EFEMA index of food emulsifiers

4th March 2019

EFEMA
European Food Emulsifier Manufacturers' Association
Verband Europäischer Hersteller von Nahrungsmittel-Emulgatoren
Association des Fabricants Européens d'Emulsifiants Alimentaires

efema
European Food Emulsifiers Manufacturers Association

Brussels, 4th March 2019

The European Food Emulsifier Manufacturers Association (EFEMA) is a non-profit making organisation founded in 1973.

Its objectives are to develop, support and promote food emulsifiers based upon edible fats, oils and their derivatives which are produced for the European food industry. By means of submissions and petitions, EFEMA maintains contact with all authorities involved in the approval of emulsifiers, including the European Commission, the FAO/WHO (Codex Alimentarius) and national authorities.

On behalf of its members, EFEMA takes active part in the preparation and regular updating of product specifications, consistent with good manufacturing practice, safety in use and, above all, protection of the consumer.

Furthermore, EFEMA co-operates with other associations representing similar interests and, of course, with the users of food emulsifiers.

In accordance with the objectives, EFEMA first published monographs for food emulsifiers permitted in Europe in October 1976, with subsequent updates in November 1986, November 1999, January 2004, September 2009, June 2013 and June 2015. This new edition updates, to the best of our knowledge, emulsifier specifications, toxicological data, methods of analysis and provides examples of applications*.

Suggestions concerning any of the information listed in this journal should be addressed to the Secretariat.

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* This information is provided for guidance purposes only and does not necessarily reflect recent changes in EU legislation.

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Table of contents

Lecithins

E Number: E 322

1. Name

English	Lecithins
German	Lecithine
French	Lécithines
Dutch	Lecithinen
Spanish	Lecitinas
Portuguese	Lecitina
Italian	Lecitine
Danish	Lecithiner
Swedish	Lecitin
Finnish	Lesitiinit
Greek	Λεκιθίνες

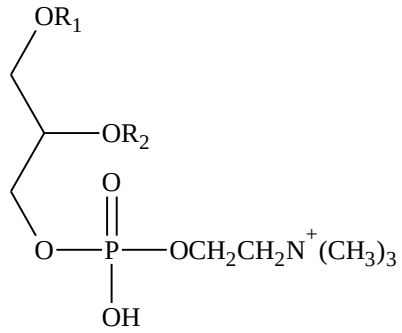
Synonyms

Phosphatides; phospholipids.

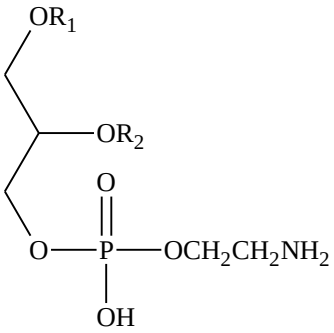
2. Description

2.1. Chemical description and typical process

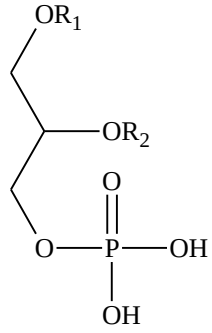
The product is a mixture of phosphatides. The structural formulae of the principal components are:



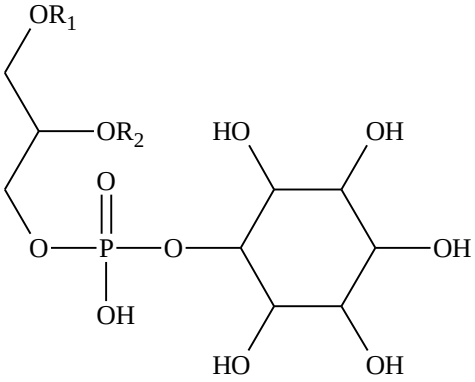
Phosphatidyl choline



Phosphatidyl ethanolamine



Phosphatidic acid



Phosphatidyl inositol

where R represents various saturated and unsaturated fatty acid moieties. At least one R represents a hydrogen moiety in the lysophospholipids.

The distribution of the principal components depends on raw material sources which may be vegetable oils and seeds (e.g. soya, maize) or animal sources (e.g. eggs).

Lecithins are typically extracted from crude vegetable oils through the "degumming" process. They can be further purified, for example by enzymatic hydrolysis, de-oiling or fractionation.

2.2. Appearance

Normally the product is a brown viscous semi-liquid with a characteristic odour. Refined lecithins, with high levels of phospholipid (> 95%), are soft, yellow-brown powders.

2.3. Solubility

The product is typically dispersible but insoluble in water, where it swells on hydration. It is soluble in oils and fats.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Lecithins have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

In the EU, the European Food Safety Authority (EFSA) Opinion on the re-evaluation of lecithins as a food additive was published in 2017 (6).

Evaluation status

Acceptable daily intake (ADI): not specified

5. Typical applications in food

Within the EU lecithins are generally permitted for use in foodstuffs (7).

Lecithins are used principally as emulsifiers, antispattering agents and as synergists for antioxidants. Applications include:

- Baked goods, e.g. bread, cakes, biscuits
- Confectionery, e.g. chocolate, chewing gum, toffees
- Dairy products, e.g. imitation creams, desserts, edible ices
- Fats, e.g. margarines, spreads, shortenings
- Starch, e.g. mashed potatoes, pasta
- Salad dressings and sauces
- Instant drinks
- Infant and follow-on formulae and foods for young children

6. Non-food applications

- Pharmaceutical and cosmetic preparations
- Livestock and poultry feed
- Paints

Specifications: E 322

Lecithins

	EU (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Acetone insoluble	min. 60.0%	min. 60%	min. 50.0%	(2)
Acetone insoluble*	min. 56.0%	min. 56%		(2)
Loss on drying (105°, 1 h)	max. 2.0%	max. 2%		A 11
Toluene-insoluble matter	max. 0.3%	max. 0.3%		(2)
Hexane-insoluble matter			max. 0.3%	(3)
Acid value	max. 35	max. 36	max. 36	(2)
Acid value*	max. 45	max. 45		(2)
Peroxide value	max. 10	max. 10	max. 100	(2)
Water			max. 1.5%	A 10
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 1 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5

* Specification applies to hydrolysed lecithins only.

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition):
- Lecithin: monograph 4 (2007);
- Lecithin: Monograph 1 (2006)
- Lecithin, partially hydrolyzed: monograph 4 (2007).

(3) Food Chemicals Codex, 8th Edition, 2012 page 634.

(4) WHO Food Additives Series No. 5, 1974, page 234-235. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents.

(5) Reports of the Scientific Committee for Food, Fifth Series, 1978.

(6) Re-evaluation of lecithins (E 322) as a food additive

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Polyoxyethylene sorbitan monolaurate (Polysorbate 20)

E Number: E 432

1. Name

English	Polyoxyethylene sorbitan monolaurate
German	Polyoxyethylen-sorbitan-monolaurat
French	Monolaurate de polyoxyéthylène sorbitane
Dutch	Polyoxyethyleen-20-sorbitaan-monolauraat
Spanish	Monolaurato de sorbitan polioxietilenado
Portuguese	Monolaurato de polioxietileno 20 sorbitano
Italian	Monolaurato di poliossietilensorbitano
Danish	Polyoxyethylensorbitanmonolaurat
Swedish	Polyoxietylensorbitanmonolaurat
Finnish	Polyoksyetyleenisorbitaanimonolauraatti
Greek	Μονολαυρική πολυοξυ-αιθυλενο-σορβιτάνη

Synonyms

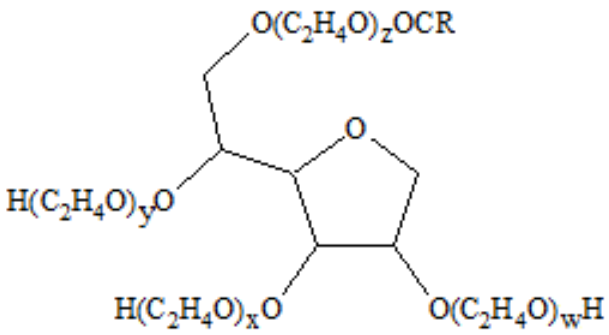
Polysorbate; polyoxyethylene (20) sorbitan monolaurate; sorbitan monododecanoate; poly(oxy-1,2-ethanediyl) derivative.

2. Description

2.1. Chemical description and typical process

Polyoxyethylene sorbitan monolaurate is a mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial lauric acid, condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides.

A nominal formula for polyoxyethylene sorbitan monolaurate is as follows:



where w + x + y + z = approximately 20 and RCO- is the lauric acid moiety.

2.2. Appearance

Polyoxyethylene sorbitan monolaurate is a lemon to amber-coloured oily liquid at 25°C, with a faint characteristic odour and a warm, somewhat bitter taste.

2.3. Solubility

Polyoxyethylene sorbitan monolaurate is soluble in hot and cold water, ethanol, methanol, ethyl acetate and dioxane. It is insoluble in mineral oil and petroleum ether.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Polyoxyethylene sorbitan monolaurate has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5). The European Food Safety Authority (EFSA) Scientific Opinion on the re-evaluation of Polyoxyethylene sorbitan monolaurate (E 432), polyoxyethylene sorbitan monooleate (E 433), polyoxyethylene sorbitan monopalmitate (E 434), polyoxyethylene sorbitan monostearate (E 435) and polyoxyethylene sorbitan tristearate (E 436) as food additives was published in July 2015 (6).

Evaluation status

Acceptable daily intake (ADI): 0-25 mg/kg bw
as total polyoxyethylene(20)sorbitan esters evaluation by JECFA (2)

Group ADI: 25 mg/kg bw re-evaluation by EFSA (6)

5. Typical applications in food

Polyoxyethylene sorbitan monolaurate is a strongly hydrophilic surface-active agent. It is used as an emulsifier, often in combination with sorbitan esters, and its structure also enables it to fulfil other functions, such as the modification of fat crystallisation.

Within the EU polyoxyethylene sorbitan monolaurate is permitted in (7):

- Fine bakery wares*
- Fat emulsions for baking purposes*
- Milk and cream analogues*
- Edible ices*
- Desserts excluding products covered in categories 1, 3 and 4*
- Sugar confectionery*
- Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4*
- Emulsified sauces*
- Soups*
- Chewing gum*
- Dietary food supplements
- Food supplements supplied in a solid, liquid or syrup-type or chewable form including capsules and tablets*Dietetic foods intended for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)*
- Dietetic formulae for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)*

* The additive may be added individually or in combination with other substances in the range E 432-436.

The application of Polyoxyethylene sorbitan monolaurate is also allowed as carrier and solvent for colours, fat-soluble antioxidants and anti-foaming agents.

6. Non-food applications

- Pharmaceuticals
- Cosmetics
- Animal feed
- Industrial applications

Specifications: E 432

Polyoxyethylene sorbitan monolaurate (Polysorbate 20)

	EU (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Content	min. 97.3% (anhydrous base)	97.3-103.0% (anhydrous base)	97.3-103.0% (anhydrous base)	A 34
Oxyethylene content	min. 70%	70.0-74.0%	70.0-74.0%	A 34
Acid value	max. 2	max. 2	max. 2	A 18
Saponification value	40-50	40-50	40-50	A 19
Hydroxyl value	96-108	96-108	96-108	A 20
Water	max. 3%	max. 3%	max. 3.0%	A 10
1,4-Dioxane	max. 5 mg/kg		max. 10 mg/kg	A 9
Ethylene oxide	max. 0.2 mg/kg			No method available
Ethylene glycols (mono- and di-)	max. 0.25%			A 38
Sulphated ash		max. 0.25%		A 6
Lauric acid recovered			15-17 g / 100 g	(3)
Acid value (Lauric acid recovered)			250-275	(3)
Residue on ignition			max. 0.25%	A 6
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation (EU) No 231/2012 of 9 March 2012
laying down specifications for food additives listed in Annexes II and III to Regulation (EC)No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006)

(3) Food Chemicals Codex, 8th Edition, 2012, page 913.

(4) WHO Food Additives Series No. 5, 1974, page 254-263. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents.

(5) Reports of the Scientific Committee for Food, Fifteenth Series, 1985.

(6) Scientific Opinion on the re-evaluation of polyoxyethylene sorbitan monolaurate (E 432), polyoxyethylene sorbitan monooleate (E 433), polyoxyethylene sorbitan monopalmitate (E 434), polyoxyethylene sorbitan monostearate (E 435) and polyoxyethylene sorbitan tristearate (E 436) as food additives.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Polyoxyethylene sorbitan monooleate (Polysorbate 80)

E Number: E 433

1. Name

English	Polyoxyethylene sorbitan monooleate
German	Polyoxyethylen-sorbitan-monooleat
French	Monooléate de polyoxyéthylène sorbitane
Dutch	Polyoxyethyleen-20-sorbitaan-mono-oleaat
Spanish	Monooleato de sorbitan polioxietilenado
Portuguese	Monooleato de polioxietileno 20 sorbitano
Italian	Monooleato di poliossietilensorbitano
Danish	Polyoxyethylensorbitanmonooleat
Swedish	Polyoxietylensorbitanmonooleat
Finnish	Polyoksyetyleenisorbitaanimono-oleaatti
Greek	Μονοελαϊκή πολυοξυ-αιθυλενο-σορβιτάνη

Synonyms

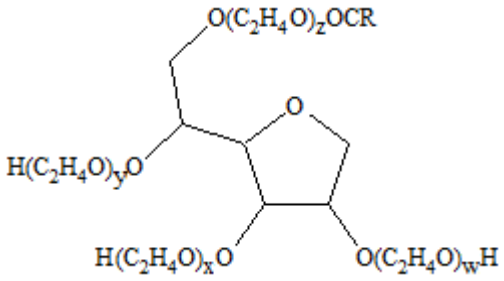
Polysorbate; polyoxyethylene (20) sorbitan monooleate; sorbitan mono 9-octa-decenoate; poly(oxy-1,2-ethanediyl) derivative.

2. Description

2.1. Chemical description and typical process

Polyoxyethylene sorbitan monooleate is a mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial oleic acid, condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides.

A nominal formula for polyoxyethylene sorbitan monooleate is as follows:



where w + x + y + z = approximately 20 and RCO- is the oleic acid moiety.

2.2. Appearance

Polyoxyethylene sorbitan monooleate is a lemon to amber-coloured oily liquid at 25°C, with a faint characteristic odour and a waxy, somewhat bitter taste

2.3. Solubility

Polyoxyethylene sorbitan monooleate is soluble in hot and cold water, ethanol, methanol, ethyl acetate and toluene. It is insoluble in mineral oil and petroleum ether.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Polyoxyethylene sorbitan monooleate has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5). The European Food Safety Authority (EFSA) Scientific Opinion on the re-evaluation of Polyoxyethylene sorbitan monolaurate (E 432), polyoxyethylene sorbitan monooleate (E 433), polyoxyethylene sorbitan monopalmitate (E 434), polyoxyethylene sorbitan monostearate (E 435) and polyoxyethylene sorbitan tristearate (E 436) as food additives was published in July 2015 (6).

Evaluation status

Acceptable daily intake (ADI): 0-25 mg/kg bw as total polyoxyethylene(20)sorbitan esters evaluation by JECFA (2)

Group ADI: 25 mg/kg bw re-evaluation by EFSA (6)

5. Typical applications in food

Polyoxyethylene sorbitan monooleate is a strongly hydrophilic surface-active agent. It is used as an emulsifier, often in combination with sorbitan esters. Its structure also enables it to fulfil other functions, such as the modification of fat crystallisation.

Within the EU polyoxyethylene sorbitan monooleate is permitted in (7):

- Fine bakery wares*
- Fat emulsions for baking purposes*
- Milk and cream analogues*
- Edible ices*
- Desserts excluding products covered in categories 1, 3 and 4*
- Sugar confectionery*
- Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4*
- Emulsified sauces*
- Soups*
- Chewing gum*
- Dietary food supplements
- Food supplements supplied in a solid, liquid or syrup-type or chewable form including capsules and tablets*Dietetic foods intended for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)*
- Dietetic formulae for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)*

* The additive may be added individually or in combination with other substances in the range E 432-436.

The application of Polyoxyethylene Sorbitan Monooleate is also allowed as carrier and solvent for colours, fat-soluble antioxidants and anti-foaming agents.

6. Non-food applications

- Pharmaceuticals
- Cosmetics
- Animal feed, calf milk replacers
- Industrial applications (plastic food wrap)

Specifications: E 433

Polyoxyethylene sorbitan monooleate (Polysorbate 80)

	EU (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Content	min. 96.5% (anhydrous base)	96.5-103.5% (anhydrous base)	96.5-103.5% (anhydrous base)	A 34
Oxyethylene content	min. 65%	65.0-69.5%	65.0-69.5%	A 34
Acid value	max. 2	max. 2	max. 2	A 18
Saponification value	45-55	45-55	45-55	A 19
Hydroxyl value	65-80	65-80	65-80	A 20
Water	max. 3%	max. 3%	max. 3.0%	A 10
1,4-Dioxane	max. 5 mg/kg		max. 10 mg/kg	A 9
Ethylene oxide	max. 0.2 mg/kg			No method available
Ethylene glycols (mono- and di-)	max. 0.25%			A 38
Sulphated ash		max. 0.25%		A 6
Oleic acid recovered			22-24 g / 100 g	(3)
Acid value (Oleic acid recovered)			193-206	A 18
Iodine value (Oleic acid recovered			80-92	A 39
Residue on ignition			max. 0.25%	A 6
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006).

(3) Food Chemicals Codex, 8th Edition, 2012, page 918.

(4) WHO Food Additives Series No. 5, 1974, page 254-263. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents.

(5) Reports of the Scientific Committee for Food, Fifteenth Series, 1985.

