Incompatibility. Polysorbates have been reported to be stable with electrolytes and weak acids and bases although saponification may occur in the presence of strong acids and bases. Discoloration or precipitation may occur with phenolic substances. The oleic acid esters are sensitive to oxidation. For reference to the possible incompatibility of polysorbate 80 with hydroxybenzoates, see p.1649.

Polysorbate 20 *(BAN, USAN, rINN)*

E432; Monolaurato de polietileno 20 sorbitano; Monolaurato de polioxietileno 20 sorbitano; Polisorbat 20; Polisorbatas 20; Polisorbato 20; Poliszorbát 20; Polyoxyethylene 20 Sorbitan Monolaurate; Polysorbaatti 20; Polysorbát 20; Polysorbat 20; Polysorbatum 20; Sorbimacrogol Laurate 300; Sorboxaethenum Laurinicum.

Полисорбат 20

$C_{58}H_{114}O_{26}$ (approximate).
CAS — 9005-64-5.

Pharmacopoeias. In *Eur.* (see p.vii) and *Int.* Also in *USNF.*
Ph. Eur. 6.2 (Polysorbate 20). A mixture of partial esters of fatty acids, mainly lauric acid, with sorbitol and its anhydrides ethoxylated with about 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides. A clear or slightly opalescent yellowish to brownish-yellow oily liquid. Relative density about 1.10. Soluble in water, in dehydrated alcohol, in ethyl acetate, and in methyl alcohol; practically insoluble in liquid paraffin and in fatty oils. Store in airtight containers. Protect from light.
USNF 26 (Polysorbate 20). A laurate ester of sorbitol and its anhydrides copolymerised with approximately 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides. A lemon to amber liquid with a faint characteristic odour. Soluble in water, in alcohol, in dioxan, in ethyl acetate, and in methyl alcohol; insoluble in liquid paraffin. Store in airtight containers.

Polysorbate 40 *(BAN, USAN, rINN)*

E434; Monopalmitato de polietileno 20 sorbitano; Monopalmitato de polioxietileno 20 sorbitano; Polisorbatas 40; Polisorbato 40; Poliszorbát 40; Polyoxyethylene 20 Sorbitan Monopalmitate; Polysorbaatti 40; Polysorbát 40; Polysorbat 40; Polysorbatum 40; Sorbimacrogol Palmitate 300.

Полисорбат 40

$C_{62}H_{122}O_{26}$ (approximate).
CAS — 9005-66-7.

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF.*
Ph. Eur. 6.2 (Polysorbate 40). Mixture of partial esters of fatty acids, mainly palmitic acid, with sorbitol and its anhydrides ethoxylated with about 20 moles of ethylene oxide for each mole of sorbitol and sorbitol anhydrides. An oily, viscous, yellowish or brownish-yellow liquid. Relative density about 1.10. Miscible with water, with dehydrated alcohol, with ethyl acetate, and with methyl alcohol; practically insoluble in fatty oils and in liquid paraffin. Store in airtight containers. Protect from light.
The BP 2008 gives Polyoxyethylene 20 Sorbitan Monopalmitate as an approved synonym.
USNF 26 (Polysorbate 40). A palmitate ester of sorbitol and its anhydrides copolymerised with about 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides. A yellow liquid with a faint characteristic odour. Soluble in water and in alcohol; insoluble in liquid paraffin and in vegetable oils. Store in airtight containers.

Polysorbate 60 *(BAN, USAN, rINN)*

E435; Monoestearato de polietileno 20 sorbitano; Monoestearato de polioxietileno 20 sorbitano; Polisorbat 60; Polisorbatas 60; Polisorbato 60; Poliszorbát 60; Polyoxyethylene 20 Sorbitan Monostearate; Polysorbaatti 60; Polysorbát 60; Polysorbat 60; Polysorbatum 60; Sorbimacrogol Stearate 300; Sorboxaethenum Stearinicum.

Полисорбат 60

$C_{64}H_{126}O_{26}$ (approximate).
CAS — 9005-67-8.

