

**Propylene Glycol Monolaurate**

E477 (propylene glycol esters of fatty acids); Propilenglikol, monolaurate de; Propilenglikolio monolauratas; Propyleenglykoli-monolauraat; Propylènglycol, monolaurate de; Propylenglycoli monolauras; Propylenglykol monolaurát; Propylenglykolmonolaurat.

Пропиленгликоля Монолаурат

CAS — 27194-74-7.

**Pharmacopoeias.** In *Eur.* (see p.vii). Also in *USNF*.

**Ph. Eur. 6.2** (Propylene Glycol Monolaurate). A mixture of the propylene glycol mono- and di-esters of lauric acid. It contains 45 to 70% of mono-esters and 30 to 55% of di-esters (type I) or a minimum of 90% of mono-esters and a maximum of 10% of di-esters (type II). The content of free propylene glycol is not more than 5% (type I) or not more than 1% (type II). A colourless or slightly yellow, clear oily liquid at 20°. Practically insoluble in water; very soluble in alcohol, in methyl alcohol, and in dichloromethane. Protect from moisture.

**USNF 26** (Propylene Glycol Monolaurate). A mixture of the propylene glycol mono- and di-esters of lauric acid. It contains 45 to 70% of mono-esters and 30 to 55% of di-esters (type I) or a minimum of 90% of mono-esters and a maximum of 10% of di-esters (type II). The content of free propylene glycol is not more than 5.0% (type I) or not more than 1.0% (type II). Protect from moisture.

**Profile**

Propylene glycol mono- and dilaurate have similar properties to propylene glycol monopalmitostearate (below) and are used as emulsifying and solubilising agents, including in food.

**Propylene Glycol Monopalmitostearate**

E477 (propylene glycol esters of fatty acids); Propilenglikol, monopalmitostearato de; Propilenglikolio monopalmitostearatas; Propilènglikol-monopalmitil-szearát; Propyleenglykolmonopalmitostearaat; Propyleenglykolmonostearaat; Propylene Glycol Monostearate; Propylene Glycol Stearate; Propylènglycol, monopalmitostéarate de; Propylènglycol (Stéarate de); Propylenglycoli monopalmitostearas; Propylenglycoli Monostearas; Propylenglykolmonopalmitostearat; Propylenglykolmonopalmitostearát; Propylenglykolmonostearat; Prostearin.

Пропиленгликоля Монопальмитостеарат

CAS — 1323-39-3 (propylene glycol monostearate); 29013-28-3 (propylene glycol monopalmitate).

**Pharmacopoeias.** In *Eur.* (see p.vii). Also in *USNF*.

**Ph. Eur. 6.2** (Propylene Glycol Monopalmitostearate). A mixture of the propylene glycol mono- and di-esters of stearic and palmitic acids. It contains a minimum of 50% of mono-esters produced from the condensation of propylene glycol and stearic acid 50. A white or almost white, waxy solid. M.p. 33° to 40°. Practically insoluble in water; soluble in hot alcohol and in acetone. Protect from light.

**USNF 26** (Propylene Glycol Monostearate). A mixture of the propylene glycol mono- and di-esters of stearic and palmitic acids. It contains not less than 90% of mono-esters of saturated fatty acids, chiefly propylene glycol monostearate and propylene glycol monopalmitate. A white, wax-like solid, beads, or flakes, with a slight agreeable fatty odour. Congealing temperature not less than 45°. Insoluble in water but it may be dispersed in hot water with the aid of a small amount of soap or other suitable surfactant; soluble in organic solvents such as alcohol, acetone, ether, benzene, and fixed or mineral oils.

**Profile**

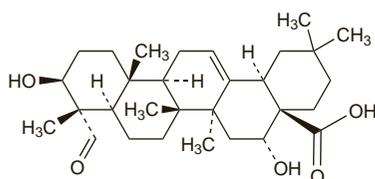
Propylene glycol monopalmitostearate is used as a stabiliser or emulsifier similarly to glyceryl monostearate (p.1915).

**Quillaia**

Corteza de Panamá; Corteza de quilla; Corteza palo de jabón; E999 (quillaia extract); Panama Wood; Quilaya; Quillaia Bark; Quillaiae cortex; Quillay; Quillaya, écorce de; Seifenrinde; Soap Bark.

Кора Мыльного Дерева

CAS — 631-01-6 (quillaia acid).



