I

(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,


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 Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners(5) 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.
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.

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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 \( \beta-\)-(1-4) linked D-mannuronic and \( \alpha-\)-(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 (Phaeophyceae).

Einecs
232-680-1

Chemical formula
\((\text{C}_6\text{H}_8\text{O}_6)_n\)

Molecular weight
10 000—600 000 (typical average)

Assay
Alginic acid yields, on the anhydrous basis, not less than 20% and not more than 23% of carbon dioxide (CO\(_2\)), equivalent to not less than 91% and not more than 104.5% of alginic acid \((\text{C}_6\text{H}_8\text{O}_6)_n\) (calculated on equivalent weight basis of 200).

Description
Alginic acid occurs in filamentous, grainy, granular and powdered forms. It is a white to yellowish brown and nearly odourless.

Identification

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 1.5% (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
E 401 SODIUM ALGINATE

**Definition**

*Chemical name*  
Sodium salt of alginic acid

*Chemical formula*  
\((C_6H_7NaO_6)_n\)

*Molecular weight*  
10 000-600 000 (typical average)

*Assay*  
Yields, on the anhydrous basis, not less than 18% and not more than 21% of carbon dioxide corresponding to not less than 90.8% and not more than 106.0% of sodium alginate (calculated on equivalent weight basis of 222)

*Description*  
Nearly odourless, white to yellowish fibrous or granular powder

**Identification**

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

*E. coli*  
Negative in 5 g

*Salmonella spp.*  
Negative in 10 g
E 402 POTASSIUM ALGINATE

Definition

*Chemical name*  
Potassium salt of alginic acid

*Chemical formula*  
$$\text{(C}_6\text{H}_{7}\text{KO}_6)\text{n}$$

*Molecular weight*  
10 000-600 000 (typical average)

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

*Description*  
Nearly odourless, white to yellowish fibrous or granular powder

Identification

A. Positive test for potassium and for alginic acid

Purity

*Loss on drying*  
Not more than 15% (105°C, 4 hours)

*Water-insoluble matter*  
Not more than 2% on the anhydrous basis

*Arsenic*  
Not more than 3 mg/kg

*Lead*  
Not more than 5 mg/kg

*Mercury*  
Not more than 1 mg/kg

*Cadmium*  
Not more than 1 mg/kg

*Heavy metals (as Pb)*  
Not more than 20 mg/kg

*Total plate count*  
Not more than 5 000 colonies per gram

*Yeast and moulds*  
Not more than 500 colonies per gram

*E. coli*  
Negative in 5 g

*Salmonella spp.*  
Negative in 10 g

E 403 AMMONIUM ALGINATE

Definition

*Chemical name*  
Ammonium salt of alginic acid

*Chemical formula*  
$$\text{(C}_6\text{H}_{11}\text{NO}_6)\text{n}$$

*Molecular weight*  
10 000-600 000 (typical average)

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

*Description*  
White to yellowish fibrous or granular powder
Identification

A. Positive test for ammonium and alginic acid

Purity

Loss on drying Not more than 15% (105°C, 4 hours)
Sulphated ash Not more than 7% on the dried basis
Water-insoluble matter Not more than 2% on the anhydrous basis
Arsenic Not more than 3 mg/kg
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
E. coli Negative in 5 g
Salmonella spp. Negative in 10 g

E 404 CALCIUM ALGINATE

Synonyms
Calcium salt of alginate

Definition

Chemical name Calcium salt of alginic acid

Chemical formula \((\text{C}_6\text{H}_7\text{Ca}_{1/2}\text{O}_6)_n\)

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

### 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-diyl 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 CO\(_2\) 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**

<table>
<thead>
<tr>
<th>Property</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 20% (105°C, 4 hours)</td>
</tr>
<tr>
<td>Total propane-1,2-diol content</td>
<td>Not less than 15% and not more than 45%</td>
</tr>
<tr>
<td>Free propane-1,2-diol content</td>
<td>Not more than 15%</td>
</tr>
<tr>
<td>Water-insoluble matter</td>
<td>Not more than 2% on the anhydrous basis</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 20 mg/kg</td>
</tr>
</tbody>
</table>
Total plate count  Not more than 5 000 colonies per gram
Yeast and moulds  Not more than 500 colonies per gram
E. coli  Negative in 5 g
Salmonella spp.  Negative in 10 g

E 406 AGAR

Synonyms
  Gelose
  Japan agar
  Bengal, Ceylon, Chinese or Japanese isinglass
  Layor Carang

Definition

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

Einacs  232-658-1

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

Description  Agar is odourless or has a slight characteristic odour. 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 CARRAGEEANAN

Synonyms

Products of commerce are sold under different names such as:

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

Definition

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

Einecs

232-524-2

Description

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

Identification

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

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 SO₄)
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

E. coli | Negative in 5 g

Salmonella spp. | Negative in 10 g

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**E 407a PROCESSED EUCHEUMA SEAWEED**

**Synonyms**

PES (acronym for processed eucheuma seaweed)

**Definition**

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

**Description**

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

**Identification**

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

B. Solubility

Forms cloudy viscous suspensions in water. Insoluble in ethanol

**Purity**

Methanol, ethanol, propane-2-ol content | Not more than 0,1 % singly or in combination

Viscosity of a 1,5% solution at 75°C | Not less than 5 mPa.s

Loss on drying | Not more than 12 % (105°C, 4 hours)
Sulphate | Not less than 15% and not more than 40% on the dried basis (as SO$_4$)
---|---
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
E. coli | Negative in 5 g
Salmonella spp. | Negative in 10 g

