EFEMA index of food emulsifiers

June 2015

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



Brussels, June 2015

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 and June 2013. 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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Lecithins

| E Number: | | E 322 |
|-----------|-------------|------------|
| 1. | <u>Name</u> | |
| | English | Lecithins |
| | German | Lecithine |
| | French | Lécithines |
| | Dutch | Lecithinen |
| | Spanish | Lecitinas |
| | Portuguese | Lecitina |
| | Italian | Lecitine |
| | Danish | Lecithiner |
| | Swedish | Lecitin |
| | Finnish | Lesitiinit |
| | Greek | Λεκιθίνες |

<u>Synonyms</u>

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:



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. <u>Analysis and specifications</u>

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).

Evaluation status

Acceptable daily intake (ADI): not specified

5. <u>Typical applications in food</u>

Within the EU lecithins are generally permitted for use in foodstuffs (6).

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. <u>Non-food applications</u>

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

Specifications: E 322

Lecithins

| | EU | FAO/WHO | FCC | Recommended |
|------------------------------|-----------------|-----------------|-----------------|-------------------------|
| | (1) | (2) | (3) | 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.

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

References

- (1) <u>Regulation 231/2012 of 9 March 2012</u> 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, 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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Polyoxyethylene sorbitan monolaurate (Polysorbate 20)

E Number: E 432

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

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

2. <u>Description</u>

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. <u>Analysis and specifications</u>

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).

Evaluation status

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

Group ADI: 0-10 mg/kg bw

evaluation by SCF

5. <u>Typical applications in food</u>

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 (6):

- 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. <u>Non-food applications</u>
 - Pharmaceuticals
 - Cosmetics

- Animal feed
- Industrial applications

Specifications: E 432

Polyoxyethylene sorbitan monolaurate (Polysorbate 20)

| | EU (1) | FAO/WHO (2) | FCC (3) | Recommended Analytical |
|--|-----------------------------------|------------------------------------|------------------------------------|---------------------------|
| 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 |

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

References

- 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Polyoxyethylene sorbitan monooleate (Polysorbate 80)

E 433

E Number:

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

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

2. <u>Description</u>

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).

Evaluation status

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

Group ADI: 0-10 mg/kg bw

evaluation by SCF

5. <u>Typical applications in food</u>

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 (6):

- 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. <u>Non-food applications</u>

• Pharmaceuticals

- Cosmetics ٠
- •
- Animal feed, calf milk replacers Industrial applications (plastic food wrap) •

Specifications: E 433

Polyoxyethylene sorbitan monooleate (Polysorbate 80)

| EU | FAO/WHO | FCC | Recommended |
|--------------|--|---|---|
| (1) | (2) | (3) | Analytical |
| min 06.5% | 06 5-103 5% | 06 5-103 5% | Methods ¤ |
| (anhvdrous | (anhvdrous | (anhydrous | A 34 |
| base) | base) | base) | |
| , | | | |
| min. 65% | 65.0-69.5% | 65.0-69.5% | A 34 |
| max. 2 | max. 2 | max. 2 | A 18 |
| | | | |
| 45-55 | 45-55 | 45-55 | A 19 |
| 65-80 | 65-80 | 65-80 | A 20 |
| max. 3% | max. 3% | max. 3.0% | A 10 |
| | | max. | |
| max. 5 mg/kg | | 10 mg/kg | A 9 |
| max. 0.2 | | | No method |
| mg/kg | + | | available |
| max. 0.25% | | | A 38 |
| | max. 0.25% | | A 6 |
| | | 22-24 g / | |
| | | 100 g | (3) |
| | | 193-206 | A 18 |
| | | 100 200 | // 10 |
| | | | |
| | | 80-92 | A 39 |
| | | | |
| | | | |
| | | | |
| | | max_0.25% | A 6 |
| max. | - | | |
| 3 mg/kg | | | A 3 |
| max. | max. | | |
| 2 mg/kg | 2 mg/kg | max. 2 mg/kg | A 2 |
| max. | | | A 6 |
| 1 mg/kg | | | C A |
| 1 ma/ka | | | A 4 |
| | EU (1) min. 96.5% (anhydrous base) min. 65% max. 2 45-55 65-80 max. 3% max. 3% max. 3% max. 0.2 mg/kg max. 0.25% max. 0.25% max. 0.25% | EU FAO/WHO (1) (2) min. 96.5% 96.5-103.5% (anhydrous) base) base) 65.0-69.5% max. 2 max. 2 45-55 45-55 65-80 65-80 max. 3% max. 3% max. 5 mg/kg max. 3% max. 0.2 max. 3% max. 0.25% max. 0.25% max. 0.25% max. 0.25% max. 3 max. 0.25% max. 0.25% max. 0.25% max. 0.25% max. 0.25% max. 0.25% max. 0.25% max. 10.25% max. 0.25% max. 2 max. 0.25% | EU (1) FAO/WHO (2) FCC (3) min. 96.5% (anhydrous base) 96.5-103.5% (anhydrous base) 96.5-103.5% (anhydrous base) min. 65% 65.0-69.5% 65.0-69.5% max. 2 max. 2 max. 2 45-55 45-55 45-55 65-80 65-80 65-80 max. 3% max. 3.0% max. 10 mg/kg max. 0.2 max. 3% max. 10 mg/kg max. 0.25% 22-24 g / 100 g 100 g max. 0.25% max. 0.25% 80-92 max. max. 0.25% max. 0.25% max. max. 2 mg/kg max. max. 2 mg/kg max. max. 2 mg/kg |

