

A hard, waxy mass or powder, or white or almost white, unctuous flakes. Practically insoluble in water; partly soluble in hot alcohol; soluble in dichloromethane. M.p. 50° to 60° (types I and II) or 50° to 70° (type III).

**USNF 26** (Glyceryl Distearate). A mixture of diglycerides, mainly glyceryl distearate, together with variable quantities of monoglycerides and triglycerides. It contains 8 to 22% of monoglycerides, 40 to 60% of diglycerides, and 25 to 35% of triglycerides. It is obtained by partial glycerolysis of vegetable oil that consists mainly of triglycerides of palmitic or stearic acid or by esterification of glycerol with stearic acid. The fatty acids may be of vegetable or animal origin.

Hard, waxy mass or powder, or white or almost white flakes. Insoluble in water; partly soluble in hot alcohol; soluble in dichloromethane and in tetrahydrofuran. Store in airtight containers.

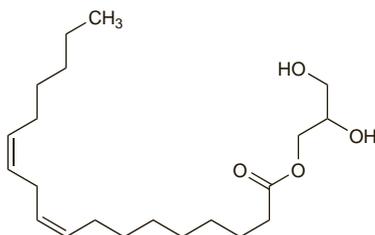
#### Profile

Glyceryl distearate is used as an emulsifying and/or solubilising agent.

### Glyceryl Monolinoleate

Glicerol-monolinoleát; Glicerol, monolinoleato de; Glicerolio monolinoleatas; Glycerol Monolinoleate; Glycérol, monolinoléate de; Glyceroli monolinoleas; Glycerol-monolinolát; Glycerolmonolinoleat; Glycerolmonolinoleaatti; Monolinolein.

Глицерилмонолилеат  
CAS — 26545-74-4.



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

**Ph. Eur. 6.2** (Glycerol Monolinoleate). A mixture of monoacylglycerols, mainly mono-oleoylglycerol and monolinoleoylglycerol, together with variable quantities of di- and triacylglycerols. It contains 32 to 52% of monoacylglycerols, 40 to 55% of diacylglycerols, and 5 to 20% of triacylglycerols, obtained by partial glycerolysis of vegetable oils mainly containing triacylglycerols of linoleic acid. A suitable antioxidant may be added.

Amber, oily liquids which may be partially solidified at room temperature. Practically insoluble in water; freely soluble in dichloromethane. Store in airtight containers. Protect from light.

**USNF 26** (Glyceryl Monolinoleate). A mixture of monoglycerides, mainly glyceryl mono-oleate and glyceryl monolinoleate, together with variable quantities of diglycerides and triglycerides. It is obtained by partial glycerolysis of vegetable oil that consists mainly of triglycerides of linoleic acid. It contains 32 to 52% of monoglycerides, 40 to 55% of diglycerides, and 5 to 20% of triglycerides. A suitable antioxidant may be added.

Amber, oily liquids that may be partially solidified at room temperature. Practically insoluble in water; freely soluble in dichloromethane; soluble in tetrahydrofuran. Store in airtight containers.

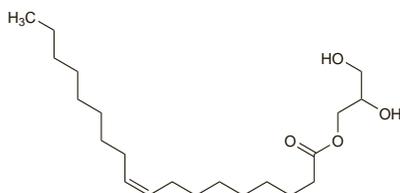
#### Profile

Glyceryl monolinoleate is used as an emulsifying and/or solubilising agent.

### Glyceryl Mono-oleate

Glicerol, monooleato de; Glycérol, mono-oléate de; Glyceroli mono-oleas; Monoolein.

Глицерилмоноолеат  
CAS — 25496-72-4.



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

**Ph. Eur. 6.2** (Glycerol Mono-oleates). Mixtures of monoacylglycerols, mainly mono-oleoylglycerol, together with variable quantities of di- and triacylglycerols. They are defined by the

nominal content of monoacylglycerols and obtained by partial glycerolysis of vegetable oils mainly containing triacylglycerols of oleic acid, or by esterification of glycerol by oleic acid. A suitable antioxidant may be added.

Amber, oily liquids which may be partially solidified at room temperature. Practically insoluble in water; freely soluble in dichloromethane. Store in airtight containers. Protect from light.

