

Preparations

BP 2008: Cetomacrogol Emulsifying Wax.

Macrogol 15 Hydroxystearate

Macrogol 15, hydroxystéarate de; Macrogoli 15 hydroxystearas; Makrogol 15 hydroxystearát; Makrogol-15-hydroxistearat; Makrogoli-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.

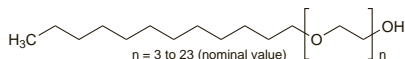
Profile

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

Macrogol Lauril Ethers

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

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



Description. Macrogol lauril ethers have the general formula $\text{C}_{12}\text{H}_{25}(\text{OCH}_2\text{CH}_2)_n\text{OH}$.

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

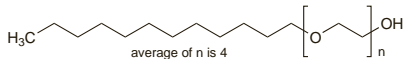
Ph. Eur. 6.2 (Macrogol Lauryl Ether). A mixture of ethers of mixed macrogols with fatty alcohols, mainly $\text{C}_{12}\text{H}_{25}\text{O}$. It contains a variable amount of free $\text{C}_{12}\text{H}_{25}\text{O}$ and it may contain free macrogols. The number of moles of ethylene oxide reacted per mole of $\text{C}_{12}\text{H}_{25}\text{O}$ 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)

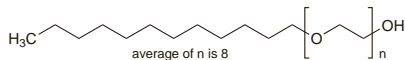
Laureth 9 (USAN); Lauromacrogolum 400; Polidocanol; Polidocanolum; Polidokanol; Polidokanolol.

Лаурмакрогол 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;¹ 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.:** Aetoxisclerol; **Ger.:** Aethoxysclerol; **Anaesthetisul;** Recessan; **Gr.:** Aethoxysclerol; **Etoxisclerol;** **Hung.:** Aethoxysclerol; **Ital.:** Attossiclerol Kreussler; **Mex.:** Farmaflebon; **Neth.:** Aethoxysclerol; **Pol.:** Aethoxysclerol; **Spain:** Etoxisclerol; **Swed.:** Aethoxysclerol; **Switz.:** Aethoxysclerol; **Balmed** Hermal Plus; **Thai.:** Aethoxysclerol†; **Turk.:** Aethoxysclerol; **Venez.:** Etoxisclerol.

Multi-ingredient: **Arg.:** Nene Dent NF; Solcoseryl Dental†; **Austral:** TAGG†; **Austria:** Balneum Plus; Dentinox; Gingivani; Optiderm; Paididont; Prurimix; Solcoseryl Dental; Vonum; **Belg.:** Cose-Anal; **Braz.:** Nene Dent N; **Chile:** Mentobalsam; Ureadin Rx DB; Ureadin Rx PS; Ureadin Rx RD; **Vatana:** **Cz.:** Balneum Hermal Plus; Dentinox N†; Prurimix†; **Ger.:** Acoini; Alcos-Anal†; Balneum Plus; Brand- u. Wundgel-Medice N; Collomack†; Corti-Dynexan†; Dentinox N; Haemo-Exhirud†; Hexamon; Inflam†; Meaverin†; Medigel†; Optiderm; Solcoseryl Dental; Tamposit N†; **Thesit†; 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; Pitiren; **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 Дентальный); **Singapore:** Balneum Intensiv Plus; Collomack†; Solcoseryl Dental; **Switz.:** Balneum Hermal Plus†; Decascept N; Optiderm; Oxydermine; Pruri-med; Raluri†; Remexal; Sclerovein; Solcoseryl Dentaire; Sportusol; Sportusol Spray sine heparino; Venucurem; Venugel; **Thai.:** Balneum Intensiv Plus†; Collomack†; Solcoseryl Dental; **Turk.:** Dentinox; Kortos; **UK:** Anacal; Balneum Plus; E45 Itch Relief; **Venez.:** Collomack.

Macrogol Monomethyl Ethers

Éteres monometílicos de polietilenglicol; Macrogol, éteres monometílicos 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 $\text{CH}_3(\text{OCH}_2\text{CH}_2)_n\text{OH}$, 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 olélicos de; Macrogol, éther oléique de; Macrogoli aether oleicum; Macrogoli Aetherum Oleicum; Makrogolio oleilo eteris; Makrogolioleylieetteri; Makrogol-oleil-éter; Makrogolioleyleter; Oletho Compounds.

