

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; Unilulle; **Braz.:** Vaseline; **Canad.:** Prevez; Vaseline; **Fr.:** Cuticren; Jelonet; Tulle Gras; Vasellitulle; **Ger.:** Oleo Tull; **Gr.:** Vaseline Pur; **Ir.:** Dermamist; **Ital.:** Adaptic; Jelonet; Lomatuell H; **Mex.:** Formula Dermica; Lubrilin; **Philipp.:** Apollo; **Rus.:** Klotex (Клотекс); **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; Dermze; 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

Dimethylcyclopolsiloxane.

Циклометикон

(C₂H₅O₂Si)_n.

CAS — 69430-24-6.

Pharmacopoeias. In *USNF*.

USNF 26 (Cyclomethicone). A fully methylated cyclic siloxane containing repeating units of the formula $[-(CH_2)_2SiO-]_n$, 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; Dimethylpolysiloxane; Dimethylsiloxane; Dimeticona; Dimeticone; Dimeticonum; Dimetikon; Dimetikonas; Dimetikoni; Dimetilpolisiloxano; Dimetykon; E900; Huile de Silicone; Methyl Polysiloxane; Metilpolisiloksan; Metilpolisiloxano; Permethylpolysiloxane; Polidimetilsiloksan; 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 $[-(CH_2)_2SiO-]_n$, 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.:** Conotranet; 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:** Conotranet; 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.

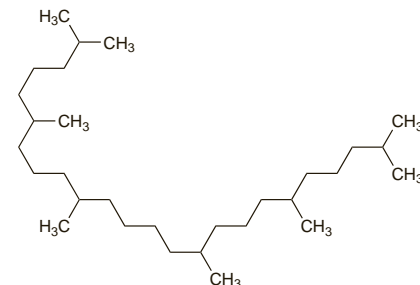
Squalene

Cosbiol; Dodecahydro-squalene; Escualano; Perhidrosqualeno; Perhidrosqualène; Skvalani; Skvalan; Skvalanas; Skvalan; Spinalcane; Squalanum; Szkváln. 2,6,10,15,19,23-Hexamethyltetracosane.

Сквалан

C₃₀H₆₂ = 422.8.

CAS — 111-01-3.



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

Ph. Eur. 6.2 (Squalane). A clear, colourless, oily liquid. Relative density about 0.815. It may be of vegetable (unsaponifiable matter of olive oil) or animal (shark liver oil) origin. Practically insoluble in water and in alcohol; freely soluble in acetone and in cyclohexane; miscible with most fats and oils.

USNF 26 (Squalane). A saturated hydrocarbon obtained by hydrogenation of squalene, an aliphatic triterpene occurring in some fish oils. It is a colourless, almost odourless, transparent oil. Insoluble in water; very slightly soluble in dehydrated alcohol; miscible with chloroform and with ether; slightly soluble in acetone. Store in airtight containers.

Profile

Squalane is a saturated derivative of squalene, a constituent of human sebum. It is miscible with human sebum and is included in topical preparations to increase skin permeability. It is also used as an emollient.

Preparations

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: *Arg.:* Cremisona†; *Hong Kong:* Apaisac; Physiogel; *Israel:* CleanEars; *Port.:* Creme Laser Hidrante; Lactonic†.

Stearyl Alcohol

Alcohol stearílico; Alcohol octadecílico; Alcohol stearílico; Alcohol Stéarylique; Alkohol stearýlowý; 1-Octadecanol; Octadecan-1-ol; Octadecyl Alcohol; Stearil alkohol; Stearylalkohol; Stéarylique; alcool; Stearylalkohol; Stearil-alkohol.

Стеариловый Спирт

$C_{18}H_{38}O = 270.5$.

CAS — 112-92-5.



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

Ph. Eur. 6.2 (Stearyl Alcohol). A mixture of solid alcohols; it contains not less than 95.0% of stearyl alcohol. White or almost white, unctuous flakes, granules, or mass. M.p. 57° to 60°. Practically insoluble in water; soluble in alcohol. When melted, it is miscible with fatty oils, with liquid paraffin, and with melted wool fat.

USNF 26 (Stearyl Alcohol). It contains not less than 90% of stearyl alcohol the remainder consisting chiefly of related alcohols. White unctuous flakes or granules with a faint characteristic odour. M.p. 55° to 60°. Insoluble in water; soluble in alcohol and in ether.