(6) Scientific Opinion on the re-evaluation of polyoxyethylene sorbitan monolaurate (E 432), polyoxyethylene sorbitan monooleate (E 433), polyoxyethylene sorbitan monopalmitate (E 434), polyoxyethylene sorbitan monostearate (E 435) and polyoxyethylene sorbitan tristearate (E 436) as food additives.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Polyoxyethylene sorbitan monopalmitate (Polysorbate 40)

E Number: E 434

1. Name

English	Polyoxyethylene sorbitan monopalmitate
German	Polyoxyethylen-sorbitan-monopalmitat
French	Monopalmitate de polyoxyéthylène sorbitane
Dutch	Polyoxyethyleen-20-sorbitaan-monopalmitaat
Spanish	Monopalmitato de sorbitan polioxietilenado
Portuguese	Monopalmitato de polioxietileno 20 sorbitano
Italian	Monopalmitato di poliossietilensorbitano
Danish	Polyoxyethylensorbitanmonopalmitat
Swedish	Polyoxietylensorbitanmonopalmitat
Finnish	Polyoksyetyleenisorbitaanimonopalmitaatti
Greek	Μονοπαλμιτική πολυοξυ-αιθυλενο-σορβιτάνη

Synonyms

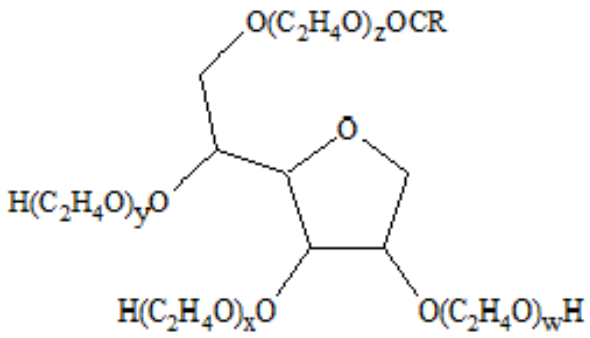
Polysorbate; polyoxyethylene (20) sorbitan monopalmitate.

2. Description

2.1. Chemical description and typical process

Polyoxyethylene sorbitan monopalmitate is a mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial palmitic acid, condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides.

A nominal formula for polyoxyethylene sorbitan monopalmitate is as follows:



where w + x + y + z = approximately 20 and RCO- is the palmitic acid moiety.

2.2. Appearance

Polyoxyethylene sorbitan monopalmitate is a lemon to orange-coloured oily liquid or semi-gel at 25°C, with a faint characteristic odour and a warm, somewhat bitter taste.

2.3. Solubility

Polyoxyethylene sorbitan monopalmitate is soluble in cold and hot water, ethanol, methanol, ethyl acetate and acetone. It is insoluble in mineral oil.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Polyoxyethylene sorbitan monopalmitate has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

The European Food Safety Authority (EFSA) Scientific Opinion on the re-evaluation of Polyoxyethylene sorbitan monolaurate (E 432), polyoxyethylene sorbitan monooleate (E 433), polyoxyethylene sorbitan monopalmitate (E 434), polyoxyethylene sorbitan monostearate (E 435) and polyoxyethylene sorbitan tristearate (E 436) as food additives was published in July 2015 (6).

Evaluation status

Acceptable daily intake (ADI): 0-25 mg/kg bw
as total polyoxyethylene(20)sorbitan esters evaluation by JECFA (2)

Group ADI: 25 mg/kg bw re-evaluation by EFSA (6)

5. Typical applications in food

Polyoxyethylene sorbitan monopalmitate is a strongly hydrophilic surface-active agent. It is used as an emulsifier, often in combination with sorbitan esters, and its structure also enables it to fulfil other functions, such as the modification of fat crystallisation.

Within the EU polyoxyethylene sorbitan monopalmitate is permitted in (7):

- Fine bakery wares*
- Fat emulsions for baking purposes*
- Milk and cream analogues*
- Edible ices*
- Desserts excluding products covered in categories 1, 3 and 4*
- Sugar confectionery*
- Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4*
- Emulsified sauces*
- Soups*
- Chewing gum*
- Dietary food supplements
- Food supplements supplied in a solid, liquid or syrup-type or chewable form including capsules and tablets*Dietetic foods intended for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)*

- Dietetic formulae for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)*

* The additive may be added individually or in combination with other substances in the range E 432-436.

The application of Polyoxyethylene sorbitan monopalmitate is also allowed as carrier and solvent for colours, fat-soluble antioxidants and anti-foaming agents.

6. Non-food applications

- Cosmetics
- Animal feed
- Plastics industry

Specifications: E 434

Polyoxyethylene sorbitan monopalmitate (Polysorbate 40)

	EU (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Content	min. 97% (anhydrous base)	97.0-103.0% (anhydrous base)	97.0-103.0% (anhydrous base)	A 34
Oxyethylene content	min. 66%	66.0-70.5%	66.0-70.5%	A 34
Acid value	max. 2	max. 2	max. 2	A 18
Saponification value	41-52	41-52	41-52	A 19
Hydroxyl value	90-107	90-107	90-107	A 20
Water	max. 3%	max. 3%	max. 3%	A 10
1,4-Dioxane	max. 5 mg/kg			A 9
Ethylene oxide	max. 0.2 mg/kg			No method available
Ethylene glycols (mono- and di-)	max. 0.25%			A 38
Sulphated ash		max. 0.25%	max. 0.25%	A 6
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006)

(3) Food Chemicals Codex, 8th Edition, 2012, page 915

(4) WHO Food Additives Series No. 5, 1974, page 254-263. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents.

(5) Reports of the Scientific Committee for Food, Fifteenth Series, 1985.

(6) Scientific Opinion on the re-evaluation of polyoxyethylene sorbitan monolaurate (E 432), polyoxyethylene sorbitan monooleate (E 433), polyoxyethylene sorbitan monopalmitate (E 434), polyoxyethylene sorbitan monostearate (E 435) and polyoxyethylene sorbitan tristearate (E 436) as food additives.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Polyoxyethylene sorbitan monostearate (Polysorbate 60)

E Number: E 435

1. Name

English	Polyoxyethylene sorbitan monostearate
German	Polyoxyethylen-sorbitan-monostearat
French	Monostéarate de polyoxyéthylène sorbitane
Dutch	Polyoxyethyleen-20-sorbitaan-monostearaat
Spanish	Monoestearato de sorbitan polioxietilenado
Portuguese	Monoestearato de polioxietileno 20 sorbitano
Italian	Monostearato di poliossietilensorbitano
Danish	Polyoxyethylensorbitanmonostearat
Swedish	Polyoxietylensorbitanmonostearat
Finnish	Polyoksyetyleenisorbitaanimonostearaatti
Greek	Μονοστεατική πολυοξυ-αιθυλενο-σορβιτάνη

Synonyms

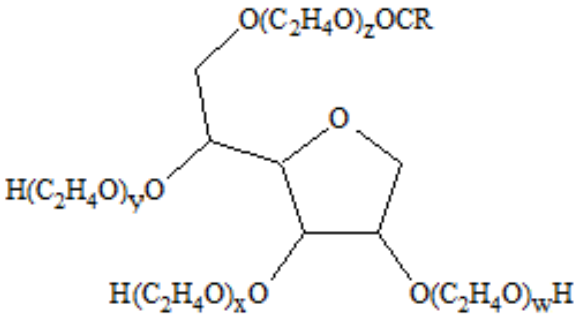
Polysorbate; polyoxyethylene (20) sorbitan monostearate; sorbitan monoocta-decanoate; poly(oxy-1,2-ethanediyl) derivative.

2. Description

2.1. Chemical description and typical process

Polyoxyethylene sorbitan monostearate is a mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial stearic acid, condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides.

A nominal formula for polyoxyethylene sorbitan monostearate is as follows:



where w + x + y + z = approximately 20 and RCO- is the stearic acid moiety.

2.2. Appearance

Polyoxyethylene sorbitan monostearate is a lemon to orange-coloured oily liquid or semi-gel at 25°C, with a faint characteristic odour and a warm, somewhat bitter taste.

2.3. Solubility

Polyoxyethylene sorbitan monostearate is soluble in cold and hot water, ethyl acetate and toluene. It is insoluble in mineral and vegetable oil.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Polyoxyethylene sorbitan monostearate has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

The European Food Safety Authority (EFSA) Scientific Opinion on the re-evaluation of Polyoxyethylene sorbitan monolaurate (E 432), polyoxyethylene sorbitan monooleate (E 433), polyoxyethylene sorbitan monopalmitate (E 434), polyoxyethylene sorbitan monostearate (E 435) and polyoxyethylene sorbitan tristearate (E 436) as food additives was published in July 2015 (6).

Evaluation status

Acceptable daily intake (ADI): 0-25 mg/kg bw
as total polyoxyethylene(20)sorbitan esters evaluation by JECFA (2)

Group ADI: 25 mg/kg bw re-evaluation by EFSA (6)

5. Typical applications in food

Polyoxyethylene sorbitan monostearate is a strongly hydrophilic surface active agent. It is used as an emulsifier, often in combination with sorbitan esters, and its structure also enables it to fulfil other functions, such as the modification of fat crystallisation.

Within the EU polyoxyethylene sorbitan monostearate is permitted in (7):

- Fine bakery wares*
- Fat emulsions for baking purposes*
- Milk and cream analogues*
- Edible ices*
- Desserts excluding products covered in categories 1, 3 and 4*
- Sugar confectionery*
- Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4*
- Emulsified sauces*
- Soups*
- Chewing gum*
- Dietary food supplements
- Food supplements supplied in a solid, liquid or syrup-type or chewable form including capsules and tablets*Dietetic foods intended for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)*
- Dietetic formulae for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)*

* The additive may be added individually or in combination with other substances in the range E 432-436.

The application of Polyoxyethylene sorbitan monostearate is also allowed as carrier and solvent for colours, fat-soluble antioxidants and anti-foaming agents.

6. Non-food applications

- Pharmaceuticals
- Cosmetics
- Animal feed
- Plastics industry

Specifications: E 435

Polyoxyethylene sorbitan monostearate (Polysorbate 60)

	EU (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Content	min. 97% (anhydrous base)	97.0-103.0% (anhydrous base)	97.0-103.0% (anhydrous base)	A 34
Oxyethylene content	min. 65%	65.0-69.5%	65.0-69.5%	A 34
Acid value	max. 2	max. 2	max. 2	A 18
Saponification value	45-55	41-52	45-55	A 19
Hydroxyl value	81-96	90-107	81-96	A 20
Water	max. 3%	max. 3%	max. 3.0%	A 10
1,4-Dioxane	max. 5 mg/kg	max. 10 mg/kg	max. 10 mg/kg	A 9
Ethylene oxide	max. 0.2 mg/kg			No method available
Ethylene glycols (mono- and di-)	max. 0.25%			A 38
Sulphated ash		max. 0.25%		A 6
Residue on ignition			max. 0.25%	A 6
Stearic and palmitic acids recovered			21.5-26.0 g / 100 g	(3)
Acid value (Stearic and palmitic acids recovered)			200-212	A 18
Solidification point (Stearic and palmitic acids recovered)			52°	(3)
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5

Cadmium	max. 1 mg/kg			A 4

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 16 (2014)
Monograph 1 (2006).

(3) Food Chemicals Codex, 8th Edition, 2012, page 915.

(4) WHO Food Additives Series No. 5, 1974, page 254-263. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents.

(5) Reports of the Scientific Committee for Food, Fifteenth Series, 1985.

(6) Scientific Opinion on the re-evaluation of polyoxyethylene sorbitan monolaurate (E 432), polyoxyethylene sorbitan monooleate (E 433), polyoxyethylene sorbitan monopalmitate (E 434), polyoxyethylene sorbitan monostearate (E 435) and polyoxyethylene sorbitan tristearate (E 436) as food additives.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Polyoxyethylene sorbitan tristearate (Polysorbate 65)

E Number: E 436

1. Name

English	Polyoxyethylene sorbitan tristearate
German	Polyoxyethylen-sorbitan-tristearat
French	Tristéarate de polyoxyéthylène sorbitane
Dutch	Polyoxyethyleen-20-sorbitaan-tristearaat
Spanish	Triestearato de sorbitan polioxietilenado
Portuguese	Triestearato de polioxietileno 20 sorbitano
Italian	Tristearato di poliossietilensorbitano
Danish	Polyoxyethylensorbitantristearat
Swedish	Polyoxietylensorbitantristearat
Finnish	Polyoksyetyleenisorbitaanitristearaatti
Greek	Τριστεατική πολυοξυ-αιθυλενο-σορβιτάνη

Synonyms

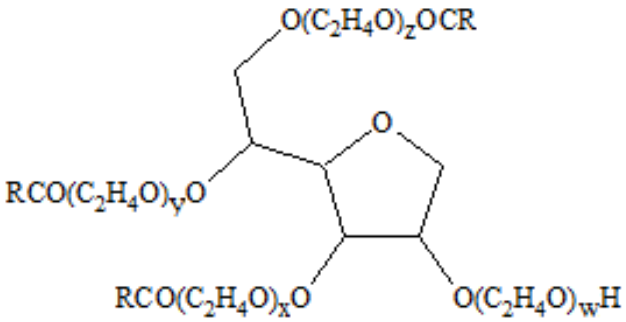
Polysorbate; polyoxyethylene (20) sorbitan tristearate.

2. Description

2.1. Chemical description and typical process

Polyoxyethylene sorbitan tristearate is a mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial stearic acid, condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides.

A nominal formula for polyoxyethylene sorbitan tristearate is as follows:



where w + x + y + z = approximately 20 and RCO- is the stearic acid moiety.

2.2. Appearance

Polyoxyethylene sorbitan tristearate is a tan-coloured, waxy solid at 25°C, with a faint characteristic odour and a waxy, somewhat bitter taste.

2.3. Solubility

Polyoxyethylene sorbitan tristearate is dispersible in cold and hot water. It is soluble in mineral and vegetable oil, petroleum ether, acetone, ether, dioxane, ethanol and methanol.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Polyoxyethylene sorbitan tristearate has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

The European Food Safety Authority (EFSA) Scientific Opinion on the re-evaluation of Polyoxyethylene sorbitan monolaurate (E 432), polyoxyethylene sorbitan monooleate (E 433), polyoxyethylene sorbitan monopalmitate (E 434), polyoxyethylene sorbitan monostearate (E 435) and polyoxyethylene sorbitan tristearate (E 436) as food additives was published in July 2015 (6).

Evaluation status

Acceptable daily intake (ADI): 0-25 mg/kg bw
as total polyoxyethylene(20)sorbitan esters evaluation by JECFA (2)

Group ADI: 25 mg/kg bw re-evaluation by EFSA (6)

5. Typical applications in food

Polyoxyethylene sorbitan tristearate is a strongly hydrophilic surface active agent. It is used as an emulsifier, often in combination with sorbitan esters, and its structure also enables it to fulfil other functions, such as the modification of fat crystallisation.

Within the EU polyoxyethylene sorbitan tristearate is permitted in (7):

- Fine bakery wares*
- Fat emulsions for baking purposes*
- Milk and cream analogues*
- Edible ices*
- Desserts excluding products covered in categories 1, 3 and 4*
- Sugar confectionery*
- Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4*
- Emulsified sauces*
- Soups*
- Chewing gum*
- Dietary food supplements
- Food supplements supplied in a solid, liquid or syrup-type or chewable form including capsules and tablets*Dietetic foods intended for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)*
- Dietetic formulae for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)*

* The additive may be added individually or in combination with other substances in the range E 432-436.

The application of Polyoxyethylene sorbitan tristearate is also allowed as carrier and solvent for colours, fat-soluble antioxidants and anti-foaming agents.

6. Non-food applications

- Cosmetics
- Animal feed
- Plastics industry

Specifications: E 436

Polyoxyethylene sorbitan tristearate (Polysorbate 65)

	EU (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Content	96% (anhydrous base)	96.0-104.0% (anhydrous base)	96.0-104.0% (anhydrous base)	A 34
Oxyethylene content	min. 46%	46.0-50.0%	46.0-50.0%	A 34
Congealing range	29-33°C	29-33°C		A 35
Acid value	max. 2	max. 2	max. 2	A 18
Saponification value	88-98	88-98	88-98	A 19
Hydroxyl value	40-60	40-60	44-60	A 20
Water	max. 3%	max. 3%	max. 3.0%	A 10
1,4-Dioxane	max. 5 mg/kg	max. 10 mg/kg	max. 10 mg/kg	A 9
Ethylene oxide	max. 0.2 mg/kg			No method available
Ethylene glycols (mono- and di-)	max. 0.25%			A 38
Sulphated ash		max. 0.25%		A 6
Residue on ignition			max. 0.25%	A 6
Stearic and palmitic acids recovered			42-44 g / 100 g	(3)
Acid value (Stearic and palmitic acids recovered)			200-212	A 18
Solidification point (Stearic and palmitic acids recovered)			52°	
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
	max.			

Mercury	1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006)

(3) Food Chemicals Codex, 8th Edition, 2012, page 917.

(4) WHO Food Additives Series No. 5, 1974, page 254-263. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents.

(5) Reports of the Scientific Committee for Food, Fifteenth Series, 1985.

