	7,5-9,0 (5 % aqueous solution)
Test for acetate	Passes test
Test for potassium	Passes test
Purity	
Loss on drying	Not more than 8 % (150 °C, 2 hours)
Formic acid, formates and other oxidisable substances	Not more than 1 000 mg/kg expressed as formic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

▼M2

E 261 (ii) POTASSIUM DIACETATE

Synonyms	
Definition	Potassium diacetate is a molecular compound of potassium acetate and acetic acid
Einecs	224-217-7
Chemical name	Potassium hydrogen diacetate
Chemical formula	$C_4H_7KO_4$

▼M2

Molecular weight	158,2
Assay	Content 36 to 38 % of free acetic acid and 61 to 64 % of potassium acetate
Description	White crystals
Identification	
pH	4,5-5 (10 % aqueous solution)
Test for acetate	Passes test
Test for potassium	Passes test
Purity	
Water content	Not more than 1 % (Karl Fischer method)
Formic acid, formates and other oxidisable substances	Not more than 1 000 mg/kg expressed as formic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 262 (i) SODIUM ACETATE

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

▼B

Identification		
pH	8,0-9,5 (1 % aqueous solution)	
Test for acetate	Passes test	
Test for sodium	Passes test	
Purity		
Loss on drying	Anhydrous:	Not more than 2 % (120 °C, 4 hours)
	Trihydrate:	Between 36 and 42 % (120 °C, 4 hours)
Formic acid, formates and other oxidisable substances	Not more than 1 000 mg/kg expressed as formic acid	
Arsenic	Not more than 3 mg/kg	
Lead	Not more than 2 mg/kg	
Mercury	Not more than 1 mg/kg	

E 262 (ii) SODIUM DIACETATE

Synonyms	
Definition	Sodium diacetate is a molecular compound of sodium acetate and acetic acid
Einecs	204-814-9
Chemical name	Sodium hydrogen diacetate
Chemical formula	$C_4H_7NaO_4 \cdot nH_2O$ (n = 0 or 3)
Molecular weight	142,09 (anhydrous)

▼M34

Assay	Content 39 to 43 % of free acetic acid and 57 to 60 % of sodium acetate

▼B

Description	White, hygroscopic crystalline solid with an acetic odour
Identification	
pH	4,5-5,0 (10 % aqueous solution)
Test for acetate	Passes test
Test for sodium	Passes test
Purity	
Water content	Not more than 2 % (Karl Fischer method)
Formic acid, formates and other oxidisable substances	Not more than 1 000 mg/kg expressed as formic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 263 CALCIUM ACETATE

Synonyms	
Definition	
Einecs	200-540-9

▼B

Chemical name	Calcium acetate	
Chemical formula	Anhydrous:	$C_4H_6O_4Ca$
	Monohydrate:	$C_4H_6O_4Ca \cdot H_2O$
Molecular weight	Anhydrous:	158,17
	Monohydrate:	176,18
Assay	Content not less than 98 % on the anhydrous basis	
Description	Anhydrous calcium acetate is a white, hygroscopic, bulky, crystalline solid with a slightly bitter taste. A slight odour of acetic acid may be present. The monohydrate may be needles, granules or powder	
Identification		
pH	6,0-9,0 (10 % aqueous solution)	
Test for acetate	Passes test	
Test for calcium	Passes test	
Purity		
Loss on drying	Not more than 11 % (155 °C to constant weight, for the monohydrate)	
Water insoluble matter	Not more than 0,3 %	
Formic acid, formates and other oxidisable substances	Not more than 1 000 mg/kg expressed as formic acid	
Arsenic	Not more than 3 mg/kg	
Lead	Not more than 2 mg/kg	
Mercury	Not more than 1 mg/kg	

▼M43

E 267 BUFFERED VINEGAR

Synonyms	Buffered vinegar (liquid); buffered vinegar (powder)
Definition	Buffered vinegar is a liquid or dried product prepared by adding buffering agents to vinegar. The buffering agents used are sodium/potassium hydroxides (E 524 to E 525) and sodium/potassium carbonates (E 500 to E 501). The vinegar is compliant with the European Standard EN 13188:2000 and is exclusively obtained from an agricultural source origin (except wood/cellulose) by double fermentation, alcoholic and acetous. The primary constituents of buffered vinegar are acetic acid and its salts.

▼M43

Assay	Liquid: 15–40 % (w/w) acetic acid equivalents Powder: 55–75 % (w/w) acetic acid equivalents 2 to 20 % (w/w) free acetic acid
Description	Liquid: colourless to brown viscous liquid Powder: white to creamy-white crystalline powder
Identification	Liquid: pH 4,75–7,5 Powder: pH 4,75–6,75 (10 % aqueous solution)
Purity	
Cations	Liquid: Not more than 10 % sodium and 30 % potassium Powder: Not more than 30 % sodium and 40 % potassium
Water content	Powder: Not more than 18 % (Karl Fischer Method)
Ethanol	Not more than 0,5 % w/w
Arsenic	Not more than 0,05 mg/kg
Lead	Not more than 0,05 mg/kg
Cadmium	Not more than 0,05 mg/kg
Mercury	Not more than 0,05 mg/kg

▼B

E 270 LACTIC ACID

Synonyms	
Definition	Consists 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. Lactic acid is hygroscopic and when concentrated by boiling, it condenses to form lactic acid lactate, which on dilution and heating hydrolyses to lactic acid.
Einecs	200-018-0
Chemical name	Lactic acid; 2-Hydroxypropionic acid; 1-Hydroxyethane-1-carboxylic acid
Chemical formula	$C_3H_6O_3$
Molecular weight	90,08
Assay	Content not less than 76 %
Description	Colourless or yellowish, nearly odourless, syrupy liquid to solid
Identification	
Test for lactate	Passes test

▼B

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

Note: This specification refers to a 80 % aqueous solution; for weaker aqueous solutions, calculate values corresponding to their lactic acid content

E 280 PROPIONIC ACID

Synonyms	
Definition	
Einecs	201-176-3
Chemical name	Propionic acid; Propanoic acid
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	
Melting point	– 22 °C
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 2 mg/kg
Mercury	Not more than 1 mg/kg

E 281 SODIUM PROPIONATE

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

▼B

Description	White crystalline hygroscopic powder, or a fine white powder
Identification	
Test for propionate	Passes test
Test for sodium	Passes test
pH	7,5-10,5 (10 % aqueous solution)
Purity	
Loss on drying	Not more than 4 % (105 °C, 2 hours)
Water insoluble matter	Not more than 0,1 %
Iron	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 282 CALCIUM PROPIONATE

Synonyms	
Definition	
Einecs	223-795-8
Chemical name	Calcium propionate
Chemical formula	$C_6H_{10}O_4Ca$
Molecular weight	186,22
Assay	Content not less than 99 %, after drying for two hours at 105 °C
Description	White crystalline powder
Identification	
Test for propionate	Passes test
Test for calcium	Passes test
pH	6,0-9,0 (10 % aqueous solution)
Purity	
Loss on drying	Not more than 4 % (105 °C, 2 hours)
Water insoluble matter	Not more than 0,3 %
Iron	Not more than 50 mg/kg

▼M16

Fluoride	Not more than 20 mg/kg

▼B

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

E 283 POTASSIUM PROPIONATE

Synonyms	
Definition	
Einecs	206-323-5

▼B

Chemical name	Potassium propionate; Potassium propanoate
Chemical formula	$C_3H_5KO_2$
Molecular weight	112,17
Assay	Content not less than 99 % after drying for two hours at 105 °C
Description	White crystalline powder
Identification	
Test for propionate	Passes test
Test for potassium	Passes test
Purity	
Loss on drying	Not more than 4 % (105 °C, 2 hours)
Water insoluble matter	Not more than 0,1 %
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

E 284 BORIC ACID

Synonyms	Boracic acid; Orthoboric acid; Borofax
Definition	
Einecs	233-139-2
Chemical name	
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	
Melting point	At approximately 171 °C
Burning test	Burns with a nice green flame
pH	3,8-4,8 (3,3 % aqueous solution)
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

▼B

E 285 SODIUM TETRABORATE (BORAX)

Synonyms	Sodium borate
Definition	
Einecs	215-540-4
Chemical name	Sodium tetraborate; Sodium biborate; Sodium pyroborate; Anhydrous tetraborate
Chemical formula	$Na_2B_4O_7$ $Na_2B_4O_7 \cdot 10H_2O$
Molecular weight	201,27
Assay	
Description	Powder or glass-like plates becoming opaque on exposure to air; slowly soluble in water
Identification	
Melting range	Between 171 °C and 175 °C with decomposition
Purity	
Peroxides	No colour develops with added KI-solution
Arsenic	Not more than 1 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 290 CARBON DIOXIDE

Synonyms	Carbonic acid gas; Dry ice (solid form); Carbonic anhydride
Definition	
Einecs	204-696-9
Chemical name	Carbon dioxide
Chemical formula	CO_2
Molecular weight	44,01
Assay	Content not less than 99 % v/v on the gaseous basis
Description	A colourless gas under normal environmental conditions with a slight pungent odour. Commercial carbon dioxide is shipped and handled as a liquid in pressurised cylinders or bulk storage systems, or in compressed solid blocks of ‘dry ice’. Solid (dry ice) forms usually contain added substances, such as propylene glycol or mineral oil, as binders
Identification	
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)

▼B

Reducing substances, hydrogen phosphide and sulphide	915 ml of gas bubbled through 25 ml of ammoniacal silver nitrate reagent to which has been added 3 ml of ammonia must not cause clouding or blackening of this solution
Carbon monoxide	Not more than 10 µl/l
Oil content	Not more than 5 mg/kg

E 296 MALIC ACID

Synonyms	Pomalous acid
Definition	
Einecs	230-022-8, 210-514-9, 202-601-5
Chemical name	hydroxybutanedioic acid; hydroxysuccinic acid
Chemical formula	$C_4H_6O_5$
Molecular weight	134,09
Assay	Content not less than 99,0 %
Description	White or nearly white crystalline powder or granules
Identification	
Melting range	127-132 °C
Test for malate	Passes test
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 2 mg/kg
Mercury	Not more than 1 mg/kg

E 297 FUMARIC ACID

Synonyms	
Definition	
Einecs	203-743-0
Chemical name	*trans*-Butenedioic acid; *trans*-1,2-Ethylene-dicarboxylic acid
Chemical formula	$C_4H_4O_4$
Molecular weight	116,07
Assay	Content not less than 99,0 % on the anhydrous basis
Description	White crystalline powder or granules
Identification	
Melting range	286-302 °C (closed capillary, rapid heating)
Test for double bonds	Passes test
Test for 1,2-dicarboxylic acid	Passes test
pH	3,0-3,2 (0,05 % solution at 25 °C)

▼B

Purity	
Loss on drying	Not more than 0,5 % (120 °C, 4 hours)
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 2 mg/kg
Mercury	Not more than 1 mg/kg

E 300 ASCORBIC ACID, L-ASCORBIC ACID

Synonyms	L-xylo-Ascorbic acid; L(+)- Ascorbic acid
Definition	
Einecs	200-066-2
Chemical name	L-ascorbic acid; Ascorbic acid; 2,3-Didehydro-L-threo-hexono-1,4-lactone; 3-Keto-L-gulofuranolactone
Chemical formula	$C_6H_8O_6$
Molecular weight	176,13
Assay	contains not less than 99 % of $C_6H_8O_6$ after drying in a vacuum desiccator over sulphuric acid for 24 hours,
Description	White to pale yellow, odourless crystalline powder
Melting range	Between 189 °C and 193 °C with decomposition
Identification	
Test for ascorbic acid	Passes test
pH	Between 2,4 and 2,8 (2 % aqueous solution)
Specific rotation	$[\alpha]_D^{20}$ between + 20,5° and + 21,5° (10 % w/v aqueous solution)
Purity	
Loss on drying	Not more than 0,4 % (in vacuum over sulphuric acid, 24 hours)
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 301 SODIUM ASCORBATE

Synonyms	Sodium L-ascorbate; L-Ascorbic acid monosodium salt
Definition	
Einecs	205-126-1
Chemical name	Sodium ascorbate; Sodium L-ascorbate; 2,3-Didehydro-L-threo-hexono-1,4-lactone sodium enolate; 3-Keto-L-gulofurano-lactone sodium enolate
Chemical formula	$C_6H_7O_6Na$

▼B

Molecular weight	198,11
Assay	Sodium ascorbate, after drying in a vacuum desiccator over sulphuric acid for 24 hours, contains not less than 99 % of $C_6H_7O_6Na$
Description	White or almost white, odourless crystalline powder which darkens on exposure to light
Identification	
Test for ascorbate	Passes test
Test for sodium	Passes test
pH	Between 6,5 and 8,0 (10 % aqueous solution)
Specific rotation	$[\alpha]_D^{20}$ between + 103° and + 106° (10 % w/v aqueous solution)
Purity	
Loss on drying	Not more than 0,25 % (in vacuum over sulphuric acid, 24 hours)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 302 CALCIUM ASCORBATE

Synonyms	Calcium ascorbate dihydrate
Definition	
Einecs	227-261-5
Chemical name	Calcium ascorbate dihydrate; Calcium salt of 2,3-didehydro-L-threo-hexono-1,4-lactone dihydrate
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	
Test for ascorbate	Passes test
Test for calcium	Passes test
pH	Between 6,0 and 7,5 (10 % aqueous solution)
Specific rotation	$[\alpha]_D^{20}$ between + 95° and + 97° (5 % w/v aqueous solution)
Purity	
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
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 2 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 304 (i) ASCORBYL PALMITATE

Synonyms	L-ascorbyl palmitate
Definition	
Einecs	205-305-4
Chemical name	Ascorbyl palmitate; L-ascorbyl palmitate; 2,3-didehydro-L-threo-hexono-1,4-lactone-6-palmitate; 6-palmitoyl-3-keto-L-gulofuranol-actone
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 powder with a citrus-like odour
Identification	
Melting range	Between 107 °C and 117 °C
Specific rotation	$[\alpha]_D^{20}$ between + 21° and + 24° (5 % w/v in methanol solution)
Purity	
Loss on drying	Not more than 2,0 % (vacuum oven, 56-60 °C, 1 hour)
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 304 (ii) ASCORBYL STEARATE

Synonyms	
Definition	
Einecs	246-944-9
Chemical name	Ascorbyl stearate; L-ascorbyl stearate; 2,3-didehydro-L-threo-hexono-1,4-lactone-6-stearate; 6-stearoyl-3-keto-L-gulofuranolactone
Chemical formula	$C_{24}H_{42}O_7$
Molecular weight	442,6
Assay	Content not less than 98 %
Description	White or yellowish, white powder with a citrus-like odour
Identification	
Melting point	About 116 °C
Purity	
Loss on drying	Not more than 2,0 % (vacuum oven, 56-60 °C, 1 hour)
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg

▼B

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

E 306 TOCOPHEROL-RICH EXTRACT

Synonyms	
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-δ-tocopherols
Einecs	
Chemical name	
Chemical formula	
Molecular weight	430,71 (d-α-tocopherol)
Assay	Content not less than 34 % of total tocopherols
Description	Brownish red to red, clear, viscous oil having a mild, characteristic odour and taste. May show a slight separation of wax-like constituents in microcrystalline form
Identification	
By suitable gas liquid chromatographic method	
Specific rotation	$[\alpha]_D^{20}$ not less than + 20°
Solubility	Insoluble in water. Soluble in ethanol. Miscible in ether
Purity	
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 307 ALPHA-TOCOPHEROL

Synonyms	dl-α-Tocopherol; (all rac)-α-Tocopherol
Definition	
Einecs	233-466-0
Chemical name	DL-5,7,8-Trimethyltocol; DL-2,5,7,8-tetramethyl-2-(4′,8′,12′-trimethyltridecyl)-6-chromanol
Chemical formula	$C_{29}H_{50}O_2$
Molecular weight	430,71
Assay	Content not less than 96 %
Description	Slightly yellow to amber, nearly odourless, clear, viscous oil which oxidises and darkens on exposure to air or light
Identification	
Solubility	Insoluble in water, freely soluble in ethanol, miscible in ether

▼B

Spectrophotometry	In absolute ethanol the maximum absorption is about 292 nm
Specific rotation	$[\alpha]_D^{25}$ 0° ± 0,05° (1 in 10 solution in chloroform)
Purity	
Refractive index	$[n]_D^{20}$ 1,503-1,507
Specific absorption in ethanol	$E_{1cm}^{1\%}$ (292 nm) 71-76 (0,01 g in 200 ml of absolute ethanol)
Sulphated ash	Not more than 0,1 %
Lead	Not more than 2 mg/kg

E 308 GAMMA-TOCOPHEROL

Synonyms	dl-γ-Tocopherol
Definition	
Einecs	231-523-4
Chemical name	2,7,8-trimethyl-2-(4′,8′,12′-trimethyltridecyl)-6-chromanol
Chemical formula	$C_{28}H_{48}O_2$
Molecular weight	416,69
Assay	Content not less than 97 %
Description	Clear, viscous, pale yellow oil which oxidises and darkens on exposure to air or light
Identification	
Spectrometry	Maximum absorptions in absolute ethanol at about 298 nm and 257 nm
Purity	
Specific absorption in ethanol	$E_{1cm}^{1\%}$ (298 nm) between 91 and 97 $E_{1cm}^{1\%}$ (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 2 mg/kg
Mercury	Not more than 1 mg/kg

E 309 DELTA-TOCOPHEROL

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

▼B

Identification	
Spectrometry	Maximum absorptions in absolute ethanol at about 298 nm and 257 nm
Purity	
Specific absorption $E^{1\%}_{1cm}$ in ethanol	$E^{1\%}_{1cm}$ (298 nm) between 89 and 95 $E^{1\%}_{1cm}$ (257 nm) between 3,0 and 6,0
Refractive index	$[n]_D^{20}$ 1,500-1,504
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 310 PROPYL GALLATE

Synonyms	
Definition	
Einecs	204-498-2
Chemical name	Propyl gallate; Propyl ester of gallic acid; n-propyl ester of 3,4,5-trihydroxybenzoic acid
Chemical formula	$C_{10}H_{12}O_5$
Molecular weight	212,20
Assay	Content not less than 98 % on the anhydrous basis
Description	White to creamy-white, crystalline, odourless solid
Identification	
Solubility	Slightly soluble in water, freely soluble in ethanol, ether and propane-1,2-diol
Melting range	Between 146 °C and 150 °C after drying at 110 °C for four hours
Purity	
Loss on drying	Not more than 0,5 % (110 °C, 4 hours)
Sulphated ash	Not more than 0,1 %
Free acid	Not more than 0,5 % (as gallic acid)
Chlorinated organic compound	Not more than 100 mg/kg (as C1)
Specific absorption in ethanol	$E^{1\%}_{1cm}$ (275 nm) not less than 485 and not more than 520
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

▼M30

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▼B

E 315 ERYTHORBIC ACID

Synonyms	Isoascorbic acid; D-Araboascorbic acid
Definition	
Einecs	201-928-0
Chemical name	D-Erythro-hex-2-enoic acid γ-lactone; Isoascorbic acid; D-Isoascorbic acid
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	
Melting range	About 164 °C to 172 °C with decomposition
Test for ascorbic acid/colour reaction	Passes test
Specific rotation	$[\alpha]_D^{25}$ 10 % (w/v) aqueous solution between – 16,5° to – 18,0°
Purity	
Loss on drying	Not more than 0,4 % after drying under (reduced pressure on silica gel, 3 hours)
Sulphated ash	Not more than 0,3 %
Oxalate	To a solution of 1 g in 10 ml of water add 2 drops of glacial acetic acid and 5 ml of 10 % calcium acetate solution. The solution should remain clear
Lead	Not more than 2 mg/kg

E 316 SODIUM ERYTHORBATE

Synonyms	Sodium isoascorbate
Definition	
Einecs	228-973-9
Chemical name	Sodium isoascorbate; Sodium D-isoascorbic acid; Sodium salt of 2,3-didehydro-D-erythro-hexono-1,4-lactone; 3-keto-D-gulofurano-lactone sodium enolate monohydrate
Chemical formula	$C_6H_7O_6Na \cdot H_2O$
Molecular weight	216,13
Assay	Content not less than 98 % after drying in a vacuum desiccator over sulphuric acid for 24 hours expressed on the monohydrate basis

▼B

Description	White crystalline solid
Identification	
Solubility	Freely soluble in water, very slightly soluble in ethanol
Test for ascorbic acid/colour reaction	Passes test
Test for sodium	Passes test
pH	5,5 to 8,0 (10 % aqueous solution)
Specific rotation	$[\alpha]_D^{25}$ 10 % (w/v) aqueous solution between + 95° and + 98°
Purity	
Loss on drying	Not more than 0,25 % after drying (in vacuum over sulphuric acid, 24 hours)
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 2 mg/kg
Mercury	Not more than 1 mg/kg

E 319 TERTIARY-BUTYLHYDROQUINONE (TBHQ)

Synonyms	TBHQ
Definition	
Einecs	217-752-2
Chemical name	Tert-butyl-1,4-benzenediol; 2-(1,1-Dimethylethyl)-1,4-benzenediol
Chemical formula	$C_{10}H_{14}O_2$
Molecular weight	166,22
Assay	Content not less than 99 % of $C_{10}H_{14}O_2$
Description	White crystalline solid having a characteristic odour
Identification	
Solubility	Practically insoluble in water; soluble in ethanol
Melting point	Not less than 126,5 °C
Phenolics	Dissolve about 5 mg of the sample in 10 ml of methanol and add 10,5 ml of dimethylamine solution (1 in 4). A red to pink colour is produced
Purity	
Tertiary-Butyl-*p*-benzoquinone	Not more than 0,2 %
2,5-Di-tertiary-butyl hydroquinone	Not more than 0,2 %
Hydroxyquinone	Not more than 0,1 %
Toluene	Not more than 25 mg/kg
Lead	Not more than 2 mg/kg

▼B

E 320 BUTYLATED HYDROXYANISOLE (BHA)

Synonyms	BHA
Definition	
Einecs	246-563-8
Chemical name	3-Tertiary-butyl-4-hydroxyanisole; A mixture of 2-tertiary-butyl-4-hydroxyanisole and 3-tertiary-butyl-4-hydroxyanisole
Chemical formula	$C_{11}H_{16}O_2$
Molecular weight	180,25
Assay	Content not less than 98,5 % of $C_{11}H_{16}O_2$ and not less than 85 % of 3-tertiary-butyl-4-hydroxyanisole isomer
Description	White or slightly yellow flakes or waxy solid with a slight aromatic smell
Identification	
Solubility	Insoluble in water, freely soluble in ethanol
Melting range	Between 48 °C and 63 °C
Colour reaction	Passes test for phenol groups
Purity	
Sulphated ash	Not more than 0,05 % after calcination at 800 ± 25 °C
Phenolic impurities	Not more than 0,5 %
Specific absorption	$E^{1\%}_{1cm}$ (290 nm) not less than 190 and not more than 210 $E^{1\%}_{1cm}$ (228 nm) not less than 326 and not more than 345
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 321 BUTYLATED HYDROXYTOLUENE (BHT)

Synonyms	BHT
Definition	
Einecs	204-881-4
Chemical name	2,6-Ditertiary-butyl-*p*-cresol; 4-Methyl-2,6-ditertiarybutylphenol
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	
Solubility	Insoluble in water and propane- 1,2-diol Freely soluble in ethanol
Melting point	At 70 °C

▼B

Spectrometry	The absorption in the range 230 to 320 nm of a 2 cm layer of a 1 in 100 000 solution in dehydrated ethanol exhibits a maximum only at 278 nm
Purity	
Sulphated ash	Not more than 0,005 %
Phenolic impurities	Not more than 0,5 %
Specific absorption in ethanol	$E^{1\%}_{1cm}$ (278 nm) not less than 81 and not more than 88
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 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
Chemical name	
Chemical formula	
Molecular weight	
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	
Test for choline	Passes test
Test for phosphorus	Passes test
Test for fatty acids	Passes test
Test for hydrolysed lecithin	To a 800 ml beaker add 500 ml of water (30-35 °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 % (105 °C, 1 hour)
Toluene-insoluble matter	Not more than 0,3 %

▼B

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

▼M35

E 322a OAT LECITHIN

Synonyms	Fractionated oat oil
Definition	Oat lecithin is a fractionated oat oil rich in polar lipids, mainly galactolipids. Oat lecithin is produced from food grade oat kernels that are sieved and extracted using ethanol at an elevated temperature to produce a crude lipid extract. This crude extract undergoes multistage evaporation and filtration, yielding crude oat oil, which is separated, evaporated and filtered to produce oat lecithin. Only ethanol may be used in the extraction as extraction solvent.
Einecs	281-672-4
Assay	Not less than 30 % of polar lipids insoluble in acetone
Description	Yellowish-brown viscous liquid
Identification	
Choline	Not more than 2 g/100 g
Phosphorous	Not less than 0,5 %
Polar lipids	Not less than 35 % w/w
Neutral lipids	55–65 % w/w
Saturated	17–20 % w/w
Monounsaturated	38–42 % w/w
Polyunsaturated	38–42 % w/w
Purity	
Loss of drying	Not more than 2 %
Toluene-insoluble matter	Not more than 1 % w/w
Acid value	Not more than 30 mg KOH/g
Peroxide value	less than 10 meq O2/kg fat
Solvent residues	Ethanol: not more than 300 mg/kg
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,05 mg/kg
Mercury	Not more than 0,02 mg/kg
Cadmium	Not more than 0,05 mg/kg

▼M35

Microbiological criteria	
Aerobic plate count	Not more than 1 000 CFU/g
Yeast	Not more than 100 CFU/g
Moulds	Not more than 100 CFU/g
Enterobacteriaceae	Not more than 10 CFU/g
Aerobic spores	Not more than 1 CFU/g
Other	
Gluten	Not more than 20 mg/kg

▼B

E 325 SODIUM LACTATE

Synonyms	
Definition	
Einecs	200-772-0
Chemical name	Sodium lactate; Sodium 2-hydroxypropanoate
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	
Test for lactate	Passes test

▼M3

Test for sodium	Passes test

▼B

pH	6,5 to 7,5 (20 % aqueous solution)
Purity	
Acidity	Not more than 0,5 % after drying expressed as lactic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Reducing substances	No reduction of Fehling's solution

Note: This specification refers to a 60 % aqueous solution

E 326 POTASSIUM LACTATE

Synonyms	
Definition	
Einecs	213-631-3
Cheminal name	Potassium lactate; Potassium 2-hydroxypropanoate
Chemical formula	$C_3H_5O_3K$
Molecular weight	128,17 (anhydrous)
Assay	Content not less than 57 % and not more than 66 %

▼B

Description	Slightly viscous, almost odourless clear liquid. Odourless, or with a slight, characteristic odour
Identification	
Ignition	Ignite potassium lactate solution to an ash. The ash is alkaline, and an effervescence occurs when acid is added
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
Test for potassium	Passes test
Test for lactate	Passes test
Purity	
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 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	No reduction of Fehling's solution

Note: This specification refers to a 60 % aqueous solution

E 327 CALCIUM LACTATE

Synonyms	
Definition	
Einecs	212-406-7
Chemical name	Calcium dilactate; Calcium dilactate hydrate; 2-Hydroxypropanoic acid calcium salt
Chemical formula	$(C_3H_5O_2)_2$ Ca·nH_2O (n = 0 - 5)
Molecular weight	218,22 (anhydrous)
Assay	Content not less than 98 % on the anhydrous basis
Description	Almost odourless, white crystalline powder or granules
Identification	
Test for lactate	Passes test
Test for calcium	Passes test
Solubility	Soluble in water and practically insoluble in ethanol
pH	Between 6,0 and 8,0 (5 % solution)
Purity	
Loss on drying	anhydrous: not more than 3,0 % (120 °C, 4 hours) with 1 molecule of water: not more than 8,0 % (120 °C, 4 hours) with 3 molecules of water: not more than 20,0 % (120 °C, 4 hours) with 4,5 molecules of water: not more than 27,0 % (120 °C, 4 hours)
Acidity	Not more than 0,5 % of the dry matter expressed as lactic acid

▼B

Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Reducing substances	No reduction of Fehling's solution

E 330 CITRIC ACID

Synonyms	
Definition	Citric acid is produced from lemon or pineapple juice, by fermentation of carbohydrate solutions or other suitable media using *Candida* spp. or non-toxicogenic strains of *Aspergillus niger*
Einecs	201-069-1
Chemical name	Citric acid; 2-Hydroxy-1,2,3-propanetricarboxylic acid; β-Hydroxytricarballylic acid
Chemical formula	(a) $C_6H_8O_7$ (anhydrous) (b) $C_6H_8O_7 \cdot H2O$ (monohydrate)
Molecular weight	(a) 192,13 (anhydrous) (b) 210,15 (monohydrate)
Assay	Citric acid may be anhydrous or it may contain 1 molecule of water. Citric acid contains not less than 99,5 % of $C_6H_8O_7$, calculated on the anhydrous basis
Description	Citric acid is a white or colourless, odourless, crystalline solid, having a strongly acid taste. The monohydrate effloresces in dry air
Identification	
Solubility	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 0,5 mg/kg
Mercury	Not more than 1 mg/kg
Oxalates	Not more than 100 mg/kg, expressed as oxalic acid, after drying
Readily carbonisable substances	Heat 1 g of powdered sample with 10 ml of 98 % minimum sulphuric acid in a water bath at 90 °C in the dark for one hour. Not more than a pale brown colour should be produced (Matching Fluid K)

▼B

E 331 (i) MONOSODIUM CITRATE

Synonyms	Monobasic sodium citrate
Definition	
Einecs	242-734-6
Chemical name	Monosodium citrate; Monosodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid
Chemical formula	(a) $C_6H_7O_7Na$ (anhydrous) (b) $C_6H_7O_7Na \cdot H_2O$ (monohydrate)
Molecular weight	(a) 214,11 (anhydrous) (b) 232,23 (monohydrate)
Assay	Content not less than 99 % on the anhydrous basis
Description	Crystalline white powder or colourless crystals
Identification	
Test for citrate	Passes test
Test for sodium	Passes test
pH	Between 3,5 and 3,8 (1 % aqueous solution)
Purity	
Loss on drying	anhydrous: not more than 1,0 % (140 °C, 0,5 hour) monohydrate: not more than 8,8 % (180 °C, 4 hours)
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 331 (ii) DISODIUM CITRATE

Synonyms	Dibasic sodium citrate
Definition	
Einecs	205-623-3
Chemical name	Disodium citrate; Disodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid; Disodium salt of citric acid with 1,5 molecules of water
Chemical formula	$C_6H_6O_7Na_2 \cdot 1{,}5H_2O$
Molecular weight	263,11
Assay	Content not less than 99 % on the anhydrous basis
Description	Crystalline white powder or colourless crystals
Identification	
Test for citrate	Passes test
Test for sodium	Passes test
pH	Between 4,9 and 5,2 (1 % aqueous solution)

▼B

Purity	
Loss on drying	Not more than 13,0 % (180 °C, 4 hours)
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 331 (iii) TRISODIUM CITRATE

Synonyms	Tribasic sodium citrate
Definition	
Einecs	200-675-3
Chemical name	Trisodium citrate; Trisodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid; Trisodium salt of citric acid, in anhydrous, dihydrate or pentahydrate form
Chemical formula	Anhydrous: $C_6H_5O_7Na_3$ Hydrated: $C_6H_5O_7Na_3 \cdot nH_2O$ (n = 2 or 5)
Molecular weight	258,07 (anhydrous) 294,10 (hydrated n = 2) 348,16 (hydrated n = 5)
Assay	Not less than 99 % on the anhydrous basis
Description	Crystalline white powder or colourless crystals
Identification	
Test for citrate	Passes test
Test for sodium	Passes test
pH	Between 7,5 and 9,0 (5 % aqueous solution)
Purity	
Loss of drying	Anhydrous: not more than 1,0 % (180 °C, 18 hours) Dihydrate: 10,0 to 13,0 % (180 °C, 18 hours) Pentahydrate: not more than 30,3 % (180 °C, 4 hours)
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 332 (i) MONOPOTASSIUM CITRATE

Synonyms	Monobasic potassium citrate
Definition	
Einecs	212-753-4
Chemical name	Monopotassium citrate; Monopotassium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid; Anhydrous monopotassium salt of citric acid

▼B

Chemical formula	$C_6H_7O_7K$
Molecular weight	230,21
Assay	Content not less than 99 % on the anhydrous basis
Description	White, hygroscopic, granular powder or transparent crystals
Identification	
Test for citrate	Passes test
Test for potassium	Passes test
pH	Between 3,5 and 3,8 (1 % aqueous solution)
Purity	
Loss on drying	Not more than 1,0 % (180 °C, 4 hours)
Oxalates	Not more than 100 mg/kg expressed as oxalic acid, after drying
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 332 (ii) TRIPOTASSIUM CITRATE

Synonyms	Tribasic potassium citrate
Definition	
Einecs	212-755-5
Chemical name	Tripotassium citrate; Tripotassium salt of 2-hydroxy-1,2,3-propane-tricarboxylic acid; Monohydrated tripotassium salt of citric acid
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	
Test for citrate	Passes test
Test for potassium	Passes test
pH	Between 7,5 and 9,0 (5 % aqueous solution)
Purity	
Loss on drying	Not more than 6,0 % (180 °C, 4 hours)
Oxalates	Not more than 100 mg/kg (expressed as oxalic acid, after drying)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 333 (i) MONOCALCIUM CITRATE

Synonyms	Monobasic calcium citrate
Definition	
Einecs	
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	
Test for citrate	Passes test
Test for calcium	Passes test
pH	Between 3,2 and 3,5 (1 % aqueous solution)
Purity	
Loss on drying	Not more than 7,0 % (180 °C, 4 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
Aluminium	Not more than 30 mg/kg (only if added to food for infants and young children) Not more than 200 mg/kg (for all uses except food for infants and young children)
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	Dibasic calcium citrate
Definition	
Einecs	
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

▼B

Identification	
Test for citrate	Passes test
Test for calcium	Passes test
Purity	
Loss on drying	Not more than 20,0 % (180 °C, 4 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
Aluminium	Not more than 30 mg/kg (only if added to food for infants and young children) Not more than 200 mg/kg (for all uses except food for infants and young children)
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	Tribasic calcium citrate
Definition	
Einecs	212-391-7
Chemical name	Tricalcium citrate; Tricalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid; Tetrahydrated tricalcium salt of citric acid
Chemical formula	$(C_6H_6O_7)_2Ca_3 \cdot 4H_2O$
Molecular weight	570,51
Assay	Not less than 97,5 % on the anhydrous basis
Description	Fine white powder
Identification	
Test for citrate	Passes test
Test for calcium	Passes test
Purity	
Loss on drying	Not more than 14,0 % (180 °C, 4 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

▼B

Aluminium	Not more than 30 mg/kg (only if added to food for infants and young children) Not more than 200 mg/kg (for all uses except food for infants and young children)
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, TARTARIC ACID

Synonyms	
Definition	
Einecs	201-766-0
Chemical name	L-tartaric acid; L-2,3-dihydroxybutanedioic acid; d-α,β-dihydroxy-succinic acid
Chemical formula	$C_4H_6O_6$
Molecular weight	150,09
Assay	Content not less than 99,5 % on the anhydrous basis
Description	Colourless or translucent crystalline solid or white crystalline powder
Identification	
Melting range	Between 168 °C and 170 °C
Test for tartrate	Passes test
Specific rotation	$[\alpha]_D^{20}$ between + 11,5° and + 13,5° (20 % w/v aqueous solution)
Purity	
Loss on drying	Not more than 0,5 % (over P_2O_5, 3 hours)
Sulphated ash	Not more than 1 000 mg/kg (after calcination at 800 ± 25 °C)
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 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	
Einecs	
Chemical name	Monosodium salt of L-2,3-dihydroxybutanedioic acid; Monohydrated monosodium salt of L-(+)-tartaric acid
Chemical formula	$C_4H_5O_6Na{\cdot}H_2O$
Molecular weight	194,05
Assay	Content not less than 99 % on the anhydrous basis
Description	Transparent colourless crystals

▼B

Identification	
Test for tartrate	Passes test
Test for sodium	Passes test
Purity	
Loss on drying	Not more than 10,0 % (105 °C, 4 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 2 mg/kg
Mercury	Not more than 1 mg/kg

E 335 (ii) DISODIUM TARTRATE

Synonyms	
Definition	
Einecs	212-773-3
Chemical name	Disodium L-tartrate; Disodium (+)-tartrate; Disodium salt of (+)-2,3-dihydroxybutanedioic acid; Dihydrated disodium salt of L-(+)-tartaric acid
Chemical formula	$C_4H_4O_6Na_2 \cdot 2H_2O$
Molecular weight	230,8
Assay	Content not less than 99 % on the anhydrous basis
Description	Transparent, colourless crystals
Identification	
Test for tartrate	Passes test
Test for sodium	Passes test
Solubility	1 gram is insoluble in 3 ml of water. Insoluble in ethanol
pH	Between 7,0 and 7,5 (1 % aqueous solution)
Purity	
Loss on drying	Not more than 17,0 % (150 °C, 4 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 2 mg/kg
Mercury	Not more than 1 mg/kg

