

Preparations

BP 2008: Cetomacrogol Emulsifying Wax.

Macrogol 15 Hydroxystearate

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

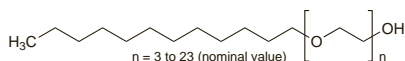
Profile

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

Macrogol Lauril Ethers

α -Dodecyl- ω -hydroxypoly(oxyethylene); Éteres laurílicos de macrogol; Laureth Compounds; Lauromacrogols; Macrogol, éteres laurílicos de; Macrogol, éther laurique de; Macrogol Lauryl Ethers; Macrogoli aether laurilicum; Makrogoli-laurylietteri; Makrogolio laurilo eteris; Makrogol-lauryleter; 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*.

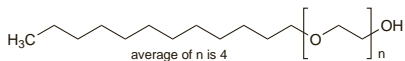
Ph. Eur. 6.2 (Macrogol Lauryl Ether). A mixture of ethers of mixed macrogols with fatty alcohols, mainly $C_{12}H_{25}O$. It contains a variable amount of free $C_{12}H_{25}O$ and it may contain free macrogols. The number of moles of ethylene oxide reacted per mole of $C_{12}H_{25}O$ is 3 to 23 (nominal 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)

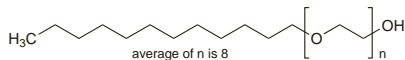
Laureth 9 (USAN); Lauromacrogolum 400; Polidocanol; Polidocanolum; Polidokanol; Polidokanolin.

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 patient² suffered a reversible ischaemic neurological deficit after sclerotherapy with lauromacrogol 400 for varicose veins of the leg, and ischaemic stroke³ and other neurological symptoms,⁴ 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:** Balneum 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.:** Balneum Hermal Plus; Dentinox N†; Prurimix†; **Ger.:** Acoin; Alcos-Anal†; Balneum Plus; Brand- u. Wundgel-Medice N; Collomack†; Corti-Dynexan†; Dentinox N; Haemo-Exhirud†; Hexamon; Inflamm†; Meaverin†; Medigel†; Optiderm; Solcoseryl Dental; Tamposit N†; **Hong Kong:** Balneum Intensiv Plus; Collomack; Haemoral; Solcoseryl Dental; **Hung.:** Dentinox N; **Indon.:** Solcoseryl Dental; **Irl.:** Balneum Plus; **Israel:** Balneum Plus; Derma-Care; **Ital.:** Optiderm; Pittire; **Malaysia:** Balneum Intensiv Plus; Collomack†; Solcoseryl Dental; **Mex.:** Nene Dent; **Neth.:** Epianal; **Norw.:** Alcos-Anal; **Philipp.:** Solcoseryl Dental; **Pol.:** Balneum Hermal Plus; Dentinox N; Optiderm; **Port.:** Anacal; Hidratante VV; **Rus.:** Hepatrombin H (Гепатромбин H); Solcoseryl Dental (Солкосерил Дентальная); **Singapore:** Balneum Intensiv Plus; Collomack†; Solcoseryl Dental; **Switz.:** Balneum Hermal Plus†; Decascept N; Optiderm; Oxydermine; Pruri-med; Ralurl†; Remexal; Sclerovein; Solcoseryl Dentaire; Sportusol; Sportusol Spray sine heparino; Venureme; Venugel; **Thai.:** Balneum Intensiv Plus†; Collomack†; Solcoseryl Dental; **Turk.:** Dentinox; Kortos; **UK:** Anacal; Balneum Plus; E45 Itch Relief; **Venez.:** Collomack.

Macrogol Monomethyl Ethers

Éteres monometilícos de polietilenglicol; Macrogol, éteres monometilícos de; Polyethylene Glycol Monomethyl Ethers. α -Methyl- ω -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 oleilícos 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

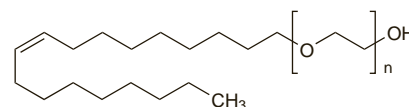
Pharmacopoeias. In *Eur.* (see p.vii).

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 oleilico 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