(6) Scientific Opinion on the re-evaluation of polyoxyethylene sorbitan monolaurate (E 432), polyoxyethylene sorbitan monooleate (E 433), polyoxyethylene sorbitan monopalmitate (E 434), polyoxyethylene sorbitan monostearate (E 435) and polyoxyethylene sorbitan tristearate (E 436) as food additives.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Ammonium phosphatides

E Number: E 442

1. Name

English	Ammonium phosphatides
German	Ammoniumsalze von Phosphatidsäuren
French	Phosphatides d'ammonium
Dutch	Ammoniumfosfatiden
Spanish	Fosfátidos de amonio
Portuguese	Fosfatidatos de amónio
Italian	Fosfati d'ammonio
Danish	Ammoniumphosphatider
Swedish	Ammoniumfosfatider
Finnish	Ammoniumfosfatidit
Greek	Φωσφατίδια του αμμωνίου

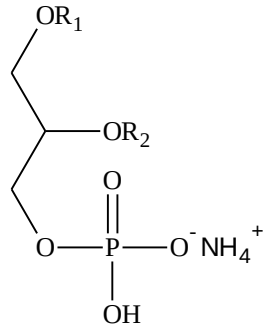
Synonyms

Ammonium salts of phosphatidic acid; mixed ammonium salts of phosphorylated glycerides; EMULSIFIER YN.

2. Description

2.1. Chemical description and typical process

The product consists of a mixture of the ammonium compounds of phosphatidic acids derived from edible fat and oil (usually partially hardened rapeseed oil) together with unreacted fat and oil. The structural formula of the principal components is:



where R_1, R_2 or both represent a fatty acid moiety and the other may represent a fatty acid moiety or hydrogen. Moreover, two phosphorus esters may be linked together as phosphatidyl phosphatides.

The product is produced by phosphorylating partial fatty esters of glycerol. Ammonium salts are then formed by neutralisation with ammonia.

2.2. Appearance

The product is an unctuous semi-solid to oily solid at 25°C.

2.3. Solubility

The product is insoluble in water, partially soluble in ethanol and acetone and soluble in fats.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Ammonium phosphatides have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

The European Food Safety Authority (EFSA) Scientific Opinion on the re-evaluation of Ammonium phosphatides was published in November 2016 (6).

Evaluation status

Acceptable daily intake (ADI): 0-30 mg/kg bw evaluation by SCF, confirmed by EFSA (6)

ADI: of 0-30 mg/kg bw evaluation by JECFA (2)

5. Typical applications in food

Ammonium phosphatides are used to control the viscosity of molten chocolate as a flavour-free substitute for soya lecithin.

Within the EU ammonium phosphatides are permitted in (7):

- Food category (5.1) Cocoa and Chocolate products as covered by Directive 2000/36/EC - ML = 10000 mg/kg
- Food category (5.2) Other confectionery including breath refreshening microsweets - ML = 10000 mg/kg , only cocoa based confectionery
- Food category (5.4) Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4 - ML = 10000 mg/kg , only cocoa based confectionery

The application of Ammonium phosphatides is also allowed as carrier and solvent for colours, fat-soluble antioxidants and anti-foaming agents.

6. Non-food applications

No specific application.

Specifications: E 442

Ammonium phosphatides

	EU (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Phosphorus content	3-3.4%	3.0-3.4%	3.0-3.4%	(2)
Ammonium content calculated as nitrogen (N)	1.2-1.5%	1.2-1.5%	1.2-1.5%	(2)
Petroleum ether insoluble matter	max. 2.5%			A 13
Arsenic	max. 3 mg/kg		max. 3 mg/kg	A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006).

(3) No Food Chemicals Codex specifications available.

(4) WHO Food Additives Series No. 6, 1975, page 160-163. Toxicological evaluation of some food colours, enzymes, flavours enhancers, thickening agents, and certain other food additives.

(5) Reports of the Scientific Committee for Food, Seventh Series, 1978.

(6) Re-evaluation of ammonium phosphatides (E 442) as a food additive.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Sodium, potassium and calcium salts of fatty acids

E Number: E 470a

1. Name

English	Sodium, potassium and calcium salts of fatty acids
German	Natrium-, Kalium- und Calciumsalze von Speisefettsäuren
French	Sels de sodium, de potassium et de calcium d'acides gras
Dutch	Natrium-, kalium- en calciumzouten van vetzuren
Spanish	Sales sódicas, potásicas y cálcicas de ácidos grasos
Portuguese	Sais de cálcio, potássio e sódio de ácidos gordos
Italian	Sali di sodio, di potassio e di calcio degli acidi grassi
Danish	Natrium-, kalium- og calciumsalte af fedtsyrer
Swedish	Natrium-, kalium- och kalciumsalter av fettsyror
Finnish	Rasvahappojen natrium-, kalium- ja kalsiumsuolat
Greek	Άλατα λιπαρών οξέων με νάτριο, κάλιο και ασβέστιο

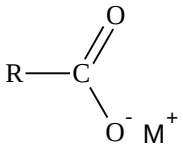
Synonyms

Salts of myristic, palmitic and stearic acids; salts of fatty acids; "soaps"; "stearates".

2. Description

2.1. Chemical description and typical process

The structural formula of the principal components is:



M = Na, K or ½Ca

RCOO represents a fatty acid moiety.

The salts are prepared by the interaction of sodium, potassium or calcium hydroxides or carbonates with edible oils or fats or food grade distilled fatty acids derived from such oils or fats.

2.2. Appearance

White or creamy white light powders, flakes or semi-solids

2.3. Solubility

Sodium and potassium salts are soluble in water. Calcium salts are insoluble in water ethanol and ether.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Sodium, potassium and calcium salts of fatty acids have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

The European Food Safety Authority (EFSA) Scientific Opinion on the re-evaluation of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) as food additives was published in March 2018 (6).

Evaluation status

Acceptable daily intake (ADI): not specified

5. Typical applications in food

Within the EU sodium, potassium and calcium salts of fatty acids are generally permitted for use in foodstuffs (7).

Sodium, potassium and calcium salts of fatty acids are used either alone or together with other fatty acid based emulsifiers, either by direct addition or, as a result of the manufacturing process, as co-emulsifiers. Applications include:

- Baked goods, e.g. bread, cakes, biscuits, rusks
- Confectionery, e.g. chewing gum, toffees, sugar confectionery
- Dairy products, e.g. imitation creams, desserts, edible ices
- Fats, e.g. margarines, spreads, shortenings
- Starch, e.g. mashed potatoes, pasta
- Salad dressings and sauces
- Table-top sweeteners in tablets
- Dried herbs and spices

6. Non-food applications

- Pharmaceutical and cosmetic preparations
- General washing and cleaning
- Paints
- Binding agents

Specifications: E 470a

Sodium, potassium and calcium salts of fatty acids

	EU (1)	**FAO/WHO** (2)	**FCC** ** (3)	Recommended Analytical Methods ¤
Fatty acid salts (anhydrous basis)	min. 95%	min. 95%		(2)
Unsaponifiable matter	max. 2%	max. 2%		(2)
Free fatty acids	max. 3% (as oleic acid)	max. 3%	max. 3.0% (as stearic acid)	A 15
Free alkali	max. 0.1% (as NaOH)			A 7 + A 8 ***
Matter insoluble in alcohol	max. 0.2%*			A 12
Sodium	9-14% (as Na_2O)			A 31
Potassium	13-21.5% (as K_2O)			A 30
Calcium	8.5-13% (as CaO)		9.0-10.5% (as CaO)	(3)
Loss on drying (105°, 1 h)			max. 4.0%	A 11
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

* Sodium and potassium salts only.

** Calcium stearates and palmitates.

*** Free alkali in sodium salts - A 7
Free alkali in potassium salts - A 8
Free alkali in calcium salts - no official method.

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): INS No 470 "Salts of Fatty Acids" - Monograph 1 (2006)

(3) Food Chemicals Codex, 8th Edition, 2012, page 193.

(4) WHO Food Additives Series No. 5, 1974, page 19-20. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents.

(5) Reports of the Scientific Committee for Food, Twenty-Fifth Series, 1990.

(6) Re-evaluation of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) as food additives.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Magnesium salts of fatty acids

E Number: E 470b

1. Name

English	Magnesium salts of fatty acids
German	Magnesiumsalze von Speisefettsäuren
French	Sels de magnésium d'acides gras
Dutch	Magnesiumzouten van vetzuren
Spanish	Sales magnésicas de ácidos grasos
Portuguese	Sais de magnésio de ácidos gordos
Italian	Sali di magnesio degli acidi grassi
Danish	Magnesiumsalte af fedtsyrer
Swedish	Magnesiumsalter av fettsyror
Finnish	Rasvahappojen magnesiumsuolat
Greek	Άλατα λιπαρών οξέων με μαγνήσιο

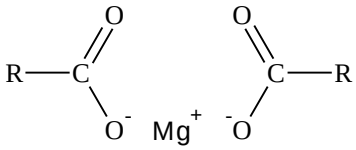
Synonyms

Magnesium salts of myristic, palmitic and stearic acids; magnesium salts of fatty acids; magnesium "soaps"; magnesium stearate.

2. Description

2.1. Chemical description and typical process

The structural formula of the principal components is:



RCOO represents a fatty acid moiety

The salts are prepared by the interaction of magnesium hydroxide or carbonate with edible oils or fats or food grade distilled fatty acids derived from such oils or fats.

2.2. Appearance

Magnesium salts of fatty acids occur as white or creamy-white light powders, flakes or semi-solids.

2.3. Solubility

Magnesium salts are insoluble in water and partially soluble in ethanol and ether.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Magnesium salts of fatty acids have been evaluated by the Scientific Committee for Food (5). The European Food Safety Authority (EFSA) Scientific Opinion on the re-evaluation of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) as food additives was published in March 2018 (6).

Evaluation status

Acceptable daily intake (ADI): not specified

5. Typical applications in food

Within the EU magnesium salts of fatty acids are generally permitted for use in foodstuffs (7).

Magnesium salts of fatty acids are used as anticaking and binding agents. In addition, they can also be used together with other fatty acid based emulsifiers, either by direct addition or, as a result of the manufacturing process, as co-emulsifiers.
Applications include:

- Baked goods, e.g. bread, cakes, biscuits
- Confectionery, e.g. chewing gum, toffees, sugar confectionery
- Dairy products, e.g. milk powders, desserts, edible ices
- Fats, e.g. margarines, spreads, shortenings
- Starch, e.g. mashed potatoes, pasta
- Salad dressings and sauces
- Instant drinks
- Table top sweeteners in tablets

6. Non-food applications

- Pharmaceutical and cosmetic preparations
- Anticaking agent
- Binding and tabletting agent.

Specifications: E 470b

Magnesium salts of fatty acids

	EU (1)	**FAO/WHO** (2)	**FCC*** (3)	Recommended Analytical Methods ¤
Fatty acid salts (anhydrous basis)	min. 95%			No official method
Unsaponifiable matter	max. 2%			A 14
Free fatty acids	max. 3% (as oleic acid)			A 15
Free alkali	max. 0.1% (as MgO)			No official method
Magnesium	6.5-11% (as MgO)		6.8-8.3% (as MgO)	(3)
Loss on drying (105°, 1 h)			max 4.0%	A 11
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg		max. 5 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

* Magnesium stearate and palmitate.

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) No FAO/WHO specifications available.

(3) Food Chemicals Codex, 8th Edition, 2012, page 682.

(4) No WHO evaluation available.

(5) Reports of the Scientific Committee for Food, Twenty-fifth Series, 1990.

(6) Re-evaluation of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) as food additives.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Mono- and diglycerides of fatty acids

E Number: E 471

1. Name

English	Mono- and diglycerides of fatty acids
German	Mono- und Diglyceride von Speisefettsäuren
French	Mono- et diglycérides d'acides gras
Dutch	Mono- en diglyceriden van vetzuren
Spanish	Mono- y diglicéridos de ácidos grasos
Portuguese	Mono e diglicéridos de ácidos gordos
Italian	Mono- e digliceridi degli acidi grassi
Danish	Mono- og diglycerider af fedtsyrer
Swedish	Mono- och diglycerider av fettsyror
Finnish	Rasvahappojen mono- ja diglyseridit
Greek	Μονο- και δι-γλυκερίδια λιπαρών οξέων

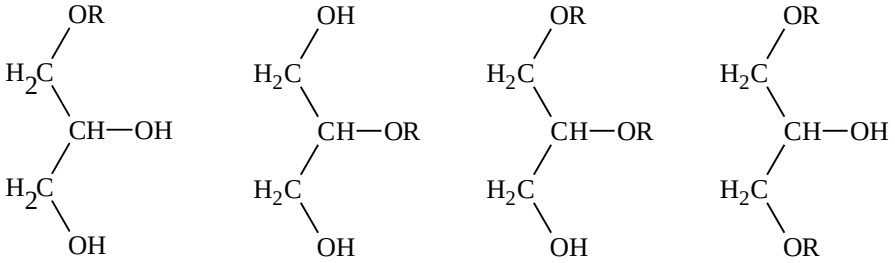
Synonyms

Glyceryl monostearate, glyceryl monopalmitate, glyceryl monooleate, etc.; monostearin, monopalmitin, monoolein, etc.; GMS (for glycerol monostearate). INS No. 471

2. Description

2.1. Chemical description and typical process

These products consist of mixtures of glycerol mono-, diesters of fatty acids occurring in food oils and fats. They may contain small amounts of free fatty acids, triesters of fatty acids and glycerol. The structural formulae of the principal components are:



1-monoester	2-monoester	1,2-diester	1,3-diester
α-monoester	β-monoester	α,β-diester	α,α-diester

R represents a fatty acid moiety.

The products are produced either by heating oils or fats with an excess of glycerol or by direct esterification of glycerol with fatty acids.

The proportion of monoester thus produced is dependent on the proportion of glycerol and the temperature of reaction and is usually in the range of 30-60%. Products with more than 90% monoester content are produced by high vacuum distillation or other techniques.

2.2. Appearance

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.

2.3. Solubility

The product is typically insoluble in water, soluble in ethanol and toluene at 50 °C.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Mono- and diglycerides of fatty acids have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

The European Food Safety Authority (EFSA) Scientific Opinion on the re-evaluation of Mono- and diglycerides of fatty acids were re-evaluated was published in November 2017 (6).

Evaluation status

No need for a numerical ADI EFSA re-evaluation (6)

An ADI not limited' JECFA evaluation (2)

5. Typical applications in food

Within the EU mono- and diglycerides of fatty acids are generally permitted for use in foodstuffs (7).

Mono- and diglycerides of fatty acids are used principally as emulsifiers, starch-complexing agents, and aerating agents and they are widely used.

Applications include:

- Bread prepared solely with the following ingredients: wheat flour, water, yeast or leaven, salt, e.g. pain courant Français, Friss búzakenyér, fehér és félbarna kenyerek
- Confectionery, e.g. chocolate, chewing gum, toffees, caramels, coatings and decorations
- Dairy products, e.g. cream and cream powder, imitation creams, desserts, edible ices
- Unflavoured live fermented cream products and substitute products with a fat content of less than 20 %
- Fats and oils essentially free from water (excluding anhydrous milkfat), e.g. margarines, shortenings
- Starch, e.g. mashed potatoes, pasta
- Fresh and pre-cooked pasta and cereals (quick-cook rice)
- as defined by Directive 2001/113/EC
- Jam, jellies, extra jam, extra jelly, marmalades and sweetened chestnut purée as defined by Directive 2001/113/EC
- Other similar fruit or vegetable spreads
- Table top sweeteners in tablets
- Precooked and processed cereals
- Infant formulae and follow-on formulae as defined by Directive 2006/141/EC*
- Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC**

- Other foods for young children***
- Dietary foods for infants for special medical purposes and special formulae for infants
- Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC

* If more than one of the substances E 322, E 471, E 472c and E 473 are added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substances together in that foodstuff
** E 471, E 472a, E 472b and E 472c are authorised individually or in combination
*** If more than one of the substances E 322, E 471, E 472c and E 473 are added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substances together in that foodstuff

6. Non-food applications

- Cosmetics
- Pharmaceutical preparations
- Cement and concrete additives (mould release agent)
- Polishes
- Shoe waxes
- Plastics industry (polymer additive)
- Paper cutting industry
- Coatings

Specifications: E 471

Mono- and diglycerides of fatty acids

	EU * (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Mono- and Diesters	min. 70%			A 27
α-monoglyceride content		min. 30%		A 28
Total glycerol	16-33%			A 22
Free glycerol	max. 7%	max. 7%	max. 7.0%	A 16
Polyglycerols **	max. 4% + 1%			A 26
Soap (as sodium oleate)		max. 6%		(2)
Sulphated ash	max. 0.5% (determined at 800 ± 25°C)			A 6
Acid value	max. 6	max. 6	max. 6	A 18
Water	max. 2%	max. 2.0%		A 10
Residue on ignition			max. 0.5%	A 6
Arsenic	max. 3 mg/kg		max. 3 mg/kg	A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

* 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).

** Not more than 4% diglycerol and not more than 1% higher polyglycerols both based on total glycerol content.

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006)

(3) Food Chemicals Codex, 8th Edition, 2012, page 773.

(4) WHO Food Additives Series No. 5, 1974, page 238-240. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents.

(5) Reports of the Scientific Committee for Food, Fifth Series, 1978.

(6) Re-evaluation of mono- and di-glycerides of fatty acids (E 471) as food additives.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Acetic acid esters of mono- and diglycerides of fatty acids

E Number: E 472a

1. Name

English	Acetic acid esters of mono- and diglycerides of fatty acids
German	Essigsäureester von Mono- und Diglyceriden von Speisefettsäuren
French	Esters acétiques des mono- et diglycérides d'acides gras
Dutch	Mono- en diglyceriden van vetzuren veresterd met azijnzuur
Spanish	Ésteres acéticos de los mono- y diglicéridos de los ácidos grasos
Portuguese	Ésteres acéticos de mono e diglicéridos de ácidos gordos
Italian	Esteri acetici di mono- e digliceridi degli acidi grassi
Danish	Eddikesyreestere af mono- og diglycerider af fedtsyrer
Swedish	Mono- och diglyceriders ättiksyraestrar
Finnish	Rasvahappojen mono- ja diglyseridien etikkahappoesterit
Greek	Εστέρες του οξικού οξέος με μονο- και δι-γλυκερίδια λιπαρών οξέων

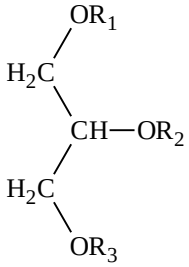
Synonyms

ACETEM; acetic acid esters of mono- and diglycerides; acetoglycerides; acetylated mono- and diglycerides; acetic and fatty acid esters of glycerol; acetylated monoglycerides., INS 472a.