E 336 (i) MONOPOTASSIUM TARTRATE

Synonyms	Monobasic potassium tartrate
Definition	
Einecs	
Chemical name	Anhydrous monopotassium salt of L-(+)-tartaric acid; Monopotassium salt of L-2,3-dihydroxybutanedioic acid

▼B

Chemical formula	$C_4H_5O_6K$
Molecular weight	188,16
Assay	Content not less than 98 % on the anhydrous basis
Description	White crystalline or granulated powder
Identification	
Test for tartrate	Passes test
Test for potassium	Passes test
Melting point	230 °C
pH	3,4 (1 % aqueous solution)
Purity	
Loss on drying	Not more than 1,0 % (105 °C, 4 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 2 mg/kg
Mercury	Not more than 1 mg/kg

E 336 (ii) DIPOTASSIUM TARTRATE

Synonyms	Dibasic potassium tartrate
Definition	
Einecs	213-067-8
Chemical name	Dipotassium salt of L-2,3-dihydroxybutanedioic acid; Dipotassium salt with half a molecule of water of L-(+)-tartaric acid
Chemical formula	$C_4H_4O_6K_2 \cdot ½H_2O$
Molecular weight	235,2
Assay	Content not less than 99 % on the anhydrous basis
Description	White crystalline or granulated powder
Identification	
Test for tartrate	Passes test
Test for potassium	Passes test
pH	Between 7,0 and 9,0 (1 % aqueous solution)
Purity	
Loss on drying	Not more than 4,0 % (150 °C, 4 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 2 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 337 POTASSIUM SODIUM TARTRATE

Synonyms	Potassium sodium L-(+)-tartrate; Rochelle salt; Seignette salt
Definition	
Einecs	206-156-8
Chemical name	Potassium sodium salt of L-2,3-dihydroxybutanedioic acid; Potassium sodium L-(+)-tartrate
Chemical formula	$C_4H_4O_6KNa{\cdot}4H_2O$
Molecular weight	282,23
Assay	Content not less than 99 % on the anhydrous basis
Description	Colourless crystals or white crystalline powder
Identification	
Test for tartrate	Passes test
Test for potassium	Passes test
Test for sodium	Passes test
Solubility	1 gram is soluble in 1 ml of water, insoluble in ethanol
Melting range	70-80 °C
pH	Between 6,5 and 8,5 (1 % aqueous solution)
Purity	
Loss on drying	Not more than 26,0 % and not less than 21,0 % (150 °C, 3 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 2 mg/kg
Mercury	Not more than 1 mg/kg

E 338 PHOSPHORIC ACID

Synonyms	Orthophosphoric acid; Monophosphoric acid
Definition	
Einecs	231-633-2
Chemical name	Phosphoric acid
Chemical formula	H_3PO_4
Molecular weight	98,00
Assay	Content not less than 67,0 % and not more than 85,7 %. Phosphoric acid is commercially available as an aqueous solution at variable concentrations.
Description	Clear, colourless, viscous liquid
Identification	
Test for acid	Passes test
Test for phosphate	Passes test

▼B

Purity	
Volatile acids	Not more than 10 mg/kg (as acetic acid)
Chlorides	Not more than 200 mg/kg (expressed as chlorine)
Nitrates	Not more than 5 mg/kg (as $NaNO_3$)
Sulphates	Not more than 1 500 mg/kg (as $CaSO_4$)
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 1 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	
Einecs	231-449-2
Chemical name	Sodium dihydrogen monophosphate
Chemical formula	Anhydrous: NaH_2PO_4 Monohydrate: $NaH_2PO_4 \cdot H_2O$ Dihydrate: $NaH_2PO_4 \cdot 2H_2O$
Molecular weight	Anhydrous: 119,98 Monohydrate: 138,00 Dihydrate: 156,01
Assay	After drying at 60 °C for one hour and then at 105 °C for four hours, contains not less than 97 % of NaH_2PO_4 P_2O_5 content between 58,0 % and 60,0 % on the anhydrous basis
Description	A white odourless, slightly deliquescent powder, crystals or granules
Identification	
Test for sodium	Passes test
Test for phosphate	Passes test
Solubility	Freely soluble in water. Insoluble in ethanol or ether
pH	Between 4,1 and 5,0 (1 % solution)
Purity	
Loss on drying	The anhydrous salt loses not more than 2,0 %, the monohydrate not more than 15,0 %, the dihydrate not more than 25 % (60 °C, 1 hour then 105 °C, 4 hours)
Water insoluble matter	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)

▼B

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

E 339 (ii) DISODIUM PHOSPHATE

Synonyms	Disodium monophosphate; Secondary sodium phosphate; Disodium orthophosphate;
Definition	
Einecs	231-448-7
Chemical name	Disodium hydrogen monophosphate; Disodium hydrogen orthophosphate
Chemical formula	Anhydrous:Na_2HPO_4 Hydrate: $Na_2HPO_4 \cdot nH_2O$ (n = 2, 7 or 12)
Molecular weight	141,98 (anhydrous)
Assay	After drying at 40 °C for three hours and subsequently at 105 °C for five hours, contains not less than 98 % of Na_2HPO_4 P_2O_5 content between 49 % and 51 % on the anhydrous basis
Description	Anhydrous disodium hydrogen phosphate is a white, hygroscopic, odourless powder. Hydrated forms available include the dihydrate: a white crystalline, odourless solid; the heptahydrate: white, odourless, efflorescent crystals or granular powder; and the dodecahydrate: white, efflorescent, odourless powder or crystals
Identification	
Test for sodium	Passes test
Test for phosphate	Passes test
Solubility	Freely soluble in water. Insoluble in ethanol
pH	Between 8,4 and 9,6 (1 % solution)
Purity	
Loss on drying	The anhydrous salt loses not more than 5,0 %, the dihydrate not more than 22,0 %, the heptahydrate not more than 50,0 %, the dodecahydrate not more than 61,0 % (40 °C, 3 hours then 105 °C, 5 hours)
Water insoluble matter	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 339 (iii) TRISODIUM PHOSPHATE

Synonyms	Sodium phosphate; Tribasic sodium phosphate; Trisodium orthophosphate

▼B

Definition	Trisodium phosphate is obtained from aqueous solutions and crystallises in the anhydrous form and with 1/2, 1, 6, 8 or 12 H_2O. The dodecahydrate always crystallises from aqueous solutions with an excess of sodium hydroxide. It contains ¼ molecule of NaOH
Einecs	231-509-8
Chemical name	Trisodium monophosphate; Trisodium phosphate; Trisodium orthophosphate
Chemical formula	Anhydrous: Na_3PO_4 Hydrated: Na_3PO_4 nH_2O (n = 1/2, 1, 6, 8, or 12)
Molecular weight	163,94 (anhydrous)
Assay	Sodium phosphate anhydrous and the hydrated forms, with the exception of the dodecahydrate, contain not less than 97,0 % of Na_3PO_4 calculated on the dried basis. Sodium phosphate dodecahydrate contains not less than 92,0 % of Na_3PO_4 calculated on the ignited basis P_2O_5 content between 40,5 % and 43,5 % on the anhydrous basis
Description	White odourless crystals, granules or crystalline powder
Identification	
Test for sodium	Passes test
Test for phosphate	Passes test
Solubility	Freely soluble in water. Insoluble in ethanol
pH	Between 11,5 and 12,5 (1 % solution)
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 matter	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 340 (i) MONOPOTASSIUM PHOSPHATE

Synonyms	Monobasic potassium phosphate; Monopotassium monophosphate; Mono potassium orthophosphate
Definition	
Einecs	231-913-4
Chemical name	Potassium dihydrogen phosphate; Monopotassium dihydrogen orthophosphate; Monopotassium dihydrogen monophosphate
Chemical formula	KH_2PO_4
Molecular weight	136,09

▼B

Assay	Content not less than 98,0 % after drying at 105 °C for four hours P_2O_5 content between 51,0 % and 53,0 % on the anhydrous basis
Description	Odourless, colourless crystals or white granular or crystalline powder
Identification	
Test for potassium	Passes test
Test for phosphate	Passes test
Solubility	Freely soluble in water. Insoluble in ethanol
pH	Between 4,2 and 4,8 (1 % solution)
Purity	
Loss on drying	Not more than 2,0 % (105 °C, 4 hours)
Water insoluble matter	Not more than 0,2 % on the anhydrous basis
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 340 (ii) DIPOTASSIUM PHOSPHATE

Synonyms	Dipotassium monophosphate; Secondary potassium phosphate; Dipotassium orthophosphate; Dibasic potassium phosphate
Definition	
Einecs	231-834-5
Chemical name	Dipotassium hydrogen monophosphate; Dipotassium hydrogen phosphate; Dipotassium hydrogen orthophosphate
Chemical formula	K_2HPO_4
Molecular weight	174,18
Assay	Content not less than 98 % after drying at 105 °C for four hours P_2O_5 content between 40,3 % and 41,5 % on the anhydrous basis
Description	Colourless or white granular powder, crystals or masses; deliquescent substance, hygroscopic
Identification	
Test for potassium	Passes test
Test for phosphate	Passes test
Solubility	Freely soluble in water. Insoluble in ethanol
pH	Between 8,7 and 9,4 (1 % solution)
Purity	
Loss on drying	Not more than 2,0 % (105 °C, 4 hours)

▼B

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

E 340 (iii) TRIPOTASSIUM PHOSPHATE

Synonyms	Tribasic potassium phosphate; Tripotassium orthophosphate
Definition	
Einecs	231-907-1
Chemical name	Tripotassium monophosphate; Tripotassium phosphate; Tripotassium orthophosphate
Chemical formula	Anhydrous: K_3PO_4 Hydrated: $K_3PO_4 \cdot nH_2O$ (n = 1 or 3)
Molecular weight	212,27 (anhydrous)
Assay	Content not less than 97 % calculated on the ignited basis P_2O_5 content between 30,5 % and 34,0 % on the ignited basis
Description	Colourless or white, odourless hygroscopic crystals or granules. Hydrated forms available include the monohydrate and trihydrate
Identification	
Test for potassium	Passes test
Test for phosphate	Passes test
Solubility	Freely soluble in water. Insoluble in ethanol
pH	Between 11,5 and 12,3 (1 % solution)
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 matter	Not more than 0,2 % (on the anhydrous basis)
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 341 (i) MONOCALCIUM PHOSPHATE

Synonyms	Monobasic calcium phosphate; Monocalcium orthophosphate
Definition	
Einecs	231-837-1

▼B

Chemical name	Calcium dihydrogen phosphate
Chemical formula	Anhydrous: $Ca(H_2PO_4)_2$ Monohydrate: $Ca(H_2PO_4)_2 \cdot H_2O$
Molecular weight	234,05 (anhydrous) 252,08 (monohydrate)
Assay	Content not less than 95 % on the dried basis P_2O_5 content between 55,5 % and 61,1 % on the anhydrous basis
Description	Granular powder or white, deliquescent crystals or granules
Identification	
Test for calcium	Passes test
Test for phosphate	Passes test
CaO content	Between 23,0 % and 27,5 % (anhydrous) Between 19,0 % and 24,8 % (monohydrate)
Purity	
Loss on drying	Anhydrous: not more than 14 % (105 °C, 4 hours) Monohydrate: not more than 17,5 % (105 °C, 4 hours)
Loss on ignition	Anhydrous: not more than 17,5 % (after ignition at 800 °C ± 25 °C for 30 minutes) Monohydrate: not more than 25,0 % (determined by drying at 105 °C for one hour, then ignite at 800 °C ± 25 °C for 30 minutes)
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Aluminium	Not more than 70 mg/kg (only if added to food for infants and young children) Not more than 200 mg/kg (for all uses except food for infants and young children)

E 341 (ii) DICALCIUM PHOSPHATE

Synonyms	Dibasic calcium phosphate; Dicalcium orthophosphate
Definition	
Einecs	231-826-1
Chemical name	Calcium monohydrogen phosphate; Calcium hydrogen orthophosphate; Secondary calcium phosphate
Chemical formula	Anhydrous: $CaHPO_4$ Dihydrate: $CaHPO_4 \cdot 2H_2O$
Molecular weight	136,06 (anhydrous) 172,09 (dihydrate)

▼B

Assay	Dicalcium phosphate, after drying at 200 °C for three hours, contains not less than 98 % and not more than the equivalent of 102 % of $CaHPO_4$ P_2O_5 content between 50,0 % and 52,5 % on the anhydrous basis
Description	White crystals or granules, granular powder or powder
Identification	
Test for calcium	Passes test
Test for phosphate	Passes test
Solubility	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 1 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Aluminium	Not more than 100 mg/kg for the anhydrous form and not more than 80 mg/kg for the dihydrated form (only if added to food for infants and young children) Not more than 600 mg/kg for the anhydrous form and not more than 500 mg/kg for the dihydrated form (for all uses except food for infants and young children). This applies until 31 March 2015. Not more than 200 mg/kg for the anhydrous form and the dihydrated form (for all uses except food for infants and young children). This applies from 1 April 2015.

E 341 (iii) TRICALCIUM PHOSPHATE

Synonyms	Calcium phosphate, tribasic; Calcium orthophosphate; Pentacalcium hydroxy monophosphate; Calcium hydroxyapatite

▼M31

Definition	Tricalcium phosphate consists of a variable mixture of calcium phosphates obtained from neutralisation of phosphoric acid with calcium hydroxide or calcium carbonate and having the approximate composition of $10CaO{\cdot}3P_2O_5{\cdot}H_2O$

▼B

Einecs	235-330-6 (Pentacalcium hydroxy monophosphate) 231-840-8 (Calcium orthophosphate)
Chemical name	Pentacalcium hydroxy monophosphate; Tricalcium monophosphate
Chemical formula	$Ca_5(PO_4)_3 \cdot OH$ or $Ca_3(PO_4)_2$
Molecular weight	502 or 310
Assay	Content not less than 90 % calculated on the ignited basis P_2O_5 content between 38,5 % and 48,0 % on the anhydrous basis
Description	A white, odourless powder which is stable in air

▼B

Identification	
Test for calcium	Passes test
Test for phosphate	Passes test
Solubility	Practically insoluble in water; insoluble in ethanol, soluble in dilute hydrochloric and nitric acid
Purity	
Loss on ignition	Not more than 8 % after ignition at 800 °C ± 25 °C for 0,5 hour
Fluoride	Not more than 50 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Aluminium	Not more than 150 mg/kg (only if added to food for infants and young children) Not more than 500 mg/kg (for all uses except food for infants and young children). This applies until 31 March 2015 Not more than 200 mg/kg (for all uses except food for infants and young children). This applies from 1 April 2015.

E 343 (i) MONOMAGNESIUM PHOSPHATE

Synonyms	Magnesiumdihydrogenphosphate; Magnesiumphosphate, monobasic; Monomagnesium orthophosphate
Definition	
Einecs	236-004-6
Chemical name	Monomagnesiumdihydrogenmonophosphate
Chemical formula	$Mg(H_2PO_4)_2$ nH_2O (where n = 0 to 4)
Molecular weight	218,30 (anhydrous)
Assay	Not less than 51,0 % after ignition calculated as P2O5 at the ignited basis (800 °C ± 25 °C for 30 minutes)
Description	White, odourless, crystalline powder, slightly soluble in water
Identification	
Test for magnesium	Passes test
Test for phosphate	Passes test
MgO content	Not less than 21,5 % after ignition or at an anhydrous basis (105 °C, 4 hours)
Purity	
Fluoride	Not more than 10 mg/kg (as fluorine)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 343 (ii) DIMAGNESIUM PHOSPHATE

Synonyms	Magnesiumhydrogenphosphate; Magnesiumphosphate, dibasic; Dimagnesium orthophosphate; Secondary magnesiumphosphate
Definition	
Einecs	231-823-5
Chemical name	Dimagnesiummonohydrogenmonophosphate
Chemical formula	$MgHPO_4 \cdot nH_2O$ (where n = 0-3)
Molecular weight	120,30 (anhydrous)
Assay	Not less than 96 % after ignition (800 °C ± 25 °C for 30 minutes)
Description	White, odourless, crystalline powder, slightly soluble in water
Identification	
Test for magnesium	Passes test
Test for phosphate	Passes test
MgO content	Not less than 33,0 % calculated on the anhydrous basis (105 °C, 4 hours)
Purity	
Fluoride	Not more than 10 mg/kg (as fluorine)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

▼M46

E 345 (i) TRIMAGNESIUM DICITRATE

Synonyms	Magnesium citrate; trimagnesium citrate
Definition	
Einecs	222-093-9
Chemical name	Trimagnesium bis (2-hydroxypropane-1,2,3- tricarboxylate), anhydrous
Chemical formula	$(C_6H_5O_7)_2\ Mg_3$
Molecular weight	451,12 (anhydrous)
Assay	15,0-16,5 % Mg on dry substance/matter equal to 92,8-102,1 % trimagnesium dicitrate anhydrous
Description	White or almost white, fine, slightly hygroscopic powder
Appearance of a solution	Not more opalescent than ref. susp. III and not more intensely coloured than ref. sol. Y7 or BY6
Identification	
Test for citrate	Positive
Test for magnesium	Positive
pH (5 % solution)	6,0-8,5
Solubility	Soluble in water, practically insoluble in ethanol (96 %), it dissolves in diluted hydrochloric acid.

▼M46

Particle size	by STEM method – Median (D_{50}) particle size (number-based) not below 130 nm by laser diffraction method – Median (D_{50}) particle size (mass-based) not below 50 μm
Purity	
Loss on drying	Maximum 3,5 %, determined on 1 000 g by drying in an oven at 180 ± 10 °C for 5 h
Oxalic/oxalate	≤ 280 mg/kg (0,028 %) as oxalic acid
Sulfates	≤ 2 000 mg/kg (0,2 %)
Calcium	≤ 2 000 mg/kg (0,2 %)
Iron	≤ 100 mg/kg
Mercury	≤ 0,1 mg/kg
Lead	≤ 1 mg/kg
Cadmium	≤ 0,1 mg/kg
Arsenic	≤ 1 mg/kg
Not identified material	No process or product related impurities. The unintended presence of hydrated forms of trimagnesium dicitrate such as the nonahydrate cannot be excluded.

▼B

E 350 (i) SODIUM MALATE

Synonyms	Sodium salt of malic acid
Definition	
Einecs	
Chemical name	Disodium DL-malate; disodium salt of hydroxybutanedioic acid
Chemical formula	Hemihydrate: $C_4H_4Na_2O_5$ ½ H_2O Trihydrate: $C_4H_4Na_2O_5$ $3H_2O$
Molecular weight	Hemihydrate: 187,05 Trihydrate: 232,10
Assay	Content not less than 98,0 % on the anhydrous basis
Description	White crystalline powder or lumps
Identification	
Test for 1,2-dicarboxylic acid	Passes test
Test for sodium	Passes test
Azo dye formation	Positive
Solubility	Freely soluble in water

▼B

Purity	
Loss on drying	Hemihydrate: Not more than 7,0 % (130 °C, 4 hours) Trihydrate: 20,5-23,5 % (130 °C, 4 hours)
Alkalinity	Not more than 0,2 % as Na_2CO_3
Fumaric acid	Not more than 1,0 %
Maleic acid	Not more than 0,05 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 350 (ii) SODIUM HYDROGEN MALATE

Synonyms	Monosodium salt of DL-malic acid
Definition	
Einecs	
Chemical name	Monosodium DL-malate; monosodium 2-DL-hydroxy succinate
Chemical formula	$C_4H_5NaO_5$
Molecular weight	156,07
Assay	Content not less than 99,0 % on the anhydrous basis
Description	White powder
Identification	
Test for 1,2-dicarboxylic acid	Passes test
Test for sodium	Passes test
Azo dye formation	Positive
Purity	
Loss on drying	Not more than 2,0 % (110 °C, 3 hours)
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 2 mg/kg
Mercury	Not more than 1 mg/kg

E 351 POTASSIUM MALATE

Synonyms	Potassium salt of malic acid
Definition	
Einecs	
Chemical name	Dipotassium DL-malate; dipotassium salt of hydroxybutanedioic acid
Chemical formula	$C_4H_4K_2O_5$
Molecular weight	210,27

▼B

Assay	Content not less than 59,5 %
Description	Colourless or almost colourless aqueous solution
Identification	
Test for 1,2-dicarboxylic acid	Passes test
Test for potassium	Passes test
Azo dye formation	Positive
Purity	
Alkalinity	Not more than 0,2 % as K_2CO_3
Fumaric acid	Not more than 1,0 %
Maleic acid	Not more than 0,05 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 352 (i) CALCIUM MALATE

Synonyms	Calcium salt of malic acid
Definition	
Einecs	
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	
Test for malate	Passes test
Test 1,2-dicarboxylic acid	Passes test
Test for calcium	Passes test
Azo dye formation	Positive
Solubility	Slightly soluble in water
Purity	
Loss on drying	Not more than 2 % (100 °C, 3 hours)
Alkalinity	Not more than 0,2 % as $CaCO_3$
Maleic acid	Not more than 0,05 %
Fumaric acid	Not more than 1,0 %
Fluoride	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 352 (ii) CALCIUM HYDROGEN MALATE

Synonyms	Monocalcium salt of DL-malic acid
Definition	
Einecs	
Chemical name	Monocalcium DL-malate; monocalcium 2-DL-hydroxysuccinate
Chemical formula	$(C_4H_5O_5)_2Ca$
Molecular weight	
Assay	Content not less than 97,5 % on the anhydrous basis
Description	White powder
Identification	
Test for 1,2-dicarboxylic acid	Passes test
Test for calcium	Passes test
Azo dye formation	Positive
Purity	
Loss on drying	Not more than 2,0 % (110 °C, 3 hours)
Maleic acid	Not more than 0,05 %
Fumaric acid	Not more than 1,0 %
Fluoride	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 353 METATARTARIC ACID

Synonyms	Ditartaric acid
Definition	
Einecs	
Chemical name	Metatartaric acid
Chemical formula	$C_4H_6O_6$
Molecular weight	
Assay	Not less than 99,5 %
Description	Crystalline or powder form with a white or yellowish colour. Very deliquescent with a faint odour of caramel
Identification	
Solubility	Very soluble in water and ethanol
Identification test	Place a sample of 1 to 10 mg of this substance in a test tube with 2 ml of concentrated sulphuric 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

▼B

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

E 354 CALCIUM TARTRATE

Synonyms	L-Calcium tartrate
Definition	
Einecs	
Chemical name	Calcium L(+)-2,3-dihydroxybutanedioate di-hydrate
Chemical formula	$C_4H_4CaO_6 \cdot 2H_2O$
Molecular weight	224,18
Assay	Not less than 98,0 %
Description	Fine crystalline powder with a white or off-white colour
Identification	
Solubility	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
Specific rotation	$[\alpha]_D^{20}$ + 7,0° to + 7,4° (0,1 % in a 1N HCl solution)
pH	Between 6,0 and 9,0 (5 % slurry)
Purity	
Sulphates	Not more than 1 g/kg (as H_2SO_4)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 355 ADIPIC ACID

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

▼B

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

E 356 SODIUM ADIPATE

Synonyms	
Definition	
Einecs	231-293-5
Chemical name	Sodium adipate
Chemical formula	$C_6H_8Na_2O_4$
Molecular weight	190,11
Assay	Content not less than 99,0 % (on anhydrous basis)
Description	White odourless crystals or crystalline powder
Identification	
Melting range	151-152 °C (for adipic acid)
Solubility	Approximately 50 g/100 ml water (20 °C)
Test for sodium	Passes test
Purity	
Water content	Not more than 3 % (Karl Fischer)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 357 POTASSIUM ADIPATE

Synonyms	
Definition	
Einecs	242-838-1
Chemical name	Potassium adipate
Chemical formula	$C_6H_8K_2O_4$
Molecular weight	222,32
Assay	Content not less than 99,0 % (on anhydrous basis)
Description	White odourless crystals or crystalline powder
Identification	
Melting range	151-152 °C (for adipic acid)
Solubility	Approximately 60 g/100 ml water (20 °C)
Test for potassium	Passes test
Purity	
Water	Not more than 3 % (Karl Fischer)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 363 SUCCINIC ACID

Synonyms	
Definition	
Einecs	203-740-4
Chemical name	Butanedioic acid
Chemical formula	$C_4H_6O_4$
Molecular weight	118,09
Assay	Content no less than 99,0 %
Description	Colourless or white, odourless crystals
Identification	
Melting range	185,0-190,0 °C
Purity	
Residue on ignition	Not more than 0,025 % (800 °C, 15 min)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 380 TRIAMMONIUM CITRATE

Synonyms	Tribasic ammonium citrate
Definition	
Einecs	222-394-5
Chemical name	Triammonium salt of 2-hydroxypropan-1,2,3-tricarboxylic acid
Chemical formula	$C_6H_{17}N_3O_7$
Molecular weight	243,22
Assay	Content not less than 97,0 %
Description	White to off-white crystals or powder
Identification	
Test for ammonium	Passes test
Test for citrate	Passes test
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 2 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 385 CALCIUM DISODIUM ETHYLENEDIAMINETETRAACETATE

Synonyms	Calcium disodium EDTA; Calcium disodium edetate
Definition	
Einecs	200-529-9
Chemical name	N,N′-1,2-Ethanediylbis [N-(carboxymethyl)-glycinate] [(4-)-O,O′,O^N,O^N]calciate(2)-disodium; Calcium disodium ethylenediaminetetra acetate; Calcium disodium (ethylenedinitrilo)tetra acetate
Chemical formula	$C_{10}H_{12}O_8CaN_2Na_2 \cdot 2H_2O$
Molecular weight	410,31
Assay	Content not less than 97 % on the anhydrous basis
Description	White, odourless crystalline granules or white to nearly white powder, slightly hygroscopic
Identification	
Test for sodium	Passes test
Test for calcium	Passes test
Chelating activity to metal ions	Positive
pH	Between 6,5 and 7,5 (1 % solution)
Purity	
Water content	5 to 13 % (Karl Fischer method)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 392 EXTRACTS OF ROSEMARY

Synonyms	Extract of rosemary leaf (antioxidant)
Definition	Extracts of rosemary contain several components, which have been proven to exert antioxidative functions. These components belong mainly to the classes of phenolic acids, flavonoids, diterpenoids. Besides the antioxidant compounds, the extracts can also contain triterpenes and organic solvent extractable material specifically defined in the following specification.
Einecs	283-291-9
Chemical name	Rosemary extract (*Rosmarinus officinalis*)
Description	Rosemary leaf extract antioxidant is prepared by extraction of the leaves of *Rosmarinus officinalis* using a food approved solvent system. Extracts may then be deodorised and decolourised. Extracts may be standardised.
Identification	
Reference antioxidative compounds: phenolic diterpenes	Carnosic acid ($C_{20}H_{28}O_4$) and Carnosol ($C_{20}H_{26}O_4$) (which comprise not less than 90 % of the total phenolic diterpenes)

▼B

Reference key volatiles	Borneol, Bornyl Acetate, Camphor, 1,8-Cineol, Verbenone
Density	> 0,25 g/ml
Solubility	Insoluble in water
Purity	
Loss of drying	< 5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg

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

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

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

Description	Extracts of rosemary produced from dried rosemary leaves extracted by means of supercritical carbon dioxide with a small amount of ethanol as entrainer.
Identification	
Content of reference antioxidative compounds	≥ 13 % w/w, expressed as the total of carnosic acid and carnosol
Antioxidant/Volatiles – Ratio	(Total % w/w of carnosic acid and carnosol) ≥ 15 (% w/w of reference key volatiles)* (* as a percentage of total volatiles in the extract, measured by Gas Chromatography — Mass Spectrometry Detection, 'GC-MSD')
Purity	
Residual solvents	Ethanol: not more than 2 %

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

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

▼B

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

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

Description	Extracts of rosemary which are prepared from a deodorised ethanolic extract of rosemary, undergone a hexane extraction. The extract may be further purified, for example by treatment with active carbon and/or molecular distillation. They may be suspended in suitable and approved carriers or spray dried.
Identification	
Content of reference antioxidative compounds	≥ 5 % w/w, expressed as the total of carnosic acid and carnosol
Antioxidant/Volatiles – Ratio	(Total % w/w of carnosic acid and carnosol) ≥ 15 (% w/w of reference key volatiles)* (* as a percentage of total volatiles in the extract, measured by Gas Chromatography – Mass Spectrometry Detection, 'GC-MSD')
Purity	
Residual solvents	Hexane: not more than 25 mg/kg Ethanol: not more than 500 mg/kg

E 400 ALGINIC ACID

Synonyms	
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 strains of various species of brown seaweeds (*Phaeophyceae*)
Einecs	232-680-1
Chemical name	
Chemical formula	$(C_6H_8O_6)_n$
Molecular weight	10 000-600 000 (typical average)
Assay	Alginic acid yields, on the anhydrous basis, not less than 20 % and not more than 23 % of carbon dioxide (CO_2), equivalent to not less than 91 % and not more than 104,5 % of alginic acid $(C_6H_8O_6)_n$ (calculted on equivalent weight basis of 200)
Description	Alginic acid occurs in filamentous, grainy, granular and powdered forms. It is a white to yellowish brown and nearly odourless

▼B

Identification	
Solubility	Insoluble in water and organic solvents, slowly soluble in solutions of sodium carbonate, sodium hydroxide and trisodium phosphate
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.
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.
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.
pH	Between 2,0 and 3,5 (3 % suspension)
Purity	
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) insoluble matter	Not more than 2 % on the anhydrous basis
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Microbiological criteria	
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
Escherichia coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

E 401 SODIUM ALGINATE

Synonyms	
Definition	
Einecs	
Chemical name	Sodium salt of alginic acid
Chemical formula	$(C_6H_7NaO_6)_n$
Molecular weight	10 000-600 000 (typical average)

▼B

Assay	Yields, on the anhydrous basis, not less than 18 % and not more than 21 % of carbon dioxide corresponding to not less than 90,8 % and not more than 106,0 % of sodium alginate (calculated on equivalent weight basis of 222)
Description	Nearly odourless, white to yellowish fibrous or granular powder
Identification	
Test for sodium	Passes test
Test for alginic acid	Passes test
Purity	
Loss on drying	Not more than 15 % (105 °C, 4 hours)
Water insoluble matter	Not more than 2 % on the anhydrous basis
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Microbiological criteria	
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
Escherichia coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

E 402 POTASSIUM ALGINATE

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

▼B

Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Microbiological criteria	
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
Escherichia coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

E 403 AMMONIUM ALGINATE

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

▼B

E 404 CALCIUM ALGINATE

Synonyms	Calcium salt of alginate
Definition	
Einecs	
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	
Test for calcium	Passes test
Test for alginic acid	Passes test
Purity	
Loss on drying	Not more than 15,0 % (105 °C, 4 hours)
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Microbiological criteria	
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
Escherichia coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

E 405 PROPANE-1,2-DIOL ALGINATE

Synonyms	Hydroxypropyl alginate; 1,2-Propanediol ester of alginic acid; Propylene glycol alginate
Definition	
Einecs	
Chemical name	1,2-Propanediol ester of alginic acid; varies in composition according to its degree of esterification and the percentage of free and neutralised carboxyl groups in the molecule
Chemical formula	$(C_9H_{14}O_7)_n$ (esterified)
Molecular weight	10 000-600 000 (typical average)
Assay	Yields, on the anhydrous basis, not less than 16 % and not more than 20 % of carbon dioxide (CO_2)
Description	Nearly odourless, white to yellowish brown fibrous or granular powder

▼B

Identification	
Test for 1,2-propanediol	Passes test (after hydrolysis)
Test for alginic acid	Passes test (after hydrolysis)
Purity	
Loss on drying	Not more than 20 % (105 °C, 4 hours)
Total propane-1,2-diol content	Not less than 15 % and not more than 45 %
Free propane-1,2-diol content	Not more than 15 %
Water insoluble matter	Not more than 2 % on the anhydrous basis
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Microbiological criteria	
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
Escherichia coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

E 406 AGAR

Synonyms	Gelose; Kanten, Bengal, Ceylon, Chinese or Japanese isinglass; Layor Carang
Definition	Agar is a hydrophilic colloidal polysaccharide consisting mainly of galactose units with a regular alternation of L and D isomeric forms. These hexoses are alternately linked with alpha-1,3 and beta-1,4 bonds in the copolymer. 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 strains of marine algae of the families *Gelidiaceae* and *Gracilariaceae* and relevant red algae of the class *Rhodophyceae*
Einecs	232-658-1
Chemical name	
Chemical formula	
Molecular weight	
Assay	The threshold gel concentration should not be higher than 0,25 %
Description	Agar is odourless or has a slight characteristic odour. Unground agar usually occurs in bundles consisting of thin, membranous, agglutinated strips, or in cut, flaked or granulated forms. It may be light yellowish-orange, yellowish-grey to pale yellow, or colourless. It is tough when damp, brittle when dry. Powdered agar is white to yellowish-white or pale yellow. When examined in water under a microscope, agar powder appears more transparent. In chloral hydrate solution, the powdered agar appears more transparent than in water, more or less granular, striated, angular and occasionally contains frustules of diatoms. Gel strength may be standardised by the addition of dextrose and maltodextrines or sucrose

▼B

Identification	
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 (after stirring for 10 minutes 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
Microbiological criteria	
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
Escherichia coli	Absent in 5 g
Salmonella spp.	Absent in 5 g

E 407 CARRAGEENAN

Synonyms	Products of commerce are sold under different names such as: Irish moss gelose; Eucheuman (from *Eucheuma* spp.); Iridophycan (from *Iridaea* spp.); Hypnean (from *Hypnea* spp.); Furcellaran or Danish agar (from *Furcellaria fastigiata*); Carrageenan (from *Chondrus* and *Gigartina* spp.)
Definition	Carrageenan is obtained by extraction with water or dilute aqueous alkali of strains of seaweeds of *Gigartinaceae*, *Solieriaceae*, *Hypneaceae* and *Furcellariaceae*, families of the class *Rhodophyceae* (red seaweeds). Carrageenan consists chiefly of the potassium, sodium, magnesium and calcium sulphate esters of galactose and 3,6-anhydrogalactose polysacharide. These hexoses are alternately linked α-1,3 and β-1,4 in the copolymer.

