

**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; Lactonico†.

### Stearyl Alcohol

Alcohol stearílico; Alcohol octadecílico; Alcohol stearílico; Alcool Stéarylique; Alkohol stearýlowy; 1-Octadecanol; Octadecan-1-ol; Octadecyl Alcohol; Stearilo alkoholis; Stearylalkohol; Stéarylique; alcool; Stearylalkoholi; 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.<sup>1-3</sup>

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 Efidux cream (5-fluorouracil). *Contact Dermatitis* 1992; **26**: 138.
3. Yesudian PD, King CM. Allergic contact dermatitis from stearyl alcohol in Efidux 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; Mantecca 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; Alkoholy tuky z ovčí vlny; Gyapjúviaszalkoholok; Lanalcolum; Lanolin Alcohols; Ullfettalkoholer; Villa-alkoholit; Vilny riebaly 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.:* Lacrilube; *NZ:* Lacrilube; *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 riebaly; Wollfett; Wollwachs.

Ланолин; Шерстяной Жир

CAS — 8006-54-0.

**Pharmacopoeias.** In *Chin.*, *Eur.* (see p.vii), *Int.*, *Jpn.*, *US*, and *Viet.* Some pharmacopoeias include Hydrated 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.<sup>1</sup> The allergens are unknown but are thought to be in the alcoholic fraction. A retrospective study<sup>2</sup> 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,<sup>1-3</sup> 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; Lubiderm†; 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; Lacrilube†; **Mex.:** Acuafl†; **Neth.:** Duratears Z; **NZ:** Alpha Ker; BK; DP; DP Lotion - HC; Hydroderm; Oralfit Peppermint; **Pol.:** E45; **Singapore:** Balneum; Duratears; Lacrilube; **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.:** Lacrimart†; Oleoderm.