

Cetostearyl Alcohol

1 Nonproprietary Names

BP: Cetostearyl alcohol
PhEur: Alcohol cetylicus et stearyliscus
USPNF: Cetostearyl alcohol

2 Synonyms

Cetearyl alcohol; *Crodacol CS90*; *Lanette O*; *Tego Alkanol 1618*; *Tego Alkanol 6855*.

3 Chemical Name and CAS Registry Number

Cetostearyl alcohol [67762-27-0] and [8005-44-5]

4 Empirical Formula Molecular Weight

Cetostearyl alcohol is a mixture of solid aliphatic alcohols consisting mainly of stearyl ($C_{18}H_{38}O$) and cetyl ($C_{16}H_{34}O$) alcohols. The proportion of stearyl to cetyl alcohol varies considerably, but the material usually consists of about 50–70% stearyl alcohol and 20–35% cetyl alcohol, with limits specified in pharmacopeias. The combined stearyl alcohol and cetyl alcohol comprise at least 90% of the material. Small quantities of other alcohols, chiefly myristyl alcohol, make up the remainder of the material. Two emulsifying grades of cetostearyl alcohol are recognized by the PhEur 2002 and contain at least 7% surfactant, with Type A containing sodium cetostearyl sulfate and Type B containing sodium lauryl sulfate.

5 Structural Formula

See Section 4.

6 Functional Category

Emollient; emulsifying agent; viscosity-increasing agent.

7 Applications in Pharmaceutical Formulation or Technology

Cetostearyl alcohol is used in cosmetics and topical pharmaceutical preparations. In topical pharmaceutical formulations, cetostearyl alcohol will increase the viscosity and impart body in both water-in-oil and oil-in-water emulsions. Cetostearyl alcohol will stabilize an emulsion and also act as a co-emulsifier, thus decreasing the amount of surfactant required to form a stable emulsion. Cetostearyl alcohol is also used in the preparation of nonaqueous creams and sticks. Research articles have been published in which cetostearyl alcohol has been used to slow the dissolution of water-soluble drugs.^(1–4) In combination with surfactants, cetostearyl alcohol forms emulsions with very complex microstructures. These microstructures can include liquid crystals, lamellar structures, and gel phases.^(5–16)

8 Description

Cetostearyl alcohol occurs as white or cream-colored unctuous masses, or almost white flakes or granules. It has a faint, characteristic sweet odor. On heating, cetostearyl alcohol melts to a clear, colorless or pale yellow-colored liquid free of suspended matter.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for cetostearyl alcohol.

Test	PhEur 2002	USPNF 20
Identification	+	+
Characters	+	—
Appearance of solution	+	—
Melting range	49–56°C	48–55°C
Acid value	≤ 1.0	≤ 2.0
Iodine value	≤ 2.0	≤ 4.0
Hydroxyl value	208–228	208–228
Saponification value	≤ 2.0	—
Assay		
of $C_{18}H_{38}O$	≥ 40.0%	≥ 40.0%
of $C_{16}H_{34}O$ and $C_{18}H_{38}O$	≥ 90.0%	≥ 90.0%

10 Typical Properties

Solubility: soluble in ethanol (95%), ether, and oil; practically insoluble in water.

11 Stability and Storage Conditions

Cetostearyl alcohol is stable under normal storage conditions. Cetostearyl alcohol should be stored in a well-closed container in a cool, dry place.

12 Incompatibilities

Incompatible with strong oxidizing agents and metal salts.

13 Method of Manufacture

Cetostearyl alcohol is prepared by the reduction of the appropriate fatty acids from vegetable and animal sources. Cetostearyl alcohol can also be prepared directly from hydrocarbon sources.

14 Safety

Cetostearyl alcohol is mainly used in topical pharmaceutical formulations and topical cosmetic formulations.

Cetostearyl alcohol is generally regarded as a nontoxic material.⁽¹⁷⁾ Although it is essentially nonirritating, sensitization reactions to cetostearyl, cetyl, and stearyl alcohols^(18–23) have been reported.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection and gloves are recommended. Cetostearyl alcohol is flammable and on combustion may produce fumes containing carbon monoxide.

16 Regulatory Status

Accepted as an indirect food additive and as an adhesive and a component of packaging coatings in the USA. Included in the FDA Inactive Ingredients Guide (oral tablets and topical emulsions, lotions, and ointments). Included in nonparenteral medicines licensed in the UK.

17 Related Substances

Cetyl alcohol; sodium lauryl sulfate; stearyl alcohol.

18 Comments

The composition of cetostearyl alcohol from different sources may vary considerably. The composition of the minor components, typically straight-chain and branched-chain alcohols, varies greatly depending upon the source, which may be animal, vegetable, or synthetic. This has been reported in the literature to impart differences in emulsification behavior, particularly with respect to emulsion consistency or stability.⁽¹⁴⁻¹⁶⁾

19 Specific References

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20 General References

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21 Authors

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22 Date of Revision

23 October 2002.