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(Acts whose publication is obligatory)

COMMISSION DIRECTIVE 98/86/EC

of 11 November 1998

amending Commission Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

After consulting the Scientific Committee for Food;

Whereas, it is necessary to establish purity criteria for all additives other than colours and sweeteners mentioned in European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners⁽³⁾, as last amended by Directive 98/72/EC⁽⁴⁾;

Whereas, it is necessary to replace the purity criteria set out in Council Directive 78/663/EEC of 25 July 1978 laying down specific criteria of purity for emulsifiers, stabilisers, thickeners and gelling agents which may be used in foodstuffs intended for human consumption⁽⁵⁾, as last amended by Commission Directive 92/4/EEC⁽⁶⁾;

Whereas Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners⁽⁷⁾ set out a first list of purity criteria for a number of food additives; whereas this list should now be complemented with the newly established purity criteria for other additives;

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

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

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 96/77/EC shall be amended as follows:

⁽¹⁾ OJ L 40, 11.2.1989, p. 27.

⁽²⁾ OJ L 237, 10.9.1994, p. 1.

⁽³⁾ OJ L 61, 18.3.1995, p. 1.

⁽⁴⁾ OJ L 295, 4.11.1998, p. 18.

⁽⁵⁾ OJ L 223, 14.8.1978, p. 7.

⁽⁶⁾ OJ L 55, 29.2.1992, p. 96.

⁽⁷⁾ OJ L 339, 30.12.1996, p. 1.

1. Article 2 is replaced by the following:

Article 2

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

2. In the Annex, the text of the Annex to this Directive shall be added.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1999. They shall immediately inform the Commission thereof.

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

2. Products put on the market or labelled before 1 July 1999 which do not comply with this Directive may be marketed until stocks are exhausted.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 11 November 1998.

For the Commission
Martin BANGEMANN
Member of the Commission

ANNEX

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

E 400 ALGINIC ACID

Definition	Linear glycuronoglycan consisting mainly of β -(1-4) linked D-mannuronic and α -(1-4) linked L-guluronic acid units in pyranose ring form. Hydrophilic colloidal carbohydrate extracted by the use of dilute alkali from natural strains of various species of brown seaweeds (<i>Phaeophyceae</i>)
Einecs	232-680-1
<i>Chemical formula</i>	$(C_6H_8O_6)_n$
<i>Molecular weight</i>	10 000—600 000 (typical average)
<i>Assay</i>	Alginic acid yields, on the anhydrous basis, not less than 20 % and not more than 23 % of carbon dioxide (CO ₂), equivalent to not less than 91 % and not more than 104,5 % of alginic acid (C ₆ H ₈ O ₆) _n (calculated on equivalent weight basis of 200)
<i>Description</i>	Alginic acid occurs in filamentous, grainy, granular and powdered forms. It is a white to yellowish brown and nearly odourless
Identification	
A. Solubility	Insoluble in water and organic solvents, slowly soluble in solutions of sodium carbonate, sodium hydroxide and trisodium phosphate
B. Calcium chloride precipitation test	To a 0,5 % solution of the sample in 1 M sodium hydroxide solution, add one fifth of its volume of a 2,5 % solution of calcium chloride. A voluminous, gelatinous precipitate is formed. This test distinguishes alginic acid from acacia gum, sodium carboxymethyl cellulose, carboxymethyl starch, carrageenan, gelatin, gum ghatti, karaya gum, locust bean gum, methyl cellulose and tragacanth gum
C. Ammonium sulphate precipitation test	To a 0,5 % solution of the sample in 1 M sodium hydroxide solution, add one half of its volume of a saturated solution of ammonium sulphate. No precipitate is formed. This test distinguishes alginic acid from agar, sodium carboxymethyl cellulose, carrageenan, de-esterified pectin, gelatin, locust bean gum, methyl cellulose and starch
D. Colour reaction	Dissolve as completely as possible 0,01 g of the sample by shaking with 0,15 ml of 0,1 N sodium hydroxide and add 1 ml of acid ferric sulphate solution. Within 5 minutes, a cherry-red colour develops that finally becomes deep purple
Purity	
pH of a 3 % suspension	Between 2,0 and 3,5
Loss on drying	Not more than 15 % (105 °C, 4 hours)
Sulphated ash	Not more than 8 % on the anhydrous basis
Sodium hydroxide (1 M solution)	Not more than 2 % on the anhydrous basis insoluble matter
Arsenic	Not more than 3 mg/kg

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

E 401 SODIUM ALGINATE

Definition

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

Identification

- A. Positive test for sodium and alginic acid

Purity

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

E 402 POTASSIUM ALGINATE

Definition

<i>Chemical name</i>	Potassium salt of alginic acid
<i>Chemical formula</i>	$(C_6H_7KO_6)_n$
<i>Molecular weight</i>	10 000-600 000 (typical average)
<i>Assay</i>	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)
<i>Description</i>	Nearly odourless, white to yellowish fibrous or granular powder

Identification

- A. Positive test for potassium and for alginic acid

Purity

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

E 403 AMMONIUM ALGINATE

Definition

<i>Chemical name</i>	Ammonium salt of alginic acid
<i>Chemical formula</i>	$(C_6H_{11}NO_6)_n$
<i>Molecular weight</i>	10 000-600 000 (typical average)
<i>Assay</i>	Yields, on the anhydrous basis, not less than 18 % and not more than 21 % of carbon dioxide corresponding to not less than 88,7 % and not more than 103,6 % ammonium alginate (calculated on an equivalent weight basis of 217)
<i>Description</i>	White to yellowish fibrous or granular powder

Identification

A. Positive test for ammonium and alginic acid

Purity

Loss on drying	Not more than 15 % (105 °C, 4 hours)
Sulphated ash	Not more than 7 % on the dried basis
Water-insoluble matter	Not more than 2 % on the anhydrous basis
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals	Not more than 20 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

E 404 CALCIUM ALGINATE**Synonyms**

Calcium salt of alginate

Definition

Chemical name

Calcium salt of alginic acid

Chemical formula

$(C_6H_7Ca_{1/2}O_6)_n$

Molecular weight

10 000-600 000 (typical average)

Assay

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

Description

Nearly odourless, white to yellowish fibrous or granular powder

Identification

A. Positive test for calcium and alginic acid

Purity

Loss on drying	Not more than 15,0 % (105 °C, 4 hours)
Arsenic	Not more than 3 mg/kg

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

E 405 PROPANE-1,2-DIOL ALGINATE

Synonyms

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

Definition

Chemical name

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

Chemical formula

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

Molecular weight

10 000—600 000 (typical average)

Assay

Yields, on the anhydrous basis, not less than 16 % and not more than 20 % of CO₂ of carbon dioxide

Description

Nearly odourless, white to yellowish brown fibrous or granular powder

Identification

A. Positive test for 1,2-propanediol and alginic acid after hydrolysis

Purity

Loss on drying	Not more than 20 % (105 °C, 4 hours)
Total propane-1,2-diol content	Not less than 15 % and not more than 45 %
Free propane-1,2-diol content	Not more than 15 %
Water-insoluble matter	Not more than 2 % on the anhydrous basis
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g
E 406 AGAR	
Synonyms	Gelose Japan agar Bengal, Ceylon, Chinese or Japanese isinglass Layor Carang
Definition	
<i>Chemical name</i>	Agar is a hydrophilic colloidal polysaccharide consisting mainly of D-galactose units. On about every tenth D-galactopyranose unit one of the hydroxyl groups is esterified with sulphuric acid which is neutralised by calcium, magnesium, potassium or sodium. It is extracted from certain natural strains of marine algae of the families <i>Gelidiaceae</i> und <i>Sphaerococcaceae</i> and related red algae of the class <i>Rhodophyceae</i>
Einecs	232-658-1
<i>Assay</i>	The threshold gel concentration should not be higher than 0,25 %
<i>Description</i>	Agar is odourless or has a slight characteristic odour. Unground agar usually occurs in bundles consisting of thin, membranous, agglutinated strips, or in cut, flaked or granulated forms. It may be light yellowish-orange, yellowish-grey to pale yellow, or colourless. It is tough when damp, brittle when dry. Powdered agar is white to yellowish-white or pale yellow. When examined in water under a microscope, the agar appears granular and somewhat filamentous. A few fragments of the spicules of sponges and a few frustules of diatoms may be present. In chloral hydrate solution, the powdered agar appears more transparent than in water, more or less granular, striated, angular and occasionally contains frustules of diatoms. Gel strength may be standardised by the addition of dextrose and maltodextrines or sucrose
Identification	
A. Solubility	Insoluble in cold water; soluble in boiling water
Purity	
Loss on drying	Not more than 22 % (105 °C, 5 hours)
Ash	Not more than 6,5 % on the anhydrous basis determined at 550 °C
Acid-insoluble ash (insoluble in approximately 3N Hydrochloric acid)	Not more than 0,5 % determined at 550 °C on the anhydrous basis
Insoluble matter (in hot water)	Not more than 1,0 %
Starch	Not detectable by the following method: to a 1 in 10 solution of the sample add a few drops of iodine solution. No blue colour is produced

