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Delegations will find attached Commission document D015454/02.

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EUROPEAN COMMISSION

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COMMISSION REGULATION (EU) No …/..

of XXX

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)

COMMISSION REGULATION (EU) No …/..

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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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[1], and in particular Articles 14 and 30(4) thereof, and Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings[2], and in particular Article 7(5) thereof,

Whereas:

(1) Specifications relating to origin, purity criteria and any other necessary information should be adopted for food additives listed in the Union lists in Annex II and III to Regulation (EC) No 1333/2008.

(2) To that end, specifications previously developed for food additives in Commission Directive 2008/128/EC of 22 December 2008 laying down specific purity criteria concerning colours for use in foodstuffs[3], Commission Directive 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners[4] and Commission Directive 2008/60/EC of 17 June 2008 laying down specific purity criteria concerning sweeteners for use in foodstuffs[5] should be updated and taken over to this Regulation. As a consequence, those Directives should be repealed.

(3) It is necessary to take into account the specifications and analytical techniques as set out in the Codex Alimentarius drafted by the Joint FAO/WHO Expert Committee on Food Additives (hereafter JECFA).

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1 OJ L 354, 31.12.2008, p. 16.
2 OJ L 354, 31.12.2008, p. 1.
3 OJ L 6, 10.1.2009, p. 20.
4 OJ L 253, 20.9.2008, p. 1.
5 OJ L 158, 18.6.2008, p. 17.

(4) The European Food Safety Authority (hereinafter "the Authority") expressed its opinion on the safety of basic methacrylate copolymer[6] as a glazing agent. That food additive has subsequently been authorised on the basis of specific uses and has been allocated the number E 1205. Therefore specifications should be adopted for that food additive.

(5) Food colours ethyl ester of beta-apo-8'-carotenic acid (E 160 f), and brown FK (E 154), as well as the aluminium containing carrier bentonite (E 558) are not used any more according to information submitted by food manufacturers. Therefore, current specifications for those food additives should not be taken over to this Regulation.

(6) On 10 February 2010 the Authority expressed an opinion on the safety of sucrose esters of fatty acids (E 473) prepared from vinyl esters of fatty acids[7]. Current specifications should be adapted accordingly in particular by reducing maximum limits for impurities of safety concern.

(7) Specific purity criteria currently applicable should be adapted by reducing maximum limits for individual heavy metals of interest where feasible and where the JECFA limits are lower than those currently in force. Pursuant to that approach maximum limits for the contaminant 4-methylimidazole in ammonia caramel (E 150 c), sulphated ash in beta-carotene (E 160 a (i)), and magnesium and alkali salts in calcium carbonate (E 170), should be lowered. That approach should be departed from only for additives trisodium citrate (E 331 (iii)) (lead content), carrageenan (E 407) and processed euchema seaweed (E407 a) (cadmium content), as manufacturers have declared that compliance with stricter Union provisions, reflecting JECFA limits, would not be technically feasible. The contribution to the total intake of those two contaminants (lead and cadmium) in those three individual food additives is not considered to be significant. On the contrary for phosphates (E 338 – E 341 and E 450- E 452) new significantly lower values, compared to the ones indicated by JECFA, should be established due to new developments of the manufacturing processes, by taking into account the recent recommendations of the Authority on a reduction of the intake of arsenic, especially in the inorganic form[8]. In addition, a new provision on arsenic for glutamic acid (E 620) should be introduced for safety reasons. The total balance of those adaptations benefits the consumers as maximum limits for heavy metals are becoming stricter in general and in most of the food additives. Detailed information on the production process and starting materials of a food additive should be included in the specifications to facilitate any future decision pursuant to Article 12 of Regulation (EC) No 1333/2008.

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6 EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the use of Basic Methacrylate Copolymer as a food additive on request from the European Commission. EFSA Journal 2010; 8(2):1513.

7 EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the safety of sucrose esters of fatty acids prepared from vinyl esters of fatty acids and on the extension of use of sucrose esters of fatty acids in flavourings on request from the European Commission. EFSA Journal 2010; 8(3):1512.

8 EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on Arsenic in Food. EFSA Journal 2009; 7(10):1351.

(8) Specifications should not make reference to organoleptic tests related to the taste as it cannot be expected by the control authorities to take the risk to taste a chemical substance.

(9) Specifications should not make reference to classes as there is no added value in this reference.

(10) Specifications should not make reference to the general parameter "Heavy metals" as this parameter does not relate with toxicity, but rather with a generic analytical method. Parameters related to individual heavy metals are toxicity related and are included in the specifications.

(11) Some food additives are currently listed under various names (carboxy methyl cellulose (E 466), cross-linked sodium carboxymethylcellulose (E 468), enzymatically hydrolised carboxymethylcellulose (E 469) and beeswax, white and yellow (E 901)) in various provisions of Directive 95/2/EC[9]. Therefore the specifications established by this Regulation should refer to those various names.

(12) Current provisions on Polycyclic Aromatic Hydrocarbons (PAHs) are too generic and not relevant to safety and should be replaced by maximum limits for individual PAHs of concern for food additives vegetable carbon (E 153) and microcrystalline wax (E 905). Similar maximum limits should be established for formaldehyde in carageenan (E 407) and processed euchema seaweed (E 407 a), for particular microbiological criteria in agar (E 406) and for salmonella spp. content in mannitol (E 421 (ii)) manufactured by fermentation.

(13) The use of propan-2-ol (isopropanol, isopropyl alcohol) should be allowed for manufacturing the additives curcumin (E 100) and paprika extract (E 160 c), in line with JECFA specifications, as this particular use has been considered safe by the Authority[10]. The use of ethanol in replacement of propan-2-ol in the manufacturing of gellan gum (E 418) should be permitted where the final product still complies with all other specifications and ethanol is considered to be of less safety concern.

(14) The percentage of the colouring principle in cochineal, carminic acid, carmines (E 120) should be specified, as maximum limits are to apply to quantities of that principle.

(15) The numbering system for subcategories of carotenes (E 160 a) should be updated in order to bring it in line with the Codex alimentarius numbering system.

(16) The solid form of lactic acid (E 270) should also be included in the specifications, as it can now be manufactured in the solid form and there is no safety concern.

(17) The current temperature value in loss on drying for monosodium citrate (E 331 (i)), anhydrous form should be adjusted as under the currently listed conditions the substance decomposes. Drying conditions for trisodium citrate (E 331 (iii)) should also be adjusted to improve the reproducibility of the method.

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9 OJ L 61, 18.3.1995, p. 1.

10 EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the re-evaluation of curcumin (E 100) as a food additive. EFSA Journal 2010; 8(9):1679.

(18) The current specific absorption value for alpha-tocopherol (E 307) should be corrected and the sublimation point for sorbic acid (E 200) should be replaced by a "solubility test" as the former is not relevant. The specification of bacterial sources for the manufacturing of nisin (E 234) and natamycin (E 235) should be updated according to the current taxonomic nomenclature.

(19) As new innovative manufacturing techniques resulting in less contaminated food additives are now available, the presence of aluminium in food additives should be restricted. In order to enhance legal certainty and non-discrimination it is appropriate to provide the manufacturers of food additives with a transitional period to adapt gradually to those restrictions.

(20) Maximum limits for aluminium should be established for food additives where relevant, and particularly for calcium phosphates (E 341 (i)-(iii)) intended to be used in food for infants and young children[11], according to the relevant opinion of Scientific Committee on Food expressed on 7 June 1996[12]. In this framework a maximum limit for aluminum in calcium citrate (E 333) should also be established.