Profile

Stearyl alcohol is used to thicken topical and vaginal ointments and creams, and to increase their water-holding capacity; it has emollient and weak emulsifying properties. Stearyl alcohol is also used in oral solid dosage forms, including modified-release preparations.

Stearyl alcohol can cause hypersensitivity.

Hypersensitivity. Stearyl alcohol is usually considered to have a low potential for sensitisation although there have been isolated case reports of contact dermatitis to topical products containing it.¹⁻³

1. Black H. Contact dermatitis from stearyl alcohol in Metosyn (fluocinonide) cream. *Contact Dermatitis* 1975; **1**: 125.
2. de Berker D, et al. Contact sensitivity to the stearyl alcohol in Efidix cream (5-fluorouracil). *Contact Dermatitis* 1992; **26**: 138.
3. Yesudian PD, King CM. Allergic contact dermatitis from stearyl alcohol in Efidix cream. *Contact Dermatitis* 2001; **45**: 313-14.

Preparations

Proprietary Preparations (details are given in Part 3)

USA: SFC Lotion.

Multi-ingredient: *Arg.:* Caien.

Theobroma Oil

Beurre de Cacao; Burro di Cacao; Butyrum Cacao; Cacao Butter; Cacao Oleum; Cocoa Butter; Kakaobutter; Kakaový olej; Manteca de cacao; Manteiga de Cacaú; Ol. Theobrom; Olej kakaowy; Oleum Cacao; Oleum Theobromatis.

Какао-Масло; Масло Какао

CAS — 8002-31-1.

Pharmacopoeias. In *Br.*, *Fr.*, *Ger.*, *Jpn.* and *Pol.* Also in *USNF*.

BP 2008 (Theobroma Oil). The solid fat obtained from the roasted seeds of *Theobroma cacao*. A yellowish-white, somewhat brittle, solid fat, with a slight odour of cocoa. M.p. 31° to 34°. Slightly soluble in alcohol; freely soluble in chloroform, in ether, and in petroleum spirit (boiling range, 40° to 60°). Store at a temperature not exceeding 25°.

The symbol † denotes a preparation no longer actively marketed

USNF 26 (Cocoa Butter). A fat obtained from the seeds of *Theobroma cacao* (Sterculiaceae). It is a yellowish-white, usually brittle solid with a faint agreeable odour. M.p. 31° to 35°. Slightly soluble in alcohol; soluble in boiling dehydrated alcohol; freely soluble in chloroform and in ether.

Profile

Theobroma oil is used as a basis for suppositories. If it is heated to more than 36° during preparation the solidification point will be appreciably lowered due to the formation of metastable states; this leads to subsequent difficulty in setting. Theobroma oil is a major ingredient of chocolate.

Preparations

Proprietary Preparations (details are given in Part 3)

Spain: Lapiz Gras†.

Multi-ingredient: *Malaysia:* Palmer's Cocoa Butter Formula; Palmer's Cocoa Butter Formula Scar Serum.

Wool Alcohols

Alcoholes adipis lanae; Alcoholes de lana; Alcoholes de lanolina; Alcoholia Lanae; Alcolanum; Alcools de graisse de laine; Alkoholny tuky z ovčí vlny; Gyapjúviaszalkoholok; Lanalcolum; Lanolin Alcohols; Ullfettalkoholer; Villa-alkoholit; Vilny riebalų alkoholiai; Wollwachsalkohole; Wool Wax Alcohols.

Спирты Шерстяного Жира

CAS — 8027-33-6.

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

Ph. Eur. 6.2 (Wool Alcohols). A mixture of sterols and higher aliphatic alcohols obtained from wool fat and containing not less than 30.0% of cholesterol. It may contain not more than 200 ppm of butylated hydroxytoluene. A pale yellow to brownish-yellow, brittle mass becoming plastic on heating. M.p. not lower than 58°. Practically insoluble in water; slightly soluble in alcohol (90%); soluble in boiling dehydrated alcohol, and in dichloromethane. Store in well-filled containers. Protect from light.

USNF 26 (Lanolin Alcohols). A mixture of sterols, aliphatic alcohols, and tripenoid alcohols obtained by the hydrolysis of wool fat. It may contain not more than 0.1% of a suitable antioxidant. It is a hard, waxy amber solid with a characteristic odour. M.p. not below 56°. Insoluble in water; slightly soluble in alcohol; freely soluble in chloroform, in ether, and in petroleum spirit. Store at a temperature not exceeding 25°. Protect from light.