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

References

- (1) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Polyoxyethylene sorbitan monopalmitate (Polysorbate 40)

E Number: E 434

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

Polysorbate; polyoxyethylene (20) sorbitan monopalmitate.

2. <u>Description</u>

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 orangecoloured 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. <u>Analysis and specifications</u>

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).

Evaluation status

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

Group ADI: 0-10 mg/kg bw

evaluation by SCF

5. <u>Typical applications in food</u>

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 (6):

- 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. <u>Non-food applications</u>

- Cosmetics
- Animal feed
- Plastics industry

Specifications: E 434

Polyoxyethylene sorbitan monopalmitate (Polysorbate 40)

| | EU (1) | FAO/WHO (2) | FCC (3) | Recommended Analytical |
|-------------------------------------|---------------------------------|------------------------------------|------------------------------------|---------------------------|
| 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 |

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

References

- (1) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Polyoxyethylene sorbitan monostearate (Polysorbate 60)

E Number: E 435

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

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

2. <u>Description</u>

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 orangecoloured 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. <u>Analysis and specifications</u>

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).

Evaluation status

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

Group ADI: 0-10 mg/kg bw

evaluation by SCF

5. <u>Typical applications in food</u>

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 (6):

- 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. <u>Non-food applications</u>

• Pharmaceuticals

- Cosmetics
- Animal feed
- Plastics industry

Specifications: E 435

Polyoxyethylene sorbitan monostearate (Polysorbate 60)

| | EU | FAO/WHO | FCC | Recommended |
|--------------------|--------------|------------------|------------------|-------------------------|
| | (1) | (2) | (3) | Analytical Methods # |
| | min. 97% | 97.0-103.0% | 97.0-103.0% | |
| Content | (anhvdrous | (anhvdrous | (anhvdrous | A 34 |
| | base) | base) | base) | |
| 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 |
| | max. 0.2 | | | No method |
| Ethylene oxide | mg/kg | | | 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 | | | 21.5-26.0 g / | (2) |
| recovered | | | 100 g | (3) |
| Tecovereu | | | 200-212 | A 18 |
| Acid value | | | 200 212 | // 10 |
| (Stearic and | | | | |
| palmitic acids | | | | |
| recovered) | | | | |
| | | | 52° | (3) |
| Solidification | | | | |
| point (Stearic and | | | | |
| recovered) | | | | |
| 100010100) | max. | | | |
| Arsenic | 3 mg/kg | | | A 3 |
| | max. | max. | | |
| Lead | 2 mg/kg | 2 mg/kg | max. 2 mg/kg | A 2 |
| | max. | | | |
| Mercury | 1 mg/kg | | | A 5 |
| Codmisure | max. | | | |
| Cadmium | n mg/kg | | | A 4 |

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

References

- (1) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Polyoxyethylene sorbitan tristearate (Polysorbate 65)

E Number: E 436

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

Polysorbate; polyoxyethylene (20) sorbitan tristearate.

2. <u>Description</u>

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. <u>Analysis and specifications</u>

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).

Evaluation status

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

Group ADI: 0-10 mg/kg bw

evaluation by SCF

5. <u>Typical applications in food</u>

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 (6):

- 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 antifoaming agents.