**USNF 26** (Glyceryl Monooleate). A mixture of monoglycerides, mainly glyceryl mono-oleate, together with variable quantities of di- and triglycerides. It is obtained by partial glycerolysis of vegetable oil that consists mainly of triglycerides of oleic acid, or by esterification of glycerol with oleic acid of vegetable or animal origin. It is defined by the nominal content of monoglycerides. A suitable antioxidant may be added.

Amber, oily liquids that may be partially solidified at room temperature. Practically insoluble in water; freely soluble in dichloromethane; soluble in tetrahydrofuran. Store in airtight containers.

#### Profile

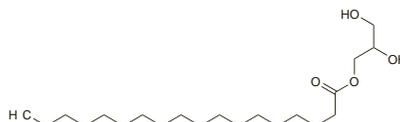
Glyceryl mono-oleate has similar properties to glyceryl monostearate or self-emulsifying glyceryl monostearate (below).

### Glyceryl Monostearate

Gliceril, monoestearato de; Glicerol-monostearát; Glicerolio monostearatas; Glicerolu monostearanyian; Glycérol, monostéarate de; Glyceroli monostearas; Glycerolmonostearat; Glycerolmonostearát; Glycerolmonostearaatti; GMS; Monostearin.

Глицерилмоностеарат

CAS — 31566-31-1 (glyceryl monostearate); 26657-96-5 (glyceryl monopalmitate).



**Pharmacopoeias.** In *Eur.* (see p.vii), *Int.*, and *Jpn.* Also in *US-NF*.

**Ph. Eur. 6.2** (Glycerol Monostearate 40-55). A mixture of monoacylglycerols, mainly monostearoylglycerol, together with variable quantities of di- and triacylglycerols. It contains 40 to 55% of monoacylglycerols, 30 to 45% of diacylglycerols, and 5 to 15% of triacylglycerols, obtained by partial glycerolysis of vegetable oils mainly containing triacylglycerols of palmitic or stearic acid, or by esterification of glycerol with stearic acid. The fatty acids may be of vegetable or animal origin.

A white or almost white, hard, waxy mass or unctuous powder or flakes. Practically insoluble in water; soluble in alcohol at 60°. M.p. 54° to 66°.

**USNF 26** (Glyceryl Monostearate). It contains not less than 90% of monoglycerides of saturated fatty acids, chiefly glyceryl monostearate (C<sub>21</sub>H<sub>42</sub>O<sub>4</sub> = 358.6) and glyceryl monopalmitate (C<sub>19</sub>H<sub>38</sub>O<sub>4</sub> = 330.5). It may contain a suitable antioxidant.

A white to yellowish wax-like solid, beads, flakes, or powder with a slight, agreeable, fatty odour. M.p. not below 55°. Insoluble in water but may be dispersed in hot water with the aid of a small amount of soap or other suitable surfactant; soluble 1 in 10 of chloroform, 1 in 100 of ether and of methyl alcohol, 1 in 33 of isopropyl alcohol; dissolves in hot organic solvents such as alcohol, acetone, mineral or fixed oils, and benzene. Store in airtight containers. Protect from light.

### Self-emulsifying Glyceryl Monostearate

Glicerol autoemulsionable, monoestearato de; Monostearato de glicerilo autoemulsionable; Monostearin Emulsificans; Self-emulsifying Mono- and Diglycerides of Food Fatty Acids; Self-emulsifying Monostearin.

Глицерилмоностеарат Самоэмульгирующий

**Pharmacopoeias.** In *Br.*

**BP 2008** (Self-emulsifying Glyceryl Monostearate). A mixture consisting principally of mono-, di-, and triglycerides of stearic and palmitic acids, and of minor proportions of other fatty acids; it may also contain free fatty acids, free glycerol, and soap. It contains not less than 30% of monoglycerides, not more than 7% of free glycerol, and not more than 6% of soap, calculated as sodium oleate, all calculated with reference to the anhydrous substance.

A white to cream-coloured, hard, waxy solid with a faint fatty odour. Dispersible in hot water; soluble in hot dehydrated alcohol and in hot liquid paraffin; soluble in hot vegetable oils, but may give turbid solutions at concentrations below 20%.