Incompatibility. Wool alcohols is incompatible with coal tar, ichthammol, resorcinol, and phenol.

Profile

Wool alcohols is an emulsifying agent and emulsion stabiliser used in the preparation of water-in-oil creams and ointments. It increases the water absorbing capacity of hydrocarbon mixtures; the addition of 5% of wool alcohols permits a threefold increase in the amount of water that can be incorporated in soft paraffin and such emulsions are not 'cracked' by the addition of weak acids.

It has an emollient action on the skin and is used in preparations for dry skin and dry eyes.

Derivatives of wool alcohols with similar uses include acetylated wool alcohols and ethoxylated wool alcohols.

Wool alcohols may cause hypersensitivity (but see also under Wool Fat, below).

Preparations

BP 2008: Wool Alcohols Ointment.

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: *Arg.:* Macoderm; *Canada:* Refresh Laci-Lube; *Fin.:* Laci-Lube; *Ger.:* Coliquifilm; *Irl.:* Oilatum Emollient; *Israel:* Adinol; *Ital.:* LaciLube; *NZ:* LaciLube; *Switz.:* Coliquifilm; *UK:* Ashbourne Emollient Medicinal Bath Oil†; *Dermalo:* Laci-Lube; *Oilatum Emollient; USA:* Hydrocerin; Refresh PM.

Wool Fat

Adeps lanae; Adeps lanae hydrogenatus (wool fat, hydrogenated); Anhydrous Lanolin; Cera Lanae; Graisse de laine; Graisse de laine hydrogénée (wool fat, hydrogenated); Graisse de Suint Purifiée; Gyapjúviasz; Lanoléine; Lanolin; Lanolina; Lanolina anhidra; Lanolinum; Purified Lanolin; Refined Wool Fat; Suarda; Tuk z ovčí vlny; Tuk z ovčí vlny hydrogenovaný (wool fat, hydrogenated); Ullfett; Villarasva; Vilny riebalai; Wollfett; Wollwachs.

Ланолин; Шерстяной Жир

CAS — 8006-54-0.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Int.*, *Jpn.*, *US*, and *Viet.* Some pharmacopoeias include Hydrous Wool Fat which is prepared by the addition of water to wool fat.

Eur. also includes Hydrogenated Wool Fat.

US also includes Modified Lanolin.

Ph. Eur. 6.2 (Wool Fat). A purified, anhydrous, waxy material obtained from the wool of the sheep (*Ovis aries*). It may contain

not more than 200 ppm of butylated hydroxytoluene. A yellow, unctuous substance. When melted, it is a clear or almost clear, yellow liquid. Drop point 38° to 44°. 10 g absorbs not less than 20 mL of water. Practically insoluble in water; slightly soluble in boiling dehydrated alcohol; it forms an opalescent solution in petroleum spirit. Store at a temperature not exceeding 25°.

Ph. Eur. 6.2 (Wool Fat, Hydrogenated; Adeps Lanae Hydrogenatus). A mixture of higher aliphatic alcohols and sterols obtained from the direct, high-pressure, high-temperature hydrogenation of anhydrous wool fat during which the esters and acids present are reduced to corresponding alcohols. It may contain butylated hydroxytoluene. A white or pale yellow, unctuous substance. M.p. 45° to 55°. Practically insoluble in water; soluble in boiling alcohol and in petroleum spirit. Store in well-filled containers. Protect from light.

Ph. Eur. 6.2 (Wool Fat, Hydrous; Adeps Lanae Cum Aqua). A mixture of 75% of wool fat and 25% of water. It may contain not more than 150 ppm of butylated hydroxytoluene. A pale yellow, unctuous substance. Drop point 38° to 44°. Store at a temperature not exceeding 25°.

USP 31 (Lanolin). A purified wax-like substance obtained from the wool of the sheep, *Ovis aries* (Bovidae). It is a yellow tenacious unctuous mass with a slight characteristic odour. Melting range 38° to 44°. It contains not more than 0.25% of water. It may contain not more than 0.02% of a suitable antioxidant. Insoluble in water, but mixes without separation with about twice its weight of water; sparingly soluble in cold alcohol; more soluble in hot alcohol; freely soluble in chloroform and in ether. Store at a temperature preferably between 15° and 30°.

USP 31 (Modified Lanolin). It is Lanolin that has been processed to reduce the contents of free lanolin alcohols and detergent and pesticide residues. It contains not more than 0.25% of water. It may contain not more than 0.02% of a suitable antioxidant. Store in airtight, preferably rust-proof, containers and preferably at a temperature of 15° to 30°.