Gelatin and other proteins	Dissolve about 1 g of agar in 100 ml of boiling water and allow to cool of about 50°C. To 5 ml of the solution add 5 ml of trinitrophenol solution (1 g of anhydrous trinitrophenol/100 ml of hot water). No turbidity appears within 10 minutes
Water absorption	Place 5 g to agar in a 100 ml graduated cylinder, fill to the mark with water, mix and allow to stand at about 25°C for 24 hours. Pour the contents of the cylinder through moistened glass wool, allowing the water to drain into a second 100 ml graduated cylinder. Not more than 75 ml of water is obtained
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 407 CARRAGEENAN

Synonyms	<p>Products of commerce are sold under different names such as:</p> <ul style="list-style-type: none"> – Irish moss gelose – Eucheuman (from <i>Eucheuma</i> spp.) – Iridophycan (from <i>Irididaea</i> spp.) – Hypnean (from <i>Hypnea</i> spp.) – Furcellaran or Danish agar (from <i>Furcellaria fastigiata</i>) – Carrageenan (from <i>Chondrus</i> and <i>Gigartina</i> spp.)
Definition	Carrageenan is obtained by aqueous extraction of natural strains of seaweeds of <i>Gigartinaceae</i> , <i>Solieriaceae</i> , <i>Hypneaceae</i> and <i>Furcellariaceae</i> , families of the class <i>Rhodophyceae</i> (red seaweeds). No organic precipitant shall be used other than methanol, ethanol and propane-2-ol. Carrageenan consists chiefly of the potassium, sodium, magnesium and calcium salts of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3,6-anhydrogalactose. Carrageenan shall not be hydrolysed or otherwise chemically degraded
Einecs	232-524-2
<i>Description</i>	Yellowish to colourless, coarse to fine powder which is practically odourless
Identification	
A. Positive tests for galactose, for anhydrogalactose and for sulphate	
Purity	
Methanol, ethanol propane-2-ol content	Not more than 0,1 % singly or in combination
Viscosity of a 1,5 % solution at 75°C	Not less than 5 mPa.s
Loss on drying	Not more than 12 % (105°C, 4 hours)
Sulphate	Not less than 15 % and not more than 40 % on the anhydrous basis (as SO ₄)

Ash	Not less than 15 % and not more than 40 % determined on the anhydrous basis at 550 °C
Acid-insoluble ash	Not more than 1 % on the anhydrous basis (insoluble in 10 % hydrochloric acid)
Acid-insoluble matter	Not more than 2 % on the anhydrous basis (insoluble in 1 % v/v sulphuric acid)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

E 407a PROCESSED EUCHEUMA SEAWEED

Synonyms	PES (acronym for processed eucheuma seaweed)
Definition	Processed eucheuma seaweed is obtained by aqueous alkaline (KOH) treatment of the natural strains of seaweeds <i>Eucheuma cottonii</i> und <i>Eucheuma spinosum</i> , of the class <i>Rhodophyceae</i> (red seaweeds) to remove impurities and by fresh water washing and drying to obtain the product. Further purification may be achieved by washing with methanol, ethanol or propane-2-ol and drying. The product consists chiefly of the potassium salts of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3,6-anhydrogalactose. Sodium, calcium and magnesium salts of the polysaccharide sulphate esters are present in lesser amounts. Up to 15 % algal cellulose is also present in the product. The carrageenan in processed eucheuma seaweed shall not be hydrolysed or otherwise chemically degraded
<i>Description</i>	Tan to yellowish, coarse to fine powder which is practically odourless
Identification	
A. Positive tests for galactose, for anhydrogalactose and for sulphate	
B. Solubility	Forms cloudy viscous suspensions in water. Insoluble in ethanol
Purity	
Methanol, ethanol, propane-2-ol content	Not more than 0,1 % singly or in combination
Viscosity of a 1,5 % solution at 75 °C	Not less than 5 mPa.s
Loss on drying	Not more than 12 % (105 °C, 4 hours)

Sulphate	Not less than 15 % and not more than 40 % on the dried basis (as SO ₄)
Ash	Not less than 1 % and not more than 40 % determined on the dried basis at 550 °C
Acid-insoluble ash	Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)
Acid-insoluble matter	Not less than 8 % and not more than 15 % on the dried basis (insoluble in 1 % v/v sulphuric acid)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and mould	Not more than 300 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

E 410 LOCUST BEAN GUM

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

Purity

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

E 412 GUAR GUM**Synonyms**

Gum cyamopsis
Guar flour

Definition

Guar gum is the ground endosperm of the seeds of natural strains of the guar plant, *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

Einecs

232-536-0

Molecular weight

50 000—8 000 000

Assay

Galactomannan content not less than 75 %

Description

A white to yellowish-white, nearly odourless powder

Identification

A. Positive tests for galactose and for mannose

B. Solubility

Soluble in cold water

Purity

Loss on drying	Not more than 15 % (105 °C, 5 hours)
Ash	Not more than 1,5 % determined at 800 °C
Acid-insoluble matter	Not more than 7 %
Protein (N × 6,25)	Not more than 10 %

Starch	Not detectable by the following method: to a 1 in 10 solution of the sample add a few drops of iodine solution. (No blue colour is produced)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 413 TRAGACANTH

Synonyms	Tragacanth gum Tragant
Definition	Tragacanth is a dried exudation obtained from the stems and branches of natural strains of <i>Astragalus gummifer</i> Labillardiere and other Asiatic species of <i>Astragalus</i> (family <i>Leguminosae</i>). It consists mainly of high molecular weight polysaccharides (galactoarabans and acidic polysaccharides) which, on hydrolysis, yield galacturonic acid, galactose, arabinose, xylose and fucose. Small amounts of rhamnose and of glucose (derived from traces of starch and/or cellulose) may also be present
<i>Molecular weight</i>	Approximately 800 000
Einecs	232-252-5
<i>Description</i>	Unground Tragacanth gum occurs as flattened, lamellated, straight or curved fragments or as spirally twisted pieces 0,5-2,5 mm thick and up to 3 cm in length. It is white to pale yellow in colour but some pieces may have a red tinge. The pieces are horny in texture, with a short fracture. It is odourless and solutions have an insipid mucilaginous taste. Powdered tragacanth is white to pale yellow or pinkish brown (pale tan) in colour
Identification	
A. Solubility	1 g of the sample in 50 ml of water swells to form a smooth, stiff, opalescent mucilage; insoluble in ethanol and does not swell in 60 % (w/v) aqueous ethanol
Purity	
Negative test for Karaya gum	Boil 1 g with 20 ml of water until a mucilage is formed. Add 5 ml of hydrochloric acid and again boil the mixture for five minutes. No permanent pink or red colour develops
Loss on drying	Not more than 16 % (105 °C , 5 hours)
Total ash	Not more than 4 %
Acid insoluble ash	Not more than 0,5 %
Acid insoluble matter	Not more than 2 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
<i>Salmonella</i> spp.	Negative in 10 g
<i>E. coli</i>	Negative in 5 g
E 414 ACACIA GUM	
Synonyms	Gum arabic
Definition	Acacia gum is a dried exudation obtained from the stems and branches of natural strains of <i>Acacia senegal</i> (L) Willdenow or closely related species of Acacia (family <i>Leguminosae</i>). It consists mainly of high molecular weight polysaccharides and their calcium, magnesium and potassium salts, which on hydrolysis yield arabinose, galactose, rhamnose and glucuronic acid
<i>Molecular weight</i>	Approximately 350 000
Einecs	232-519-5
<i>Description</i>	Unground acacia gum occurs as white or yellowish-white spheroidal tears of varying sizes or as angular fragments and is sometimes mixed with darker fragments. It is also available in the form of white to yellowish-white flakes, granules, powder or spray-dried material.
Identification	
A. Solubility	1 g dissolves in 2 ml of cold water forming a solution which flows readily and is acid to litmus, insoluble in ethanol
Purity	
Loss on drying	Not more than 17% (105°C, 5 hours) for granular and not more than 10% (105°C, 4 hours) for spray-dried material
Total ash	Not more than 4%
Acid insoluble ash	Not more than 0,5%
Acid insoluble matter	Not more than 1%
Starch or dextrin	Boil a 1 in 50 solution of the gum and cool. To 5 ml add 1 drop of iodine solution. No bluish or reddish colours are produced
Tannin	To 10 ml of a 1 in 50 solution add about 0,1 ml of ferric chloride solution (9 g FeCl ₃ ·6H ₂ O made up to 100 ml with water). No blackish colouration or blackish precipitate is formed
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