**Incompatibility.** Because of the presence of soap, self-emulsifying glyceryl monostearate is incompatible with acids and high concentrations of ionisable salts, hard water, calcium compounds, zinc oxide, and oxides of heavy metals.

#### Profile

Glyceryl monostearate is a poor water-in-oil emulsifying agent but it is a useful stabiliser of water-in-oil and oil-in-water emulsions in preparations for internal and external use. It has emollient properties. Glyceryl monostearate is also used in the food and cosmetic industries.

It is usual to add a small amount of soap, sulfated fatty alcohol, or other surfactant, to glyceryl monostearate, which has the effect of making the product self-emulsifying and capable of producing satisfactory oil-in-water emulsions. Self-emulsifying glyceryl monostearate is used as an emulsifying agent for oils, fats, solvents, and waxes in the preparation of bases of the non-emulsified, emulsified, and vanishing-cream types. It is not intended for inclusion in preparations for internal use.

Aqueous preparations containing self-emulsifying glyceryl monostearate should contain a preservative to prevent fungal or bacterial growth.

### Macrogol Cetostearyl Ethers

Ceteareth Compounds; Macrogol, éteres cetoestearílicos de; Macrogol, ether cétostéarylique de; Macrogoli aether cetoestearylicus; Makrogol-cetil-sztearil-éter; Makrogolcetoestearyl-eter; Makrogolio cetoestearilo eteris; Makrogolisetostearyliieetteri.

Полиэтиленгликоля и Цетостеарилового Спирта Эфиры  
CAS — 68439-49-6.

**Pharmacopoeias.** In *Eur.* (see p.vii).

**Ph. Eur. 6.2** (Macrogol Cetostearyl Ether). A mixture of ethers of mixed macrogols with linear fatty alcohols, mainly cetoestearyl alcohol. It may contain some free macrogols and it contains various amounts of free cetoestearyl alcohol. The amount of ethylene oxide reacted with cetoestearyl alcohol is from 2 to 33 units per molecule (nominal value). White or yellowish-white waxy, unctuous mass, pellets, microbeads, or flakes. Macrogol cetoestearyl ether with low numbers of ethylene oxide units per molecule is practically insoluble in water; soluble in alcohol and in dichloromethane. Macrogol cetoestearyl ether with higher numbers of ethylene oxide units per molecule is dispersible or soluble in water; soluble in alcohol and in dichloromethane. Macrogol cetoestearyl ether solidifies at 32° to 52°. Store in airtight containers. The labelling states the amount of ethylene oxide reacted with cetoestearyl alcohol (nominal value).

### Cetomacrogol 1000

Cétomacrogol 1000; Cetomacrogolum 1000; Éter monocétílico de polietilenglicol 1000; Polyethylene Glycol 1000 Monocetyl Ether; Polyoxoethylene Glycol 1000 Monocetyl Ether.

Кетомакрогол 1000; Цетомакрогол 1000  
CAS — 9004-95-9 (macrogol cetyl ethers); 68439-49-6 (macrogol cetoestearyl ethers).

**Description.** Cetomacrogol 1000 is a macrogol ether containing 20 to 24 oxoethylene groups in the polyoxoethylene chain. It may be prepared from either cetyl alcohol or from cetoestearyl alcohol. It is represented by the formula CH<sub>3</sub>[CH<sub>2</sub>]<sub>m</sub>[OCH<sub>2</sub>CH<sub>2</sub>]<sub>n</sub>OH, where *m* may be 15 or 17 and *n* may be 20 to 24. The more specific term macrogol cetoestearyl ether (22), representing such an ether in which *n* = 22, has replaced cetomacrogol 1000 in BP formulations. Macrogol cetyl ethers are also sometimes termed ceteth compounds.

**Pharmacopoeias.** In *Int.*

**Incompatibility.** Cetomacrogol has been reported to be incompatible with phenols and to reduce the antibacterial activity of quaternary ammonium compounds. Cetomacrogol may separate from solutions in the presence of a high concentration of electrolytes.

### Polyoxyl 20 Cetostearyl Ether

Polioxil 20, éter cetoestearílico de.

Полиоксиэтилендиола 20 и Цетостеариловой Кислоты Эфир  
CAS — 68439-49-6.