Profile

Wool fat is used in the formulation of water-in-oil creams and ointments. When mixed with a suitable vegetable oil or with soft paraffin it gives emollient creams that penetrate the skin. It can absorb about 30% of water. Wool fat is also used in other topical, vaginal, rectal, and ophthalmic preparations.

Derivatives and modifications of wool fat include hydrogenated wool fat (hydrogenated lanolin), hydrous wool fat (hydrous lanolin), poloxyl lanolin (ethoxylated lanolin), isopropyl lanolate, lanolin oil, and lanolin wax.

Wool fat can cause sensitivity reactions.

Hypersensitivity. Wool fat is widely regarded as a common sensitising agent, but the true extent of allergy to it is controversial. Suspected sensitivity reactions have proved difficult to reproduce in skin patch testing.¹ The allergens are unknown but are thought to be in the alcoholic fraction. A retrospective study² of more than 24 000 patients with eczema who received skin patch testing found that sensitivity reactions to a standard patch reagent of wool alcohols 30% in soft paraffin were rare; an average of 1.7% of patients per year showed sensitivity.

1. Wolf R. The lanolin paradox. *Dermatology* 1996; **192**: 198-202.
2. Wakelin SH, et al. A retrospective analysis of contact allergy to lanolin. *Br J Dermatol* 2001; **145**: 28-31.

Pesticide residues. Concerns have been raised in the past about pesticide residues in wool fat,¹⁻³ because of the possible risk to breast-fed infants whose mothers were using wool fat-based nipple ointments. Official published standards such as Ph. Eur. and USP now include limits for pesticide levels in wool fat.

1. Copeland CA, et al. Pesticide residue in lanolin. *JAMA* 1989; **261**: 242.
2. Cade PH. Pesticide in lanolin. *JAMA* 1989; **262**: 613.
3. Copeland CA, Wagner SL. Pesticide in lanolin. *JAMA* 1989; **262**: 613.

Preparations

BP 2008: Simple Eye Ointment; Simple Ointment;

USP 31: Modified Lanolin.

Proprietary Preparations (details are given in Part 3)

Austral.: Lansinoh†; **Canada:** Lansinoh†; **Purelan.:** Oleo Tull; **Port.:** Lansinoh; **Multi-Mam Lanolina†; S.Afr.:** Duratears; **Turk.:** Duratears.

Multi-ingredient: *Arg.:* Alcon Lagrimas; Crema Para Paspaduras; Dr Selby; Ninderm; Quem Plus†; **Austral.:** Alpha Ker; Duratears; E45; Laci-Lube; Poly Visc; Rikodem†; Silcon†; Soothe'n Heal; **Austria:** Tiroler Steinol; **Belg.:** Duratears; Lacrytube; **Canada:** A & D Ointment; Akwa Tears; Alpha Ker†; Duratears; Huile de Bain Therapeutique; Lubriderm†; Optilube; Tears Naturelle PM; Therapeutic Bath Oil†; Therapeutic Skin Lotion†; **Chile:** Duratears; Laci-Lube; Pasta Lassar; **Fr.:** Grassolind Neutral; **Ger.:** Sofra-Tull sine; Vita-POS; **Gr.:** Duratears; Fissan-Pate†; **Hong Kong:** Alpha Ker; **Balneum;** Duratears; **Indon.:** Yanthi Baby Oil; **Irl.:** Laci-Lube; **Israel:** Duratears; Kamil Blue; Lacrimol; Pedisol; **Malaysia:** Balneum; Duratears Naturelle; LaciLube†; **Mex.:** Acuafl†; **Neth.:** Duratears Z; **NZ:** Alpha Ker; BK; DP; DP Lotion - HC; Hydroderm; Oralfit Peppermint; **Pol.:** E45; **Singapore:** Balneum; Duratears; LaciLube; **Spain:** Lubrifilm; Tears Lubricante†; **Thai.:** Balneum†; Duratears; **UK:** Alpha Ker; Hewlett's; Lubri-Tears; Melrose; **USA:** Akwa Tears; Alpha Ker; Bodi Oil; Bottom Better; Dermadrox; Dry Eyes; Duratears Naturelle; Geri-Silk; Laci-Gel; Laci-Lube; LubriFresh PM; LubriTears; Paladin; **Venez.:** Lacimart†; Oleoderm.