(quillaia acid)

**Pharmacopoeias.** In *Br.*, *Fr.*, and *Swiss*.

**BP 2008** (Quillaia). The dried inner part of the bark of *Quillaia saponaria* and other species of *Quillaia* containing not less than 22% of alcohol (45%) -soluble extractive. It is odourless or almost odourless, but the dust or powder is strongly sternutatory.

**Adverse Effects**

Quillaia taken by mouth has been reported to produce gastrointestinal irritation. It has been suggested that the ingestion of large amounts may produce liver damage, respiratory failure, convulsions, and coma.

**Uses**

Quillaia contains 2 amorphous saponin glycosides, quillaic acid and quillaiasapotoxin. It is used as an emulsifying agent and frothing agent, including in foodstuffs; it is often used with tragacanth mucilage or another thickening agent. Quillaia is also used for its surfactant properties in preparations for skin and respiratory-tract disorders.

**Preparations**

**BP 2008:** Quillaia Liquid Extract; Quillaia Tincture.

**Proprietary Preparations** (details are given in Part 3)

**Multi-ingredient:** *Braz.:* Bluderm†; *Chile:* Fitotos; Notosil†; Sedotus†; *Cz.:* Solutan†; *Fin.:* Kvilla; *Hong Kong:* Pectoral†; *Rus.:* Solutan (Солутан); *Swed.:* Quilla simplex; *Switz.:* Expectoran Codein†; Expectoran†.

**Sorbitan Esters**

Sorbitán, ésteres del.

Эфиры Сорбитана

**Description.** A series of mixtures of the partial esters of sorbitol and its mono- and di-anhydrides with fatty acids.

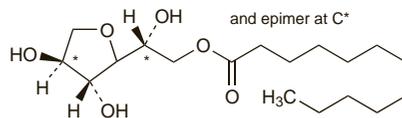
**Sorbitan Laurate** (*BAN, rINN*)

E493; Laurato de sorbitán; Monolaurato de sorbitán; Sorbitaani-lauraat; Sorbitan, laurate de; Sorbitan Monolaurate (*USAN*); Sorbitani lauras; Sorbitanlaurat; Sorbitan-laurát; Sorbitano lauratas; Szorbitán-laurát.

Сорбитана Лаурат

C<sub>18</sub>H<sub>34</sub>O<sub>6</sub> (approximate).

CAS — 1338-39-2.



**Pharmacopoeias.** In *Eur.* (see p.vii). Also in *USNF*.

**Ph. Eur. 6.2** (Sorbitan Laurate). A mixture of the partial esters of sorbitol and its mono- and di-anhydrides with lauric acid. A brownish-yellow viscous liquid. Relative density about 0.98. Practically insoluble but dispersible in water; miscible with alcohol; slightly soluble in cottonseed oil. Protect from light.

**USNF 26** (Sorbitan Monolaurate). A partial ester of sorbitol and its mono- and di-anhydrides with lauric acid. A yellow to amber oily liquid with a bland characteristic odour. Insoluble in water; soluble in liquid paraffin; slightly soluble in cottonseed oil and in ethyl acetate. Store in airtight containers.

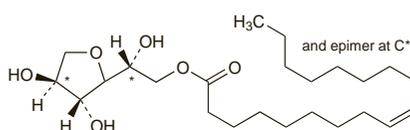
**Sorbitan Oleate** (*BAN, rINN*)

E494; Monooleato de sorbitán; NSC-406239; Oleato de sorbitán; Sorbitaanioleaat; Sorbitan Monooleate (*USAN*); Sorbitan Mono-oleate; Sorbitan, oléate de; Sorbitani oleas; Sorbitano oleatas; Sorbitanoleat; Sorbitan-oleát; Szorbitán-oleát.

Сорбитана Олеат

C<sub>24</sub>H<sub>44</sub>O<sub>6</sub> (approximate).

CAS — 1338-43-8.



**Pharmacopoeias.** In *Eur.* (see p.vii). Also in *USNF*.

**Ph. Eur. 6.2** (Sorbitan Oleate). A mixture usually obtained by esterification of 1 mole of sorbitol and its mono- and di-anhydrides per mole of oleic acid. A suitable antioxidant may be added. A brownish-yellow viscous liquid. Relative density about 0.99. Practically insoluble but dispersible in water; miscible with alcohol; soluble in fatty oils producing a hazy solution. Protect from light.