**Pharmacopoeias.** In *USNF*.

**USNF 26** (Polyoxyl 20 Cetostearyl Ether). A mixture of the monocetostearyl (mixed hexadecyl and octadecyl) ethers of mixed macrogols, the average polymer length being equivalent to 17.2 to 25.0 oxoethylene units. A cream-coloured waxy unctuous mass, melting, when heated, to a clear brownish-yellow liquid. Soluble in water, in alcohol, and in acetone; insoluble in petroleum spirit. A 10% solution in water has a pH of 4.5 to 7.5. Store at a temperature of 8° to 15° in airtight containers.

#### Profile

Macrogol cetoestearyl ethers are used as surfactants and emulsifiers. Macrogol cetoestearyl ether (22) is used with cetoestearyl alcohol (for example, in the form of Cetomacrogol Emulsifying Wax BP 2008) as an emulsifying agent for making oil-in-water emulsions that are unaffected by moderate concentrations of electrolytes and that are stable over a wide pH range. It is also used to disperse volatile oils in water to form transparent sols.

**Preparations**

**BP 2008:** Cetomacrogol Emulsifying Wax.

**Macrogol 15 Hydroxystearate**

Macrogol 15, hydroxystéarate de; Macrogoli 15 hydroxystearas; Makrogol-15-hydroxystearát; Makrogol-15-hydroxystearat; Makrogol-15-hydroksistearaatti; Makrogolio 15 hidroksistearatas.

Полиэтиленгликоля 15 Гидроксистеарат

**Pharmacopoeias.** In *Eur.* (see p.vii).

**Ph. Eur. 6.2** (Macrogol 15 Hydroxystearate). A mixture of mainly mono- and di-esters of 12-hydroxystearic acid and macrogols obtained by ethoxylation of 12-hydroxystearic acid. The number of moles of ethylene oxide reacted per mole of 12-hydroxystearic acid is 15 (nominal value). It contains free macrogols. A yellowish, waxy mass. It solidifies at about 25°. Very soluble in water; soluble in alcohol; insoluble in liquid paraffin. Store in airtight containers.

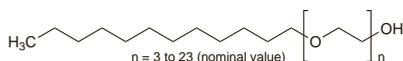
**Profile**

Macrogol 15 hydroxystearate is a nonionic surfactant used as a solubilising agent.

**Macrogol Lauril Ethers**

$\alpha$ -Dodecyl- $\omega$ -hydroxypoly(oxyethylene); Éteres laurílicos de macrogol; Laureth Compounds; Lauromacrogols; Macrogol, éteres láuricos de; Macrogol, éther laurique de; Macrogol Lauryl Ethers; Macrogoli aether laurilicum; Makrogolilaurylietteri; Makrogolio laurilo eteris; Makrogolilauryleter; Oxypolyethoxydodecanes; Polyoxyl Lauryl Ethers.

Полиэтиленгликоля и Лаурилового Спирта Эфиры  
CAS — 9002-92-0.



**Description.** Macrogol lauril ethers have the general formula  $C_{12}H_{25}(OCH_2CH_2)_nOH$ .

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

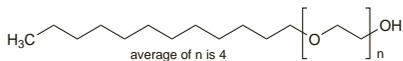
**Ph. Eur. 6.2** (Macrogol Lauryl Ether). A mixture of ethers of mixed macrogols with fatty alcohols, mainly  $C_{12}H_{25}O$ . It contains a variable amount of free  $C_{12}H_{25}O$  and it may contain free macrogols. The number of moles of ethylene oxide reacted per mole of  $C_{12}H_{25}O$  is 3 to 23 (nominal value). Macrogol lauril ether with 3 to 5 units of ethylene oxide per molecule is a colourless liquid. Practically insoluble in water and in petroleum spirit; soluble or dispersible in alcohol. Macrogol lauril ether with 9 to 23 units of ethylene oxide per molecule is a white or almost white, waxy mass. Soluble or dispersible in water; soluble in alcohol; practically insoluble in petroleum spirit. Macrogol lauril ether should be stored in airtight containers.

**USNF 26** (Polyoxyl Lauryl Ether). A mixture of the monolauril ethers of mixed polyethylene glycols, the average polymer length being equivalent to not less than 3 and not more than 23 oxyethylene units (nominal value). It contains various amounts of free lauril alcohol, and it may contain some free polyethylene glycols. Store in airtight containers in a dry place at a temperature of 8° to 15°.

