

Lanolin Alcohols

1 Nonproprietary Names

BP: Wool alcohols
PhEur: Alcoholes adipis lanae
USPNF: Lanolin alcohols

2 Synonyms

Alcoholia lanae; alcolanum; *Argowax*; *Hartolan*; lanalcohol; *Ritawax*; wool wax alcohols.

3 Chemical Name and CAS Registry Number

Lanolin alcohols [8027-33-6]

4 Empirical Formula Molecular Weight

Lanolin alcohols is a crude mixture of steroidal and triterpene alcohols, including not less than 30% cholesterol, and 10–13% isocholesterol. The USPNF 20 permits the inclusion of up to 0.1% w/w of a suitable antioxidant, while the PhEur 2002 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

Emulsifying agent; ointment base.

7 Applications in Pharmaceutical Formulation or Technology

Lanolin alcohols is used in topical pharmaceutical formulations and cosmetics as a hydrophobic vehicle with emollient properties, e.g., in preparations for dry skin and dry eyes. It is also used in the preparation of water-in-oil creams and ointments at concentrations as low as 2% w/w. The proportion of water that can be incorporated into petrolatum is increased threefold by the addition of 5% lanolin alcohols. Such emulsions do not crack upon the addition of citric, lactic, or tartaric acids.

8 Description

Lanolin alcohols is 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 2002	USPNF 20
Identification	+	+
Characters	+	—
Melting range	≥ 58°C	≥ 56°C
Acidity and 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	—
Peroxide value	≤ 15	—
Saponification value	≤ 12	≤ 12
Water absorption capacity	+	—
Butylated hydroxytoluene	≤ 200 ppm	—
Content of sterols (as cholesterol)	≥ 30.0%	≥ 30.0%

10 Typical Properties

Solubility: freely soluble in chloroform, dichloromethane, ether, and light petroleum; soluble 1 in 25 parts of boiling ethanol; 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.

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.
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 Guide (ophthalmic and topical preparations). Included in nonparenteral medicines licensed in the UK.

17 Related Substances

Cholesterol; lanolin; lanolin, hydrous; petrolatum and lanolin alcohols.

18 Comments

Water-in-oil emulsions prepared with lanolin alcohols, unlike those made with lanolin, do not show surface darkening, nor do they develop an objectionable odor in hot weather.

The EINECS number for lanolin alcohols is 232-430-1.

19 Specific References

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20 General References

Barnett G. Lanolin and derivatives. *Cosmet Toilet* 1986; **101**(3): 23–44.

Khan AR, Iyer BV, Cirelli RA, Vasavada RC. *In vitro* release of salicylic acid from lanolin alcohols-ethylcellulose films. *J Pharm Sci* 1984; **73**: 302–305.

Osborne DW. Phase behavior characterization of ointments containing lanolin or a lanolin substitute. *Drug Dev Ind Pharm* 1993; **19**: 1283–1302.

Smolinske SC. *Handbook of Food, Drug, and Cosmetic Excipients*. Boca Raton, FL: CRC Press, 1992: 225–229.

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22 Date of Revision

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