Pharmacopoeias. In *Eur.* (see p.vii) and *Int.* Also in *USNF.*
Ph. Eur. 6.2 (Polysorbate 60). A mixture of partial esters of fatty acids, mainly stearic acid 50, with sorbitol and its anhydrides ethoxylated with about 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides. A yellowish-brown gelatinous mass which becomes a clear liquid at temperatures above 25°. Relative density about 1.10. Soluble in water, in dehydrated alcohol, in ethyl acetate, and in methyl alcohol; practically insoluble in liquid paraffin and in fatty oils. Store in airtight containers. Protect from light.
USNF 26 (Polysorbate 60). A mixture of stearate and palmitate esters of sorbitol and its anhydrides copolymerised with approximately 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides. A lemon to orange-coloured oily liquid or semi-gel with a faint characteristic odour. Soluble in water, in ethyl acetate, and in toluene; insoluble in liquid paraffin and in vegetable oils. Store in airtight containers.

Polysorbate 80 *(BAN, USAN, rINN)*

E433; Monooleato de polietileno 20 sorbitano; Monooleato de polioxietileno 20 sorbitano; Olethytan 20; Polisorbat 80; Polisorbatas 80; Polisorbato 80; Poliszorbát 80; Polyäthylenglykol-Sorbitanoleat; Polyoxyethylene 20 Sorbitan Mono-oleate; Polysorbaatti 80; Polysorbát 80; Polysorbat 80; Polysorbatum 80; Polysorbitanum 80 Oleinatum; Sorbimacrogol Oleate 300; Sorboxaethenum Oleinicum; Sorethytan 20 Mono-oleate.

Полисорбат 80

$C_{64}H_{124}O_{26}$ (approximate).
CAS — 9005-65-6.

Pharmacopoeias. In *Chin., Eur.* (see p.vii), *Int.,* and *Jpn.* Also in *USNF.*
Ph. Eur. 6.2 (Polysorbate 80). A mixture of partial esters of fatty acids, mainly oleic acid, with sorbitol and its anhydrides ethoxylated with about 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides. An oily, yellowish or brownish-yellow, clear or slightly opalescent liquid. Relative density about 1.10. Dispersible in water, in dehydrated alcohol, in ethyl acetate, and in methyl alcohol; practically insoluble in liquid paraffin and in fatty oils. Store in airtight containers. Protect from light.
USNF 26 (Polysorbate 80). An oleate ester of sorbitol and its anhydrides copolymerised with about 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides. A lemon to amber-coloured oily liquid with a faint characteristic odour. Sp. gr. between 1.06 and 1.09; viscosity, at 25°, between 300 and 500 mPa s. Very soluble in water, producing an odourless and practically colourless solution; soluble in alcohol and in ethyl acetate; insoluble in liquid paraffin. Store in airtight containers.

Polysorbate 85 *(BAN, USAN, rINN)*

Polisorbatas 85; Polisorbato 85; Poliszorbát 85; Polyoxyethylene 20 Sorbitan Trioleate; Polysorbaatti 85; Polysorbat 85; Polysorbát 85; Polysorbatum 85; Sorbimacrogol Trioleate 300; Trioleato de polietileno 20 sorbitano; Trioleato de polioxietileno 20 sorbitano.

Полисорбат 85

$C_{100}H_{188}O_{28}$ (approximate).
CAS — 9005-70-3.

Description. A mixture of mainly trioleate esters of sorbitol and its anhydrides copolymerised with about 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides.

Adverse Effects and Precautions

Polysorbates may increase the absorption of fat-soluble substances.

There have been occasional reports of hypersensitivity after topical application of preparations containing polysorbates.

For discussion of fatalities in low-birth-weight infants associated with the injection of a polysorbate-containing preparation, see below.

Polysorbates used as excipients may also lead to adverse effects due to alterations in the pharmacokinetics of the formulated drug.

◊ References.

1. ten Tije AJ, *et al.* Pharmacological effects of formulation vehicles: implications for cancer chemotherapy. *Clin Pharmacokinet* 2003; **42:** 665–85.

Effects in infants. After the introduction in the USA of an intravenous preparation of vitamin E (*E-Ferol*) there were a number of reports of unusual liver and kidney disorders, with 38 deaths being reported among treated low-birth-weight infants. Affected infants had unexplained hypotension, thrombocytopenia, renal dysfunction, hepatomegaly, cholestasis, ascites, and metabolic acidosis;[1-3] the preparation was subsequently withdrawn from the market in April 1984 about 5 months after it was introduced. *In-vitro* evidence was produced showing that *E-Ferol* suppressed the response of human lymphocytes to phytohaemagglutinin. However, it was the mixture of polysorbates, polysorbate 20 and in particular polysorbate 80, that was shown to be responsible for this suppression rather than the α-tocopherol acetate component. Despite this *in-vitro* data, overwhelming infection was not a feature in the affected infants.[2] Large doses of polysorbates were unavoidably injected when *E-Ferol* was used and it was suggested that polysorbates may accumulate as a result of an alteration in the metabolism by low-birth-weight infants; polysorbate-induced alteration of membrane fluidity in cells of vessel walls may have led to changes in structure and function.[2]