Полиэтиленгликоля и Олеилового Спирта Эфиры

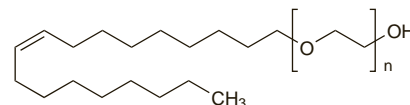
Pharmacopoeias. In *Eur.* (see p.vii).

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 oléilico 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

Éstères de polietilenglicol; Éstères de polioxiétieno; Macrogol, éstères del; Macrogol, stéarate de; Macrogoli stearas; Makrogolio stearatas; Makrogolistearaatti; Makrogolstearat; Makrogolstearát; Makrogol-szearát; Polyoxethylene Glycol Stearates; Polyoxethylene Stearates; Polyoxyl Stearates.

Макрогола Стеараты; Полиэтиленгликоля Стеараты
CAS — 9004-99-3.

Nomenclature. There are two systems of nomenclature used for these compounds; these substances have the general formula $\text{C}_{17}\text{H}_{35}\text{COO}[\text{O}(\text{CH}_2\text{CH}_2)_n\text{H}]$. 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; Polyoxethylene 40 Stearate; Stearethate 40.

Макрогола 2000 Стеарат

Pharmacopoeias. In *Jpn.* Also in *USNF*.

USNF 26 (Polyoxyl 40 Stearate). A mixture of the mono- and diesters of stearic acid and mixed macrogols, the average polymer length being about 40 oxyethylene units. It contains not less than 17% and not more than 27% of free macrogols. It is a waxy, white to light tan solid, odourless or with a faint fat-like odour. Congealing range 37° to 47°. Soluble in water, in alcohol, in acetone, and in ether; insoluble in liquid paraffin and in vegetable oils. Store in airtight containers.

Incompatibility. Macrogol stearates have been reported to be generally stable with electrolytes and weak acids or bases although strong acids or bases may cause hydrolysis and saponification. Discoloration or precipitation may occur with phenolic substances and complexation with preservatives. Decrease in the antimicrobial activity of bacitracin, chloramphenicol, phenoxymethylpenicillin, and tetracycline has been stated to occur with concentrations of macrogol stearates exceeding 5%.

Profile

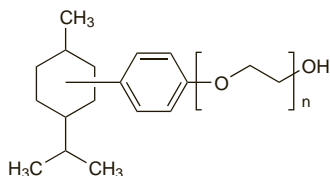
Macrogol stearates are macrogol esters that are used as emulsifying and solubilising agents.

Menfegol (*rINN*)

Menfégol; Menfegolum; Menpegol. α -[*p*-(*p*-Menthyl)phenyl]- ω -hydroxypoly(oxyethylene).

Менфегол

CAS — 57821-32-6.



Profile

Menfegol consists of menthylphenyl ethers of macrogols represented by the formula $C_{16}H_{23}(OCH_2CH_2)_nOH$. It is a nonionic surfactant used as a spermicide.

Adverse effects. Frequent use of menfegol in spermicidal foaming tablets has been associated with a high incidence of genital ulceration, which could increase the risk of infection by HIV.¹

- Goeman, J. *et al.* Frequent use of menfegol spermicidal vaginal foaming tablets associated with a high incidence of genital lesions. *J Infect Dis* 1995; **171**: 1611–14.

Preparations

Proprietary Preparations (details are given in Part 3)

Hong Kong: Neo Sampooin; **Malaysia:** Neo Sampooin; **Philipp:** Neo Sampooin; **Singapore:** Neo Sampooin.

Mono- and Di-glycerides

E471 (mono- and di-glycerides of fatty acids); Mono γ diglicéridos.

Моно- и диглицериды

Pharmacopoeias. In *USNF*.

USNF 26 (Mono- and Di-glycerides). A mixture of glycerol mono- and di-esters, with minor amounts of tri-esters, of fatty acids from edible oils. It contains not less than 40% of monoglycerides. It may contain suitable stabilisers. Store in airtight containers. Protect from light.