2. Description

2.1. Chemical description and typical process

The product is a mixture of esters of acetic acid 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. The structural formula of the principal components is:



where at least one of R_1, R_2 or R_3 represents an acetic acid moiety, one represents a fatty acid moiety, and the remainder may represent acetic acid, fatty acid or hydrogen.

The distribution of the principal components is dependent on the proportion of acetic acid, fatty acids and glycerol and the reaction conditions used.

The product may be manufactured by reacting mono- and diglycerides of edible fatty acids with acetic anhydride or by transesterification of edible fats with triacetin.

2.2. Appearance

The product is a clear, mobile liquids to solids, from white to pale yellow in colour.

2.3. Solubility

The product is typically insoluble in cold and hot water and soluble in ethanol.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Acetic acid esters of mono- and diglycerides of fatty acids have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

Evaluation status

Acceptable daily intake (ADI): not specified

ADI 'not limited' JECFA evaluation (2)

5. Typical applications in food

Within the EU acetic acid esters of mono- and diglycerides are generally permitted for use in foodstuffs (6).

Acetic acid esters of mono- and diglycerides have excellent aerating and foam stabilising properties. They are also used as lubricants and release agents. Applications include:

- Topping powders
- Chewing gum base
- Coatings
- Cakes
- Quick-cook rice
- Bread prepared solely with the following ingredients: wheat flour, water, yeast or leaven, salt
- Biscuits and rusks, cereal-based foods, baby foods*
- Pre-cooked or processed cereals
- Processed cereal based foods and baby foods for infants and young children

* Authorised individually or in combination with E 471, E472b and E 472c.

6. Non-food applications

- Emulsifier in cosmetic preparations
- Plasticiser and slip agent for waxes on paper products
- Solvating plasticiser for polyvinyl chloride and other plastics

Specifications: E 472a

Acetic acid esters of mono- and diglycerides of fatty acids

	EU * (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Acids other than acetic and fatty acids	< 1%			No official method.
Total acetic acid	9-32%			A 23
Total glycerol	14-31%			A 22
Free glycerol	max. 2%			A 16
Free fatty acids (and acetic acid)	max. 3% (as oleic acid)			A 15
Sulphated ash	max. 0.5% (800 ± 25°C)			A 6
Acid value			max. 6	A 18
Reichert-Meissl Value			75-200	A 32
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

* 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).

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006)

(3) Food Chemicals Codex, 8th Edition, 2012, page 20.

(4) WHO Food Additives Series No. 5, 1974, page 210-213. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents.

(5) Reports of the Scientific Committee for Food, Seventh Series, 1978.

(6) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Lactic acid esters of mono- and diglycerides of fatty acids

E Number: E 472b

1. Name

English	Lactic acid esters of mono- and diglycerides of fatty acids
German	Milchsäureester von Mono- und Diglyceriden von Speisefettsäuren
French	Esters lactiques des mono- et diglycérides d'acides gras
Dutch	Mono- en diglyceriden van vetzuren veresterd met melkzuur
Spanish	Ésteres lácticos de los mono- y diglicéridos de los ácidos grasos
Portuguese	Ésteres lácticos de mono e diglicéridos de ácidos gordos
Italian	Esteri lattici di mono- e digliceridi degli acidi grassi
Danish	Mælkesyreestere af mono- og diglycerider af fedtsyrer
Swedish	Mono- och diglyceriders mjölksyraestrar
Finnish	Rasvahappojen mono- ja diglyseridien maitohappoesterit
Greek	Εστέρες του γαλακτικού οξέος με μονο- και δι-γλυκερίδια λιπαρών οξέων

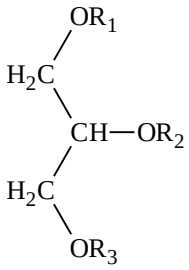
Synonyms

LACTEM; lactic acid esters of mono- and diglycerides; lactoglycerides; lactic and fatty acid esters of glycerol; mono- and diglycerides of fatty acids esterified with lactic acid; glyceryl-lacto esters of fatty acids; lactated mono-diglycerides; GLP, INS 472b.

2. Description

2.1. Chemical description and typical process

The product consists of 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. The structural formula of the principal components is:



where at least one of R_1, R_2 or R_3 represents a lactic acid moiety, one represents a fatty acid moiety, and the remainder may represent lactic acid, fatty acid or hydrogen.

The distribution of the principal components is dependent on the proportion of lactic acid, fatty acids and glycerol and the reaction conditions used.

The product may be manufactured by the esterification of glycerol with lactic acid and edible fatty acids or by lactylation of a mixture of mono- and diglycerides of edible fatty acids.

2.2. Appearance

Clear, mobile liquids to waxy solids of variable consistency, from white to pale yellow in colour.

2.3. Solubility

The product is typically dispersible in hot water but insoluble in cold water.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Lactic acid esters of mono- and diglycerides of fatty acids have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

Evaluation status

Acceptable daily intake (ADI): not specified

ADI 'not limited' JECFA evaluation (2)

5. Typical applications in food

Within the EU lactic acid esters of mono- and diglycerides are generally permitted for use in foodstuffs (6).

Lactic acid esters of mono- and diglycerides are used to improve aeration and foam stability as well as texture and volume. Applications include:

- Topping powders
- Non-dairy creams
- Dairy and recombined creams
- Fine bakery wares
- Shortening
- Chocolate compounds
- Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC (only biscuits and rusks, cereal-based foods, baby foods)*

* Authorised individually or in combination with E 471, E472a and E 472c.

6. Non-food applications

No specific applications.

Specifications: E 472b

Lactic acid esters of mono- and diglycerides of fatty acids

	EU * (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Acids other than lactic and fatty acids	<1%			No official method
Total lactic acid	13-45%			A 24
Total glycerol	13-30%			A 22
Free glycerol	max. 2%			A 16
Free fatty acids (and lactic acid)	max. 3% (as oleic acid)			A 15
Sulphated ash	max. 0.5% (800 ± 25°C)			A 6
Unsaponifiable matter			max. 2.0%	A 14
Residue on ignition			max. 0.1%	A 6
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 0.5 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

* 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).

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006)

(3) Food Chemicals Codex, 8th Edition, 2012, page 513.

(4) WHO Food Additives Series No. 5, 1974, page 231-233. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents.

(5) Reports of the Scientific Committee for Food, Seventh Series, 1978.

(6) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Citric acid esters of mono- and diglycerides of fatty acids

E Number: E 472c

1. Name

English	Citric acid esters of mono- and diglycerides of fatty acids
German	Citronensäureester von Mono- und Diglyceriden von Speisefettsäuren
French	Esters citriques des mono- et diglycérides d'acides gras
Dutch	Mono- en diglyceriden van vetzuren veresterd met citroenzuur
Spanish	Ésteres cítricos de los mono- y diglicéridos de los ácidos grasos
Portuguese	Ésteres cítricos de mono e diglicéridos de ácidos gordos
Italian	Esteri citrici di mono- e digliceridi degli acidi grassi
Danish	Citronsyreestere af mono- og diglycerider af fedtsyrer
Swedish	Mono- och diglyceriders citronsyraestrar
Finnish	Rasvahappojen mono- ja diglyseridien sitruunahappoesterit
Greek	Εστέρες του κιτρικού οξέος με μονο- και δι-γλυκερίδια λιπαρών οξέων

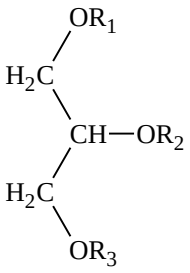
Synonyms

CITREM; citric acid esters of mono- and diglycerides; citroglycerides; citric and fatty acid esters of glycerol; mono- and diglycerides of fatty acids esterified with citric acid.

2. Description

2.1. Chemical description and typical process

The product is a mixture of esters of citric acid and edible fatty acids with glycerol. They may contain small amounts of free glycerol, free fatty acids, free citric acid and free glycerides. The structural formula of the principal components is:



where at least one of R_1, R_2 or R_3 represents a citric acid moiety, one represents a fatty acid moiety, and the remainder may represent citric acid, fatty acid or hydrogen.

The distribution of the principal components is dependent on the proportion of citric acid, fatty acids and glycerol and the reaction conditions used. The product can be partially or wholly neutralised to the corresponding sodium or potassium salts.

The esters may be produced by the esterification of glycerol with citric acid and edible fatty acids or by reaction of a mixture of mono- and diglycerides of edible fatty acids with citric acid.

2.2. Appearance

Yellowish or light brown liquids to waxy solids or semi-solids.

2.3. Solubility

The product is typically dispersible in hot water, insoluble in cold water and in cold ethanol and soluble in edible oils and fats.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Citric acid esters of mono- and diglycerides of fatty acids have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

Evaluation status

Acceptable daily intake (ADI): not specified

ADI 'not limited' JECFA evaluation (2)

5. Typical applications in food

Within the EU citric acid esters of mono- and diglycerides of fatty acids are generally permitted for use in foods (6).

The product is widely used within the food industry, e.g. as an emulsifier, stabiliser, antispattering agent, flour improver, protein-binding agent and as a synergist for antioxidants. The following should only be considered as typical major applications:

- In fats for stabilising, also as synergists for antioxidants
- In baking fat emulsions, bakery margarines and shortening for stabilising
- In fats and oils essentially free from water, excluding anhydrous milkfat (only for cooking and/or frying purposes or for the preparation of gravy)
- In flour for improving the baking performance of "ready-to-use" flours
- In bread dough or other yeast doughs for improving baking performance
- In margarine as emulsifiers and antispattering agents
- In mayonnaise, salad dressings, sauces etc. as emulsifiers and stabilisers
- In sausages for enhancing the binding effects of meat
- In low-calorie food for fats, shortenings and baking fat emulsions with high water content to lower the fat intake
- In cocoa and Chocolate products as covered by Directive 2000/36/EC
- In infant formulae as defined by Directive 2006/141/EC (only when sold as powder or only sold as liquid where the products contain partially hydrolysed proteins, peptides or amino acids)*
- Follow-on formulae as defined by Directive 2006/141/EC (only when sold as powder or only sold as liquid where the products contain partially hydrolysed proteins, peptides or amino acids)*
- Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC (only biscuits and rusks, cereal-based foods, baby foods)**

- Other foods for young children (only when sold as powder or only sold as liquid where the products contain partially hydrolysed proteins, peptides or amino acids)*
- Dietary foods for infants for special medical purposes and special formulae for infants (only when sold as powder or liquid; From birth onwards)Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC (only when sold as powder or liquid; From birth onwards)

* If more than one of the substances E 322, E 471, E 472c and E 473 are added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substances together in that foodstuff
** E 471, E 472a, E 472b and E 472c are authorised individually or in combination

6. Non-food applications

- Pharmaceutical preparations and cosmetic creams
- As blending agent in coatings for cellophane food-contact film

Specifications: E 472c

Citric acid esters of mono- and diglycerides of fatty acids

	EU * (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Acids other than citric and fatty acids	<1%			No official method
Total citric acid	13-50%	13-50%	13-50%	(2)
Total glycerol	8-33%	8-33%	8-33%	(2)
Free glycerol	max. 2%	max. 4%	max. 4%	A 16
Total fatty acids (as oleic acid)		37-81%	37-81%	(2)
Sulphated ash (800 ± 25°C)	max. 0.5% max10%**	max. 0.5% max. 10%**		A 6
Residue on ignition			max. 0.5% max. 10%**	A 6
Lead	max. 2 mg/kg	max. 2 mg/kg Max. 0.5 mg/kg for use in infant formula and formula for special medical purposes intended for infants.	max. 2 mg/kg	A 2
Acid value	Max. 130			A 18

* 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).

** Not neutralised products: max. 0.5%; partially or wholly neutralised products: max. 10%.

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition):

Monograph 19 (2016)
Monograph 16 (2014)
Monograph 1 (2006)

(3) Food Chemicals Codex, 7th Edition, 3rd Supplement.

(4) WHO Food Additives Series No. 5, 1974, page 220-221. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents.

(5) Reports of the Scientific Committee for Food, Seventh Series, 1978.

(6) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Mono- and diacetyl tartaric acid esters of mono- and diglycerides of fatty acids

E Number: E 472e

1. Name

English	Mono- and diacetyl tartaric acid esters of mono- and diglycerides of fatty acids
German	Mono- und Diacetylweinsäureester von Mono- und Diglyceriden von Speisefettsäuren
French	Esters monoacétyltartrique et diacétyltartrique des mono- et diglycérides d'acides gras
Dutch	Mono- en diglyceriden van vetzuren veresterd met mono- en diacetylwijnsteenzuur
Spanish	Ésteres monoacetil y diacetil tartárico de los mono- y diglicéridos de los ácidos grasos
Portuguese	Ésteres monoacetiltartáricos e diacetiltartáricos de mono e diglicéridos de ácidos gordos
Italian	Esteri mono- e diacetiltartarici di mono- e digliceridi degli acidi grassi
Danish	Mono- og diacetylvinsyreestere af mono- og diglycerider af fedtsyrer
Swedish	Mono- och diglyceriders mono- och diacetylvinsyra-estrar
Finnish	Rasvahappojen mono- ja diglyseridien mono- ja diasetyyliviinihappoesterit
Greek	Εστέρες του μονο- και δι-ακετυλο-τρυγικού οξέος με μονο-και δι-γλυκερίδια λιπαρών οξέων

Synonyms

DATEM; diacetyltartaric acid esters of mono- and diglycerides; mono- and diglycerides of fatty acids esterified with mono- and diacetyltartaric acid; diacetyltartaric and fatty acid esters of glycerol.

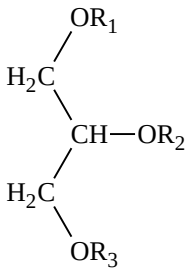
2. Description

2.1. Chemical description and typical process

Mono- and diacetyl tartaric acid esters of mono- and diglycerides can be described as esters of glycerol with mono- and diacetyl tartaric acids and fatty acids occurring in food fats and oils.

The products are obtained either by reacting mono- and diglycerides of fatty acids with diacetyl tartaric acid anhydride in the presence of acetic acid or by esterification of mono- and diglycerides with tartaric acid and acetic acid in the presence of acetic acid anhydride.

Due to inter and intra-molecular acyl group exchange, both methods of production lead to the same essential components that can be described as follows:



in which one of R1, R2 or R3 is a fatty acid moiety with another hydrogen, or two of R1, R2, R3 are fatty acid moieties. The remainder is either

a) diacetylated tartaric acid moiety
b) monoacetylated tartaric acid moiety
c) tartaric acid moiety
d) acetic acid moiety

The distribution of the components described above depends on the relative proportions of the basic raw materials and the reaction conditions used. The products may contain small amounts of free glycerol, free fatty acids, free tartaric and acetic acids and their combinations and free glycerides.

2.2. Appearance

The product varies from sticky viscous liquids through a fat-like consistency to yellow waxes in flake or powder form, which hydrolyse in moist air to liberate acetic acid.

2.3. Solubility

The product is typically dispersible in cold and hot water and soluble in methanol, ethanol and acetone.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Mono- and diacetyl tartaric acid esters of mono- and diglycerides of fatty acids have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

Evaluation status

Acceptable daily intake (ADI): 0-50 mg/kg bw - evaluation by JECFA

Acceptable daily intake (ADI): 0-25 mg/kg bw (temp.) - evaluation by SCF

5. Typical applications in food

Within the EU mono- and diacetyl tartaric acid esters of mono- and diglycerides are generally permitted for use in foodstuffs (6).

Mono- and diacetyl tartaric acid esters of mono- and diglycerides are used as dough conditioners for all baked products, particularly yeast-leavened products, white bread and rusks, and in ready-mixed flours, particularly for use in the "all-in" method. Other applications include:

- Beverage whiteners
- Cream analogues
- Chewing gum
- Meat and poultry products
- Emulsified sauces
- Canned coffee or tea
- Carriers or solvents for colours and food antioxidants
- Bread prepared solely with the following ingredients: wheat flour, water, yeast or leaven, salt

6. Non-food applications

No specific applications.

Specifications: E 472e

Mono- and diacetyl tartaric acid esters of mono- and diglycerides of fatty acids

	EU * (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Acids other than acetic, tartaric and fatty acids	< 1%			No official method.
Total tartaric acid	10-40%	10-40%	17.0-20.0 g / 100 g	(2)
Total acetic Acid	8-32%	8-32%	14.0-17.0 g / 100 g	(2)
Total glycerol	11-28%	11-28%	12.0 g / 100 g	(2)
Free glycerol	max. 2%	max. 2.0%		A 16
Total fatty acids			min. 56.0 g / 100 g	A 21
Sulphated ash (800 ± 25°C)	max. 0.5%	max. 0.5%	Max 0,5%	A 6
Acid value	40-130	40-130	62-76	A 18
Residue on Ignition				A 6
Saponification value			380-425	A 19
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

* 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).

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): INS 472e and 472 f "Diacetyl tartaric and fatty acid esters of Glycerol" -Monograph 7 (2009), Monograph 1 (2006)

(3) Food Chemicals Codex, 8th Edition, 2012, page 336.