E 410 LOCUST BEAN GUM

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 15% (105°C, 5 hours)</td>
</tr>
<tr>
<td>Ash</td>
<td>Not more than 1,2% determined at 800°C</td>
</tr>
<tr>
<td>Protein (N × 6.25)</td>
<td>Not more than 7%</td>
</tr>
<tr>
<td>Acid-insoluble matter</td>
<td>Not more than 4%</td>
</tr>
<tr>
<td>Starch</td>
<td>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</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 20 mg/kg</td>
</tr>
<tr>
<td>Ethanol and propane-2-ol</td>
<td>Not more than 1%, single or in combination</td>
</tr>
</tbody>
</table>

E 412 GUAR GUM

Synonyms

<table>
<thead>
<tr>
<th>Synonym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gum cyamopsis</td>
<td></td>
</tr>
<tr>
<td>Guar flour</td>
<td></td>
</tr>
</tbody>
</table>

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

Einnes

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 15% (105°C, 5 hours)</td>
</tr>
<tr>
<td>Ash</td>
<td>Not more than 1,5% determined at 800°C</td>
</tr>
<tr>
<td>Acid-insoluble matter</td>
<td>Not more than 7%</td>
</tr>
<tr>
<td>Protein (N × 6.25)</td>
<td>Not more than 10%</td>
</tr>
</tbody>
</table>
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 Astragalus gummifer Labillardiere and other Asiatic species of Astragalus (family Leguminosae). It consists mainly of high molecular weight polysaccharides (galactoarabans and acidic polysaccharides) which, on hydrolysis, yield galacturonic acid, galactose, arabinose, xylose and fucose. Small amounts of rhamnose and of glucose (derived from traces of starch and/or cellulose) may also be present

Molecular weight
Approximately 800 000

Einacs
232-252-5

Description
Unground Tragacanth gum occurs as flattened, lamellated, straight or curved fragments or as spirally twisted pieces 0,5-2,5 mm thick and up to 3 cm in length. It is white to pale yellow in colour but some pieces may have a red tinge. The pieces are horny in texture, with a short fracture. It is odourless and solutions have an insipid mucilaginous taste. Powdered tragacanth is white to pale yellow or pinkish brown (pale tan) in colour

Identification
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
Salmonella spp. | Negative in 10 g
E. coli | 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 Acacia senegal (L) Willdenow or closely related species of Acacia (family Leguminosae). It consists mainly of high molecular weight polysaccharides and their calcium, magnesium and potassium salts, which on hydrolysis yield arabinose, galactose, rhamnose and glucuronic acid.

Molecular weight | Approximately 350 000

Description | Unground acacia gum occurs as white or yellowish-white spheroidal tears of varying sizes or as angular fragments and is sometimes mixed with darker fragments. It is also available in the form of white to yellowish-white flakes, granules, powder or spray-dried material.

Identification

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 FeCl₃·6H₂O 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
### E 415 XANTHAN GUM

**Definition**

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

**Molecular weight**

Approximately 1 000 000

**Einacs**

234-394-2

**Assay**

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

**Description**

Cream-coloured powder

**Identification**

A. Solubility

Soluble in water. Insoluble in ethanol

**Purity**

- **Loss on drying**
  
  Not more than 15% (105°C, 2½ hours)

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

- **Pyruvic acid**
  
  Not less than 1,5%

- **Nitrogen**
  
  Not more than 1,5%

- **Propane-2-ol**
  
  Not more than 500 mg/kg

- **Arsenic**
  
  Not more than 3 mg/kg

- **Lead**
  
  Not more than 5 mg/kg

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

- **Cadmium**
  
  Not more than 1 mg/kg

- **Heavy metals (as Pb)**
  
  Not more than 20 mg/kg

- **Total plate count**
  
  Not more than 10 000 colonies per gram

- **Yeast and mould**
  
  Not more than 300 colonies per gram
| **E. coli** | Negative in 5 g |
| **Salmonella spp.** | Negative in 10 g |
| **Xanthomonas campestris** | 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**

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Solubility</td>
<td>Insoluble in ethanol</td>
</tr>
<tr>
<td>B. Swelling in ethanol solution</td>
<td>Karaya gum swells in 60% ethanol distinguishing it from other gums</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 20% (105°C, 5 hours)</td>
</tr>
<tr>
<td>Total ash</td>
<td>Not more than 8%</td>
</tr>
<tr>
<td>Acid insoluble ash</td>
<td>Not more than 1%</td>
</tr>
<tr>
<td>Acid insoluble matter</td>
<td>Not more than 3%</td>
</tr>
<tr>
<td>Volatile acid</td>
<td>Not less than 10% (as acetic acid)</td>
</tr>
<tr>
<td>Starch</td>
<td>Not detectable</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 20 mg/kg</td>
</tr>
<tr>
<td><em>Salmonella</em> spp.</td>
<td>Negative in 10 g</td>
</tr>
<tr>
<td><em>E. coli</em></td>
<td>Negative in 5 g</td>
</tr>
</tbody>
</table>
TARA GUM

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

**Einecs**
254-409-6

**Description**
A white to white-yellow odourless powder

**Identification**

A. Solubility
- Soluble in water
- Insoluble in ethanol

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

**Purity**

- Loss on drying: Not more than 15%
- Ash: Not more than 1,5%
- Acid insoluble matter: Not more than 2%
- Protein: Not more than 3,5% (factor N x 5,7)
- Starch: Not detectable
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 5 mg/kg
- Mercury: Not more than 1 mg/kg
- Cadmium: Not more than 1 mg/kg
- Heavy metals (as Pb): Not more than 20 mg/kg