1. Alade SL, *et al.* Polysorbate 80 and E-Ferol toxicity. *Pediatrics* 1986; **77:** 593–7.
2. Balistreri WF, *et al.* Lessons from the E-Ferol tragedy. *Pediatrics* 1986; **78:** 503–6.
3. Golightly LK, *et al.* Pharmaceutical excipients: adverse effects associated with inactive ingredients in drug products. *Med Toxicol* 1988; **3:** 128–65 and 209–240.

Hypersensitivity. Local inflammatory reactions after intramuscular injection of a vitamin A preparation were considered[1] to be due to a hypersensitivity reaction to polysorbate 80, included as an excipient. Anaphylactoid reactions which occurred in 2 patients after treatment with omalizumab for 27 and 13 months respectively, were likely to be due to the polysorbate excipient and not to the monoclonal antibody itself.[2] The presence of polysorbate 80 in the injection may also contribute to hypersensitivity reactions to docetaxel (see Adverse Effects of Docetaxel, p.710).

1. Shelley WB, *et al.* Polysorbate 80 hypersensitivity. *Lancet* 1995; **345:** 1312–13.
2. Price KS, Hamilton RG. Anaphylactoid reactions in two patients after omalizumab administration after successful long-term therapy. *Allergy Asthma Proc* 2007; **28:** 313–19.

Uses

Polysorbates are hydrophilic nonionic surfactants that are used as emulsifying agents for the preparation of stable oil-in-water emulsions in pharmaceutical products; they are frequently used with a sorbitan ester in varying proportions to produce products with a range of texture and consistency. Polysorbates have also been used in the formulation of insecticide and herbicide sprays, industrial detergents, and cosmetic products. They are also used as emulsifiers in the food industry.

Polysorbates are used as solubilising agents for a variety of substances including essential oils and oil-soluble vitamins such as vitamins A, D, and E, and as wetting agents in the formulation of oral and parenteral suspensions. However, hypersensitivity reactions have been attributed to the presence of polysorbates, see Hypersensitivity, above.

Polysorbates may also be used for their surfactant properties in preparations for the removal of ear wax, and for the management of dry eyes and upper respiratory-tract disorders.

Preparations

Proprietary Preparations (details are given in Part 3)
Arg.: Sinroncar; ***Belg.:*** Oleosorbate; ***Canad.:*** Dioptears; Tears Encore; ***Fr.:*** Cerumenol; ***USA:*** OptiZen; Viva-Drops.

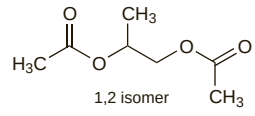
Multi-ingredient: ***Arg.:*** Balsan†; Otoclean Gotas Oticas; ***Fin.:*** Expigen; ***Fr.:*** Ceruspray; Fluisedal; Fluisedal sans promethazine; Paroplak; Prorhinel; ***S.Afr.:*** Expigen; ***Switz.:*** Prorhinel; Rhinocure; Rhinocure simplex; ***Turk.:*** Kansilak; Libalaks; ***UK:*** Asonor; ***USA:*** Refresh Dry Eye Therapy; Soothe; Soothe XP.

Propylene Glycol Diacetate

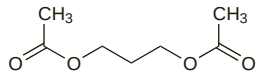
Propilenglicol, diacetato de. Propanediol diacetate.

Диацетат Пропиленгликоля

$C_7H_{12}O_4$ = 160.2.
CAS — 623-84-7 (1,2-isomer); 628-66-0 (1,3-isomer).



1,2 isomer



1,3 isomer

Profile

Propylene glycol diacetate is an emulsifying and/or solubilising agent, and a solvent. It is included in some external preparations for ear infection.

Preparations

Proprietary Preparations (details are given in Part 3)
Multi-ingredient: ***Canad.:*** VoSoL HC†; ***NZ:*** VoSoL; ***USA:*** Acetasol; Acetasol HC; VoSoL HC†; VoSoL†.

Propylene Glycol Laurates

E477 (propylene glycol esters of fatty acids); Propilenglicol, laurato de.

