

Lanolin Alcohols

1 Nonproprietary Names

BP: Wool Alcohols

PhEur: Wool Alcohols

USP–NF: Lanolin Alcohols

2 Synonyms

Alcoholes adipis lanae; alcoholia lanae; alcolanum; *Argowax*; lanalcolum; *Lanis AL*; *Lantrol 1780*; *Ritawax*; *Super Hartolan*; wool wax alcohols.

3 Chemical Name and CAS Registry Number

Lanolin alcohols [8027-33-6]

4 Empirical Formula and Molecular Weight

Lanolin alcohols is a mixture of aliphatic alcohols, triterpenoid alcohols, and sterols obtained by hydrolysis of lanolin, including not less than 30% cholesterol. The cholesterol found in lanolin is a mixture of different stereochemical isomers.

The USP 40–NF 35 S1 permits the inclusion of up to 0.1% w/w of a suitable antioxidant, while the PhEur 9.2 specifies that lanolin alcohols may contain up to 200 ppm of butylated hydroxytoluene as an antioxidant.

5 Structural Formula

See Section 4.

6 Functional Category

Emollient; emulsifying agent; ointment base; solubilizing agent.

7 Applications in Pharmaceutical Formulation or Technology

Lanolin alcohols is used in topical pharmaceutical formulations as an absorption base with emollient properties. It is also used in the preparation of water-in-oil creams and ointments at concentrations as low as 2% w/w. Lanolin alcohols have been used as carrier systems to deliver pharmacologically active substances through the skin.

The proportion of water that can be incorporated into petrolatum is increased threefold by the addition of 5% lanolin alcohols. It is stable over a wide pH range and can be used in acidic and alkaline water-in-oil emulsions, where it acts as a viscosity-increasing agent. Such emulsions do not crack upon the addition of citric, lactic, or tartaric acids.

Lanolin alcohols is also used as a nongelling thickener and emollient in cosmetic creams, lotions, lip balms, lipsticks, and other stick cosmetics.

8 Description

Lanolin alcohols occurs as a pale yellow to golden-brown-colored solid that is plastic when warm but brittle when cold. It has a faint characteristic odor. See also Section 4.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for lanolin alcohols.

Test	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+
Characters	+	–
Melting range	≥56°C	≥56°C
Acidity/alkalinity	+	+
Clarity of solution	+	–
Loss on drying	≤0.5%	≤0.5%
Residue on ignition	≤0.1%	≤0.15%
Copper	–	≤5 ppm
Acid value	≤2.0	≤2.0
Hydroxyl value	120–180	120–180
Peroxide value	≤15	≤15
Saponification value	≤12	≤12
Water absorption capacity	+	–
Content of sterols (as cholesterol)	≥30.0%	≥30.0%

10 Typical Properties

Density 0.98 g/cm³

Solubility Freely soluble in chloroform, dichloromethane, ether, and light petroleum; soluble 1 part in 25 parts of boiling ethanol (95%); slightly soluble in ethanol (90%); practically insoluble in water.

11 Stability and Storage Conditions

Lanolin alcohols may gradually undergo autoxidation during storage. Store in a well-closed, well-filled container, protected from light, in a cool, dry place. Normal storage life is approximately 2 years.

12 Incompatibilities

Incompatible with coal tar, ichthammol, phenol, and resorcinol.

13 Method of Manufacture

Lanolin alcohols is prepared by the saponification of lanolin followed by separation of the fraction containing cholesterol and other alcohols. It is further refined during a multistage molecular distillation process, which improves color and odor, producing a purified, semicrystalline wax.

14 Safety

Lanolin alcohols is widely used in cosmetics and topical pharmaceutical formulations and is generally regarded as a nontoxic material. However, lanolin alcohols may be irritant to the skin and hypersensitivity can occur in some individuals.^(1,2) It has been shown to be a mild irritant to the eyes.⁽³⁾

LD₅₀ (rat, oral): >20 ml/kg⁽³⁾

LD₅₀ (rat, oral): >42.7 g/kg (66% in corn oil)⁽³⁾

See also Lanolin.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled.

16 Regulatory Status

Included in the FDA Inactive Ingredients Database (ophthalmic and topical preparations). Included in nonparenteral medicines licensed