**Laureth 4 (USAN)**

Лаурет 4

CAS — 9002-92-0.



**Description.** A mixture of monolauril ethers of macrogols where the average value of  $n$  in the formula given above is 4.

**Lauromacrogol 400 (rINN)**

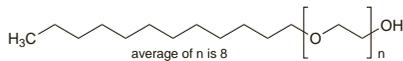
Laureth 9 (USAN); Lauromacrogolum 400; Polidocanol; Polidocanolum; Polidokanol; Polidokanolin.

Лауромакрогол 400

CAS — 9002-92-0; 3055-99-0.

ATC — C05BB02.

ATC Vet — QC05BB02.



**Description.** Lauromacrogol 400 is a mixture of monolauril ethers of macrogols where the average value of  $n$  in the formula given above is 9 and the number 400 corresponds approximately

to the average molecular mass of the macrogol portion. It has sometimes, however, been erroneously described as containing 8, rather than 9, oxyethylene groups. However, note that Lauromacrogol (BAN) is described as containing an average of 8 ethylene oxide groups per molecule.

**Adverse Effects**

There have been occasional reports of allergic skin reactions after topical application of preparations containing macrogol lauril ethers.

◇ A 63-year-old man developed pulmonary oedema, a dramatic fall in heart rate, transient left pyramidal syndrome and died after sclerotherapy with lauromacrogol 400 to control gastric variceal bleeding; the fatality was attributed to the action of the drug that had passed into the systemic circulation. Another patient<sup>2</sup> suffered a reversible ischaemic neurological deficit after sclerotherapy with lauromacrogol 400 for varicose veins of the leg, and ischaemic stroke<sup>3</sup> and other neurological symptoms,<sup>4</sup> probably due to embolism after passage of foam through a patent foramen ovale, have been reported after foam injection sclerotherapy using the compound.

1. Paterlini A, *et al.* Heart failure and endoscopic sclerotherapy of variceal bleeding. *Lancet* 1984; **i**: 1241.
2. Van der Plas JPL, *et al.* Reversible ischaemic neurological deficit after sclerotherapy of varicose veins. *Lancet* 1994; **343**: 428.
3. Forlee MV, *et al.* Stroke after varicose vein foam injection sclerotherapy. *J Vasc Surg* 2006; **43**: 162-4.
4. Ceulen RPM, *et al.* Microembolism during foam sclerotherapy of varicose veins. *N Engl J Med* 2008; **358**: 1525-6.

**Uses and Administration**

Macrogol lauril ethers (laureth compounds) have been used as surfactants and spermicides. Lauromacrogol 400 is used as a sclerosant in the treatment of oesophageal and gastric varices (p.2346) and varicose veins (p.2347), and has been tried in endoscopic injection therapy for bleeding peptic ulcer (p.1702); it has also been used as a local anaesthetic and antipruritic (see p.1582) in combination topical preparations.

**Preparations**

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

**Arg.:** Aet; Aetoxyl Sklerol; **Austral.:** Aethoxysclerol†; **Austria:** Aethoxysclerol; **Belg.:** Aethoxysclerol; **Braz.:** Aethoxysclerol†; **Cz.:** Aethoxysclerol; **Denm.:** Aethoxysclerol; **Fin.:** Aethoxysclerol; **Fr.:** Aethoxysclerol; **Ger.:** Aethoxysclerol; Anaesthetisulf; Recessan; **Gr.:** Aethoxysclerol; Etoxisclerol; **Hung.:** Aethoxysclerol; **Ital.:** Atossisclerol Kreuzler; **Mex.:** Farmaflebon; **Neth.:** Aethoxysclerol; **Pol.:** Aethoxysclerol; **Spain:** Etoxisclerol; **Swed.:** Aethoxysclerol; **Switz.:** Aethoxysclerol; Balmel Hermal Plus; **Thai.:** Aethoxysclerol†; **Turk.:** Aethoxysclerol; **Venez.:** Etoxisclerol.

