

Preparations

BP 2008: Cetomacrogol Emulsifying Ointment; Cetrimide Emulsifying Ointment; Emulsifying Ointment; Paraffin Ointment; Simple Eye Ointment; Simple Ointment; Wool Alcohols Ointment;
USP 31: Bland Lubricating Ophthalmic Ointment; Hydrophilic Ointment; Hydrophilic Petrolatum; Petrolatum Gauze; White Ointment; Yellow Ointment.

Proprietary Preparations (details are given in Part 3)

Austral.: Jelonet; Uni Salvet; Uniltulle; **Braz.:** Vaseline; **Canad.:** Prevez; Vaseline; **Fr.:** Cuticren; Jelonet; Tulle Gras; Vaselitulle; **Ger.:** Oleo Tull; **Gr.:** Vaseline Pur; **Ir.:** Dermamist; **Ital.:** Adaptic; Jelonet; Lomatuell H; **Mex.:** Formula Dermica; Lubrilin; **Philipp.:** Apollo; **Rus.:** Klotex (Клютекс); **S.Afr.:** Jelonet; **Spain:** Lacrilube; **Turk.:** Duretears; **UK:** Dermamist; Jelonet; Paratulle; Vaseline; **USA:** Ocu-Lube.

Multi-ingredient: **Arg.:** Alcon Lagrimas; Aqualane; Benzalcrem; **Austral.:** DermaVeen Moisturising; Dermeze; E45; Gold Cross Skin Basics Zinc Cream; Laci-Lube; Poly Visc; **Austria:** Tiroler Steinol; **Belg.:** Duretears; Lacrytulle; Tulle Vaseline; **Canad.:** A & D Ointment; Akwa Tears; Chapstick Medicated Lip Balm; Duolube; Duretears; Hydrophil; Hypotears; Moisture; Optilube; Puralube; Refresh Laci-Lube; Tears Naturelle PM; **Chile:** Chapstick Medicated; Durasole; Duretears; Laci-Lube; Pasta Laxar; **Denm.:** Ojensalve Neutral; **Fin.:** Laci-Lube; **Fr.:** Celloso; Celloso Zinc; Dexery; Grassolind Neutral; Ictyane; Ictyane HD; Oilatium Cream; Transulose; **Ger.:** Allergika; Celloso; Coliquifilm; Sofra-Tull sine; Vita-POS; **Gr.:** Duretears; Vaseline Borique; Vaseline Oxide Zinc; **Hong Kong:** Balneum; Duretears; Dyprote; Oilatium Cream; **India:** Cetra; **Ir.:** Laci-Lube; Oilatium Junior; **Israel:** Duretears; Kamil Blue; Lacrimol; **Ital.:** Laci-Lube; **Malaysia:** Balneum; Duretears Naturelle; Lacrilube; Oilatium; **Neth.:** Duretears Z; Transulose; **Norw.:** Simplex; **NZ:** Lacrilube; Poly-Visc; **Philipp.:** Oilatium; **Pol.:** Amfobase; Diprobase; E45; Unibasis; **Singapore:** Balneum; Duretears; Lacrilube; **Spain:** Lubrifilm; Tears Lubricant; Vaselina Boricada; Vaselina Mentolada; **Switz.:** Coliquifilm; **Thai:** Balneum; Duretears; Oilatium Cream; **Turk.:** Cinkos; **UK:** 50/50; Cetra; Embolint; Diprobase; Emollin; Epaderm; Hewletts; Hydromol; Imuderm; Laci-Lube; Laci-Lube; Melrose; Oilatium Cream; Oilatium Junior; **USA:** Akwa Tears; Bodi Care Lotion; Bottom Better; Chapstick Medicated Lip Balm; Destin Creamy; Diaper Guard; Dry Eyes; Duretears Naturelle; Formulation R; Hemoid For Women; Hydrocortin; Hypotears; Laci-Gel; Laci-Lube; Lubri-Fresh PM; LubriTears; Paladin; Puralube; Refresh PM; Styer; Tears Again; Tears Renewed; **Venez.:** Lacrimart.

Shea Butter

Manteca de Karité.

Карите; Масло Ши

Profile

Shea butter is a natural fat obtained from the kernel of the fruit of *Vitellaria paradoxa* (*Butyrospermum parkii*) (Sapotaceae) indigenous to West Africa. It is used as an ointment and cream base. Shea butter is widely used in cosmetics. It is also used in cooking oil, and as a substitute for theobroma oil in chocolate manufacturing.

Preparations

Silicones

Siliconas.