- 6. <u>Non-food applications</u>
 - Cosmetics
- Animal feed
- Plastics industry

Specifications: E 436

Polyoxyethylene sorbitan tristearate (Polysorbate 65)

| | EU (1) | FAO/WHO | FCC | Recommended Analytical |
|--|----------------------------|------------------------------------|------------------------------------|---------------------------|
| | (') | (2) | (0) | 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 | | | 200-212 | A 18 |
| palmitic acids | | | | |
| Solidification | | | 52° | |
| point (Stearic and | | | 02 | |
| palmitic acids | | | | |
| recovered) | | | | |
| Arsonic | max. | | | Δ 3 |
| | max | max | | |
| Lead | 2 mg/kg | 2 mg/kg | max. 2 mg/kg | A 2 |
| | max. | | ; ; | |
| Mercury | 1 mg/kg | | | A 5 |
| Cadraine | max. | | | |
| Cadmium | т mg/кg | | | A 4 |

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

References

- (1) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Ammonium phosphatides

E Number: E 442

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

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

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. <u>Analysis and specifications</u>

See attached specification sheet.

4. <u>Safety in use</u>

Ammonium phosphatides 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): 0-30 mg/kg bw

5. <u>Typical applications in food</u>

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 (6):

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

6. <u>Non-food applications</u>

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 |

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

References

- (1) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Sodium, potassium and calcium salts of fatty acids

E Number: E 470a

1. <u>Name</u>

| English | Sodium, potassium and calcium salts of fatty acids |
|------------|--|
| German | Natrium-, Kalium- und Calciumsalze von Speisefett- säuren |
| 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 |

<u>Synonyms</u>

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

2.1. Chemical description and typical process

The structural formula of the principal components is:



 $M = Na, K \text{ or } \frac{1}{2}Ca$

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. <u>Safety in use</u>

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).

Evaluation status

Acceptable daily intake (ADI): not specified

5. <u>Typical applications in food</u>

Within the EU sodium, potassium and calcium salts of fatty acids are generally permitted for use in foodstuffs (6).

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. <u>Non-food applications</u>
 - Pharmaceutical and cosmetic preparations
 - General washing and cleaning
 - Paints
 - Binding agents

Specifications: E 470a

Sodium, potassium and calcium salts of fatty acids

| | EU | FAO/WHO | FCC ** | Recommended |
|-------------------|------------------------|----------|-------------------|---------------|
| | (1) | (2) | (3) | Analytical |
| | | | | Methods ¤ |
| Fatty acid salts | | | | |
| (anhydrous basis) | min. 95% | min. 95% | | (2) |
| Unsaponifiable | | | | |
| matter | max. 2% | max. 2% | | (2) |
| | max. 3% | | max. 3.0% | |
| Free fatty acids | (as oleic acid) | max. 3% | (as stearic acid) | A 15 |
| | max. 0.1% | | | |
| Free alkali | (as NaOH) | | | A 7 + A 8 *** |
| Matter insoluble | | | | |
| in alcohol | max. 0.2%* | | | A 12 |
| | 9-14% | | | |
| Sodium | (as Na ₂ O) | | | A 31 |
| | 13-21.5% | | | |
| Potassium | (as K ₂ O) | | | A 30 |
| | 8.5-13% | | 9.0-10.5% | |
| Calcium | (as CaO) | | (as CaO) | (3) |
| Loss on drying | | | | |
| (105°, 1 h) | | | max. 4.0% | A 11 |
| | max. | | | |
| Arsenic | 3 mg/kg | | | A 3 |
| | max. | max. | | |
| Lead | 2 mg/kg | 2 mg/kg | max. 2 mg/kg | A 2 |
| | max. | | | |
| Mercury | 1 mg/kg | | | A 5 |
| | max. | | | |
| Cadmium | 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.
- a do not necessarily reflect the official methods used for the stated specifications.

References

- (1) <u>Regulation 231/2012</u> 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" <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Magnesium salts of fatty acids

| E Number: | E 470b |
|-----------|--------|
| | = 1105 |

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

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

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. <u>Analysis and specifications</u>

See attached specification sheet.

4. Safety in use

Magnesium salts of fatty acids have been evaluated by the Scientific Committee for Food (5).

Evaluation status

Acceptable daily intake (ADI): not specified

5. <u>Typical applications in food</u>

Within the EU magnesium salts of fatty acids are generally permitted for use in foodstuffs (6).

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. <u>Non-food applications</u>

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

Specifications: E 470b

Magnesium salts of fatty acids

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

* Magnesium stearate and palmitate.