GELLAN GUM

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

**Einecs**
275-117-5

**Molecular weight**
Approximately 500 000
Assay
Yields, on the dried basis, not less than 3,3 % and not more than 6,8 % of CO₂

Description
An off-white powder

Identification
A. Solubility
Soluble in water, forming a viscous solution. Insoluble in ethanol

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

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

E. coli
Negative in 5 g

Salmonella spp.
Negative in 10 g

E 422 GLYCEROL

Synonyms
Glycerin
Glycerine

Definition
Chemical names
1,2,3-propanetriol
Glycerol
Trihydroxypropane

Einecs
200-289-5

Chemical formula
C₃H₈O₃

Molecular weight
92,10

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

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

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

B. Specific gravity (25/25°C)
Not less than 1,257

C. Refractive index [n]D°
Between 1,471 and 1,474
### E 431 POLYOXYETHYLENE (40) STEARATE

<table>
<thead>
<tr>
<th><strong>Synonyms</strong></th>
<th>Polyoxyl (40) stearate, polyoxyethylene (40) monostearate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>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</td>
</tr>
<tr>
<td><strong>Assay</strong></td>
<td>Content not less than 97.5% on the anhydrous basis</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Cream-coloured flakes or waxy solid at 25°C with a faint odour</td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td></td>
</tr>
<tr>
<td>A. Solubility</td>
<td>Soluble in water, ethanol, methanol and ethyl acetate Insoluble in mineral oil</td>
</tr>
<tr>
<td>B. Congealing range</td>
<td>39-44°C</td>
</tr>
<tr>
<td>C. Infrared absorption spectrum</td>
<td>Characteristic of a partial fatty acid ester of a polyoxyethylated polyol</td>
</tr>
</tbody>
</table>

### Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not more than 3% (Karl Fischer method)</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not more than 1</td>
</tr>
<tr>
<td>Saponification value</td>
<td>Not less than 25 and not more than 35</td>
</tr>
<tr>
<td>Hydroxyl value</td>
<td>Not less than 27 and not more than 40</td>
</tr>
<tr>
<td>1,4-Dioxane</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Free ethylene oxide</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Substance</td>
<td>Limit</td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Ethylene glycols (mono- and di-)</td>
<td>Not more than 0.25%</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

**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

**Assay**
Content not less than 70% of oxyethylene groups, equivalent to not less than 97.3% of polyoxyethylene (20) sorbitan monolaurate on the anhydrous basis

**Description**
A lemon to amber-coloured oily liquid at 25°C with a faint characteristic odour

**Identification**
- **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%
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 di-anhydrides with edible commercial oleic 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 96.5% of polyoxyethylene (20) sorbitan monooleate on the anhydrous basis

Description
A lemon to amber-coloured oily liquid at 25°C with a faint characteristic odour

Identification
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 di-anhydrides with edible commercial palmitic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides

Assay
Content not less than 66% of oxyethylene groups, equivalent to not less than 97% of polyoxyethylene (20) sorbitan monopalmitate on the anhydrous basis

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

**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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not more than 3% (Karl Fischer method)</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not more than 2</td>
</tr>
<tr>
<td>Saponification value</td>
<td>Not less than 41 and not more than 52</td>
</tr>
<tr>
<td>Hydroxyl value</td>
<td>Not less than 90 and not more than 107</td>
</tr>
<tr>
<td>1,4-Dioxane</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Free ethylene oxide</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Ethylene glycols (mono- and di-)</td>
<td>Not more than 0.25%</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

### 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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not more than 3% (Karl Fischer method)</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not more than 2</td>
</tr>
<tr>
<td>Saponification value</td>
<td>Not less than 45 and not more than 55</td>
</tr>
</tbody>
</table>
### 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 di-anhydrides 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 46% of oxyethylene groups, equivalent to not less than 96% of polyoxyethylene (20) sorbitan tristearate on the anhydrous basis

**Description**
A tan-coloured, waxy solid at 25°C with a faint characteristic odour

**Identification**

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

**Assay**

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

**Description**

White, light yellow, light grey or light brown powder.

**Identification**

A. **Solubility**

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

**Purity**

- **Loss on drying**
  
  Not more than 12% (105°C, 2 hours)

- **Acid insoluble ash**
  
  Not more than 1% (insoluble in approximately 3N hydrochloric acid)

- **Sulphur dioxide**
  
  Not more than 50 mg/kg on the anhydrous basis

- **Nitrogen content**
  
  Not more than 1.0% after washing with acid and ethanol

- **Free methanol, ethanol and propane-2-ol**
  
  Not more than 1%, singly or in combination, on the anhydrous basis

- **Arsenic**
  
  Not more than 3 mg/kg

- **Lead**
  
  Not more than 5 mg/kg

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

- **Cadmium**
  
  Not more than 1 mg/kg

- **Heavy metals (as Pb)**
  
  Not more than 20 mg/kg

### E 440 (ii) AMIDATED PECTIN

**Definition**

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

**Assay**

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

**Description**

White, light yellow, light greyish or light brownish powder.
Identification

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

Purity

Loss on drying
Not more than 12% (105°C, 2 hours)

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

Degree of amidation
Not more than 25% of total carboxyl groups

Sulphur dioxide residue
Not more than 50 mg/kg on the anhydrous basis

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

Free methanol, ethanol and propane-2-ol
Not more than 1% single or in combination, on a volatile matter-free basis