Пропиленгликоля Лаураты

Propylene Glycol Dilaurate

E477 (propylene glycol esters of fatty acids); Propilenglicol, dilaurato de; Propilenglikolio dilauratas; Propyleeniglykolidilauraatti; Propylene Dilaurate; Propylèneglycol, dilaurate de; Propylenglycoli dilauras; Propylenglykoldilaurat; Propylenglykol-dilaurát.

Пропиленгликоля Дилаурат

CAS — 22788-19-8.

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF.*
Ph. Eur. 6.2 (Propylene Glycol Dilaurate). A mixture of the propylene glycol mono- and di-esters of lauric acid. It contains a minimum of 70% of di-esters and a maximum of 30% of mono-esters. The content of free propylene glycol is not more than 2%. 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 Dilaurate). A mixture of the propylene glycol mono- and di-esters of lauric acid. It contains not less than 70.0% of di-esters and not more than 30.0% of mono-esters. Protect from moisture.

Propylene Glycol Monolaurate

E477 (propylene glycol esters of fatty acids); Propilenglicol, monolaurate de; Propilenglikolio monolauratas; Propyleeniglykolimonolauraatti; Propylèneglycol, 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); Propilenglicol, monopalmitoestearato de; Propilenglikolio monopalmitostearatas; Propiléglikol-monopalmitil-sztearát; Propyleeniglykolimonopalmitostearaatti; Propyleeniglykolimonostearaatti; Propylene Glycol Monostearate; Propylene Glycol Stearate; Propylèneglycol, monopalmitostéarate de; Propylèneglycol (Stéarate de); Propylenglycoli monopalmitostearas; Propylenglycoli Monostearas; Propylenglykolmonopalmitostearat; Propylenglykol-monopalmitostearát; 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

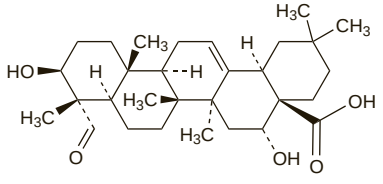
Propylene glycol monopalmitostearate is used as a stabiliser or emulsifier similarly to glyceryl monostearate (p.1915).

Quillaia

Corteza de Panamá; Corteza de quillay; 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 (quillaic acid).



(quillaic acid)

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

BP 2008 (Quillaia). The dried inner part of the bark of *Quillaja saponaria* and other species of *Quillaja* 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.

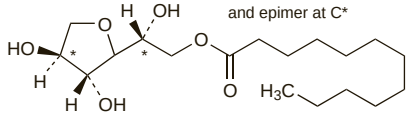
Sorbitan Laurate *(BAN, rINN)*

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

Сорбитана Лаурат

$C_{18}H_{34}O_6$ (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.

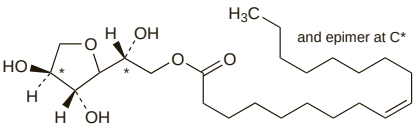
Sorbitan Oleate *(BAN, rINN)*

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

Сорбитана Олеат

$C_{24}H_{44}O_6$ (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 antoxidant 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.

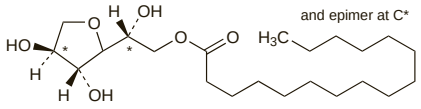
Sorbitan Palmitate *(BAN, rINN)*

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

Сорбитана Пальмитат

$C_{22}H_{42}O_6$ (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; Sorbitaaniseskvioleaatti; Sorbitan, sesquioléate de; Sorbitani sesquioleas; Sorbitano seskvioleatas; Sorbitanseskvioleat; Sorbitan-seskvioleát; Szorbitán-szeszkvioleát.

Сорбитана Сесквиолеат

$C_{33}H_{60}O_{6.5}$ (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 antoxidant 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.

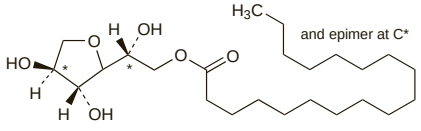
Sorbitan Stearate *(BAN, rINN)*

E491; Estearato de sorbitán; Monoestearato de sorbitán; Sorbitaanistearaatti; Sorbitan Monostearate *(USAN)*; Sorbitan, stéarate de; Sorbitani stearas; Sorbitano stearatas; Sorbitanstearat; Sorbitan-stearát; Szorbitán-sztearát.

Сорбитана Стеарат

$C_{24}H_{46}O_6$ (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.