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

References

- (1) <u>Regulation 231/2012</u> 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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Mono- and diglycerides of fatty acids

- E Number: E 471
- 1. <u>Name</u>

| 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 |

<u>Synonyms</u>

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

2.1. Chemical description and typical process

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



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).

Evaluation status

Acceptable daily intake (ADI): not specified

5. <u>Typical applications in food</u>

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

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. <u>Non-food applications</u>

- 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 * | FAO/WHO | FCC | Recommended |
|-------------------------|--|--------------|--------------|---|
| | (1) | (2) | (3) | Analytical |
| | | | | Methods ¤ |
| Mono- and | | | | |
| Diesters | min. 70% | | | A 27 |
| α -monoglyceride | | min. 30% | | |
| content | | | | A 28 |
| T (al altra and | 40.000/ | | | 4.00 |
| I otal glycerol | 16-33% | | | A 22 |
| Free glycerol | max. 7% | max. 7% | max. 7.0% | A 16 |
| | max. | | | |
| Polyglycerols ** | 4% + 1% | | | A 26 |
| Soap (as | | | | (-) |
| sodium oleate) | | max. 6% | | (2) |
| Sulphated ash | max. 0.5% | | | A 6 |
| | (determined at $800 \pm 25^{\circ}$ C) | | | |
| | | | | |
| Acid value | max. 6 | max. 6 | max. 6 | A 18 |
| | | | | |
| Water | max. 2% | max. 2.0% | | A 10 |
| Residue on | | | max 0.5% | A 6 |
| Ightion | max | | max | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, |
| Arsenic | 3 mg/kg | | 3 mg/kg | A 3 |
| | max. | | | |
| Lead | 2 mg/kg | max. 2 mg/kg | max. 2 mg/kg | A 2 |
| | max. | | | |
| Mercury | 1 mg/kg | | | A 5 |
| | max. | | | |
| Cadmium | 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.

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

- (1) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Acetic acid esters of mono- and diglycerides of fatty acids

E Number: E 472a

1. <u>Name</u>

| 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.

2.1. 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. <u>Analysis and specifications</u>

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

5. <u>Typical applications in food</u>

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. <u>Non-food applications</u>

- 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) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Lactic acid esters of mono- and diglycerides of fatty acids

E Number: E 472b

1. <u>Name</u>

| 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 monodiglycerides; GLP, INS 472b.

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 monoand 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 insolublein 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

5. <u>Typical applications in food</u>

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. <u>Non-food applications</u>

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).

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

References

- (1) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> 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 Mono- en diglyceriden van vetzuren veresterd met Dutch 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 Rasvahappojen mono- ja diglyseridien Finnish sitruunahappoesterit Greek Εστέρες του κιτρικού οξέος με μονο- και δι-γλυκερίδια λιπαρών οξέων

<u>Synonyms</u>

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.

2.1. 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:

$$H_2 C$$

 $H_2 C$
 $H_2 C$
 OR_3

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

5. <u>Typical applications in food</u>

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

** E 471, E 472a, E 472b and E 472c are authorised individually or in combination

6. <u>Non-food applications</u>

- 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 * | FAO/WHO | FCC | Recommended |
|-------------------|-------------------|------------|--------------|-------------|
| | (1) | (2) | (3) | Analytical |
| | | | | Methods ¤ |
| Acids other than | <1% | | | No official |
| citric and fatty | | | | method |
| acids | | | | |
| | | | 13-50% | |
| Total citric acid | 13-50% | 13-50% | | (2) |
| | | | 8-33% | |
| Total glycerol | 8-33% | 8-33% | | (2) |
| | | | max. 4% | |
| Free glycerol | max. 2% | max. 4% | | A 16 |
| Total fatty acids | $\prod_{i=1}^{n}$ | | 37-81% | |
| (as oleic acid) | | 37-81% | | (2) |
| | max. 0.5% | max. 0.5% | | |
| Sulphated ash | max10%** | max. 10%** | | A 6 |
| (800 ± 25°C) | | | | |
| Residue on | | | max. 0.5% | A 6 |
| ignition | | | max. 10%** | |
| | | | | |
| | | | | |
| | max. | max. | max. 2 mg/kg | |
| Lead | 2 mg/kg | 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%.
- a do not necessarily reflect the official methods used for the stated specifications.