(4) WHO Food Additives Series No. 5, 1974, page 222-224. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents.

SUMMARY AND CONCLUSIONS. JECFA 61. meeting Rome, 10-19 June 2003.

(5) Minutes of the 107th Meeting of the Scientific Committee for Food, 1997.

(6) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids

E Number: E 472f

1. Name

English	Mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids
German	Gemischte Essig- und Weinsäureester von Mono- und Diglyceriden von Speisefettsäuren
French	Esters mixtes acétiques et tartriques des mono- et diglycérides d'acides gras
Dutch	Mono- en diglyceriden van vetzuren veresterd met een mengsel van azijnzuur en wijnsteenzuur
Spanish	Ésteres mixtos acéticos y tartáricos de los mono- y diglicéridos de los ácidos grasos
Portuguese	Ésteres mistos acéticos e tartáricos de mono e diglicéridos de ácidos gordos
Italian	Esteri misti acetici-tartarici di mono- e digliceridi degli acidi grassi
Danish	Blandede eddike- og vinsyreestere af mono- og diglycerider af fedtsyrer
Swedish	Blandning av mono- och diglyceriders ättiksyra- och vinsyraestrar
Finnish	Rasvahappojen mono- ja diglyseridien sekoitetut etikka- ja viinihappoesterit
Greek	Μικτοί εστέρες του οξικού και τρυγικού οξέος με μονο- και δι-γλυκερίδια λιπαρών οξέων

Synonyms

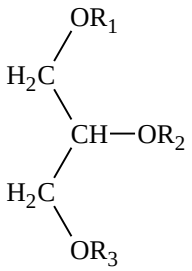
MATEM; mono- and diglycerides of fatty acids esterified with acetic acid and tartaric acid; tartaric, acetic and fatty acid esters of glycerol, mixed.

2. Description

2.1. Chemical description and typical process

Mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids can be described as esters of glycerol with acetic and tartaric acids and fatty acids occurring in food fats and oils. The products are obtained either by reacting mono- and diglycerides of fatty acids with tartaric acid anhydride in the presence of acetic acid or by esterification of mono- and diglycerides with tartaric acid and acetic acid in the presence of acetic acid anhydride.

Due to inter and intra-molecular acyl group exchange, both methods of production result in the same essential components. These can be described as follows:



in which one of R1, R2 or R3 is a fatty acid moiety with another hydrogen, or two of R1, R2, R3 are fatty acid moieties. The remainder is either

a) tartaric acid moiety
b) acetic acid moiety
c) diacetylated tartaric acid moiety
d) monoacetylated tartaric acid moiety

The distribution of the components described above depends on the relative proportions of the basic raw materials and the reaction conditions used. The products may contain small amounts of free glycerol, free fatty acids, free tartaric and acetic acids and free glycerides. The product may contain mono- and diacetyltartaric esters of mono- and diglycerides of fatty acids.

2.2. Appearance

The product varies from sticky liquids to solids, from white to pale-yellow in colour.

2.3. Solubility

The product is typically dispersible in water and soluble in methanol, ethanol and acetone.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids have been evaluated by the Scientific Committee for Food (4). This emulsifier has also been considered by the Joint FAO/WHO Expert Committee on Food Additives in conjunction with DATEM (5).

Evaluation status

Acceptable daily intake (ADI): not specified - evaluation by SCF

Acceptable daily intake (ADI): 0-50 mg/kg bw - evaluation by JECFA

5. Typical applications in food

Within the EU mixed acetic and tartaric acid esters of mono- and diglycerides are generally permitted for use in foodstuffs (6).

Mixed acetic and tartaric acid esters of mono- and diglycerides are used as dough conditioners for all baked products, particularly yeast-leavened products, white bread and rusks, and in ready-mixed flours, particularly for use in the "all-in" method. Other applications include:

- Beverage whiteners
- Cream analogues
- Chewing gum
- Meat and poultry products
- Emulsified sauces
- Canned coffee or tea
- Carriers or solvents for colours and food antioxidants
- Bread prepared solely with the following ingredients: wheat flour, water, yeast or leaven, salt

6. Non-food applications

No specific applications.

Specifications: E 472f

Mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids

	EU * (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Acids other than acetic, tartaric and fatty acids	**<1.0%**			No official method
Total tartaric acid	20-40%			(2)
Total acetic Acid	10-20%			(2)
Total glycerol	12-27%			(2)
Free glycerol	max. 2%			A 16
Free fatty acids (as oleic acid)	max. 3%			No official method
Sulphated ash	max. 0.5% (800 ± 25°C)			A 6
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg			A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

* 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).

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) No JECFA specification available.

(3) No Food Chemicals Codex specifications available.

(4) Reports of the Scientific Committee for Food, Seventh Series, 1978.

(5) SUMMARY AND CONCLUSIONS. JECFA 61. meeting Rome, 10-19 June 2003.

(6) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Sucrose esters of fatty acids

E Number: E 473

1. Name

English	Sucrose esters of fatty acids
German	Zuckerester von Speisefettsäuren
French	Sucroesters d'acides gras
Dutch	Sucrose-vetzuuresters
Spanish	Sucroésteres de ácidos grasos
Portuguese	Ésteres de sacarose de ácidos gordos
Italian	Esteri di saccarosio degli acidi grassi
Danish	Saccharoseestere af fedtsyrer
Swedish	Sackarosestrar av fettsyror
Finnish	Rasvahappojen sakkaroosiesterit
Greek	Εστέρες λιπαρών οξέων με σακχαρόζη

Synonyms

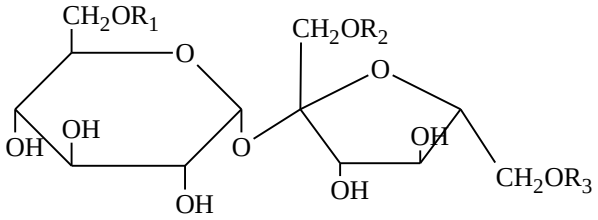
Sucroesters; sugar esters; sucrose fatty acid esters.

2. Description

2.1. Chemical description and typical process

Sucrose esters of fatty acids are essentially the mono-, di- and triesters of sucrose with fatty acids occurring in food fats and oils.

The structural formula of the principal components is:



where at least one of R_1, R_2 or R_3 represents a fatty acid moiety and the remainder may represent fatty acid or hydrogen.

The products may be prepared from sucrose and the methyl and ethyl esters of food fatty acids or by extraction from sucroglycerides.

Depending on the food legislation applicable the following organic solvents are used in their production: dimethylsulphoxide, dimethylformamide, ethyl acetate, propane-2-ol, 2-methyl-1-propanol, propylene glycol, methyl ethyl ketone or isobutanol.

2.2. Appearance

Products based on saturated fatty acids are white to slightly greyish powders.

Products based on unsaturated fatty acids are yellowish, pasty to waxy substances.

2.3. Solubility

The products are sparingly soluble in water and soluble in ethanol. They are insoluble in vegetable oils.

The more fatty acids are linked to saccharose, the higher the fat solubility and the lower the swelling ability in water.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Sucrose esters of fatty acids have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4).

Evaluation status

Acceptable daily intake (ADI): 0-30 mg/kg bw
(Group ADI for sucrose esters of fatty acids and sucroglycerides)

The European Food safety Authority (EFSA) Scientific Opinion on the safety of sucrose esters of fatty acids prepared from vinyl esters of fatty acids and on the extension of use of sucrose esters of fatty acids in flavourings was published in March 2010 (5).

EFSA: exposure assessment published in 2012 and "refined exposure assessment)" on November 2017 (6),

5. Typical applications in food

Sucrose esters of fatty acids are used, for instance, as aerating and starch-complexing agents. They are also used to improve fat dispersion and stability.

Within the EU sucrose esters of fatty acids are permitted in (7):

- Canned liquid coffee*
- Heat-treated processed meat products (except foie gras, foie gras entier, blocs de foie gras, Libamáj, libamáj egészben, libamáj tömbben)*
- Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions (fat emulsions for baking purposes)
- Fine bakery wares*
- Beverage whiteners
- Edible ices*
- Chewing gum*
- Sugar confectionery
- Desserts excluding products covered in categories 1, 3 and 4*
- Beverage whiteners and cream analogues
- Other creams (only sterilised cream and sterilised cream with reduced fat content)*
- Sterilised cream
- Sauces*
- Soups and broths*
- Fresh fruits, surface treatment*

- Non-alcoholic aniseed-based drinks
- Non-alcoholic coconut and almond drinks
- Spirituous beverages as defined in Regulation (EC) No 110/2008 (excluding whiskey/whisky)*
- Powders for the preparation of hot beverages
- Dairy-based drinks (flavoured fermented milk products including heat-treated products)
- Dietary food supplements
- Food supplements supplied in a solid and liquid form or in a syrup-type or chewable form including capsules and tablets and similar forms, excluding chewable forms*
- Carriers and solvents for colours and fat-soluble antioxidants
- Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4
- Infant formulae as defined by Directive 2006/141/EC**
- Follow-on formulae as defined by Directive 2006/141/EC**
- Other foods for young children (only in products containing hydrolysed proteins, peptides or amino acids)**
- Dietary foods for infants for special medical purposes and special formulae for infants (only products containing hydrolysed proteins, peptides and amino acids)
- Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC (only products containing hydrolysed proteins, peptides and amino acids)
- Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)*
- Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)*
- Flavoured drinks (only aniseed-based, dairy-based, coconut and almond drinks or powders for the preparation of hot beverages)*
- Cider and Perry*
- Fruit wine and made wine
- Aromatised wines and aromatised wine-product cocktails*
- Mead***
- Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol*

*The additive may be added individually or in combination with E 474

** If more than one of the substances E 322, E 471, E 472c and E 473 are added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substances together in that foodstuff

*** Ingoing amount, residues not detectable

6. Non-food applications

In cosmetics and pharmaceuticals as emulsifiers in creams, lotions, cleansing lotions and ointments.

Specifications: E 473

Sucrose esters of fatty acids

	EU * (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Content	min. 80%	min. 80%	min. 80.0%	(2)
Free sugar	max. 5%	max. 5%	max. 5.0%	(2)
Free fatty acids (as oleic acid)	max. 3%			A 15
Sulphated ash	max. 2%	max. 2%		A 6
Dimethyl Formamide	max. 1 mg/kg	max. 1 mg/kg		(2)
Dimethyl Sulphoxide	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	(2)
Methanol	max. 10 mg/kg	max. 10 mg/kg	max. 10 mg/kg	(2)
2-methyl-1-propanol	max. 10 mg/kg			No official method
Ethyl acetate, propane-2-ol, propylene glycol	max. 350 mg/kg singly or in combination	max. 350 mg/kg singly or in combination	max. 350 mg/kg	(2)
Methyl ethyl ketone	max. 10 mg/kg	max. 10 mg/kg	max. 10 mg/kg	(2)
Isobutanol		max. 10 mg/kg	max. 10 mg/kg	(2)
Acid value		max. 6	max. 6	A 18
Residue on ignition			max. 2.0%	A 6
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

* 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).

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition):
Monograph 20 (2017)
Monograph 10 (2010)
Monograph 7 (2009)
Monograph 4 (2007)
Monograph 1 (2006)

(3) Food Chemicals Codex, 8th Edition, 2012, page 1099.

(4) WHO Food Additives Series No. 40, 1998, page 79-81. Safety evaluation of certain food additives and contaminants.

(5) Scientific Opinion on the safety of sucrose esters of fatty acids prepared from vinyl esters of fatty acids and on the extension of use of sucrose esters of fatty acids in flavourings.

(6) Scientific Opinion on the exposure assessment of sucrose esters of fatty acids (E 473) from its use as food additive.

Refined exposure assessment of sucrose esters of fatty acids (E 473) from its use as a food additive.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Sucroglycerides

E Number: E 474

1. Name

English	Sucroglycerides
German	Zuckerglyceride
French	Sucroglycérides
Dutch	Sucroglyceriden
Spanish	Sucroglicéridos
Portuguese	Sacaridoglicéridos
Italian	Sucrogliceridi
Danish	Saccharoseestere i blanding med mono- og diglycerider af fedtsyrer
Swedish	Mono- och diglyceriders sackarosestrar
Finnish	Sokeriglyseridit
Greek	Σακχαρογλυκερίδια

Synonyms

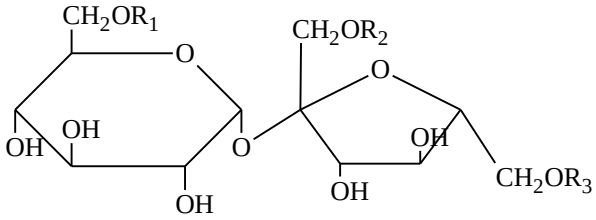
Sugar glycerides.

2. Description

2.1. Chemical description and typical process

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.

The structural formula of the principal components is:



where at least one of R1, R2 or R3 represents a fatty acid moiety and the remainder may represent fatty acid or hydrogen.

Depending on the food legislation applicable the following organic solvents are used in their production: dimethylformamide, ethyl acetate, propane-2-ol, 2-methyl-1-propanol, cyclohexane.

2.2. Appearance

Soft solid masses, stiff gels or white to off-white powders.

2.3. Solubility

Soluble in ethanol, insoluble in cold water.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Sucroglycerides have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4).

Evaluation status

Acceptable daily intake (ADI): 0-30 mg/kg bw
(Group ADI for sucrose esters of fatty acids and sucroglycerides)

5. Typical applications in food

Sucroglycerides are used, for instance, as aerating and starch-complexing agents. They are also used to improve fat dispersion and stability.

Within the EU sucroglycerides are permitted in (5):

- Canned liquid coffee*
- Heat-treated processed meat products (except foie gras, foie gras entier, blocs de foie gras, Libamáj, libamáj egészben, libamáj tömbben)*
- Other fat emulsions for baking purposes including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions*
- Fine bakery wares*
- Beverage whiteners
- Edible ices*
- Chewing gum*
- Sugar confectionery
- Desserts excluding products covered in categories 1, 3 and 4*
- Cream analogues*
- Other creams (only sterilised cream and sterilised cream with reduced fat content)*
- Other creams (only sterilised cream and sterilised cream with reduced fat content)*
- Sterilised cream
- Sauces*
- Soups and broths*
- Fresh fruits, surface treatment*
- Non-alcoholic aniseed-based drinks
- Non-alcoholic coconut and almond drinks
- Spirituous beverages as defined in Regulation (EC) No 110/2008 (excluding whiskey/whisky)*
- Powders for the preparation of hot beverages
- Dairy-based drinks

- Dietary food supplements
- Food supplements supplied in a solid and liquid form or in a syrup-type or chewable form including capsules and tablets and similar forms, excluding chewable forms*
- Dietetic foods intended for medical purposes
- Carriers and solvents for colours and fat-soluble antioxidants
- Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)*
- Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)*
- Flavoured drinks (only aniseed-based, dairy-based, coconut and almond drinks or powders for the preparation of hot beverages)*
- Cider and Perry*
- Aromatised wines and aromatised wine-product cocktails*
- Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol*
- Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4
- Fruit wine and made wine
- Mead**

* The additive may be added individually or in combination with E 473
** Ingoing amount, residues not detectable

6. Non-food applications

In cosmetics and pharmaceuticals as emulsifiers in creams, lotions, cleansing lotions and ointments.

Specifications: E 474

Sucroglycerides

	EU * (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Sucrose fatty acid esters	40-60%	40-60%		(2)
Free sugar	max. 5%	max. 5%		(2)
Free fatty acids (as oleic acid)	max. 3%			A 15
Sulphated ash	max. 2% (800 ± 25°C)	max. 2%		A 6
Dimethyl Formamide	max. 1 mg/kg	max. 1 mg/kg		(2)
Methanol	max. 10 mg/kg			(2)
2-methyl-1-propanol, Cyclohexane	max. 10 mg/kg singly or in combination			(2)
Cyclohexane, isobutanol		max. 10 mg/kg singly or in combination		(2)
Ethyl acetate, propane-2-ol	max. 350 mg/kg singly or in combination	max. 350 mg/kg singly or in combination		(2)
Acid value		max. 6		A 18
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg		A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

* 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)

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition):
Monograph 10 (2010)
Monograph 7 (2009)
Monograph 1 (2006)

(3) No Food Chemicals Codex specifications available.

(4) WHO Food Additives Series No. 40, 1998, page 79-81. Safety evaluation of certain food additives and contaminants.

(5) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Polyglycerol esters of fatty acids

E Number: E 475

1. Name

English	Polyglycerol esters of fatty acids
German	Polyglycerinester von Speisefettsäuren
French	Esters polyglycéridiques d'acides gras
Dutch	Polyglycerolesters van vetzuren
Spanish	Ésteres poliglicéridos de ácidos grasos
Portuguese	Ésteres de poliglicerol de ácidos gordos
Italian	Esteri poliglicerici degli acidi grassi
Danish	Polyglycerolestere af fedtsyrer
Swedish	Polyglycerolestrar av fettsyror
Finnish	Rasvahappojen polyglyseroliesterit
Greek	Πολυγλυκερίδια λιπαρών οξέων

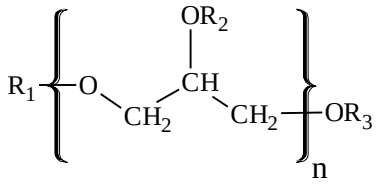
Synonyms

Polyglycerol fatty acid esters; polyglycerin esters of fatty acid esters; PGE.

2. Description

2.1. Chemical description and typical process

The product is a mixture of esters of polyglycerol and edible fatty acids. The structural formula of the principal components is:



where R_1, R_2 and R_3 can be a fatty acid moiety or hydrogen and where the average value of n is greater than one.