**USNF 26** (Sorbitan Monooleate). A partial oleate ester of sorbitol and its mono- and di-anhydrides. A yellow to amber-coloured, viscous, oily liquid with a bland characteristic odour.

Insoluble in water and in propylene glycol; miscible with mineral and vegetable oils. Store in airtight containers.

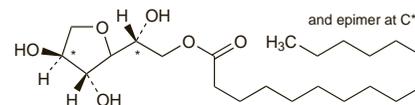
**Sorbitan Palmitate** (*BAN, rINN*)

E495; Monopalmitato de sorbitán; Palmitato de sorbitán; Sorbitaani-palmitaat; Sorbitan Monopalmitate (*USAN*); Sorbitan, palmitate de; Sorbitani palmitas; Sorbitano palmitatas; Sorbitanpalmitat; Sorbitan-palmitát; Szorbitán-palmitát.

Сорбитана Пальмитат

C<sub>22</sub>H<sub>42</sub>O<sub>6</sub> (approximate).

CAS — 26266-57-9.



**Pharmacopoeias.** In *Eur.* (see p.vii). Also in *USNF*.

**Ph. Eur. 6.2** (Sorbitan Palmitate). A mixture of the partial esters of sorbitol and its mono- and di-anhydrides with palmitic acid. A yellowish or yellow powder, waxy flakes, or hard masses. M.p. 44° to 51°. Practically insoluble in water; slightly soluble in alcohol; soluble in fatty oils. Protect from light.

**USNF 26** (Sorbitan Monopalmitate). A partial ester of sorbitol and its mono- and di-anhydrides with palmitic acid. A cream-coloured, waxy solid with a faint fatty odour. Insoluble in water; soluble in warm dehydrated alcohol; soluble with haze in warm liquid paraffin and in warm arachis oil.

**Sorbitan Sesquioleate** (*BAN, USAN, rINN*)

Sesquioleato de sorbitán; Sorbitaaniseskivoleaat; Sorbitan, sesquioléate de; Sorbitani sesquioleas; Sorbitano sesquioleatas; Sorbitanseskivoleat; Sorbitan-sesquioléat; Szorbitán-szeszkivoleát.

Сорбитана Сесквиолеат

C<sub>33</sub>H<sub>60</sub>O<sub>6.5</sub> (approximate).

CAS — 8007-43-0.

**Pharmacopoeias.** In *Eur.* (see p.vii) and *Jpn.* Also in *USNF*.

**Ph. Eur. 6.2** (Sorbitan Sesquioleate). A mixture usually obtained by esterification of 2 moles of sorbitol and its mono- and di-anhydrides per 3 moles of oleic acid. A suitable antioxidant may be added. Relative density about 0.99. A pale yellow or slightly brownish-yellow paste, which becomes a viscous, oily, brownish-yellow liquid at about 25°. Dispersible in water; slightly soluble in dehydrated alcohol; soluble in fatty oils. Protect from light.

**USNF 26** (Sorbitan Sesquioleate). A partial oleate ester of sorbitol and its mono- and di-anhydrides. A yellow to amber-coloured, oily viscous liquid. Insoluble in water and in propylene glycol; soluble in alcohol, in isopropyl alcohol, in cottonseed oil, and in liquid paraffin. Store in airtight containers.

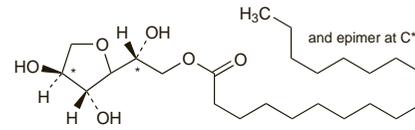
**Sorbitan Stearate** (*BAN, rINN*)

E491; Estearato de sorbitán; Monoestearato de sorbitán; Sorbitaaniestearaat; Sorbitan Monostearate (*USAN*); Sorbitan, stéarate de; Sorbitani stearas; Sorbitano stearatas; Sorbitanestearat; Sorbitan-stearát; Szorbitán-szearát.

Сорбитана Стеарат

C<sub>24</sub>H<sub>46</sub>O<sub>6</sub> (approximate).

CAS — 1338-41-6.



**Pharmacopoeias.** In *Eur.* (see p.vii). Also in *USNF*.

**Ph. Eur. 6.2** (Sorbitan Stearate). A mixture of the partial esters of sorbitol and its mono- and di-anhydrides with stearic acid. A pale yellow, waxy solid. M.p. 50° to 55°. Practically insoluble but dispersible in water; slightly soluble in alcohol. Protect from light.