Heavy metals (as Pb)	Not more than 20 mg/kg
Hydrolysis products	Mannose, xylose and galacturonic acid are absent (determined by chromatography)
<i>Salmonella</i> spp.	Negative in 10 g
<i>E. coli</i>	Negative in 5 g

E 415 XANTHAN GUM

Definition	Xanthan gum is a high molecular weight polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with natural strains of <i>Xanthomonas campestris</i> , purified by recovery with ethanol or propane-2-ol, dried and milled. It contains D-glucose and D-mannose as the dominant hexose units, along with D-glucuronic acid and pyruvic acid, and is prepared as the sodium, potassium or calcium salt. Its solutions are neutral
<i>Molecular weight</i>	Approximately 1 000 000
Einecs	234-394-2
<i>Assay</i>	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
<i>Description</i>	Cream-coloured powder
Identification	
A. Solubility	Soluble in water. Insoluble in ethanol
Purity	
Loss on drying	Not more than 15% (105°C, 2½ hours)
Total ash	Not more than 16% on the anhydrous basis determined at 650°C after drying at 105°C for four hours
Pyruvic acid	Not less than 1,5%
Nitrogen	Not more than 1,5%
Propane-2-ol	Not more than 500 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Total plate count	Not more than 10 000 colonies per gram
Yeast and mould	Not more than 300 colonies per gram

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

E 416 KARAYA-GUM**Synonyms**

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

Definition

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

Einecs

232-539-4

Description

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

Identification

A. Solubility

Insoluble in ethanol

B. Swelling in ethanol solution

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

Purity

Loss on drying

Not more than 20 % (105 °C, 5 hours)

Total ash

Not more than 8 %

Acid insoluble ash

Not more than 1 %

Acid insoluble matter

Not more than 3 %

Volatile acid

Not less than 10 % (as acetic acid)

Starch

Not detectable

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 20 mg/kg

Salmonella spp.

Negative in 10 g

E. coli

Negative in 5 g

E 417 TARA GUM

Definition	Tara gum is obtained by grinding the endosperm of the seeds of natural strains of <i>Caesalpinia spinosa</i> (family <i>Leguminosae</i>). 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
<i>Description</i>	A white to white-yellow odourless powder
Identification	
A. Solubility	Soluble in water Insoluble in ethanol
B. Gel formation	To an aqueous solution of the sample add small amounts of sodium borate. A gel is formed
Purity	
Loss on drying	Not more than 15 %
Ash	Not more than 1,5 %
Acid insoluble matter	Not more than 2 %
Protein	Not more than 3,5 % (factor N x 5,7)
Starch	Not detectable
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 418 GELLAN GUM

Definition	Gellan gum is a high molecular weight polysaccharide gum produced by a pure culture fermentation of a carbohydrate by natural strains of <i>Pseudomonas elodea</i> , purified by recovery with isopropyl alcohol, dried, and milled. The high molecular weight polysaccharide is principally composed of a tetrasaccharide repeating unit of one rhamnose, one glucuronic acid, and two glucoses, and substituted with acyl (glyceryl and acetyl) groups as the O-glycosidically linked esters. The glucuronic acid is neutralised to a mixed potassium, sodium, calcium, and magnesium salt
Einecs	275-117-5
<i>Molecular weight</i>	Approximately 500 000

<i>Assay</i>	Yields, on the dried basis, not less than 3,3 % and not more than 6,8 % of CO ₂
<i>Description</i>	An off-white powder
Identification	
A. Solubility	Soluble in water, forming a viscous solution. Insoluble in ethanol
Purity	
Loss on drying	Not more than 15 % after drying (105 °C, 2½ hours)
Nitrogen	Not more than 3 %
Propane-2-ol	Not more than 750 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Total plate count	Not more than 10 000 colonies per gram
Yeast and mould	Not more than 400 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g
E 422 GLYCEROL	
Synonyms	Glycerin Glycerine
Definition	
<i>Chemical names</i>	1,2,3-propanetriol Glycerol Trihydroxypropane
Einecs	200-289-5
<i>Chemical formula</i>	C ₃ H ₈ O ₃
<i>Molecular weight</i>	92,10
<i>Assay</i>	Content not less than 98 % of glycerol on the anhydrous basis
<i>Description</i>	Clear, colourless hygroscopic syrupy liquid with not more than a slight characteristic odour, which is neither harsh nor disagreeable
Identification	
A. Acrolein formation on heating	Heat a few drops of the sample in a test tube with about 0,5 g of potassium bisulphate. The characteristic pungent vapours of acrolein are evolved
B. Specific gravity (25/25 °C)	Not less than 1,257
C. Refractive index [n] _D ²⁰	Between 1,471 and 1,474

Purity	
Water	Not more than 5 % (Karl Fischer method)
Sulphated ash	Not more than 0,01 % determined at 800 ± 25 °C
Butanetriols	Not more than 0,2 %
Acrolein, glucose and ammonium compounds	Heat a mixture of 5 ml of glycerol and 5 ml of potassium hydroxide solution (1 in 10) at 60 °C for five minutes. It neither becomes yellow nor emits an odour of ammonia
Fatty acids and esters	Not more than 0,1 % calculated as butyric acid
Chlorinated compounds	Not more than 30 mg/kg (as chlorine)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

E 431 POLYOXYETHYLENE (40) STEARATE

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

Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 432 POLYOXYETHYLENE SORBITAN MONOLAURATE (POLYSORBATE 20)

Synonyms	Polysorbate 20 Polyoxyethylene (20) sorbitan monolaurate
Definition	A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial lauric acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides
<i>Assay</i>	Content not less than 70 % of oxyethylene groups, equivalent to not less than 97,3 % of polyoxyethylene (20) sorbitan monolaurate on the anhydrous basis
<i>Description</i>	A lemon to amber-coloured oily liquid at 25 °C with a faint characteristic odour
Identification	
A. Solubility	Soluble in water, ethanol, methanol, ethyl acetate and dioxane. Insoluble in mineral oil and petroleum ether
B. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
Purity	
Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 40 and not more than 50
Hydroxyl value	Not less than 96 and not more than 108
1,4-Dioxane	Not more than 5 mg/kg
Free ethylene oxide	Not more than 1 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 433 POLYOXYETHYLENE SORBITAN MONOOLEATE (POLYSORBATE 80)

Synonyms	Polysorbate 80 Polyoxyethylene (20) sorbitan monooleate
Definition	A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial oleic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides
<i>Assay</i>	Content not less than 65 % of oxyethylene groups, equivalent to not less than 96,5 % of polyoxyethylene (20) sorbitan monooleate on the anhydrous basis
<i>Description</i>	A lemon to amber-coloured oily liquid at 25 °C with a faint characteristic odour
Identification	
A. Solubility	Soluble in water, ethanol, methanol, ethyl acetate and toluene. Insoluble in mineral oil and petroleum ether
B. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
Purity	
Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 45 and not more than 55
Hydroxyl value	Not less than 65 and not more than 80
1,4-Dioxane	Not more than 5 mg/kg
Free ethylene oxide	Not more than 1 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 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
<i>Assay</i>	Content not less than 66 % of oxyethylene groups, equivalent to not less than 97 % of polyoxyethylene (20) sorbitan monopalmitate on the anhydrous basis
<i>Description</i>	A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour

Identification

- | | |
|---------------------------------|---|
| A. Solubility | Soluble in water, ethanol, methanol, ethyl acetate and acetone.
Insoluble in mineral oil |
| B. Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyoxyethylated polyol |

Purity

- | | |
|----------------------------------|---|
| Water | Not more than 3 % (Karl Fischer method) |
| Acid value | Not more than 2 |
| Saponification value | Not less than 41 and not more than 52 |
| Hydroxyl value | Not less than 90 and not more than 107 |
| 1,4-Dioxane | Not more than 5 mg/kg |
| Free ethylene oxide | Not more than 1 mg/kg |
| Ethylene glycols (mono- and di-) | Not more than 0,25 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 435 POLYOXYETHYLENE SORBITAN MONOSTEARATE (POLYSORBATE 60)**Synonyms**

Polysorbate 60
Polyoxyethylene (20) sorbitan monostearate

Definition

A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial stearic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides

Assay Content not less than 65 % of oxyethylene groups, equivalent to not less than 97 % of polyoxyethylene (20) sorbitan monostearate on the anhydrous basis

Description A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour

Identification

- | | |
|---------------------------------|--|
| A. Solubility | Soluble in water, ethyl acetate and toluene. Insoluble in mineral oil and vegetable oils |
| B. Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyoxyethylated polyol |