The esters may be formed from a reaction between polyglycerols and edible fats, oils or fatty acids. The products can contain minor amounts of mono-, di-, and triglycerides together with free glycerol and polyglycerols and free fatty acids. Salts of fatty acids may also be present.

2.2. Appearance

The product is 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.

2.3. Solubility

The product is typically dispersible in water and soluble inorganic solvents and oils.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Polyglycerol esters of fatty acids have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

The European Food Safety Authority Scientific Opinion on the re-evaluation of Polyglycerol esters of fatty acids were re-evaluated by (EFSA) was published in December 2017 (6).

Evaluation status

Acceptable daily intake (ADI): No need for a numerical ADI EFSA re-evaluation (6)

ADI: 0-25 mg/kg bw JECFA evaluation (2)

5. Typical applications in food

Polyglycerol esters are widely used in foods as aerating agents, crystal modifiers, starch-complexing agents, dough conditioners, humectants, defoaming agents and anti-spattering agents.

Within the EU polyglycerol esters of fatty acids are permitted in (7):

- Fine bakery wares
- Emulsified liqueurs
- Processed eggs and egg products
- Beverage whiteners
- Chewing gum
- Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions
- Milk and cream analogues
- Flavoured fermented milk products including heat-treated products
- Sugar confectionery
- Granola-type breakfast cereals
- Desserts excluding products covered in categories 1, 3 and 4
- Dietary food supplements supplied in a solid, liquid or syrup-type or chewable form including capsules and tablets and similar forms, excluding chewable forms
- Dietetic foods intended for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)
- Dietetic formulae for weight control intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)
- Carriers and solvents for colours and fat-soluble antioxidants

- Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4

6. Non-food applications

Pharmaceutical industries: as emulsifiers for ointment bases, creams and lotions as well as solubilisers and bases for controlled release tablets and suppositories.

Cosmetic industries: as emulsifiers for ointment bases, creams, lotions, shampoos, dyes, fragrances.

Various industries: e.g. as spin finishes for polymeric textiles.

Specifications: E 475

Polyglycerol esters of fatty acids

	EU * (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Acids other than fatty acids	<1%			No official method
Total fatty acid ester content	min. 90%			No official method
Free fatty acids (as oleic acid)	max. 6%			A 15
Total glycerol and polyglycerol	18-60%			A 26
Free glycerol and polyglycerol	max. 7%			A 17
Sulphated ash	max. 0.5% (800 ± 25°C)			A 6
Polyol composition	**	***		A 26
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

* 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).

** The polyglycerol moiety is predominantly di-, tri- and tetraglycerol and contains not more than 10% of polyglycerol equal to or higher than heptaglycerol.

*** The polyglycerol moiety shall be composed of not less than 70% of di-, tri- and tetraglycerols and shall contain no more than 10% of polyglycerols equal to or higher than heptaglycerol.

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006)

(3) Food Chemicals Codex, Fifth Edition, 2004, page 343.

(4) WHO Food Additives Series No. 5, 1974, page 241-245. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents.

(5) Reports of the Scientific Committee for Food, Seventh Series, 1978.

(6) Re-evaluation of polyglycerol esters of fatty acids (E 475) as a food additive.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Polyglycerol polyricinoleate

E Number: E 476

1. Name

English	Polyglycerol polyricinoleate
German	Polyglycerin-Polyricinoleat
French	Polyricinoléate de polyglycérol
Dutch	Polyglycerol-polyricinoleaat
Spanish	Poliricinoleato de poliglicerol
Portuguese	Poliricinoleato de poliglicerol
Italian	Poliricinoleato di poliglicerolo
Danish	Polyglycerolpolyricinoleat
Swedish	Polyglycerolpolyricinoleat
Finnish	Polyglyserolipolyrisiinioleaatti
Greek	Πολυγλυκερίδια του πολυρυκινελαϊκού οξέος

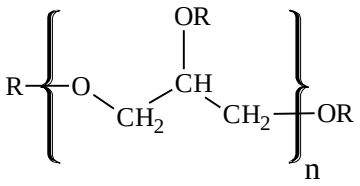
Synonyms

Glycerol esters of condensed castor oil fatty acids; polyglycerol esters of polycondensed fatty acids from castor oil; polyglycerol esters of interesterified ricinoleic acid; PGPR; glyceran esters of condensed castor oil fatty acids. INS 476

2. Description

2.1. Chemical description and typical process

The product is a complex mixture of partial esters of polyglycerol with linear esterified fatty acids derived from castor oil. The structural formula of the principal components is:



where

R = H or a fatty acyl group derived from polycondensed ricinoleic acid
n = degree of polymerisation of glycerol (average >1)

The product is prepared by the esterification of condensed castor oil fatty acids with polyglycerol. Polyglycerol is made by heating glycerol under vacuum with a catalyst. Condensed castor oil fatty acids are made by heating castor oil fatty acids in an inert atmosphere and condensing to an average of about five fatty acid residues per molecule.

The polyglycerol moiety is predominantly di-, tri- and tetraglycerol.

2.2. Appearance

The product exists as a highly viscous light brown liquid at 25°C; it does not crystallise at 0°C.

2.3. Solubility

The product is insoluble in cold and hot water and ethanol, soluble inether, hydrocarbons and halogenated hydrocarbons.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Polyglycerol polyricinoleate has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

The European Food Safety Authority (EFSA) Scientific Opinion on the re-evaluation of Polyglycerol polyricinoleate was published in March 2017 (6).

Evaluation status
Acceptable daily intake (ADI):
0-25 mg/kg bw (EFSA 2017) (6)
0-7.5 mg/kg bw (JECFA 1973) (2)

5. Typical applications in food

Polyglycerol polyricinoleate is used principally as a viscosity modifier. It is also used to maintain stable emulsions of oil and water systems at high water content.

Within the EU polyglycerol polyricinoleate is permitted in (7):

- Spreadable fats as defined in Article 115 of and Annex XV to Regulation (EC) No 1234/2007, having a fat content of 41 % or less and similar spreadable products with a fat content of less than 10 % fat
- Dressings
- Spreads
- Breath refreshing micro sweets
- Decorations coatings and fillings
- Sauces
- Cocoa-based confectionery, including chocolate as covered by Directive 2000/36/EC

6. Non-food applications

- Pharmaceutical and cosmetic preparations
- Oil and water emulsions
- Release agents

Specifications: E 476

Polyglycerol polyricinoleate

	EU (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Hydroxyl value	80-100		80-100	A 20
Iodine value			72-103	A 39
Refractive index (n^{65})	1.4630-1.4665		1.463-1.467	A 29
Saponification Value			170-210	A 19
Acid value	max. 6		max. 6	A 18
Polyglycerols	Min. 75% di-tri-, and tetraglyceridols, and max. 10% heptaglycerols or higher *	*	Min. 75% di-tri-, and tetraglyceridols, and max. 10% heptaglycerols or higher	A 26
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 1 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

* The polyglycerol moiety shall be composed of not less than 75% of di-, tri- and tetraglycerols and shall contain no more than 10% of polyglycerols equal to or higher than heptaglycerol.

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006)

(3) Food Chemicals Codex, 8th Edition, 2012, page 910.

(4) WHO Food Additives Series No. 5, 1974, page 246-253. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents.

(5) Reports of the Scientific Committee for Food, Seventh Series, 1978.

(6) Re-evaluation of polyglycerol polyricinoleate (E 476) as a food additive.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Propane-1,2-diol esters of fatty acids

E Number: E 477

1. Name

English	Propane-1,2-diol esters of fatty acids
German	Propylenglycolester von Speisefettsäuren
French	Esters de propane-1,2-diol d'acides gras
Dutch	Propyleenglycolesters van vetzuren
Spanish	Ésteres de propano-1,2-diol de ácidos grasos
Portuguese	Ésteres de propilenoglicol de ácidos gordos
Italian	Esteri dell'1.2 propandiolo degli acidi grassi
Danish	Propylenglycolestere af fedtsyrer
Swedish	1,2-Propylenglykolestrar av fettsyror
Finnish	Rasvahappojen propyleeniglykoliesterit
Greek	Εστέρες λιπαρών οξέων με προπανοδιόλη-1,2

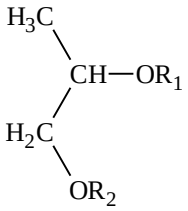
Synonyms

Propylene glycol esters of fatty acids; propylene glycol mono- and diester; propylene glycol mono- and diesters of fatty acids; propylene glycol monostearate (or another appropriate ester); PGME.

2. Description

2.1. Chemical description and typical process

The product consists mainly of propane-1,2-diol mono- and diesters of fatty acids occurring in food fats and oils. The structural formula of the principal components is:



where one of R_1 or R_2 represents a fatty acid moiety. The remainder may represent a fatty acid or hydrogen.

The distribution of the principal components depends on the proportion of the fatty acids and propylene glycol and the reaction conditions used.

The product is produced either by the direct esterification of 1,2 propylene glycol with fatty acids or by transesterification of 1,2 propylene glycol with fats and oils. The process may be followed by molecular distillation or other separation techniques to separate the monoesters.

2.2. Appearance

Clear liquids or waxy white flakes, beads or solids having a bland odour

2.3. Solubility

The product is typically dispersible in hot water, non-dispersible in cold water and soluble in edible oils and fats.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Propane-1,2-diol esters of fatty acids have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

The European Food Safety Authority Scientific Opinion on the re-evaluation of propane-1,2-diol esters of fatty acids as a food additive was published in December 2018 (6).

Evaluation status

Acceptable daily intake (ADI): 0-25 mg/kg bw
(calculated as propylene glycol)

5. Typical applications in food

The product imparts excellent aerating and foam stabilising properties.

Within the EU propane-1,2-diol esters of fatty acids are permitted in (7):

- Fine bakery wares
- Fat emulsions for baking purposes
- Milk and cream analogues
- Flavoured fermented milk products including heat-treated products
- Beverage whiteners
- Edible ices
- Sugar confectionery
- Chewing gum
- Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4
- Desserts excluding products covered in categories 1, 3 and 4
- Whipped dessert toppings other than cream
- Dietetic foods intended for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)
- Dietetic formulae for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)

6. Non-food applications

No specific application.

Specifications: E 477

Propane-1,2-diol esters of fatty acids

	EU * (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Acids other than fatty acids	<1%			
Total fatty acid ester content	min. 85%	min. 85%		(2)
Total propane-1,2-diol	11-31%	min. 11%		(2)
Free propane-1,2-diol	max. 5%	max. 1.5%	max. 1.5%	(2)
Dimer and trimer of propylene glycol	max. 0.5%	max. 0.5%		A 25
Free fatty acids (as oleic acid)	max. 6%			A 15
Sulphated ash	max. 0.5% (800 ± 25°C)	max. 0.5%		A 6
Acid value		max. 4	max. 4	A 18
Soap (as potassium stearate)		max. 7%	max. 7.0%	(2)
Residue on ignition			max. 0.5%	A 6
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

* 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).

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006).

(3) Food Chemicals Codex, 8th Edition, 2012, page 965.

(4) WHO Food Additives Series No. 5, 1974, page 275-277. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents.

(5) Reports of the Scientific Committee for Food, Seventh Series, 1978.

(6) Re-evaluation of propane-1,2-diol esters of fatty acids (E 477) as a food additive.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Thermally oxidised soya bean oil interacted with mono- and diglycerides of fatty acids

E Number: E 479b

1. Name

English	Thermally oxidised soya bean oil interacted with mono- and diglycerides of fatty acids
German	Thermooxidiertes Sojaöl mit Mono- und Diglyceriden von Speisefettsäuren
French	Huile de soja oxydée par chauffage ayant réagi avec des mono- et diglycérides d'acides gras
Dutch	Thermisch geoxideerde sojaolie verkregen door reactie met mono- en diglyceriden van vetzuren
Spanish	Aceite de soja oxidado térmicamente y en interacción con mono- y diglicéridos de ácidos grasos
Portuguese	Produto da reacção de óleo de soja oxidado por via térmica com mono e diacligliceróis
Italian	Prodotto di reazione dell'olio di soia ossidato termicamente con mono- e digliceridi degli acidi grassi
Danish	Thermisk oxideret sojaolie omsat med mono- og diglycerider af fedtsyrer
Swedish	Termiskt oxiderad sojabönsolja blandad med mono- och diglycerider av fettsyror
Finnish	Termisesti hapetettu ja polymeroitu soijaöljy
Greek	Θερμικώς οξειδωμένο σογιέλαιο που έχει αντιδράσει με μονο- και δι-γλυκερίδια λιπαρών οξέων

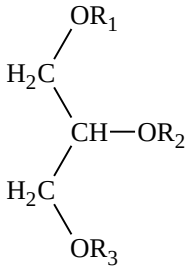
Synonyms

TOSOM.

2. Description

2.1. Chemical description and typical process

The product consists of esters of glycerol and fatty acids occurring in food fats and fatty acids from thermally oxidised soya bean oil. It may contain small quantities of free glycerol and free fatty acids. The structural formula of the principal components is:



where at least one of R_1, R_2 or R_3 represents a normal fatty acid moiety or a thermally oxidised fatty acid. The remainder may represent the fatty acids or hydrogen.

The distribution of the principal components within the ester depends on the proportion of glycerol and fatty acids and the reaction conditions used.

The product is made from 10% thermally oxidised soya bean oil - oxidised with air at 190-200°C - and 90% mono- and diglycerides of food fatty acids by interaction and deodorisation under vacuum at 130°C .

2.2. Appearance

The product is pale yellow to light brown with a waxy to solid consistency.

2.3. Solubility

The product is typically insoluble in water. Soluble in hot oil or fat.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Thermally oxidised soya bean oil interacted with mono- and diglycerides have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

The European Food Safety Authority (EFSA) Scientific Opinion on the re-evaluation of thermally oxidised soya bean oil interacted with mono- and diglycerides as a food additive was published in October 2018 (6).

Evaluation status

Acceptable daily intake (ADI): 0-30 mg/kg bw evaluation by JECFA (2)

Acceptable daily intake (ADI): 0-25 mg/kg bw evaluation by SCF, ADI not supported by EFSA, who nevertheless considered *"the use of TOSOM (E 479b) to be of no safety concern, in particular when considering the limited current use of this food additive"* (6)

5. Typical applications in food

The product provides excellent frying and anti-spattering properties.

Within the EU thermally oxidised soya bean oil interacted with mono- and diglycerides of fatty acids is permitted in (7):

- Fat emulsions for frying purposes

6. Non-food applications

No specific application.

Specifications: E 479b

Thermally oxidised soya bean oil interacted with mono- and diglycerides of fatty acids.

	EU (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Free fatty acids (as oleic acid)	max. 1.5%	max. 1.5%		(2)
Free glycerol	max. 2%	max. 2%		(2)
Total glycerol	16-22%	16-22%		(2)
Total fatty acids	83-90%	83-90%		(2)
Fatty acids insoluble in petroleum ether	max. 2% of total fatty acids	max. 2%		(2)
Fatty acid methyl esters, not forming adduct with urea	max. 9% of total fatty acid methyl esters	max. 9.0%		(2)
Melting range	55-65°C	55-65°C		A 33
Peroxide value	max. 3	max. 3		(2)
Epoxides	max. 0.03% oxirane oxygen	max. 0.03% oxirane oxygen		(2)
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg		A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006)

(3) No Food Chemicals Codex specifications available.

(4) WHO Food Additives Series No. 30, 1993, page 3-12. Toxicological evaluation of certain food additives and naturally occurring toxicants.

(5) Reports of the Scientific Committee for Food, Twenty-first Series, 1989.

(6) Re-evaluation of oxidised soya bean oil interacted with mono- and diglycerides of fatty acids (E 479b) as a food additive.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Sodium stearoyl-2-lactylate

E Number: E 481

1. Name

English	Sodium stearoyl-2-lactylate
German	Natriumstearoyl-2-lactylat
French	Stéaroyl-2-lactylate de sodium
Dutch	Natriumstearoyl-2-lactylaat
Spanish	Estearoil-2-lactilato sódico
Portuguese	Oleostearilo-2-lactilato de sódio
Italian	Stearoil-2-lattilato di sodio
Danish	Natriumstearoyllactylat
Swedish	Natriumstearoyl-2-laktylat
Finnish	Natriumstearoli-2-laktylaatti
Greek	Στεατοϋλο-2-γαλακτυλικό νάτριο

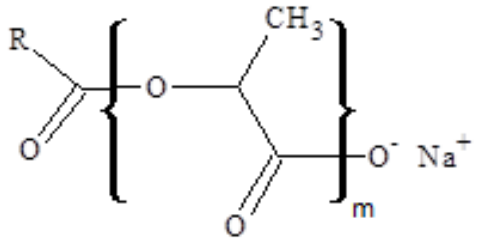
Synonyms

Sodium stearoyl lactylate; sodium stearoyl lactate; SSL.

2. Description

2.1. Chemical description and typical process

The structural formula of the principal components is:



m normally average 2
RO is a fatty acid moiety.

The distribution of the principal components depends on the relative proportion of lactic acid, fatty acid and the amount of sodium salt used in the neutralisation process.

Other components present in the product may include sodium salts of fatty acids, sodium lactate, non-neutralised stearoyl lactylic acid, free fatty acids, free lactic acid or polymers thereof.

Sodium stearoyl-2-lactylate is the partially neutralised esterification product of lactic acid and a fatty acid.

2.2. Appearance

Normally the product is a white or slightly yellowish powder or brittle solid with a characteristic odour.

2.3. Solubility

The product is typically insoluble in water and soluble in ethanol.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Sodium stearoyl-2-lactylate has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

The European Food Safety Authority (EFSA) Scientific Opinion on the re-evaluation of Sodium stearoyl-2-lactylate (E 481) and calcium stearoyl-2-lactylate (E 482) was published in May 2013 (6).