▼B

	The prevalent polysaccharides in carrageenan are designated as kappa, iota, lambda depending on the number of sulphate by repeating unit (i.e. 1,2,3 sulphate). Between kappa and iota there is a continuum of intermediate compositions differing in number of sulphates per repeat units between 1 and 2. During the process, no organic precipitant shall be used other than methanol, ethanol and propan-2-ol. The wording carrageenan is reserved for the non hydrolysed or otherwise chemically degraded polymer. Formaldehyde may be present as an adventitious impurity up to a maximum of 5 mg/kg.
Einecs	232-524-2
Chemical name	Sulphate esters of polygalactose
Chemical formula	
Molecular weight	
Assay	
Description	Yellowish to colourless, coarse to fine powder which is practically odourless
Identification	
Test for galactose	Passes test
Test for anhydrogalactose	Passes test
Test for sulphate	Passes test
Solubility	Soluble in hot water; insoluble in alcohol for a 1,5 % dilution
Purity	
Solvent residues	Not more than 0,1 % of methanol, ethanol, propan-2-ol, singly or in combination
Viscosity	Not less than 5 mPa.s (1,5 % solution at 75 °C)
Loss on drying	Not more than 12 % (105 °C, 4 hours)
Sulphates	Not less than 15 % and not more than 40 % on the dried basis (as SO_4)
Ash	Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C
Acid-insoluble ash	Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)
Acid-insoluble matter	Not more than 2 % on the dried basis (insoluble in 1 % v/v sulphuric acid)
Low molecular weight carrageenan (Molecular weight fraction below 50 kDa)	Not more than 5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 2 mg/kg
Microbiological criteria	
Total plate count	Not more than 5 000 colonies per gram

▼B

Yeast and moulds	Not more than 300 colonies per gram
Escherichia coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

E 407a PROCESSED EUCHEUMA SEAWEED

Synonyms	PES (acronym for processed eucheuma seaweed). The PES obtained from *Euchema cottonii* is generally called kappa PES and the PES from *Euchema spinosum* iota PES.
Definition	Processed eucheuma seaweed is obtained by aqueous alkaline (KOH) treatment at high temperature of the strains of seaweeds *Eucheuma cottonii* and *Eucheuma spinosum*, of the class *Rhodophyceae* (red seaweeds) followed by fresh water washing to remove impurities and drying to obtain the product. Further purification may be achieved by washing with an alcohol. The alcohols authorised are restricted to methanol, ethanol or propan-2-ol. The product consists chiefly of the potassium, sodium, magnesium and calcium sulphate esters of galactose and 3,6-anhydrogalactose polysaccharide. Up to 15 % algal cellulose is also present in the product. The wording processed eucheuma seaweed is reserved to the non hydrolysed or otherwise chemically degraded polymer. Formaldehyde may be present up to a maximum of 5 mg/kg.
Description	Tan to yellowish, coarse to fine powder which is practically odourless
Identification	
Test for galactose	Passes test
Test for anhydrogalactose	Passes test
Test for sulphate	Passes test
Solubility	Forms cloudy viscous suspensions in water. Insoluble in ethanol for a 1,5 % solution.
Purity	
Solvent residues	Not more than 0,1 % of methanol, ethanol, propan-2-ol, singly or in combination
Viscosity	Not less than 5 mPa.s (1,5 % solution at 75 °C)
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)
Ash	Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C
Acid-insoluble ash	Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)
Acid-insoluble matter	Not less than 8 % and not more than 15 % on the dried basis (insoluble in 1 % v/v sulphuric acid)
Low molecular weight carrageenan (Molecular weight fraction below 50 kDa)	Not more than 5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

▼B

Cadmium	Not more than 2 mg/kg
Microbiological criteria	
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
Escherichia coli	Absent in 5 g
Salmonella spp.	Absent 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 strains of carob tree, *Cerationia 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
Einecs	232-541-5
Chemical name	
Chemical formula	
Molecular weight	50 000-3 000 000
Assay	Galactomannan content not less than 75 %
Description	White to yellowish-white, nearly odourless powder
Identification	
Test for galactose	Passes test
Test for mannose	Passes test
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 than in guar gum. Guar gum shows close groups of round to pear shaped cells. Their contents are yellow to brown
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 2 mg/kg
Mercury	Not more than 1 mg/kg

▼B

Cadmium	Not more than 1 mg/kg
Ethanol and propan-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 strains of the guar plant, *Cyamopsis tetragonolobus* (L.) Taub. (family *Leguminosae*). Consists mainly of a high molecular weight hydrocolloidal polysaccharide composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as galactomannan. The gum may be partially hydrolysed by either heat treatment, mild acid or alcaline oxidative treatment for viscosity adjustment.
Einecs	232-536-0
Chemical name	
Chemical formula	
Molecular weight	50 000-8 000 000
Assay	Galactomannan content not less than 75 %
Description	A white to yellowish-white, nearly odourless powder
Identification	
Test for galactose	Passes test
Test for mannose	Passes test
Solubility	Soluble in cold water
Purity	
Loss on drying	Not more than 15 % (105 °C, 5 hours)
Ash	Not more than 5,5 % determined at 800 °C
Acid-insoluble matter	Not more than 7 %
Protein	Not more than 10 % (factor N x 6,25)
Starch	Not detectable by the following method: to a 1 in 10 solution of the sample add a few drops of iodine solution. (No blue colour is produced)
Organic peroxides	Not more than 0,7 meq active oxygen/kg sample
Furfural	Not more than 1 mg/kg
Pentachlorophenol	Not more than 0,01 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

E 413 TRAGACANTH

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

▼B

Einecs	232-252-5
Chemical name	
Chemical formula	
Molecular weight	Approximately 800 000
Assay	
Description	Unground Tragacanth gum occurs as flattened, lamellated, straight or curved fragments or as spirally twisted pieces 0,5-2,5 mm thick and up to 3 cm in length. It is white to pale yellow in colour but some pieces may have a red tinge. The pieces are horny in texture, with a short fracture. It is odourless and solutions have an insipid mucilaginous taste. Powdered tragacanth is white to pale yellow or pinkish brown (pale tan) in colour
Identification	
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	
Test for Karaya gum	Negative. 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 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Microbiological criteria	
Salmonella spp.	Absent in 10 g
Escherichia coli	Absent in 5 g

E 414 ACACIA GUM

Synonyms	Gum arabic
Definition	Acacia gum is a dried exudation obtained from the stems and branches of strains of *Acacia senegal* (L) Willdenow or closely related species of Acacia (family *Leguminosae*). It consists mainly of high molecular weight polysaccharides and their calcium, magnesium and potassium salts, which on hydrolysis yield arabinose, galactose, rhamnose and glucuronic acid
Einecs	232-519-5
Chemical name	
Chemical formula	
Molecular weight	Approximately 350 000
Assay	

▼B

Description	Unground acacia gum occurs as white or yellowish-white spheroidal tears of varying sizes or as angular fragments and is sometimes mixed with darker fragments. It is also available in the form of white to yellowish-white flakes, granules, powder or spray-dried material.
Identification	
Solubility	1 g dissolves in 2 ml of cold water forming a solution which flows readily and is acid to litmus, insoluble in ethanol
Purity	
Loss on drying	Not more than 17 % (105 °C, 5 hours) for granular and not more than 10 % (105 °C, 4 hours) for spray-dried material
Total ash	Not more than 4 %
Acid insoluble ash	Not more than 0,5 %
Acid insoluble matter	Not more than 1 %
Starch or dextrin	Boil a 1 in 50 solution of the gum and cool. To 5 ml add 1 drop of iodine solution. No bluish or reddish colours are produced
Tannin	To 10 ml of a 1 in 50 solution add about 0,1 ml of ferric chloride solution (9 g $FeCl_3.6H_2O$ made up to 100 ml with water). No blackish colouration or blackish precipitate is formed
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Hydrolysis products	Mannose, xylose and galacturonic acid are absent (determined by chromatography)
Microbiological criteria	
Salmonella spp.	Absent in 10 g
Escherichia coli	Absent in 5 g

E 415 XANTHAN GUM

Synonyms	
Definition	Xanthan gum is a high molecular weight polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with strains of *Xanthomonas campestris*, purified by recovery with ethanol or propan-2-ol, dried and milled. It contains D-glucose and D-mannose as the dominant hexose units, along with D-glucuronic acid and pyruvic acid, and is prepared as the sodium, potassium or calcium salt. Its solutions are neutral
Einecs	234-394-2
Chemical name	
Chemical formula	
Molecular weight	Approximately 1 000 000
Assay	Yields, on dried basis, not less than 4,2 % and not more than 5 % of CO_2 corresponding to between 91 % and 108 % of xanthan gum

▼B

Description	Cream-coloured powder
Identification	
Solubility	Soluble in water. Insoluble in ethanol
Purity	
Loss on drying	Not more than 15 % (105 °C, 2,5 hours)
Total ash	Not more than 16 % on the anhydrous basis determined at 650 °C after drying at 105 °C for four hours
Pyruvic acid	Not less than 1,5 %
Nitrogen	Not more than 1,5 %
Ethanol and propan-2-ol	Not more than 500 mg/kg singly or in combination
Lead	Not more than 2 mg/kg
Microbiological criteria	
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
Escherichia coli	Absent in 5 g
Salmonella spp.	Absent in 10 g
Xanthomonas campestris	Viable cells absent in 1 g

E 416 KARAYA-GUM

Synonyms	Katilo; Kadaya; Gum *sterculia*; *Sterculia*; Karaya, gum karaya; Kullo; Kuterra
Definition	Karaya gum is a dried exudation from the stems and branches of 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
Chemical name	
Chemical formula	
Molecular weight	
Assay	
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	
Solubility	Insoluble in ethanol
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)

▼B

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 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Microbiological criteria	
Salmonella spp.	Absent in 10 g
Escherichia coli	Absent in 5 g

E 417 TARA GUM

Definition	Tara gum is obtained by grinding the endosperm of the seeds of 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
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	A white to white-yellow odourless powder
Identification	
Solubility	Soluble in water, insoluble in ethanol
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 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

▼B

E 418 GELLAN GUM

Synonyms	
Definition	Gellan gum is a high molecular weight polysaccharide gum produced by a pure culture fermentation of a carbohydrate by strains of *Pseudomonas elodea*, purified by recovery with propan-2-ol or ethanol, 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
Chemical name	
Chemical formula	
Molecular weight	Approximately 500 000
Assay	Yields, on the dried basis, not less than 3,3 % and not more than 6,8 % of CO_2
Description	An off-white powder
Identification	
Solubility	Soluble in water, forming a viscous solution. Insoluble in ethanol
Purity	
Loss on drying	Not more than 15 % after drying (105 °C, 2,5 hours)
Nitrogen	Not more than 3 %
Propan-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
Microbiological criteria	
Total plate count	Not more than 10 000 colonies per gram
Yeast and moulds	Not more than 400 colonies per gram
Escherichia coli	Negative in 5 g
Salmonella spp.	Negative in 10 g

E 420 (i) SORBITOL

Synonyms	D-glucitol; D-sorbitol
Definition	Sorbitol is obtained by hydrogenation of D-glucose. It is mainly composed of D-sorbitol. According to the level of D-glucose, the part of the products which is not D-sorbitol is composed of related substances such as mannitol, iditol, maltitol.
Einecs	200-061-5
Chemical name	D-glucitol
Chemical formula	$C_6H_{14}O_6$

▼B

Molecular weight	182,2
Assay	Content not less than 97 % of total glycitols and not less than 91 % of D-sorbitol on dry weight basis (glycitols are compounds with the structural formula CH_2OH-$(CHOH)_n$-CH_2OH, where '*n*' is an integer).
Description	White hygroscopic powder, crystalline powder, flakes or granules.
Appearance of the aqueous solution:	The solution is clear.
Identification	
Solubility	Very soluble in water, slightly soluble in ethanol
Melting range	88 to 102 °C
Sorbitol monobenzylidene derivative	To 5 g of the sample add 7 ml of methanol, 1 ml of benzaldehyde and 1 ml of hydrochloric acid. Mix and shake in a mechanical shaker until crystals appear. Filter with the aid of suction, dissolve the crystals in 20 ml of boiling water containing 1 g of sodium bicarbonate, filter while hot, cool the filtrate, filter with suction, wash with 5 ml of methanol-water mixture (1 in 2) and dry in air. The crystals so obtained melt between 173 and 179 °C

▼M4

Purity	
Water content	Not more than 1,5 % (Karl Fischer Method)
Conductivity	Not more than 20 µS/cm (on 20 % dry solids solution) at temperature 20 °C
Reducing sugars	Not more than 0,3 % (expressed as glucose on dry weight basis)
Total sugars	Not more than 1 % (expressed as glucose on dry weight basis)
Nickel	Not more than 2 mg/kg (expressed on dry weight basis)
Arsenic	Not more than 3 mg/kg (expressed on dry weight basis)
Lead	Not more than 1 mg/kg (expressed on dry weight basis)

▼B

E 420 (ii) SORBITOL SYRUP

Synonyms	D-glucitol syrup
Definition	Sorbitol syrup formed by hydrogenation of glucose syrup is composed of D-sorbitol, D-mannitol and hydrogenated saccharides. The part of the product which is not D-sorbitol is composed mainly of hydrogenated oligosaccharides formed by the hydrogenation of glucose syrup used as raw material (in which case the syrup is non-crystallising) or mannitol. Minor quantities of glycitols where $n \leq 4$ may be present (glycitols are compounds with the structural formula CH_2OH-$(CHOH)_n$-CH_2OH, where '*n*' is an integer)
Einecs	270-337-8
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content not less than 69 % total solids and not less than 50 % of D-sorbitol on the anhydrous basis

▼B

Description	Clear and colourless aqueous solution
Identification	
Solubility	Miscible with water, with glycerol, and with propane-1,2-diol
Sorbitol monobenzylidene derivative	To 5 g of the sample add 7 ml of methanol, 1 ml of benzaldehyde and 1 ml of hydrochloric acid. Mix and shake in a mechanical shaker until crystals appear. Filter with the aid of suction, dissolve the crystals in 20 ml of boiling water containing 1 g of sodium bicarbonate, filter while hot. Cool the filtrate filter with suction, wash with 5 ml of methanol-water mixture (1 in 2) and dry in air. The crystals so obtained melt between 173 and 179 °C

▼M4

Purity	
Water content	Not more than 31 % (Karl Fischer Method)
Conductivity	Not more than 10 µS/cm (on the product as such) at temperature 20 °C
Reducing sugars	Not more than 0,3 % (expressed as glucose on dry weight basis)
Nickel	Not more than 2 mg/kg (expressed on dry weight basis)
Arsenic	Not more than 3 mg/kg (expressed on dry weight basis)
Lead	Not more than 1 mg/kg (expressed on dry weight basis)

E 421 (i) MANNITOL BY HYDROGENATION

▼B

(i) MANNITOL

Synonyms	D-mannitol

▼M4

Definition	Manufactured by catalytic hydrogenation of carbohydrate solutions containing glucose and/or fructose. The product contains min. 96 % mannitol. The part of the product which is not mannitol is mainly composed of sorbitol (2 % max), maltitol (2 % max) and isomalt (1,1 GPM (1-O-alpha-D-Glucopyranosyl-D-mannitol dehydrate): 2 % max and 1,6 GPS (6-O-alpha-D- Glucopyranosyl-D-Sorbitol): 2 % max). Unspecified impurities shall not represent more than 0,1 % of each.

▼B

Einecs	200-711-8
Chemical name	D-mannitol
Chemical formula	$C_6H_{14}O_6$
Molecular weight	182,2
Assay	Content not less than 96,0 % D-mannitol and not more than 102 % on the dried basis
Description	White, odourless, crystalline powder
Identification	
Solubility	Soluble in water, very slightly soluble in ethanol, practically insoluble in ether
Melting range	Between 164 and 169 °C
Infrared absorption spectrometry	Comparison with a reference standard e.g. EP or USP
Specific rotation	$[\alpha]_D^{20}$ + 23° to + 25° (borate solution)

▼B

pH	Between 5 and 8. Add 0,5 ml of a saturated solution of potassium chloride to 10 ml of a 10 % w/v solution of the sample, then measure the pH

▼M4

Purity

Water content	Not more than 0,5 % (Karl Fischer Method)
Conductivity	Not more than 20 µS/cm (on 20 % dry solids solution) at temperature 20 °C
Reducing sugars	Not more than 0,3 % (expressed as glucose)
Total sugars	Not more than 1 % (expressed as glucose)
Nickel	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg

▼B

(ii) MANNITOL MANUFACTURED BY FERMENTATION

Synonyms	D-mannitol
Definition	Manufactured by discontinuous fermentation under aerobic conditions using a conventional strain of the yeast *Zygosaccharomyces rouxii.* The part of the product which is not mannitol is mainly composed of sorbitol, maltitol and isomalt.
Einecs	200-711-8
Chemical name	D-mannitol
Chemical formula	$C_6H_{14}O_6$
Molecular weight	182,2
Assay	Not less than 99 % on the dried basis
Description	White, odourless crystalline powder
Identification	
Solubility	Soluble in water, very slightly soluble in ethanol, practically insoluble in ether
Melting range	Between 164 and 169 °C
Infrared absorption spectrometry	Comparison with a reference standard e.g. EP or USP
Specific rotation	$[\alpha]_D^{20}$ + 23° to + 25° (borate solution)
pH	Between 5 and 8 Add 0,5 ml of a saturated solution of potassium chloride to 10 ml of a 10 % w/v solution of the sample, then measure the pH

▼M4

Purity

Arabitol	Not more than 0,3 %
Water content	Not more than 0,5 % (Karl Fischer Method)
Conductivity	Not more than 20 µS/cm (on 20 % dry solids solution) at temperature 20 °C
Reducing sugars	Not more than 0,3 % (expressed as glucose)
Total sugars	Not more than 1 % (expressed as glucose)
Lead	Not more than 1 mg/kg

▼B

Microbiological criteria	
Aerobic mesophilic bacteria	Not more than 1 000 colonies per gram
Coliforms	Absent in 10 g
Salmonella spp.	Absent in 25 g
Escherichia coli	Absent in 10 g
Staphylococcus aureus	Absent in 10 g
Pseudomonas aeruginosa	Absent in 10 g
Moulds	Not more than 100 colonies per gram
Yeasts	Not more than 100 colonies per gram

▼M41

E 422 GLYCEROL

Synonyms	Glycerin; Glycerine
Definition	Glycerol is obtained only from vegetable oils and fats, either directly or from the crude glycerol obtained as a by-product of biodiesel production and undergoes purification processes that involve distillation, and other clean up steps to obtain refined glycerol.
Einecs	200-289-5
Chemical name	1,2,3-propanetriol; Glycerol; Trihydroxypropane
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	
Specific gravity (25 °C/25 °C)	Not less than 1,257
Refractive index	$[n]_D^{20}$ between 1,471 and 1,474
Purity	
Water content	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	Not more than 3 mg/kg
Fatty acids and esters	Not more than 0,1 % calculated as butyric acid
Chlorinated compounds	Not more than 30 mg/kg (as chlorine)
3-Monochloropropane-1,2-diol (3- MCPD)	Not more than 0,1 mg/kg
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg

▼M7

E 423 OCTENYL SUCCINIC ACID MODIFIED GUM ARABIC

Synonyms	Gum arabic hydrogen octenylbutandioate; Gum arabic hydrogen octenylsuccinate; OSA modified gum arabic; OSA modified gum acacia
Definition	Octenyl succinic acid modified gum arabic is produced by esterifying gum arabic (*Acacia seyal*), or gum arabic (*Acacia senegal*) in aqueous solution with not more than 3 % of octenyl succinic acid anhydride. It is subsequently spray dried.
Einecs	
Chemical name	
Chemical formula	
Weight Average Molecular Weight	Fraction (i): 3,105 g/mol Fraction (ii) 1,106 g/mol
Assay	
Description	Off-white to light tan, free flowing powder
Identification	
Viscosity of a 5 % solution at 25 °C	Not more than 30 mPa.s.
Precipitation reaction	Forms flocculent precipitate in lead sub-acetate solution (TS)
Solubility	Freely soluble in water; insoluble in ethanol
pH for a 5 % aqueous solution	3,5 to 6,5
Purity	
Loss on drying	Not more than 15 % (105 °C, 5 h)
Degree of esterification	Not more than 0,6 %
Total ash	Not more than 10 % (530 °C)
Acid-insoluble ash	Not more than 0,5 %
Water insoluble matter	Not more than 1,0 %
Test for starch or dextrine	Boil a 1 in 50 aqueous solution of the sample, add about 0,1 ml iodine TS. No bluish or reddish colour should be produced.
Test for tannin-bearing gums	To 10 ml of a 1 in 50 aqueous solution of the sample add about 0,1 ml ferric chloride TS. No blackish coloration or blackish precipitate should be formed.
Residual octenyl succinic acid	Not more than 0,3 %
Lead	Not more than 2 mg/kg
Microbiological criteria	
Salmonella sp.	Absent in 25 g
Escherichia coli	Absent in 1 g

▼B

E 425 (i) KONJAC GUM

Synonyms	
Definition	Konjac gum is a water-soluble hydrocolloid obtained from the Konjac flour by aqueous extraction. Konjac flour is the unpurified raw product from the root of the perennial plant *Amorphophallus konjac.* The main component of Konjac gum is the water-soluble high-molecular-weight polysaccharide glucomannan, which consists of D-mannose and D-glucose units at a molar ratio of 1,6:1,0, connected by β(1-4)-glycosidic bonds. Shorter side chains are attached through β(1-3)-glycosidic bonds, and acetyl groups occur at random at a ratio of about 1 group per 9 to 19 sugar units
Einecs	
Chemical name	
Chemical formula	
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	
Solubility	Dispersible in hot or cold water forming a highly viscous solution with a pH between 4,0 and 7,0
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
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
Purity	
Loss on drying	Not more than 12 % (105 °C, 5 hours)
Starch	Not more than 3 %
Protein	Not more than 3 % (factor N × 5,7)
Viscosity (1 % solution)	Not less than 3 $kgm^{-1}s^{-1}$ at 25 °C
Ether-soluble material	Not more than 0,1 %
Total ash	Not more than 5,0 % (800 °C, 3 to 4 hours)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Microbiological criteria	
Salmonella spp.	Absent in 12,5 g
Escherichia coli	Absent in 5 g

E 425 (ii) KONJAC GLUCOMANNAN

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

▼B

Einecs	
Chemical name	
Chemical formula	
Molecular weight	500 000 to 2 000 000
Assay	Total dietary fibre: not less than 95 % on a dry weight basis
Description	White to slightly brownish fine particle size, free flowing and odourless powder
Identification	
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
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
Purity	
Loss on drying	Not more than 8 % (105 °C, 3 hours)
Starch	Not more than 1 %
Viscosity (1 % solution)	Not less than 20 $kgm^{-1}s^{-1}$ at 25 °C
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 material	Not more than 2,0 %
Total ash	Not more than 2,0 % (800 °C, 3 to 4 hours)
Lead	Not more than 1 mg/kg
Microbiological criteria	
Salmonella spp.	Absent in 12,5 g
Escherichia coli	Absent in 5 g

E 426 SOYBEAN HEMICELLULOSE

Synonyms	
Definition	Soybean Hemicellulose is a refined water-soluble polysaccharide obtained from strain soybean fibre by hot water extraction. No organic precipitant shall be used other than ethanol
Einecs	
Chemical name	Water soluble soybean polysaccharides; Water soluble soybean fibre
Chemical formula	
Molecular weight	
Assay	Not less than 74 % carbohydrate

▼B

Description	Free flowing white or yellowish white powder
Identification	
Solubility	Soluble in hot and cold water without gel formation
pH	5,5 ± 1,5 (1 % solution)
Purity	
Loss on drying	Not more than 7 % (105 °C, 4 hours)
Protein	Not more than 14 %
Viscosity	Not more than 200 mPa.s (10 % solution)
Total ash	Not more than 9,5 % (600 °C, 4 hours)
Arsenic	Not more than 2 mg/kg
Ethanol	Not more than 2 %
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Microbiological criteria	
Total plate count	Not more than 3 000 colonies per gram
Yeast and moulds	Not more than 100 colonies per gram
Escherichia coli	Absent in 10 g

E 427 CASSIA GUM

Synonyms	
Definition	Cassia gum is the ground purified endosperm of the seeds of *Cassia tora* and *Cassia obtusifoli* (*Leguminosae*) containing less than 0,05 % of *Cassia occidentalis*. It consists mainly of high molecular weight polysaccharides composed primarily of a linear chain of 1,4-β-D-mannopyranose units linked with 1,6-α-D-galactopyranose units. The ratio of mannose to galactose is about 5:1. In the manufacture the seeds are dehusked and degermed by thermal mechanical treatment followed by milling and screening of the endosperm. The ground endosperm is further purified by extraction with propan-2-ol.
Assay	Not less than 75 % of Galactomannan
Description	Pale yellow to off-white, odourless powder
Identification	
Solubility	Insoluble in ethanol. Disperses well in cold water forming a colloidal solution.
Gel formation with borate	To an aqueous dispersion of the sample add sufficient sodium borate test solution (TS) to raise the pH to above 9; a gel is formed.
Gel formation with xanthan gum	Weigh 1,5 g of the sample and 1,5 g of xanthan gum and blend them. Add this blend (with rapid stirring) into 300 ml water at 80 °C in a 400 ml beaker. Stir until the mixture is dissolved and continue stirring for an extra 30 min after dissolution (maintain the temperature above 60 °C during the stirring process). Discontinue stirring and allow the mixture to cool at room temperature for at least 2 h.

▼B

	A firm, viscoelastic gel forms after the temperature drops below 40 °C, but no such gel forms in a 1 % control solution of cassia gum or xanthan gum alone prepared in a similar manner.
Viscosity	Less than 500 mPa.s (25 °C, 2h, 1 % solution) corresponding to an average molecular weight of 200 000-300 000 Da
Purity	
Acid insoluble matter	Not more than 2,0 %
pH	5,5-8 (1 % aqueous solution)
Crude fat	Not more than 1 %
Protein	Not more than 7 %
Total ash	Not more than 1,2 %
Loss on drying	Not more than 12 % (5h, 105 °C)
Total anthraquinones	Not more than 0,5 mg/kg(detection limit)
Solvent residues	Not more than 750 mg/kg Propan-2-ol
Lead	Not more than 1 mg/kg
Microbiological criteria	
Total plate count	Not more than 5 000 colony forming units per gram
Yeast and moulds	Not more than 100 colony forming units per gram
Salmonella spp.	Absent in 25 g
Escherichia coli	Absent in 1 g

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
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content not less than 97,5 % on the anhydrous basis
Description	Cream-coloured flakes or waxy solid at 25 °C with a faint odour
Identification	
Solubility	Soluble in water, ethanol, methanol and ethyl acetate. Insoluble in mineral oil
Congealing range	39-44 °C
Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
Purity	
Water content	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

▼M37

———————	

▼B

Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 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
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content not less than 70 % of oxyethylene groups, equivalent to not less than 97,3 % of polyoxyethylene (20) sorbitan monolaurate on the anhydrous basis
Description	A lemon to amber-coloured oily liquid at 25 °C with a faint characteristic odour
Identification	
Solubility	Soluble in water, ethanol, methanol, ethyl acetate and dioxane. Insoluble in mineral oil and petroleum ether
Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
Purity	
Water content	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 40 and not more than 50
Hydroxyl value	Not less than 96 and not more than 108
1,4-dioxane	Not more than 5 mg/kg

▼M37

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▼B

Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 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

▼B

Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content not less than 65 % of oxyethylene groups, equivalent to not less than 96,5 % of polyoxyethylene (20) sorbitan monooleate on the anhydrous basis
Description	A lemon to amber-coloured oily liquid at 25 °C with a faint characteristic odour
Identification	
Solubility	Soluble in water, ethanol, methanol, ethyl acetate and toluene. Insoluble in mineral oil and petroleum ether
Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
Purity	
Water content	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

▼M37

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Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 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
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content not less than 66 % of oxyethylene groups, equivalent to not less than 97 % of polyoxyethylene (20) sorbitan monopalmitate on the anhydrous basis
Description	A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour
Identification	
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 content	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

▼M37

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▼B

Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 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
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content not less than 65 % of oxyethylene groups, equivalent to not less than 97 % of polyoxyethylene (20) sorbitan monostearate on the anhydrous basis
Description	A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour
Identification	
Solubility	Soluble in water, ethyl acetate and toluene. Insoluble in mineral oil and vegetable oils
Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
Purity	
Water content	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

▼M37

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Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 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
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content not less than 46 % of oxyethylene groups, equivalent to not less than 96 % of polyoxyethylene (20) sorbitan tristearate on the anhydrous basis
Description	A tan-coloured, waxy solid at 25 °C with a faint characteristic odour
Identification	
Solubility	Dispersible in water. Soluble in mineral oil, vegetal oils, petroleum ether, acetone, ether, dioxane, ethanol and methanol
Congealing range	29-33 °C
Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
Purity	
Water content	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

▼M37

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▼B

Ethylene glycols (mono- and di-)	Not more than 0,25 %
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

▼B

E 440 (i) PECTIN

Synonyms	
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 strains of appropriate edible plant material, usually citrus fruits or apples. No organic precipitant shall be used other than methanol, ethanol and propan-2-ol
Einecs	232-553-0
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content not less than 65 % of galacturonic acid on the ash-free and anhydrous basis after washing with acid and alcohol
Description	White, light yellow, light grey or light brown powder
Identification	
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
Total insolubles	Not more than 3 %
Solvent residues	Not more than 1 % of free methanol, ethanol and propan-2-ol, singly or in combination, on the 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

E 440 (ii) AMIDATED PECTIN

Synonyms	
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 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 propan-2-ol
Einecs	
Chemical name	

▼B

Chemical formula	
Molecular weight	
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	
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
Total insolubles:	Not more than 3 %
Solvent residues	Not more than 1 % of methanol, ethanol and propan-2-ol, singly 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

E 442 AMMONIUM PHOSPHATIDES

Synonyms	Ammonium salts of phosphatidic acid; Mixed ammonium salts of phoshorylated glycerides
Definition	A mixture of the ammonium compounds of phosphatidic acids derived from edible fat and oil. One or two or three glyceride moieties may be attached to phosphorus. Moreover, two phosphorus esters may be linked together as phosphatidyl phosphatides
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	The phosphorus content is not less than 3 % and not more than 3,4 % by weight; the ammonium content is not less than 1,2 % and not more than 1,5 % (calculated as N)

▼M3

Description	Unctuous semi-solid to oily liquid

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Identification	
Solubility	Soluble in fats. Insoluble in water. Partially soluble in ethanol and in acetone
Test for glycerol	Passes test
Test fatty acids	Passes test

▼B

Test for phosphate	Passes test
Purity	
Petroleum ether insoluble matter	Not more than 2,5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 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
Chemical name	Sucrose diacetate hexaisobutyrate
Chemical formula	$C_{40}H_{62}O_{19}$
Molecular weight	832-856 (approximate), $C_{40}H_{62}O_{19}$: 846,9
Assay	Content not less than 98,8 % and not more than 101,9 % of $C_{40}H_{62}O_{19}$
Description	A pale straw-coloured liquid, clear and free of sediment and having a bland odour
Identification	
Solubility	Insoluble in water. Soluble in most organic solvents
Refractive index	$[n]_D^{40}$: 1,4492-1,4504
Specific gravity	$[d]^{25}{}_D$: 1,141-1,151
Purity	
Triacetin	Not more than 0,1 %
Acid value	Not more than 0,2
Saponification value	Not less than 524 and not more than 540
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 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)

▼B

	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
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	Hard, yellow to pale amber-coloured solid
Identification	
Solubility	Insoluble in water, soluble in acetone
Infrared absorption spectrum	Characteristic of the compound
Purity	
Specific gravity of solution	$[d]^{20}_{25}$ not less than 0,935 when determined in a 50 % solution in d-limonene (97 %, boiling point 175,5-176 °C, d^{20}_4: 0,84)
Ring and ball softening range	Between 82 °C and 90 °C
Acid value	Not less than 3 and not more than 9
Hydroxyl value	Not less than 15 and not more than 45
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Test for absence of tall oil rosin (sulphur test)	When sulphur-containing organic compounds are heated in the presence of sodium formate, the sulphur is converted to hydrogen sulphide which can readily be detected by the use of lead acetate paper. A positive test indicates the use of tall oil rosin instead of wood rosin

E 450 (i) DISODIUM DIPHOSPHATE

Synonyms	Disodium dihydrogen diphosphate; Disodium dihydrogen pyrophosphate; Sodium acid pyrophosphate; Disodium pyrophosphate
Definition	
Einecs	231-835-0
Chemical name	Disodium dihydrogen diphosphate
Chemical formula	$Na_2H_2P_2O_7$
Molecular weight	221,94
Assay	Content not less than 95 % of disodium diphosphate P_2O_5 content not less than 63,0 % and not more than 64,5 %

▼B

Description	White powder or grains
Identification	
Test for sodium	Passes test
Test for phosphate	Passes test
Solubility	Soluble in water
pH	Between 3,7 and 5,0 (1 % solution)
Purity	
Loss on drying	Not more than 0,5 % (105 °C, 4 hours)
Water insoluble matter	Not more than 1 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Aluminium	Not more than 200 mg/kg

E 450 (ii) TRISODIUM DIPHOSPHATE

Synonyms	Trisodium pyrophosphate; Trisodium monohydrogen diphosphate; Trisodium monohydrogen pyrophosphate; Trisodium diphosphate
Definition	
Einecs	238-735-6
Chemical name	
Chemical formula	Monohydrate: $Na_3HP_2O_7 \cdot H_2O$ Anhydrous: $Na_3HP_2O_7$
Molecular weight	Monohydrate: 261,95 Anhydrous: 243,93
Assay	Content not less than 95 % on the dried basis P_2O_5 content not less than 57 % and not more than 59 %
Description	White powder or grains, occurs anhydrous or as a monohydrate
Identification	
Test for sodium	Passes test
Test for phosphate	Passes test
Solubility	Soluble in water
pH	Between 6,7 and 7,5 (1 % solution)
Purity	
Loss on ignition	Not more than 4,5 % on the anhydrous compound (450-550 °C). Not more than 11,5 % on the monohydrate basis
Loss on drying	Not more than 0,5 % (105 °C, 4 hours) for anhydrous Not more than 1,0 % (105 °C, 4 hours) for monohdyrate

▼B

Water insoluble matter	Not more than 0,2 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 450 (iii) TETRASODIUM DIPHOSPHATE

Synonyms	Tetrasodium pyrophosphate; Tetrasodium disphosphate; Tetrasodium phosphate
Definition	
Einecs	231-767-1
Chemical name	Tetrasodium diphosphate
Chemical formula	Anhydrous: $Na_4P_2O_7$ Decahydrate: $Na_4P_2O_7 \cdot 10H_2O$
Molecular weight	Anhydrous: 265,94 Decahydrate: 446,09
Assay	Content not less than 95 % of $Na_4P_2O_7$ on the ignited basis P_2O_5 content not less than 52,5 % and not more than 54,0 %
Description	Colourless or white crystals, or a white crystalline or granular powder. The decahydrate effloresces slightly in dry air
Identification	
Test for sodium	Passes test
Test for phosphate	Passes test
Solubility	Soluble in water. Insoluble in ethanol
pH	Between 9,8 and 10,8 (1 % solution)
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 (105 °C, 4 hours then 550 °C, 30 minutes)
Water insoluble matter	Not more than 0,2 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 1mg/kg
Mercury	Not more than 1 mg/kg

E 450 (v) TETRAPOTASSIUM DIPHOSPHATE

Synonyms	Tetrapotassium pyrophosphate
Definition	
Einecs	230-785-7
Chemical name	Tetrapotassium diphosphate

▼B

Chemical formula	$K_4P_2O_7$
Molecular weight	330,34 (anhydrous)
Assay	Content not less than 95 % (800 °C for 0,5 hours) P_2O_5 content not less than 42,0 % and not more than 43,7 % on the anhydrous basis
Description	Colourless crystals or white, very hygroscopic powder
Identification	
Test for potassium	Passes test
Test for phosphate	Passes test
Solubility	Soluble in water, insoluble in ethanol
pH	Between 10,0 and 10,8 (1 % solution)
Purity	
Loss on ignition	Not more than 2 % (105 °C, 4 hours then 550 °C, 30 minutes)
Water insoluble matter	Not more than 0,2 %
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 450 (vi) DICALCIUM DIPHOSPHATE

Synonyms	Calcium pyrophosphate
Definition	
Einecs	232-221-5
Chemical name	Dicalcium diphosphate Dicalcium pyrophosphate
Chemical formula	$Ca_2P_2O_7$
Molecular weight	254,12
Assay	Content not less than 96 % P_2O_5 content not less than 55 % and not more than 56 %
Description	A fine, white, odourless powder
Identification	
Test for calcium	Passes test
Test for phosphate	Passes test
Solubility	Insoluble in water. Soluble in dilute hydrochloric and nitric acids
pH	Between 5,5 and 7,0 (10 % suspension in water)
Purity	
Loss on ignition	Not more than 1,5 % (800 °C ± 25 °C, 30 minutes
Fluoride	Not more than 50 mg/kg (expressed as fluorine)

▼B

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

E 450 (vii) CALCIUM DIHYDROGEN DIPHOSPHATE

Synonyms	Acid calcium pyrophosphate; Monocalcium dihydrogen pyrophosphate
Definition	
Einecs	238-933-2
Chemical name	Calcium dihydrogen diphosphate
Chemical formula	$CaH_2P_2O_7$
Molecular weight	215,97
Assay	Content not less than 90 % on the anhydrous basis P_2O_5 content not less than 61 % and not more than 66 %
Description	White crystals or powder
Identification	
Test for calcium	Passes test
Test for phosphate	Passes test
Purity	
Acid-insoluble matter	Not more than 0,4 %
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Aluminium	Not more than 800 mg/kg. This applies until 31 March 2015. Not more than 200 mg/kg. This applies from 1 April 2015.

▼M10

E 450 (ix) MAGNESIUM DIHYDROGEN DIPHOSPHATE

Synonyms	Acid magnesium pyrophosphate, monomagnesium dihydrogen pyrophosphate; magnesium diphosphate, magnesium pyrophosphate
Definition	Magnesium dihydrogen diphosphate is the acidic magnesium salt of diphosphoric acid. It is manufactured by adding an aqueous dispersion of magnesium hydroxide slowly to phosphoric acid, until a molar ratio about 1:2 between Mg and P is reached. The temperature is held under 60 °C during the reaction. About 0,1 % hydrogen peroxide is added to the reaction mixture and the slurry is then heated and milled.