Purity

- | | |
|----------------------|---|
| Water | Not more than 3 % (Karl Fischer method) |
| Acid value | Not more than 2 |
| Saponification value | Not less than 45 and not more than 55 |

Hydroxyl value	Not less than 81 and not more than 96
1,4-Dioxane	Not more than 5 mg/kg
Free ethylene oxide	Not more than 1 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 436 POLYOXYETHYLENE SORBITAN TRISTEARATE (POLYSORBATE 65)

Synonyms	Polysorbate 65 Polyoxyethylene (20) sorbitan tristearate
Definition	A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial stearic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides
<i>Assay</i>	Content not less than 46 % of oxyethylene groups, equivalent to not less than 96 % of polyoxyethylene (20) sorbitan tristearate on the anhydrous basis
<i>Description</i>	A tan-coloured, waxy solid at 25 °C with a faint characteristic odour
Identification	
A. Solubility	Dispersible in water. Soluble in mineral oil, vegetable oils, petroleum ether, acetone, ether, dioxane, ethanol and methanol
B. Infrared absorption spectrum	Characteristic of a partial fatty acid ester of a polyoxyethylated polyol
C. Congealing range	29-33 °C
Purity	
Water	Not more than 3 % (Karl Fischer method)
Acid value	Not more than 2
Saponification value	Not less than 88 and not more than 98
Hydroxyl value	Not less than 40 and not more than 60
1,4-Dioxane	Not more than 5 mg/kg
Free ethylene oxide	Not more than 1 mg/kg
Ethylene glycols (mono- and di-)	Not more than 0,25 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 440 (i) PECTIN

Definition	Pectin consists mainly of the partial methyl esters of polygalacturonic acid and their ammonium, sodium, potassium and calcium salts. It is obtained by extraction in an aqueous medium of natural strains of appropriate edible plant material, usually citrus fruits or apples. No organic precipitant shall be used other than methanol, ethanol and propane-2-ol
Einecs	232-553-0
<i>Assay</i>	Content not less than 65 % of galacturonic acid on the ash-free and anhydrous basis after washing with acid and alcohol
<i>Description</i>	White, light yellow, light grey or light brown powder
Identification	
A. Solubility	Soluble in water forming a colloidal, opalescent solution. Insoluble in ethanol
Purity	
Loss on drying	Not more than 12 % (105 °C, 2 hours)
Acid insoluble ash	Not more than 1 % (insoluble in approximately 3N hydrochloric acid)
Sulphur dioxide	Not more than 50 mg/kg on the anhydrous basis
Nitrogen content	Not more than 1,0 % after washing with acid and ethanol
Free methanol, ethanol and propane-2-ol	Not more than 1 %, singly or in combination, on the anhydrous basis
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 440 (ii) AMIDATED PECTIN

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

Identification

A. Solubility

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

Purity

Loss on drying

Not more than 12% (105°C, 2 hours)

Acid-insoluble ash

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

Degree of amidation

Not more than 25% of total carboxyl groups

Sulphur dioxide residue

Not more than 50 mg/kg on the anhydrous basis

Nitrogen content

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

Free methanol, ethanol and propane-2-ol

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

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 20 mg/kg

E 442 AMMONIUM PHOSPHATIDES**Synonyms**

Ammonium salts of phosphatidic acid, mixed ammonium salts of phosphorylated glycerides

Definition

A mixture of the ammonium compounds of phosphatidic acids derived from edible fat and oil (usually partially hardened rapeseed oil). One or two or three glyceride moieties may be attached to phosphorus. Moreover, two phosphorus esters may be linked together as phosphatidyl phosphatides

Assay

The phosphorus content is not less than 3% and not more than 3,4% by weight; the ammonium content is not less than 1,2% and not more than 1,5% (calculated as N)

Description

Unctuous semi-solid

Identification

A. Solubility

Soluble in fats. Insoluble in water. Partially soluble in ethanol and in acetone

B. Positive tests for glycerol, for fatty acid and for phosphate

Purity

Petroleum ether insoluble matter

Not more than 2,5%

Arsenic

Not more than 3 mg/kg

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

E 444 SUCROSE ACETATE ISOBUTYRATE

Synonyms	SAIB
Definition	Sucrose acetate isobutyrate is a mixture of the reaction products formed by the esterification of food grade sucrose with acetic acid anhydride and isobutyric anhydride, followed by distillation. The mixture contains all possible combinations of esters in which the molar ratio of acetate to butyrate is about 2:6
Einecs	204-771-6
<i>Chemical name</i>	Sucrose diacetate hexaisobutyrate
<i>Chemical formulae</i>	$C_{40}H_{62}O_{19}$
<i>Molecular weight</i>	832-856 (approximate), $C_{40}H_{62}O_{19}$: 846,9
<i>Assay</i>	Content not less than 98,8 % and not more than 101,9 % of $C_{40}H_{62}O_{19}$
<i>Description</i>	A pale straw-coloured liquid, clear and free of sediment and having a bland odour
Identification	
A. Solubility	Insoluble in water. Soluble in most organic solvents
B. Refractive index	$[n]_D^{40}$: 1,4492 - 1,4504
C. Specific gravity	$[d]_D^{25}$: 1,141 - 1,151
Purity	
Triacetin	Not more than 0,1 %
Acid value	Not more than 0,2
Saponification value	Not less than 524 and not more than 540
Arsenic	Not more than 3 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Lead	Not more than 3 mg/kg
Heavy metals (as Pb)	Not more than 5 mg/kg

E 445 GLYCEROL ESTERS OF WOOD ROSIN

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

E 450 (i) DISODIUM DIPHOSPHATE

Synonyms	Disodium dihydrogen diphosphate Disodium dihydrogen pyrophosphate Sodium acid pyrophosphate
Definition	
<i>Chemical name</i>	Disodium dihydrogen diphosphate
Einecs	
231-835-0	
<i>Chemical formula</i>	$Na_2H_2P_2O_7$

<i>Molecular weight</i>	221,94
<i>Assay</i>	Content not less than 95 % of disodium diphosphate and not less than 63 % and not more than 64,5 % expressed as P ₂ O ₅
<i>Description</i>	White powder or grains
Identification	
A. Positive tests for sodium and for phosphate	
B. Solubility	Soluble in water
Purity	
pH of a 1 % solution	Between 3,7 and 5,0
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 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 450 (ii) TRISODIUM DIPHOSPHATE

Synonyms	Acid trisodium pyrophosphate Trisodium monohydrogen diphosphate
Definition	
Einecs	
238-735-6	
<i>Chemical formula</i>	Monohydrate: Na ₃ HP ₂ O ₇ ·H ₂ O Anhydrous: Na ₃ HP ₂ O ₇
<i>Molecular weight</i>	Monohydrate: 261,95 Anhydrous: 243,93
<i>Assay</i>	Content not less than 95 % on the anhydrous basis and not less than 57 % and not more than 59 % expressed as P ₂ O ₅
<i>Description</i>	White powder or grains, occurs anhydrous or as a monohydrate
Identification	
A. Positive tests for sodium and for phosphate	
B. Soluble in water	

Purity

pH of a 1 % solution	Between 6,7 and 7,3
Loss on ignition	4,5 % on the anhydrous compound 11,5 % on the monohydrous basis
Loss on drying	Not more than 0,5 % (105 °C, 4 hours)
Water-insoluble matter	Not more than 0,2 %
Fluoride	Not more than 10 mg/kg expressed as fluorine
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 450 (iii) TETRASODIUM DIPHOSPHATE**Synonyms**

Tetrasodium pyrophosphate
Sodium pyrophosphate

Definition

Chemical name Tetrasodium diphosphate

Einecs

231-767-1

Chemical formula

Anhydrous: $\text{Na}_4\text{P}_2\text{O}_7$
Decahydrate: $\text{Na}_4\text{P}_2\text{O}_7 \cdot 10 \text{H}_2\text{O}$

Molecular weight

Anhydrous: 265,94
Decahydrate: 446,09

Assay

Content not less than 95 % of $\text{Na}_4\text{P}_2\text{O}_7$, in the ignited basis and not less than 52,5 % and not more than 54 % expressed as P_2O_5

Description

Colourless or white crystals, or a white crystalline or granular powder. The decahydrate effloresces slightly in dry air

Identification

A. Positive tests for sodium and for phosphate

B. Solubility

Soluble in water. Insoluble in ethanol

Purity

pH of a 1 % solution Between 9,8 and 10,8

Loss on ignition Not more than 0,5 % for the anhydrous salt, not less than 38 % and not more than 42 % for the decahydrate, in both cases determined after drying at 105 °C for four hours, followed by ignition at 550 °C for 30 minutes

Water-insoluble matter	Not more than 0,2 %
Fluoride	Not more than 10 mg/kg expressed as fluorine
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 450 (v) TETRAPOTASSIUM DIPHOSPHATE