(21) The maximum limits for aluminium in calcium phosphates (E 341 (i)-(iii)), disodium diphosphate (E 450 (i)) and calcium dihydrogen diphosphate (E 450 (vii)) should be in accordance with the opinion of the Authority of 22 May 2008[13]. Current limits should be reduced, where this is technically feasible, and where the contribution to the total aluminium intake is significant. In this framework aluminium lakes of individual food colours should be authorised only if technically needed.

(22) Provisions on maximum limits for aluminium in dicalcium phosphate (E 341 (ii)), tricalcium phosphate (E 341 (iii)) and calcium dihydrogen diphosphate (E 450 (vii)) should not cause any disruption of the market, due to a possible lack of supplies.

(23) According to Commission Regulation (EU) No 258/2010 of 25 March 2010 imposing special conditions on the imports of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins[14], maximum limits should be set for the contaminant pentachlorophenol in guar gum (E 412).

(24) According to recital 48 of Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs[15] Member States are requested to examine other foodstuffs than the ones included in that Regulation for the occurrence of contaminant 3-MCPD in order to consider the need to set maximum levels for that substance. French authorities have submitted data on high concentrations of 3-MCPD in the food additive glycerol (E 422) and the average use level of this food additive in various food categories. Maximum limits for 3-MCPD in this particular food additive should be set in order to avoid contamination

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11 As defined in Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (Codified version), OJ L 339, 6.12.2006, p. 16.

12 Opinion on Additives in nutrient preparations for use in infant formulae, follow-on formulae and weaning foods. Reports of the Scientific Committee on food (40th Series), p.13-30, (1997).

13 Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials on a request from European Commission on Safety of aluminium from dietary intake. The EFSA Journal (2008) 754, 1-34.

14 OJ L 80, 26.3.2010, p. 28.

15 OJ L 364, 20.12.2006, p. 5.

of the final food at a higher than permissible level, taking into account the dilution factor.

(25) Due to the development of analytical methods certain current specifications should be updated. The current limit value "not detectable" is linked to the evolution of analytical methodologies and should be replaced by a specific number for additives acid esters of mono- and di-glycerides (E 472 a-f), polyglycerol esters of fatty acids (E 475) and propane-1,2-diol esters of fatty acids (E 477).

(26) Specifications relating to the manufacturing procedure should be updated for citric acid esters of mono- and diglycerides of fatty acids (E 472 c), as the use of alkaline bases is replaced today by the use of their milder acting salts.

(27) The current criterion "free fatty acids" for additives citric acid esters of mono- and diglycerides of fatty acids (E 472 c) and mono and diacetyltartaric acid esters of mono- and diglycerides of fatty acids (E 472 e) is not appropriate. It should be replaced by the criterion "acid value" as the latter expresses better the titrimetric estimation of the free acidic groups. This is in accordance with the 71st report on food additives from JECFA[16] where such change was adopted for mono and diacetyltartaric acid esters of mono- and diglycerides of fatty acids (E 472 e).

(28) The current erroneous description of additive magnesium oxide (E 530) should be corrected according to information submitted by the manufacturers, in order to bring it in line with the Pharmacopoeia Europea[17]. The current maximum value for the reducing matter in additive gluconic acid (E 574) should also be updated as this limit is not technically feasible. For the estimation of the water content of xylitol (E 967) the current method based on "loss on drying", should be replaced by a more appropriate method.

(29) Some current specifications for additive candelilla wax (E 902) should not be taken over to this Regulation since they are erratic. For calcium dihydrogen diphosphate (E 450 (vii)) the current entry concerning P_2O_5 content should be corrected.

(30) In the current entry "assay" for thaumatin (E 957) a calculation factor should be corrected. That factor is to be used in the Kjeldahl method for the estimation of the total content of the substance based on the measurement of nitrogen. The calculation factor should be updated according to the relevant published literature for thaumatin (E 957).

(31) The Authority evaluated the safety of steviol glycosides, as a sweetener and expressed its opinion of 10 March 2010[18]. The use of steviol glycosides, which have been allocated number E 960, has subsequently been permitted on the basis of well defined conditions of use. Therefore specifications should be adopted for this food additive.

(32) Due to a taxonomic change, current specifications for source materials (yeasts) used in the manufacturing of erythritol (E 968) should be updated.

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16 WHO Technical Report Series, No 956, 2010.

17 EP 7.0 volume 2, p. 2415- 2416.

18 EFSA Panel on Food Additives and Nutrient Sources (ANS); Scientific Opinion on the safety of steviol glycosides for the proposed uses as a food additive. *The EFSA Journal* (2010); 8(4):1537.

(33) For quillaia extract (E 999) the current specification relating to the pH range should be adjusted in order to bring it in line with JECFA.

(34) The combination of citric acid and phosphoric acid (which are currently both individually authorised for use in the manufacturing of additive polydextrose (E 1200)), should be allowed, where the final product still complies with the purity specifications, as it improves yields and results to more controllable reaction kinetics. There is no safety concern involved in such amendment.

(35) Unlike for small molecules, the molecular mass of a polymer is not one unique value. A given polymer may have a distribution of molecules with different masses. The distribution may depend on the way the polymer is produced. Polymer physical properties and behaviors are related to the mass and to the distribution of molecules with a certain mass in the mixture. A group of mathematical models describe the mixture in different ways in order to clarify the distribution of molecules in the mixture. Among the different models available, it is recommended in scientific literature to use the weight average molecular weight (Mw) to describe polymers. The specifications for polyvinylpyrrolidone (E 1201) should be adjusted accordingly.

(36) The criterion "Distillation range" referred to in current specifications for propane-1,2 diol (E 1520) leads to contradictory conclusions compared to results from the assay. That criterion should therefore be corrected and renamed into "Distillation test".

(37) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

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 twentieth day following that of 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.

Done at Brussels,

For the Commission
José Manuel BARROSO
The President

ANNEX

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

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 $E_{1cm}^{1\%}$ 1607 at ca 426 nm in ethanol
Description		Orange-yellow crystalline powder
Identification		
	Spectrometry	Maximum in ethanol at ca 426 nm
	Melting Range	179 °C—182 °C

Purity			
	Solvent residues	Ethylacetate	Not more than 50 mg/kg, singly or in combination
		Acetone	
		n-butanol	
		Methanol	
		Ethanol	
		Hexane	
		Propan-2-ol	
		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-tetrahydroxypentyl)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

		$E_{1\ cm}^{1\ \%}$ 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)
	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

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 $C_{17}H_{20}N_4NaO_9P.2H_2O$ $E_{1\ cm}^{1\ \%}$ 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)
	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 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 $E_{1cm}^{1\%}$ 530 at ca 426 nm in aqueous solution
Description		Light orange powder or granules
	Appearance of the aqueous	Yellow

solution	
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	
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 $E_{1cm}^{1\%}$ 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
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
		$E_{1cm}^{1\%}$ 555 at ca 485 nm in aqueous solution at pH 7
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.

E 120 COCHINEAL, CARMINIC ACID, CARMINES

Synonyms	CI Natural Red 4

Definition		Carmines and carminic acid are obtained from aqueous, aqueous alcoholic or alcoholic extracts from Cochineal, which consists of the dried bodies of the female insect *Dactylopius coccus* Costa. The colouring principle is carminic acid. Aluminium lakes of carminic acid (carmines) can be formed in which aluminium and carminic acid are thought to be present in the molar ratio 1:2. In commercial products the colouring principle is 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, and may also contain free carminate or a small residue of unbound aluminium cations.
	Colour Index No	75470
	EINECS	Cochineal: 215-680-6; 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)
	Assay	Content not less than 2,0 % carminic acid in the extracts containing carminic acid; not less than 50 % carminic acid in the chelates.
Description		Red to dark red, friable, solid or powder. Cochineal extract is generally a dark red liquid but can also be dried as a powder.
Identification		
	Spectrometry	Maximum in aqueous ammonia solution at ca 518 nm

		Maximum in dilute hydrochloric solution at ca 494 nm for carminic acid $E_{1cm}^{1\%}$ 139 at peak around 494 nm in dilute hydrochloric acid for carminic acid
Purity		
	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

Aluminium lakes of this colour may be used.