▼M10

EINECS	244-016-8
Chemical name	Mono magnesium dihydrogen diphosphate
Chemical formula	$MgH_2P_2O_7$
Molecular Weight	200,25
Assay	P_2O_5 content not less than 68,0 % and not more than 70,5 % expressed as P_2O_5 MgO content not less than 18,0 % and not more than 20,5 % expressed as MgO
Description	White crystals or powder
Identification	
Solubility	Slightly soluble in water, practically insoluble in ethanol
Particle size:	The average particle size will deviate between 10 and 50 μm
Purity	
Loss on ignition	Not more than 12 % (800 °C, 0,5 hours)
Fluoride	Not more than 20 mg/kg (expressed as fluorine)
Aluminium	Not more than 50 mg/kg
Arsenic	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg.
Lead	Not more than 1 mg/kg

▼B

E 451 (i) PENTASODIUM TRIPHOSPHATE

Synonyms	Pentasodium tripolyphosphate; Sodium tripolyphosphate
Definition	
Einecs	231-838-7
Chemical name	Pentasodium triphosphate
Chemical formula	$Na_5O_{10}P_3 \cdot nH_2O$ (n = 0 or 6)
Molecular weight	367,86
Assay	Content not less than 85,0 % (anhydrous) or 65,0 % (hexahydrate) P_2O_5 content not less than 56 % and not more than 59 % (anhydrous) or not less than 43 % and not more than 45 % (hexahydrate)

▼B

Description	White, slightly hygroscopic granules or powder
Identification	
Solubility	Freely soluble in water. Insoluble in ethanol
Test for sodium	Passes test
Test for phosphate	Passes test
pH	Between 9,1 and 10,2 (1 % solution)
Purity	
Loss on drying	Anhydrous: Not more than 0,7 % (105 °C, 1 hour) Hexahydrate: Not more than 23,5 % (60 °C, 1 hour, then 105 °C, 4 hours)
Water insoluble matter	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 1 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 451 (ii) PENTAPOTASSIUM TRIPHOSPHATE

Synonyms	Pentapotassium tripolyphosphate; Potassium triphosphate; Potassium tripolyphosphate
Definition	
Einecs	237-574-9
Chemical name	Pentapotassium triphosphate; Pentapotassium tripolyphosphate
Chemical formula	$K_5O_{10}P_3$
Molecular weight	448,42
Assay	Content not less than 85 % on the anhydrous basis P_2O_5 content not less than 46,5 % and not more than 48 %
Description	White, very hygroscopic powder or granules
Identification	
Solubility	Very soluble in water
Test for potassium	Passes test
Test for phosphate	Passes test
pH	Between 9,2 and 10,5 (1 % solution)
Purity	
Loss on ignition	Not more than 0,4 % (105 °C, 4 hours, then 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 1 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg

▼B

Mercury	Not more than 1 mg/kg

E 452 (i) SODIUM POLYPHOSPHATE

I. SOLUBLE POLYPHOSPHATE

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

II. 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
Einecs	272-808-3

▼B

Chemical name	Sodium polyphosphate
Chemical formula	Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula $H_{(n+2)}P_nO_{(3n+1)}$ where 'n' is not less than 2
Molecular weight	$(102)_n$
Assay	P_2O_5 content not less than 68,7 % and not more than 70,0 %
Description	White crystalline powder
Identification	
Solubility	Insoluble in water, soluble in mineral acids and in solutions of potassium and ammonium (but not sodium) chlorides
Test for sodium	Passes test
Test for phosphate	Passes test
pH	About 6,5 (1 in 3 suspension in water)
Purity	
Fluoride	Not more than 10 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 452 (ii) POTASSIUM POLYPHOSPHATE

Synonyms	Potassium metaphosphate; Potassium polymetaphosphate; Kurrol salt
Definition	
Einecs	232-212-6
Chemical name	Potassium polyphosphate
Chemical formula	$(KPO_3)n$ Heterogenous mixtures of potassium salts of linear condensed polyphosphoric acids of general formula $H_{(n+2)}P_nO_{(3n+1)}$ where 'n' is not less than 2
Molecular weight	$(118)_n$
Assay	P_2O_5 content not less than 53,5 % and not more than 61,5 % on the ignited basis
Description	Fine white powder or crystals or colourless glassy platelets
Identification	
Solubility	1 g dissolves in 100 ml of a 1 in 25 solution of sodium acetate
Test for potassium	Passes test
Test for phosphate	Passes test
pH	Not more than 7,8 (1 % suspension)
Purity	
Loss on ignition	Not more than 2 % (105 °C, 4 hours then 550 °C, 30 minutes)
Cyclic phosphate	Not more than 8 % on P_2O_5 content

▼B

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

E 452(iii) SODIUM CALCIUM POLYPHOSPHATE

Synonyms	Sodium calcium polyphosphate, glassy
Definition	
Einecs	233-782-9
Chemical name	Sodium calcium polyphosphate
Chemical formula	$(NaPO_3)_n$ CaO where n is typically 5
Molecular weight	
Assay	P_2O_5 content not less than 61 % and not more than 69 % on the ignited basis
Description	White glassy crystals, spheres
Identification	
pH	Approximately 5 to 7 (1 % m/m slurry)
CaO content	7 % - 15 % m/m
Purity	
Fluoride	Not more than 10 mg/kg
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 452 (iv) CALCIUM POLYPHOSPHATE

Synonyms	Calcium metaphosphate; Calcium polymetaphosphate
Definition	
Einecs	236-769-6
Chemical name	Calcium polyphosphate
Chemical formula	$(CaP_2O_6)n$ Heterogenous mixtures of calcium salts of condensed polyphosphoric acids of general formula $H_{(n+2)}P_nO_{(n+1)}$ where ‘n’ is not less than 2
Molecular weight	$(198)_n$
Assay	P_2O_5 content not less than 71 % and not more than 73 % on the ignited basis
Description	Odourless, colourless crystals or white powder
Identification	
Solubility	Usually sparingly soluble in water. Soluble in acid medium
Test for calcium	Passes test

▼B

Test for phosphate	Passes test
CaO content	27 to 29,5 %
Purity	
Loss on ignition	Not more than 2 % (105 °C, 4 hours then 550 °C, 30 minutes)
Cyclic phosphate	Not more than 8 % (on P_2O_5 content)
Fluoride	Not more than 30 mg/kg (expressed as fluorine)
Arsenic	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

▼M23

E 456 POTASSIUM POLYASPARTATE

Synonyms	
Definition	Potassium polyaspartate is the potassium salt of polyaspartic acid, produced from L-aspartic acid and potassium hydroxide. The thermic process transforms the aspartic acid in polysuccinimide that is insoluble. Polysuccinimide is treated with potassium hydroxide allowing the opening of the ring and polymerisation of the units. The last step is the spray drying phase, which results in a light tan powder
CAS number	64723-18-8
Chemical name	L-aspartic acid, homopolymer, potassium salt
Chemical formula	$[C_4H_4NO_3K]_n$
Weight average molecular weight	Approximately 5 300 g/mol
Assay	Not less than 98 % on dry weight basis
Particle size	Not less than 45 μm (not more than 1 % in weight of particles of less than 45 μm)
Description	A light brown odourless powder
Identification	
Solubility	Very soluble in water and slightly soluble in organic solvents
pH	7,5-8,5 (40 % aqueous solution)
Purity	
Degree of substitutions	Not less than 91,5 % on dry weight basis
Loss on drying	Not more than 11 % (105 °C,12 hours)
Potassium hydroxide	Not more than 2 %
Aspartic acid	Not more than 1 %
Other impurities	Not more than 0,1 %
Arsenic	Not more than 2,5 mg/kg

▼M23

Lead	Not more than 1,5 mg/kg
Mercury	Not more than 0,5 mg/kg
Cadmium	Not more than 0,1 mg/kg

▼B

E 459 BETA-CYCLODEXTRIN

Synonyms	
Definition	Beta-cyclodextrin is a non-reducing cyclic saccharide consisting of seven α-1,4-linked D-glucopyranosyl units. The product is manufactured by the action of the enzyme cycloglycosyltransferase (CGTase) obtained from *Bacillus circulans, Paenibacillus macerans* or recombinant *Bacillus licheniformis* strain SJ1608 on partially hydrolysed starch
Einecs	231-493-2
Chemical name	Cycloheptaamylose
Chemical formula	$(C_6H_{10}O_5)_7$
Molecular weight	1 135
Assay	Content not less than 98,0 % of $(C_6H_{10}O_5)_7$ on an anhydrous basis
Description	Virtually odourless white or almost white crystalline solid
Appearance of the aqueous solution	Clear and colourless
Identification	
Solubility	Sparingly soluble in water; freely soluble in hot water; slightly soluble in ethanol
Specific rotation	$[\alpha]_D^{25}$ + 160° to + 164° (1 % solution)
pH value:	5,0-8,0 (1 % solution)
Purity	
Water content	Not more than 14 % (Karl Fischer method)
Other cyclodextrins	Not more than 2 % on an anhydrous basis
Solvent residues	Not more than 1 mg/kg of each of toluene and trichloroethylene
Sulphated ash	Not more than 0,1 %
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg

▼M8

E 460 (i) MICROCRYSTALLINE CELLULOSE, CELLULOSE GEL

Synonyms	

▼B

Definition	Microcrystalline cellulose is purified, partially depolymerised cellulose prepared by treating alpha-cellulose, obtained as a pulp from strains of fibrous plant material, with mineral acids. The degree of polymerisation is typically less than 400
Einecs	232-674-9

▼B

Chemical name	Cellulose
Chemical formula	$(C_6H_{10}O_5)_n$
Molecular weight	About 36 000
Assay	Not less than 97 % calculated as cellulose on the anhydrous basis
Particle size	Not less than 5 μm (not more than 10 % of particles of less than 5 μm)
Description	A fine white or almost white odourless powder
Identification	

▼M24

Solubility	Insoluble in water, ethanol, ether and dilute mineral acids. Practically insoluble or insoluble in sodium hydroxide solution (concentration: 50 g NaOH/L)

▼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
Infrared absorption spectroscopy	To be identified
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
pH	The pH of the supernatant liquid is between 5,0 and 7,5 (10 % suspension in water)
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 % (800 ± 25 °C)
Starch	Not detectable To 20 ml of the dispersion obtained in Identification, suspension test, add a few drops of iodine solution and mix. No purplish to blue or blue colour should be produced
Carboxyl groups	Not more than 1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 460 (ii) POWDERED CELLULOSE

Definition	Purified, mechanically disintegrated cellulose prepared by processing alpha-cellulose obtained as a pulp from strains of fibrous plant materials
Einecs	232-674-9
Chemical name	Cellulose; Linear polymer of 1:4 linked glucose residues
Chemical formula	$(C_6H_{10}O_5)_n$
Molecular weight	$(162)_n$ (n is predominantly 1 000 and greater)
Assay	Content not less than 92 %

▼B

Particle size	Not less than 5 μm (not more than 10 % of particles of less than 5 μm)
Description	A white, odourless powder
Identification	
Solubility	Insoluble in water, ethanol, ether and dilute mineral acids. Slightly soluble in sodium hydroxide solution
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
pH	The pH of the supernatant liquid is between 5,0 and 7,5 (10 % suspension in water)
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 % (800 ± 25 °C)
Starch	Not detectable To 20 ml of the dispersion obtained in Identification, suspension test, 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 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 461 METHYL CELLULOSE

Synonyms	Cellulose methyl ether
Definition	Methyl cellulose is cellulose obtained directly from strains of fibrous plant material and partially etherified with methyl groups
Einecs	
Chemical name	Methyl ether of cellulose
Chemical formula	The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$ where R_1, R_2, R_3 each may be one of the following: — H — CH_3 or — CH_2CH_3
Molecular weight	From about 20 000 to 380 000
Assay	Content not less than 25 % and not more than 33 % of methoxyl groups ($-OCH_3$) and not more than 5 % of hydroxyethoxyl groups ($-OCH_2CH_2OH$)

▼B

Description	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	
Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol, ether and chloroform. Soluble in glacial acetic acid
pH	Not less than 5,0 and not more than 8,0 (1 % colloidal solution)
Purity	
Loss on drying	Not more than 10 % (105 °C, 3 hours)
Sulphated ash	Not more than 1,5 % (800 ± 25 °C)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 462 ETHYL CELLULOSE

Synonyms	Cellulose ethyl ether
Definition	Ethyl cellulose is cellulose obtained directly from fibrous plant material and partially etherified with ethyl groups
Einecs	
Chemical name	Ethyl ether of cellulose
Chemical formula	The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)$ where R_1 and R_2 may be any of the following: — H — CH_2CH_3
Molecular weight	
Assay	Content not less than 44 % and not more than 50 % of ethoxyl groups ($-OC_2H_5$) on the dried basis (equivalent to not more than 2,6 ethoxyl groups per anhydroglucose unit)
Description	Slightly hygroscopic white to off-white, odourless and tasteless powder
Identification	
Solubility	Practically insoluble in water, in glycerol and in propane-1,2-diol but soluble in varying proportions in certain organic solvents depending upon the ethoxyl content. Ethyl cellulose containing less than 46 to 48 % of ethoxyl groups is freely soluble in tetrahydrofuran, in methyl acetate, in chloroform and in aromatic hydrocarbon ethanol mixtures. Ethyl cellulose containing 46 to 48 % or more of ethoxyl groups is freely soluble in ethanol, in methanol, in toluene, in chloroform and in ethyl acetate
Film forming test	Dissolve 5 g of the sample in 95 g of an 80:20 (w/w) mixture of toluene ethanol. A clear, stable, slightly yellow solution is formed. Pour a few ml of the solution onto a glass plate and allow the solvent to evaporate. A thick, tough, continuous, clear film remains. The film is flammable

▼B

pH	Neutral to litmus (1 % colloidal solution)
Purity	
Loss on drying	Not more than 3 % (105 °C, 2 hours)
Sulphated ash	Not more than 0,4 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 463 HYDROXYPROPYL CELLULOSE

Synonyms	Cellulose hydroxypropyl ether
Definition	Hydroxypropylcellulose is cellulose obtained directly from strains of fibrous plant material and partially etherified with hydroxypropyl groups
Einecs	
Chemical name	Hydroxypropyl ether of cellulose
Chemical formula	The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$, where R_1, R_2, R_3 each may be one of the following: — H — $CH_2CHOHCH_3$ — $CH_2CHO(CH_2CHOHCH_3)CH_3$ — $CH_2CHO[CH_2CHO(CH_2CHOHCH_3)CH_3]CH_3$
Molecular weight	From about 30 000 to 1 000 000
Assay	Content not more than 80,5 % of hydroxypropoxyl groups ($-OCH_2CHOHCH_3$) equivalent to not more than 4,6 hydroxypropyl groups per anhydroglucose unit on the anhydrous basis
Description	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	
Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Soluble in ethanol. Insoluble in ether
Gas chromatography	Determine the substituents by gas chromotography
pH	Not less than 5,0 and not more than 8,0 (1 % colloidal solution)
Purity	
Loss on drying	Not more than 10 % (105 °C, 3 hours)
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
Propylene chlorohydrins	Not more than 0,1 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

▼M27

E 463a LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE (L-HPC)

Synonyms	Cellulose hydroxypropyl ether, low substituted
Definition	L-HPC is a low-substituted poly (hydroxypropyl) ether of cellulose. L-HPC is manufactured by partial etherification of the anhydroglucose units of pure cellulose (wood pulp) with propylene oxide/hydroxypropyl groups. The resulting product is then purified, dried and milled to yield low-substituted hydroxypropyl cellulose. L-HPC contains not less than 5,0 % and not more than 16,0 % of hydroxypropoxy groups, calculated on the dried basis. L-HPC differs from hydroxypropyl cellulose (E 463) with respect to the degree of molar substitution with hydroxypropoxy groups of the glucose ring unit (0,2 for L-HPC vs 3,5 for E 463) of the cellulose backbone.
IUPAC name	Cellulose, 2-hydroxypropyl ether (low substituted)
CAS number	9004-64-2
Einecs number	
Chemical name	Hydroxypropyl ether of cellulose, low-substituted
Chemical formula	The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$ where R_1, R_2, R_3 each may be one of the following: — H — $CH_2CHOHCH_3$ — $CH_2CHO(CH_2CHOHCH_3)CH_3$ — $CH_2CHO[CH_2CHO(CH_2CHOHCH_3)CH_3]CH_3$
Molecular weight	From about 30 000 to 150 000 g/mol
Assay	The average number of hydroxypropoxy groups ($–OCH_2CHOHCH_3$) corresponds to 0,2 hydroxypropyl groups per anhydroglucose unit on the anhydrous basis
Particle size	by laser diffraction method — Not less than 45 μm (not more than 1 % in weight of particles of less than 45 μm) and not more than 65 μm by size-exclusion chromatography (SEC) — Average (D50) particle size between 47,3 μm and 50,3 μm; D90 value (90 % below given value) between 126,2 μm and 138 μm
Description	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	Passes test
Solubility	Insoluble in water; swelling in water. It dissolves in a solution of 10 % sodium hydroxide producing a viscous solution.
Assay	Determination of the degree of molar substitution by gas chromatography
pH	Not less than 5,0 and not more than 7,5 (1 % colloidal suspension)
Purity	
Loss on drying	Not more than 5,0 % (105 °C, 1 hour)
Residue on ignition	Not more than 0,8 % determined at 800 °C ± 25 °C
Propylene chlorohydrins	Not more than 0,1 mg/kg (on an anhydrous basis) (gas chromatography–mass spectrometry (GC–MS))
Arsenic	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 0,5 mg/kg
Cadmium	Not more than 0,15 mg/kg

▼B

E 464 HYDROXYPROPYL METHYL CELLULOSE

Synonyms	
Definition	Hydroxypropyl methyl cellulose is cellulose obtained directly from strains of fibrous plant material and partially etherified with methyl groups and containing a small degree of hydroxypropyl substitution
Einecs	
Chemical name	2-Hydroxypropyl ether of methylcellulose
Chemical formula	The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$, where R_1, R_2, R_3 each may be one of the following: — H — CH_3 — $CH_2CHOHCH_3$ — CH_2CHO ($CH_2CHOHCH_3$) CH_3 — $CH_2CHO[CH_2CHO$ ($CH_2CHOHCH_3$) $CH_3]CH_3$
Molecular weight	From about 13 000 to 200 000
Assay	Content not less than 19 % and not more than 30 % methoxyl groups ($-OCH_3$) and not less than 3 % and not more than 12 % hydroxypropoxyl groups ($-OCH_2CHOHCH_3$), on the anhydrous basis
Description	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	
Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol
Gas chromatography	Determine the substituents by gas chromatography
pH	Not less than 5,0 and not more than 8,0 (1 % colloidal solution)
Purity	
Loss on drying	Not more than 10 % (105 °C, 3 hours)
Sulphated ash	Not more than 1,5 % for products with viscosities of 50 mPa.s or above Not more than 3 % for products with viscosities below 50 mPa.s
Propylene chlorohydrins	Not more than 0,1 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

E 465 ETHYL METHYL CELLULOSE

Synonyms	Methylethylcellulose
Definition	Ethyl methyl cellulose is cellulose obtained directly from strains of fibrous plant material and partially etherified with methyl and ethyl groups
Einecs	
Chemical name	Ethyl methyl ether of cellulose

▼B

Chemical formula	The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$, where R_1, R_2, R_3 each may be one of the following: — H — CH_3 — 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 alkoxyl groups, calculated as methoxyl
Description	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	
Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Soluble in ethanol. Insoluble in ether
pH	Not less than 5,0 and not more than 8,0 (1 % colloidal solution)
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 %
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

▼M8

E 466 SODIUM CARBOXY METHYL CELLULOSE, CELLULOSE GUM

Synonyms	NaCMC; Sodium CMC
Definition	Sodium carboxy methyl cellulose is the partial sodium salt of a carboxymethyl ether of cellulose, the cellulose being obtained directly from strains of fibrous plant material

▼B

Einecs	
Chemical name	Sodium salt of the carboxymethyl ether of cellulose
Chemical formula	The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$, where R_1, R_2, R_3 each may be one of the following: — H — CH_2COONa — CH_2COOH
Molecular weight	Higher than approximately 17 000 (degree of polymerisation approximately 100)
Assay	Content on the anhydrous basis not less than 99,5 %
Description	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder

▼B

Identification	
Solubility	Yields a viscous colloidal solution with water. Insoluble in ethanol
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)
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)
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
pH	Not less than 5,0 and not more than 8,5 (1 % colloidal solution)
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)
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
Total glycolate	Not more than 0,4 %, calculated as sodium glycolate on the anhydrous basis
Sodium	Not more than 12,4 % on the anhydrous basis

E 468 CROSS-LINKED SODIUM CARBOXYMETHYLCELLULOSE, CROSS-LINKED CELLULOSE GUM

Synonyms	Cross-linked carboxymethyl cellulose; Cross-linked CMC; Cross-linked sodium CMC;
Definition	Cross-linked sodium carboxymethyl cellulose is the sodium salt of thermally cross-linked partly O-carboxymethylated cellulose
Einecs	
Chemical name	Sodium salt of the cross-linked carboxymethyl ether cellulose
Chemical formula	The polymers containing substituted anhydroglucose units with the general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$ where R_1, R_2 and R_3 may be any of the following: — H — CH_2COONa — CH_2COOH
Molecular weight	
Assay	

▼B

Description	Slightly hygroscopic, white to off white, odourless powder
Identification	
Precipitate formation	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
Colour reaction	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
Test for sodium	Passes test
pH	Not less than 5,0 and not more than 7,0 (1 % solution)
Purity	
Loss on drying	Not more than 6 % (105 °C, 3 hours)
Water soluble matter	Not more than 10 %
Degree of substitution	Not less than 0,2 and not more than 1,5 carboxymethyl groups per anhydroglucose unit
Sodium content	Not more than 12,4 % on anhydrous basis
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 469 ENZYMATICALLY HYDROLYSED CARBOXYMETHYLCELLULOSE, ENZYMATICALLY HYDROLISED CELLULOSE GUM

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*)
Einecs	
Chemical name	Carboxymethyl cellulose, sodium, partially enzymatically hydrolysed
Chemical formula	Sodium salts of polymers containing substituted anhydroglucose units with the general formula: $[C_6H_7O_2(OH)_x(OCH_2COONa)_y]_n$ where n is the degree of polymerisation x = 1,50 to 2,80 y = 0,2 to 1,50 x + y = 3,0 (y = degree of substitution)
Molecular 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

▼B

Description	White or slightly yellowish or greyish, odourless, slightly hygroscopic granular or fibrous powder
Identification	
Solubility	Soluble in water, insoluble in ethanol
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
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
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
Viscosity (60 % solids)	Not less than 2 500 $kgm^{-1}s^{-1}$ at 25 °C corresponding to an average molecule weight of 5 000 Da
pH	Not less than 6,0 and not more than 8,5 (1 % colloidal solution)
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
Sodium chloride and sodium glycolate	Not more than 0,5 % singly or in combination
Residual enzyme activity	Passes test. No change in viscosity of test solution occurs, which indicates hydrolysis of the sodium carboxymethyl cellulose
Lead	Not more than 3 mg/kg

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

Synonyms	
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.
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content on the anhydrous basis not less than 95 % (105 °C till a constant weight)
Description	White or creamy white light powders, flakes or semi-solids

▼B

Identification	
Solubility	Sodium and potassium salts: soluble in water and ethanol. Calcium salts: insoluble in water, ethanol and ether
Test for cations	Passes test
Test for fatty acids	Passes test
Purity	
Sodium	Not less than 9 % and not more than 14 % expressed as Na_2O
Potassium	Not less than 13 % and not more than 21,5 % expressed as K_2O
Calcium	Not less than 8,5 % and not more than 13 % expressed as CaO
Unsaponifiable matter	Not more than 2 %
Free fatty acids	Not more than 3 % estimated as oleic acid
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
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

Synonyms	
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
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content on the anhydrous basis not less than 95 % (105 °C till a constant weight)
Description	White or creamy-white light powders, flakes or semi-solids
Identification	
Solubility	Insoluble in water, partially soluble in ethanol and ether
Test for magnesium	Passes test
Test for fatty acids	Passes test
Purity	
Magnesium	Not less than 6,5 % and not more than 11 % expressed as MgO
Free alkali	Not more than 0,1 % expressed as MgO
Unsaponifiable matter	Not more than 2 %
Free fatty acids	Not more than 3 % estimated as oleic acid
Arsenic	Not more than 3 mg/kg

▼B

Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

▼M42

E 471 MONO- AND DIGLYCERIDES OF FATTY ACIDS

Synonyms	
Definition	Mono- and diglycerides of fatty acids consist of mixtures of glycerol mono-, di- and tri-esters of fatty acids occurring in food oils and fats. They may contain small amounts of free fatty acids and glycerol. Glycerol used for the manufacture of mono- and diglycerides of fatty acids should comply with the specifications for E 422. E 471 shall be produced from fats and oils complying with Union food safety requirements for edible fats and oils.
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content of mono- and di-esters: not less than 70 % Content of erucic acid, including erucic acid bound in the mono/diglyceride: Not more than 0,2 % (only if added to food for infants and young children) Not more than 0,5 % (for all uses except for foods intended for infants and young children)
Description	The product varies from a pale yellow to pale brown oily liquid to a white or slightly off-white hard waxy solid. The solids may be in the form of flakes, powders or small beads.
Identification	
Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyol
Test for glycerol	Passes test
Test for fatty acids	Passes test
Solubility	Insoluble in water, soluble in ethanol and toluene at 50 °C
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 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg
Sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters, expressed as 3-MCPD	Not more than 0,75 mg/kg (only if added to food for infants and young children) Not more than 2,5 mg/kg (for all uses except for foods intended for infants and young children)
Glycidyl esters of fatty acids, expressed as glycidol	From 30 July 2023 until 30 January 2024, not more than 5 mg/kg if added to food for infants and young children) and not more than 10 mg/kg for all other uses. From 30 January 2024, not more than 5 mg/kg for all uses.
Total glycerol	Not less than 16 % and not more than 33 %
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
Soap	—

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

▼B

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
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	Clear, mobile liquids to solids, from white to pale yellow in colour
Identification	
Test for glycerol	Passes test
Test for fatty acids	Passes test
Test for acetic acid	Passes test
Solubility	Insoluble in water. Soluble in ethanol
Purity	
Acids other than acetic and fatty acids	Less than 1 %
Free glycerol	Not more than 2 %
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
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

▼B

Description	Clear, mobile liquids to waxy solids of variable consistency, from white to pale yellow in colour
Identification	
Test for glycerol,	Passes test
Test for fatty acids	Passes test
Test for lactic acid	Passes test
Solubility	Insoluble in cold water but dispersible in hot water
Purity	
Acids other than lactic and fatty acids	Less than 1 %
Free glycerol	Not more than 2 %
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
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 % (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	Citrem; Citric acid esters of mono- and diglycerides; Citroglycerides; Mono- and diglycerides of fatty acids esterified with citric acid
Definition	Esters of glycerol with citric acid and fatty acids occurring in food oils and fats. They may contain small amounts of free glycerol, free fatty acids, free citric acid and free glycerides. They may be partially or wholly neutralised with sodium, potassium or calcium salts suitable for the purpose and authorised as food additives according to this Regulation.
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	Yellowish or light brown liquids to waxy solids or semi-solids
Identification	
Test for glycerol	Passes test

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Test for fatty acids	Passes test
Test for citric acid	Passes test
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	Less than 1 %
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	Non-neutralised products: not more than 0,5 % (800 ± 25 °C) Partially or wholly neutralised products: not more than 10 % (800 ± 25 °C)
Lead	Not more than 2 mg/kg
Acid value	Not more than 130

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

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

Synonyms	Tartaric acid esters of mono- and diglycerides; Mono- and diglycerides of fatty acids esterified with tartaric acid
Definition	Esters of glycerol with tartaric acid and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free tartaric acid and free glycerides
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	Sticky viscous yellowish liquids to hard yellow waxes
Identification	
Test for glycerol	Passes test
Test for fatty acids	Passes test
Test for tartaric acid	Passes test
Purity	
Acids other than tartaric and fatty acids	Less than 1,0 %
Free glycerol	Not more than 2 %
Total glycerol	Not less than 12 % and not more than 29 %
Arsenic	Not more than 3 mg/kg

▼B

Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 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 % (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
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	Sticky viscous liquids through a fat-like consistency to yellow waxes which hydrolyse in moist air to liberate acetic acid
Identification	
Test for glycerol	Passes test
Test for fatty acids	Passes test
Test for tartaric acid	Passes test
Test for acetic acid	Passes test
Purity	
Acids other than acetic, tartaric and fatty acids	Less than 1 %
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 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

▼B

Total tartaric acid	Not less than 10 % and not more than 40 %
Total acetic acid	Not less than 8 % and not more than 32 %
Acid value	Not less than 40 and not more than 130

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
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	Sticky liquids to solids, from white to pale-yellow in colour
Identification	
Test for glycerol	Passes test
Test for fatty acids	Passes test
Test for tartaric acid	Passes test
Test for acetic acid	Passes test
Purity	
Acids other than acetic, tartaric and fatty acids	Less than 1,0 %
Free glycerol	Not more than 2 %
Total glycerol	Not less than 12 % and not more than 27 %
Sulphated ash	Not more than 0,5 % (800 ± 25 °C)
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
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

▼B

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, ethyl and vinyl esters of food fatty acids (including lauric acid) or by extraction from sucroglycerides. No organic solvent other than dimethylsulphoxide, dimethylformamide, ethyl acetate, propan-2-ol, 2-methyl-1-propanol, propylene glycol, methyl ethyl ketone and supercritical carbondioxide may be used for their preparation. *p*-methoxy phenol can be used as a stabiliser during the manufacturing procedure.
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content not less than 80 %
Description	Stiff gels, soft solids or white to slightly greyish-white powders
Identification	
Test for sugar	Passes test
Test for fatty acids	Passes test
Solubility	Sparingly soluble in water, soluble in ethanol
Purity	
Sulphated ash	Not more than 2 % (800 ± 25 °C)
Free sugar	Not more than 5 %
Free fatty acids	Not more than 3 % estimated as oleic acid
p-methoxy-phenol	Not more than 100 µg/kg
Acetaldehyde	Not more than 50 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
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 Propan-2-ol Propylene glycol	Not more than 350 mg/kg, singly or in combination
Methyl ethyl ketone	Not more than 10 mg/kg

▼B

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 (including lauric acid) 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 propan-2-ol
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content not less than 40 % and not more than 60 % of sucrose fatty acid esters
Description	Soft solid masses, stiff gels or white to off-white powders
Identification	
Test for sugar	Passes test
Test for fatty acids	Passes test
Solubility	Insoluble in cold water, soluble in ethanol
Purity	
Sulphated ash	Not more than 2 % (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 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Methanol	Not more than 10 mg/kg
Dimethylformamide	Not more than 1 mg/kg
2-Methyl-1-propanol	Not more than 10 mg/kg, single or in combination
Cyclohexane	
Ethyl acetate	Not more than 350 mg/kg, single or in combination
Propan-2-ol	

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)

▼M41

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. The polyglycerol is produced from glycerol complying with the specifications for E 422.
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content of total fatty acid ester not less than 90 %
Description	Light yellow to amber, oily to very viscous liquids; light tan to medium brown, plastic or soft solids; and light tan to brown, hard, waxy solids
Identification	
Test for glycerol	Passes test
Test for polyglycerols	Passes test
Test for fatty acids	Passes test
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 % (800 ± 25 °C)
Acids other than fatty acids	Less than 1 %
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 0,1 mg/kg
Lead	Not more than 0,3 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg
Sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters, expressed as 3-MCPD	Not more than 2,5 mg/kg
Glycidyl fatty acid esters, expressed as glycidol	Not more than 10 mg/kg. This applies from 20 July 2023 until 20 January 2024. Not more than 5 mg/kg. This applies from 20 January 2024.
Erucic acid	Not more than 2 %

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

▼M41

Definition	Polyglycerol polyricinoleate is prepared by the esterification of polyglycerol with condensed castor oil fatty acids. Castor oil used for the production of polyglycerol polyricinoleate is free of ricin. The polyglycerol is produced from glycerol complying with the specifications for E 422.
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	Clear, highly viscous liquid
Identification	
Solubility	Insoluble in water and in ethanol; soluble in ether, hydrocarbons and halogenated hydrocarbons
Test for glycerol	Passes test
Test for polyglycerols	Passes test
Test for ricinoleic acid	Passes test
Refractive index	$[n]_D^{65}$ 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 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg
Sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD)	Not more than 2,5 mg/kg
Glycidyl fatty acid esters (expressed as glycidol)	Not more than 1 mg/kg

▼B

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
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content of total fatty acid ester not less than 85 %
Description	Clear liquids or waxy white flakes, beads or solids having a bland odour
Identification	
Test for propylene glycol	Passes test

▼B

Test for fatty acids	Passes test
Purity	
Sulphated ash	Not more than 0,5 % (800 ± 25 °C)
Acids other than fatty acids	Less than 1 %
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 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 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 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 deodorisation 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 strains of soya beans
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	Pale yellow to light brown a waxy or solid consistency
Identification	
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

▼B

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

E 481 SODIUM STEAROYL-2-LACTYLATE

Synonyms	Sodium stearoyl lactylate; Sodium stearoyl lactate
Definition	A mixture of the sodium salts of stearoyl lactylic acids and its polymers and minor amounts of sodium salts of other related acids, manufactured by the reaction of stearic acid and lactic acid. Other food fatty acids may also be present, free or esterified, due to their presence in the stearic acid used
Einecs	246-929-7
Chemical name	Sodium di-2-stearoyl lactate Sodium di(2-stearoyloxy)propionate
Chemical formula	$C_{21}H_{39}O_4Na$; $C_{19}H_{35}O_4Na$ (major components)
Molecular weight	
Assay	
Description	White or slightly yellowish powder or brittle solid with a characteristic odour
Identification	
Test for sodium	Passes test
Test for fatty acids	Passes test
Test for lactic acid	Passes test
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 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 482 CALCIUM STEAROYL-2-LACTYLATE

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

▼B

Einecs	227-335-7
Chemical name	Calcium di-2-stearoyl lactate Calcium di(2-stearoyloxy)propionate
Chemical formula	$C_{42}H_{78}O_8Ca$; $C_{38}H_{70}O_8Ca$, $C_{40}H_{74}O_8Ca$ (major components)
Molecular weight	
Assay	
Description	White or slightly yellowish powder or brittle solid with a characteristic odour
Identification	
Test for calcium	Passes test
Test for fatty acids	Passes test
Test for lactid acid	Passes test
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 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

▼M44

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▼B

E 491 SORBITAN MONOSTEARATE

Synonyms	
Definition	A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial stearic acid
Einecs	215-664-9
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters
Description	Light, cream- to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour
Identification	
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

▼M28

Identification test	By acid value, iodine value (not more than 4), gas chromatography

▼B

Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyol
Purity	
Water content	Not more than 2 % (Karl Fischer method)
Sulphated ash	Not more than 0,5 %
Acid value	Not more than 10
Saponification value	Not less than 147 and not more than 157

▼B

Hydroxyl value	Not less than 235 and not more than 260
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 492 SORBITAN TRISTEARATE

Synonyms	
Definition	A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial stearic acid
Einecs	247-891-4
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters
Description	Light, cream- to tan-coloured beads or flakes or hard, waxy solid with a slight odour
Identification	
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

▼M28

Identification test	By acid value, iodine value (not more than 4), gas chromatography

▼B

Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyol
Purity	
Water content	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 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 493 SORBITAN MONOLAURATE

Synonyms	
Definition	A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial lauric acid
Einecs	215-663-3
Chemical name	
Chemical formula	
Molecular weight	

▼B

Assay	Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters
Description	Amber-coloured oily viscous liquid, light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight odour
Identification	
Solubility	Dispersible in hot and cold water
Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyol
Purity	
Water content	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 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 494 SORBITAN MONOOLEATE

Synonyms	
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
Chemical name	
Chemical formula	
Molecular weight	
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	
Solubility	Soluble at temperatures above its melting point in ethanol, ether, ethyl acetate, aniline, toluene, dioxane, petroleum ether and carbon tetra-chloride. Insoluble in cold water, dispersible in warm water
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 content	Not more than 2 % (Karl Fischer method)
Sulphated ash	Not more than 0,5 %

▼B

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 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 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
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters
Description	Light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour
Identification	
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

▼M28

Identification test	By acid value, iodine value (not more than 4), gas chromatography

▼B

Infrared absorption spectrum	Characteristic of a partial fatty acid ester of polyol
Purity	
Water content	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 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

▼M5

E 499 STIGMASTEROL-RICH PLANT STEROLS

Synonyms	
Definition	Stigmasterol-rich plant sterols are derived from soybeans and are a chemically defined simple mixture that comprises not less than 95 % of plant sterols (stigmasterol, β-sitosterol, campesterol and brassicasterol), with stigmasterol representing not less than 85 % of the stigmasterol-rich plant sterols.