Profile

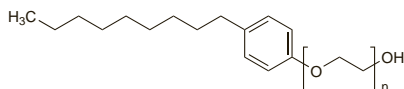
A mixture of mono- and di-glycerides is used as an emulsifying agent and food additive.

Nonoxinolins

Macrogol Nonylphenyl Ethers; Nonoxinolins; Nonoxynols. α -(4-Nonylphenyl)- ω -hydroxypoly(oxyethylene).

Ноноксинолы

CAS — 26027-38-3.



Nomenclature. Nonoxinolins are a series of nonylphenyl ethers of macrogols of differing chain lengths, represented by the formula $C_{15}H_{23}[O(CH_2CH_2)]_nOH$.

Nonoxinol is *BAN* and *rINN*. The name may be followed by a figure indicating the approximate number of oxyethylene groups in the polyoxyethylene chain. *USAN* specifies Nonoxynol 4, Nonoxynol 9, Nonoxynol 15, and Nonoxynol 30.

The symbol † denotes a preparation no longer actively marketed

Nonoxinol 9 (*BAN, rINN*)

Nonoxinol-9; Nonoxinol-9; Nonoxinolum 9; Nonoxynol 9 (*USAN*). α -(4-Nonylphenyl)- ω -hydroxynona(oxyethylene).

Ноноксинол 9

$C_{33}H_{60}O_{10}$ (nominal) = 616.8.

Pharmacopoeias. In *Eur.* (see p.vii), *Int.*, and *US*.

Ph. Eur. 6.2 (Nonoxinol 9). A mixture consisting mainly of monononylphenyl ethers of macrogols corresponding to the formula: $C_{15}H_{23}[O(CH_2CH_2)]_nOH$ where the average value of *n* is 9. A clear, colourless to light yellow, viscous liquid. Miscible with water, with alcohol, and with vegetable oils. Store in airtight containers.

USP 31 (Nonoxynol 9). An anhydrous liquid mixture consisting chiefly of monononylphenyl ethers of macrogols corresponding to the formula $C_{15}H_{23}[O(CH_2CH_2)]_nOH$, in which the average value of *n* is about 9. A clear, colourless to light yellow, viscous liquid. Soluble in water, in alcohol, and in maize oil. Store in airtight containers.

Nonoxinol 10 (*BAN, rINN*)

Nonoxinolum 10; Nonoxynol 10. α -(4-Nonylphenyl)- ω -hydroxydeca(oxyethylene).

Ноноксинол 10

$C_{35}H_{64}O_{11}$ (nominal) = 660.9.

Nonoxinol 11 (*BAN, rINN*)

Nonoxinolum 11; Nonoxynol 11. α -(4-Nonylphenyl)- ω -hydroxyundeca(oxyethylene).

Ноноксинол 11

$C_{37}H_{68}O_{12}$ (nominal) = 704.9.

Adverse Effects and Precautions

Nonoxinolins used as vaginal spermicides may cause local irritation.

Genito-urinary infections. Use of spermicidal foam or jelly containing nonoxinol 9 may disturb the normal vaginal flora and predispose to colonisation with *Escherichia coli* and the development of bacteriuria.¹ An increased risk of acute *E. coli* urinary-tract infection has been reported² associated with the use of condoms coated with nonoxinol 9. However, another study³ of women using nonoxinol-9 spermicidal contraceptives showed that most users experienced minimal disruption to the vaginal microbial ecosystem.

For reference to an increased incidence of some sexually transmitted diseases in women using nonoxinol 9, see Antimicrobial Activity, below.

- Hooton TM, *et al.* *Escherichia coli* bacteriuria and contraceptive method. *JAMA* 1991; **265**: 64–9.
- Fihn SD, *et al.* Association between use of spermicide-coated condoms and *Escherichia coli* urinary tract infection in young women. *Am J Epidemiol* 1996; **144**: 512–20.
- Schreiber CA, *et al.* Effects of long-term use of nonoxynol-9 on vaginal flora. *Obstet Gynecol* 2006; **107**: 136–43.