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 $E_{1\ cm}^{1\%}$ 510 at ca 516 nm in aqueous solution

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		Total not more than 0,5 %
4-hydroxynaphthalene-1-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.

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 $E_{1\ cm}^{1\ \%}$ 440 at ca 520 nm in aqueous solution
Description		Reddish-brown powder or granules
	Appearance of the aqueous solution	Red
Identification		
Spectrometry		Maximum in water at ca 520 nm
Purity		
	Water insoluble	Not more than 0,2 %

matter	
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
	Assay	Content not less than 80 % total colouring matters, calculated as the sodium salt. $E_{1\ cm}^{1\ \%}$ 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	Not more than 1,0 %

colouring matters	
Organic compounds other than colouring matters:	
4-aminonaphthalene-1-sulfonic acid 7-hydroxynaphthalene-1,3-disulfonic acid 3-hydroxynaphthalene-2,7-disulfonic acid 6-hydroxynaphthalene-2-sulfonic acid 7-hydroxynaphthalene-1,3-6-trisulfonic 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 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	$C_{20}H_6I_4Na_2O_5\ H_2O$
	Molecular weight	897,88
	Assay	Content not less than 87 % total colouring matters, calculated as the anhydrous sodium salt $E_{1\ cm}^{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	Not more than 4,0 %

matters (except fluorescein)	
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
	Assay	Content not less than 85 % total colouring matters, calculated as the sodium salt
		$E_{1\ cm}^{1\ \%}$ 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-methylbenezene sulfonic acid		Not more than 0,2 %
6,6-oxybis (2-naphthalene sulfonic		Not more than 1,0 %

acid) disodium salt		
	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
	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	Calcium compound: 579,72

	weight	Sodium compound: 582,67
	Assay	Content not less than 85 % total colouring matters, calculated as the sodium salt
		$E_{1\ cm}^{1\ \%}$ 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		Total not more than 0,5 %
3-hydroxy benzoic acid		
3-hydroxy-4-sulfobenzoic acid		
N,N-diethylamino benzene sulfonic acid		
	Leuco base	Not more than 4,0 %
	Unsulfonated primary aromatic	Not more than 0,01 % (calculated as aniline)

amines	
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.
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 % $E_{1\ cm}^{1\ \%}$ 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		Total not more than 0,5 %
5-sulfoanthranilic acid		
Anthranilic 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 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
	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\ cm}^{1\ \%}$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 co-ordinated 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.
	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-tetrahydrocyclopenta[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 %	
		$E_{1\ cm}^{1\ \%}$ 700 at ca 409 nm in chloroform	
Description		Waxy solid ranging in colour from olive green to dark green depending on the content of co-ordinated magnesium	
Identification			
	Spectrometry	Maximum in chloroform at ca 409 nm	
Purity			
	Solvent residues	Acetone	Not more than 50 mg/kg, singly or in combination
		Methyl Ethyl ketone	
		Methanol	
		Ethanol	
		Propan-2-ol	
		Hexane	
		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	

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 neutralized 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. $E_{1\ cm}^{1\ \%}$ 700 at ca 405 nm in aqueous solution at pH 9 $E_{1\ cm}^{1\ \%}$ 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	Not more than 50 mg/kg, singly or in combination
		Methyl ethyl ketone	
		Methanol	
		Ethanol	
		Propan-2-ol	
		Hexane	
		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	

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-tetrahydrocyclopenta[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 %. $E_{1\ cm}^{1\ \%}$ 540 at ca 422 nm in chloroform $E_{1\ cm}^{1\ \%}$ 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
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 neutralized 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. $E_{1\ cm}^{1\ \%}$ 565 at ca 405 nm in aqueous phosphate buffer at pH 7,5 $E_{1\ cm}^{1\ \%}$ 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
		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 $E_{1\ cm}^{1\ \%}$ 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 %
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[19]	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

[19] 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.

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

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[20]	0,05—0,13
Total nitrogen	Not more than 0,3 %[21]
Sulphur dioxide	Not more than 0,2 %[3]
Total sulphur	0,3—3,5 %[3]
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

[20] 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.

[21] Expressed on equivalent colour basis i.e. is expressed in terms of a product having a colour intensity of 0,1 absorbance units.

		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	Not more than 50 %
	Colour bound by phosphoryl cellulose	More than 50 %
	Colour intensity[22]	0,08—0,36
	Ammoniacal nitrogen	Not more than 0,3 %[23]
	4-methylimidazole	Not more than 200 mg/kg[5]
	2-acetyl-4-tetrahydroxy-butylimidazole	Not more than 10 mg/kg[5]
	Total sulphur	Not more than 0,2 %[5]

[22] 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.

[23] Expressed on equivalent colour basis i.e. is expressed in terms of a product having a colour intensity of 0,1 absorbance units.

Total nitrogen	0,7—3,3 %[5]
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	
Molecular weight	
Assay	

Description		Dark brown to black liquids or solids
Identification		
Purity		
	Colour bound by DEAE cellulose	More than 50 %
	Colour intensity[24]	0,10 - 0,60
	Ammoniacal nitrogen	Not more than 0,6 %[25]
	Sulphur dioxide	Not more than 0,2 %[7]
	4-methylimidazole	Not more than 250 mg/kg[7]
	Total nitrogen	0,3 - 1,7 %[7]
	Total sulphur	0,8 - 2,5 %[7]
	Nitrogen/sulphur ratio of alcohol precipitate	0,7 - 2,7
	Absorbance ratio of alcohol precipitate[26]	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

[24] 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.

[25] Expressed on equivalent colour basis i.e. is expressed in terms of a product having a colour intensity of 0,1 absorbance units.

[26] 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).

Cadmium	Not more than 1 mg/kg

E 151 BRILLIANT BLACK BN, BLACK PN

Synonyms		CI Food Black 1
Definition		Brilliant Black BN 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 BN is described as the sodium salt. The calcium and the potassium salt are also permitted.
	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
	Assay	Content not less than 80 % total colouring matters calculated as the sodium salt $E_{1\ cm}^{1\ \%}$ 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	Not more than 0,2 %

matter	
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 carbonization 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 fraction 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.
	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% (120oC 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. $E_{1\ cm}^{1\ \%}$ 403 at ca 460 nm in aqueous solution at pH 7
Description		Reddish-brown powder or granules
	Appearance of the aqueous solution	Brown

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) $E^{1\%}_{1\ cm}$ 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

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[27], 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 $E^{1\%}_{1\ cm}$ 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	

[27] Benzene not more than 0,05 % v/v.