Synonyms	Potassium pyrophosphate Tetrapotassium pyrophosphate
Definition	
<i>Chemical name</i>	Tetrapotassium diphosphate
Einecs	230-785-7
<i>Chemical formula</i>	$K_4P_2O_7$
<i>Molecular weight</i>	330,34 (anhydrous)
<i>Assay</i>	Content not less than 95 % on the ignited basis and not less than 42 % and not more than 43,7 % expressed as P_2O_5
<i>Description</i>	Colourless crystals or white, very hygroscopic powder
Identification	
A. Positive tests for potassium and for phosphate	
B. Solubility	Soluble in water, insoluble in ethanol
Purity	
pH of a 1 % solution	Between 10,0 and 10,8
Loss on ignition	Not more than 2 % after drying at 105 °C for 4 hours then ignition at 550 °C for 30 minutes
Water-insoluble matter	Not more than 0,2 %
Fluoride	Not more than 10 mg/kg expressed as fluorine
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 450 (vi) DICALCIUM DIPHOSPHATE

Synonyms	Calcium pyrophosphate
Definition	
<i>Chemical name</i>	Dicalcium diphosphate Dicalcium pyrophosphate
Einecs	232-221-5
<i>Chemical formula</i>	Ca ₂ P ₂ O ₇
<i>Molecular weight</i>	254,12
<i>Assay</i>	Content not less than 96 % and not less than 55 % and not more than 56 % expressed as P ₂ O ₅
<i>Description</i>	A fine, white, odourless powder
Identification	
A. Positive tests for calcium and for phosphate	
B. Solubility	Insoluble in water. Soluble in dilute hydrochloric and nitric acids
Purity	
pH of a 10 % suspension in water	Between 5,5 and 7,0
Loss on ignition	Not more than 1,5 % at 800 ± 25 °C for 30 minutes
Fluoride	Not more than 50 mg/kg expressed as fluorine
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 450 (vii) CALCIUM DIHYDROGEN DIPHOSPHATE

Synonyms	Acid calcium pyrophosphate Monocalcium dihydrogen pyrophosphate
Definition	
<i>Chemical name</i>	Calcium dihydrogen diphosphate
Einecs	238-933-2
<i>Chemical formula</i>	CaH ₂ P ₂ O ₇
<i>Molecular weight</i>	215,97
<i>Assay</i>	Content not less than 90 % on the anhydrous basis and not less than 61 % and not more than 64 % expressed as P ₂ O ₅
<i>Description</i>	White crystals or powder

Identification

A. Positive tests for calcium and for phosphate

Purity

Acid-insoluble matter	Not more than 0,4 %
Fluoride	Not more than 30 mg/kg expressed as fluorine
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 451 (i) PENTASODIUM TRIPHOSPHATE**Synonyms**

Pentasodium tripolyphosphate
Sodium tripolyphosphate

Definition

Chemical name Pentasodium triphosphate

Einecs

231-838-7

Chemical formulae $\text{Na}_5\text{O}_{10}\text{P}_3 \cdot x\text{H}_2\text{O}$ (x = 0 or 6)

Molecular weight 367,86

Assay Content not less than 85 %
Content in P_2O_5 not less than 56 % and not more than 58 % (anhydrous) or not less than 43 % and not more than 45 % (hexahydrate)

Description White, slightly hygroscopic granules or powder

Identification

A. Solubility Freely soluble in water.
Insoluble in ethanol

B. Positive tests for sodium and for phosphate

C. pH of a 1 % solution Between 9,1 and 10,2

Purity

Loss on drying Anhydrous: Not more than 0,7 % (105 °C, 1 hour)
Hexahydrate: Not more than 23,5 % (60 °C, 1 hour, followed by drying at 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
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 451 (ii) PENTAPOTASSIUM TRIPHOSPHATE

Synonyms	Pentapotassium tripolyphosphate Potassium triphosphate Potassium tripolyphosphate
Definition	
<i>Chemical name</i>	Pentapotassium triphosphate Pentapotassium tripolyphosphate
Einecs	237-574-9
<i>Chemical formulae</i>	$K_5O_{10}P_3$
<i>Molecular weight</i>	448,42
<i>Assay</i>	Content not less than 85 % on the dried basis Content in P_2O_5 not less than 46,5 % and not more than 48 %
<i>Description</i>	White, hygroscopic powder or granules
Identification	
A. Solubility	Very soluble in water
B. Positive tests for potassium and for phosphate	
C. pH of a 1 % solution	Between 9,2 and 10,5
Purity	
Loss on ignition	Not more than 0,4 % (105 °C, 4 hours, followed by ignition at 550 °C, 30 minutes)
Water insoluble matter	Not more than 2 %
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
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 452 (i) SODIUM POLYPHOSPHATE

1. SOLUBLE POLYPHOSPHATE

Synonyms	Sodium hexametaphosphate Sodium tetrapolyphosphate Graham's salt Sodium polyphosphates, glassy Sodium polymetaphosphate Sodium metaphosphate
Definition	Soluble sodium polyphosphates are obtained by fusion and subsequent chilling of sodium orthophosphates. These compounds are a class consisting of several amorphous, water-soluble polyphosphates composed of linear chains of metaphosphate units, $(\text{NaPO}_3)_x$ where $x \geq 2$, terminated by Na_2PO_4 groups. These substances are usually identified by their $\text{Na}_2\text{O}/\text{P}_2\text{O}_5$ ratio or their P_2O_5 content. The $\text{Na}_2\text{O}/\text{P}_2\text{O}_5$ ratios vary from about 1,3 for sodium tetrapolyphosphate, where $x =$ approximately 4; to about 1,1 for Graham's salt, commonly called sodium hexametaphosphate, where $x = 13$ to 18; and to about 1,0 for the higher molecular weight sodium polyphosphates, where $x = 20$ to 100 or more. The pH of their solutions varies between 3,0 and 9,0
<i>Chemical name</i>	Sodium polyphosphate
Einecs	272-808-3
<i>Chemical formulae</i>	Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula $\text{H}_{(n+2)}\text{P}_n\text{O}_{(3n+1)}$ where 'n' is not less than 2
<i>Molecular weight</i>	$(102)_n$
<i>Assay</i>	Content in P_2O_5 not less than 60 % and not more than 71 % on the ignited basis
<i>Description</i>	Colourless or white, transparent platelets, granules, or powders
Identification	
A. Solubility	Very soluble in water
B. Positive tests for sodium and for phosphate	
C. pH of a 1 % solution	Between 3,0 and 9,0
Purity	
Loss on ignition	Not more than 1 %
Water insoluble matter	Not more than 0,1 %
Fluoride	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

2. *INSOLUBLE POLYPHOSPHATE*

Synonyms	Insoluble sodium metaphosphate Maddrell's salt Insoluble sodium polyphosphate, IMP
Definition	Insoluble sodium metaphosphate is a high molecular weight sodium polyphosphate composed of two long metaphosphate chains $(\text{NaPO}_3)_x$ that spiral in opposite directions about a common axis. The $\text{Na}_2\text{O}/\text{P}_2\text{O}_5$ ratio is about 1,0. The pH of 1 in 3 suspension in water is about 6,5
<i>Chemical name</i>	Sodium polyphosphate
Einecs	272-808-3
<i>Chemical formulae</i>	Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula $\text{H}_{(n+2)}\text{P}_n\text{O}_{(3n+1)}$ where 'n' is not less than 2
<i>Molecular weight</i>	$(102)_n$
<i>Assay</i>	Not less than 68,7% and not more than 70% of P_2O_5
<i>Description</i>	White crystalline powder
Identification	
A. Solubility	Insoluble in water, soluble in mineral acids and in solutions of potassium and ammonium (but not sodium) chlorides
B. Positive tests for sodium and for phosphate	
C. pH of a 1 in 3 suspension in water	About 6,5
Purity	
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
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 452 (ii) **POTASSIUM POLYPHOSPHATE**

Synonyms	Potassium metaphosphate Potassium polymetaphosphate Kurrol salt
Definition	
<i>Chemical name</i>	Potassium polyphosphate

Einecs	232-212-6
<i>Chemical formulae</i>	(KPO ₃) _n Heterogenous mixtures of potassium salts of linear condensed polyphosphoric acids of general formula H _(n+2) P _n O _(3n+1) where 'n' is not less than 2
<i>Molecular weight</i>	(134) _n
<i>Assay</i>	Content in P ₂ O ₅ not less than 53,5% and not more than 61,5% on the ignited basis
<i>Description</i>	Fine white powder or crystals or colourless glassy platelets
Identification	
A. Solubility	1 g dissolves in 100 ml of a 1 in 25 solution of sodium acetate
B. Positive tests for potassium and for phosphate	
C. pH of a 1% solution	Not more than 7,8
Purity	
Loss on ignition	Not more than 2% (105°C, 4 hours followed by ignition at 550°C, 30 minutes)
Water insoluble matter	Not more than 0,2%
Cyclic phosphate	Not more than 8% on P ₂ O ₅ content
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
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 452 (iv) CALCIUM POLYPHOSPHATES