Pregnancy. Maternal use of spermicidal contraceptives has been linked to an increased frequency of congenital abnormalities, including trisomy, but it has been suggested that such studies may be flawed by recall bias.¹ Meta-analysis of 9 studies also supported the view that peri- and postconceptional maternal use of spermicides was not associated with adverse fetal outcome.²

- Mishell DR. Contraception. *N Engl J Med* 1989; **320**: 777–87.
- Einarson TR, *et al.* Maternal spermicide use and adverse reproductive outcome: a meta-analysis. *Am J Obstet Gynecol* 1990; **162**: 655–60.

Toxic shock syndrome. Toxic shock syndrome has been associated with the use of a vaginal contraceptive sponge impregnated with nonoxinol 9. A review¹ of 13 cases reported in the USA up to November 1984 found that in 4 of the cases there were other predisposing conditions: postpartum use, use during menstruation, and prolonged retention.

- Faich G, *et al.* Toxic shock syndrome and the vaginal contraceptive sponge. *JAMA* 1986; **255**: 216–18.

Uses

Nonoxinolins have surface active properties and may be used as solubilising agents. Nonoxinol 9 is used as a spermicide (see Contraception, p.2070).

Antimicrobial activity. Nonoxinol 9 has activity *in vitro* against a number of bacteria and viruses and it was hoped^{1,2} that use of spermicidal contraceptives containing nonoxinol 9 might provide some protection against sexually transmitted diseases, including chlamydial, gonococcal, and HIV infection. However, controlled studies involving HIV-negative female sex workers or other high-risk women have found that use of nonoxinol 9 does not reduce the rate of new HIV,^{3,4} or gonorrhoea or chlamydia infection;^{3,5} meta-analyses^{6,7} including these and other studies have come to similar conclusions. Furthermore, nonoxinol 9 has an irritant action and may increase the risk of genital ulceration, leading to an increased risk of infection by HIV. The United Nations,⁸ WHO,⁹ and FDA¹⁰ have therefore advised against its use by women at high risk.

- North BB. Vaginal contraceptives: effective protection from sexually transmitted diseases for women? *J Reprod Med* 1988; **33**: 307–311.

- Anonymous. Multipurpose spermicides. *Lancet* 1992; **340**: 211–13.

- Roddy RE, *et al.* A controlled trial of nonoxynol 9 film to reduce male-to-female transmission of sexually transmitted diseases. *N Engl J Med* 1998; **339**: 504–10.
- Van Damme L, *et al.* Effectiveness of COL-1492, a nonoxynol-9 vaginal gel, on HIV-1 transmission in female sex workers: a randomised controlled trial. *Lancet* 2002; **360**: 971–7. Correction. *ibid.*; 1892.
- Roddy RE, *et al.* Effect of nonoxynol-9 gel on urogenital gonorrhea and chlamydial infection: a randomized controlled trial. *JAMA* 2002; **287**: 1117–22.
- Wilkinson D, *et al.* Nonoxynol-9 for preventing vaginal acquisition of HIV infection by women from men. Available in The Cochrane Database of Systematic Reviews; Issue 3. Chichester: John Wiley; 2002 (accessed 21/04/08).
- Wilkinson D, *et al.* Nonoxynol-9 for preventing vaginal acquisition of sexually transmitted infections by women from men. Available in The Cochrane Database of Systematic Reviews; Issue 1. Chichester: John Wiley; 2002 (accessed 21/04/08).
- Anonymous. UN warns against use of spermicide. *BMJ* 2000; **321**: 194.
- Anonymous. Nonoxinol 9 ineffective in preventing HIV infection. *WHO Drug Inf* 2002; **16**: 120–1.
- Food and Drug Administration. FDA mandates new warning for nonoxynol 9 OTC contraceptive products (issued 18/12/07). Available at: <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01758.html> (accessed 21/04/08)

Preparations

Proprietary Preparations (details are given in Part 3)