Evaluation status

Group Acceptable daily intake (ADI): 22 mg/kg bw (EFSA re-evaluation) (6)

0-20 mg/kg (JECFA) (2)

5. Typical applications in food

Sodium stearoyl-2-lactylate is used principally in bakery applications to increase the softness and crumb structure of bread and rolls and maintain softness during storage. It is also used in coffee creamers to ensure good dispersion and whitening power and in fine bakery wares as a fat replacer.

Within the EU sodium stearoyl-2-lactylate is permitted in (7):

- Fine bakery wares*
- Quick-cook rice
- Breakfast cereals*
- Emulsified liqueur*
- Flavoured drinks with less than 15% alcohol by volume*
- Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions*
- Desserts excluding products covered in categories 1, 3 and 4*
- Sugar confectionery*
- Chewing gum*
- Beverage whiteners*
- Powders for the preparation of (hot) beverages*
- Cereal- and potato-based snacks*
- Minced and diced canned meat products*
- Dietetic foods and foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)*
- Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)*
- Bread and rolls (except products in 7.1.1 and 7.1.2)*

- Flavoured fermented milk products including heat-treated products
- Mostarda di frutta*
- Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4*

* The additive may be added individually or in combination with E 482

6. Non-food applications

- Pharmaceutical and cosmetic preparations

Specifications: E 481

Sodium stearoyl-2-lactylate

	EU (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Total lactic acid	15-40%	15-40%	23.0-34.0%	(2)
Sodium content	2.5-5%	2.5-5.0%	3.5-5.0%	(2)
Ester value	90-190	90-190	120-190	(2)
Acid value	60-130	60-130	60-80	(2)
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006)

(3) Food Chemicals Codex, 8th Edition, 2012page1062.

(4) WHO Food Additives Series No. 5, 1974, page 505-511. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents.

(5) Reports of the Scientific Committee for Food, Seventh Series, 1978.

(6) Scientific Opinion on the re-evaluation of sodium stearoyl-2-lactylate (E 481) and calcium stearoyl-2-lactylate (E 482) as food additives.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Calcium stearoyl-2-lactylate

E Number: E 482

1. Name

English	Calcium stearoyl-2-lactylate
German	Calciumstearoyl-2-lactylat
French	Stéaroyl-2-lactylate de calcium
Dutch	Calciumstearoyl-2-lactylaat
Spanish	Estearoil-2-lactilato cálcico
Portuguese	Oleostearilo-2-lactilato de cálcio
Italian	Stearoil-2-lattilato di calcio
Danish	Calciumstearoyllactylat
Swedish	Kalciumstearoyl-2-laktylat
Finnish	Kalsiumstearoli-2-laktylaatti
Greek	Στεατοϋλο-2-γαλακτυλικό ασβέστιο

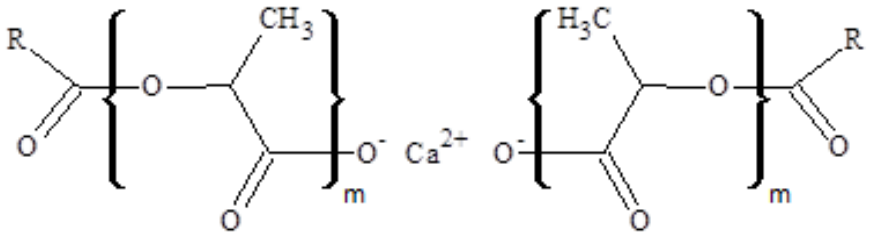
Synonyms

Calcium stearoyl lactylate; calcium stearoyl lactate; CSL.

2. Description

2.1. Chemical description and typical process

The structural formula of the principal components is:



m normally average 2
RO is a fatty acid moiety.

The mean value of M depends on the proportion of lactic acid present.

The distribution of the principal components depends on the relative proportion of lactic acid, fatty acid and the amount of calcium salt used in the neutralisation process.

Other components present in the product may include calcium salts of fatty acids, calcium lactate, non-neutralised stearoyl lactylic acid, free fatty acids, free lactic acid or polymers thereof.

Calcium stearoyl-2-lactylate is the partially neutralised esterification product of lactic acid and a fatty acid.

2.2. Appearance

Normally the product is white or slightly yellowish powder or brittle solid with a characteristic odour.

2.3. Solubility

The product is slightly soluble in hot water.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Calcium stearoyl-2-lactylate has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

The European Food Safety Authority (EFSA) Scientific Opinion on the re-evaluation of Sodium stearoyl-2-lactylate (E 481) and calcium stearoyl-2-lactylate (E 482) was published May 2013 (6).

Evaluation status

Group Acceptable daily intake (ADI): 22 mg/kg bw EFSA re-evaluation (6)

ADI of 0-20 mg/kg bw JECFA evaluation (2)

5. Typical applications in food

Calcium stearoyl-2-lactylate is used principally in bakery applications to increase the softness and crumb structure of bread and rolls and maintain softness during storage. It is also used in fine bakery wares as a fat replacer.

Within the EU calcium stearoyl-2-lactylate is permitted in (7):

- Fine bakery wares*
- Quick-cook rice
- Breakfast cereals*
- Emulsified liqueur*
- Spirits with less than 15% alcohol by volume
- Other fat emulsions and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions*
- Desserts excluding products covered in categories 1, 3 and 4*
- Sugar confectionery*
- Chewing gum*
- Beverage whiteners*
- Powders for the preparation of hot beverages*
- Cereal- and potato-based snacks*
- Minced and diced canned meat products*
- Dietetic foods*
- Bread and rolls (except products in 7.1.1 and 7.1.2)*
- Flavoured fermented milk products including heat-treated products
- Mostarda di frutta*
- Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4*

- Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)*
- Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)
- Flavoured drinks*

* The additive may be added individually or in combination with E 481

6. Non-food applications

- Pharmaceutical and cosmetic preparations

Specifications: E 482

Calcium stearoyl-2-lactylate

	EU (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Total lactic acid	15-40%	15-40%	32.0-38.0%	(2)
Calcium content	1-5.2%	1.0-5.2%	4.2-5.2%	(2)
Ester value	125-190	125-190	125-164	(2)
Acid value	50-130	50-130	50-86	(2)
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006).

(3) Food Chemicals Codex, 8th Edition, 2012, page 194.

(4) WHO Food Additives Series No. 5, 1974, page 505-511. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents.

(5) Reports of the Scientific Committee for Food, Seventh Series, 1978.

(6) Scientific Opinion on the re-evaluation of sodium stearoyl-2-lactylate (E 481) and calcium stearoyl-2-lactylate (E 482) as food additives.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Sorbitan monostearate

E Number: E 491

1. Name

English	Sorbitan monostearate
German	Sorbitanmonostearat
French	Monostéarate de sorbitane
Dutch	Sorbitaanmonostearaat
Spanish	Monoestearato de sorbitano
Portuguese	Monoestearato de sorbitano
Italian	Monostearato di sorbitano
Danish	Sorbitanmonostearat
Swedish	Sorbitanmonostearat
Finnish	Sorbitaanimonostearaatti
Greek	Μονοστεατική σορβιτάνη

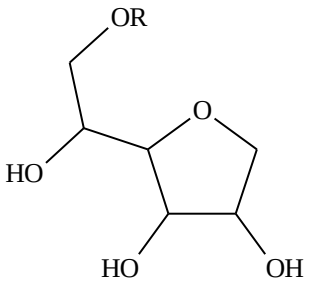
Synonyms

Sorbitan esters; SMS.

2. Description

2.1. Chemical description and typical process

The nominal formula of the principal components is:



where R represents a stearic acid moiety.

Sorbitan monostearate is a mixture of the partial esters of sorbitol and its anhydrides with edible, commercial stearic acid. It is produced by the esterification of sorbitol with commercial stearic acid derived from food fats and oils and consists of approximately 95% of a mixture of the esters of sorbitol and its mono- and dianhydrides.

2.2. Appearance

Sorbitan monostearate is a light cream to tan-coloured, hard, waxy solid with a slight characteristic odour and bland taste.

2.3. Solubility

The product is insoluble in cold water and dispersible in hot water. It is soluble above its melting point in edible oils, adding a hazy appearance.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Sorbitan monostearate has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

The European Food Safety Authority (EFSA) Scientific Opinion on the re-evaluation of Sorbitan monostearate (E 491), sorbitan tristearate (E 492), sorbitan monolaurate (E 493), sorbitan monooleate (E 494) and sorbitan monopalmitate (E 495) was published in May 2017 (6).

Evaluation status

Acceptable daily intake (ADI): 0-25 mg/kg bw as the sum of sorbitan esters of lauric, oleic, palmitic and stearic acid evaluation by JECFA (2)

Group ADI: 10 mg/kg bw per day expressed as sorbitan for sorbitan esters (E 491–495) singly or in combination - equivalent to 26 mg sorbitan monostearate/kg bw per day EFSA re-evaluation (6)

5. Typical applications in food

Sorbitan monostearate is a lipophilic surface-active agent. It is often used as an emulsifier in combination with polysorbates. It is also used to modify crystallisation of fats.

Within the EU sorbitan monostearate is permitted in (7):

- Fine bakery wares*
- Toppings and coatings for fine bakery wares
- Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4*
- Fat emulsions
- Milk and cream analogues*
- Flavoured fermented milk products including heat-treated products
- Beverage whiteners
- Liquid tea concentrates and liquid fruit and herbal infusion concentrates*
- Edible ices*
- Desserts excluding products covered in categories 1, 3 and 4*
- Sugar confectionery*
- Emulsified sauces*
- food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children*

- Food supplements supplied in a liquid, syrup-type or chewable form
- Dry yeast and yeast for baking
- Chewing gum*
- Dietetic foods intended for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)*
- Dietetic formulae for weight control
- Carriers and solvents for colours and anti-foaming agents
- Jelly marmalade
- Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions*

* The additive may be added individually or in combination with E 495

6. Non-food applications

- Pharmaceuticals and cosmetics
- Plastic food wrap

Specifications: E 491

Sorbitan monostearate

	EU (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Sorbitol, sorbitan and isosorbide esters content	min. 95%	min. 95%		A 36
Acid value	max. 10	5-10	5-10	A 18
Saponification value	147-157	147-157	147-157	A 19
Hydroxyl value	235-260	235-260	235-260	A 20
Water	max. 2% (Karl Fischer method)	max. 1.5%	max. 1.5%	A 10
Sulphated ash	max. 0.5%			A 6
Congealing range		50-52°C		
Identification test	by acid value, iodine value (not more than 4), gas chromatography'			
Polyols (as sorbitol and its mono- and dianhydrides)			27.0-34.0 g / 100 g	(3)
Fatty acids (on the anhydrous basis)			68-76 g / 100g	(3)
Acid value (fatty acid residue)			200-215	A 18
Iodine value (fatty acid residue)			max. 4	A 39
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

- do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

Commission Regulation (EU) 2018/1462 of 28 September 2018 amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for certain sorbitan esters (E 491 Sorbitan monostearate, E 492 Sorbitan tristearate and E 495 Sorbitan monopalmitate).

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006).

(3) Food Chemicals Codex, 8th Edition, 2012, page 1073.

(4) WHO Food Additives Series No. 17, 1982, page 218-228. Toxicological evaluation of certain food additives.

(5) Reports of the Scientific Committee for Food, Seventh Series, 1978.

(6) Re-evaluation of sorbitan monostearate (E 491), sorbitan tristearate (E 492), sorbitan monolaurate (E 493), sorbitan monooleate (E 494) and sorbitan monopalmitate (E 495) when used as food additives.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Sorbitan tristearate

E Number: E 492

1. Name

English	Sorbitan tristearate
German	Sorbitantristearat
French	Tristéarate de sorbitane
Dutch	Sorbitaantristearaat
Spanish	Triestearato de sorbitano
Portuguese	Triestearato de sorbitano
Italian	Triestearato di sorbitano
Danish	Sorbitantristearat
Swedish	Sorbitantristearat
Finnish	Sorbitaanitristearaatti
Greek	Τριστεατική σορβιτάνη

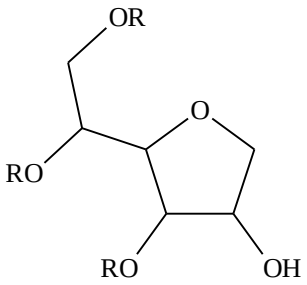
Synonyms

Sorbitan esters; STS.

2. Description

2.1. Chemical description and typical process

The nominal formula of the principal components is:



where R represents a stearic acid moiety.

Sorbitan tristearate is a mixture of the partial esters of sorbitol and its anhydrides with stearic acid. It is produced by the esterification of sorbitol with commercial stearic acid derived from food fats and oils and consists of approximately 95% of a mixture of the esters of sorbitol and its mono- and dianhydrides.

2.2. Appearance

Sorbitan tristearate is a light cream to tan-coloured beads or flakes or hard, waxy solid with a slight characteristic odour and bland taste.

2.3. Solubility

The product is 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.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Sorbitan tristearate has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

The European Food Safety Authority (EFSA) Scientific Opinion on the re-evaluation of Sorbitan monostearate (E 491), sorbitan tristearate (E 492), sorbitan monolaurate (E 493), sorbitan monooleate (E 494) and sorbitan monopalmitate (E 495) was published in May 2017 (6).

Evaluation status

Acceptable daily intake (ADI): 0-25 mg/kg bw as the sum of sorbitan esters of lauric, oleic, palmitic and stearic acid	evaluation by JECFA
Group ADI: 10 mg/kg bw per day expressed as sorbitan for sorbitan esters (E 491–495) singly or in combination - equivalent to 26 mg sorbitan monostearate/kg bw per day	EFSA re-evaluation

5. Typical applications in food

Sorbitan tristearate is a lipophilic surface-active agent. It is often used as an emulsifier in combination with polysorbates. It is also used to modify crystallisation of fats.

Within the EU sorbitan tristearate is permitted in (7):

- Fine bakery wares*
- Toppings and coatings for fine bakery wares
- Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4*
- Fat emulsions
- Milk and cream analogues*
- Flavoured fermented milk products including heat-treated products
- Beverage whiteners
- Liquid tea concentrates and liquid fruit and herbal infusion concentrates*
- Edible ices*
- Desserts excluding products covered in categories 1, 3 and 4*
- Sugar confectionery*
- Cocoa-based confectionery, including chocolate
- Emulsified sauces*

- Food supplements supplied in a solid, liquid, syrup-type or chewable form including capsules and tablets and similar forms, excluding chewable forms*Dry yeast and yeast for baking*
- Chewing gum*
- Dietetic foods intended for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)*
- Dietetic formulae for weight control
- Carriers and solvents for colours and anti-foaming agents
- Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions*

* The additive may be added individually or in combination with other substances in the range E 491-495.

6. Non-food applications

- Pharmaceuticals and cosmetics
- Plastic food packaging

Specifications: E 492

Sorbitan tristearate

	EU (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Sorbitol, sorbitan and isosorbide esters content	min. 95%	min. 95%		(2)
Acid value	max. 15	max. 15	max. 15	A 18
Saponification value	176-188	176-188	max. 0.5%	A 19
Hydroxyl value	66-80	66-80	66-80	A 20
Water	max. 2% (Karl Fischer method)	max. 1.5%	max. 0.5%	A 10
Sulphated ash	max. 0.5%	max. 0.5%	max. 0.5%	A 6
Congealing range		47-50°C	47-50°C	
Identification test	by acid value, iodine value (not more than 4), gas chromatography'			
Fatty acids			85%–92%	(3)
Polyols (as sorbitol, 1,4-sorbitan, and isosorbide)			13.3%–20.0%	(3)
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

Commission Regulation (EU) 2018/1462 of 28 September 2018 amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for certain sorbitan esters (E 491 Sorbitan monostearate, E 492 Sorbitan tristearate and E 495 Sorbitan monopalmitate).

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006)

(3) Food Chemicals Codex, 8th Edition, 2012, page 1074

(4) WHO Food Additives Series No. 17, 1982, page 218-228. Toxicological evaluation of certain food additives.

(5) Reports of the Scientific Committee for Food, Seventh Series, 1978.

(6) Re-evaluation of sorbitan monostearate (E 491), sorbitan tristearate (E 492), sorbitan monolaurate (E 493), sorbitan monooleate (E 494) and sorbitan monopalmitate (E 495) when used as food additives.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Sorbitan monolaurate

E Number: E 493

1. Name

English	Sorbitan monolaurate
German	Sorbitanmonolaurat
French	Monolaurate de sorbitane
Dutch	Sorbitaanmonolauraat
Spanish	Monolaurato de sorbitano
Portuguese	Monolaurato de sorbitano
Italian	Monolaurato di sorbitano
Danish	Sorbitanmonolaurat
Swedish	Sorbitanmonolaurat
Finnish	Sorbitaanimonolauraatti
Greek	Μονολαυρική σορβιτάνη

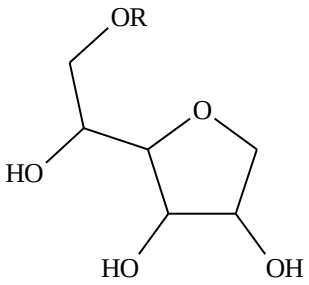
Synonyms

Sorbitan esters; SML.

2. Description

2.1. Chemical description and typical process

The nominal formula of the principal components is:



where R represents a lauric acid moiety.

Sorbitan monolaurate is a mixture of the partial esters of sorbitol and its anhydrides with lauric acid. It is produced by the esterification of sorbitol with commercial lauric acid derived from food fats and oils and consists of approximately 95% of a mixture of the esters of sorbitol and its mono- and dianhydrides.