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.
	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) $E_{1cm}^{1\%}$ 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
Definition		Mixed carotenes may also be produced from strains of the algae *Dunaliella salina*, grown in large saline lakes located in Whyalla, South Australia. 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.
	Colour Index No	75130
	EINECS	
	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 20 %
		$E_{1cm}^{1\ \%}$ 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

E 160 b ANNATTO, BIXIN, NORBIXIN

(I) SOLVENT EXTRACTED BIXIN AND NORBIXIN

Synonyms	CI Natural Orange 4
Definition	Bixin is prepared by the extraction of the outer coating of the seeds of the annatto tree (*Bixa orellana* L.) with one or more of the following solvents: acetone, methanol, hexane or dichloromethane, carbon dioxide followed by the removal of the solvent. Norbixin is prepared by hydrolysis by aqueous alkali of the extracted bixin. Bixin and norbixin may contain other materials extracted from the annatto seed. The bixin powder contains several coloured components, the major single one being bixin, which may be present in both cis- and trans- forms. Thermal degradation products of bixin may also be present. The norbixin powder contains the hydrolysis product of bixin, in the form of the sodium or potassium salts as the major colouring principle. Both cis- and trans-forms may be present.
Colour Index No	75120

EINECS	Annatto: 215-735-4, annatto seed extract: 289-561-2; bixin: 230-248-7		
Chemical name	Bixin:	6′-Methylhydrogen-9′-*cis*-6,6′-diapocarotene-6,6′-dioate 6′-Methylhydrogen-9′-*trans*-6,6′-diapocarotene-6,6′-dioate	
	Norbixin:	9′*cis*-6,6′-Diapocarotene-6,6′-dioic acid 9′-*trans*-6,6′-Diapocarotene-6,6′-dioic acid	
Chemical formula	Bixin:	$C_{25}H_{30}O_4$	
	Norbixin:	$C_{24}H_{28}O_4$	
Molecular weight	Bixin:	394,51	
	Norbixin:	380,48	
Assay	Content of bixin powders not less than 75 % total carotenoids calculated as bixin. Content of norbixin powders not less than 25 % total carotenoids calculated as norbixin		
	Bixin:	$E_{1\ cm}^{1\ \%}$ 2 870 at ca 502 nm in chloroform	
	Norbixin:	$E_{1\ cm}^{1\ \%}$ 2 870 at ca 482 nm in KOH solution	
Description	Reddish-brown powder, suspension or solution		
Identification			
Spectrometry	Bixin:	maximum in chloroform at ca 502 nm	
	Norbixin:	maximum in dilute KOH solution at ca 482 nm	
Purity			
Solvent residues	Acetone Methanol 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

(II) ALKALI EXTRACTED ANNATTO

Synonyms	CI Natural Orange 4	
Definition	Water soluble annatto is prepared by extraction with aqueous alkali (sodium or potassium hydroxide) of the outer coating of the seeds of the annatto tree (*Bixa orellana L.*) Water soluble annatto contains norbixin, the hydrolysis product of bixin, in the form of the sodium or potassium salts, as the major colouring principle. Both cis- and trans- forms may be present.	
Colour Index No	75120	
EINECS	Annatto: 215-735-4, annatto seed extract: 289-561-2; bixin: 230-248-7	
Chemical name	Bixin:	6′-Methylhydrogen-9′-*cis*-6,6′-diapocarotene-6,6′-dioate 6′-Methylhydrogen-9′-*trans*-6,6′-diapocarotene-6,6′-dioate
	Norbixin:	9′*cis*-6,6′-Diapocarotene-6,6′-dioic acid 9′-*trans*-6,6′-Diapocarotene-6,6′-dioic acid
Chemical formula	Bixin:	$C_{25}H_{30}O_4$
	Norbixin:	$C_{24}H_{28}O_4$
Molecular weight	Bixin:	394,51
	Norbixin:	380,48
Assay	Contains not less than 0,1 % of total carotenoids expressed as norbixin	
	Norbixin:	$E_{1\ cm}^{1\ \%}$ 2 870 at ca 482 nm in KOH solution
Description	Reddish-brown powder, suspension or solution	
Identification		

Spectrometry	Bixin:	maximum in chloroform at ca 502 nm
	Norbixin:	maximum in dilute KOH solution at ca 482 nm

Purity

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

(III) OIL EXTRACTED ANNATTO

Synonyms	CI Natural Orange 4
Definition	Annatto extracts in oil, as solution or suspension, are prepared by extraction of the outer coating of the seeds of the annatto tree (*Bixa orellana L.*) with edible vegetable oil. Annatto extract in oil contains several coloured components, the major single one being bixin, which may be present in both cis- and trans- forms. Thermal degradation products of bixin may also be present.

Colour Index No	75120	
EINECS	Annatto: 215-735-4, annatto seed extract: 289-561-2; bixin: 230-248-7	
Chemical name	Bixin:	6′-Methylhydrogen-9′-*cis*-6,6′-diapocarotene-6,6′-dioate 6′-Methylhydrogen-9′-*trans*-6,6′-diapocarotene-6,6′-dioate
	Norbixin:	9′*cis*-6,6′-Diapocarotene-6,6′-dioic acid 9′-*trans*-6,6′-Diapocarotene-6,6′-dioic acid
Chemical formula	Bixin:	$C_{25}H_{30}O_4$
	Norbixin:	$C_{24}H_{28}O_4$
Molecular weight	Bixin:	394,51
	Norbixin:	380,48

Assay	Contains not less than 0,1 % of total carotenoids expressed as bixin	
	Bixin:	$E_{1\ cm}^{1\ \%}$ 2 870 at ca 502 nm in chloroform
Description	Reddish-brown powder, suspension or solution	
Identification		
Spectrometry	Bixin:	maximum in chloroform at ca 502 nm
	Norbixin:	maximum in dilute KOH solution at ca 482 nm
Purity		
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 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	
	$E_{1\ cm}^{1\ \%}$ 2 100 at ca 462 nm in acetone	
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	Not more than 50 mg/kg, singly or in combination
	Methanol	
	Ethanol	
	Acetone	
	Hexane	
	Propan-2-ol	
	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) $E_{1cm}^{1\%}$ at 465 - 475 nm in hexane (for 100% pure all-*trans*-lycopene) is 3450
Description		Red crystalline powder
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-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriacontatridecaene
	Chemical	$C_{40}H_{56}$

	formula		
	Molecular weight	536,85	
	Assay	$E_{1\ cm}^{1\ \%}$ at 465 - 475 nm in hexane (for 100% pure all-*trans*-lycopene) is 3450. Content not less than 5% total colouring matters	
Description		Dark red viscous liquid	
Identification			
	Spectrophotometry	Maximum in hexane at ca 472 nm	
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 crystallization 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 $E_{1\ cm}^{1\ \%}$ at 465 - 475 nm in hexane (for 100% pure all-*trans*-lycopene) is 3450
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
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 stabilized 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 $E_{1\ cm}^{1\ \%}$ 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 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

		$E_{1\ cm}^{1\ \%}$ 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 stabilized 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
	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)
		$E_{1\ cm}^{1\ \%}$ 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
	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 % $E_{1\ cm}^{1\ \%}$ 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)
	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	$E_{1\ cm}^{1\ \%}$ 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	$CaCO_3$
	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)	Not more than 100 mg/kg, singly or in combination
	Copper (as Cu)	
	Chromium (as Cr)	
	Zinc (as Zn)	
	Barium (as Ba)	
	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
	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
	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: $FeO(OH) \cdot H2O$	
		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	By total dissolution
	Copper	Not more than 50 mg/kg	
	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.
	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	
	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-naphthalene-carboxylate
	Chemical formula	$C_{18}H_{12}CaN_2O_6S$
	Molecular weight	424,45
	Assay	Content not less than 90 % total colouring matters
		$E_{1\ cm}^{1\ \%}$ 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)
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

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 recrystallized 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

E 203 CALCIUM SORBATE

Synonyms		
Definition		
	EINECS	231-321-6
	Chemical name	Calcium sorbate; Calcium salts of *trans*, *trans*-2,4-hexadienoic acid
	Chemical formula	$C_{12}H_{14}O_4Ca$
	Molecular weight	262,32
	Assay	Content not less than 98 % on the dried basis
Description		Fine white crystalline powder not showing any change in colour after heating at 105 °C for 90 minutes
Identification		
	Melting range for sorbic acid	Melting range of sorbic acid isolated by acidification and not recrystallized 133 °C to 135 °C after vacuum

		drying in a sulphuric acid desiccator
	Test for calcium	Passes test
	Test for double bonds	Passes test
Purity		
	Loss on drying	Not more than 2,0 %, determined by vacuum drying for four hours in a sulphuric acid desiccator
	Aldehydes	Not more than 0,1 % (as formaldehyde)
	Fluoride	Not more than 10 mg/kg
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 2 mg/kg
Mercury		Not more than 1 mg/kg

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
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[28], 0,3 ml of ferric chloride TSC[29], 0,1 ml of copper sulphate TSC[30] and 4,4 ml of water

[28] 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.