Arg.: Delfen†; Lorphyn; **Austral.:** Lubarol; **Austria:** Delfen†; **Patentex:** **Braz.:** Pessarios Proflaticos Rendell†; Preserv Nonoxinol-9; **Canada.:** Advantage 24†; Delfen; Gynol II†; K-Y Plus Spermicidal Lubricant; Lifestyles; Ortho-Gynol; Ramses; Sheik; Shields†; Today; Trojan; VCF; **Chile:** Impidol; Supoviol; VCF†; **Cz.:** Delfen†; **Patentex:** Oval N; **Fin.:** Patentex; **Ger.:** Patentex; **Hong Kong:** Patentex; **Hung.:** Patentex; **India:** Delfen; **Irl.:** Delfen†; Gynol II†; Ortho-Creme; **Israel:** Delfen†; **Mex.:** Lorphyn; **NZ:** Lifestyles; Rendells Plus†; **Pol.:** Patentex; **Port.:** Delfen†; Rendells; **Rus.:** Patentex; **S. Afr.:** Delfen†; **Spain:** Nacha†; **Sweden.:** Gynol-Oval; Secural; **Switz.:** C-Film†; Delfen†; **Turk.:** Lorphyn; **UK:** Delfen†; Duragel†; Gygel; Gynol II†; Ortho-Creme†; Orthoforms†; Prelude; **USA:** Advantage 24; Delfen; Encare; Gynol II; Sernicid; Sheik Elite; Shur-Seal; Today; VCF.

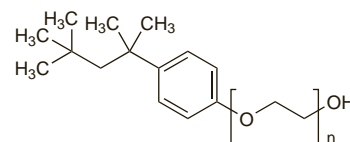
Multi-ingredient: **Arg.:** Meritholate Iodopovidona; **Canada.:** Protectaid; **Ger.:** A-gen 53; **Hong Kong:** Protectaid; **Israel:** Glovan; **Mex.:** Nor-forms†; Sin-A-Gen; **Spain:** Lavolen; **Turk.:** Agen; **UK:** Protectaid.

Octoxinolins

Macrogol Tetramethylbutylphenyl Ethers; Octoxinolins; Octoxynols; Octylphenoxy Polyethoxyethanol. α -(4-(1,1,3,3-Tetramethylbutyl)phenyl)- ω -hydroxypoly(oxyethylene).

ОКТОКСИНОЛЫ

CAS — 9002-93-1.



Nomenclature. Octoxinolins are a series of tetramethylbutylphenyl ethers of macrogols of differing chain lengths, represented by the formula $C_{14}H_{21}[O(CH_2CH_2)]_nOH$.

Octoxinol is *BAN* and *rINN*. The name may be followed by a figure indicating the approximate number of oxyethylene groups in the polyoxyethylene chain. *USAN* specifies Octoxynol 9.

The name *p*-di-isobutyl-phenoxypolyethoxyethanol has been used to describe octoxinol 9 but may have also been applied to other octoxinolins.

Octoxinol 9 (*BAN, rINN*)

Octoxinolum 9; Octoxynol 9 (*USAN*).

ОКТОКСИНОЛ 9

$C_{32}H_{58}O_{10}$ (nominal) = 602.8.

Pharmacopoeias. In *USNF*.

USNF 26 (Octoxynol 9). An anhydrous liquid mixture consisting chiefly of mono-octylphenyl ethers of macrogols, corresponding to the formula $C_{14}H_{21}[O(CH_2CH_2)]_nOH$, in which the average value of *n* is about 9. A clear, pale yellow, viscous liquid with a faint odour. Miscible with water, with alcohol, and with acetone; soluble in toluene and in benzene; practically insoluble in petroleum spirit. Store in airtight containers.

Octoxinol 10 (*BAN, rINN*)

Octoxinolum 10; Oktoksinoli-10; Oktoksinolis 10; Oktoksynol 10; Oktoksinol-10; Oktoksinol 10.

ОКТОКСИНОЛ 10

$C_{34}H_{62}O_{11}$ (nominal) = 646.8.

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

Ph. Eur. 6.2 (Octoxinol 10). A mixture consisting mainly of mono-octylphenyl ethers of macrogols corresponding to the formula: $C_{14}H_{21}[O(CH_2CH_2)]_nOH$ where the average value of *n* is