References

- (1) <u>Regulation 231/2012</u> 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 16 (2014).
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

| | Mono- and diacet | yl tartaric acid | esters of mono | o- and digl | vcerides of fat | y acids |
|--|------------------|------------------|----------------|-------------|-----------------|---------|
|--|------------------|------------------|----------------|-------------|-----------------|---------|

| E Numb | er: | E 472e |
|--------|-------------|---|
| 1. | <u>Name</u> | |
| | 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 |

<u>Synonyms</u>

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. <u>Description</u>

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 or two of R_1 , R_2 or R_3 is a fatty acid moiety. The remainder is either

- a) diacetylated tartaric acid moiety
- b) monoacetylated tartaric acid moiety
- c) tartaric acid moiety
- d) acetic acid moiety
- e) hydrogen

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. <u>Analysis and specifications</u>

See attached specification sheet.

4. <u>Safety in use</u>

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. <u>Typical applications in food</u>

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. <u>Non-food applications</u>

No specific applications.

Specifications: E 472e

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

| | EU * | FAO/WHO | FCC | Recommended |
|--------------------------|----------------|-----------|----------------|----------------------|
| | (1) | (2) | (3) | Analytical |
| | (1) | (2) | (3) | Mothodo x |
| | | | | wethous a |
| Acids other than | < 1% | | | No official |
| acetic, tartaric | | | | method. |
| and fatty acids | | | | |
| Total tartaria goid | | | 17.0.20.0 a / | |
| Total tartanc aciu | 40.400/ | 40.400/ | 17.0-20.0 g / | |
| | 10-40% | 10-40% | 100 g | (2) |
| Total acetic | | | 14.0-17.0 g / | |
| acid | 8-32% | 8-32% | 100 g | (2) |
| | 0 02/0 | | | (=/ |
| Total alveared | 11 000/ | 11 200/ | 12.0 a / 100 a | (2) |
| Total glycerol | 11-28% | 11-28% | 12.0 g / 100 g | (2) |
| | | | | |
| Free glycerol | max. 2% | max. 2.0% | | A 16 |
| | | | | |
| | | | | |
| | | | | |
| | | | min. 56.0 g / | |
| I otal fatty acids | | | 100 g | A 21 |
| | | | | |
| Sulphated | max. 0.5% | max. 0.5% | Max 0.5% | A 6 |
| $ash(800 + 25^{\circ}C)$ | | | | _ |
| | | | | |
| A | 40,400 | 10 100 | 00.70 | 1.40 |
| Acid value | 40-130 | 40-130 | 62-76 | A 18 |
| Residue on | | | | |
| ignition | | | | A 6 |
| Saponification | | | | |
| voluo | | | 290 125 | A 10 |
| value | | | 300-423 | A 19 |
| | max. | | | |
| Arsenic | 3 mg/kg | | | A 3 |
| | max. | max. | | |
| Lead | 2 ma/ka | 2 ma/ka | max, 2 mg/kg | A 2 |
| 2000 | <u>z mg/kg</u> | 2 mg/kg | max. 2 mg/ng | 7.2 |
| N.4 | 111dX. | | | |
| Mercury | 1 mg/kg | | | A 5 |
| | max. | | | |
| Cadmium | 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).

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

References

- (1) <u>Regulation 231/2012</u> 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.
- Combined Compendium of Food Additive Specifications (online edition): INS 472e and 472 f "Diacetyl tartaric and fatty acid esters of Glycerol" -Monograph 7 (2009).
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

| Mixed acetic and tartaric acid | l esters of mono | b- and digly | cerides of fatt | y 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 |

<u>Synonyms</u>

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

2. <u>Description</u>

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 or two of $\mathsf{R}_1,\,\mathsf{R}_2$ or R_3 is a fatty acid moiety. The remainder is either

- a) tartaric acid moiety
- b) acetic acid moiety
- c) hydrogen
- d) diacetylated tartaric acid moiety
- e) 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 paleyellow in colour.

2.3. Solubility

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

3. <u>Analysis and specifications</u>

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. <u>Typical applications in food</u>

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. <u>Non-food applications</u>

No specific applications.

Specifications: E 472f

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

| | EU * | FAO/WHO | FCC | Recommended |
|---------------------|--------------|---------|-----|-------------|
| | (1) | (2) | (3) | Analytical |
| | | | | Methods ¤ |
| Acids other than | <1.0% | | | No official |
| acetic, tartaric | | | | method |
| and fatty acids | | | | |
| 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 | | | | No official |
| (as oleic acid) | max. 3% | | | method |
| | | | | |
| Sulphated ash | max. 0.5% | | | A 6 |
| | (800 ± 25°C) | | | |
| | max. | | | |
| Arsenic | 3 mg/kg | | | A 3 |
| | max. | | | |
| Lead | 2 mg/kg | | | A 2 |
| | max. | | | |
| Mercury | 1 mg/kg | | | A 5 |
| | max. | | | |
| Cadmium | 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) <u>Regulation 231/2012</u> 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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Sucrose esters of fatty acids

E Number: E 473

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

Sucroesters; sugar esters; sucrose fatty acid esters.