[29] 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.

[30] 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

	Polycyclic acids	On fractional acidification of a neutralized solution of benzoic acid, the first precipitate must not have a different melting point from that of the benzoic acid
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 2 mg/kg
	Mercury	Not more than 1 mg/kg

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 recrystallized 121,5 °C to 123,5 °C, after drying in a sulphuric acid desiccator

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.

	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 (neutralized) solution of sodium benzoate, the first precipitate must not have a different melting range from that of benzoic acid
	Chlorinated organic compounds	Not more than 0,06 % expressed as chloride, corresponding to 0,25 % expressed as monochlorobenzoic acid
	Acidity or alkalinity	Neutralization of 1 g of sodium benzoate, in the presence of phenolphthalein, must not require more than 0,25 ml of 0,1 N NaOH or 0,1 N HCl
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 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
	Chemical	$C_7H_5KO_2 \cdot 3H_2O$

	formula	
	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 recrystallized 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 (neutralized) solution of potassium benzoate, the first precipitate must not have a different melting range from that of benzoic acid

Acidity or alkalinity	Neutralization of 1 g of potassium benzoate, in the presence of phenolphthalein, must not require more than 0,25 ml of 0,1 N NaOH or 0,1 N HCl
Arsenic	Not more than 3 mg/kg
Lead	Not more than 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:	$C_{14}H_{10}O_4Ca \cdot 3H_2O$
	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 recrystallized 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 (neutralized) solution of calcium benzoate, the first precipitate must not be a different melting range from that of benzoic acid
	Acidity or alkalinity	Neutralization of 1 g of calcium benzoate, in the presence of phenolphthalein, must not require more than 0,25 ml of 0,1 N NaOH or 0,1 N HCl
	Fluoride	Not more than 10 mg/kg
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 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
	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 °C - 118 °C
	Test for *p*-hydroxybenzoate	Melting range of *p*-hydroxybenzoic acid isolated by acidification and not recrystallized: 213 °C to 217 °C, after vacuum drying in a sulphuric acid desiccator
	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 %
	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
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	

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

E 222 SODIUM BISULPHITE

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
	Test for sodium	Passes test
	pH	2,5 - 5,5 (10 % aqueous solution)
Purity		
	Iron	Not more than 10 mg/kg of Na_2SO_3 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 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
	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

E 227 CALCIUM BISULPHITE

Synonyms		
Definition		
	EINECS	237-423-7
	Chemical name	Calcium bisulphite; Calcium hydrogen sulphite
	Chemical formula	$Ca(HSO_3)_2$
	Molecular	202,22

	weight	
	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

E 228 POTASSIUM BISULPHITE

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

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
	pH	5,5 - 7,5 (1 % w/v solution in previously neutralized 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

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

E 249 POTASSIUM NITRITE

Synonyms		
Definition		
	EINECS	231-832-4
	Chemical name	Potassium nitrite
	Chemical	KNO_2

	formula	
	Molecular weight	85,11
	Assay	Content not less than 95 % on the anhydrous basis[31]
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)
Purity		
	Loss on drying	Not more than 3 % (4 hours, over silica gel)
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 2 mg/kg
	Mercury	Not more than 1 mg/kg

E 250 SODIUM NITRITE

Synonyms		
Definition		
	EINECS	231-555-9
	Chemical name	Sodium nitrite
	Chemical formula	$NaNO_2$
	Molecular weight	69,00

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

	Assay	Content not less than 97 % on the anhydrous basis[32]
Description		White crystalline powder or yellowish lumps
Identification		
	Test for nitrite	Passes test
	Test for sodium	Passes test
Purity		
	Loss on drying	Not more than 0,25 % (4 hours, over silica gel)
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 2 mg/kg
	Mercury	Not more than 1 mg/kg

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
Identification		

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

	Test for nitrate	Passes test
	Test for sodium	Passes test
	pH	5,5 - 8,3 (5 % solution)
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 3 mg/kg
	Lead	Not more than 2 mg/kg
	Mercury	Not more than 1 mg/kg

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
Purity		
	Free nitric acid	Not more than 0,01 %
	Nitrites	Not more than 10 mg/kg expressed as $NaNO_2$
	Arsenic	Not more than 1 mg/kg
	Lead	Not more than 1 mg/kg
	Mercury	Not more than 0,3 mg/kg

This specification refers to a 35 % aqueous solution

E 252 POTASSIUM NITRATE

Synonyms		Chile saltpetre; Cubic or soda nitre
Definition		
	EINECS	231-818-8
	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)
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 3 mg/kg
	Lead	Not more than 2 mg/kg
	Mercury	Not more than 1 mg/kg

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 oxidizable substances	Not more than 1 000 mg/kg expressed as formic acid
Readily oxidisable substances	Dilute 2 ml of the sample in a glass-stoppered container with 10 ml of water and add 0,1 ml of 0,1 N potassium permanganate. The pink colour does not change to brown within 30 minutes
Arsenic	Not more than 1 mg/kg
Lead	Not more than 0,5 mg/kg
Mercury	Not more than 1 mg/kg

E 261 POTASSIUM ACETATE

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 oxidizable 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 (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
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 oxidizable 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)
	Assay	Content 39 to 41 % of free acetic acid and 58 to 60 % of sodium acetate
Description		White, hygroscopic crystalline solid with an acetic odour
Identification		

	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 oxidizable 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	
	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 oxidizable 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 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 hydrolyzes 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
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
Description		White crystalline hygroscopic powder, or a fine white powder
Identification		
	Test for	Passes test

	propionate	
	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
	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 283 POTASSIUM PROPIONATE

Synonyms		
Definition		
	EINECS	206-323-5
	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

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 pressurized cylinders or bulk storage systems, or in compressed solid blocks of «dry ice». Solid (dry ice) forms usually contain added substances, such as propylene glycol or mineral oil, as binders
Identification		
	Precipitate formation	When a stream of the sample is passed through a solution of barium hydroxide, a white precipitate is produced which dissolves with effervescence in dilute acetic acid
Purity		
	Acidity	915 ml of gas bubbled through 50 ml of freshly boiled water must not render the latter more acid to methylorange than is 50 ml freshly boiled water to which has been added 1 ml of hydrochloric acid (0,01 N)
	Reducing substances, hydrogen phosphide and	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

	sulphide	
	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 °C - 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 °C - 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)
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	$C_6H_7O_6Na$
	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

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-gulofuranolactone
	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 °C - 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 °C - 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 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 oxidizes and darkens on exposure to air or light
Identification		
	Solubility	Insoluble in water, freely soluble in ethanol, miscible in ether
	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	$E\ ^{1\%}_{1cm}$(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 oxidizes 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	$E^{1\%}_{1cm}$ (298 nm) between 91 and 97 $E^{1\%}_{1cm}$ (257 nm) between 5,0 and 8,0
	Refractive index	$[n]_D^{20}$ 1,503—1,507
	Sulphated ash	Not more than 0,1 %
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 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 oxidizes 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 $E^{1\%}_{1cm}$ 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