▼M5

Einecs	
Chemical name	
Stigmasterol	(3S,8S,9S,10R,13R,14S,17R)-17-(5-ethyl-6-methyl-hept-3-en-2-yl)-10,13-dimethyl-2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1Hcyclopenta[a]phenanthren-3-ol
β-Sitosterol	(3S,8S,9S,10R,13R,14S,17R)-17-[(2S,5S)-5-ethyl-6-methylheptan-2-yl]-10,13-dimethyl-2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1Hcyclopenta[a]phenanthren-3-ol
Campesterol	(3S,8S,9S,10R,13R,14S,17R)-17-(5,6-dimethylheptan-2-yl)-10,13-dimethyl-2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1Hcyclopenta[a]phenanthren-3-ol
Brassicasterol	(3S,8S,9S,10R,13R,14S,17R)-17-[(E,2R,5R)-5,6-dimethylhept-3-en-2-yl]-10,13-dimethyl-2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1Hcyclopenta[a]phenanthren-3-ol
Chemical formula	
Stigmasterol	$C_{29}H_{48}O$
β-Sitosterol	$C_{29}H_{50}O$
Campesterol	$C_{28}H_{48}O$
Brassicasterol	$C_{28}H_{46}O$
Molecular weight	
Stigmasterol	412,6 g/mol
β-Sitosterol	414,7 g/mol
Campesterol	400,6 g/mol
Brassicasterol	398,6 g/mol
Assay (products containing only free sterols and stanols)	Content not less than 95 % on a total free sterol/stanol basis on the anhydrous basis
Description	Free-flowing, white to off-white powders, pills or pastilles; colourless to pale yellow liquids
Identification	
Solubility	Practically insoluble in water. Phytosterols and phytostanols are soluble in acetone and ethyl acetate.
Stigmasterol content	Not less than 85 % (w/w)
Other plant sterols/stanols: either singularly or in combination including Brassicasterol, campestanol, campesterol, Δ-7-campesterol, cholesterol, chlerosterol, sitostanol and β-sitosterol.	Not more than 15 % (w/w)
Purity	
Total Ash	Not more than 0,1 %
Residual Solvents	Ethanol: Not more than 5 000 mg/kg
	Methanol: Not more than 50 mg/kg
Water content	Not more than 4 % (Karl Fischer method)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 1 mg/kg
Microbiological criteria	
Total plate count	Not more than 1 000 CFU/g
Yeasts	Not more than 100 CFU/g
Moulds	Not more than 100 CFU/g

▼M5

Escherichia coli	Not more than 10 CFU/g
Salmonella spp.	Absent in 25 g

▼B

E 500 (i) SODIUM CARBONATE

Synonyms	Soda ash
Definition	
Einecs	207-838-8
Chemical name	Sodium carbonate
Chemical formula	$Na_2CO_3 \cdot nH_2O$ (n = 0, 1 or 10)
Molecular weight	106,00 (anhydrous)
Assay	Content not less than 99 % of Na_2CO_3 on the anhydrous basis
Description	Colourless crystals or white, granular or crystalline powder The anhydrous form is hygroscopic, the decahydrate efflorescent
Identification	
Test for sodium	Passes test
Test for carbonate	Passes test
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 2 mg/kg
Mercury	Not more than 1 mg/kg

E 500 (ii) SODIUM HYDROGEN CARBONATE

Synonyms	Sodium bicarbonate; sodium acid carbonate; Bicarbonate of soda; Baking soda
Definition	
Einecs	205-633-8
Chemical name	Sodium hydrogen carbonate
Chemical formula	$NaHCO_3$
Molecular weight	84,01
Assay	Content not less than 99 % on the anhydrous basis
Description	Colourless or white crystalline masses or crystalline powder
Identification	
Test for sodium	Passes test
Test for carbonate	Passes test
pH	Between 8,0 and 8,6 (1 % solution)
Solubility	Soluble in water. Insoluble in ethanol
Purity	
Loss on drying	Not more than 0,25 % (over silica gel, 4 hours)
Ammonium salts	No odour of ammonia detectable after heating

▼B

Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 500 (iii) SODIUM SESQUICARBONATE

Synonyms	
Definition	
Einecs	208-580-9
Chemical name	Sodium monohydrogen dicarbonate
Chemical formula	$Na_2CO_3 \cdot NaHCO_3 \cdot 2H_2O$
Molecular weight	226,03
Assay	Content between 35,0 % and 38,6 % of $NaHCO_3$ and between 46,4 % and 50,0 % of Na_2CO_3
Description	White flakes, crystals or crystalline powder
Identification	
Test for sodium	Passes test
Test for carbonate	Passes test
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 2 mg/kg
Mercury	Not more than 1 mg/kg

E 501 (i) POTASSIUM CARBONATE

Synonyms	
Definition	
Einecs	209-529-3
Chemical name	Potassium carbonate
Chemical formula	$K_2CO_3 \cdot nH_2O$ (n = 0 or 1,5)
Molecular weight	138,21 (anhydrous)
Assay	Content not less than 99,0 % on the anhydrous basis
Description	White, very deliquescent powder. The hydrate occurs as small, white, translucent crystals or granules
Identification	
Test for potassium	Passes test
Test for carbonate	Passes test
Solubility	Very soluble in water. Insoluble in ethanol
Purity	
Loss on drying	Not more than 5 % (anhydrous) or 18 % (hydrate) (180 °C, 4 hours)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg

▼B

Mercury	Not more than 1 mg/kg

E 501 (ii) POTASSIUM HYDROGEN CARBONATE

Synonyms	Potassium bicarbonate; Acid potassium carbonate
Definition	
Einecs	206-059-0
Chemical name	Potassium hydrogen carbonate
Chemical formula	$KHCO_3$
Molecular weight	100,11
Assay	Content not less than 99,0 % and not more than 101,0 % $KHCO_3$ on the anhydrous basis
Description	Colourless crystals or white powder or granules
Identification	
Test for potassium	Passes test
Test for carbonate	Passes test
Solubility	Freely soluble in water. Insoluble in ethanol
Purity	
Loss on drying	Not more than 0,25 % (over silica gel, 4 hours)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 503 (i) AMMONIUM CARBONATE

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

▼B

Purity	
Non-volatile matter	Not more than 500 mg/kg
Chlorides	Not more than 30 mg/kg
Sulphate	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 503 (ii) AMMONIUM HYDROGEN CARBONATE

Synonyms	Ammonium bicarbonate
Definition	
Einecs	213-911-5
Chemical name	Ammonium hydrogen carbonate
Chemical formula	CH_5NO_3
Molecular weight	79,06
Assay	Content not less than 99,0 %
Description	White crystals or crystalline powder
Identification	
Test for ammonium	Passes test
Test for carbonate	Passes test
pH	About 8,0 (5 % solution)
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 2 mg/kg
Mercury	Not more than 1 mg/kg

E 504 (i) MAGNESIUM CARBONATE

Synonyms	Hydromagnesite
Definition	Magnesium carbonate is a basic hydrated or a monohydrated magnesium carbonate or a mixture of the two.
Einecs	208-915-9
Chemical name	Magnesium carbonate
Chemical formula	$MgCO_3 \cdot nH_2O$
Assay	Not less than 24 % and not more than 26,4 % of Mg
Description	Odourless, light, white friable masses or as a bulky white powder

▼B

Identification	
Test for magnesium	Passes test
Test for carbonate	Passes test
Solubility	Practically insoluble both in water or ethanol
Purity	
Acid insoluble matter	Not more than 0,05 %
Water soluble matter	Not more than 1,0 %
Calcium	Not more than 0,4 %
Arsenic	Not more than 4 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 504 (ii) MAGNESIUM HYDROXIDE CARBONATE

Synonyms	Magnesium hydrogen carbonate; Magnesium subcarbonate (light or heavy); Hydrated basic magnesium carbonate; Magnesium carbonate hydroxide
Definition	
Einecs	235-192-7
Chemical name	Magnesium carbonate hydroxide hydrated
Chemical formula	$4MgCO_3Mg(OH)_2 \cdot 5H_2O$
Molecular weight	485
Assay	Mg content not less than 40,0 % and not more than 45,0 % calculated as MgO
Description	Light, white friable mass or bulky white powder
Identification	
Test for magnesium	Passes test
Test for carbonate	Passes test
Solubility	Practically insoluble in water. Insoluble in ethanol
Purity	
Acid insoluble matter	Not more than 0,05 %
Water soluble matter	Not more than 1,0 %
Calcium	Not more than 1,0 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 507 HYDROCHLORIC ACID

Synonyms	Hydrogen chloride; Muriatic acid
Definition	
Einecs	231-595-7
Chemical name	Hydrochloric acid

▼B

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	
Test for acid	Passes test
Test for chloride	Passes test
Solubility	Soluble in water and in ethanol
Purity	
Total organic compounds	Total organic compounds (non-fluorine containing): not more than 5 mg/kg Benzene: not more than 0,05 mg/kg Fluorinated compounds (total): not more than 25 mg/kg
Non-volatile matter	Not more than 0,5 %
Reducing substances	Not more than 70 mg/kg (as SO_2)
Oxidising substances	Not more than 30 mg/kg (as Cl_2)
Sulphate	Not more than 0,5 %
Iron	Not more than 5 mg/kg
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 508 POTASSIUM CHLORIDE

Synonyms	Sylvine; Sylvite
Definition	
Einecs	231-211-8
Chemical name	Potassium chloride
Chemical formula	KCl
Molecular weight	74,56
Assay	Content not less than 99 % on the dried basis
Description	Colourless, elongated, prismatic or cubital crystals or white granular powder. Odourless
Identification	
Solubility	Freely soluble in water. Insoluble in ethanol
Test for potassium	Passes test
Test for chloride	Passes test
Purity	
Loss on drying	Not more than 1 % (105 °C, 2 hours)
Test for sodium	Negative

▼B

Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 509 CALCIUM CHLORIDE

Synonyms	
Definition	
Einecs	233-140-8
Chemical name	Calcium chloride
Chemical formula	$CaCl_2 \cdot nH_2O$ (n = 0,2 or 6)
Molecular weight	110,99 (anhydrous), 147,02 (dihydrate), 219,08 (hexahydrate)
Assay	Content not less than 93,0 % on the anhydrous basis
Description	White, odourless, hygroscopic powder or deliquescent crystals
Identification	
Test for calcium	Passes test
Test for chloride	Passes test
Solubility	Soluble in water and in ethanol
Purity	
Magnesium and alkali salts	Not more than 5 % on the dried basis (calculated as sulphates)
Fluoride	Not more than 40 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 511 MAGNESIUM CHLORIDE

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

▼B

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

E 512 STANNOUS CHLORIDE

Synonyms	Tin chloride; Tin dichloride
Definition	
Einecs	231-868-0
Chemical name	Stannous chloride dihydrate
Chemical formula	$SnCl_2 \cdot 2H_2O$
Molecular weight	225,63
Assay	Content not less than 98,0 %
Description	Colourless or white crystals May have a slight odour of hydrochloric acid
Identification	
Test for tin (II)	Passes test
Test for chloride	Passes test
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 2 mg/kg

E 513 SULPHURIC ACID

Synonyms	Oil of vitriol; Dihydrogen sulphate
Definition	
Einecs	231-639-5
Chemical name	Sulphuric acid
Chemical formula	H_2SO_4
Molecular weight	98,07
Assay	Sulphuric acid is commercially available in varying concentrations. The concentrated form contains not less than 96,0 %
Description	Clear, colourless or slightly brown, very corrosive oily liquid
Identification	
Test for acid	Passes test
Test for sulphate	Passes test
Solubility	Miscible with water, with generation of much heat, also with ethanol

▼B

Purity	
Ash	Not more than 0,02 %
Reducing matter	Not more than 40 mg/kg (as SO_2)
Nitrate	Not more than 10 mg/kg (on H_2SO_4 basis)
Chloride	Not more than 50 mg/kg
Iron	Not more than 20 mg/kg
Selenium	Not more than 20 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 514 (i) SODIUM SULPHATE

Synonyms	
Definition	
Einecs	
Chemical name	Sodium sulphate
Chemical formula	$Na_2SO_4 \cdot nH_2O$ (n = 0 or 10)
Molecular weight	142,04 (anhydrous) 322,04 (decahydrate)
Assay	Content not less than 99,0 % on the anhydrous basis
Description	Colourless crystals or a fine, white, crystalline powder The decahydrate is efflorescent
Identification	
Test for sodium	Passes test
Test for sulphate	Passes test
pH	Neutral or slightly alkaline to litmus paper (5 % solution)
Purity	
Loss on drying	Not more than 1,0 % (anhydrous) or not more than 57 % (decahydrate) at 130 °C
Selenium	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 514 (ii) SODIUM HYDROGEN SULPHATE

Synonyms	Acid sodium sulphate; Sodium bisulphate; Nitre cake
Definition	
Chemical name	Sodium hydrogen sulphate
Chemical formula	$NaHSO_4$
Molecular weight	120,06

▼B

Assay	Content not less than 95,2 %
Description	White, odourless crystals or granules
Identification	
Test for sodium	Passes test
Test for sulphate	Passes test
pH	Solutions are strongly acidic
Purity	
Loss on drying	Not more than 0,8 %
Water insoluble matter	Not more than 0,05 %
Selenium	Not more than 30 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 515 (i) POTASSIUM SULPHATE

Synonyms	
Definition	
Einecs	
Chemical name	Potassium sulphate
Chemical formula	K_2SO_4
Molecular weight	174,25
Assay	Content not less than 99,0 %
Description	Colourless or white crystals or crystalline powder
Identification	
Test for potassium	Passes test
Test for sulphate	Passes test
pH	Between 5,5 and 8,5 (5 % solution)
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 2 mg/kg
Mercury	Not more than 1 mg/kg

E 515 (ii) POTASSIUM HYDROGEN SULPHATE

Synonyms	Potassium bisulphate; Potassium acid sulphate
Definition	
Einecs	
Chemical name	Potassium hydrogen sulphate
Chemical formula	$KHSO_4$

▼B

Molecular weight	136,17
Assay	Content not less than 99 %
Description	White deliquescent crystals, pieces or granules
Identification	
Melting point	197 °C
Test for potassium	Passes test
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 2 mg/kg
Mercury	Not more than 1 mg/kg

E 516 CALCIUM SULPHATE

Synonyms	Gypsum; Selenite; Anhydrite
Definition	
Einecs	231-900-3
Chemical name	Calcium sulphate
Chemical formula	$CaSO_4 \cdot nH_2O$ (n = 0 or 2)
Molecular weight	136,14 (anhydrous), 172,18 (dihydrate)
Assay	Content not less than 99,0 % on the anhydrous basis
Description	Fine, white to slightly yellowish-white odourless powder
Identification	
Test for calcium	Passes test
Test for sulphate	Passes test
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 % (250 °C, constant weight)
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 2 mg/kg
Mercury	Not more than 1 mg/kg

E 517 AMMONIUM SULPHATE

Synonyms	
Definition	
Einecs	231-984-1
Chemical name	Ammonium sulphate

▼B

Chemical formula	$(NH_4)_2SO_4$
Molecular weight	132,14
Assay	Content not less than 99,0 % and not more than 100,5 %
Description	White powder, shining plates or crystalline fragments
Identification	
Test for ammonium	Passes test
Test for sulphate	Passes test
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 3 mg/kg

E 520 ALUMINIUM SULPHATE

Synonyms	Alum
Definition	
Einecs	
Chemical name	Aluminium sulphate
Chemical formula	$Al_2(SO_4)_3$
Molecular weight	342,13
Assay	Content not less than 99,5 % on the ignited basis
Description	White powder, shining plates or crystalline fragments
Identification	
Test for aluminium	Passes test
Test for sulphate	Passes test
pH	2,9 or above (5 % solution)
Solubility	Freely soluble in water, insoluble in ethanol
Purity	
Loss on ignition	Not more than 5 % (500 °C, 3 hours)
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 5 mg/kg
Mercury	Not more than 1 mg/kg

E 521 ALUMINIUM SODIUM SULPHATE

Synonyms	Soda alum; Sodium alum
Definition	
Einecs	233-277-3

▼B

Chemical name	Aluminium sodium sulphate
Chemical formula	$AlNa(SO_4)_2 \cdot nH_2O$ (n = 0 or 12)
Molecular weight	242,09 (anhydrous)
Assay	Content on the anhydrous basis not less than 96,5 % (anhydrous) and 99,5 % (dodecahydrate)
Description	Transparent crystals or white crystalline powder
Identification	
Test for aluminium	Passes test
Test for sodium	Passes test
Test for sulphate	Passes test
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, 16 hours) Dodecahydrate: not more than 47,2 % (50-55 °C, 1 hour then 200 °C, 16 hours)
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	
Einecs	233-141-3
Chemical name	Aluminium potassium sulphate dodecahydrate
Chemical formula	$AlK(SO_4)_2 \cdot 12\ H_2O$
Molecular weight	474,38
Assay	Content not less than 99,5 %
Description	Large, transparent crystals or white crystalline powder
Identification	
Test for aluminium	Passes test
Test for potassium	Passes test
Test for sulphate	Passes test
pH	Between 3,0 and 4,0 (10 % solution)
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

▼B

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	
Einecs	232-055-3
Chemical name	Aluminium ammonium sulphate
Chemical formula	$AlNH_4(SO_4)_2 \cdot 12\ H_2O$
Molecular weight	453,32
Assay	Content not less than 99,5 %
Description	Large, colourless crystals or white powder
Identification	
Test for aluminium	Passes test
Test for ammonium	Passes test
Test for sulphate	Passes test
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 3 mg/kg
Mercury	Not more than 1 mg/kg

E 524 SODIUM HYDROXIDE

Synonyms	Caustic soda; Lye
Definition	
Einecs	215-185-5
Chemical name	Sodium hydroxide
Chemical formula	NaOH
Molecular weight	40,0
Assay	Content of solid forms not less than 98,0 % of total alkali (as NaOH). Content of solutions accordingly, based on the stated or labelled percentage of NaOH
Description	White or nearly white pellets, flakes, sticks, fused masses or other forms. Solutions are clear or slightly turbid, colourless or slightly coloured, strongly caustic and hygroscopic and when exposed to the air they absorb carbon dioxide, forming sodium carbonate

▼B

Identification	
Test for sodium	Passes test
pH	Strongly alkaline (1 % solution)
Solubility	Very soluble in water. Freely soluble in ethanol
Purity	
Water insoluble and organic matter	A 5 % solution is completely clear and colourless to slightly coloured
Carbonate	Not more than 0,5 % (as Na_2CO_3)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 0,5 mg/kg
Mercury	Not more than 1 mg/kg

E 525 POTASSIUM HYDROXIDE

Synonyms	Caustic potash
Definition	
Einecs	215-181-3
Chemical name	Potassium hydroxide
Chemical formula	KOH
Molecular weight	56,11
Assay	Content not less than 85,0 % of alkali calculated as KOH
Description	White or nearly white pellets, flakes, sticks, fused masses or other forms
Identification	
Test for potassium	Passes test
pH	Strongly alkaline (1 % solution)
Solubility	Very soluble in water. Freely soluble in ethanol
Purity	
Water insoluble matter	A 5 % solution is completely clear and colourless
Carbonate	Not more than 3,5 % (as K_2CO_3)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 526 CALCIUM HYDROXIDE

Synonyms	Slaked lime; Hydrated lime
Definition	
Einecs	215-137-3
Chemical name	Calcium hydroxide
Chemical formula	$Ca(OH)_2$
Molecular weight	74,09

▼B

Assay	Content not less than 92,0 %
Description	White powder
Identification	
Test for alkali	Passes test
Test for calcium	Passes test
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 2,7 %
Barium	Not more than 300 mg/kg
Fluoride	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg

E 527 AMMONIUM HYDROXIDE

Synonyms	Aqua ammonia; Strong ammonia solution
Definition	
Einecs	
Chemical name	Ammonium hydroxide
Chemical formula	NH_4OH
Molecular weight	35,05
Assay	Content not less than 27 % of NH_3
Description	Clear, colourless solution, having an exceedingly pungent, characteristic odour
Identification	
Test for ammonia	Passes test
Purity	
Non-volatile matter	Not more than 0,02 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg

E 528 MAGNESIUM HYDROXIDE

Synonyms	
Definition	
Einecs	
Chemical name	Magnesium hydroxide
Chemical formula	$Mg(OH)_2$
Molecular weight	58,32
Assay	Content not less than 95,0 % on the anhydrous basis
Description	Odourless, white bulky powder

▼B

Identification	
Test for magnesium	Passes test
Test for alkali	Passes test
Solubility	Practically insoluble in water and in ethanol
Purity	
Loss on drying	Not more than 2,0 % (105 °C, 2 hours)
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 2 mg/kg

E 529 CALCIUM OXIDE

Synonyms	Burnt lime
Definition	
Einecs	215-138-9
Chemical name	Calcium oxide
Chemical formula	CaO
Molecular weight	56,08
Assay	Content not less than 95,0 % on the ignited basis
Description	Odourless, hard, white or greyish white masses of granules, or white to greyish powder
Identification	
Test for alkali	Passes test
Test for calcium	Passes test
Reaction with water	Heat is generated on moistening the sample with water
Solubility	Slightly soluble in water. Insoluble in ethanol. Soluble in glycerol
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 3,6 %
Fluoride	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg

E 530 MAGNESIUM OXIDE

Synonyms	
Definition	
Einecs	215-171-9
Chemical name	Magnesium oxide

▼B

Chemical formula	MgO
Molecular weight	40,31
Assay	Content not less than 98,0 % on the ignited basis
Description	A very bulky, white powder known as light magnesium oxide or a relative dense, white powder known as heavy magnesium oxide. 5 g of light magnesium oxide occupy a volume of at least 33 ml, while 5 g of heavy magnesium oxide occupy a volume of not more than 20 ml
Identification	
Test for alkali	Passes test
Test for magnesium	Passes test
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 2 mg/kg

▼M20

E 534 IRON TARTRATE

Synonyms	Iron *meso*-tartrate; complexation product of sodium tartrate with iron(III) chloride
Definition	Iron tartrate is manufactured by the isomerisation of L-tartrate to an equilibrium mixture of D-, L- and *meso*-tartrate followed by addition of iron(III) chloride.
CAS number	1280193-05-9
Chemical name	Iron(III) complexation product of D(+)-, L(-)- and meso-2,3 dihydroxybutanedioic acids
Chemical formula	$Fe(OH)_2$ $C_4H_4O_6Na$
Molecular weight	261,93
Assay	
meso-tartrate	> 28 %, expressed as the anion on dry basis
D(-)- and L(+)-tartrate	> 10 %, expressed as the anion on dry basis
Iron(III)	> 8 %, expressed as the anion on dry basis
Description	Dark green aqueous solution typically comprising ca 35 % by weight complexation products
Identification	Highly soluble in water
	Positive tests for tartrate and iron
	pH of a 35 % aqueous solution of complexation products between 3,5 and 3,9
Purity	
Chloride	Not more than 25 %
Sodium	Not more than 23 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Oxalate	Not more than 1,5 % expressed as oxalate on dry basis

▼B

E 535 SODIUM FERROCYANIDE

Synonyms	Yellow prussiate of soda; Sodium hexacyanoferrate
Definition	
Einecs	237-081-9
Chemical name	Sodium ferrocyanide
Chemical formula	$Na_4Fe(CN)_6 \cdot 10\ H_2O$
Molecular weight	484,1
Assay	Content not less than 99,0 %
Description	Yellow crystals or crystalline powder
Identification	
Test for sodium	Passes test
Test for ferrocyanide	Passes test
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 536 POTASSIUM FERROCYANIDE

Synonyms	Yellow prussiate of potash; Potassium hexacyanoferrate
Definition	
Einecs	237-722-2
Chemical name	Potassium ferrocyanide
Chemical formula	$K_4Fe(CN)_6 \cdot 3\ H_2O$
Molecular weight	422,4
Assay	Content not less than 99,0 %
Description	Lemon yellow crystals
Identification	
Test for potassium	Passes test
Test for ferrocyanide	Passes test
Purity	
Free moisture	Not more than 1,0 %
Water insoluble matter	Not more than 0,03 %
Chloride	Not more than 0,2 %

▼B

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	
Einecs	215-476-7
Chemical name	Calcium ferrocyanide
Chemical formula	$Ca_2Fe(CN)_6 \cdot 12H_2O$
Molecular weight	508,3
Assay	Content not less than 99,0 %
Description	Yellow crystals or crystalline powder
Identification	
Test for calcium	Passes test
Test for ferrocyanide	Passes test
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 541 SODIUM ALUMINIUM PHOSPHATE, ACIDIC

Synonyms	SALP
Definition	
Einecs	232-090-4
Chemical name	Sodium trialuminium tetradecahydrogen octaphosphate tetrahydrate (A); Trisodium dialuminium pentadecahydrogen octaphosphate (B)
Chemical formula	$NaAl_3H_{14}(PO_4)_8 \cdot 4H_2O$ (A) $Na_3Al_2H_{15}(PO_4)_8$ (B)
Molecular weight	949,88 (A) 897,82 (B)
Assay	Content not less than 95,0 % (both forms)

▼B

Description	White odourless powder
Identification	
Test for sodium	Passes test
Test for aluminium	Passes test
Test for phosphate	Passes test
pH	Acid to litmus
Solubility	Insoluble in water. Soluble in hydrochloric acid
Purity	
Loss on ignition	19,5-21,0 % (A) (750-800 °C, 2 hours) 15-16 % (B) (750-800 °C, 2 hours)
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
Einecs	231-545-4
Chemical name	Silicon dioxide
Chemical formula	$(SiO_2)_n$
Molecular weight	60,08 (SiO_2)
Assay	Content after ignition not less than 99,0 % (fumed silica) or 94,0 % (hydrated forms)
Description	White, fluffy powder or granules. Hygroscopic
Identification	
Test for silica	Positive
Purity	
Loss on drying	Not more than 2,5 % (fumed silica, 105 °C, 2 hours) Not more than 8,0 % (precipitated silica and silica gel, 105 °C, 2 hours)

▼B

	Not more than 70 % (hydrous silica, 105 °C, 2 hours)
Loss on ignition	Not more than 2,5 % after drying (1 000 °C, fumed silica) Not more than 8,5 % after drying (1 000 °C, hydrated forms)
Soluble ionisable salts	Not more than 5,0 % (as Na_2SO_4)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 552 CALCIUM SILICATE

Synonyms	
Definition	Calcium silicate is a hydrous or anhydrous silicate with varying proportions of CaO and SiO_2. The product should be free of asbestos.
Einecs	215-710-8
Chemical name	Calcium silicate
Chemical formula	
Molecular weight	
Assay	Content on the anhydrous basis: — as SiO_2 not less than 50 % and not more than 95 % — as CaO not less than 3 % and not more than 35 %
Description	White to off-white free-flowing powder that remains so after absorbing relatively large amounts of water or other liquids
Identification	
Test for silicate	Passes test
Test for calcium	Passes test
Gel formation	Forms a gel with mineral acids
Purity	
Loss on drying	Not more than 10 % (105 °C, 2 hours)
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 2 mg/kg
Mercury	Not more than 1 mg/kg

E 553a (i) MAGNESIUM SILICATE

Synonyms	
Definition	Magnesium silicate is a synthetic compound of which the molar ratio of magnesium oxide to silicon dioxide is approximately 2:5
Einecs	
Chemical name	

▼B

Chemical formula	
Molecular weight	
Assay	Content not less than 15 % of MgO and not less than 67 % of SiO_2 on the ignited basis
Description	Very fine, white, odourless powder, free from grittiness
Identification	
Test for magnesium	Passes test
Test for silicate	Passes test
pH	Between 7,0 and 10,8 (10 % slurry)
Purity	
Loss on drying	Not more than 15 % (105 °C, 2 hours)
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

Synonyms	
Definition	
Einecs	239-076-7
Chemical name	Magnesium trisilicate
Chemical formula	$Mg_2Si_3O_8 \cdot nH_2O$ (approximate composition)
Molecular weight	
Assay	Content not less than 29,0 % of MgO and not less than 65,0 % of SiO_2 both on the ignited basis
Description	Fine, white powder, free from grittiness
Identification	
Test for magnesium	Passes test
Test for silicate	Passes test
pH	Between 6,3 and 9,5 (5 % slurry)
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

▼B

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. The product should be free of asbestos.
Einecs	238-877-9
Chemical name	Magnesium hydrogen metasilicate
Chemical formula	$Mg_3(Si_4O_{10})(OH)_2$
Molecular weight	379,22
Assay	
Description	Light, homogeneous, white or almost white powder, greasy to the touch
Identification	
Infrared absorption spectrum	Characteristic peaks at 3 677, 1 018 and 669 cm^{-1}
X-ray diffraction	Peaks at 9,34/4,66/3,12 Å
Solubility	Insoluble in water and ethanol
Purity	
Loss on drying	Not more than 0,5 % (105 °C, 1 hour)
Acid soluble matter	Not more than 6 %
Water soluble matter	Not more than 0,2 %
Acid-soluble iron	Not detectable
Arsenic	Not more than 10 mg/kg
Lead	Not more than 2 mg/kg

E 554 SODIUM ALUMINIUM SILICATE

Synonyms	Sodium silicoaluminate; Sodium aluminosilicate; Aluminium sodium silicate
Definition	
Einecs	
Chemical name	Sodium aluminium silicate
Chemical formula	
Molecular weight	
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	
Test for sodium	Passes test
Test for aluminium	Passes test
Test for silicate	Passes test
pH	Between 6,5 and 11,5 (5 % slurry)

▼B

Purity	
Loss on drying	Not more than 8,0 % (105 °C, 2 hours)
Loss on ignition	Not less than 5,0 % and not more than 11,0 % on the anhydrous basis (1 000 °C to constant weight)
Sodium	Not less than 5 % and not more than 8,5 % (as Na_2O) on the anhydrous basis
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 555 POTASSIUM ALUMINIUM SILICATE

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

▼M3

E 556 CALCIUM ALUMINIUM SILICATE [1]

▼B

Synonyms	Calcium aluminosilicate; Calcium silicoaluminate; Aluminium calcium silicate
Definition	
Einecs	
Chemical name	Calcium aluminium silicate

[1] Period of application: until 31 January 2014.

▼B

Chemical formula	
Molecular weight	
Assay	Content on the anhydrous basis: — as SiO_2 not less than 44,0 % and not more than 50,0 % — as Al_2O_3 not less than 3,0 % and not more than 5,0 % — as CaO not less than 32,0 % and not more than 38,0 %
Description	Fine white, free-flowing powder
Identification	
Test for calcium	Passes test
Test for aluminium	Passes test
Test for silicate	Passes test
Purity	
Loss on drying	Not more than 10,0 % (105 °C, 2 hours)
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 5 mg/kg
Mercury	Not more than 1 mg/kg

▼M3

E 559 ALUMINIUM SILICATE (KAOLIN) [1]

▼B

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

[1] Period of application: until 31 January 2014.

▼B

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

E 570 FATTY ACIDS

Synonyms	
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 ($C_{18:1}$)
Einecs	
Chemical name	Octanoic acid (C_8); decanoic acid (C_{10}); dodecanoic acid (C_{12}); tetradecanoic acid (C_{14}); hexadecanoic acid (C_{16}); octadecanoic acid (C_{18}); 9-octadecenoic acid ($C_{18:1}$)
Chemical formula	
Molecular weight	
Assay	Not less than 98 % by chromatography
Description	A colourless liquid or white solid obtained from oils and fats
Identification	
Identification test	Individual fatty acids can be identified by acid value, iodine value, gas chromatography
Purity	
Residue on ignition	Not more than 0,1 %
Unsaponifiable matter	Not more than 1,5 %
Water content	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
Einecs	
Chemical name	Gluconic acid
Chemical formula	$C_6H_{12}O_7$ (gluconic acid)

▼B

Molecular weight	196,2
Assay	Content not less than 49,0 % (as gluconic acid)
Description	Colourless to light yellow, clear syrupy liquid
Identification	
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 % 550 °C +/– 20 °C till disappearance of organic residues (black spots).
Reducing matter	Not more than 2,0 % (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 1 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
Einecs	202-016-5
Chemical name	D-Glucono-1,5-lactone
Chemical formula	$C_6H_{10}O_6$
Molecular weight	178,14
Assay	Content not less than 99,0 % on the anhydrous basis
Description	Fine, white, nearly odourless, crystalline powder
Identification	
Formation of phenylhydrazine derivative of gluconic acid	Positive. Compound formed melts between 196 °C and 202 °C with decomposition
Solubility	Freely soluble in water. Sparingly soluble in ethanol
Purity	
Water content	Not more than 0,2 % (Karl Fischer method)
Reducing substances	Not more than 0,5 % (as D-glucose)
Lead	Not more than 1 mg/kg

E 576 SODIUM GLUCONATE

Synonyms	Sodium salt of D-gluconic acid
Definition	Manufactured by fermentation or chemical catalytic oxidation

▼B

Einecs	208-407-7
Chemical name	Sodium D-gluconate
Chemical formula	$C_6H_{11}NaO_7$ (anhydrous)
Molecular weight	218,14
Assay	Content not less than 99,0 %
Description	White to tan, granular to fine, crystalline powder
Identification	
Test for sodium	Passes test
Test for gluconate	Passes test
Solubility	Very soluble in water. Sparingly soluble in ethanol
pH	Between 6,5 and 7,5 (10 % solution)
Purity	
Reducing matter	Not more than 1,0 % (as D-glucose)
Lead	Not more than 1 mg/kg

E 577 POTASSIUM GLUCONATE

Synonyms	Potassium salt of D-gluconic acid
Definition	
Einecs	206-074-2
Chemical name	Potassium D-gluconate
Chemical formula	$C_6H_{11}KO_7$ (anhydrous) $C_6H_{11}KO_7 \cdot H_2O$ (monohydrate)
Molecular weight	234,25 (anhydrous) 252,26 (monohydrate)
Assay	Content not less than 97,0 % and not more than 103,0 % on dried basis
Description	Odourless, free flowing white to yellowish white, crystalline powder or granules
Identification	
Test for potassium	Passes test
Test for gluconate	Passes test
pH	Between 7,0 and 8,3 (10 % solution)
Purity	
Loss on drying	Anhydrous: not more than 3,0 % (105 °C, 4 hours, vacuum) Monohydrate: not less than 6 % and not more than 7,5 % (105 °C, 4 hours, 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	
Einecs	206-075-8
Chemical name	Calcium di-D-gluconate

▼B

Chemical formula	$C_{12}H_{22}CaO_{14}$ (anhydrous) $C_{12}H_{22}CaO_{14} \cdot H_2O$ (monohydrate)
Molecular weight	430,38 (anhydrous form) 448,39 (monohydrate)
Assay	anhydrous: Content not less than 98 % and not more than 102 % on the dried basis monohydrate: not less than 98 % and not more than 102 % on the 'as is' basis.
Description	Odourless, white crystalline granules or powder, stable in air
Identification	
Test for calcium	Passes test
Test for gluconate	Passes test
Solubility	Soluble in water, insoluble in ethanol
pH	Between 6,0 and 8,0 (5 % solution)
Purity	
Loss on drying	Not more than 3,0 % (105 °C, 16 hours) (anhydrous) Not more than 2,0 % (105 °C, 16 hours) (monohydrate)
Reducing substances	Not more than 1,0 % (as D-glucose)
Lead	Not more than 2 mg/kg

E 579 FERROUS GLUCONATE

Synonyms	
Definition	
Einecs	206-076-3
Chemical name	Ferrous di-D-gluconate dihydrate; Iron(II) di-gluconate dihydrate
Chemical formula	$C_{12}H_{22}FeO_{14} \cdot 2H_2O$
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	
Solubility	Soluble with slight heating in water. Practically insoluble in ethanol
Test for ferrous ion	Passes test
Formation of phenylhy-drazine derivative of gluconic acid	Positive
pH	Between 4 and 5,5 (10 % solution)
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

▼B

Lead	Not more than 2 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	
Einecs	227-608-0
Chemical name	Ferrous 2-hydroxy propanoate
Chemical formula	$C_6H_{10}FeO_6 \cdot nH_2O$ (n = 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	
Solubility	Soluble in water. Practically insoluble in ethanol
Test for ferrous ion	Passes test
Test for lactate	Passes test
pH	Between 4 and 6 (2 % solution)
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 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

E 586 4-HEXYLRESORCINOL

Synonyms	4-Hexyl-1,3-benzenediol; Hexylresorcinol
Definition	
Einecs	205-257-4
Chemical name	4-Hexylresorcinol
Chemical formula	$C_{12}H_{18}O_2$
Molecular weight	197,24
Assay	Not less than 98 % on the dried basis (4 hours at room temperature)
Description	White powder

▼B

Identification	
Solubility	Freely soluble in ether and acetone; very slightly soluble in water
Nitric acid test	To 1 ml of a saturated solution of the sample, add 1 ml of nitric acid. A light red colour appears
Bromine test	To 1 ml of saturated solution of the sample, add 1 ml of bromine TS. A yellow, flocculent precipitate dissolves producing a yellow solution
Purity	
Melting range	62 to 67 °C
Acidity	Not more than 0,05 %
Sulphated ash	Not more than 0,1 %
Resorcinol and other phenols	Shake about 1 g of the sample with 50 ml of water for a few minutes, filter, and to the filtrate add 3 drops of ferric chloride TS. No red or blue colour is produced
Nickel	Not more than 2 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 3 mg/kg

E 620 GLUTAMIC ACID

Synonyms	L-Glutamic acid; L-α-Aminoglutaric acid
Definition	
Einecs	200-293-7
Chemical name	L-Glutamic acid; L-2-amino-pentanedioic acid
Chemical formula	$C_5H_9NO_4$
Molecular weight	147,13
Assay	Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis
Solubility	Sparingly soluble in water; practically insoluble in ethanol or ether
Description	White crystals or crystalline powder
Identification	
Test for glutamic acid (by thin layer chromatography)	Passes test
Specific rotation	$[\alpha]_D^{20}$ between + 31,5° and + 32,2° (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
pH	Between 3,0 and 3,5 (saturated solution)
Purity	
Loss on drying	Not more than 0,2 % (80 °C, 3 hours)
Sulphated ash	Not more than 0,2 %
Chloride	Not more than 0,2 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Arsenic	Not more than 2,5 mg/kg
Lead	Not more than 1 mg/kg