Силиконы

ATC — A03AX13.

ATC Vet — QA03AX13.

Description. Silicones are polymers with a structure consisting of alternate atoms of silicon and oxygen, with organic groups attached to the silicon atoms. As the degree of polymerisation increases, the products become more viscous and the various grades are distinguished by a number, approximately corresponding to the viscosity of the particular grade. Silicones may be fluids, greases, waxes, resins, or rubbers depending on the degree of polymerisation.

Cyclomethicone

Dimethylcyclopolyisiloxane.

Циклометикон

(C₂H₆O_{Si})_n.

CAS — 69430-24-6.

Pharmacopoeias. In *USNF*.

USNF 26 (Cyclomethicone). A fully methylated cyclic siloxane containing repeating units of the formula $[-(CH_3)_2SiO-]_n$, in which *n* is 4, 5, or 6, or a mixture of them. Store in airtight containers.

Dimeticone (BAN, rINN)

Dimeticone (*USAN*); Dimethyl Silicone Fluid; Dimethylpolyisiloxane; Dimethylsiloxane; Dimeticona; Dimeticone; Dimeticonum; Dimetikon; Dimetikonas; Dimetikoni; Dimetilpolisiloxano; Dimetykon; E900; Huile de Silicone; Methyl Polyisiloxane; Metilpolisiloksan; Metilpolisiloxano; Permethylpolyisiloxane; Polidimetilsiloxano; Silicone Oil; Siliconum Liquidum. Poly(dimethylsiloxane).

Диметикон

CH₃[Si(CH₃)₂O]_nSi(CH₃)₃.

CAS — 9006-65-9.

ATC — A03AX13.

ATC Vet — QA03AX13.

Description. Dimeticones are fluid silicones in which the organic group is a methyl radical.

Simeticone (activated dimeticone), a mixture of liquid dimeticones with silicon dioxide, is described on p.1770.

Pharmacopoeias. In *Chin.* and *Eur.* (see p.vii). Also in *USNF*. **Ph. Eur. 6.2** (Dimeticone). The degree of polymerisation is such that the kinematic viscosities are nominally between 20 and 1300 mm²/second; dimeticones with a nominal viscosity of 50 mm²/second or lower are intended for external use only. Dimeticones are clear, colourless, liquids of various viscosities. Practically insoluble in water; very slightly soluble to practically insoluble in dehydrated alcohol; miscible with ethyl acetate, with methyl ethyl ketone, and with toluene.

USNF 26 (Dimeticone). A mixture of fully methylated linear siloxane polymers containing repeating units of the formula $[-(CH_3)_2SiO-]_n$, stabilised with trimethylsiloxy end-blocking units of the formula $[(CH_3)_3SiO-]$, wherein *n* has an average value such that the corresponding nominal viscosity is in a discrete range between 20 and 30 000 centistokes. It is a clear colourless, odourless liquid. Insoluble in water, in alcohol, in acetone, and in methyl alcohol; very slightly soluble in isopropyl alcohol; soluble in amyl acetate, in chlorinated hydrocarbons, in ether, in *n*-hexane, in petroleum spirit, in benzene, in toluene, and in xylene. Store in airtight containers.

Adverse Effects and Precautions

Adverse effects from the clinical use of silicones appear to be rare. Foreign-body reactions have been reported after their use as joint implants. Other implants, notably breast implants used for reconstruction after mastectomy or for cosmetic purposes, carry the risk of migration of silicone with cyst formation and other complications; accidental intravascular injection has been fatal. Late adverse ocular effects can follow the intravitreal injection of liquid silicone in the management of retinal detachment (see below).

Breast feeding. Concern has been raised regarding the possible effects on infants of mothers with silicone breast implants who breast feed. Oesophageal dysfunction has been reported in a number of such children,¹ although this finding has not been confirmed by subsequent reports. The American Academy of Pediatrics therefore states² that the current evidence does not justify classifying silicone implants as a contra-indication to breast feeding.