**Multi-ingredient Arg.:** Nene Dent NF; Solcoseryl Dental†; **Austral.:** TAGG†; **Austria:** Baileum Plus; Dentinox; Gingivan; Optiderm; Paididont; Prurimix; Solcoseryl Dental; Vonum; **Belg.:** Cose-Anal; **Braz.:** Nene Dent N; **Chile:** Mentobalsam; Ureadin Rx DB; Ureadin Rx PS; Ureadin Rx RD; Vatanal; **Cz.:** Baileum Hermal Plus; Dentinox N†; Prurimix†; **Ger.:** Acoin; Alcos-Anal†; Baileum Plus; Brand- u. Wundgel-Medice N; Collomack†; Corti-Dynexan†; Dentinox N; Haemo-Exhirud†; Hexamon; Inflamm†; Meaverin†; Medigel†; Optiderm; Solcoseryl Dental; Tamposit N†; **Hong Kong:** Baileum Intensiv Plus; Collomack; Haemoral; Solcoseryl Dental; **Hung.:** Dentinox N; **Indon.:** Solcoseryl Dental; **Irl.:** Baileum Plus; **Israel:** Baileum Plus; Derma-Care; **Ital.:** Optiderm; Pittire; **Malaysia:** Baileum Intensiv Plus; Collomack†; Solcoseryl Dental; **Mex.:** Nene Dent; **Neth.:** Epianal; **Norw.:** Alcos-Anal; **Philipp.:** Solcoseryl Dental; **Pol.:** Baileum Hermal Plus; Dentinox N; Optiderm; **Port.:** Anacal; Hidratante VV; **Rus.:** Hepatrombin H (Гепатромбин H); Solcoseryl Dental (Солкосерил Дентальная); **Singapore:** Baileum Intensiv Plus; Collomack†; Solcoseryl Dental; **Switz.:** Baileum Hermal Plus†; Decascept N; Optiderm; Oxydermine; Pruri-med; Raluri†; Remexal; Sclerovein; Solcoseryl Dentaire; Sportusol; Sportusol Spray sine heparino; Venureme; Venugel; **Thai.:** Baileum Intensiv Plus†; Collomack†; Solcoseryl Dental; **Turk.:** Dentinox; Kortos; **UK:** Anacal; Baileum Plus; E45 Itch Relief; **Venez.:** Collomack.

**Macrogol Monomethyl Ethers**

Éteres monometílicos de polietilenglicol; Macrogol, éteres monometílicos de; Polyethylene Glycol Monomethyl Ethers.  $\alpha$ -Methyl- $\omega$ -hydroxypoly(oxyethylene).

Полиэтиленгликоля и Метилового Спирта Эфиры

CAS — 9004-74-4.

**Pharmacopoeias.** In *USNF*.

**USNF 26** (Polyethylene Glycol Monomethyl Ether). Addition polymers of ethylene oxide and methyl alcohol, represented by the formula  $CH_3(OCH_2CH_2)_nOH$ , where  $n$  represents the average number of oxyethylene groups. The name is usually designated by a number that corresponds approximately to its average molecular weight.

As the average molecular weight increases, the water solubility, vapour pressure, hygroscopicity, and solubility in organic solvents decrease while congealing temperature, specific gravity, flash-point, and viscosity increase. Liquid grades occur as clear to slightly hazy, colourless or practically colourless, slightly hygroscopic, viscous liquids with a slight characteristic odour. Solid grades occur as practically odourless, white, waxy, plastic material with a consistency similar to beeswax, or as creamy white flakes, beads, or powders. Liquid grades are miscible with water; solid grades are freely soluble in water; all grades are soluble in alcohol, in acetone, in chloroform, in ethyl acetate, in ethylene glycol monoethyl ether, and in toluene; all grades are insoluble in ether and in hexane. Store in airtight containers.

**Profile**

Macrogol monomethyl ethers may be used as ointment bases, solvents, and plasticisers.

**Macrogol Oleyl Ethers**

Macrogol, éteres oleílicos de; Macrogol, éther oléique de; Macrogoli aether oleicum; Macrogoli Aetherum Oleicum; Makrogolio oleilo eteris; Makrogolioleyli(eetteri); Makrogol-oleil-éter; Makrogolioleyleter; Oletho Compounds.