▼B

E 621 MONOSODIUM GLUTAMATE

Synonyms	Sodium glutamate; MSG
Definition	
Einecs	205-538-1
Chemical name	Monosodium L-glutamate monohydrate
Chemical formula	$C_5H_8NaNO_4 \cdot H_2O$
Molecular weight	187,13
Assay	Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis
Solubility	Freely soluble in water; practically insoluble in ethanol or ether
Description	White, practically odourless crystals or crystalline powder
Identification	
Test for sodium	Passes test
Test for glutamic acid (by thin-layer chromatography)	Passes test
Specific rotation	$[\alpha]_D^{20}$ between + 24,8° and + 25,3° (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
pH	Between 6,7 and 7,2 (5 % solution)
Purity	
Loss on drying	Not more than 0,5 % (98 °C, 5 hours)
Chloride	Not more than 0,2 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Lead	Not more than 1 mg/kg

E 622 MONOPOTASSIUM GLUTAMATE

Synonyms	Potassium glutamate; MPG
Definition	
Einecs	243-094-0
Chemical name	Monopotassium L-glutamate monohydrate
Chemical formula	$C_5H_8KNO_4 \cdot H_2O$
Molecular weight	203,24
Assay	Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis
Solubility	Freely soluble in water; practically insoluble in ethanol or ether
Description	White, practically odourless crystals or crystalline powder
Identification	
Test for potassium	Passes test
Test for glutamic acid (by thin-layer chromatography)	Passes test

▼B

Specific rotation	$[\alpha]_D^{20}$ between + 22,5° and + 24,0° (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
pH	Between 6,7 and 7,3 (2 % solution)
Purity	
Loss on drying	Not more than 0,2 % (80 °C, 5 hours)
Chloride	Not more than 0,2 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Lead	Not more than 1 mg/kg

E 623 CALCIUM DIGLUTAMATE

Synonyms	Calcium glutamate
Definition	
Einecs	242-905-5
Chemical name	Monocalcium di-L-glutamate
Chemical formula	$C_{10}H_{16}CaN_2O_8 \cdot nH_2O$ (n = 0, 1, 2 or 4)
Molecular weight	332,32 (anhydrous)
Assay	Content not less than 98,0 % and not more than 102,0 % on the anhydrous basis
Solubility	Freely soluble in water; practically insoluble in ethanol or ether
Description	White, practically odourless crystals or crystalline powder
Identification	
Test for calcium	Passes test
Test for glutamic acid (by thin-layer chromatography)	Passes test
Specific rotation	$[\alpha]_D^{20}$ between + 27,4° and + 29,2° (for calcium diglutamate with n = 4) (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
Purity	
Water content	Not more than 19,0 % (for calcium diglutamate with n = 4) (Karl Fischer)
Chloride	Not more than 0,2 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Lead	Not more than 1 mg/kg

E 624 MONOAMMONIUM GLUTAMATE

Synonyms	Ammonium glutamate
Definition	
Einecs	231-447-1
Chemical name	Monoammonium L-glutamate monohydrate
Chemical formula	$C_5H_{12}N_2O_4 \cdot H_2O$
Molecular weight	182,18
Assay	Content not less than 99,0 % and not more 101,0 % on the anhydrous basis

▼B

Solubility	Freely soluble in water; practically insoluble in ethanol or ether
Description	White, practically odourless crystals or crystalline powder
Identification	
Test for ammonium	Passes test
Test for glutamic acid (by thin-layer chromatography)	Passes test
Specific rotation	$[\alpha]_D^{20}$ between + 25,4° and + 26,4° (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
pH	Between 6,0 and 7,0 (5 % solution)
Purity	
Loss on drying	Not more than 0,5 % (50 °C, 4 hours)
Sulphated ash	Not more than 0,1 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Lead	Not more than 1 mg/kg

E 625 MAGNESIUM DIGLUTAMATE

Synonyms	Magnesium glutamate
Definition	
Einecs	242-413-0
Chemical name	Monomagnesium di-L-glutamate tetrahydrate
Chemical formula	$C_{10}H_{16}MgN_2O_8 \cdot 4H_2O$
Molecular weight	388,62
Assay	Content not less than 95,0 % and not more than 105,0 % on the anhydrous basis
Solubility	Very soluble in water; practically insoluble in ethanol or ether
Description	Odourless, white or off-white crystals or powder
Identification	
Test for magnesium	Passes test
Test for glutamic acid (by thin-layer chromatography)	Passes test
Specific rotation	$[\alpha]_D^{20}$ between + 23,8° and + 24,4° (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
pH	Between 6,4 and 7,5 (10 % solution)
Purity	
Water content	Not more than 24 % (Karl Fischer)
Chloride	Not more than 0,2 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Lead	Not more than 1 mg/kg

E 626 GUANYLIC ACID

Synonyms	5'-Guanylic acid
Definition	
Einecs	201-598-8

▼B

Chemical name	Guanosine-5'-monophosphoric acid
Chemical formula	$C_{10}H_{14}N_5O_8P$
Molecular weight	363,22
Assay	Content not less than 97,0 % on the anhydrous basis
Solubility	Slightly soluble in water, practically insoluble in ethanol
Description	Odourless, colourless or white crystals or white crystalline powder
Identification	
Test for ribose	Passes test
Test for organic phosphate	Passes test
pH	Between 1,5 and 2,5 (0,25 % solution)
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, 4 hours)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 1 mg/kg

E 627 DISODIUM GUANYLATE

Synonyms	Sodium guanylate; Sodium 5'-guanylate
Definition	

▼M3

Einecs	226-914-1

▼B

Chemical name	Disodium guanosine-5'-monophosphate
Chemical formula	$C_{10}H_{12}N_5Na_2O_8P \cdot nH_2O$ (n = ca. 7)
Molecular weight	407,19 (anhydrous)
Assay	Content not less than 97,0 % on the anhydrous basis
Solubility	Soluble in water, sparingly soluble in ethanol, practically insoluble in ether
Description	Odourless, colourless or white crystals or white crystalline powder
Identification	
Test for ribose	Passes test
Test for organic phosphate	Passes test
Test for sodium	Passes test
pH	Between 7,0 and 8,5 (5 % solution)
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, 4 hours)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 1 mg/kg

▼B

E 628 DIPOTASSIUM GUANYLATE

Synonyms	Potassium guanylate; Potassium 5'-guanylate
Definition	
▼M3	
Einecs	221-849-5
▼B	
Chemical name	Dipotassium guanosine-5'-monophosphate
Chemical formula	$C_{10}H_{12}K_2N_5O_8P$
Molecular weight	439,40
Assay	Content not less than 97,0 % on the anhydrous basis
Solubility	Freely soluble in water, practically insoluble in ethanol
Description	Odourless, colourless or white crystals or white crystalline powder
Identification	
Test for ribose	Passes test
Test for organic phosphate	Passes test
Test for potassium	Passes test
pH	Between 7,0 and 8,5 (5 % solution)
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, 4 hours)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 1 mg/kg

E 629 CALCIUM GUANYLATE

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

▼B

Purity	
Loss on drying	Not more than 23,0 % (120 °C, 4 hours)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 1 mg/kg

E 630 INOSINIC ACID

Synonyms	5'-Inosinic acid
Definition	
Einecs	205-045-1
Chemical name	Inosine-5'-monophosphoric acid
Chemical formula	$C_{10}H_{13}N_4O_8P$
Molecular weight	348,21
Assay	Content not less than 97,0 % on the anhydrous basis
Solubility	Freely soluble in water, slightly soluble in ethanol
Description	Odourless, colourless or white crystals or powder
Identification	
Test for ribose	Passes test
Test for organic phosphate	Passes test
pH	Between 1,0 and 2,0 (5 % solution)
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, 4 hours)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 1 mg/kg

E 631 DISODIUM INOSINATE

Synonyms	Sodium inosinate; Sodium 5'-inosinate
Definition	
Einecs	225-146-4
Chemical name	Disodium inosine-5'-monophosphate
Chemical formula	$C_{10}H_{11}N_4Na_2O_8P \cdot H_2O$
Molecular weight	392,17 (anhydrous)
Assay	Content not less than 97,0 % on the anhydrous basis
Solubility	Soluble in water, sparingly soluble in ethanol, practically insoluble in ether
Description	Odourless, colourless or white crystals or powder
Identification	
Test for ribose	Passes test
Test for organic phosphate	Passes test
Test for sodium	Passes test

▼B

pH	Between 7,0 and 8,5
Spectrometry	Maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm
Purity	
Water content	Not more than 28,5 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 1 mg/kg

E 632 DIPOTASSIUM INOSINATE

Synonyms	Potassium inosinate; Potassium 5'-inosinate
Definition	
Einecs	243-652-3
Chemical name	Dipotassium inosine-5'-monophosphate
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
Solubility	Freely soluble in water; practically insoluble in ethanol
Description	Odourless, colourless or white crystals or powder
Identification	
Test for ribose	Passes test
Test for organic phosphate	Passes test
Test for potassium	Passes test
pH	Between 7,0 and 8,5 (5 % solution)
Spectrometry	Maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm
Purity	
Water content	Not more than 10,0 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 1 mg/kg

E 633 CALCIUM INOSINATE

Synonyms	Calcium 5'-inosinate
Definition	
Einecs	
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
Solubility	Sparingly soluble in water
Description	Odourless, colourless or white crystals or powder

▼B

Identification	
Test for ribose	Passes test
Test for organic phosphate	Passes test
Test for calcium	Passes test
pH	Between 7,0 and 8,0 (0,05 % solution)
Spectrometry	Maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm
Purity	
Water content	Not more than 23,0 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 1 mg/kg

E 634 CALCIUM 5'-RIBONUCLEOTIDE

Synonyms	
Definition	
Einecs	
Chemical name	Calcium 5′-ribonucleotide is essentially a mixture of calcium inosine-5′-monophosphate and calcium guanosine-5′-monophosphate
Chemical formula	$C_{10}H_{11}N_4CaO_8P \cdot nH_2O$ $C_{10}H_{12}N_5CaO_8P \cdot nH_2O$
Molecular weight	
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
Solubility	Sparingly soluble in water
Description	Odourless, white or nearly white crystals or powder
Identification	
Test for ribose	Passes test
Test for organic phosphate	Passes test
Test for calcium	Passes test
pH	Between 7,0 and 8,0 (0,05 % solution)
Purity	
Water content	Not more than 23,0 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 1 mg/kg

E 635 DISODIUM 5'-RIBONUCLEOTIDE

Synonyms	Sodium 5'-ribonucleotide
Definition	
Einecs	
Chemical name	Disodium 5'-ribonucleotide is essentially a mixture of disodium inosine-5'-monophosphate and disodium guanosine-5'-monophosphate

▼B

Chemical formula	$C_{10}H_{11}N_4O_8P \cdot nH_2O$ $C_{10}H_{12}N_5Na_2O_8P \cdot nH_2O$
Molecular weight	
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
Solubility	Soluble in water, sparingly soluble in ethanol practically insoluble in ether
Description	Odourless, white or nearly white crystals or powder
Identification	
Test for ribose	Passes test
Test for organic phosphate	Passes test
Test for sodium	Passes test
pH	Between 7,0 and 8,5 (5 % solution)
Purity	
Water content	Not more than 26,0 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 1 mg/kg

E 640 GLYCINE AND ITS SODIUM SALT

(i) GLYCINE

Synonyms	Aminoacetic acid; Glycocoll
Definition	
Einecs	200-272-2
Chemical name	Aminoacetic acid
Chemical formula	$C_2H_5NO_2$
Molecular weight	75,07
Assay	Content not less than 98,5 % on the anhydrous basis
Description	White crystals or crystalline powder
Identification	
Test for amino acid	Passes test
Purity	
Loss on drying	Not more than 0,2 % (105 °C, 3 hours)
Residue on ignition	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

(ii) SODIUM GLYCINATE

Synonyms	
Definition	
Einecs	227-842-3

▼B

Chemical name	Sodium glycinate
Chemical formula	$C_2H_5NO_2$ Na
Molecular weight	98
Assay	Content not less than 98,5 % on the anhydrous basis
Description	White crystals or crystalline powder
Identification	
Test for amino acid	Passes test
Test for sodium	Passes test
Purity	
Loss on drying	Not more than 0,2 % (105 °C, 3 hours)
Residue on ignition	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

▼M18

E 641 L-LEUCINE

Synonyms	2-Aminoisobutylacetic acid; L-2-Amino-4-methylvaleric acid; alpha-Aminoisocaproic acid; (*S*)-2-Amino-4-methylpentanoic acid; L-Leu
Definition	
Einecs	200-522-0
CAS number	61-90-5
Chemical name	L-Leucine; L-2-Amino-4-methylpentanoic acid
Chemical formula	$C_6H_{13}NO_2$
Molecular Weight	131,17
Assay	Content not less than 98,5 % and not more than 101,0 % on the anhydrous basis
Description	White or almost white crystalline powder or shiny flakes
Identification	
Solubility	Soluble in water, acetic acid, dilute HCl and alkaline hydroxides and carbonates; slightly soluble in ethanol
Specific rotation	$[\alpha]_D^{20}$ between + 14,5° and + 16,5° (4 % solution (anhydrous basis) in 6N HCl)
Purity	
Loss on drying	Not more than 0,5 % (100 °C – 105 °C)
Sulphated Ash	Not more than 0,1 %
Chlorides	Not more than 200 mg/kg
Sulphates	Not more than 300 mg/kg
Ammonium	Not more than 200 mg/kg
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

▼B

E 650 ZINC ACETATE

Synonyms	Acetic acid, zinc salt, dihydrate
Definition	
Einecs	
Chemical name	Zinc acetate dihydrate
Chemical formula	$C_4H_6O_4$ Zn · $2H_2O$
Molecular weight	219,51
Assay	Content not less than 98 % and not more than 102 % of $C_4H_6O_4$ Zn · $2H_2O$
Description	Colourless crystals or fine, off-white powder
Identification	
Test for acetate	Passes test
Test for zinc	Passes test
pH	Between 6,0 and 8,0 (5 % solution)
Purity	
Water insoluble matter	Not more than 0,005 %
Chlorides	Not more than 50 mg/kg
Sulphates	Not more than 100 mg/kg
Alkalines and alkaline earths	Not more than 0,2 %
Organic volatile impurities	Passes test
Iron	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 20 mg/kg
Cadmium	Not more than 5 mg/kg

E 900 DIMETHYL POLYSILOXANE

Synonyms	Polydimethyl siloxane; Silicone fluid; Silicone oil; Dimethyl silicone

▼B

Definition	Dimethylpolysiloxane is a mixture of fully methylated linear siloxane polymers containing repeating units of the formula $(CH_3)_2$ SiO and stabilised with trimethylsiloxy end-blocking units of the formula $(CH_3)_3$ SiO
Einecs	
Chemical name	Siloxanes and silicones, di-methyl
Chemical formula	$(CH_3)_3$-Si-[O-Si$(CH_3)_2]_n$-O-Si$(CH_3)_3$
Molecular weight	
Assay	Content of total silicon not less than 37,3 % and not more than 38,5 %
Description	Clear, colourless, viscous liquid
Identification	
Specific gravity (25 °C/25 °C)	Between 0,964 and 0,977
Refractive index	$[n]_D^{25}$ between 1,400 and 1,405
Infrared absorption spectrum	The infrared absorption spectrum of a liquid film of the sample between two sodium chloride plates exhibits relative maxima at the same wavelengths as those of a similar preparation of Dimethylpolysiloxane Reference Standard
Purity	
Loss on drying	Not more than 0,5 % (150 °C, 4h)
Viscosity	Not less than $1{,}00 \cdot 10^{-4}$ m^2s^{-1} at 25 °C
Arsenic	Not more than 3 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 901 BEESWAX, WHITE AND YELLOW

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
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	Yellowish white (white form) or yellowish to greyish brown (yellow form) pieces or plates with a fine-grained and non-crystalline fracture, having an agreeable, honey-like odour
Identification	
Melting range	Between 62 °C and 65 °C

▼B

Specific gravity	About 0,96
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	Transfer 3,0 g of the sample to a 100 ml round-bottomed flask, add 30 ml of a 4 % w/v solution of potassium hydroxide in aldehyde-free ethanol and boil gently under a reflux condenser for 2 h. Remove the condenser and immediately insert a thermometer. Place the flask in water at 80 °C and allow to cool, swirling the solution continuously. No precipitate is formed before the temperature reaches 65 °C, although the solution may be opalescent.
Fats, Japan wax, rosin and soaps	Boil 1 g of the sample for 30 min with 35 ml of a 1 in 7 solution of sodium hydroxide, maintaining the volume by the occasional addition of water, and cool the mixture. The wax separates and the liquid remains clear. Filter the cold mixture and acidify the filtrate with hydrochloric acid. No precipitate is formed.
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 902 CANDELILLA WAX

Synonyms	
Definition	Candelilla wax is a purified wax obtained from the leaves of the candelilla plant, *Euphorbia antisyphilitica*
Einecs	232-347-0
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	Hard, yellowish brown, opaque to translucent wax
Identification	
Specific gravity	About 0,98
Melting range	Between 68,5 °C and 72,5 °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
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

▼B

E 903 CARNAUBA WAX

Synonyms	
Definition	Carnauba wax is a purified wax obtained from the leaf buds and leaves of the Brazilian Mart wax palm, *Copernicia cerifera*
Einecs	232-399-4
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	Light brown to pale yellow powder or flakes or hard and brittle solid with a resinous fracture
Identification	
Specific gravity	About 0,997
Melting range	Between 82 °C and 86 °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 2 mg/kg
Mercury	Not more than 1 mg/kg

E 904 SHELLAC

Synonyms	Bleached shellac; White shellac
Definition	Shellac is the purified and bleached lac, the resinous secretion of the insect *Laccifer (Tachardia) lacca* Kerr (Fam. *Coccidae*)
Einecs	232-549-9
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	Bleached shellac — off-white, amorphous, granular resin Wax-free bleached shellac — light yellow, amorphous, granular resin
Identification	
Solubility	Insoluble in water; freely (though very slowly) soluble in alcohol; slightly soluble in acetone
Acid value	Between 60 and 89

▼B

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

E 905 MICROCRYSTALLINE WAX

Synonyms	Petroleum wax; Hydrocarbon wax; Fischer-Tropsch wax; Synthetic wax; Synthetic paraffin
Definition	Refined mixtures of solid, saturated hydrocarbons, obtained from petroleum or synthetic feedstocks
Description	White to amber, odourless wax
Identification	
Solubility	Insoluble in water, very slightly soluble in ethanol
Refractive index	$[n]_D^{100}$ 1,434-1,448 Alternative $[n]_D^{120}$1,426-1,440
Purity	
Molecular weight	Average not less than 500
Viscosity	Not less than $1,1 \times 10^{-5}$ m^2s^{-1}at 100 °C Alternative: Not less than $0,8 \times 10^{-5}$ m^2s^{-1}at 120 °C, if solid at 100 °C
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 wt %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 3 mg/kg
Polycyclic aromatic compounds	Benzo(a)pyrene no more than 50 μg/kg

E 907 HYDROGENATED POLY-1-DECENE

Synonyms	Hydrogenated polydec-1-ene; Hydrogenated poly-alpha-olefin
Definition	
Einecs	
Chemical name	
Chemical formula	$C_{10n}H_{20n+2}$ where n = 3-6
Molecular weight	560 (average)
Assay	Not less than 98,5 % of hydrogenated poly-1-decene, having the following oligomer distribution: C_{30}: 13-37 % C_{40}: 35-70 % C_{50}: 9-25 % C_{60}: 1-7 %

▼B

Description	
Identification	
Solubility	Insoluble in water; slightly soluble in ethanol; soluble in toluene
Burning	Burns with a bright flame and a paraffin-like characteristic smell
Viscosity	Between $5,7 \times 10^{-6}$ and $6,1 \times 10^{-6}$ m^2s^{-1} at 100 °C
Purity	
Compounds with carbon number less than 30	Not more than 1,5 %
Readily carbonisable substances	After 10 minutes shaking in a boiling water bath, a tube of sulphuric acid with a 5 g sample of hydrogenated poly-1-decene is not darker than a very slight straw colour
Nickel	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg

▼M15 _____

▼B

E 914 OXIDISED POLYETHYLENE WAX

Synonyms	
Definition	Polar reaction products from mild oxidation of polyethylene
Einecs	
Chemical name	Oxidised polyethylene
Chemical formula	
Molecular weight	
Assay	
Description	Almost white flakes, powder, granules or pellets
Identification	
Density	Between 0,92 and 1,05 (20 °C)
Drop point	Greater than 95 °C
Purity	
Acid value	Not more than 70
Viscosity	Not less than $8,1 \cdot 10^{-5}$ m^2s^{-1} at 120 °C
Other wax types	Not detectable (by differential scanning calorimetry and/or infrared spectroscopy)
Oxygen	Not more than 9,5 %
Chromium	Not more than 5 mg/kg
Lead	Not more than 2 mg/kg

▼B

E 920 L-CYSTEINE

Synonyms	
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 name	
Chemical formula	$C_3H_7NO_2S \cdot HCl \cdot nH_2O$ (where n = 0 or 1)
Molecular weight	157,62 (anhydrous)
Assay	Content not less than 98,0 % and not more than 101,5 % on the anhydrous basis
Description	White powder or colourless crystals
Identification	
Solubility	Freely soluble in water and in ethanol
Melting range	Anhydrous form melts at about 175 °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
Chemical name	
Chemical formula	CH_4N_2O
Molecular weight	60,06
Assay	Content not less than 99,0 % on the anhydrous basis

▼B

Description	Colourless to white, prismatic, crystalline powder or small, white pellets
Identification	
Solubility	Very soluble in water Soluble in ethanol
Precipitation with nitric acid	To pass the test a white, crystalline precipitate is formed
Colour reaction	To pass the test a reddish-violet colour is produced
Melting range	132 °C to 135 °C
Purity	
Loss on drying	Not more than 1,0 % (105 °C, 1 hour)
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 2 mg/kg

E 938 ARGON

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

E 939 HELIUM

Synonyms	
Definition	
Einecs	231-168-5
Chemical name	Helium
Chemical formula	He
Atomic weight	4
Assay	Not less than 99 %

▼B

Description	Colourless, odourless, non-flammable gas
Identification	
Purity	
Water content	Not more than 0,05 %
Methane and other hydrocarbons	Not more than 100 µl/l (calculated as methane)

E 941 NITROGEN

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

E 942 NITROUS OXIDE

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

▼B

E 943a BUTANE

Synonyms	n-Butane
Definition	
Einecs	
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	
Vapour pressure	108,935 kPa at 20 °C
Purity	
Methane	Not more than 0,15 % v/v
Ethane	Not more than 0,5 % v/v
Propane	Not more than 1,5 % v/v
Isobutane	Not more than 3,0 % v/v
1,3-butadiene	Not more than 0,1 % v/v
Moisture	Not more than 0,005 %

E 943b ISOBUTANE

Synonyms	2-Methyl propane
Definition	
Einecs	
Chemical name	2-methyl propane
Chemical formula	$(CH_3)_2CH\ CH_3$
Molecular weight	58,12
Assay	Content not less than 94 %
Description	Colourless gas or liquid with mild, characteristic odour
Identification	
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 %

▼B

E 944 PROPANE

Synonyms	
Definition	
Einecs	
Chemical name	Propane
Chemical formula	$CH_3CH_2CH_3$
Molecular weight	44,09
Assay	Content not less than 95 %
Description	Colourless gas or liquid with mild, characteristic odour
Identification	
Vapour pressure	732,910 kPa at 20 °C
Purity	
Methane	Not more than 0,15 % v/v
Ethane	Not more than 1,5 % v/v
Isobutane	Not more than 2,0 % v/v
n-Butane	Not more than 1,0 % v/v
1,3-butadiene	Not more than 0,1 % v/v
Moisture	Not more than 0,005 %

E 948 OXYGEN

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

E 949 HYDROGEN

Synonyms	
Definition	
Einecs	215-605-7
Chemical name	Hydrogen
Chemical formula	H_2
Molecular weight	2

▼B

Assay	Content not less than 99,9 %
Description	Colourless, odourless, highly flammable gas
Identification	
Purity	
Water content	Not more than 0,005 % v/v
Oxygen	Not more than 0,001 % v/v
Nitrogen	Not more than 0,07 % v/v

E 950 ACESULFAME K

Synonyms	Acesulfame potassium; Potassium salt of 3,4-dihydro-6-methyl-1,2,3-oxathiazin-4-one-2,2-dioxide
Definition	
Einecs	259-715-3
Chemical name	6-methyl-1,2,3-oxathiazin-4(3H)-one-2,2-dioxide potassium salt
Chemical formula	$C_4H_4KNO_4S$
Molecular weight	201,24
Assay	Content not less than 99 % of $C_4H_4KNO_4S$ on the anhydrous basis
Description	Odourless, white, crystalline powder. Approximately 200 times as sweet as sucrose
Identification	
Solubility	Very soluble in water, very slightly soluble in ethanol
Ultraviolet absorption	Maximum 227 ± 2 nm for a solution of 10 mg in 1 000 ml of water
Test for potassium	Passes test (test the residue obtained by igniting 2 g of the sample)
Precipitation test	Add a few drops of a 10 % solution of sodium cobaltnitrite to a solution of 0,2 g of the sample in 2 ml of acetic acid and 2 ml of water. A yellow precipitate is produced
Purity	
Loss on drying	Not more than 1 % (105 °C, 2 hours)
Organic impurities	Passes test for 20 mg/kg of UV active components
Fluoride	Not more than 3 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

E 951 ASPARTAME

Synonyms	Aspartyl phenylalanine methyl ester
Definition	
Einecs	245-261-3
Chemical name	N-L-α-Aspartyl-L-phenylalanine-1-methyl ester, 3-amino-N-(α-carbomethoxy-phenethyl)-succinamic acid-N-methyl ester
Chemical formula	$C_{14}H_{18}N_2O_5$
Molecular weight	294,31

▼B

Assay	Not less than 98 % and not more than 102 % of $C_{14}H_{18}N_2O_5$ on the anhydrous basis
Description	White, odourless, crystalline powder having a sweet taste. Approximately 200 times as sweet as sucrose
Identification	
Solubility	Slightly soluble in water and in ethanol
pH	Between 4,5 and 6,0 (1 in 125 solution)
Specific rotation	$[\alpha]_D^{20}$: + 14,5° to + 16,5° Determine in a 4 in 100/15 N formic acid solution within 30 minutes after preparation of the sample solution
Purity	
Loss on drying	Not more than 4,5 % (105 °C, 4 hours)
Sulphated ash	Not more than 0,2 % (expressed on dry weight basis)
Transmittance	The transmittance of a 1 % solution in 2N hydrochloric acid, determined in a 1-cm cell at 430 nm with a suitable spectrophotometer, using 2N hydrochloric acid as a reference, is not less than 0,95, equivalent to an absorbance of not more than approximately 0,022
Arsenic	Not more than 3 mg/kg (expressed on dry weight basis)
Lead	Not more than 1 mg/kg (expressed on dry weight basis)
5-Benzyl-3,6-dioxo-2-piperazineacetic acid	Not more than 1,5 % (expressed on dry weight basis)

E 952 CYCLAMIC ACID AND ITS Na AND Ca SALTS

(i) CYCLAMIC ACID

Synonyms	Cyclohexylsulphamic acid; Cyclamate
Definition	
Einecs	202-898-1
Chemical name	Cyclohexanesulphamic acid; cyclohexylaminosulphonic acid
Chemical formula	$C_6H_{13}NO_3S$
Molecular weight	179,24
Assay	Cyclohexylsulphamic acid contains not less than 98 % and not more than the equivalent of 102 % of $C_6H_{13}NO_3S$, calculated on the anhydrous basis
Description	A practically colourless, white crystalline powder. Approximately 40 times as sweet as sucrose
Identification	
Solubility	Soluble in water and in ethanol
Precipitation test	Acidify a 2 % solution with hydrochloric acid, add 1 ml of an approximately molar solution of barium chloride in water and filter if any haze or precipitate forms. To the clear solution add 1 ml of a 10 % solution of sodium nitrite. A white precipitate forms.
Purity	
Loss on drying	Not more than 1 % (105 °C, 1 hour)
Selenium	Not more than 30 mg/kg (expressed as selenium on dry weight basis)

▼B

Lead	Not more than 1 mg/kg (expressed on dry weight basis)
Arsenic	Not more than 3 mg/kg (expressed on dry weight basis)
Cyclohexylamine	Not more than 10 mg/kg (expressed on dry weight basis)
Dicyclohexylamine	Not more than 1 mg/kg (expressed on dry weight basis)
Aniline	Not more than 1 mg/kg (expressed on dry weight basis)

(ii) SODIUM CYCLAMATE

Synonyms	Cyclamate; Sodium salt of cyclamic acid
Definition	
Einecs	205-348-9
Chemical name	Sodium cyclohexanesulphamate, sodium cyclohexylsulphamate
Chemical formula	$C_6H_{12}NNaO_3S$ and the dihydrate form $C_6H_{12}NNaO_3S{\cdot}2H_2O$
Molecular weight	201,22 calculated on the anhydrous form 237,22 calculated on the hydrated form
Assay	Not less than 98 % and not more than 102 % on the dried basis Dihydrate form: not less than 84 % on the dried basis
Description	White, odourless crystals or crystalline powder. Approximately 30 times as sweet as sucrose
Identification	
Solubility	Soluble in water, practically insoluble in ethanol
Purity	
Loss on drying	Not more than 1 % (105 °C, 1 hour) Not more than 15,2 % (105 °C, 2 hours) for the dihydrate form
Selenium	Not more than 30 mg/kg (expressed as selenium on dry weight basis)
Arsenic	Not more than 3 mg/kg (expressed on dry weight basis)
Lead	Not more than 1 mg/kg (expressed on dry weight basis)
Cyclohexylamine	Not more than 10 mg/kg (expressed on dry weight basis)
Dicyclohexylamine	Not more than 1 mg/kg (expressed on dry weight basis)
Aniline	Not more than 1 mg/kg (expressed on dry weight basis)

(iii) CALCIUM CYCLAMATE

Synonyms	Cyclamate; Calcium salt of cyclamic acid
Definition	
Einecs	205-349-4
Chemical name	Calcium cyclohexanesulphamate, calcium cyclohexylsulphamate
Chemical formula	$C_{12}H_{24}CaN_2O_6S_2{\cdot}\ 2H_2O$
Molecular weight	432,57
Assay	Not less than 98 % and not more than 101 % on the dried basis
Description	White, colourless crystals or crystalline powder. Approximately 30 times as sweet as sucrose
Identification	
Solubility	Soluble in water, sparingly soluble in ethanol

▼B

Purity	
Loss on drying	Not more than 1 % (105 °C, 1 hour) Not more than 8,5 % (140 °C, 4 hours) for the dihydrate form
Selenium	Not more than 30 mg/kg (expressed as selenium on dry weight basis)
Arsenic	Not more than 3 mg/kg (expressed on dry weight basis)
Lead	Not more than 1 mg/kg (expressed on dry weight basis)
Cyclohexylamine	Not more than 10 mg/kg (expressed on dry weight basis)
Dicyclohexylamine	Not more than 1 mg/kg (expressed on dry weight basis)
Aniline	Not more than 1 mg/kg (expressed on dry weight basis)

E 953 ISOMALT

Synonyms	Hydrogenated isomaltulose.
Definition	Manufactured by enzymatic conversion of sucrose with nonviable cells of *Protaminobacter rubrum* followed by catalytic hydrogenation
Einecs	
Chemical name	Isomalt is a mixture of hydrogenated mono- and disaccharides whose principal components are the disaccharides: 6-O-α-D-Glucopyranosyl-D-sorbitol (1,6-GPS) and 1-O-α-D-Glucopyranosyl-D-mannitol dihydrate (1,1-GPM)
Chemical formula	6-O-α-D-Glucopyranosyl-D-sorbitol: $C_{12}H_{24}O_{11}$ 1-O-α-D-Glucopyranosyl-D-mannitol dihydrate: $C_{12}H_{24}O_{11}.2H_2O$
Molecular weight	6-O-α-D-Glucopyranosyl-D-sorbitol: 344,3 1-O-α-D-Glucopyranosyl-D-mannitol dihydrate: 380,3
Assay	Content not less than 98 % of hydrogenated mono- and disaccharides and not less than 86 % of the mixture of 6-O-α-D-Glucopyranosyl-D-sorbitol and 1-O-α-D-Glucopyranosyl-D-mannitol dihydrate determined on the anhydrous basis.

▼M4

Description	Odourless, white, slightly hygroscopic, crystalline mass or aqueous solution with a minimum concentration of 60 %

▼B

Identification	
Solubility	Soluble in water, very slightly soluble in ethanol.
HPLC test	Comparison with an appropriate reference standard of Isomalt shows that the 2 principal peaks in the chromatogram of the test solution are similar in retention time to the 2 principal peaks in the chromatogram obtained with the reference solution.