2. <u>Description</u>

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. <u>Analysis and specifications</u>

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)

5. <u>Typical applications in food</u>

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

Within the EU sucrose esters of fatty acids 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 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 heattreated products)
- Dietary food supplements
- Food supplements supplied in a solid and liquid form or in a syruptype 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 nonalcoholic 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. <u>Non-food applications</u>

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).

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

References

- (1) <u>Regulation 231/2012</u> 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)
- (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.
- (6) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Sucroglycerides

| Е | Number: | E 474 |
|---|---------|-------|
| _ | | |

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

Sugar glycerides.

2. <u>Description</u>

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. <u>Safety in use</u>

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. <u>Typical applications in food</u>

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 syruptype 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 nonalcoholic 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. <u>Non-food applications</u>

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

Specifications: E 474

Sucroglycerides

| | EU * | FAO/WHO | FCC | Recommended |
|--------------------------------|---|---|-----|-------------------------|
| | (1) | (2) | (3) | 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 | max. | max. | | |
| formamide | 1 mg/kg | 1 mg/kg | | (2) |
| Methanol | max. 10 mg/kg | | | (2) |
| 2-methyl-1- | max. 10 mg/kg | | | |
| propanol, | singly or in | | | (2) |
| cyclohexane | combination | | | |
| 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)

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

References

- (1) <u>Regulation 231/2012</u> 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).
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Polyglycerol esters of fatty acids

| Е | Number: | E 475 |
|---|---------|-------|
| _ | | |

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

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

2. <u>Description</u>

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:

$$R_{1} \left\{ \begin{array}{c} OR_{2} \\ | \\ O \\ CH_{2} \end{array} \right\} CH_{2} OR_{3}$$

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. <u>Safety in use</u>

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).

Evaluation status

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

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 (6):

- 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. <u>Non-food applications</u>

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 * | FAO/WHO | FCC | Recommended |
|-------------------|--------------|---------|--------------|-------------|
| | (1) | (2) | (3) | Analytical |
| | | | | Methods ¤ |
| Acids other than | <1% | | | No official |
| fatty acids | | | | method |
| Total fatty acid | | | | No official |
| ester content | min. 90% | | | 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% | | | A 6 |
| | (800 ± 25°C) | | | |
| Polyol | | | | |
| composition | ** | *** | | A 26 |
| | max. | | | |
| Arsenic | 3 mg/kg | | | A 3 |
| | max. | max. | | |
| Lead | 2 mg/kg | 2 mg/kg | max. 2 mg/kg | A 2 |
| | max. | | | |
| Mercury | 1 mg/kg | | | A 5 |
| | max. | | | |
| Cadmium | 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-, triand tetraglycerols and shall contain not more than 10% of polyglycerols equal to or higher than heptaglycerol.
- a do not necessarily reflect the official methods used for the stated specifications.

References

- (1) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Polyglycerol polyricinoleate

E Number: E 476

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

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. <u>Description</u>

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:

$$R \left\{ \begin{array}{c} OR \\ | \\ CH_2 \\ CH_2 \\ CH_2 \end{array} \right\} OR$$

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. <u>Safety in use</u>

Polyglycerol polyricinoleate has 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): 0-7.5 mg/kg bw

5. <u>Typical applications in food</u>

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 (6):

- 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 % fatDressings
- Spreads
- Breath refressing microsweets
- Decorations coatings and fillings
- Sauces
- Cocoa-based confectionery, including chocolate as covered by Directive 2000/36/EC

6. <u>Non-food applications</u>

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

Specifications: E 476

Polyglycerol polyricinoleate

| | EU | FAO/WHO | FCC | Recommended |
|-------------------------------------|--|-----------------|---|-------------|
| | (1) | (2) | (3) | Analytical |
| | | | | Methods ¤ |
| Hydroxyl value | 80-100 | | 80-100 | A 20 |
| lodine 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-, triand tetraglycerols and shall contain not more than 10% of polyglycerols equal to or higher than heptaglycerol.