Arsenic
Not more than 3 mg/kg

Lead
Not more than 5 mg/kg

Mercury
Not more than 1 mg/kg

Cadmium
Not more than 1 mg/kg

Heavy metals (as Pb)
Not more than 20 mg/kg

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
E 444 SUCROSE ACETATE ISOBUTYRATE

Synonyms
SAIB

Definition
Sucrose acetate isobutyrate is a mixture of the reaction products formed by the esterification of food grade sucrose with acetic acid anhydride and isobutyric anhydride, followed by distillation. The mixture contains all possible combinations of esters in which the molar ratio of acetate to butyrate is about 2:6

Einecs
204-771-6

Chemical name
Sucrose diacetate hexaisobutyrate

Chemical formulae
C_{40}H_{62}O_{19}

Molecular weight
832-856 (approximate), C_{40}H_{62}O_{19} : 846.9

Assay
Content not less than 98.8% and not more than 101.9% of C_{40}H_{62}O_{19}

Description
A pale straw-coloured liquid, clear and free of sediment and having a bland odour

Identification
A. Solubility
Insoluble in water. Soluble in most organic solvents

B. Refractive index
[n]_{D}^{20} : 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.

Description
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]_{20}^{25} \text{ not less than 0.935 when determined in a 50% solution in } d\text{-limonene (97\%, boiling point } 175.5-176^\circ C, d_{20}^{25}: 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
Chemical name
Disodium dihydrogen diphosphate

Einecs
231-835-0

Chemical formula
Na_2H_2P_2O_7
**Molecular weight**

221,94

**Assay**

Content not less than 95% of disodium diphosphate and not less than 63% and not more than 64,5% expressed as P₂O₅

**Description**

White powder or grains

**Identification**

A. Positive tests for sodium and for phosphate

B. 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

**Chemical formula**

- **Monohydrate:** Na₃HP₂O₇·H₂O
- **Anhydrous:** Na₃HP₂O₇

**Molecular weight**

- **Monohydrate:** 261,95
- **Anhydrous:** 243,93

**Assay**

Content not less than 95% on the anhydrous basis and not less than 57% and not more than 59% expressed as P₂O₅

**Description**

White powder or grains, occurs anhydrous or as a monohydrate

**Identification**

A. Positive tests for sodium and for phosphate

B. Soluble in water
### Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH of a 1% solution</td>
<td>Between 6.7 and 7.3</td>
</tr>
<tr>
<td>Loss on ignition</td>
<td>4.5% on the anhydrous compound 11.5% on the monohydrated basis</td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Not more than 0.5% (105°C, 4 hours)</td>
</tr>
<tr>
<td>Water-insoluble matter</td>
<td>Not more than 0.2%</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 10 mg/kg expressed as fluorine</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 20 mg/kg</td>
</tr>
</tbody>
</table>

### E 450 (iii) TETRASODIUM DIPHOSPHATE

**Synonyms**
- Tetrasodium pyrophosphate
- Sodium pyrophosphate

**Definition**

- **Chemical name**: Tetrasodium diphosphate

**Einces**
- 231-767-1

**Chemical formula**
- Anhydrous: \( \text{Na}_4P_2O_7 \)
- Decahydrate: \( \text{Na}_4P_2O_7\cdot10\text{H}_2\text{O} \)

**Molecular weight**
- Anhydrous: 265.94
- Decahydrate: 446.09

**Assay**
- Content not less than 95% of \( \text{Na}_4P_2O_7 \), 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**

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH of a 1% solution</td>
<td>Between 9.8 and 10.8</td>
</tr>
<tr>
<td>Loss on ignition</td>
<td>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</td>
</tr>
</tbody>
</table>
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

Chemical name Tetrapotassium diphosphate

Einacs 230-785-7

Chemical formula K₄P₂O₇

Molecular weight 330,34 (anhydrous)

Assay Content not less than 95% on the ignited basis and not less than 42% and not more than 43,7% expressed as P₂O₅

Description 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**
- **Chemical name**: Dicalcium diphosphate
- **Einecs**: 232-221-5
- **Chemical formula**: Ca$_2$P$_2$O$_7$
- **Molecular weight**: 254.12
- **Assay**: Content not less than 96% and not less than 55% and not more than 56% expressed as P$_2$O$_5$
- **Description**: 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**
- **Chemical name**: Calcium dihydrogen diphosphate
- **Einecs**: 238-933-2
- **Chemical formula**: CaH$_2$P$_2$O$_7$
- **Molecular weight**: 215.97
- **Assay**: Content not less than 90% on the anhydrous basis and not less than 61% and not more than 64% expressed as P$_2$O$_5$
- **Description**: White crystals or powder
### Identification

A. Positive tests for calcium and for phosphate

### Purity

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acid-insoluble matter</td>
<td>Not more than 0.4%</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 30 mg/kg expressed as fluorine</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 20 mg/kg</td>
</tr>
</tbody>
</table>

#### 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 $\text{P}_2\text{O}_5$ 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 tripolyphosphate

**Definition**  
*Chemical name*  
Pentapotassium triphosphate  
Pentapotassium tripolyphosphate

**Einces**  
237-574-9

**Chemical formulae**  
K$_5$O$_{10}$P$_3$

**Molecular weight**  
448,42

**Assay**  
Content not less than 85% on the dried basis  
Content in P$_2$O$_5$ not less than 46,5% and not more than 48%

**Description**  
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, \( (NaPO_3)_x \), where \( x \geq 2 \), terminated by \( Na_2PO_4 \) groups. These substances are usually identified by their \( Na_2O/P_2O_5 \) ratio or their \( P_2O_5 \) content. The \( Na_2O/P_2O_5 \) ratios vary from about 1.3 for sodium tetrapolyphosphate, where \( x = \text{approximately} \ 4 \); 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.