Полиэтиленгликоля и Олеилового Спирта Эфиры

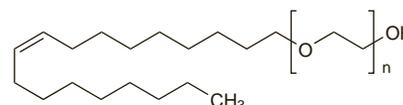
**Pharmacopoeias.** In *Eur.* (see p.vii).

**Ph. Eur. 6.2** (Macrogol Oleyl Ether). A mixture of ethers of mixed macrogols with linear fatty alcohols, mainly oleyl alcohol. It may contain some free macrogols and it contains various amounts of free oleyl alcohol. Macrogol oleyl ether with 2 to 5 units of ethylene oxide per molecule is a yellow liquid. Practically insoluble in water and in petroleum spirit; soluble in alcohol. Macrogol oleyl ether with 10 to 20 units of ethylene oxide per molecule is a yellowish-white, waxy mass. Dispersible or soluble in water; soluble in alcohol; practically insoluble in petroleum spirit. Macrogol oleyl ethers should be stored in airtight containers. Protect from light.

**Polyoxyl 10 Oleyl Ether**

Polioxil 10, éter oleílico de; Polyethylene Glycol Mono-oleyl Ether.

Полиоксиэтиленгликоля и Олеиновой Кислоты Эфир  
CAS — 9004-98-2.



**Pharmacopoeias.** In *USNF*.

**USNF 26** (Polyoxyl 10 Oleyl Ether). A mixture of the mono-oleyl ethers of mixed macrogols, the average polymer length being equivalent to not less than 9.1 and not more than 10.9 oxyethylene units. It may contain suitable stabilisers.

A soft white semisolid or pale yellow liquid with a bland odour. Soluble in water and in alcohol; dispersible in liquid paraffin and in propylene glycol with possible separation on standing. Store at a temperature of 8° to 15° in airtight containers.

**Profile**

Macrogol oleyl ethers such as polyoxyl 10 oleyl ether are used as surfactants.

**Macrogol Stearates**

Ésteres de polietilenglicol; Ésteres de polioxietileno; Macrogol, ésteres del; Macrogol, stéarate de; Macrogoli stearas; Makrogolio stearatas; Makrogolistearaatti; Makrogolstearat; Makrogolstearát; Makrogol-sztearát; Makroxyethylene Glycol Stearates; Polyoxyethylene Stearates; Polyoxyl Stearates.

Макрогюла Стеараты; Полиэтиленгликоля Стеараты

CAS — 9004-99-3.

**Nomenclature.** There are two systems of nomenclature used for these compounds; these substances have the general formula  $C_{17}H_{35}COO.[O(CH_2CH_2)_n]_mH$ . In the systems used by *BAN* and *USAN* the numbers in the names refer to the approximate polymer length in oxyethylene units whereas in the system used by *INN* the number refers to the average molecular weight of the polymer chain. Thus, the names Macrogol 8 Stearate (*BAN*), Polyoxyl 8 Stearate (*USAN*), and Macrogol Stearate 400 (*rINN*) all describe the same compound.

**Pharmacopoeias.** In *Eur.* (see p.vii).

**Ph. Eur. 6.2** (Macrogol Stearate). A mixture of the mono- and di-esters of mainly stearic acid and/or palmitic acid and macrogols. It may be obtained by ethoxylation or by esterification of macrogols with stearic acid 50 (type I) or stearic acid 95 (type II). The average polymer length is equivalent to 6 to 100 ethylene oxide units per molecule (nominal value). It may contain free macrogols. White or slightly yellowish waxy mass. Soluble in alcohol and in isopropyl alcohol. Compounds containing 6 to 9 units of ethylene oxide per molecule are practically insoluble but freely dispersible in water; miscible with fatty oils and with waxes. Compounds containing 20 to 100 units of ethylene oxide per molecule are soluble in water; practically insoluble in fatty oils and in waxes. Store in airtight containers.

**Polyoxyl 40 Stearate (USAN)**

Macrogol Stearate 2000 (*rINN*); E431; Estearato de macrogol 2000; Estearato de Polioxila 40; Macrogol 40 Stearate (*BAN*); Macrogol 2000, Stéarate de; Macrogol Ester 2000; Macrogoli Stearas 2000; Polyoxyethylene 40 Stearate; Stearethate 40.

Макрогюла 2000 Стeарат