- Levine JJ, Howitt NT. Scleroderma-like esophageal disease in children breast-fed by mothers with silicone breast implants. *JAMA* 1994; **271**: 213–6. Correction. *ibid.*; **272**: 770.
- American Academy of Pediatrics. The transfer of drugs and other chemicals into human milk. *Pediatrics* 2001; **108**: 776–89. Correction. *ibid.*; 1029. Also available at: <http://aappolicy.aappublications.org/cgi/content/full/pediatrics%3b108/3/776> (accessed 20/11/07)

Connective tissue disorders. Since the introduction of silicone breast implants in the early 1960s there have been numerous anecdotal reports of connective tissue disorders in women who have undergone breast reconstruction or augmentation with these implants. Scleroderma has been the most frequently reported disorder; others have included SLE, rheumatoid arthritis, and inflammatory myopathies. A syndrome of vague musculoskeletal symptoms, fever, and fatigue has also been reported. These cases led the FDA to call for a moratorium in the USA on the use of silicone breast implants in January 1992. However, with the exception of one study of self-reported symptoms which showed only a small increase in risk,³ large epidemiological studies,^{2,5} meta-analyses,^{6,8} and a review by the Medical Devices Agency in the UK have so far failed to show any association between silicone breast implants and connective tissue disorders. After conducting a review of the evidence, the FDA in 2006 re-approved the sale of silicone breast implants, for use in women of all ages for breast reconstruction, and for cosmetic use in women aged 22 years or more;⁹ the approval obliges the manufacturers to conduct a 10-year post-approval safety study.

- Hennekens CH, *et al.* Self-reported breast implants and connective-tissue diseases in female health professionals: a retrospective cohort study. *JAMA* 1996; **275**: 616–21.
- Gabriel SE, *et al.* Risk of connective-tissue diseases and other disorders after breast implantation. *N Engl J Med* 1994; **330**: 1697–1702.
- Sánchez-Guerrero J, *et al.* Silicone breast implants and the risk of connective-tissue diseases and symptoms. *N Engl J Med* 1995; **332**: 1666–70.
- Silverman BG, *et al.* Reported complications of silicone gel breast implants: an epidemiologic review. *Ann Intern Med* 1996; **124**: 744–56.
- Nyrén O, *et al.* Risk of connective tissue disease and related disorders among women with breast implants: a nation-wide retrospective cohort study in Sweden. *BMJ* 1998; **316**: 417–22.
- Janowsky EC, *et al.* Meta-analyses of the relation between silicone breast implants and the risk of connective-tissue diseases. *N Engl J Med* 2000; **342**: 781–90.
- Lipworth L, *et al.* Silicone breast implants and connective tissue disease: an updated review of the epidemiologic evidence. *Ann Plast Surg* 2004; **52**: 598–601.
- Lipworth L, *et al.* Breast implants and fibromyalgia: a review of the epidemiological evidence. *Ann Plast Surg* 2004; **52**: 284–7.
- Food and Drug Administration. FDA approves silicone gel-filled breast implants after in-depth evaluation (issued 17/11/06). Available at: <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01512.html> (accessed 20/11/07)

Uses and Administration

Dimeticones and other silicones are water-repellent and have a low surface tension. They are used in topical barrier preparations for protecting the skin against water-soluble irritants. Creams, lotions, and ointments containing a dimeticone are used for the prevention of bedsores and napkin rash and to protect the skin

against trauma due to incontinence or stoma discharge. A 4% solution of dimeticone is used for the treatment of head pediculosis in adults and children aged over 6 months. Silicone preparations should not be applied where free drainage is necessary or to inflamed or abraded skin. Silicones, usually a dimeticone, are also used typically as wound dressings, and to reduce scar elevation and pigmentation. They are also used in oral solid dosage forms, including modified-release preparations.

Silicones have also been used for arthroplasty in rheumatic disorders, by intravitreal injection for retinal detachment, and by subcutaneous injection or implantation in reconstructive or cosmetic surgery.

Dimeticones, in particular simeticone (activated dimeticone) (p.1770), are used in the treatment of flatulence.

Retinal detachment. Retinal detachment is separation of the retina from the underlying retinal pigmented epithelium and usually requires surgical repair. Intravitreal injection of liquid silicone, either alone or with a gas,¹ is used for retinal tamponade with or after surgery in complicated or persistent detachment of the retina.² In most cases, the silicone fluid is later removed from the eye.³ High-density silicone fluids are increasingly being used.⁴ Use of silicone fluid is reported to trigger a local inflammatory response, which may persist after the fluid is removed.⁵ Other late complications after its use may include cataract, glaucoma, and keratopathy.

