

Mineral Oil and Lanolin Alcohols

1 Nonproprietary Names

None adopted.

2 Synonyms

Amerchol L-101; liquid paraffin and lanolin alcohols; *Protalan M-16*; *Protalan M-26*.

3 Chemical Name and CAS Registry Number

Mineral oil [8012-95-1]
Lanolin alcohols [8027-33-6]

4 Empirical Formula Molecular Weight

A mixture of mineral oil and lanolin alcohols.

5 Structural Formula

See Section 4.

6 Functional Category

Emollient; emulsifying agent; plasticizer.

7 Applications in Pharmaceutical Formulation or Technology

Mineral oil and lanolin alcohols is an oily liquid used in topical pharmaceutical formulations and cosmetics as an emulsifying agent with emollient properties; see Table I. It is used as a primary emulsifier in the preparation of water-in-oil creams and lotions and as an auxiliary emulsifier and stabilizing agent in oil-in-water creams and lotions.

Table I: Uses of mineral oil and lanolin alcohols.

Use	Concentration (%)
Emollient	3.0–6.0
Emulsifier in w/o creams and lotions	5.0–15.0
Emulsifier in o/w creams and lotions	0.5–6.0

8 Description

A pale yellow-colored, oily liquid with a faint characteristic sterol odor.

9 Pharmacopeial Specifications

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10 Typical Properties

Acid value: ≤ 1
Arsenic: ≤ 2 ppm
Ash: $\leq 0.2\%$
Heavy metals: ≤ 20 ppm
HLB value: ≈ 8
Hydroxyl value: 10–15
Iodine number: ≤ 12
Microbiological count: the total bacterial count, when packaged, is less than 10 per gram of sample.
Moisture content: $\leq 0.2\%$
Saponification value: ≤ 2
Solubility: soluble 1 in 2 parts of chloroform, 1 in 4 parts of castor oil, and 1 in 4 parts of corn oil. Practically insoluble in ethanol (95%) and water. Precipitation occurs in hexane.
Specific gravity: 0.840–0.860 at 25°C

11 Stability and Storage Conditions

Mineral oil and lanolin alcohols is stable and should be stored in a well-closed container in a cool, dry place.

12 Incompatibilities

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

13 Method of Manufacture

Lanolin alcohols is dissolved in mineral oil.

14 Safety

Mineral oil and lanolin alcohols is generally regarded as an essentially nontoxic and nonirritant material. However, lanolin alcohols may be irritant to the skin and causes hypersensitivity in some individuals.⁽¹⁾

15 Handling Precautions

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

16 Regulatory Status

Accepted for use in topical pharmaceutical formulations and cosmetics.

17 Related Substances

Lanolin alcohols; mineral oil; petrolatum and lanolin alcohols.

18 Comments

See Lanolin Alcohols and Mineral Oil for further information.

19 Specific References

- 1 Wakelin SH, Smith H, White IR, *et al.* A retrospective analysis of contact allergy to lanolin. *Br J Dermatol* 2001; 145(1): 28–31.

20 General References

- Davis SS. Viscoelastic properties of pharmaceutical semisolids I: ointment bases. *J Pharm Sci* 1969; 58: 412–418.
- Prosperio G, Gatti S, Genesi P. Lanolin and its derivatives for cosmetic creams and lotions. *Cosmet Toilet* 1980; 95(4): 81–85.

21 Author

AH Kibbe.

22 Date of Revision

20 August 2002.