Chemical name

Sodium polyphosphate

Einecs

272-808-3

Chemical formulae

Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula \( H_{(n+2)}P_nO_{(3n+1)} \), where \( n \) is not less than 2

Molecular weight

\( (102)^n \)

Assay

Content in \( P_2O_5 \) not less than 60% and not more than 71% on the ignited basis.

Description

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

Chemical name
Sodium polyphosphate

Einecs
272-808-3

Chemical formulae
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

Molecular weight
\((102)_n\)

Assay
Not less than 68,7% and not more than 70% of \(\text{P}_2\text{O}_5\)

Description
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

Chemical name
Potassium polyphosphate
### E 452 (iv) CALCIUM POLYPHOSPHATES

**Synonyms**  
- calcium metaphosphate  
- calcium polymetaphosphate

**Definition**  
**Chemical name**: calcium polyphosphate

**Einacs**  
236-769-6

**Chemical formulae**  
$(\text{CaP}_2\text{O}_6)_n$

A heterogeneous mixture of calcium salts of condensed polyphosphoric acids of general formula $H_{(n+2)}P_n\text{O}(n+1)$, where 'n' is not less than 2

**Molecular weight**  
$(198)_n$

**Assay**  
Content in $P_2\text{O}_5$ not less than 50% and not more than 71% on the ignited basis

**Description**  
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 P2O5 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
(C6H10O5)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-following suspension or a heavy, lumpy suspension which flows poorly, if at all, settles only slightly and contains many trapped air bubbles. If a free-flowing suspension is obtained, transfer 100 ml into a 100-ml graduated cylinder and allow to stand for 1 hour. The solids settles and a supernatant liquid appears.

Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 7% (105°C, 3 hours)</td>
</tr>
<tr>
<td>Water-soluble matter</td>
<td>Not more than 0,24%</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0,5% determined at 800 ± 25°C</td>
</tr>
<tr>
<td>pH of a 10% suspension in water</td>
<td>The pH of the supernatant liquid is between 5,0 and 7,5</td>
</tr>
<tr>
<td>Starch</td>
<td>Not detectable</td>
</tr>
<tr>
<td>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</td>
<td></td>
</tr>
<tr>
<td>Particle size</td>
<td>Not less than 5 μm (not more than 10 % of particles of less than 5 μm)</td>
</tr>
<tr>
<td>Carboxyl groups</td>
<td>Not more than 1%</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

E 460 (ii) POWDERED CELLULOSE

Definition

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

Chemical name

Cellulose
Linear polymer of 1:4 linked glucose residues

Einchem

232-674-9

Chemical formula

(C₆H₁₀O₅)ₙ

Molecular weight

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

Assay

Content not less than 92%

Description

A white, odourless powder

Identification

A. Solubility

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

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

Purity

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 7% (105°C, 3 hours)</td>
</tr>
<tr>
<td>Water-soluble matter</td>
<td>Not more than 1,0%</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0,3% determined at 800 ± 25°C</td>
</tr>
<tr>
<td>pH of a 10% suspension in water</td>
<td>The pH of the supernatant liquid is between 5,0 and 7,5</td>
</tr>
<tr>
<td>Starch</td>
<td>Not detectable</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not less than 5 µm (not more than 10% of particles of less than 5 µm)</td>
</tr>
</tbody>
</table>

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.

Chemical name

Methyl ether of cellulose

Chemical formula

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

\[ C_6H_7O_2(OR_1)(OR_2)(OR_3) \]

where \( R_1, R_2, R_3 \) each may be one of the following:

- \( H \)
- \( CH_3 \) or
- \( CH_2CH_3 \)

Molecular weight

From about 20 000 to 380 000

Assay

Content not less than 25% and not more than 33% of methoxyl groups (\( -OCH_3 \)) and not more than 5% of hydroxyethoxyl groups (\( -OCH_2CH_2OH \))

Description

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

Identification

A. Solubility

Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol, ether and chloroform. Soluble in glacial acetic acid.
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:
C₆H₇O₂(OR₁)(OR₂)(OR₃), where R₁, R₂, R₃ each may be one of the following:
- H
- CH₂CHOHCH₃
- CH₂CHO(CH₂CHOHCH₃)CH₃
- CH₂CHO[CH₂CHO(CH₂CHOHCH₃)]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

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.

**Chemical name**
2-Hydroxypropyl ether of methylcellulose

**Chemical formula**
The polymers contain substituted anhydroglucose units with the following general formula:
\[ \text{C}_6\text{H}_7\text{O}_2(\text{OR}_1)(\text{OR}_2)(\text{OR}_3) \]
where \( R_1, R_2, R_3 \) each may be one of the following:
- \( \text{H} \)
- \( \text{CH}_3 \)
- \( \text{CH}_2\text{CHOHCH}_3 \)
- \( \text{CH}_2\text{CHO} (\text{CH}_2\text{CHOHCH}_3) \text{CH}_3 \)
- \( \text{CH}_2\text{CHO} (\text{CH}_2\text{CHO} (\text{CH}_2\text{CHOHCH}_3) \text{CH}_3 ) \text{CH}_3 \)

**Molecular weight**
From about 13 000 to 200 000

**Assay**
Content not less than 19% and not more than 30% methoxyl groups (\(-\text{OCH}_3\)) and not less than 3% and not more than 12% hydroxypropoxyl groups (\(-\text{OCH}_2\text{CHOHCH}_3\)), 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. Insoluble in ethanol.