Synonyms	Calcium metaphosphate Calcium polymetaphosphate
Definition	
<i>Chemical name</i>	Calcium polyphosphate
Einecs	236-769-6
<i>Chemical formulae</i>	(CaP ₂ O ₆) _n A heterogeneous mixture of calcium salts of condensed polyphosphoric acids of general formula H _(n+2) P _n O _(n+1) where 'n' is not less than 2
<i>Molecular weight</i>	(198) _n
<i>Assay</i>	Content in P ₂ O ₅ not less than 50% and not more than 71% on the ignited basis
<i>Description</i>	Odourless, colourless crystals or white powder

Identification

- | | |
|---|--|
| A. Solubility | Usually sparingly soluble in water. Soluble in acid medium |
| B. Positive tests for calcium and for phosphate | |
| C. CaO content | 27-29,5 % |

Purity

- | | |
|----------------------|---|
| Loss on ignition | Not more than 2 % (105°C, 4 hours followed by ignition at 550 °C, 30 minutes) |
| Cyclic phosphate | Not more than 8 % on P ₂ O ₅ content |
| Fluoride | Not more than 30 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 20 mg/kg |

E 460 (i) MICROCRISTALLINE CELLULOSE**Synonyms**

Cellulose gel

Definition

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

Chemical name

Cellulose

Einecs

232-674-9

Chemical formula $(C_6H_{10}O_5)_n$ *Molecular weight*

About 36 000

Assay

Not less than 97 % calculated as cellulose on the anhydrous basis

Description

A fine white or almost white odourless powder

Identification

- | | |
|--|--|
| A. Solubility | Insoluble in water, ethanol, ether and dilute mineral acids. Slightly soluble in sodium hydroxide solution |
| B. Colour reaction | To 1 mg of the sample, add 1 ml of phosphoric acid and heat on a water bath for 30 minutes. Add 4 ml of a 1 in 4 solution of pyrocatechol in phosphoric acid and heat for 30 minutes, A red colour is produced |
| C. To be identified by IR spectroscopy | |

D. Suspension test	Mix 30 g of the sample with 270 ml of water in a high-speed (12 000 rpm) power blender for 5 minutes. The resultant mixture will be either a free-flowing suspension or a heavy, lumpy suspension which flows poorly, if at all, settles only slightly and contains many trapped air bubbles. If a free-flowing suspension is obtained, transfer 100 ml into a 100-ml graduated cylinder and allow to stand for 1 hour. The solids settle and a supernatant liquid appears
Purity	
Loss on drying	Not more than 7% (105 °C, 3 hours)
Water-soluble matter	Not more than 0,24%
Sulphated ash	Not more than 0,5% determined at 800 ± 25 °C
pH of a 10% suspension in water	The pH of the supernatant liquid is between 5,0 and 7,5
Starch	Not detectable To 20 ml of the dispersion obtained in identification, test D, add a few drops of iodine solution and mix. No purplish to blue or blue colour should be produced
Particle size	Not less than 5 µm (not more than 10% of particles of less than 5 µm)
Carboxyl groups	Not more than 1%
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
E 460 (ii) POWDERED CELLULOSE	
Definition	Purified, mechanically disintegrated cellulose prepared by processing alpha-cellulose obtained as a pulp from natural strains of fibrous plant materials
<i>Chemical name</i>	Cellulose Linear polymer of 1:4 linked glucose residues
Einecs	232-674-9
<i>Chemical formula</i>	(C ₆ H ₁₀ O ₅) _n
<i>Molecular weight</i>	(162) _n (n is predominantly 1 000 and greater)
<i>Assay</i>	Content not less than 92%
<i>Description</i>	A white, odourless powder
Identification	
A. Solubility	Insoluble in water, ethanol, ether and dilute mineral acids. Slightly soluble in sodium hydroxide solution

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

E 461 METHYL CELLULOSE

Synonyms	Cellulose methyl ether
Definition	Methyl cellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with methyl groups
<i>Chemical name</i>	Methyl ether of cellulose
<i>Chemical formula</i>	The polymers contain substituted anhydroglucose units with the following general formula: C ₆ H ₇ O ₂ (OR ₁)(OR ₂)(OR ₃) where R ₁ , R ₂ , R ₃ each may be one of the following: – H – CH ₃ or – CH ₂ CH ₃
<i>Molecular weight</i>	From about 20 000 to 380 000
<i>Assay</i>	Content not less than 25% and not more than 33% of methoxyl groups (-OCH ₃) and not more than 5% of hydroxyethoxyl groups (-OCH ₂ CH ₂ OH)
<i>Description</i>	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	
A. Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol, ether and chloroform. Soluble in glacial acetic acid

Purity

Loss on drying	Not more than 10% (105 °C, 3 hours)
Sulphated ash	Not more than 1,5% determined at 800 ± 25 °C
pH of a 1% colloidal solution	Not less than 5,0 and not more than 8,0
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 463 HYDROXYPROPYL CELLULOSE**Synonyms**

Cellulose hydroxypropyl ether

Definition

Hydroxypropylcellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with hydroxypropyl groups

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 R₁, R₂, R₃ each may be one of the following:

- H
- CH₂CHOHCH₃
- CH₂CHO(CH₂CHOHCH₃)CH₃
- CH₂CHO[CH₂CHO(CH₂CHOHCH₃)CH₃]CH₃

Molecular weight

From about 30 000 to 1 000 000

*Assay*Content not less than 80,5% of hydroxypropoxyl groups (-OCH₂CHOHCH₃) 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

A. Solubility

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

B. Gas chromatography

Determine the substituents by gas chromatography

Purity

Loss on drying	Not more than 10% (105 °C, 3 hours)
Sulphated ash	Not more than 0,5% determined at 800 ± 25 °C
pH of a 1% colloidal solution	Not less than 5,0 and not more than 8,0
Propylene chlorohydrins	Not more than 0,1 mg/kg

Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 464 HYDROXYPROPYL METHYL CELLULOSE

Definition	Hydroxypropyl methyl cellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with methyl groups and containing a small degree of hydroxypropyl substitution
<i>Chemical name</i>	2-Hydroxypropyl ether of methylcellulose
<i>Chemical formula</i>	The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$, where R_1, R_2, R_3 each may be one of the following: – H – CH_3 – $CH_2CHOHCH_3$ – $CH_2CHO(CH_2CHOHCH_3)CH_3$ – $CH_2CHO[CH_2CHO(CH_2CHOHCH_3)CH_3]CH_3$
<i>Molecular weight</i>	From about 13 000 to 200 000
<i>Assay</i>	Content not less than 19% and not more than 30% methoxyl groups ($-OCH_3$) and not less than 3% and not more than 12% hydroxypropoxyl groups ($-OCH_2CHOHCH_3$), on the anhydrous basis
<i>Description</i>	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	
A. Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol
B. Gas chromatography	Determine the substituents by gas chromatography
Purity	
Loss on drying	Not more than 10% (105°C, 3 hours)
Sulphated ash	Not more than 1,5% for products with viscosities of 50 mPa.s or above Not more than 3% for products with viscosities below 50 mPa.s
pH of a 1% colloidal solution	Not less than 5,0 and not more than 8,0
Propylene chlorohydrins	Not more than 0,1 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 465 ETHYL METHYL CELLULOSE

Synonyms	Methylethylcellulose
Definition	Ethyl methyl cellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with methyl and ethyl groups
<i>Chemical name</i>	Ethyl methyl ether of cellulose
<i>Chemical formula</i>	The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$, where R_1, R_2, R_3 each may be one of the following: — H — CH_3 — CH_2CH_3
<i>Molecular weight</i>	From about 30 000 to 40 000
<i>Assay</i>	Content on the anhydrous basis not less than 3,5% and not more than 6,5% of methoxyl groups ($-OCH_3$) and not less than 14,5% and not more than 19% of ethoxyl groups ($-OCH_2CH_3$), and not less than 13,2% and not more than 19,6% of total alkoxy groups, calculated as methoxyl
<i>Description</i>	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	
A. Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Soluble in ethanol. Insoluble in ether
Purity	
Loss on drying	Not more than 15% for the fibrous form, and not more than 10% for the powdered form (105°C to constant weight)
Sulphated ash	Not more than 0,6%
pH of a 1% colloidal solution	Not less than 5,0 and not more than 8,0
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg

E 466 SODIUM CARBOXY METHYL CELLULOSE

Synonyms	Carboxy methyl cellulose CMC NaCMC Sodium CMC Cellulose gum
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Definition	Carboxy methyl cellulose is the partial sodium salt of a carboxymethyl ether of cellulose, the cellulose being obtained directly from natural strains of fibrous plant material
<i>Chemical name</i>	Sodium salt of the carboxymethyl ether of cellulose
<i>Chemical formula</i>	The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$, where R_1, R_2, R_3 each may be one of the following: – H – CH_2COONa – CH_2COOH
<i>Molecular weight</i>	Higher than approximately 17 000 (degree of polymerisation approximately 100)
<i>Assay</i>	Content on the anhydrous basis not less than 99,5 %
<i>Description</i>	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	
A. Solubility	Yields a viscous colloidal solution with water. Insoluble in ethanol
B. Foam test	A 0,1 % solution of the sample is shaken vigorously. No layer of foam appears. (This test permits the distinction of sodium carboxymethyl cellulose from other cellulose ethers)
C. Precipitate formation	To 5 ml of a 0,5 % solution of the sample, add 5 ml of 5 % solution of copper sulphate or of aluminium sulphate. A precipitate appears. (This test permits the distinction of sodium carboxymethyl cellulose from other cellulose ethers and from gelatine, locust bean gum and tragacanth)
D. Colour reaction	Add 0,5 g powdered carboxy methyl cellulose sodium to 50 ml of water, while stirring to produce an uniform dispersion. Continue the stirring until a clear solution is produced, and use the solution for the following test: To 1 mg of the sample, diluted with an equal volume of water, in a small test tube, add 5 drops of 1-naphthol solution. Incline the test tube, and carefully introduce down the side of the tube 2 ml of sulphuric acid so that it forms a lower layer. A red-purple colour develops at the interface
Purity	
Degree of substitution	Not less than 0,2 and not more than 1,5 carboxymethyl groups ($-CH_2COOH$) per anhydroglucose unit
Loss on drying	Not more than 12 % (105 °C to constant weight)
pH of a 1 % colloidal solution	Not less than 5,0 and not more than 8,5
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 20 mg/kg
Total glycolate	Not more than 0,4 %, calculated as sodium glycolate on the anhydrous basis
Sodium	Not more than 12,4 % on the anhydrous basis

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

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

E 470b MAGNESIUM SALTS OF FATTY ACIDS

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

Purity

Magnesium	Not less than 6,5 % and not more than 11 % expressed as MgO
Free alkali	Not more than 0,1 % expressed as MgO
Unsaponifiable matter	Not more than 2 %
Free fatty acids	Not more than 3 % estimated as oleic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 471 MONO- AND DIGLYCERIDES OF FATTY ACIDS**Synonyms**

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

Definition

Mono- and diglycerides of fatty acids consist of mixtures of glycerol mono-, di- and triesters of fatty acids occurring in food oils and fats. They may contain small amounts of free fatty acids and glycerol

Assay

Content of mono- and diesters: not less than 70 %

Description

The product varies from a pale yellow to pale brown oily liquid to a white or slightly off-white hard waxy solid. The solids may be in the form of flakes, powders or small beads

Identification

- | | |
|--|--|
| A. Infrared spectrum | Characteristic of a partial fatty acid ester of a polyol |
| B. Positive tests for glycerol and for fatty acids | |
| C. Solubility | Insoluble in water, soluble in ethanol and toluene |

Purity

Water content	Not more than 2 % (Karl Fischer method)
Acid value	Not more than 6
Free glycerol	Not more than 7 %
Polyglycerols	Not more than 4 % diglycerol and not more than 1 % higher polyglycerols both based on total glycerol content
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Total glycerol	Not less than 16 % and not more than 33 %
Sulphated ash	Not more than 0,5 % determined at $800 \pm 25^\circ\text{C}$

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
<i>Description</i>	Clear, mobile liquids to solids, from white to pale yellow in colour
Identification	
A. Positive tests for glycerol, for fatty acids and for acetic acid	
B. Solubility	Insoluble in water. Soluble in ethanol
Purity	
Acids other than acetic and fatty acids	Not detectable
Free glycerol	Not more than 2 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Total acetic acid	Not less than 9 % and not more than 32 %
Free fatty acids (and acetic acid)	Not more than 3 % estimated as oleic acid
Total glycerol	Not less than 14 % and not more than 31 %
Sulphated ash	Not more than 0,5 % determined at $800 \pm 25^\circ\text{C}$

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

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

Synonyms	Lactic acid esters of mono- and diglycerides Lactoglycerides Mono- and diglycerides of fatty acids esterified with lactic acid
Definition	Esters of glycerol with lactic acid and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free lactic acid and free glycerides
<i>Description</i>	Clear, mobile liquids to waxy solids of variable consistency, from white to pale yellow in colour
Identification	
A. Positive tests for glycerol, for fatty acids and for lactic acid	
B. Solubility	Insoluble in cold water but dispersible in hot water
Purity	
Acids other than lactic and fatty acids	Not detectable
Free glycerol	Not more than 2 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Total lactic acid	Not less than 13 % and not more than 45 %
Free fatty acids (and lactic acid)	Not more than 3 % estimated as oleic acid
Total glycerol	Not less than 13 % and not more than 30 %
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C

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

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

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

Identification

A. Positive tests for glycerol, for fatty acids and for citric acid

B. Solubility

Insoluble in cold water
Dispersible in hot water
Soluble in oils and fats
Insoluble in cold ethanol

Purity

Acids other than citric and fatty acids

Not detectable

Free glycerol

Not more than 2 %

Total glycerol

Not less than 8 % and not more than 33 %

Total citric acid

Not less than 13 % and not more than 50 %

Sulphated ash

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

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 mg/kg

Free fatty acids

Not more than 3 % estimated as oleic acid

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

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

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

Definition

Esters of glycerol with tartaric acid and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free tartaric acid and free glycerides

Description

Sticky viscous yellowish liquids to hard yellow waxes

Identification

A. Positive tests for glycerol, for fatty acids and for tartaric acid

Purity

Acids other than tartaric and fatty acids

Not detectable

Free glycerol

Not more than 2 %

Total glycerol

Not less than 12 % and not more than 29 %

Arsenic

Not more than 3 mg/kg

Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Total tartaric acid	Not less than 15 % and not more than 50 %
Free fatty acids	Not more than 3 % estimated as oleic acid
Sulphated ash	Not more than 0,5 % determined at $800 \pm 25^\circ\text{C}$

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

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

Synonyms	Diacetyltartaric acid esters of mono- and diglycerides Mono- and diglycerides of fatty acids esterified with mono- and diacetyltartaric acid Diacetyltartaric and fatty acid esters of glycerol
Definition	Mixed esters of glycerol with mono- and diacetyltartaric acids (obtained from tartaric acid) and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free tartaric and acetic acids and their combinations, and free glycerides. Contains also tartaric and acetic esters of fatty acids
<i>Description</i>	Sticky viscous liquids through a fat-like consistency to yellow waxes which hydrolyse in moist air to liberate acetic acid
Identification	
A. Positive tests for glycerol, for fatty acids, for tartaric acid and for acetic acid	
Purity	
Acids other than acetic, tartaric and fatty acids	Not detectable
Free glycerol	Not more than 2 %
Total glycerol	Not less than 11 % and not more than 28 %
Sulphated ash	Not more than 0,5 % determined at $800 \pm 25^\circ\text{C}$
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg
Total tartaric acid	Not less than 10 % and not more than 40 %
Total acetic acid	Not less than 8 % and not more than 32 %
Free fatty acids	Not more than 3 % estimated as oleic acid

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

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

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

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

E 473 SUCROSE ESTERS OF FATTY ACIDS

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

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

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

E 474 SUCROGLYCERIDES

Synonyms	Sugar glycerides
Definition	Sucroglycerides are produced by reacting sucrose with an edible fat or oil to produce a mixture of essentially mono-, di- and triesters of sucrose and fatty acids together with residual mono-, di- and triglycerides from fat or oil. No organic solvents shall be used in their preparation other than cyclohexane, dimethylformamide, ethyl acetate, 2-methyl-1-propanol and propane-2-ol
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

A. Positive tests for sugar and for fatty acids

B. Solubility

Insoluble in cold water
Soluble in ethanol

Purity

Sulphated ash

Not more than 2% determined at $800 \pm 25^\circ\text{C}$

Free sugar

Not more than 5%

Free fatty acids

Not more than 3% estimated as oleic acid

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 mg/kg

Methanol

Not more than 10 mg/kg

Dimethylformamide

Not more than 1 mg/kg

2-methyl-1-propanol

Cyclohexane

Not more than 10 mg/kg, single or in combination

Ethyl acetate

Propane-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

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

A. Positive tests for glycerol, for polyglycerols and for fatty acids

B. Solubility

The esters range from very hydrophilic to very lipophilic, but as a class tend to be dispersible in water and soluble in organic solvents and oils