E 311 OCTYL GALLATE

Synonyms		
Definition		
	EINECS	213-853-0
	Chemical name	Octyl gallate; Octyl ester of gallic acid; n-octyl ester of 3,4,5-trihydroxybenzoic acid
	Chemical formula	$C_{15}H_{22}O_5$
	Molecular weight	282,34
	Assay	Content not less than 98 % after drying at 90 °C for

		six hours
Description		White to creamy-white odourless solid
Identification		
	Solubility	Insoluble in water, freely soluble in ethanol, ether and propane-1,2-diol
	Melting range	Between 99 °C and 102 °C after drying at 90 °C for six hours
Purity		
	Loss on drying	Not more than 0,5 % (90 °C, 6 hours)
	Sulphated ash	Not more than 0,05 %
	Free acid	Not more than 0,5 % (as gallic acid)
	Chlorinated organic compound	Not more than 100 mg/kg (as C1)
	Specific absorption in ethanol	$E^{1\%}_{1cm}$ (275 nm) not less than 375 and not more than 390
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 2 mg/kg
	Mercury	Not more than 1 mg/kg

E 312 DODECYL GALLATE

Synonyms		Lauryl gallate
Definition		
	EINECS	214-620-6
	Chemical name	Dodecyl gallate; n-dodecyl (or lauryl) ester of 3,4,5-trihydroxybenzoic acid; Dodecyl ester of gallic acid
	Chemical formula	$C_{19}H_{30}O_5$

	Molecular weight	338,45
	Assay	Content not less than 98 % after drying at 90 °C for six hours
Description		White or creamy-white odourless solid
Identification		
	Solubility	Insoluble in water, freely soluble in ethanol and ether
	Melting range	Between 95 °C and 98 °C after drying at 90 °C for six hours
Purity		
	Loss on drying	Not more than 0,5 % (90 °C, 6 hours)
	Sulphated ash	Not more than 0,05 %
	Free acid	Not more than 0,5 % (as gallic acid)
	Chlorinated organic compound	Not more than 100 mg/kg (as Cl)
	Specific absorption in ethanol	$E^{1\%}_{1cm}$ (275 nm) not less than 300 and not more than 325
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 2 mg/kg
	Mercury	Not more than 1 mg/kg

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
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	$[\alpha]_D^{25}$ $^{25}_{D}$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

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
	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 °C—35 °C). Then slowly add 50 ml of the sample with constant stirring. Hydrolysed lecithin will form a homogeneous emulsion. Non-hydrolysed lecithin will form a distinct mass of about 50 g

Purity		
	Loss on drying	Not more than 2,0 % (105 °C, 1 hour)
	Toluene-insoluble matter	Not more than 0,3 %
	Acid value	Lecithins: not more than 35 mg of potassium hydroxide per gram
		Hydrolysed lecithins: not more than 45 mg of potassium hydroxide per gram
	Peroxide value	Equal to or less than 10
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 2 mg/kg
	Mercury	Not more than 1 mg/kg

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
	Test for	Passes test

	potassium	
	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 %
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
	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)

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 hours) 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)
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
	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-propanetricarboxylic 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

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
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
	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-dihydroxysuccinic 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
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
	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

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
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)
	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
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
	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)
	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
	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)
	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

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

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

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
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, 3h)
	Maleic acid	Not more than 0,05 %
	Fumaric acid	Not more than 1,0 %
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 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
	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

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
	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
	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 °C - 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 °C - 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

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 °C - 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

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)
	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	Ethanol: not more than 2%

	Solvents	

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.
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
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)
	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
	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

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	Not more than 500 colonies per gram

	moulds	
	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
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-	Not more than 15 %

	1,2-diol content	
	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 *Gracilriaceae* 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
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 5g
	Salmonella spp.	Absent in 5g

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. 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
	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
	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
	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
	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	
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
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	Not more than 300 colonies per gram

	moulds	
	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	Karaya gum swells in 60 % ethanol distinguishing it

	ethanol solution	from other gums
Purity		
	Loss on drying	Not more than 20 % (105 °C, 5 hours)
	Total ash	Not more than 8 %
	Acid insoluble ash	Not more than 1 %
	Acid insoluble matter	Not more than 3 %
	Volatile acid	Not less than 10 % (as acetic acid)
	Starch	Not detectable
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 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

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	$C_6H_{14}O_6$
	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 $CH_2OH\text{-}(CHOH)_n\text{-}CH_2OH$, 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
Purity		
	Water content	Not more than 1,5 % (Karl Fischer method)
	Sulphated ash	Not more than 0,1 % (expressed on dry weight basis)
	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)
	Chlorides	Not more than 50 mg/kg (expressed on dry weight basis)
	Sulphates	Not more than 100 mg/kg (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)

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
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
Purity		
	Water content	Not more than 31 % (Karl Fischer method)
	Sulphated ash	Not more than 0,1 % (on dry weight basis)
	Reducing sugars	Not more than 0,3 % (expressed as glucose on dry weight basis)
	Chlorides	Not more than 50 mg/kg (on dry weight basis)

	Sulphates	Not more than 100 mg/kg (on dry weight basis)
	Nickel	Not more than 2 mg/kg (on dry weight basis)
	Arsenic	Not more than 3 mg/kg (on dry weight basis)
	Lead	Not more than 1 mg/kg (on dry weight basis)

E 421 — MANNITOL

(I)MANNITOL

Synonyms		D-mannitol
Definition		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. Manufactured by catalytic hydrogenation of carbohydrate solutions containing glucose and/or fructose
	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)
	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
Purity		
	Water content	Not more than 0,5 % (Karl Fischer method)
	Reducing sugars	Not more than 0,3 % (as glucose)
	Total sugars	Not more than 1 % (expressed as glucose)
	Sulphated ash	Not more than 0,1 %
	Chlorides	Not more than 70 mg/kg
	Sulphate	Not more than 100 mg/kg
	Nickel	Not more than 2 mg/kg
	Lead	Not more than 1 mg/kg

(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
Purity		
	Arabitol	Not more than 0,3 %
	Water content	Not more than 0,5 % (Karl Fischer method)
	Reducing sugars	Not more than 0,3 % (expressed as glucose)
	Total sugars	Not more than 1 % (as glucose)
	Sulphated ash	Not more than 0,1 %
	Chlorides	Not more than 70 mg/kg
	Sulphate	Not more than 100 mg/kg
	Lead	Not more than 1 mg/kg
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

E 422 GLYCEROL

Synonyms		Glycerin; Glycerine
Definition		
	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		
	Acrolein formation on heating	Heat a few drops of the sample in a test tube with about 0,5 g of potassium bisulphate. The characteristic pungent vapours of acrolein are evolved

	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, glucose and ammonium compounds	Heat a mixture of 5 ml of glycerol and 5 ml of potassium hydroxide solution (1 in 10) at 60 °C for five minutes. It neither becomes yellow nor emits an odour of ammonia
	Fatty acids and esters	Not more than 0,1 % calculated as butyric acid
	Chlorinated compounds	Not more than 30 mg/kg (as chlorine)
	3-Monochloropropane-1,2-diol (3-MCPD)	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 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
	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
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 3000 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	To an aqueous dispersion of the sample add sufficient sodium borate test solution (TS) to raise

	with borate	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° in a 400 ml beaker. Stir until the mixture is dissolved and continue stirring for an extra 30 min after dissolution (maintain the temperature above 60° C during the stirring process). Discontinue stirring and allow the mixture to cool at room temperature for at least 2 h. A firm, viscoelastic gel forms after the temperature drops below 40°, 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 25g
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 °C - 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	Not less than 25 and not more than 35

	value	
	Hydroxyl value	Not less than 27 and not more than 40
	1,4-Dioxane	Not more than 5 mg/kg
	Ethylene oxide	Not more than 0,2 mg/kg
	Ethylene glycols (mono- and di-)	Not more than 0,25 %
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 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
	Ethylene oxide	Not more than 0,2 mg/kg
	Ethylene glycols (mono- and di-)	Not more than 0,25 %
	Arsenic	Not more than 3 mg/kg
	Lead	Not more than 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

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

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

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	
	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)
Description		Unctuous semi-solid to oily solid
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
	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) 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 %
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 oC). 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
	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
	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)
	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.