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

References

- (1) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.
Propane-1,2-diol esters of fatty acids

E Number: E 477

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

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

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, indispersible in cold water and soluble in edible oils and fats.

3. Analysis and specifications

See attached specification sheet.

4. <u>Safety in use</u>

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).

Evaluation status

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

5. <u>Typical applications in food</u>

The product imparts excellent aerating and foam stabilising properties.

Within the EU propane-1,2-diol esters of fatty acids are permitted in (6):

- 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. <u>Non-food applications</u>

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 potas- sium 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).

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

References

- (1) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> 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 Thermooxidiertes Sojaöl mit Mono- und Diglyceriden German von Speisefettsäuren French Huile de soja oxydée par chauffage ayant réagi avec des mono- et diglycérides d'acides gras Thermisch geoxideerde sojaolie verkregen door reactie Dutch 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.

2.1. 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. <u>Safety in use</u>

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).

Evaluation status

| Acceptable daily intake (ADI): 0-30 mg/kg bw | evaluation by JECFA |
|--|---------------------|
| Acceptable daily intake (ADI): 0-25 mg/kg bw | evaluation by SCF |

5. <u>Typical applications in food</u>

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 (6):

• Fat emulsions for frying purposes

6. <u>Non-food applications</u>

No specific application.

Specifications: E 479b

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

| | EU | FAO/WHO | FCC | Recommended |
|--|---|---------------------------|-----|-------------|
| | (1) | (2) | (3) | 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 |

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

References

- (1) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Sodium stearoyl-2-lactylate

E Number: E 481

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

Sodium stearoyl lactylate; sodium stearoyl lactate; SSL.

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, unneutralised 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. <u>Safety in use</u>

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).

Evaluation status

Acceptable daily intake (ADI): 0-20 mg/kg bw (group ADI)

5. <u>Typical applications in food</u>

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 (6):

- 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 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. <u>Non-food applications</u>
 - Pharmaceutical and cosmetic preparations

Specifications: E 481

Sodium stearoyl-2-lactylate

| | EU | FAO/WHO | FCC | Recommended |
|-------------------|-----------------|-----------------|--------------|-------------|
| | (1) | (2) | (3) | 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 |

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

References

- (1) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Calcium stearoyl-2-lactylate

E Number: E 482

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

Calcium stearoyl lactylate; calcium stearoyl lactate; CSL.

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, unneutralised 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. <u>Analysis and specifications</u>

See attached specification sheet.

4. <u>Safety in use</u>

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).

Evaluation status

Acceptable daily intake (ADI): 0-20 mg/kg bw (group ADI)

5. <u>Typical applications in food</u>

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 (6):

- 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. <u>Non-food applications</u>
 - Pharmaceutical and cosmetic preparations

Specifications: E 482

Calcium stearoyl-2-lactylate

| | EU (1) | FAO/WHO | FCC (3) | Recommended Analytical |
|-------------------|-----------------|-----------------|----------------|---------------------------|
| | () | (-) | (0) | 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 |

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

References

- (1) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Sorbitan monostearate

E Number: E 491

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

Sorbitan esters; SMS.

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. <u>Safety in use</u>

Sorbitan monostearate has 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): 0-25 mg/kg bw | evaluation by JECFA |
|---|---------------------|
| as the sum of sorbitan esters of lauric, oleic, | |
| palmitic and stearic acid | |

5. <u>Typical applications in food</u>

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 (6):

- 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. <u>Non-food applications</u>

- Pharmaceuticals and cosmetics
- Plastic food wrap

Specifications: E 491

Sorbitan monostearate

| | EU | FAO/WHO | FCC | Recommended |
|--|-------------------------------------|-----------------|------------------------|-------------------------|
| | (1) | (2) | (3) | 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 | 50-52°C | | |
| 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 |
| lodine 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 |

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

References

- (1) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Sorbitan tristearate

E Number: E 492

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

Sorbitan esters; STS.

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).

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: 0-25 mg/kg bw (for E 491, 492, 495) evaluation by SCF

5. <u>Typical applications in food</u>

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 (6):

- 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. <u>Non-food applications</u>

- Pharmaceuticals and cosmetics
- Plastic food packaging

Specifications: E 492

Sorbitan tristearate

| | EU | FAO/WHO | FCC | Recommended |
|---|-------------------------------------|-----------------|-----------------|-------------|
| | (1) | (2) | (3) | Analytical |
| | | | | Methods ¤ |
| Sorbitol, sorbitan and isosorbide esters content | min. 95% | min. 95% | | (2) |
| Acid value | max 15 | max 15 | max. 15 | A 18 |
| Saponification | | | max 0.5% | |
| value | 176-188 | 176-188 | | 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 | 47-50°C | |
| 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 |

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

References

- (1) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Sorbitan monolaurate

E Number: E 493

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

Sorbitan esters; SML.