**USNF 26** (Sorbitan Monostearate). A partial ester of sorbitol and its mono- and di-anhydrides with stearic acid. A cream-coloured to tan, hard, waxy solid with a bland odour. Insoluble in cold water and in acetone; dispersible in warm water; soluble, with haze, above 50° in ethyl acetate and in liquid paraffin.

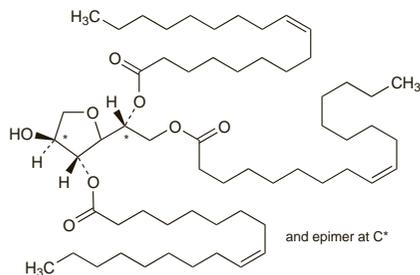
**Sorbitan Trioleate** (BAN, USAN, rINN)

Sorbitaantrioloaatti; Sorbitan, trioléate de; Sorbitani trioleas; Sorbitano trioleatas; Sorbitantrioloat; Sorbitan-trioleát; Szorbitán-trioleát; Trioleato de sorbitán.

Сорбитана Триолеат

$C_{60}H_{108}O_8$  (approximate).

CAS — 26266-58-0.



**Pharmacopoeias.** In *Eur.* (see p.vii). Also in *USNF*.

**Ph. Eur. 6.2** (Sorbitan Trioleate). A mixture usually obtained by esterification of 1 mole of sorbitol and its mono- and di-anhydrides per 3 moles of oleic acid. A suitable antioxidant may be added. A pale yellow, light yellowish or brown solid which becomes a brownish-yellow, viscous, oily liquid at about 25°. Relative density about 0.98. Practically insoluble but dispersible in water; slightly soluble in alcohol; soluble in fatty oils. Protect from light.

**USNF 26** (Sorbitan Trioleate). A tri-ester of sorbitol and its mono- and di-anhydrides with oleic acid. A yellow to amber-coloured, oily liquid. Insoluble in water, in ethylene glycol, and in propylene glycol; soluble in alcohol, in isopropyl alcohol, in methyl alcohol, in maize oil, in cottonseed oil, and in liquid paraffin. Store in airtight containers.

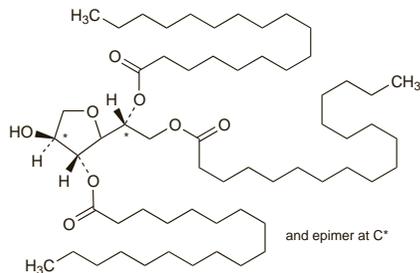
**Sorbitan Tristearate** (BAN, USAN, rINN)

E492; Sorbitan, Tristéarate de; Sorbitani Tristearas; Triestearato de sorbitán.

Сорбитана Тристеарат

$C_{60}H_{114}O_8$  (approximate).

CAS — 26658-19-5.



**Description.** A mixture of the partial tri-esters of sorbitol and its mono- and di-anhydrides with stearic acid.

**Adverse Effects**

There have been occasional reports of hypersensitive skin reactions after the topical application of creams containing sorbitan esters.

**Hypersensitivity. References.**

1. Finn OA, Forsyth A. Contact dermatitis due to sorbitan monoaurate. *Contact Dermatitis* 1975; **1**: 318.
2. Hannuksela M, *et al.* Allergy to ingredients of vehicles. *Contact Dermatitis* 1976; **2**: 105–10.
3. Austad J. Allergic contact dermatitis to sorbitan monooleate (Span 80). *Contact Dermatitis* 1982; **8**: 426–7.
4. Boyle J, Kennedy CTC. Contact urticaria and dermatitis to Al-phaderm. *Contact Dermatitis* 1984; **10**: 178.
5. Hardy MP, Maibach HI. Contact urticaria syndrome from sorbitan sesquioleate in a corticosteroid ointment. *Contact Dermatitis* 1995; **32**: 114.
6. Wakelin SH, *et al.* Sorbitan mono-oleate: a potential allergen in paste bandages. *Contact Dermatitis* 1996; **35**: 377.
7. de Waard-van der Spek FB, *et al.* Allergic contact dermatitis to sorbitan sesquioleate in Adaptic wound dressing. *Contact Dermatitis* 2007; **57**: 54–6.