2.2. Appearance

Sorbitan monolaurate is amber-coloured oily viscous liquid, light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight odour.

2.3. Solubility

The product is dispersible in both hot and cold water.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Sorbitan monolaurate has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5). The European Food Safety Authority (EFSA) Scientific Opinion on the re-evaluation of Sorbitan monostearate (E 491), sorbitan tristearate (E 492), sorbitan monolaurate (E 493), sorbitan monooleate (E 494) and sorbitan monopalmitate (E 495) was published in May 2017 (6).

Evaluation status

Acceptable daily intake (ADI): 0-25 mg/kg bw evaluation by JECFA

as the sum of sorbitan esters of lauric, oleic, palmitic and stearic acid

Group ADI: 10 mg/kg bw per day expressed as sorbitan for sorbitan esters (E 491–495) singly or in combination - equivalent to 26 mg sorbitan monostearate/kg bw per day	EFSA re-evaluation

5. Typical applications in food

Sorbitan monolaurate is a lipophilic surface-active agent. It is often used as an emulsifier in combination with polysorbates. It is also used to modify crystallisation of fats.

Within the EU sorbitan monolaurate is permitted in (7):

- Fine bakery wares*
- Toppings and coatings for fine bakery wares
- Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4*
- Jelly marmalade
- Fat emulsions
- Milk and cream analogues*
- Flavoured fermented milk products including heat-treated products
- Beverage whiteners
- Liquid tea concentrates and liquid fruit and herbal infusion concentrates*
- Edible ices*
- Desserts excluding products covered in categories 1, 3 and 4*
- Sugar confectionery*
- Emulsified sauces*
- Food supplements supplied in a solid, liquid, syrup-type or chewable form including capsules and tablets and similar forms, excluding chewable forms*
- Dry yeast and yeast for baking*
- Chewing gum*
- Dietetic foods intended for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)*
- Dietetic formulae for weight control
- Carriers and solvents for colours and anti-foaming agents
- Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions*

* The additive may be added individually or in combination with other substances in the range E 491-495.

6. Non-food applications

- Pharmaceuticals and cosmetics
- Plastic food wrap
- Textile lubricant

Specifications: E 493

Sorbitan monolaurate

	EU (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Sorbitol, sorbitan and isosorbide esters content	min. 95%	min. 95%		(2)
Acid value	max. 7	max. 7	max. 8	A 18
Saponification value	155-170	155-170	153-170	A 19
Hydroxyl value	330-358	330-358	330-360	A 20
Water	max. 2% (Karl Fischer method)	max. 2%	max. 1.5%	A 10
Sulphated ash	max. 0.5%	max. 0.5%	max. 0.5%	A 6
Fatty acids			55.0%–63.0%	(3)
Polyols (as sorbitol, 1,4-sorbitan, and isosorbide)			39.0%–45.0%	(3)
Acid value (fatty acid residue)			260-280	A 18
Iodine value (fatty acid residue)			max. 5	A 39
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006)

(3) Food Chemicals Codex, 8th Edition, 2012, page 1070.

(4) WHO Food Additives Series No. 17, 1982, page 218-228. Toxicological evaluation of certain food additives.

(5) Reports of the Scientific Committee for Food, Seventh Series, 1978.

(6) Re-evaluation of sorbitan monostearate (E 491), sorbitan tristearate (E 492), sorbitan monolaurate (E 493), sorbitan monooleate (E 494) and sorbitan monopalmitate (E 495) when used as food additives.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Sorbitan monooleate

E Number: E 494

1. Name

English	Sorbitan monooleate
German	Sorbitanmonooleat
French	Monooléate de sorbitane
Dutch	Sorbitaanmonooleaat
Spanish	Monooleato de sorbitano
Portuguese	Monooleato de sorbitano
Italian	Monooleato di sorbitano
Danish	Sorbitanmonooleat
Swedish	Sorbitanmonooleat
Finnish	Sorbitaanimono-oleaatti
Greek	Μονοελαϊκή σορβιτάνη

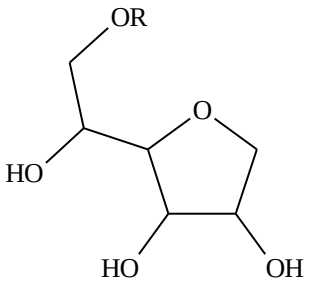
Synonyms

Sorbitan esters; SMO.

2. Description

2.1. Chemical description and typical process

The nominal formula of the principal components is:



where R represents an oleic acid moiety.

Sorbitan monooleate is a mixture of the partial esters of sorbitol and its anhydrides with oleic acid. It is produced by the esterification of sorbitol with commercial oleic acid derived from food fats and oils and consists of approximately 95% of a mixture of the esters of sorbitol and its mono- and dianhydrides.

2.2. Appearance

Sorbitan monooleate is an amber-coloured viscous liquid, light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour.

2.3. Solubility

The product is soluble at temperatures above its melting point in ethanol, ether, ethyl acetate, aniline, toluene, dioxane, petroleum ether and carbon tetra- chloride. Insoluble in cold water, dispersible in warm water.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Sorbitan monooleate has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

The European Food Safety Authority (EFSA) Scientific Opinion on the re-evaluation of Sorbitan monostearate (E 491), sorbitan tristearate (E 492), sorbitan monolaurate (E 493), sorbitan monooleate (E 494) and sorbitan monopalmitate (E 495) was published in May 2017 (6).

Evaluation status

Acceptable daily intake (ADI): 0-25 mg/kg bw as the sum of sorbitan esters of lauric, oleic, palmitic and stearic acid	evaluation by JECFA (2)
Group ADI: 10 mg/kg bw per day expressed as sorbitan for sorbitan esters (E 491–495) singly or in combination equivalent to 26 mg sorbitan monostearate/kg bw per day	re-evaluation by EFSA (6)

5. Typical applications in food

Sorbitan monooleate is a lipophilic surface-active agent. It is often used as an emulsifier in combination with polysorbates. It is also used to modify crystallisation of fats.

Within the EU sorbitan monooleate is permitted in (7):

- Fine bakery wares*
- Toppings and coatings for fine bakery wares
- Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4*
- Fat emulsions
- Milk and cream analogues*
- Beverage whiteners
- Liquid tea concentrates and liquid fruit and herbal infusion concentrates*
- Edible ices*Desserts excluding products covered in categories 1, 3 and 4*
- Sugar confectionery*
- Emulsified sauces*
- Food supplements supplied in a solid, liquid, syrup-type or chewable form including capsules and tablets and similar forms, excluding chewable forms*
- Dietary food supplements
- Dry yeast and yeast for baking*

- Chewing gum*
- Dietetic foods intended for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)*
- Dietetic formulae for weight control
- Carriers and solvents for colours and anti-foaming agents
- Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions*

* The additive may be added individually or in combination with other substances in the range E 491-495.

6. Non-food applications

- Pharmaceuticals and cosmetics
- Plastic food wrap
- Textile lubricant

Specifications: E 494

Sorbitan monooleate

	EU (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Sorbitol, sorbitan and isosorbide esters content	min. 95%	min. 95%		(2)
Acid value	max. 8	max. 8	max. 8	A 18
Saponification value	145-160	145-160		A 19
Hydroxyl value	193-210	193-210	193-210	A 20
Water	max. 2% (Karl Fischer method)	max. 2%	max. 2%	A 10
Sulphated ash	max. 0.5%	max. 0.5%	max. 0.5%	A 6
Fatty acids			73%-77%	(3)
Polyols (as sorbitol, 1,4-sorbitan and isosorbide)			26.6%-30.4%	(3)
Iodine value (oleic acid residue)			80-100	A 39
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
Mercury	max. 1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006)

(3) Food Chemicals Codex, 8th Edition, 2012, page 1071

(4) WHO Food Additives Series No. 17, 1982, page 218-228. Toxicological evaluation of certain food additives.

(5) Reports of the Scientific Committee for Food, Seventh Series, 1978.

(6) Re-evaluation of sorbitan monostearate (E 491), sorbitan tristearate (E 492), sorbitan monolaurate (E 493), sorbitan monooleate (E 494) and sorbitan monopalmitate (E 495) when used as food additives.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Sorbitan monopalmitate

E Number: E 495

1. Name

English	Sorbitan monopalmitate
German	Sorbitanmonopalmitat
French	Monopalmitate de sorbitane
Dutch	Sorbitaanmonopalmitaat
Spanish	Monopalmitato de sorbitano
Portuguese	Monopalmitato de sorbitano
Italian	Monopalmitato di sorbitano
Danish	Sorbitanmonopalmitat
Swedish	Sorbitanmonopalmitat
Finnish	Sorbitaanimonopalmitaatti
Greek	Μονοπαλμιτική σορβιτάνη

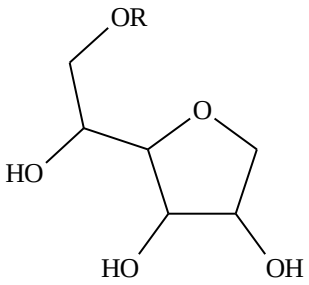
Synonyms

Sorbitan esters; SMP.

2. Description

2.1. Chemical description and typical process

The nominal formula of the principal components is:



where R represents a palmitic acid moiety.

Sorbitan monopalmitate is a mixture of the partial esters of sorbitol and its anhydrides with palmitic acid. It is produced by the esterification of sorbitol with commercial palmitic acid derived from food fats and oils and consists of approximately 95% of a mixture of the esters of sorbitol and its mono- and dianhydrides.

2.2. Appearance

Sorbitan monopalmitate is a light cream to tan-coloured beads or flakes or hard waxy solid with a slight characteristic odour and bland taste.

2.3. Solubility

The product is insoluble in cold water and dispersible in hot water. It is soluble at temperatures above its melting point in ethanol, methanol, ether, ethyl acetate, aniline, toluene, dioxane, petroleum ether and carbon tetrachloride.

3. Analysis and specifications

See attached specification sheet.

4. Safety in use

Sorbitan monopalmitate has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (4) and the Scientific Committee for Food (5).

The European Food Safety Authority (EFSA) Scientific Opinion on the re-evaluation of Sorbitan monostearate (E 491), sorbitan tristearate (E 492), sorbitan monolaurate (E 493), sorbitan monooleate (E 494) and sorbitan monopalmitate (E 495) was published in May 2017 (6).

Evaluation status

Acceptable daily intake (ADI): 0-25 mg/kg bw as the sum of sorbitan esters of lauric, oleic, palmitic and stearic acid	evaluation by JECFA (2)
Group ADI: 10 mg/kg bw per day expressed as sorbitan for sorbitan esters (E 491–495) singly or in combination - equivalent to 26 mg sorbitan monostearate/kg bw per day	re-evaluation by EFSA (6)

5. Typical applications in food

Sorbitan monopalmitate is a lipophilic surface-active agent. It is often used as an emulsifier in combination with polysorbates. It is also used to modify crystallisation of fats.

Within the EU sorbitan monopalmitate is permitted in (7):

- Fine bakery wares*
- Toppings and coatings for fine bakery wares
- Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4*
- Fat emulsions
- Milk and cream analogues*
- Beverage whiteners
- Liquid tea concentrates and liquid fruit and herbal infusion concentrates*
- Edible ices*
- Desserts excluding products covered in categories 1, 3 and 4*
- Sugar confectionery*
- Emulsified sauces*
- Food supplements supplied in a solid, liquid, syrup-type or chewable form including capsules and tablets and similar forms, excluding chewable forms*
- Dietary food supplements

- Dry yeast and yeast for baking*
- Chewing gum*
- Dietetic foods intended for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)*
- Dietetic formulae for weight control
- Carriers and solvents for colours and anti-foaming agents
- Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions*

* The additive may be added individually or in combination with other substances in the range E 491-495.

6. Non-food applications

- Pharmaceuticals and cosmetics
- Lubricant and co-emulsifier in the plastics industry

Specifications: E 495

Sorbitan monopalmitate

	EU (1)	**FAO/WHO** (2)	**FCC** (3)	Recommended Analytical Methods ¤
Sorbitol, sorbitan and isosorbide esters content	min. 95%	min. 95%		(2)
Acid value	max. 7.5	4.0-7.5	max. 8	A 18
Saponification value	140-150	140-150	140-150	A 19
Hydroxyl value	270-305	270-305	275-305	A 20
Water	max. 2% (Karl Fischer method)	max. 1.5%	max. 1.5%	A 10
Congealing range		45-47°C		
Identification test	by acid value, iodine value (not more than 4), gas chromatography'			
Fatty acids			63.0%–71.0%	(3)
Polyols (as sorbitol, 1,4-sorbitan, and isosorbide)			32.0%–38.0%	(3)
Acid value (fatty acid residue)			210-225	A 18
Iodine value (fatty acid residue)			max. 4	A 39
Sulphated ash	max. 0.5%		max. 0.5%	A 6
Arsenic	max. 3 mg/kg			A 3
Lead	max. 2 mg/kg	max. 2 mg/kg	max. 2 mg/kg	A 2
	max.			

Mercury	1 mg/kg			A 5
Cadmium	max. 1 mg/kg			A 4

¤ do not necessarily reflect the official methods used for the stated specifications.

References

(1) Regulation 231/2012 of 9 March 2012laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

Commission Regulation (EU) 2018/1462 of 28 September 2018 amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for certain sorbitan esters (E 491 Sorbitan monostearate, E 492 Sorbitan tristearate and E 495 Sorbitan monopalmitate).

(2) Combined Compendium of Food Additive Specifications (online edition): Monograph 1 (2006)

(3) Food Chemicals Codex, 8th Edition, 2012, page 1072

(4) WHO Food Additives Series No. 17, 1982, page 218-228. Toxicological evaluation of certain food additives.

(5) Reports of the Scientific Committee for Food, Seventh Series, 1978.

(6) Re-evaluation of sorbitan monostearate (E 491), sorbitan tristearate (E 492), sorbitan monolaurate (E 493), sorbitan monooleate (E 494) and sorbitan monopalmitate (E 495) when used as food additives.

(7) Regulation (EC) No 1333/2008 of 16th December 2008 on food additives.

Recommended analytical methods – Reference list

No.	Title (Subject)	Reference
A 1	Metallic impurities, heavy metals	FAO JECFA Monographs No. 1, Vol. 4, p. 62-70
A 2	Metallic impurities, lead	FAO JECFA Monographs No. 1, Vol. 4, p. 62-70
A 3	Limit test for Arsenic	FAO JECFA Monographs No. 1, Vol. 4, p. 51
A 4	Metallic impurities, cadmium	FAO JECFA Monographs No. 1, Vol. 4, p. 62-70
A 5	Metallic impurities, mercury	FAO JECFA Monographs No. 1, Vol. 4, p. 62-70
A 6	Sulphated ash/Residue on ignition	FAO JECFA Monographs No. 1, Vol. 4, p. 54
A 7	Free alkali (sodium salts)	AOCS Official Method Da 4a-48
A 8	Free alkali (potassium salts)	AOCS Official Method Da 5-44
A 9	1,4 dioxane content	FAO JECFA Monographs No. 1, Vol. 4, p. 80
A 10	Water content	FAO JECFA Monographs No. 1, Vol. 4, p. 75
A 11	Loss on drying	FAO JECFA Monographs No. 1, Vol. 4, p. 61
A 12	Alcohol insoluble substances	AOCS Official Method Da 3-48
A 13	Petroleum ether insoluble substances	AOCS Official Method Ja 3-55
A 14	Unsaponifiable matter	Food Chemicals Codex VI, p. 1146
A 15	Free fatty acids	AOCS Official Method Ca 5a - 40
A 16	Free glycerol	FAO JECFA Monographs No. 1, Vol. 4, p. 173
A 17	Free glycerol and polyglycerol	AOCS Official Method Cd 11b-91
A 18	Acid value	FAO JECFA Monographs No. 1, Vol. 4, p. 161
A 19	Saponification value	FAO JECFA Monographs No. 1, Vol. 4, p. 184
A 20	Hydroxyl value	FAO JECFA Monographs No. 1, Vol. 4, p. 168
A 21	Total fatty acids	DGF Einheitsmethoden C-III 2 (97)
A 22	Total glycerol	Food Chemicals Codex VI, p. 256
A 23	Total acetic acid	Food Chemicals Codex VI, p. 18
A 24	Total lactic acid	Food Chemicals Codex VI, p. 524
A 25	Total dimer and trimer of 1,2 propanediol	FAO JECFA Monographs No. 1, Vol. 4, p. 182
A 26	Polyglycerol determination in polyglycerol esters	FAO JECFA Monographs No. 1, Vol. 4, p. 180
A 27	Total mono- and diglycerides	AOCS, 5 Edition, Cd 11b - 91
A 28	1-monoglycerides	FAO JECFA Monographs No. 1, Vol. 4, p. 173
A 29	Refractive index	FAO JECFA Monographs No. 1, Vol. 4, p. 38
A 30	Potassium content as potassium oxide	AOCS Official Method Da 27-48
A 31	Sodium content as sodium oxide	AOCS Official Method Da 27-48
A 32	Reichert-Meissl value	Food Chemicals Codex IV, p. 826-827
A 33	Melting range	FAO JECFA Monographs No. 1, Vol. 4, p. 38
A 34	Oxyethylene content	FAO JECFA Monographs No. 1, Vol. 4, p. 221
A 35	Congealing range	FAO JECFA Monographs No. 1, Vol. 4, p. 167
A 36	Sorbitan esters content	FAO JECFA Monographs No. 1, Vol. 4, p. 185
A 38	Ethylene glycols (mono and di)	DGF Einheitsmethoden H16a (94) (only monoethylene glycol)

A 39	Iodine value	FAO Food and Nutrition Paper 5, Rev. 2, p. 194