B. Gas chromatography
Determine the substituents by gas chromatography.

**Purity**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 10% (105°C, 3 hours)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>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</td>
</tr>
<tr>
<td>pH of a 1% colloidal solution</td>
<td>Not less than 5,0 and not more than 8,0</td>
</tr>
<tr>
<td>Propylene chlorohydrins</td>
<td>Not more than 0,1 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 20 mg/kg</td>
</tr>
</tbody>
</table>
E 465 ETHYL METHYL CELLULOSE

Synonyms
Methylethylcellulose

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

Chemical name
Ethyl methyl ether of cellulose

Chemical formula
The polymers contain substituted anhydroglucose units with the following general formula:
\[ \text{C}_6\text{H}_7\text{O}_2(\text{OR}_1)(\text{OR}_2)(\text{OR}_3) \]
where \( \text{R}_1, \text{R}_2, \text{R}_3 \) each may be one of the following:
- \( \text{H} \)
- \( \text{CH}_3 \)
- \( \text{CH}_2\text{CH}_3 \)

Molecular weight
From about 30 000 to 40 000

Assay
Content on the anhydrous basis not less than 3,5 % and not more than 6,5 % of methoxyl groups (\(-\text{OCH}_3\)) and not less than 14,5 % and not more than 19 % of ethoxyl groups (\(-\text{OCH}_2\text{CH}_3\)), and not less than 13,2 % and not more than 19,6 % of total alkoxyyl groups, calculated as methoxyl

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

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

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

Sulphated ash
Not more than 0,6 %

pH of a 1 % colloidal solution
Not less than 5,0 and not more than 8,0

Arsenic
Not more than 3 mg/kg

Lead
Not more than 5 mg/kg

Mercury
Not more than 1 mg/kg

Cadmium
Not more than 1 mg/kg

Heavy metals (as Pb)
Not more than 20 mg/kg

E 466 SODIUM CARBOXY METHYL CELLULOSE

Synonyms
Carboxy methyl cellulose
CMC
NaCMC
Sodium CMC
Cellulose gum
**Definition**

Carboxy methyl cellulose is the partial sodium salt of a carboxymethyl ether of cellulose, the cellulose being obtained directly from natural strains of fibrous plant material.

**Chemical name**

Sodium salt of the carboxymethyl ether of cellulose

**Chemical formula**

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

\[ C_6H_7O_2(OR_1)(OR_2)(OR_3) \]

where \( R_1, R_2, R_3 \) each may be one of the following:

- \( \text{H} \)
- \( \text{CH}_2\text{COONa} \)
- \( \text{CH}_2\text{COOH} \)

**Molecular weight**

Higher than approximately 17,000 (degree of polymerisation approximately 100)

**Assay**

Content on the anhydrous basis not less than 99,5%

**Description**

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

**Identification**

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 \((-\text{CH}_2\text{COOH})\) 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

Assay
Content on the anhydrous basis not less than 95%

Description
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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>Not less than 9 % and not more than 14 % expressed as Na₂O</td>
</tr>
<tr>
<td>Potassium</td>
<td>Not less than 13 % and not more than 21,5 % expressed as K₂O</td>
</tr>
<tr>
<td>Calcium</td>
<td>Not less than 8,5 % and not more than 13 % expressed as CaO</td>
</tr>
<tr>
<td>Unsaponifiable matter</td>
<td>Not more than 2 %</td>
</tr>
<tr>
<td>Free fatty acids</td>
<td>Not more than 3 % estimated as oleic acid</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Free alkali</td>
<td>Not more than 0,1 % expressed as NaOH</td>
</tr>
<tr>
<td>Matter insoluble in alcohol</td>
<td>Not more than 0,2 % (sodium and potassium salts only)</td>
</tr>
</tbody>
</table>

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

Assay
Content on the anhydrous basis not less than 95%

Description
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

<table>
<thead>
<tr>
<th>Component</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium</td>
<td>Not less than 6.5% and not more than 11% expressed as MgO</td>
</tr>
<tr>
<td>Free alkali</td>
<td>Not more than 0.1% expressed as MgO</td>
</tr>
<tr>
<td>Unsaponifiable matter</td>
<td>Not more than 2%</td>
</tr>
<tr>
<td>Free fatty acids</td>
<td>Not more than 3% estimated as oleic acid</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

### 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

<table>
<thead>
<tr>
<th>Component</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water content</td>
<td>Not more than 2% (Karl Fischer method)</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not more than 6</td>
</tr>
<tr>
<td>Free glycerol</td>
<td>Not more than 7%</td>
</tr>
<tr>
<td>Polyglycerols</td>
<td>Not more than 4% diglycerol and not more than 1% higher polyglycerols both based on total glycerol content</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Substance</td>
<td>Limitations</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Total glycerol</td>
<td>Not less than 16% and not more than 33%</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.5% determined at 800 ± 25°C</td>
</tr>
</tbody>
</table>

_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

**Description**

Clear, mobile liquids to solids, from white to pale yellow in colour

**Identification**

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

B. Solubility

Insoluble in water. Soluble in ethanol

**Purity**

- Acids other than acetic and fatty acids: Not detectable
- Free glycerol: Not more than 2%
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 5 mg/kg
- Mercury: Not more than 1 mg/kg
- Cadmium: Not more than 1 mg/kg
- Heavy metals (as Pb): Not more than 10 mg/kg
- Total acetic acid: Not less than 9% and not more than 32%
- Free fatty acids (and acetic acid): Not more than 3% estimated as oleic acid
- Total glycerol: Not less than 14% and not more than 31%
- Sulphated ash: Not more than 0.5% determined at 800 ± 25°C

_Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6% (expressed as sodium oleate)_
**E 472 b LACTIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS**

**Synonyms**
- Lactic acid esters of mono- and diglycerides
- Lactoglycerides
- Mono- and diglycerides of fatty acids esterified with lactic acid

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

**Description**
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

**Description**
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 ± 25°C

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

**E 472 e MONO- AND DIACETYL TARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS**

**Synonyms**
Diacetyl tartaric acid esters of mono- and diglycerides
Mono-and diglycerides of fatty acids esterified with mono- and diacetyl tartaric 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

**Description**
Sticky viscous liquids through a fat-like consistency to yellow waxes which hydrolyse in moist air to liberate acetic acid

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

**Purity**
Acids other than acetic, tartaric and fatty acids | Not detectable
Free glycerol | Not more than 2%
Total glycerol | Not less than 11% and not more than 28%
Sulphated ash | Not more than 0.5% determined at 800 ± 25°C
Arsenic | Not more than 3 mg/kg
Lead | Not more than 5 mg/kg
Mercury | Not more than 1 mg/kg
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 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

**Description**

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**

<table>
<thead>
<tr>
<th>Component</th>
<th>Purity Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acids other than acetic, tartaric and fatty acids</td>
<td>Not detectable</td>
</tr>
<tr>
<td>Free glycerol</td>
<td>Not more than 2%</td>
</tr>
<tr>
<td>Total glycerol</td>
<td>Not less than 12% and not more than 27%</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0,5% determined at 800 ± 25°C</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Total acetic acid</td>
<td>Not less than 10% and not more than 20%</td>
</tr>
<tr>
<td>Total tartaric acid</td>
<td>Not less than 20% and not more than 40%</td>
</tr>
<tr>
<td>Free fatty acids</td>
<td>Not more than 3% estimated as oleic acid</td>
</tr>
</tbody>
</table>

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

---

### E 473 SUCROSE ESTERS OF FATTY ACIDS

**Synonyms**

Sucroesters  
Sugar esters

**Definition**

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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulphated ash</td>
<td>Not more than 2% determined at 800 ± 25°C</td>
</tr>
<tr>
<td>Free sugar</td>
<td>Not more than 5%</td>
</tr>
<tr>
<td>Free fatty acids</td>
<td>Not more than 3% estimated as oleic acid</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Methanol</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Dimethylsulphoxide</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Dimethylformamide</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>2-methyl-1-propanol</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Ethyl acetate</td>
<td><a href="#">Not more than 350 mg/kg, singly or in combination</a></td>
</tr>
<tr>
<td>Propane-2-ol</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td></td>
</tr>
<tr>
<td>Methyl ethyl ketone</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

*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 ± 25°C

Free sugar
   Not more than 5%

Free fatty acids
   Not more than 3% estimated as oleic acid

Arsenic
   Not more than 3 mg/kg

Lead
   Not more than 5 mg/kg

Mercury
   Not more than 1 mg/kg

Cadmium
   Not more than 1 mg/kg

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

Methanol
   Not more than 10 mg/kg

Dimethylformamide
   Not more than 1 mg/kg

2-methyl-1-propanol
   Not more than 10 mg/kg, single or in combination

Cyclohexane

Ethyl acetate
   Not more than 350 mg/kg, single or in combination

Propane-2-ol

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

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 tetracyglycerol 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

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

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 polycirinoleate is prepared by the esterification of polyglycerol with condensed castor oil fatty acids

Description

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]D25
Between 1,4630 and 1,4665

Purity

Polyglycerols
The polyglycerol moiety shall be composed of not less than 75 % of di-, tri- and tetragnlycerols 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.
Assay | Content of total fatty acid ester not less than 85%
Description | Clear liquids or waxy white flakes, beads or solids having a bland odour

Identification
A. Positive tests for propylene glycol and for fatty acids

Purity
- Sulphated ash: Not more than 0.5% determined at 800±25°C
- Acids other than fatty acids: Not detectable
- Free fatty acids: Not more than 6% estimated as oleic acid
- Total propane-1,2-diol: Not less than 11% and not more than 31%
- Free propane-1,2-diol: Not more than 5%
- Dimer and trimer of propylene glycol: Not more than 0.5%
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 5 mg/kg
- Mercury: Not more than 1 mg/kg
- Cadmium: Not more than 1 mg/kg
- Heavy metals (as Pb): Not more than 10 mg/kg

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
Description | Pale yellow to light brown a waxy or solid consistency
### Identification

**A. Solubility**

Insoluble in water. Soluble in hot oil or fat

### Purity

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting range</td>
<td>55—65°C</td>
</tr>
<tr>
<td>Free fatty acids</td>
<td>Not more than 1.5% estimated as oleic acid</td>
</tr>
<tr>
<td>Free glycerol</td>
<td>Not more than 2%</td>
</tr>
<tr>
<td>Total fatty acids</td>
<td>83—90%</td>
</tr>
<tr>
<td>Total glycerol</td>
<td>16—22%</td>
</tr>
<tr>
<td>Fatty acid methyl esters, not forming adduct with urea</td>
<td>Not more than 9% of total fatty acid methyl esters</td>
</tr>
<tr>
<td>Fatty acids, insoluble in petroleum ether</td>
<td>Not more than 2% of total fatty acids</td>
</tr>
<tr>
<td>Peroxide value</td>
<td>Not more than 3</td>
</tr>
<tr>
<td>Epoxides</td>
<td>Not more than 0.03% oxirane oxygen</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