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).

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: 0-5 mg/kg bw (for E 493 and E 494) evaluation by SCF

5. <u>Typical applications in food</u>

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 (6):

- 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. <u>Non-food applications</u>
 - Pharmaceuticals and cosmetics
 - Plastic food wrap
 - Textile lubricant

Specifications: E 493

Sorbitan monolaurate

| | EU | FAO/WHO | FCC | Recommended |
|---|-------------------------------------|-----------------|-----------------|-------------------------|
| | (1) | (2) | (3) | 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 |
| lodine 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 |

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

- (1) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Sorbitan monooleate

E Number: E 494

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

Sorbitan esters; SMO.

2. <u>Description</u>

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).

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: 0-5 mg/kg bw (for E 493 and E 494) evaluation by SCF

5. <u>Typical applications in food</u>

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 (6):

- 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. <u>Non-food applications</u>

- Pharmaceuticals and cosmetics
- Plastic food wrap
- Textile lubricant

Specifications: E 494

Sorbitan monooleate

| | EU | FAO/WHO | FCC | Recommended |
|--|-------------------------------------|-----------------|-----------------|-------------|
| | (1) | (2) | (3) | Analytical |
| O statistica participar | | | | Methods ¤ |
| Sorbitol, sorbitan and isosorbide esters content | min. 95% | min. 95% | | (2) |
| | | | max. 8 | |
| Acid value | 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 |
| | | | max. 0.5% | |
| Sulphated ash | 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) |
| lodine 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 |

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

References

- (1) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

Sorbitan monopalmitate

E Number: E 495

1. <u>Name</u>

| 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 |

<u>Synonyms</u>

Sorbitan esters; SMP.

2. <u>Description</u>

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).

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: 0-25 mg/kg bw (for E 491, 492, 495) evaluation by SCF

5. <u>Typical applications in food</u>

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 (6):

- 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. <u>Non-food applications</u>

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

Specifications: E 495

Sorbitan monopalmitate

| | EU | FAO/WHO | FCC | Recommended |
|--------------------|--------------------|-----------|-------------|-------------|
| | (1) | (2) | (3) | Analytical |
| Sorbitol, sorbitan | | | | |
| and isosorbide | min. 95% | min. 95% | | (2) |
| esters content | | | | |
| Acid value | max. 7.5 | 4.0-7.5 | max. 8 | A 18 |
| Saponification | | | 140-150 | |
| value | 140-150 | 140-150 | | A 19 |
| | | | 275-305 | |
| Hydroxyl value | 270-305 | 270-305 | 4.50/ | A 20 |
| Water | max. 2% (Karl | max. 1.5% | max. 1.5% | A 10 |
| | Fischer method) | | | |
| Congealing | | | | |
| range | 45-47°C | 45-47°C | | |
| Fatty acids | | | 63.0%–71.0% | (3) |
| Polyols (as | | | 32.0%-38.0% | (3) |
| sorbitol, 1,4- | | | | |
| sorbitan, and | | | | |
| 1303010100 | | | | |
| Acid value (fatty | | | 210-225 | A 18 |
| acid residue) | | | | |
| lodine value | | | max. 4 | A 39 |
| (fatty acid | | | | |
| residue) | | | | |
| Sulphotod och | may 0.5% | | mov 0 5% | A.C. |
| Sulphated ash | max. 0.5% | | max. 0.5% | A 0 |
| Arsenic | 3 mg/kg | | | A 3 |
| | max. | max. | max. | |
| Lead | 2 mg/kg | 2 mg/kg | 2 mg/kg | A 2 |
| Mercury | max. 1 mg/kg | | | A 5 |
| | max. | | | |
| Cadmium | 1 mg/kg | | | A 4 |

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

References

- (1) <u>Regulation 231/2012</u> 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): <u>monograph 1 (2006)</u>.
- (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) <u>Regulation (EC) No 1333/2008</u> of 16th December 2008 on food additives.

| 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 | lodine value | FAO Food and Nutrition Paper 5, Rev. 2, p. 194 |