▼M4

Purity	
Water content	Not more than 7 % for solid product (Karl Fischer Method)
Conductivity	Not more than 20 µS/cm (on 20 % dry solids solution) at temperature 20 °C
D-Mannitol	Not more than 3 %
D-Sorbitol	Not more than 6 %

▼M4

Reducing sugars	Not more than 0,3 % (expressed as glucose on dry weight basis)
Nickel	Not more than 2 mg/kg (expressed on dry weight basis)
Arsenic	Not more than 3 mg/kg (expressed on dry weight basis)
Lead	Not more than 1 mg/kg (expressed on dry weight basis)

▼B

E 954 SACCHARIN AND ITS Na. K AND Ca SALTS

(i) SACCHARIN

Synonyms	
Definition	
Einecs	201-321-0
Chemical name	3-Oxo-2,3dihydrobenzo(d)isothiazol-1,1-dioxide
Chemical formula	$C_7H_5NO_3S$
Molecular weight	183,18
Assay	Not less than 99 % and not more than 101 % of $C_7H_5NO_3S$ on the anhydrous basis
Description	White crystals or a white crystalline powder, odourless or with a faint, aromatic odour. Approximately between 300 and 500 times as sweet as sucrose
Identification	
Solubility	Slightly soluble in water, soluble in basic solutions, sparingly soluble in ethanol
Purity	
Loss on drying	Not more than 1 % (105 °C, 2 hours)
Melting range	226 to 230 °C
Sulphated ash	Not more than 0,2 % (expressed on dry weight basis)
Benzoic and salicylic acid	To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears
o-Toluenesulphonamide	Not more than 10 mg/kg (expressed on dry weight basis)
p-Toluenesulphonamide	Not more than 10 mg/kg (expressed on dry weight basis)
Benzoic acid *p*-sulphonamide	Not more than 25 mg/kg (expressed on dry weight basis)
Readily carbonisable substances	Absent
Arsenic	Not more than 3 mg/kg (expressed on dry weight basis)
Selenium	Not more than 30 mg/kg (expressed on dry weight basis)
Lead	Not more than 1 mg/kg (expressed on dry weight basis)

(ii) SODIUM SACCHARIN

Synonyms	Saccharin; Sodium salt of saccharin
Definition	
Einecs	204-886-1
Chemical name	Sodium o-benzosulphimide; sodium salt of 2,3-dihydro-3-oxobenzisosulphonazole; oxobenzisosulphonazole; 1,2-benzisothiazolin-3-one-1, 1-dioxide sodium salt dihydrate

▼B

Chemical formula	$C_7H_4NNaO_3S \cdot 2H_2O$
Molecular weight	241,19
Assay	Not less than 99 % and not more than 101 % of $C_7H_4NNaO_3S$ on the anhydrous basis
Description	White crystals or a white crystalline efflorescent powder, odourless or with a faint odour. Approximately between 300 and 500 times as sweet as sucrose in dilute solutions
Identification	
Solubility	Freely soluble in water, sparingly soluble in ethanol
Purity	
Loss on drying	Not more than 15 % (120 °C, 4 hours)
Benzoic and salicylic acid	To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears
o-Toluenesulphonamide	Not more than 10 mg/kg (expressed on dry weight basis)
p-Toluenesulphonamide	Not more than 10 mg/kg (expressed on dry weight basis)
Benzoic acid *p*-sulphonamide	Not more than 25 mg/kg (expressed on dry weight basis)
Readily carbonisable substances	Absent
Arsenic	Not more than 3 mg/kg (expressed on dry weight basis)
Selenium	Not more than 30 mg/kg (expressed on dry weight basis)
Lead	Not more than 1 mg/kg (expressed on dry weight basis)

(iii) CALCIUM SACCHARIN

Synonyms	Saccharin; Calcium salt of saccharin
Definition	
Chemical name	Calcium o-benzosulphimide; calcium salt of 2,3-dihydro-3-oxobenzisosulphonazole; 1,2-benzisothiazolin-3-one-1,1-dioxide calcium salt hydrate (2:7)
Einecs	229-349-9
Chemical formula	$C_{14}H_8CaN_2O_6S_2 \cdot 3½H_2O$
Molecular weight	467,48
Assay	Not less than 95 % of $C_{14}H_8CaN_2O_6S_2$ on the anhydrous basis
Description	White crystals or a white crystalline powder, odourless or with a faint odour. Approximately between 300 and 500 times as sweet as sucrose in dilute solutions
Identification	
Solubility	Freely soluble in water, soluble in ethanol
Purity	
Loss on drying	Not more than 13,5 % (120 °C, 4 hours)
Benzoic and salicylic acid	To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears

▼B

o-Toluenesulphonamide	Not more than 10 mg/kg expressed (on dry weight basis)
p-Toluenesulphonamide	Not more than 10 mg/kg expressed (on dry weight basis)
Benzoic acid *p*-sulphonamide	Not more than 25 mg/kg expressed (on dry weight basis)
Readily carbonisable substances	Absent
Arsenic	Not more than 3 mg/kg (expressed on dry weight basis)
Selenium	Not more than 30 mg/kg (expressed on dry weight basis)
Lead	Not more than 1 mg/kg (expressed on dry weight basis)

(iv) POTASSIUM SACCHARIN

Synonyms	Saccharin; Potassium salt of saccharin
Definition	
Einecs	
Chemical name	Potassium o-benzosulphimide; potassium salt of 2,3-dihydro-3-oxobenzisosulphonazole; potassium salt of 1,2-benzisothiazolin-3-one-1,1-dioxide monohydrate
Chemical formula	$C_7H_4KNO_3S \cdot H_2O$
Molecular weight	239,77
Assay	Not less than 99 % and not more than 101 % of $C_7H_4KNO_3S$ on the anhydrous basis
Description	White crystals or a white crystalline powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose
Identification	
Solubility	Freely soluble in water, sparingly soluble in ethanol
Purity	
Loss on drying	Not more than 8 % (120 °C, 4 hours)
Benzoic and salicylic acid	To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears
o-Toluenesulphonamide	Not more than 10 mg/kg (expressed on dry weight basis)
p-Toluenesulphonamide	Not more than 10 mg/kg (expressed on dry weight basis)
Benzoic acid *p*-sulphonamide	Not more than 25 mg/kg (expressed on dry weight basis)
Readily carbonisable substances	Absent
Arsenic	Not more than 3 mg/kg (expressed on dry weight basis)
Selenium	Not more than 30 mg/kg (expressed on dry weight basis)
Lead	Not more than 1 mg/kg (expressed on dry weight basis)

E 955 SUCRALOSE

Synonyms	4,1’,6’-Trichlorogalactosucrose
Definition	
Einecs	259-952-2
Chemical name	1,6-Dichloro-1,6-dideoxy-β-D-fructofuranosyl-4-chloro-4-deoxy-α-D-galactopyranoside
Chemical formula	$C_{12}H_{19}Cl_3O_8$
Molecular weight	397,64

▼B

Assay	Content not less than 98 % and not more than 102 % $C_{12}H_{19}Cl_3O_8$ calculated on an anhydrous basis.
Description	White to off-white, practically odourless, crystalline powder.
Identification	
Solubility	Freely soluble in water, methanol and ethanol Slightly soluble in ethyl acetate
Infrared absorption spectrum	The infrared spectrum of a potassium bromide dispersion of the sample exhibits relative maxima at similar wave numbers as those shown in the reference spectrum obtained using a sucralose reference standard.
Thin layer chromatography	The main spot in the test solution has the same Rf value as that of the main spot of standard solution A referred to in the test for other chlorinated disaccharides. This standard solution is obtained by dissolving 1,0g of sucralose reference standard in 10 ml of methanol.
Specific rotation	$[\alpha]_D^{20}$ + 84,0° to + 87,5° calculated on the anhydrous basis (10 % w/v solution)
Purity	
Water content	Not more than 2,0 % (Karl Fischer method)
Sulphated ash	Not more than 0,7 %
Other chlorinated disaccharides	Not more than 0,5 %
Chlorinated monosaccharides	Not more than 0,1 %
Triphenylphosphine oxide	Not more than 150 mg/kg
Methanol	Not more than 0,1 %
Lead	Not more than 1 mg/kg

E 957 THAUMATIN

Synonyms	
Definition	
Einecs	258-822-2
Chemical name	Thaumatin is obtained by aqueous extraction (pH 2,5 to 4) of the arils of the fruit of strains of *Thaumatococcus daniellii* (Benth) and consists essentially of the proteins thaumatin I and thaumatin II together with minor amounts of plant constituents derived from the source material
Chemical formula	Polypeptide of 207 amino acids
Molecular weight	Thaumatin I 22209 Thaumatin II 22293
Assay	Not less than 15,1 % nitrogen on the dried basis equivalent to not less than 93 % proteins (N × 6,2)
Description	Odourless, cream-coloured powder. Approximately 2 000 to 3 000 times as sweet as sucrose
Identification	
Solubility	Very soluble in water, insoluble in acetone
Purity	
Loss on drying	Not more than 9 % (105 °C to constant weight)
Carbohydrates	Not more than 3 % (expressed on dry weight basis)
Sulphated ash	Not more than 2 % (expressed on dry weight basis)
Aluminium	Not more than 100 mg/kg (expressed on dry weight basis)

▼B

Arsenic	Not more than 3 mg/kg (expressed on dry weight basis)
Lead	Not more than 3 mg/kg (expressed on dry weight basis)
Microbiological criteria	
Total aerobic microbial count	Not more than 1 000 colonies per gram
Escherichia coli	Absent in 1 g

E 959 NEOHESPERIDINE DIHYDROCHALCONE

Synonyms	Neohesperidin dihydrochalcone; NHDC; Hesperetin dihydrochalcone-4′-β-neohesperidoside; Neohesperidin DC
Definition	It is obtained by catalytic hydrogenation of neohesperidin
Einecs	243-978-6
Chemical name	2-O-α-L-rhamnopyranosyl-4′-β-D-glucopyranosyl hesperetin dihydrochalcone.
Chemical formula	$C_{28}H_{36}O_{15}$
Molecular weight	612,6
Assay	Content not less than 96 % on the dried basis
Description	Off-white, odourless, crystalline powder. Approximately between 1 000 and 1 800 times as sweet as sucrose
Identification	
Solubility	Freely soluble in hot water, very slightly soluble in cold water, practically insoluble in ether and benzene
Ultraviolet absorption maximum	282 to 283 nm for a solution of 2 mg in 100 ml methanol
Neu's test	Dissolve about 10 mg of neohesperidine DC in 1 ml methanol, add 1 ml of a 1 % 2-aminoethyl diphenyl borate methanolic solution. A bright yellow colour is produced
Purity	
Loss on drying	Not more than 11 % (105 °C, 3 hours)
Sulphated ash	Not more than 0,2 % (expressed on dry weight basis)
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Lead	Not more than 2 mg/kg (expressed on dry weight basis)

▼M33

E 960a STEVIOL GLYCOSIDES FROM STEVIA

▼M21

Synonyms	
Definition	The manufacturing process comprises two main phases: the first involving water extraction of the leaves of the *Stevia rebaudiana* Bertoni plant and preliminary purification of the extract by employing ion exchange chromatography to yield a steviol glycoside primary extract, and the second involving recrystallisation of the steviol glycosides from methanol or aqueous ethanol resulting in a final product containing not less than 95 % of the below identified 11 related steviol glycosides, in any combination and ratio. The additive may contain residues of ion-exchange resins used in the manufacturing process. Several other related steviol glycosides that may be generated as a result of the production process, but do not occur naturally in the *Stevia rebaudiana* plant have been identified in small amounts (0,10 to 0,37 % w/w).

▼**M21**

Chemical name

Steviolbioside: 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl) oxy]kaur-16-en-18-oic acid

Rubusoside: 13-β-D-glucopyranosyloxykaur-16-en-18-oic acid, β-D-glucopyranosyl ester

Dulcoside A: 13-[(2-O-α–L-rhamnopyranosyl-β–D-glucopyranosyl) oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester

Stevioside: 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester

Rebaudioside A: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester

Rebaudioside B: 13-[(2-O-β–D-glucopyranosyl-3-O-β–D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid

Rebaudioside C: 13-[(2-O-α–L-rhamnopyranosyl-3-O-β–D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester

Rebaudioside D: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester

Rebaudioside E: 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester

Rebaudioside F: 13[(2-O-β-D-xylofurananosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester

Rebaudioside M: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester

Molecular formula

Trivial name	**Formula**	**Conversion factor**
Steviol	$C_{20}\ H_{30}\ O_3$	1,00
Steviolbioside	$C_{32}\ H_{50}\ O_{13}$	0,50
Rubusoside	$C_{32}\ H_{50}\ O_{13}$	0,50
Dulcoside A	$C_{38}\ H_{60}\ O_{17}$	0,40
Stevioside	$C_{38}\ H_{60}\ O_{18}$	0,40
Rebaudioside A	$C_{44}\ H_{70}\ O_{23}$	0,33
Rebaudioside B	$C_{38}\ H_{60}\ O_{18}$	0,40
Rebaudioside C	$C_{44}\ H_{70}\ O_{22}$	0,34
Rebaudioside D	$C_{50}\ H_{80}\ O_{28}$	0,29
Rebaudioside E	$C_{44}\ H_{70}\ O_{23}$	0,33
Rebaudioside F	$C_{43}\ H_{68}\ O_{22}$	0,34
Rebaudioside M	$C_{56}\ H_{90}\ O_{33}$	0,25

▼M21

Molecular weight and CAS No	**Trivial name**	**CAS Number**	**Molecular weight** (g/mol)
	Steviol		318,46
	Steviolbioside	41093-60-1	642,73
	Rubusoside	64849-39-4	642,73
	Dulcoside A	64432-06-0	788,87
	Stevioside	57817-89-7	804,88
	Rebaudioside A	58543-16-1	967,01
	Rebaudioside B	58543-17-2	804,88
	Rebaudioside C	63550-99-2	951,02
	Rebaudioside D	63279-13-0	1 129,15
	Rebaudioside E	63279-14-1	967,01
	Rebaudioside F	438045-89-7	936,99
	Rebaudioside M	1220616-44-3	1 291,30
Assay	Not less than 95 % steviolbioside, rubusoside, dulcoside A, stevioside, rebaudiosides A, B, C, D, E, F and M on the dried basis, in any combination and ratio.		
Description	White to light yellow powder, approximately between 200 and 350 times sweeter than sucrose (at 5 % sucrose equivalency).		
Identification			
Solubility	Freely soluble to slightly soluble in water		
pH	Between 4,5 and 7,0 (1 in 100 solution)		
Purity			
Total ash	Not more than 1 %		
Loss on drying	Not more than 6 % (105 °C, 2h)		
Residual solvents	Not more than 200 mg/kg methanol Not more than 5 000 mg/kg ethanol		
Arsenic	Not more than 1 mg/kg		
Lead	Not more than 1 mg/kg		

▼M33

E 960c(i) REBAUDIOSIDE M PRODUCED VIA ENZYME MODIFICATION OF STEVIOL GLYCOSIDES FROM STEVIA

Synonyms	
Definition	Rebaudioside M is a steviol glycoside composed predominantly of rebaudioside M with minor amounts of other steviol glycosides such as rebaudioside A, rebaudioside B, rebaudioside D, rebaudioside I, and stevioside. Rebaudioside M is obtained via enzymatic bioconversion of purified steviol glycoside leaf extracts (95% steviol glycosides) of the *Stevia rebaudiana* Bertoni plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by the genetically modified yeasts *K. phaffi* (formerly known as *Pichia pastoris*) UGT-a and *K. phaffi* UGT-b that facilitate the transfer of glucose from sucrose and UDP-glucose to steviol glycosides via glycosidic bonds.

▼**M33**

	After removal of the enzymes by solid-liquid separation and heat treatment, the purification involves concentration of the rebaudioside M by resin adsorption, followed by recrystallisation of rebaudioside M resulting in a final product containing not less than 95 % of rebaudioside M. ►**M38** Viable cells of the yeasts *K. phaffii* UGT-a and *K. phaffii* UGT-b and their DNA shall not be detected in the food additive. ◄		
Chemical name	Rebaudioside M: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester		
Molecular formula	Trivial name	Formula	Conversion factor
	Rebaudioside M	C_{56} H_{90} O_{33}	0,25
Molecular weight and CAS No	Trivial name	CAS Number	Molecular weight (g/mol)
	Rebaudioside M	1220616-44-3	1,291.29
Assay	Not less than 95 % rebaudioside M on the dried basis.		
Description	White to light yellow powder, approximately between 200 and 350 times sweeter than sucrose (at 5 % sucrose equivalency).		
Identification			
Solubility	Freely soluble to slightly soluble in water		
pH	Between 4,5 and 7,0 (1 in 100 solution)		
Purity			
Total ash	Not more than 1 %		
Loss on drying	Not more than 6 % (105 °C, 2h)		
Residual solvent	Not more than 5 000 mg/kg ethanol		
Arsenic	Not more than 0,015 mg/kg		
Lead	Not more than 0,2 mg/kg		
Cadmium	Not more than 0,015 mg/kg		
Mercury	Not more than 0,07 mg/kg		
Residual protein	Not more than 5 mg/kg		
Particle size	Not less than 74 μm [using a mesh #200 sieve with a particle size limit of 74 μm]		

▼M38

E 960c(ii) REBAUDIOSIDE M PRODUCED VIA ENZYMATIC CONVERSION OF HIGHLY PURIFIED REBAUDIOSIDE A STEVIA LEAF EXTRACTS

Synonyms			
Definition	Rebaudioside M produced via enzymatic conversion of highly purified rebaudioside A stevia leaf extracts is a steviol glycoside composed predominantly of rebaudioside M with minor amounts of other steviol glycosides such as rebaudioside A and rebaudioside D. Rebaudioside M is produced via enzymatic conversion of highly purified steviol glycoside rebaudioside A extracts (95 % steviol glycosides) obtained from *Stevia rebaudiana* Bertoni plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by the genetically modified strains of *E. coli* (pPM294, pFAF170 and pSK401) that facilitate the transfer of glucose from sucrose and UDP-glucose to steviol glycosides via glycosidic bonds. After removal of the enzymes by solid-liquid separation and heat treatment, the purification involves concentration of the rebaudioside M by resin adsorption, followed by recrystallisation of the steviol glycosides resulting in a final product containing not less than 95 % of rebaudioside M. Viable cells of *E. coli* (pPM294, pFAF170 and pSK401) and their DNA shall not be detected in the food additive.		
Chemical name	Rebaudioside M: 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl ester		
Molecular formula	Trivial name	Formula	Conversion factor
	Rebaudioside M	$C_{56}H_{90}O_{33}$	0,25
Molecular weight and CAS No	Trivial name	CAS Number	Molecular weight (g/mol)
	Rebaudioside M	1220616-44-3	1 291,29
Assay	Not less than 95 % rebaudioside M on the dried basis.		
Description	White to light yellow powder, approximately between 150 and 350 times sweeter than sucrose (at 5 % sucrose equivalency).		
Identification			
Solubility	Freely soluble to slightly soluble in water		
pH	Between 4,5 and 7,0 (1 in 100 solution)		
Purity			
Total ash	Not more than 1 %		
Loss on drying	Not more than 6 % (105 °C, 2h)		
Residual solvent	Not more than 5 000 mg/kg ethanol		
Arsenic	Not more than 0,015 mg/kg		
Lead	Not more than 0,2 mg/kg		
Cadmium	Not more than 0,015 mg/kg		

▼M38

Mercury	Not more than 0,07 mg/kg
Residual protein	Not more than 5 mg/kg
Particle size	Not less than 74 μm [using a mesh #200 sieve with a particle size limit of 74 μm]

E 960c(iii) REBAUDIOSIDE D PRODUCED VIA ENZYMATIC CONVERSION OF HIGHLY PURIFIED REBAUDIOSIDE A STEVIA LEAF EXTRACTS

Synonyms			
Definition	Rebaudioside D produced via enzymatic conversion of highly purified rebaudioside A stevia leaf extracts is a steviol glycoside composed predominantly of rebaudioside D with minor amounts of other steviol glycosides such as rebaudioside A and rebaudioside M. Rebaudioside D is produced via enzymatic conversion of highly purified steviol glycoside rebaudioside A extracts (95 % steviol glycosides) obtained from *Stevia rebaudiana* Bertoni plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by the genetically modified strains of *E. coli* (pPM294, pFAF170 and pSK401) that facilitate the transfer of glucose from sucrose and UDP-glucose to steviol glycosides via glycosidic bonds. After removal of the enzymes by solid-liquid separation and heat treatment, the purification involves concentration of the rebaudioside D by resin adsorption, followed by recrystallisation of the steviol glycosides resulting in a final product containing not less than 95 % of rebaudioside D and rebaudioside A. Viable cells of *E. coli* (pPM294, pFAF170 and pSK401) and their DNA shall not be detected in the food additive.		
Chemical name	Rebaudioside D: 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl ester. Rebaudioside A: 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester		
Molecular formula	Trivial name	Formula	Conversion factor
	Rebaudioside D	$C_{50}H_{80}O_{28}$	0,29
	Rebaudioside A	$C_{44}H_{70}O_{23}$	0,33
Molecular weight and CAS No	Trivial name	CAS Number	Molecular weight (g/mol)
	Rebaudioside D	63279-13-0	1 291,15
	Rebaudioside A	58543-16-1	967,01
Assay	Not less than 95 % rebaudiosides D and A on the dried basis.		
Description	White to light yellow powder, approximately between 150 and 350 times sweeter than sucrose (at 5 % sucrose equivalency).		

Identification

Solubility	Freely soluble to slightly soluble in water
pH	Between 4,5 and 7,0 (1 in 100 solution)

▼M38

Purity	
Total ash	Not more than 1 %
Loss on drying	Not more than 6 % (105 °C, 2h)
Residual solvent	Not more than 5 000 mg/kg ethanol
Arsenic	Not more than 0,015 mg/kg
Lead	Not more than 0,2 mg/kg
Cadmium	Not more than 0,015 mg/kg
Mercury	Not more than 0,07 mg/kg
Residual protein	Not more than 5 mg/kg
Particle size	Not less than 74 μm [using a mesh #200 sieve with a particle size limit of 74 μm]

E 960c(iv) REBAUDIOSIDE AM PRODUCED VIA ENZYMATIC CONVERSION OF HIGHLY PURIFIED STEVIOSIDE STEVIA LEAF EXTRACTS

Synonyms			
Definition	Rebaudioside AM produced via enzymatic convertion of highly purified stevioside stevia leaf extracts is a steviol glycoside composed predominantly of rebaudioside AM with minor amounts of other steviol glycosides such as stevioside and rebaudioside E. Rebaudioside AM is produced via enzymatic conversion of highly purified steviol glycoside stevioside extracts (95 % steviol glycosides) obtained from *Stevia rebaudiana* Bertoni plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by the genetically modified strains of *E. coli* (pPM294, pFAF170 and pSK401) that facilitate the transfer of glucose from sucrose and UDP-glucose to steviol glycosides via glycosidic bonds. After removal of the enzymes by solid-liquid separation and heat treatment, the purification involves concentration of the rebaudioside AM by resin adsorption, followed by recrystallisation of the steviol glycosides resulting in a final product containing not less than 95 % of rebaudioside AM. Viable cells of *E. coli* (pPM294, pFAF170 and pSK401) and their DNA shall not be detected in the food additive.		
Chemical name	Rebaudioside AM: 13-[(2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2- *O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl ester.		
Molecular formula	Trivial name	Formula	Conversion factor
	Rebaudioside AM	C_{50} H_{80} O_{28}	0,29
Molecular weight and CAS No	Trivial name	CAS Number	Molecular weight (g/mol)
	Rebaudioside AM	2222580-26-7	1 291,15

▼M38

Assay	Not less than 95 % rebaudioside AM on the dried basis.
Description	White to light yellow powder, approximately between 150 and 350 times sweeter than sucrose (at 5 % sucrose equivalency).
Identification	
Solubility	Freely soluble to slightly soluble in water
pH	Between 4,5 and 7,0 (1 in 100 solution)
Purity	
Total ash	Not more than 1 %
Loss on drying	Not more than 6 % (105 °C, 2h)
Residual solvent	Not more than 5 000 mg/kg ethanol
Arsenic	Not more than 0,015 mg/kg
Lead	Not more than 0,2 mg/kg
Cadmium	Not more than 0,015 mg/kg
Mercury	Not more than 0,07 mg/kg
Residual protein	Not more than 5 mg/kg
Particle size	Not less than 74 μm [using a mesh #200 sieve with a particle size limit of 74 μm]

▼M40

E 960d GLUCOSYLATED STEVIOL GLYCOSIDES

Synonyms	
Definition	Mixture of larger glycosides of steviol derived by glucosylation of steviol glycosides extracted from leaves of *Stevia rebaudiana* Bertoni plant. The mixture is composed of glucosylated steviol glycosides and residual parent steviol glycosides from Stevia leaf. Glucosylated steviol glycosides are produced by treating the steviol glycosides, extracted from Stevia leaf, and starch suitable for human consumption with Cyclomaltodextrin glucanotransferase (EC 2.4.1.19) derived from a non-GMO strain of *Anoxybacillus caldiproteolyticus St-88*. The enzyme transfers glucose units from the starch to the steviol glycosides. The resulting material is heated and treated with activated carbon to remove the enzyme, then passed through adsorption/desorption resin to remove residual hydrolysed starch (dextrin), followed by purification and preparation of the final product using processes that may include decolourisation, concentration and spray drying.
Chemical name	Steviolbioside: 13-[(2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)-oxy]kaur-16-en-18-oic acid Rubusoside: 13-β-D-glucopyranosyloxykaur-16-en-18-oic acid, β-D-glucopyranosyl ester Dulcoside A: 13-[(2-*O*-α–L-rhamnopyranosyl-β–D-glucopyranosyl)-oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester Stevioside: 13-[(2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]-kaur-16-en-18-oic acid, β-D-glucopyranosyl ester Rebaudioside A: 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D- glucopyranosyl ester

▼M40

	Rebaudioside B: 13-[(2-*O*-β–D-glucopyranosyl-3-*O*-β–D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid Rebaudioside C: 13-[(2-*O*-α–L-rhamnopyranosyl-3-*O*-β–D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester Rebaudioside D: 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl ester Rebaudioside E: 13-[(2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl ester Rebaudioside F: 13-[(2-*O*-β-D-xylofurananosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester Rebaudioside M: 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl ester And their glucosylated derivatives (1-20 added glucose units)		
Molecular formula	**Trivial name**	**Formula**	**Conversion factor**
	n-Glucosylated Steviolbioside	$C_{(32+n*6)}H_{(50+n*10)}O_{(13+n*5)}$	
	n-Glucosylated Rubusoside	$C_{(32+n*6)}H_{(50+n*10)}O_{(13+n*5)}$	
	n-Glucosylated Dulcoside A	$C_{(38+n*6)}H_{(60+n*10)}O_{(17+n*5)}$	
	n-Glucosylated Stevioside	$C_{(38+n*6)}H_{(60+n*10)}O_{(18+n*5)}$	
	n-Glucosylated Rebaudioside A	$C_{(44+n*6)}H_{(70+n*10)}O_{(23+n*5)}$	
	n-Glucosylated Rebaudioside B	$C_{(38+n*6)}H_{(60+n*10)}O_{(18+n*5)}$	
	n-Glucosylated Rebaudioside C	$C_{(44+n*6)}H_{(70+n*10)}O_{(22+n*5)}$	
	n-Glucosylated Rebaudioside D	$C_{(50+n*6)}H_{(80+n*10)}O_{(28+n*5)}$	
	n-Glucosylated Rebaudioside E	$C_{(44+n*6)}H_{(70+n*10)}O_{(23+n*5)}$	
	n-Glucosylated Rebaudioside F	$C_{(43+n*6)}H_{(68+n*10)}O_{(22+n*5)}$	
	n-Glucosylated Rebaudioside M	$C_{(56+n*6)}H_{(90+n*10)}O_{(33+n*5)}$	
	n: number of glucose units enzymatically added to the parent steviol glycoside (n = 1-20) Typical conversion factor for glucosylated steviol glycosides mixtures = 0,20 (on the dried, dextrin-free, basis)		
	Steviol	$C_{20}H_{30}O_3$	1,00

▼M40

	Steviolbioside	$C_{32}H_{50}O_{13}$	0,50
	Rubusoside	$C_{32}H_{50}O_{13}$	0,50
	Dulcoside A	$C_{38}H_{60}O_{17}$	0,40
	Stevioside	$C_{38}H_{60}O_{18}$	0,40
	Rebaudioside A	$C_{44}H_{70}O_{23}$	0,33
	Rebaudioside B	$C_{38}H_{60}O_{18}$	0,40
	Rebaudioside C	$C_{44}H_{70}O_{22}$	0,34
	Rebaudioside D	$C_{50}H_{80}O_{28}$	0,29
	Rebaudioside E	$C_{44}H_{70}O_{23}$	0,33
	Rebaudioside F	$C_{43}H_{68}O_{22}$	0,34
	Rebaudioside M	$C_{56}H_{90}O_{33}$	0,25
Molecular weight and CAS No	**Trivial name**	**CAS Number**	**Molecular weight (g/mol)**
	n-Glucosylated Steviolbioside	Not available	642,73+n*162,15
	n-Glucosylated Rubusoside	Not available	642,73+n*162,15
	n-Glucosylated Dulcoside A	Not available	788,87+n*162,15
	n-Glucosylated Stevioside	Not available	804,88+n*162,15
	n-Glucosylated Rebaudioside A	Not available	967,01+n*162,15
	n-Glucosylated Rebaudioside B	Not available	804,88+n*162,15
	n-Glucosylated Rebaudioside C	Not available	951,02+n*162,15
	n-Glucosylated Rebaudioside D	Not available	1129,15+n*162,15
	n-Glucosylated Rebaudioside E	Not available	967,01+n*162,15
	n-Glucosylated Rebaudioside F	Not available	936,99+n*162,15
	n-Glucosylated Rebaudioside M	Not available	1291,30+n*162,15
	Steviol		318,46
	Steviolbioside	41093-60-1	642,73
	Rubusoside	64849-39-4	642,73
	Dulcoside A	64432-06-0	788,87
	Stevioside	57817-89-7	804,88
	Rebaudioside A	58543-16-1	967,01
	Rebaudioside B	58543-17-2	804,88
	Rebaudioside C	63550-99-2	951,02
	Rebaudioside D	63279-13-0	1 129,15
	Rebaudioside E	63279-14-1	967,01
	Rebaudioside F	438045-89-7	936,99
	Rebaudioside M	1220616-44-3	1 291,30

▼M40

Assay	Not less than 95 % of total steviol glycosides, comprised of above mentioned steviol glycosides along with their glucosylated derivatives (1-20 added glucose units), on the dried, dextrin-free, basis.
Description	White to light yellow powder, approximately between 100 and 200 times sweeter than sucrose (at 5 % sucrose equivalency).
Identification	
Solubility	Soluble in water
pH	Between 4,5 and 7,0 (1 in 100 solution)
Purity	
Total ash	Not more than 1 %
Loss on drying	Not more than 6 % (105 °C, 2 h)
Residual solvent	Not more than 200 mg/kg methanol Not more than 3 000 mg/kg ethanol
Arsenic	Not more than 0,015 mg/kg
Lead	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Microbiological criteria	
Total (aerobic) plate count	Not more than 1 000 CFU/g
Yeast and moulds	Not more than 200 CFU/g
E. coli	Negative in 1 g
Salmonella	Negative in 25 g

▼B

E 961 NEOTAME

Synonyms	N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine 1-methyl ester; N(3,3-dimethylbutyl)-L-aspartyl-L-phenylalanine methyl ester.
Definition	Neotame is manufactured by reaction under hydrogen pressure of aspartame with 3,3,-dimethylbutyraldehyde in methanol in presence of a palladium/carbon catalyst. It is isolated and purified by filtration, where diatomaceous earth may be used. After solvent removal via distillation, neotame is washed with water, isolated by centrifugation and finally vacuum dried.
CAS Nr.	165450-17-9
Chemical name	N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine 1-methyl ester
Chemical formula	$C_{20}H_{30}N_2O_5$
Molecular weight	378,47
Description	white to off-white powder
Assay	Not less than 97,0 % on the dried basis
Identification	
Solubility	4,75 % (w/w) at 60 °C in water, soluble in ethanol and ethyl acetate

▼B

Purity	
Water content	Not more than 5 % (Karl Fischer, sample size 25 ± 5mg)
pH	5,0-7,0 (0,5 % aqueous solution)
Melting range	81 °C to 84 °C
N-[(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine	Not more than 1,5 %
Lead	Not more than 1 mg/kg

E 962 SALT OF ASPARTAME-ACESULFAME

Synonyms	Aspartame-acesulfame; Aspartame-acesulfame salt
Definition	The salt is prepared by heating an approximately 2:1 ratio (w/w) of aspartame and acesulfame K in solution at acidic pH and allowing crystallisation to occur. The potassium and moisture are eliminated. The product is more stable than aspartame alone.
Einecs	
Chemical name	6-Methyl-1,2,3-oxathiazine-4(3H)-one-2,2-dioxide salt of L-phenylalanyl-2-methyl-L-α-aspartic acid
Chemical formula	$C_{18}H_{23}O_9N_3S$
Molecular weight	457,46
Assay	63,0 % to 66,0 % aspartame (dry basis) and 34,0 % to 37,0 % acesulfame (acid form on a dry basis)
Description	A white, odourless, crystalline powder
Identification	
Solubility	Sparingly soluble water; slightly soluble in ethanol
Transmittance	The transmittance of a 1 % solution in water determined in a 1 cm cell at 430 nm with a suitable spectrophotometer using water as a reference, is not less than 0,95, equivalent to an absorbance of not more than approximately 0,022.
Specific rotation	$[\alpha]_D^{20}$ + 14,5° to + 16,5° Determine at a concentration of 6,2 g in 100 ml formic acid (15N) within 30 min of preparation of the solution. Divide the calculated specific rotation by 0,646 to correct for the aspartame content of the salt of aspartame-acesulfame

▼B

Purity	
Loss on drying	Not more than 0,5 % (105 °C, 4 hours)
5-Benzyl-3,6-dioxo-2-piperazineacetic acid	Not more than 0,5 %
Lead	Not more than 1 mg/kg

▼M1

E 964 POLYGLYCITOL SYRUP

Synonyms	Hydrogenated starch hydrolysate, hydrogenated glucose syrup and polyglucitol
Definition	A mixture consisting mainly of maltitol and sorbitol and lesser amounts of hydrogenated oligo- and polysaccharides and maltrotriitol. It is manufactured by the catalytic hydrogenation of a mixture of starch hydrolysates consisting of glucose, maltose and higher glucose polymers, similar to the catalytic hydrogenation process used for the manufacture of maltitol syrup. The resulting syrup is desalted by ion exchange and concentrated to the desired level.
Einecs	
Chemical name	Sorbitol: D-glucitol Maltitol: (α)-D-Glucopyranosyl-1,4-D-glucitol
Chemical formula	Sorbitol: $C_6H_{14}O_6$ Maltitol: $C_{12}H_{24}O_{11}$
Molecular weight	Sorbitol: 182,2 Maltitol: 344,3
Assay	Content not less than 99 % of total hydrogenated saccharides on the anhydrous basis, not less than 50 % higher molecular weight polyols, not more than 50 % of maltitol and not more than 20 % of sorbitol on the anhydrous basis.
Description	Colourless and odourless clear viscous liquid
Identification	
Solubility	Very soluble in water and slightly soluble in ethanol
Test for maltitol	Passes test
Test for sorbitol	To 5 g of the sample add 7 ml of methanol, 1 ml of benzaldehyde and 1 ml of hydrochloric acid. Mix and shake in a mechanical shaker until crystals appear. Filter the crystals and dissolve in 20 ml of boiling water containing 1 g of sodium bicarbonate. Filter the crystals, wash with 5 ml of a water-methanol mixture (1 in 2) and dry in the air. The crystals of the monobenzylidine derivative of sorbitol so obtained melt between 173 and 179 °C.
Purity	
Water content	Not more than 31 % (Karl Fischer method)
Chlorides	Not more than 50 mg/kg
Sulphates	Not more than 100 mg/kg
Reducing sugars	Not more than 0,3 %
Nickel	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg

▼B

E 965 (i) MALTITOL

Synonyms	D-Maltitol; Hydrogenated maltose
Definition	Maltitol is obtained by hydrogenation of D-maltose. It is mainly composed of D-maltitol. It may contain small amounts of sorbitol and related polyhydric alcohols.
Einecs	209-567-0
Chemical name	(α)-D-Glucopyranosyl-1,4-D-glucitol
Chemical formula	$C_{12}H_{24}O_{11}$
Molecular weight	344,3
Assay	Content not less than 98 % D-maltitol $C_{12}H_{24}O_{11}$ on the anhydrous basis
Description	White crystalline powder
Identification	
Solubility	Very soluble in water, slightly soluble in ethanol
Melting range	148 to 151 °C
Specific rotation	$[\alpha]_D^{20}$ + 105,5° to + 108,5° (5 % w/v solution)

▼M4

Purity	
Appearance of the aqueous solution	The solution is clear and colourless
Water content	Not more than 1 % (Karl Fischer Method)
Conductivity	Not more than 20 µS/cm (on 20 % dry solids solution) at temperature 20 °C
Reducing sugars	Not more than 0,1 % (expressed as glucose on an anhydrous basis)
Nickel	Not more than 2 mg/kg (expressed on anhydrous basis)
Arsenic	Not more than 3 mg/kg (expressed on anhydrous basis)
Lead	Not more than 1 mg/kg (expressed on anhydrous basis)

▼B

E 965 (ii) MALTITOL SYRUP

Synonyms	Hydrogenated high-maltose-glucose syrup; Hydrogenated glucose syrup; Maltitol liquid
Definition	A mixture consisting of mainly maltitol with sorbitol and hydrogenated oligo- and polysaccharides. It is manufactured by the catalytic hydrogenation of high maltose-content glucose syrup or by the hydrogenation of its individual components followed by blending. The article of commerce is supplied both as a syrup and as a solid product.
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content not less than 99 % of total hydrogenated saccharides on the anhydrous basis and not less than 50 % of maltitol on the anhydrous basis
Description	Colourless and odourless, clear viscous liquids or white crystalline masses

▼B

Identification	
Solubility	Very soluble in water, slightly soluble in ethanol
HPLC test	Comparison with an appropriate reference standard of Maltitol shows that the principle peak in the chromatogram of the test solution is similar in retention time to the principal peak in the chromatogram obtained with the reference solution (ISO 10504:1998).

▼M4

Purity	
Appearance of the aqueous solution	The solution is clear and colourless
Water content	Not more than 31 % (Karl Fischer Method)
Conductivity	Not more than 10 µS/cm (on the product as such) at temperature 20 °C
Reducing sugars	Not more than 0,3 % (expressed as glucose on an anhydrous basis)
Nickel	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg

▼B

E 966 LACTITOL

Synonyms	Lactit; Lactositol; Lactobiosit
Definition	Lactitol is manufactured via catalytic hydrogenation of lactose
Einecs	209-566-5
Chemical name	4-O-β-D-Galactopyranosyl-D-glucitol
Chemical formula	$C_{12}H_{24}O_{11}$
Molecular weight	344,3
Assay	Not less than 95 % on the dry weight basis
Description	Crystalline powder or colourless solution. Crystalline products occur in anhydrous, monohydrate and dihydrate forms. Nickel is used as a catalyst.
Identification	
Solubility	Very soluble in water
Specific rotation	$[\alpha]_D^{20}$ = + 13° to + 16° calculated on the anhydrous basis (10 % w/v aqueous solution)
Purity	
Water content	Crystalline products; not more than 10,5 % (Karl Fischer method)
Other polyols	Not more than 2,5 % (on the anhydrous basis)
Reducing sugars	Not more than 0,2 % (expressed as glucose on dry weight basis)
Chlorides	Not more than 100 mg/kg (expressed on dry weight basis)
Sulphates	Not more than 200 mg/kg (expressed on dry weight basis)
Sulphated ash	Not more than 0,1 % (expressed on dry weight basis)
Nickel	Not more than 2 mg/kg (expressed on dry weight basis)
Arsenic	Not more than 3 mg/kg (expressed on dry weight basis
Lead	Not more than 1 mg/kg (expressed on dry weight basis)

▼B

E 967 XYLITOL

Synonyms	Xylitol
Definition	Xylitol is mainly composed of D-xylitol. The part which is not D-xylitol is composed of related substances such as L-arabinitol, galactitol, mannitol, sorbitol
Einecs	201-788-0
Chemical name	D-xylitol
Chemical formula	$C_5H_{12}O_5$
Molecular weight	152,2
Assay	Not less than 98,5 % as xylitol on the anhydrous basis
Description	White, crystalline powder, practically odourless.
Identification	
Solubility	Very soluble in water, sparingly soluble in ethanol
Melting range	92 to 96 °C
pH	5 to 7 (10 % w/v aqueous solution)
Infrared absorption spectroscopy	Comparison with a reference standard e.g. EP or USP.

▼M4

Purity	
Water content	Not more than 1 % (Karl Fischer Method)
Conductivity	Not more than 20 µS/cm (on 20 % dry solids solution) at temperature 20 °C
Reducing sugars	Not more than 0,2 % (expressed as glucose on dry weight basis)
Other polyhydric alcohols	Not more than 1 % (expressed on dry weight basis)
Nickel	Not more than 2 mg/kg (expressed on dry weight basis)
Arsenic	Not more than 3 mg/kg (expressed on dry weight basis)
Lead	Not more than 1 mg/kg (expressed on dry weight basis)

▼B

E 968 ERYTHRITOL

Synonyms	Meso-erythritol; Tetrahydroxybutane; Erythrite
Definition	Obtained by fermentation of carbohydrate source by safe and suitable food grade osmophilic yeasts such as *Moniliella pollinis* or *Moniliella megachilensis*, followed by purification and drying
Einecs	205-737-3
Chemical name	1,2,3,4-Butanetetrol
Chemical formula	$C_4H_{10}O_4$
Molecular weight	122,12
Assay	Not less than 99 % after drying
Description	White, odourless, non-hygroscopic, heat-stable crystals with a sweetness of approximately 60-80 % that of sucrose.