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)
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
	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	Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula

	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

	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
	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
	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

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

E 460 (i) MICROCRYSTALLINE CELLULOSE

Synonyms		Cellulose gel
Definition		Microcrystalline cellulose is purified, partally 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
	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		
	Solubility	Insoluble in water, ethanol, ether and dilute mineral acids. Slightly soluble in sodium hydroxide solution
	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 %

	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 ($-OCH_2CH_2OH$)
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
	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

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
	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

E 466 SODIUM CARBOXY METHYL CELLULOSE, CARBOXY METHYL CELLULOSE, CELLULOSE GUM

Synonyms		CMC; NaCMC; Sodium CMC;
Definition		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
	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
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	
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 ^oC, 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
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	Not more than 0,5 % singly or in combination

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

E 471 MONO- AND DIGLYCERIDES OF FATTY ACIDS

Synonyms		Glyceryl monostearate; Glyceryl monopalmitate; Glyceryl monooleate, etc.; Monostearin; Monopalmitin; Monoolein, etc.; GMS (for glyceryl monostearate)
Definition		Mono- and diglycerides of fatty acids consist of mixtures of glycerol mono-, di- and triesters of fatty acids occurring in food oils and fats. They may contain small amounts of free fatty acids and glycerol
	EINECS	
	Chemical name	
	Chemical	

	formula	
	Molecular weight	
	Assay	Content of mono- and diesters: not less than 70 %
Description		The product varies from a pale yellow to pale brown oily liquid to a white or slightly off-white hard waxy solid. The solids may be in the form of flakes, powders or small beads
Identification		
	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 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 glycerol	Not less than 16 % and not more than 33 %

Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C

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

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
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
	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
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		Mixted esters of glycerol with mono- and diacetyltartaric acids (obtained from tartaric acid) and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free tartaric and acetic acids and their combinations, and free glycerides. Contains also tartaric and acetic esters of fatty acids
	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
	Total tartaric acid	Not less than 10 % and not more than 40 %
	Total acetic	Not less than 8 % and not more than 32 %

	acid	
	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	Passes test

	acid	
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

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	Not more than 350 mg/kg, singly or in combination
Propylene glycol	
Methyl ethyl ketone	Not more than 10 mg/kg

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

E 474 SUCROGLYCERIDES

Synonyms	Sugar glycerides
Definition	Sucroglycerides are produced by reacting sucrose with an edible fat or oil to produce a mixture of essentially mono-, di- and triesters of sucrose and fatty acids (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 Cyclohexane	Not more than 10 mg/kg, single or in combination
	Ethyl acetate Propan-2-ol	Not more than 350 mg/kg, single or in combination

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

as sodium oleate)

E 475 POLYGLYCEROL ESTERS OF FATTY ACIDS

Synonyms		Polyglycerol fatty acid esters; Polyglycerin esters of fatty acid esters
Definition		Polyglycerol esters of fatty acids are produced by the esterification of polyglycerol with food fats and oils or with fatty acids occurring in foods fats and oils. The polyglycerol moiety is predominantly di-, tri- and tetraglycerol and contains not more than 10 % of polyglycerols equal to or higher than heptaglycerol
	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 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 476 POLYGLYCEROL POLYRICINOLEATE

Synonyms		Glycerol esters of condensed castor oil fatty acids; Polyglycerol esters of polycondensed fatty acids from castor oil; Polyglycerol esters of interesterified ricinoleic acid; PGPR
Definition		Polyglycerol polyricinoleate is prepared by the esterification of polyglycerol with condensed castor oil fatty acids
	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 polyglycerol	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 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 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
	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 desodorisation under vacuum at 130 °C of 10 % of thermally oxidised soya bean oil and 90 % mono- and diglycerides of food fatty acids. Soya bean oil is exclusively made from 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
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
	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

E 483 STEARYL TARTRATE

Synonyms		Stearyl palmityl tartrate
Definition		Product of the esterification of tartaric acid with commercial stearyl alcohol, which consists essentially of stearyl and palmityl alcohols. It consists mainly of diester, with minor amounts of monoester and of unchanged starting materials
	EINECS	
	Chemical name	Distearyl tartrate Dipalmityl tartrate Stearylpalmityl tartrate
	Chemical formula	$C_{40}H_{78}O_6$ (Distearyl tartrate) $C_{36}H_{70}O_6$ (Dipalmityl tartrate) $C_{38}H_{74}O_6$ (Stearylpalmityl tartrate)
	Molecular weight	655 (Distearyl tartrate) 599 (Dipalmityl tartrate) 627 (Stearylpalmityl tartrate)
	Assay	Content of total ester not less than 90 % corresponding to an ester value of not less than 163 and not more than 180
Description		Cream-coloured unctuous solid (at 25 °C)
Identification		
	Test for tartrate	Passes test
	Melting range	Between 67 °C and 77 °C. After saponification the saturated long chain fatty alcohols have a melting range of 49 °C to 55 °C
Purity		

Hydroxyl value	Not less than 200 and not more than 220
Acid value	Not more than 5,6
Total tartaric acid	Not less than 18 % and not more than 35 %
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
Unsaponifiable matter	Not less than 77 % and not more than 83 %
Iodine value	Not more than 4 (Wijs method)

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
	Congealing range	50 — 52 °C
	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
	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
	Congealing range	47 — 50 °C
	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	
	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 tetrachloride. 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 %
	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
	Congealing range	45 — 47 °C
	Infrared absorption	Characteristic of a partial fatty acid ester of polyol

	spectrum	
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

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
	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	Passes test

	carbonate	
	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
	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
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
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
	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
	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
	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
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
	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	$KHSO_4$
	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
	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
	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 °C - 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
	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
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
	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
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	CaO

	formula	
	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
	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

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 %
	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)
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 °C - 800 °C, 2 hours) 15 % - 16 % (B) (750 °C - 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)
		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	
	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	Not more than 15 % after drying (1 000 °C, 20 min)

	ignition	
	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

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	Peaks at 9,34/4,66/3,12 Å

	diffraction	
	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)
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

E 556 CALCIUM ALUMINIUM SILICATE

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

E 559 ALUMINIUM SILICATE (KAOLIN)

Synonyms	Kaolin, light or heavy
Definition	Aluminium silicate hydrous (kaolin) is a purified white plastic clay composed of kaolinite, potassium aluminium silicate, feldspar and quartz. Processing should not include calcination. The raw kaolinitic clay used in the production of aluminium silicate shall have a level of dioxin which does not make it injurious to

		health or unfit for human consumption. 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}
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 chromatog-raphy
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)
	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	Positive. Compound formed melts between 196 °C and 202 °C with decomposition

	of gluconic acid	
	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
	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
	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 phenylhydrazine 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
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
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

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
	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	Not more than 0,2 %

	acid	
	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
	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
	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		
	EINECS	221-849-5
	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

E 628 DIPOTASSIUM GUANYLATE

Synonyms		Potassium guanylate; Potassium 5'-guanylate
Definition		
	EINECS	226-914-1
	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, practicaly 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
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	348,21

	weight	
	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
	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	424,39

	weight	
	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	Sparingy soluble in water
Description		Odourless, colourless or 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 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	$C_{10}H_{11}N_4CaO_8P \cdot nH_2O$

	formula	$C_{10}H_{12}N_5CaO_8P \cdot nH_2O$
	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

	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, sparingy solyble 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
	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

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
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
	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