### E 481 SODIUM STEAROYL-2-LACTYLATE

**Synonyms**

Sodium stearoyl lactylate  
Sodium stearoyl lactate

**Definition**

A mixture of the sodium salts of stearoyl lactyllic 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)

C_{21}H_{39}O_{4}Na  
C_{19}H_{35}O_{4}Na

**Description**

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

### Identification

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Positive tests for sodium, for fatty acids and for lactic acid</strong></td>
<td></td>
</tr>
<tr>
<td><strong>B. Solubility</strong></td>
<td>Insoluble in water. Soluble in ethanol</td>
</tr>
</tbody>
</table>
### Purity

<table>
<thead>
<tr>
<th>Component</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>Not less than 2.5% and not more than 5%</td>
</tr>
<tr>
<td>Ester value</td>
<td>Not less than 90 and not more than 190</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not less than 60 and not more than 130</td>
</tr>
<tr>
<td>Total lactic acid</td>
<td>Not less than 15% and not more than 40%</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

### E 482 CALCIUM STEAROYL-2-LACTYLATE

**Synonyms**
- Calcium stearoyl lactate
- Calcium di-2-stearoyl lactate
- Calcium di(2-stearoyloxy)propionate

**Chemical formula**
- \( C_{42}H_{78}O_{8}Ca \)
- \( C_{38}H_{70}O_{8}Ca \)

**Chemical name**
- Calcium di-2-stearoyl lactate
- Calcium di(2-stearoyloxy)propionate

**Einecs**
- 227-335-7

**Description**
- White or slightly yellowish powder or brittle solid with a characteristic odour

**Identification**
- A. Positive tests for calcium, for fatty acids and for lactid acid
- B. Solubility: Slightly soluble in hot water

**Purity**

<table>
<thead>
<tr>
<th>Component</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium</td>
<td>Not less than 1% and not more than 5.2%</td>
</tr>
<tr>
<td>Ester value</td>
<td>Not less than 125 and not more than 190</td>
</tr>
<tr>
<td>Total lactic acid</td>
<td>Not less than 15% and not more than 40%</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not less than 50 and not more than 130</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>
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.

Chemical name
Distearyl tartrate
Dipalmityl tartrate

Chemical formula
C_{38}H_{74}O_{6} to C_{40}H_{78}O_{6}

Molecular weight
627 to 655

Assay
Content of total ester not less than 90% corresponding to an ester value of not less than 163 and not more than 180

Description
Cream-coloured unctuous solid (at 25°C)

Identification
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

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

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

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

Einacs
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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not more than 2% (Karl Fischer method)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.5%</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not more than 15</td>
</tr>
<tr>
<td>Saponification value</td>
<td>Not less than 176 and not more than 188</td>
</tr>
<tr>
<td>Hydroxyl value</td>
<td>Not less than 66 and not more than 80</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

### 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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not more than 2% (Karl Fischer method)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.5%</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not more than 7</td>
</tr>
<tr>
<td>Saponification value</td>
<td>Not less than 155 and not more than 170</td>
</tr>
<tr>
<td>Hydroxyl value</td>
<td>Not less than 330 and not more than 358</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>
E 494 SORBITAN MONOOLEATE

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

Einecs
215-665-4

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

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

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

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

Purity
Water
Not more than 2% (Karl Fischer method)

Sulphated ash
Not more than 0,5%

Acid value
Not more than 8

Saponification value
Not less than 145 and not more than 160

Hydroxyl value
Not less than 193 and not more than 210

Arsenic
Not more than 3 mg/kg

Lead
Not more than 5 mg/kg

Mercury
Not more than 1 mg/kg

Cadmium
Not more than 1 mg/kg

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

E 495 SORBITAN MONOPALMITATE

Synonyms
Sorbitan palmitate

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

Einecs
247-568-8

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

Description
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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 1% (105°C, 2 hours)</td>
</tr>
<tr>
<td>Sodium</td>
<td>Negative test</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg</td>
</tr>
</tbody>
</table>

### E 579 FERROUS GLUCONATE

#### Definition

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

**Einces**
206-076-3

**Chemical formulae**
C₁₂H₂₂FeO₁₄·2H₂O

**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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 10% (105°C, 16 hours)</td>
</tr>
<tr>
<td>Oxalic acid</td>
<td>Not detectable</td>
</tr>
<tr>
<td>Iron (Fe III)</td>
<td>Not more than 2%</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Reducing substances</td>
<td>Not more than 0,5% expressed as glucose</td>
</tr>
</tbody>
</table>
### E 585 FERROUS LACTATE

| Synonyms | Iron(II) lactate  
|          | Iron(II) 2-hydroxy propanoate  
|          | Propanoic acid, 2-hydroxy-iron(2+) salt (2:1) |

#### Definition

**Chemical name**  
Ferrous 2-hydroxy propanoate

**EINECS**  
227-608-0

**Chemical formulae**  
C₆H₁₀FeO₆·xH₂O (x = 2 or 3)

**Molecular weight**  
270.02 (dihydrate)  
288.03 (trihydrate)

**Assay**  
Content not less than 96% on the dried basis

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

#### Identification

**A. Solubility**  
Soluble in water. Practically insoluble in ethanol

**B. Positive test for ferrous ion and for lactate**

**C. pH of a 2% solution**  
Between 4 and 6

#### 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