- Rizzo S, *et al.* Long-term vitreous replacement with perfluoro-hexyloctane and silicone oil: preliminary reports of a multicentric study. *Ophthalmologica* 2005; **219**: 147–53.
- Quiram PA, *et al.* Outcomes of vitrectomy with inferior retinectomy in patients with recurrent rhegmatogenous retinal detachments and proliferative vitreoretinopathy. *Ophthalmology* 2006; **113**: 2041–7.
- Szurman P, *et al.* Primary silicone oil tamponade in the management of severe intraocular foreign body injuries: an 8-year follow-up. *Retina* 2007; **27**: 304–11.
- Herbrig E, *et al.* Anatomical and functional results of endotamponade with heavy silicone oil – Denirosin 68 – in complicated retinal detachment. *Ophthalmic Res* 2007; **39**: 198–206.
- Wickham LJ, *et al.* Immunopathology of intraocular silicone oil: retina and epiretinal membranes. *Br J Ophthalmol* 2007; **91**: 258–62.

Preparations

Proprietary Preparations (details are given in Part 3)

Arg.: Aerogal; Atodermit; Euporel; Finescar; Kurapel; Skinderm SIL; **Aust.:** Dermatic; Egozite Protective Baby Lotion; Instru-Safe; Rosken Skin Repair; Silic 15; **Canad.:** Barrier Cream; Barriere; Dermatic Si; **Chile:** Cadinol; Epi-Derm; Lomprax; Neogaso; Para; **Fr.:** Cica-Care; Dermatic; Ophthaloxane; **Ger.:** Dermatic; Jaikin Nf; Mepiform; Mepilex; Mepitek; Symadal M; **Hong Kong:** Egozite Protective Baby Lotion; Silic 15; Skin Repair; **Hung.:** Fomarex; **Ir.:** Dermatic; **Israel:** Adato-Sil Oil; **Ital.:** Cica-Care; Mepiform; Mepitel; **Malaysia:** Dermatic; Egozite Protective Baby Lotion; Silic 15; **Neth.:** SIL-1000; -5000; **NZ:** Aquim; DP Barrier Cream; Egozite Protective Baby Lotion; Silicare; **Philipp.:** Cica-Care; Dermatic; **Pol.:** Silol; **Singapore:** Baritex; Dermatic; Silic 15; Skin Repair; **UK:** Cica-Care; Dermatic; Hedrin; Mepiform; Silgel; **USA:** Mentholatum Softlips; Pro-Q.

Multi-ingredient: **Arg.:** Sumo Full Contact; **Austral.:** Dermalife Plus; Dimethicream; Eczema Cream; Egozite Baby Cream; Hamilton Pine Tar with Menthol; Hamilton Skin Repair; Nappy-Mate; Silcon; **Austria:** Ceolat Compositum; Evalgan; **Braz.:** Balmex; **Canad.:** Blistex Lip Balm; Blistex Ultra Protection Lip Balm; Complex 15; Moisture; Zilactin-Lip; **Chile:** Aero Itan; Balsamo Analgesico con Fenilbutazona; Blistprote; Neopankreoflat; Ureadin 30; Xeragel; **Denm.:** Silan; **Fr.:** Supro; **Hong Kong:** DS Emulsion; Dyprote; Egozite Baby Cream; Hamilton Skin Repair; **India:** Siloderm; Tindafyl Plus; **Ir.:** Conotrane; Siopel; Sprilon; **Israel:** Kamil Blue; Kelo-Cote; **Ital.:** Angstrom Viso; Rikospray; **Malaysia:** Egozite Baby Cream; Palmer's Cocoa Butter Formula Scar Serum; **Mex.:** Hidribet; **NZ:** Egozite; Egozite Baby; Karicare Barrier Cream; Rosken Skin Repair; Silic; **S.Afr.:** Arola Rosebalm; Siopel; **Singapore:** Egozite Baby Cream; Egozite Protective Baby Lotion; Scarfade; **Spain:** Dermo Halibut; Proskin; Silidermi; **Swed.:** Silon; **UK:** Conotrane; Siopel; Full Marks Solution; Siopel; Sprilon; Vasogen; **USA:** Blistex Lip Balm; ControlRx; Diaper Guard; Dyprote; Gold Bond Medicated Triple Action Relief; Herpecin-L; Maxilube; Mentholatum Cherry Ice; Mentholatum Natural Ice; Mentholatum Softlips Lipbalm; Mentholatum Softlips Lipbalm (UV); Soothe & Cool; **Venez.:** Hidribet.

Squalene

Cosbiol; Dodecahydroisqualene; Escualano; Perhidrosqualeno; Perhidrosqualène; Skvalani; Skvalan; Skvalanas; Skwalan; Spinalcane; Squalanum; Szkváln. 2,6,10,15,19,23-Hexamethyltetra-cosane.

Сквалан

C₃₀H₆₂ = 422.8.

CAS — 111-01-3.