Purity	
Sulphated ash	Not more than 0,5 % determined at 800±25°C
Acids other than fatty acids	Not detectable
Free fatty acids	Not more than 6 % estimated as oleic acid
Total glycerol and polyglycerol	Not less than 18 % and not more than 60 %
Free glycerol and polyglycerol	Not more than 7 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

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

E 476 POLYGLYCEROL POLYRICINOLEATE

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

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

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

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

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

Synonyms	TOSOM
Definition	Thermally oxidised soya bean oil interacted with mono- and diglycerides of fatty acids is a complex mixture of esters of glycerol and fatty acids found in edible fat and fatty acids from thermally oxidised soya bean oil. It is produced by interaction and desodorisation under vacuum at 130°C of 10 % of thermally oxidised soya bean oil and 90 % mono- and diglycerides of food fatty acids. Soya bean oil is exclusively made from natural strains of soya beans
<i>Description</i>	Pale yellow to light brown a waxy or solid consistency

Identification

A. Solubility

Insoluble in water. Soluble in hot oil or fat

Purity

Melting range

55—65 °C

Free fatty acids

Not more than 1,5 % estimated as oleic acid

Free glycerol

Not more than 2 %

Total fatty acids

83—90 %

Total glycerol

16—22 %

Fatty acid methyl esters, not forming adduct with urea

Not more than 9 % of total fatty acid methyl esters

Fatty acids, insoluble in petroleum ether

Not more than 2 % of total fatty acids

Peroxide value

Not more than 3

Epoxides

Not more than 0,03 % oxirane oxygen

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 10 mg/kg

E 481 SODIUM STEAROYL-2-LACTYLATE**Synonyms**Sodium stearoyl lactylate
Sodium stearoyl lactate**Definition**

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

*Chemical names*Sodium di-2-stearoyl lactate
Sodium di(2-stearoyloxy)propionate**Einecs**

246-929-7

*Chemical formula
(major components)*C₂₁H₃₉O₄Na
C₁₉H₃₅O₄Na*Description*

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

Identification

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

B. Solubility

Insoluble in water. Soluble in ethanol

Purity	
Sodium	Not less than 2,5 % and not more than 5 %
Ester value	Not less than 90 and not more than 190
Acid value	Not less than 60 and not more than 130
Total lactic acid	Not less than 15 % and not more than 40 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 482 CALCIUM STEAROYL-2-LACTYLATE

Synonyms	Calcium stearoyl lactate
Definition	A mixture of the calcium salts of stearoyl lactic acids and its polymers and minor amounts of calcium salts of other related acids, manufactured by the reaction of stearic acid and lactic acid. Other food fatty acids may also be present, free or esterified, due to their presence in the stearic acid used
<i>Chemical name</i>	Calcium di-2-stearoyl lactate Calcium di(2-stearoyloxy)propionate
Einecs	227-335-7
<i>Chemical formula</i>	$C_{42}H_{78}O_8Ca$ $C_{38}H_{70}O_8Ca$
<i>Description</i>	White or slightly yellowish powder or brittle solid with a characteristic odour
Identification	
A. Positive tests for calcium, for fatty acids and for lactic acid	
B. Solubility	Slightly soluble in hot water
Purity	
Calcium	Not less than 1 % and not more than 5,2 %
Ester value	Not less than 125 and not more than 190
Total lactic acid	Not less than 15 % and not more than 40 %
Acid value	Not less than 50 and not more than 130
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 483 STEARYL TARTRATE

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

E 491 SORBITAN MONOSTEARATE

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

Identification

- | | |
|---------------------------------|--|
| A. Solubility | Soluble at temperatures above its melting point in toluene, dioxane, carbon tetrachloride, ether, methanol, ethanol and aniline; insoluble in petroleum ether and acetone; insoluble in cold water but dispersible in warm water; soluble with haze at temperatures above 50 °C in mineral oil and ethyl acetate |
| B. Congealing range | 50—52 °C |
| C. Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyol |

Purity

- | | |
|----------------------|---|
| Water | Not more than 2 % (Karl Fischer method) |
| Sulphated ash | Not more than 0,5 % |
| Acid value | Not more than 10 |
| Saponification value | Not less than 147 and not more than 157 |
| Hydroxyl value | Not less than 235 and not more than 260 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 492 SORBITAN TRISTEARATE**Definition**

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

Einecs

247-891-4

Assay

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

Description

Light, cream- to tan-coloured beads or flakes or hard, waxy solid with a slight odour

Identification

- | | |
|---------------------------------|--|
| A. Solubility | Slightly soluble in toluene, ether, carbon tetrachloride and ethyl acetate; dispersible in petroleum ether, mineral oil, vegetable oils, acetone and dioxane; insoluble in water, methanol and ethanol |
| B. Congealing range | 47—50 °C |
| C. Infrared absorption spectrum | Characteristic of a partial fatty acid ester of a polyol |

Purity

Water	Not more than 2 % (Karl Fischer method)
Sulphated ash	Not more than 0,5 %
Acid value	Not more than 15
Saponification value	Not less than 176 and not more than 188
Hydroxyl value	Not less than 66 and not more than 80
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 493 SORBITAN MONOLAURATE**Definition**

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

Einecs

215-663-3

Assay

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

Description

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

Identification

A. Solubility

Dispersible in hot and cold water

B. Infrared absorption spectrum

Characteristic of a partial fatty acid ester of a polyol

Purity

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

E 494 SORBITAN MONOOLEATE

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

E 495 SORBITAN MONOPALMITATE

Synonyms	Sorbitan palmitate
Definition	A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial palmitic acid
Einecs	247-568-8
<i>Assay</i>	Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters
<i>Description</i>	Light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour

Identification

- | | |
|---------------------------------|--|
| A. Solubility | Soluble at temperatures above its melting point in ethanol, methanol, ether, ethyl acetate, aniline, toluene, dioxane, petroleum ether and carbon tetrachloride. Insoluble in cold water but dispersible in warm water |
| B. Congealing range | 45–47°C |
| C. Infrared absorption spectrum | Characteristic of a partial fatty acid ester of polyol |

Purity

- | | |
|----------------------|---|
| Water | Not more than 2 % (Karl Fischer method) |
| Sulphate ash | Not more than 0,5 % |
| Acid value | Not more than 7,5 |
| Saponification value | Not less than 140 and not more than 150 |
| Hydroxyl value | Not less than 270 and not more than 305 |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Heavy metals (as Pb) | Not more than 10 mg/kg |

E 508 POTASSIUM CHLORIDE**Synonyms**

Sylvine
Sylvite

Definition

Chemical name Potassium chloride

Einecs

231-211-8

Chemical formulae KCl

Molecular weight 74,56

Assay Content not less than 99 % on the dried basis

Description Colourless, elongated, prismatic or cubital crystals or white granular powder. Odourless

Identification

- | | |
|--|---|
| A. Solubility | Freely soluble in water. Insoluble in ethanol |
| B. Positive tests for potassium and for chloride | |

Purity

Loss on drying	Not more than 1 % (105 °C, 2 hours)
Sodium	Negative test
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 10 mg/kg

E 579 FERROUS GLUCONATE**Definition**

Chemical name Ferrous di-D-gluconate dihydrate
Iron(II) di-gluconate dihydrate

Einecs

206-076-3

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

Molecular weight 482,17

Assay Content not less than 95 % on the dried basis

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

Identification

- | | |
|--|--|
| A. Solubility | Soluble with slight heating in water. Practically insoluble in ethanol |
| B. Positive test for ferrous ion | |
| C. Formation of phenylhydrazine derivative of gluconic acid positive | |
| D. pH of a 10 % solution | Between 4 and 5,5 |

Purity

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

E 585 FERROUS LACTATE

Synonyms	Iron(II) lactate Iron(II) 2-hydroxy propanoate Propanoic acid, 2-hydroxy-iron(2+) salt (2:1)
Definition	
<i>Chemical name</i>	Ferrous 2-hydroxy propanoate
Einecs	227-608-0
<i>Chemical formulae</i>	$C_6H_{10}FeO_6 \cdot xH_2O$ (x = 2 or 3)
<i>Molecular weight</i>	270,02 (dihydrate) 288,03 (trihydrate)
<i>Assay</i>	Content not less than 96 % on the dried basis
<i>Description</i>	Greenish-white crystals or light green powder having a characteristic smell
Identification	
A. Solubility	Soluble in water. Practically insoluble in ethanol
B. Positive test for ferrous ion and for lactate	
C. pH of a 2 % solution	Between 4 and 6
Purity	
Loss on drying	Not more than 18 % (100 °C, under vacuum, approximately 700 mm Hg)
Iron (Fe III)	Not more than 0,6 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg'