**Uses**

Sorbitan esters are lipophilic nonionic surfactants that are used as emulsifying agents in the preparation of emulsions, creams, and ointments for pharmaceutical and cosmetic use. When used alone they produce stable water-in-oil emulsions but they are frequently used with a polysorbate in varying proportions to produce water-in-oil or oil-in-water emulsions or creams with a variety of different textures and consistencies. Sorbitan esters are also used as emulsifiers and stabilisers in food.

**Sucrose Esters**

E473 (sucrose esters of fatty acids); Sacarosa, ésteres de; Sacchari monopalmitas (sucrose monopalmitate); Sacchari monostearas (sucrose monostearate); Saccharose, monopalmitate de (sucrose monopalmitate); Saccharose, monostéarate de (sucrose monostearate); Sucroésteres.

Эфиры Сахарозы

**Pharmacopoeias.** *Eur.* (p.vii) includes Sucrose Monopalmitate and Sucrose Stearate.

**Ph. Eur. 6.2** (Sucrose Monopalmitate). A mixture of sucrose monoesters, mainly sucrose monopalmitate, obtained by transesterification of palmitic acid methyl esters of vegetable origin with sucrose. It contains 55.0% monoesters, a maximum 40.0% diesters, and a maximum of 20.0% for the sum of triesters and polyesters. A white or almost white, unctuous powder. Very slightly soluble in water; sparingly soluble in alcohol. Protect from humidity.

**Ph. Eur. 6.2** (Sucrose Stearate). A mixture of sucrose esters, mainly sucrose stearate, obtained by transesterification of stearic acid methyl esters of vegetable origin with sucrose. Sucrose stearate type I contains a minimum 50.0% monoesters, a maximum 40.0% diesters, and a maximum of 25.0% for the sum of triesters and polyesters. Sucrose stearate type II contains 20.0 to 45.0% monoesters, 30.0 to 40.0% diesters, and a maximum of 30.0% for the sum of triesters and polyesters. A white or almost white, unctuous powder. Very slightly soluble in water; sparingly soluble in alcohol. Protect from humidity.

**Profile**

Sucrose esters are nonionic compounds with surface-active properties produced by esterification of 1 or more hydroxyl groups in sucrose with a fatty acid such as stearic or palmitic acid. Commercial sucrose esters are mixtures of the mono-, di-, and tri-esters of palmitic and stearic acids with sucrose; various grades are available. Sucrose esters are used as dispersing, emulsifying, and stabilising agents in food and cosmetic preparations.

**Tyloxapol** (BAN, USAN, rINN)

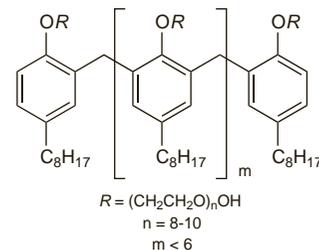
Superinone; Tiloxapol; Tyloksapoli; Tyloxapolum.

Тилоксапол

CAS — 25301-02-4.

ATC — R05CA01.

ATC Vet — QR05CA01.



**Pharmacopoeias.** In *US*.

**USP 31** (Tyloxapol). A polymer of 4-(1,1,3,3-tetramethylbutyl)phenol with ethylene oxide and formaldehyde. A viscous amber liquid, sometimes slightly turbid, with a slight aromatic odour. Slowly but freely miscible with water; soluble in chloroform, in glacial acetic acid, in carbon disulfide, in carbon tetrachloride, in toluene, and in benzene. A 5% solution has a pH of 4.0 to 7.0. Tyloxapol should not be allowed to come into contact with metals. Store in airtight containers.

**Adverse Effects**

Slight inflammation of the eyelids has been reported after prolonged use of aqueous inhalations of tyloxapol. It has been reported that occasional febrile reactions may occur.

**Uses and Administration**

Tyloxapol is a nonionic surfactant of the alkyl aryl polyether alcohol type. It is used in solutions for cleansing contact lenses and artificial eyes. Aqueous solutions have been used for inhalation as a mucolytic for tenacious bronchopulmonary secretions. Tyloxapol has also been used as a vehicle for aerosol medication and for antibacterials given in irrigation solutions for pyogenic bone or joint infections.

**Preparations**

**Proprietary Preparations** (details are given in Part 3)

**Austria:** Tacholiquin; **Canada:** Enuclene; **Ger.:** Enuclen†; Tacholiquin; **NZ:** Enuclene; **USA:** Enuclene.

**Multi-ingredient:** **Austral:** Blink-N-Clean.