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
Purity		
	Loss on	Not more than 6,0 % (40 °C, over silica gel, 15 hours)

	drying	
	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 x 10^{-5} m^2s^{-1}at 100 °C
		Alternative: Not less than 0,8 x 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 %
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 x 10^{-6} and 6,1 x 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

E 912 MONTAN ACID ESTERS

Synonyms		
Definition		Montan acids and/or esters with ethylene glycol and/or 1,3-butanediol and/or glycerol
	EINECS	
	Chemical name	Montan acid esters
	Chemical formula	
	Molecular weight	
	Assay	
Description		Almost white to yellowish flakes, powder, granules or pellets
Identification		
	Density	Between 0,98 and 1,05 (20 °C)
	Drop point	Greater than 77 °C
Purity		

	Acid value	Not more than 40
	Glycerol	Not more than 1 % (by gas chromatography)
	Other polyols	Not more than 1 % (by gas chromatography)
	Other wax types	Not detectable (by differential scanning calorimetry and/or infrared spectroscopy)
	Arsenic	Not more than 2 mg/kg
	Chromium	Not more than 3 mg/kg
	Lead	Not more than 2 mg/kg

E 914 OXIDISED POLYETHYLENE WAX

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

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	Between 8,0 % and 12,0 %

drying	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
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 %
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	44

	weight	
	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

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 %

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
	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
	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	Not more than 0,2 % (expressed on dry weight basis)

	ash	
	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)
	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)
	Cyclohexyl amine	Not more than 10 mg/kg (expressed on dry weight basis)
	Dicyclohex ylamine	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
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)
	Cyclohexyl amine	Not more than 10 mg/kg (expressed on dry weight basis)
	Dicyclohex ylamine	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.
Description		Odourless, white, slightly hygroscopic, crystalline mass.
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.
Purity		
	Water content	Not more than 7 % (Karl Fischer Method)
Sulphated ash		Not more than 0,05 % (expressed on dry weight basis)
D-Mannitol		Not more than 3 %
D-Sorbitol		Not more than 6 %
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 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-Toluenesul	Not more than 10 mg/kg (expressed on dry weight

	phonamide	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
	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	$C_{14}H_8CaN_2O_6S_2 \cdot 3½H_2O$

	formula	
	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
	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*-	Not more than 25 mg/kg (expressed on dry weight

	sulphonamide	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
	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 aminoacids
	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)
	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)

E 960 STEVIOL GLYCOSIDES

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 consisting mainly (at least 75%) of stevioside and/or rebaudioside A.

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).

Chemical name

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

Chemical formula

Trivial name	**Formula**	**Conversion factor**
Steviol	$C_{20}H_{30}O_3$	1,00
Stevioside	$C_{38}H_{60}O_{18}$	0,40
Rebaudioside A	$C_{44}H_{70}O_{23}$	0,33
Rebaudioside C	$C_{44}H_{70}O_{22}$	0,34
Dulcoside A	$C_{38}H_{60}O_{17}$	0,40
Rubusoside	$C_{32}H_{50}O_{13}$	0,50
Steviolbioside	$C_{32}H_{50}O_{13}$	0,50
Rebaudioside B	$C_{38}H_{60}O_{18}$	0,40
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
	Molecular weight and CAS Nr.	**Trivial name**	**CAS Number**	**Molecular weight**
		Stevioside	57817-89-7	804,87
		Rebaudioside A	58543-16-1	967,01
	Assay:	Not less than 95% stevioside, rebaudiosides A, B, C, D, E and F, steviolbioside, rubusoside and dulcoside on the dried basis.		
Description		White to light yellow powder, approximately between 200 and 300 times sweeter than sucrose		
Identification				
	Solubility	Freely soluble to slightly soluble in water		
	Stevioside and rebaudioside A	The main peak in the chromatogram obtained following the procedure in Method of Assay corresponds to either stevioside or rebaudioside A		
	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 5000 mg/kg ethanol		
	Arsenic	Not more than 1 mg/kg		
	Lead	Not more than 1 mg/kg		

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
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 100ml 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

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

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)
Purity		

Appearance of the aqueous solution	The solution is clear and colourless
Water content	Not more than 1 % (Karl Fischer method)
Sulphated ash	Not more than 0,1 % (expressed on an anhydrous basis)
Reducing sugars	Not more than 0,1 % (expressed as glucose on an anhydrous basis)
Chlorides	Not more than 50 mg/kg (expressed on anhydrous basis)
Sulphates	Not more than 100 mg/kg (expressed on 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)

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
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).
Purity		
	Appearance of the aqueous solution	The solution is clear and colourless
	Water content	Not more than 31 % (Karl Fischer method)
	Reducing sugars	Not more than 0,3 % (expressed as glucose on an anhydrous basis)
	Sulphated ash	Not more than 0,1 %
	Chlorides	Not more than 50 mg/kg
	Sulphate	Not more than 100 mg/kg
	Nickel	Not more than 2 mg/kg
	Lead	Not more than 1 mg/kg

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 powderor 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)

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.
Purity		
	Water content	Not more than 1% (Karl-Fischer method)
	Sulphated ash	Not more than 0,1 % (expressed on dry weight basis)

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)
Chlorides	Not more than 100 mg/kg (expressed on dry weight basis)
Sulphates	Not more than 200 mg/kg (expressed on dry weight basis)

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.
Identification		
	Solubility	Freely soluble in water, slightly soluble in ethanol, insoluble in diethyl ether.

	Melting range	119-123 °C
Purity		
	Loss on drying	Not more than 0,2 % (70 °C, 6 hours, in a vacuum desiccator)
	Sulphated ash	Not more than 0,1 %
	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

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
	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
	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 decolorised and deionised for further purification. The products may also be partially hydrogenated with Raney nickel catalyst to reduce residual glucose. Polydextrose-N is neutralised polydextrose
	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
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	$(C_6H_9NO)_n$
	Weight 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
	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		

	Solubility	Soluble in water ; sparingly soluble in ethanol
	Precipitation reaction	Dissolve 0,25g 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 0,01g 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 0,5g 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 26000-30000 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

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 oligosacchar	Not more than 10 % expressed as glucose

	ides	
	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
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 solid polymer is milled (first milling step) and extruded and granulated under vacuum to remove residual volatile components. The granules resulting are commercialised as such or undergo a second milling step (micronisation).
	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)$_2$N(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 47000g/mol

	Particle size of powder (when used forms a film)	< 50 µm more than 50% < 0,1 µm 5,1 – 5,5 %
	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.
Purity		
	Loss of drying	Not more than 2,0 % (105°C, 3H)
	Alkali value	162 – 198 mg KOH/ g of dried substance
	Sulphated ash	Not more than 0,1 %
	Residual monomers	Butylmethacrylate < 1000 mg/kg Methyl methacrylate < 1000 mg/kg Dimethylaminoethyl methacrylate < 1000 mg/kg

	Solvent residues	propan-2-ol < 0,5% Butanol < 0,5% Methanol < 0,1%
	Arsenic	Not more than 2 mg/kg
	Lead	Not more than 2 mg/kg
	Mercury	Not more than 2 mg/kg
	Copper	Not more than 10 mg/kg

E 1404 OXIDISED STARCH

Synonyms		
Definition		Oxidised starch is starch treated with sodium hypochlorite
	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	Not more than 15,0 % for cereal starch

	drying	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 tripolyphosphate
	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 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

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)
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

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)
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)
	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	Passes test (if not pregelatinised)

	observation	
	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
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)

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

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

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 °C - 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 9000 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
Identification		
	Melting	PEG 400: 4-8°C

	range	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
Ethylene oxide	Not more than 0,2 mg/kg
Ethylene glycol and diethylene glycol	Total not more than 0,25% °w/w individually or in combination
Lead	Not more than 1 mg/kg