▼B

Identification	
Solubility	Freely soluble in water, slightly soluble in ethanol, insoluble in diethyl ether.
Melting range	119-123 °C

▼M4

Purity	
Loss on drying	Not more than 0,2 % (70 °C, 6 hours, in a vacuum desiccator)
Conductivity	Not more than 20 µS/cm (on 20 % dry solids solution) at temperature 20 °C
Reducing substances	Not more than 0,3 % expressed as D-glucose
Ribitol and glycerol	Not more than 0,1 %
Lead	Not more than 0,5 mg/kg

▼M11

E 969 ADVANTAME

Synonyms	
Definition	Advantame (ANS9801) is produced by chemical synthesis in a three-step process; production of the principal manufacturing intermediate, 3-hydroxy-4-methoxycinnamaldehyde (HMCA), followed by hydrogenation to form 3-(3-hydroxy-4-methoxyphenyl) propionaldehyde (HMPA). In the final step, the HMPA methanol solution (filtrate) is combined with aspartame to give the imine that under selective hydrogenation forms advantame. The solution is allowed to crystallise and crude crystals are washed. The product is re-crystallised and crystals are separated, washed and dried.
CAS No.	714229-20-6
Chemical name	N-[*N*-[3-(3-hydroxy-4-methoxyphenyl) propyl]-α-aspartyl]-L-phenylalanine 1-methyl ester, monohydrate (IUPAC); L-phenylalanine, N-[3-(3-hydroxy-4-methoxyphenyl)propyl]-L-alpha-aspartyl-, 2-methyl ester, monohydrate (CA)
Molecular formula	$C24H30N2O7 \cdot H_2O$
Molecular weight	476,52 g/mol (monohydrate)
Assay	Not less than 97,0 % and not more than 102,0 % on an anhydrous basis
Description	White to yellow powder
Identification	
Melting Point	101,5 °C
Purity	
N-[N-[3-(3-hydroxy-4-methoxyphenyl)propyl-α-aspartyl]-L-phenylalanine (ANS9801-acid)	Not more than 1,0 %
Total other related substances	Not more than 1,5 %
Residual Solvents	Isopropyl acetate: Not more than 2 000 mg/kg Methyl acetate: Not more than 500 mg/kg Methanol: Not more than 500 mg/kg 2-Propanol: Not more than 500 mg/kg

▼M11

Water content	Not more than 5,0 % (Karl Fischer method)
Residue on ignition	Not more than 0,2 %
Arsenic	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg
Palladium	Not more than 5,3 mg/kg
Platinum	Not more than 1,7 mg/kg

▼B

E 999 QUILLAIA EXTRACT

Synonyms	Soapbark extract; Quillay bark extract; Panama bark extract; Quillai extract; Murillo bark extract; China bark extract
Definition	Quillaia extract is obtained by aqueous extraction of *Quillaia saponaria Molina*, or other *Quillaia* species, trees of the family *Rosaceae*. It contains a number of triterpenoid saponins consisting of glycosides of quillaic acid. Some sugars including glucose, galactose, arabinose, xylose, and rhamnose are also present, along with tannin, calcium oxalate and other minor components
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	Quillaia extract in the powder form is light brown with a pink tinge. It is also available as an aqueous solution
Identification	
pH	Between 3,7 and 5,5 (4 % solution)
Purity	
Water content	Not more than 6,0 % (Karl Fischer method) (powder form only)
Arsenic	Not more than 2 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

E 1103 INVERTASE

Synonyms	
Definition	Invertase is produced from *Saccharomyces cerevisiae*
Einecs	232-615-7
Enzyme Commission No	EC 3.2.1.26
Systematic name	β-D-Fructofuranoside fructohydrolase

▼B

Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	
Identification	
Purity	
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Cadmium	Not more than 0,5 mg/kg
Microbiological criteria	
Total bacterial count	Not more than 50 000 colonies per gram
Salmonella spp.	Absent in 25 g
Coliforms	Not more than 30 colonies per gram
Escherichia coli	Absent in 25 g

E 1105 LYSOZYME

Synonyms	Lysozyme hydrochloride; Muramidase
Definition	Lysozyme is a linear polypeptide obtained from hens' egg whites consisting of 129 amino acids. It possesses enzymatic activity in its ability to hydrolyse the β(1-4) linkages between N-acetylmuramic acid and N-acetylglucosamine in the outer membranes of bacterial species, in particular gram-positive organisms. Is usually obtained as the hydrochloride
Einecs	232-620-4
Enzyme Commission No	EC 3.2.1.17
Chemical name	
Chemical formula	
Molecular weight	About 14 000
Assay	Content not less than 950 mg/g on the anhydrous basis
Description	White, odourless powder having a slightly sweet taste
Identification	
Isoelectric point	10,7
pH	Between 3,0 and 3,6 (2 % aqueous solution)
Spectrophotometry	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

▼B

Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Microbiological criteria	
Total bacterial count	Not more than 5×10^4 colonies per gram
Salmonella spp.	Absent in 25 g
Staphylococcus aureus	Absent in 1 g
Escherichia coli	Absent in 1 g

E 1200 POLYDEXTROSE

Synonyms	Modified polydextroses
Definition	Randomly bonded glucose polymers with some sorbitol end-groups, and with citric acid or phosphoric acid residues attached to the polymers by mono or diester bonds. They are obtained by melting and condensation of the ingredients and consist of approximately 90 parts D-glucose, 10 parts sorbitol and 1 part citric acid and/or 0,1 part phosphoric acid. The 1,6-glucosidic linkage predominates in the polymers but other linkages are present. The products contain small quantities of free glucose, sorbitol, levoglucosan (1,6-anhydro-D-glucose) and citric acid and may be neutralised with any food grade base and/or decolourised 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
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content not less than 90 % of polymer on the ash free and anhydrous basis
Description	White to light tan-coloured solid. Polydextroses dissolve in water to give a clear, colourless to straw coloured solution
Identification	
Test for sugar	Passes test
Test for reducing sugar	Passes test
pH	Between 2,5 and 7,0 for polydextrose (10 % solution) Between 5,0 and 6,0 for polydextrose-N (10 % solution)
Purity	
Water content	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

▼B

5-Hydroxy-methylfurfural	Not more than 0,1 % (polydextrose) Not more than 0,05 % (polydextrose-N)
Lead	Not more than 0,5 mg/kg

E 1201 POLYVINYLPYRROLIDONE

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

E 1202 POLYVINYLPOLYPYRROLIDONE

Synonyms	Crospovidone; Cross-linked polyvidone; Insoluble polyvinylpyrrolidone
Definition	Polyvinylpolypyrrolidone is a poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene], cross linked in a random fashion. It is produced by the polymerisation of N-vinyl-2-pyrrolidone in the presence of either caustic catalyst or N, N'-divinyl-imidazolidone. Due to its insolubility in all common solvents the molecular weight range is not amenable to analytical determination
Einecs	
Chemical name	Polyvinylpyrrolidone; poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene]
Chemical formula	$(C_6H_9NO)_n$
Molecular weight	
Assay	Content not less than 11 % and not more than 12,8 % nitrogen (N) on the anhydrous basis
Description	A white hygroscopic powder with a faint, non-objectionable odour
Identification	
Solubility	Insoluble in water, ethanol and ether

▼B

pH	Between 5,0 and 8,0 (1 % suspension in water)
Purity	
Water content	Not more than 6 % (Karl Fischer)
Sulphated ash	Not more than 0,4 %
Water-soluble matter	Not more than 1 %
Free-N-vinylpyrrolidone	Not more than 10 mg/kg
Free-N,N'-divinyl-imidazolidone	Not more than 2 mg/kg
Lead	Not more than 2 mg/kg

E 1203 POLYVINYL ALCOHOL

Synonyms	Vinyl alcohol polymer, PVOH
Definition	Polyvinyl alcohol is a synthetic resin prepared by the polymerisation of vinyl acetate, followed by partial hydrolysis of the ester in the presence of an alkaline catalyst. The physical characteristics of the product depend on the degree of polymerisation and the degree of hydrolysis.
Chemical name	Ethenol homopolymer
Chemical formula	$(C_2H_3OR)_n$ where R = H or $COCH_3$
Description	Odourless, tasteless, translucent, white or cream-coloured granular powder
Identification	

▼M17

Solubility	Soluble in water; Practically insoluble or insoluble in ethanol (≥ 99,8 %)

▼B

Precipitation reaction	Dissolve 0,25 g of the sample in 5 ml of water with warming and let the solution cool to room temperature. The addition of 10 ml of ethanol to this solution leads to a white, turbid or flocculent precipitate.
Colour reaction	Dissolve 0,01 g of the sample in 100 ml of water with warming and let the solution cool to room temperature. A blue colour is produced when adding (to 5 ml solution) one drop of iodine test solution (TS) and a few drops of boric acid solution Dissolve 0,5 g of the sample in 10 ml of water with warming and let the solution cool to room temperature. A dark red to blue colour is produced after adding one drop of iodine TS to 5 ml of solution.
Viscosity	4,8 to 5,8 mPa.s (4 % solution at 20 °C) corresponding to an average molecular weight of 26 000-30 000 Da
Purity	
Water insoluble matter	Not more than 0,1 %
Ester value	Between 125 and 153 mg KOH/g
Degree of hydrolysis	86,5 to 89,0 %
Acid value	Not more than 3,0
Solvent residues	Not more than 1,0 % Methanol, 1,0 % Methyl acetate
pH	5,0 to 6,5 (4 % solution)
Loss on drying	Not more than 5,0 % (105 °C, 3 hours)
Residue in ignition	Not more than 1,0 %
Lead	Not more than 2 mg/kg

▼B

E 1204 PULLULAN

Synonyms	
Definition	Linear, neutral glucan consisting mainly of maltotriose units connected by -1,6 glycosidic bonds. It is produced by fermentation from a food-grade hydrolysed starch using a non-toxin-producing strain of *Aureobasidium pullulans*. After completion of the fermentation, the fungal cells are removed by microfiltration, the filtrate is heat-sterilised and pigments and other impurities are removed by adsorption and ion exchange chromatography
Einecs	232-945-1
Chemical name	
Chemical formula	$(C_6H_{10}O_5)_n$
Molecular weight	
Assay	Not less than 90 % of glucan on the dried basis
Description	White to off-white odourless powder
Identification	
Solubility	Soluble in water, practically insoluble in ethanol
pH	5,0 to 7,0 (10 % solution)
Precipitation with polyethylene glycol 600	Add 2 ml of polyethylene glycol 600 to 10 ml of a 2 % aqueous solution of pullulan. A white precipitate is formed
Depolymerisation with pullulanase	Prepare two test tubes each with 10 ml of a 10 % pullulan solution. Add 0,1 ml pullulanase solution having activity 10 units/g to one test tube, and 0,1 ml water to the other. After incubation at about 25 °C for 20 minutes, the viscosity of the pullulanase-treated solution is visibly lower than that of the untreated solution
Viscosity	100 to 180 mm^2/s (10 % w/w aqueous solution at 30 °C)
Purity	
Loss on drying	Not more than 6 % (90 °C, pressure not more than 50 mm Hg, 6 hours)
Mono-, di- and oligosaccharides	Not more than 10 % expressed as glucose
Lead	Not more than 1 mg/kg
Microbiological criteria	
Yeast and moulds	Not more than 100 colonies per gram
Coliforms	Absent in 25 g
Salmonella spp.	Absent in 25 g

E 1205 BASIC METHACRYLATE COPOLYMER

Synonyms	Basic butylated methacrylate copolymer; amino methacrylate copolymer; aminoalkyl methacrylate copolymer E; butyl methacrylate, dimethylaminoethyl methacrylate, methyl methacrylate polymer; butyl methacrylate, methyl methacrylate, dimethylaminoethyl methacrylate polymer

▼M22

Definition	Basic methacrylate copolymer is manufactured by thermic controlled polymerisation of the monomers methyl methacrylate, butyl methacrylate and dimethylaminoethyl methacrylate (dissolved in propan-2-ol), by using a free radical donor initiator system. An alkyl mercaptane is used as chain modifying agent. The polymer solution is extruded and granulated under vacuum to remove residual volatile components. The granules resulting are commercialized as such or undergo a milling step (micronisation).

▼B

Chemical name	Poly(butyl methacrylate-*co*-(2-dimethylaminoethyl)methacrylate-*co*-methyl methacrylate) 1:2:1
Chemical formula	Poly[(CH_2:$C(CH_3)CO_2(CH_2)_2N(CH_3)_2$)-co-($CH_2$:$C(CH_3)CO_2CH_3$)-co-($CH_2$:$C(CH_3)CO_2(CH_2)_3CH_3$)]
Weight average molecular weight estimated by gel permeation chromatography	Approximately 47 000 g/mol

▼M22

Particle size of the powder (when used forms a film)	< 50 μm at least 95 % < 20 μm at least 50 % < 3 μm not more than 10 %

▼B

Assay *(according to Ph. Eur. 2.2.20 'potentiometric titration')*	20,8-25,5 % dimethylaminoethyl (DMAE) groups on dry substance
Description	Granules are colourless to yellow tinged, the powder is white
Identification	
Infrared absorption spectroscopy	To be identified
Viscosity of a 12,5 % solution in 60:40 (w/w/) propan-2-ol to acetone	3-6 mPa.s
Refractive index	$[n]_D^{20}$ 1,380-1,385
Solubility	1 g dissolves in 7 g Methanol, Ethanol, propan-2-ol, dichloromethane, aqueous Hydrochloric acid 1N. Not soluble in petroleum ether.

▼M6

Purity	
Loss of drying	Not more than 2,0 % (105 °C, 3 h)
Alkali value	162-198 mg KOH/g of dried substance
Sulphated ash	Not more than 0,1 %
Residual monomers	Butylmethacrylate < 1 000 mg/kg Methyl methacrylate < 1 000 mg/kg Dimethylaminoethyl methacrylate < 1 000 mg/kg
Solvent residues	propan-2-ol < 0,5 % Butanol < 0,5 % Methanol < 0,1 %
Arsenic	Not more than 1 mg/kg
Lead	Not more than 3 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 1 mg/kg

E 1206 NEUTRAL METHACRYLATE COPOLYMER

Synonyms	Ethyl acrylate methyl methacrylate polymer; Ethyl acrylate, methyl methacrylate polymer; Ethyl acrylate, polymer with methyl methacrylate; Methyl methacrylate, ethyl acrylate polymer; Methyl methacrylate, polymer with ethyl acrylate

▼M6

Definition	Neutral methacrylate copolymer is a fully polymerised copolymer of methyl methacrylate and ethyl acrylate. It is produced using a process of emulsion polymerisation. It is manufactured by redox initiated polymerisation of the monomers ethyl acrylate, methyl methacrylate by using a free radical donor redox initiator system stabilised with polyethylene glycol monostearyl ether and vinylic acid/sodium hydroxide. Residual monomers are removed by means of water vapour distillation.
CAS No	9010-88-2
Chemical name	Poly(ethylacrylate-co-methyl methacrylate) 2:1
Chemical formula	Poly[(CH_2:$CHCO_2CH_2CH_3$)-co-(CH_2:$C(CH_3)CO_2CH_3$)]
Weight average molecular weight	Approximately 600 000 g/mol
Assay/Residue on evaporation	28,5–31,5 % 1 g dispersion is dried in an oven for 3 hours at 110 °C.
Description	Milky-white dispersion (the commercial form is a 30 % dispersion of the dry substance in water) of low viscosity with a faint characteristic odour.
Identification	
Infrared absorption spectroscopy	Characteristic of the compound
Viscosity	Max. 50 mPa.s, 30 rpm/20 °C (Brookfield viscosimetry)
pH-value	5,5–8,6
Relative density (at 20 °C)	1,037–1,047
Solubility	The dispersion is miscible with water in any proportion. The polymer and the dispersion are freely soluble in acetone, ethanol and isopropyl alcohol. Not soluble when mixed with 1 N sodium hydroxide in a ratio of 1:2.
Purity	
Sulphated ash	Not more than 0,4 % in the dispersion
Residual monomers	Total of monomers (sum of methyl methacrylate and ethyl acrylate): not more than 100 mg/kg in the dispersion
Residual emulsifier	Polyethylene glycol monostearyl ether (macrogol stearyl ether 20) not more than 0,7 % in the dispersion
Solvent residues	Ethanol not more than 0,5 % in the dispersion Methanol not more than 0,1 % in the dispersion
Arsenic	Not more than 0,3 mg/kg in the dispersion
Lead	Not more than 0,9 mg/kg in the dispersion
Mercury	Not more than 0,03 mg/kg in the dispersion
Cadmium	Not more than 0,3 mg/kg in the dispersion

E 1207 ANIONIC METHACRYLATE COPOLYMER

Synonyms	Methyl acrylate, methyl methacrylate, methacrylic acid polymer; Methacrylic acid, polymer with methyl acrylate and methyl methacrylate

▼M6

Definition	Anionic methacrylate copolymer is a fully polymerised copolymer of methacrylic acid, methyl methacrylate and methyl acrylate. It is manufactured in aqueous medium by emulsion polymerisation of methyl methacrylate, methyl acrylate and methacrylic acid using a free radical initiator stabilised with sodium lauryl sulphate and polyoxyethylene sorbitan monooleate (polysorbate 80). Residual monomers are removed by means of water vapour distillation.
CAS No	26936-24-3
Chemical name	Poly (methyl acrylate-co-methylmethacrylate-co-methacrylic acid) 7:3:1
Chemical formula	Poly[(CH_2:$CHCO_2CH_3$)-co-(CH_2:$C(CH_3)CO_2CH_3$)-co-(CH_2:$C(CH_3)COOH$)]
Weight average molecular weight	Approximately 280 000 g/mol
Assay/Residue on evaporation	28,5–31,5 % 1 g of the dispersion is dried in an oven for 5 hours at 110 °C. 9,2–12,3 % methacrylic acid units on dry substance.
Description	Milky-white dispersion (the commercial form is a 30 % dispersion of the dry substance in water) of low viscosity with a faint characteristic odour.
Identification	
Infrared absorption spectroscopy	Characteristic of the compound
Viscosity	Max. 20 mPa.s, 30 rpm/20 °C (Brookfield viscosimetry)
pH-value	2,0–3,5
Relative density (at 20 °C)	1,058–1,068
Solubility	The dispersion is miscible with water in any proportion. The polymer and the dispersion are freely soluble in acetone, ethanol and isopropyl alcohol. Soluble when mixed with 1 N sodium hydroxide in a ratio of 1:2. Soluble above pH 7,0.
Purity	
Acid value	60–80 mg KOH/g of dried substance
Sulphated ash	Not more than 0,2 % in the dispersion
Residual monomers	Total of monomers (sum of methacrylic acid, methyl methacrylate and methyl acrylate): not more than 100 mg/kg in the dispersion
Residual emulsifiers	Sodium lauryl sulphate not more than 0,3 % on the dry substance Polysorbate 80 not more than 1,2 % on the dry substance
Solvent residues	Methanol not more than 0,1 % in the dispersion
Arsenic	Not more than 0,3 mg/kg in the dispersion
Lead	Not more than 0,9 mg/kg in the dispersion
Mercury	Not more than 0,03 mg/kg in the dispersion
Cadmium	Not more than 0,3 mg/kg in the dispersion

▼M9

E 1208 POLYVINYLPYRROLIDONE-VINYL ACETATE COPOLYMER

Synonyms	Copolyvidon; copovidone; 1-vinyl-2-pyrrolidone-vinyl acetate copolymer; 2-pyrrolidinone, 1-ethenyl-, polymer with ethenyl acetate
Definition	It is produced by free radical copolymerisation of N-vinyl-2-pyrrolidone and vinyl acetate in solution in propan-2-ol, in the presence of initiators.
Einecs	
Chemical name	Acetic acid, ethenyl ester, polymer with 1-ethenyl-2-pyrrolidinone
Chemical formula	$(C_6H_9NO)_n.(C_4H_6O_2)_m$
Average Viscosity Molecular Weight	Between 26 000 and 46 000 g/mol.
Assay	Nitrogen content 7,0-8,0 %
Description	The physical state is described as a white to yellowish-white powder or flakes with an average particle size of 50-130 μm.
Identification	
Solubility	Freely soluble in water, ethanol, ethylene chloride and ether.
Infrared absorption spectroscopy	To be identified
European Colour Test (BY Colour)	Minimum BY5
K-value ([1]) (1 % solids in aqueous solution)	25,2-30,8
pH value	3,0-7,0 (10 % aqueous solution)
Purity	
Vinylacetate component in copolymer	Not more than 42,0 %
Free vinyl acetate	Not more than 5 mg/kg
Total ash	Not more than 0,1 %
Aldehyde	Not more than 2 000 mg/kg (as acetaldehyde)
Free-N-vinylpyrrolidone	Not more than 5 mg/kg
Hydrazine	Not more than 0,8 mg/kg
Peroxide content	Not more than 400 mg/kg
Propan-2-ol	Not more than 150 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

([1]) K-value: dimensionless index, calculated from kinematic viscosity measurements of dilute solutions, used to indicate the likely degree of polymerisation or molecular size of a polymer.

▼M13

E 1209 POLYVINYL ALCOHOL-POLYETHYLENE GLYCOL-*GRAFT*-COPOLYMER

Synonyms	Macrogol poly(vinyl alcohol) grafted co-polymer; poly(ethan-1,2-diol-graft-ethanol); ethenol, polymer with oxirane, graft; oxirane, polymer with ethanol, graft; ethylene oxide-vinyl alcohol graft co-polymer
Definition	Polyvinyl alcohol-polyethylene glycol-graft-co-polymer is a synthetic co-polymer that consists of approximately 75 % PVA units and 25 % PEG units.
CAS number	96734-39-3
Chemical name	Polyvinyl alcohol-polyethylene glycol-*graft*-co-polymer
Chemical formula	
Weight Average Molecular Weight	40 000 to 50 000 g/mol
Description	White to faintly yellow powder
Identification	
Solubility	Freely soluble in water and dilute acids and dilute solutions of alkali hydroxides; practically insoluble in ethanol, acetic acid, acetone, and chloroform
IR Spectrum	Must comply
pH value	5,0-8,0
Purity	
Ester Value	10 to 75 mg/g KOH
Dynamic viscosity	50 to 250 mPa·s
Loss on drying	Not more than 5 %
Sulphated Ash	Not more than 2 %
Vinyl Acetate	Not more than 20 mg/kg
Acetic acid/Total Acetate	Not more than 1,5 %

▼M26

Ethylene glycols (mono- and di-)	Not more than 400 mg/kg (singly or in combination)

▼M13

1,4-Dioxane	Not more than 10 mg/kg

▼M37

———————

▼M13

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

▼M39

E 1210 CARBOMER

Synonyms	carbomer, carboxypolymethylene; carbomer homopolymer
Definition	High-molecular mass polymers obtained by polymerisation of acrylic acid and crosslinking with allyl pentaerythritol. The polymers are synthesised in ethyl acetate using a peroxide to initiate free-radical polymerisation.
CAS No	9007-20-9 (primary CAS), 9003-01-4 (secondary CAS)

▼M39

Chemical name	Carbomer homopolymer, allyl pentaerythritol cross-linked		
Chemical formula	$-(CH_2-CH)_{\mathbf{m}}-(\mathbf{XM})_{\mathbf{p}}$ COOH **m:** number of monomer units; **XM:** crosslinker, **p:** number of crosslinker units, **with m>>p**		
Weight average molecular weight			
Assay	Carboxylic acid content not less than 56 % and not more than 68 % (on dried substance)		
Description	White or almost white, fluffy, hygroscopic powder or granules		
Identification			
Attenuated total reflective infra-red spectroscopy	Characteristic of the compound		
Proton nuclear magnetic resonance spectroscopy			
Viscosity (Brookfield viscosimetry, 20 rpm) 25 °C	Type B 29 400-39 400 mPa.s	Type A 4 000-11 000 mPa.s	Type A
Physical form	powder	powder	granules
Pass through 40 mesh, % 425 µm	-	-	95 min
Pass through 100 mesh, % 150 µm	-	-	10 max
Solubility	Insoluble in water. Water-swellable and forms hydrogels in aqueous dispersions.		
Purity			
Residual monomers	Acrylic acid not more than 100 mg/kg		
Residual crosslinker	tri and tetra-allyl pentaerythritol not more than 1 000 mg/kg		
Residual solvant	Ethyl acetate not more than 0,5 % w/w		
2-ethylhexanol	not more than 100 mg/kg		
2-ethylhexylacetate	not more than 100 mg/kg		
Lower molecular weight fraction < 1 000 Da	Not more than 0,75 % w/w		
Loss on drying	Not more than 2 %		
Sulphated ashes	Not more than 2,5 %		

▼B

E 1404 OXIDISED STARCH

Synonyms	
Definition	Oxidised starch is starch treated with sodium hypochlorite
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	

▼B

Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification	
Microscopic observation	Passes test (if not pregelatinised)
Iodine staining	Passes test (dark blue to light red colour)
Purity	
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 % (on an anhydrous basis)
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis) Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg (on an anhydrous basis)
Mercury	Not more than 0,1 mg/kg

E 1410 MONOSTARCH PHOSPHATE

Synonyms	
Definition	Monostarch phosphate is starch esterified with ortho-phosphoric acid, or sodium or potassium ortho-phosphate or sodium tripoly-phosphate
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification	
Microscopic observation	Passes test (if not pregelatinised)
Iodine staining	Passes test (dark blue to light red colour)
Purity	
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

▼B

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

E 1412 DISTARCH PHOSPHATE

Synonyms	
Definition	Distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification	
Microscopic observation	Passes test (if not pregelatinised)
Iodine staining	Passes test (dark blue to light red colour)
Purity	
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 (on an anhydrous basis) Not more than 0,4 % (as P) for other starches (on an anhydrous basis)
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis) Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg (on an anhydrous basis)
Mercury	Not more than 0,1 mg/kg

▼B

E 1413 PHOSPHATED DISTARCH PHOSPHATE

Synonyms	
Definition	Phosphated distarch phosphate is starch having undergone a combination of treatments as described for monostarch phosphate and for distarch phosphate
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification	
Microscopic observation	Passes test (if not pregelatinised)
Iodine staining	Passes test (dark blue to light red colour)
Purity	
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 (on an anhydrous basis) Not more than 0,4 % (as P) for other starches (on an anhydrous basis)
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis) Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg (on an anhydrous basis)
Mercury	Not more than 0,1 mg/kg

E 1414 ACETYLATED DISTARCH PHOSPHATE

Synonyms	
Definition	Acetylated distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride and esterified by acetic anhydride or vinyl acetate
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification	
Microscopic observation	Passes test (if not pregelatinised)
Iodine staining	Passes test (dark blue to light red colour)

▼B

Purity	
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 % (on an anhydrous basis)
Residual phosphate	Not more than 0,14 % (as P) for wheat or potato starch (on an anhydrous basis) Not more than 0,04 % (as P) for other starches (on an anhydrous basis)
Vinyl acetate	Not more than 0,1 mg/kg (on an anhydrous basis)
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis) Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg (on an anhydrous basis)
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
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification	
Microscopic observation	Passes test (if not pregelatinised)
Iodine staining	Passes test (dark blue to light red colour)
Purity	
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 % (on an anhydrous basis)
Vinyl acetate	Not more than 0,1 mg/kg (on an anhydrous basis)
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis) Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg (on an anhydrous basis)
Mercury	Not more than 0,1 mg/kg

▼B

E 1422 ACETYLATED DISTARCH ADIPATE

Synonyms	
Definition	Acetylated distarch adipate is starch cross-linked with adipic anhydride and esterified with acetic anhydride
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification	
Microscopic observation	Passes test (if not pregelatinised)
Iodine staining	Passes test (dark blue to light red colour)
Purity	
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 % (on an anhydrous basis)
Adipate groups	Not more than 0,135 % (on an anhydrous basis)
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis) Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg (on an anhydrous basis)
Mercury	Not more than 0,1 mg/kg

E 1440 HYDROXYPROPYL STARCH

Synonyms	
Definition	Hydroxypropyl starch is starch etherified with propylene oxide
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification	
Microscopic observation	Passes test (if not pregelatinised)
Iodine staining	Passes test (dark blue to light red colour)

▼B

Purity	
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 % (on an anhydrous basis)
Propylene chlorohydrin	Not more than 1 mg/kg (on an anhydrous basis)
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis) Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg (on an anhydrous basis)
Mercury	Not more than 0,1 mg/kg

E 1442 HYDROXYPROPYL DISTARCH PHOSPHATE

Synonyms	
Definition	Hydroxypropyl distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride and etherified with propylene oxide
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification	
Microscopic observation	Passes test (if not pregelatinised)
Iodine staining	Passes test (dark blue to light red colour)
Purity	
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 % (on an anhydrous basis)
Residual phosphate	Not more than 0,14 % (as P) for wheat or potato starch (on an anhydrous basis) Not more than 0,04 % (as P) for other starches (on an anhydrous basis)
Propylene chlorohydrin	Not more than 1 mg/kg (on an anhydrous basis)
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis) Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)

▼B

Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg (on an anhydrous basis)
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
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification	
Microscopic observation	Passes test (if not pregelatinised)
Iodine staining	Passes test (dark blue to light red colour)
Purity	
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 % (on an anhydrous basis)
Octenylsuccinic acid residue	Not more than 0,3 % (on an anhydrous basis)
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis) Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg (on an anhydrous basis)
Mercury	Not more than 0,1 mg/kg

E 1451 ACETYLATED OXIDISED STARCH

Synonyms	
Definition	Acetylated oxidised starch is starch treated with sodium hypochlorite followed by esterification with acetic anhydride
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

▼B

Identification	
Microscopic observation	Passes test (if not pregelatinised)
Iodine staining	Passes test (dark blue to light red colour)
Purity	
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 % (on an anhydrous basis)
Acetyl groups	Not more than 2,5 % (on an anhydrous basis)
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis) Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg (on an anhydrous basis)
Mercury	Not more than 0,1 mg/kg

E 1452 STARCH ALUMINIUM OCTENYL SUCCINATE

Synonyms	
Definition	Starch aluminium octenyl succinate is starch esterified with octenylsuccinic anhydride and treated with aluminium sulphate
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification	
Microscopic observation	Passes test (if not pregelatinised)
Iodine staining	Passes test (dark blue to light red colour)
Purity	
Loss on drying	Not more than 21,0 %
Octenylsuccinyl groups	Not more than 3 % (on an anhydrous basis)
Octenylsuccinic acid residue	Not more than 0,3 % (on an anhydrous basis)
Sulphur dioxide	Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis) Not more than 10 mg/kg for the other modified starches, unless otherwise specified (on an anhydrous basis)
Arsenic	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg (on an anhydrous basis)
Mercury	Not more than 0,1 mg/kg
Aluminium	Not more than 0,3 % (on an anhydrous basis)

▼B

E 1505 TRIETHYL CITRATE

Synonyms	Ethyl citrate
Definition	
Einecs	201-070-7
Chemical name	Triethyl-2-hydroxypropan-1,2,3-tricarboxylate
Chemical formula	$C_{12}H_{20}O_7$
Molecular weight	276,29
Assay	Content not less than 99,0 %
Description	Odourless, practically colourless, oily liquid
Identification	
Specific gravity (25 °C/25 °C)	1,135-1,139
Refractive index	$[n]_D^{20}$: 1,439-1,441
Purity	
Water content	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 2 mg/kg

E 1517 GLYCERYL DIACETATE

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

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E 1518 GLYCERYL TRIACETATE

Synonyms	Triacetin
Definition	
Einecs	203-051-9
Chemical name	Glyceryl triacetate
Chemical formula	$C_9H_{14}O_6$
Molecular weight	218,21
Assay	Content not less than 98,0 %
Description	Colourless, somewhat oily liquid having a slightly fatty odour
Identification	
Test for acetate	Passes test
Test for glycerol	Passes test
Refractive index	$[n]_D^{25}$ between 1,429 and 1,431
Specific gravity (25 °C/25 °C)	Between 1,154 and 1,158
Boiling range	Between 258 and 270 °C
Purity	
Water content	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 2 mg/kg

E 1519 BENZYL ALCOHOL

Synonyms	Phenylcarbinol; Phenylmethyl alcohol; Benzenemethanol; Alpha-hydroxytoluene
Definition	
Einecs	
Chemical name	Benzyl alcohol; Phenylmethanol
Chemical formula	C_7H_8O
Molecular weight	108,14
Assay	Not less than 98,0 %
Description	Colourless, clear liquid with a faint, aromatic odour
Identification	
Solubility	Soluble in water, ethanol and ether
Refractive index	$[n]_D^{20}$ 1,538-1,541
Specific gravity (25 °C/25 °C)	1,042-1,047
Test for peroxides	Passes test
Distillation range	Not less than 95 % v/v distils between 202 and 208 °C
Purity	
Acid value	Not more than 0,5
Aldehydes	Not more than 0,2 % v/v (as benzaldehyde)
Lead	Not more than 2 mg/kg

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E 1520 PROPANE-1,2-DIOL

Synonyms	Propylene glycol
Definition	
Einecs	200-338-0
Chemical name	1,2-dihydroxypropane
Chemical formula	$C_3H_8O_2$
Molecular weight	76,10
Assay	Content not less than 99,5 % on the anhydrous basis
Description	Clear, colourless, hygroscopic, viscous liquid
Identification	
Solubility	Soluble in water, ethanol and acetone
Specific gravity (20 °C/20 °C)	1,035-1,040
Refractive index	$[n]_D^{20}$: 1,431-1,433
Purity	
Distillation test	99,5 % of the product distils between 185-189 °C. The remaining 0,5 % consists mainly of dimers and traces of trimers from propylene glycol.
Sulphated ash	Not more than 0,07 %
Water content	Not more than 1,0 % (Karl Fischer method)
Lead	Not more than 2 mg/kg

E 1521 POLYETHYLENE GLYCOL

Synonyms	PEG; Macrogol; Polyethylene oxide
Definition	Addition polymers of ethylene oxide and water usually designated by a number roughly corresponding to the molecular weight.
Chemical name	alpha-Hydro-omega-hydroxypoly (oxy-1,2-ethanediol)
Chemical formula	$(C_2H_4O)_n H_2O$ (n = number of ethylene oxide units corresponding to a molecular weight of 6 000, about 140)
Average molecular weight	380 to 9 000 Da
Assay	PEG 400: Not less than 95 % and not more than 105 % PEG 3000: Not less than 90 % and not more than 110 % PEG 3350: Not less than 90 % and not more than 110 % PEG 4000: Not less than 90 % and not more than 110 % PEG 6000:Not less than 90 % and not more than 110 % PEG 8000: Not less than 87,5 % and not more than 112,5 %
Description	PEG 400 is a clear, viscous, colourless or almost colourless hygroscopic liquid PEG 3000, PEG 3350, PEG 4000, PEG 6000 and PEG 8000 are white or almost white solids with a waxy or paraffin-like appearance

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Identification	
Melting range	PEG 400: 4-8 °C
	PEG 3000: 50-56 °C
	PEG 3350: 53-57 °C
	PEG 4000: 53-59 °C
	PEG 6000:55-61 °C
	PEG 8000: 55-62 °C
Viscosity	PEG 400: 105 to 130 mPa.s at 20 °C
	PEG 3000: 75 to 100 mPa.s at 20 °C
	PEG 3350: 83 to 120 mPa.s at 20 °C
	PEG 4000: 110 to 170 mPa.s at 20 °C
	PEG 6000: 200 to 270 mPa.s at 20 °C
	PEG 8000: 260 to 510 mPa.s at 20 °C
	For polyethylene glycols having a average molecular weight greater than 400, the viscosity is determined on a 50 per cent m/m solution of the candidate substance in water
Solubility	PEG 400 is miscible with water, very soluble in acetone, in alcohol and in methylene chloride, practically insoluble in fatty oils and in mineral oils
	PEG 3000 and PEG 3350: very soluble in water and in methylene chloride, very slightly soluble in alcohol, practically insoluble in fatty oils and in mineral oils
	PEG 4000, PEG 6000 and PEG 8000: very soluble in water and in methylene chloride, practically insoluble in alcohol and in fatty oils and in mineral oils.
Purity	
Hydroxyl value	PEG 400: 264-300
	PEG 3000: 34-42
	PEG 3350: 30-38
	PEG 4000: 25-32
	PEG 6000: 16-22
	PEG 8000: 12-16
Sulphated ash	Not more than 0,2 %
1,4-Dioxane	Not more than 10 mg/kg

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Ethylene glycol and diethylene glycol	Total not more than 0,25 % °w/w individually or in combination
Lead	Not more than 1 mg/kg