

# Stearyl Alcohol

## 1 Nonproprietary Names

BP: Stearyl alcohol  
JP: Stearyl alcohol  
PhEur: Alcohol stearylicus  
USPNF: Stearyl alcohol

## 2 Synonyms

*Cachalot*; *Crodacol S95*; *Hyfatol 18-95*; *Hyfatol 18-98*; *Lanette 18*; *Lipocol S*; *Lipocol S-DEO*; *n*-octadecanol; octadecyl alcohol; *Rita SA*; *stenol*; *Tego Alkanol 18*.

## 3 Chemical Name and CAS Registry Number

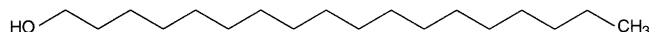
1-Octadecanol [112-92-5]

## 4 Empirical Formula Molecular Weight

$C_{18}H_{38}O$  270.48 (for pure material)

The PhEur 2002 describes stearyl alcohol as a mixture of solid alcohols containing not less than 95% of 1-octadecanol,  $C_{18}H_{38}O$ . The USPNF 20 states that stearyl alcohol contains not less than 90% of 1-octadecanol.

## 5 Structural Formula



## 6 Functional Category

Stiffening agent.

## 7 Applications in Pharmaceutical Formulation or Technology

Stearyl alcohol is used in cosmetics<sup>(1,2)</sup> and topical pharmaceutical creams and ointments as a stiffening agent. By increasing the viscosity of an emulsion, stearyl alcohol increases its stability. Stearyl alcohol also has some emollient and weak emulsifying properties and is used to increase the water-holding capacity of ointments, e.g., petrolatum. In addition, stearyl alcohol has been used in controlled-release tablets,<sup>(3,4)</sup> suppositories,<sup>(5,6)</sup> and microspheres.<sup>(7,8)</sup> It has also been investigated for use as a transdermal penetration enhancer.<sup>(9)</sup>

## 8 Description

Stearyl alcohol occurs as hard, white, waxy pieces, flakes, or granules with a slight characteristic odor and bland taste.

## 9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for stearyl alcohol.

Test	JP 2001	PhEur 2002	USPNF 20
Identification	—	+	+
Characters	—	+	—
Appearance of solution	+	+	—
Melting range	56–62 °C	57–60 °C	55–60 °C
Acid value	≤1.0	≤1.0	≤2.0
Iodine value	≤2.0	≤2.0	≤2.0
Hydroxyl value	200–220	197–217	195–220
Saponification value	—	≤2.0	—
Ester value	≤3.0	—	—
Residue on ignition	≤0.05%	—	—
Assay (of $C_{18}H_{38}O$ )	—	≥95%	≥90.0%

## 10 Typical Properties

Autoignition temperature: 450 °C

Boiling point: 210.5 °C at 2 kPa (15 mmHg)

Density (true): 0.884–0.906 g/cm<sup>3</sup><sup>(10)</sup>

Flash point: 191 °C (open cup)

Freezing point: 55–57 °C

Melting point: 59.4–59.8 °C for the pure material.

Refractive index:  $n_D^{60}$  = 1.4388 at 60 °C

Solubility: soluble in chloroform, ethanol (95%), ether, hexane, propylene glycol, and vegetable oils; practically insoluble in water.

Vapor pressure: 133.3 Pa (1 mmHg) at 150.3 °C

Viscosity (dynamic): 9.82 mPa s at 64 °C<sup>(10)</sup>

## 11 Stability and Storage Conditions

Stearyl alcohol is stable to acids and alkalis and does not usually become rancid. It should be stored in a well-closed container in a cool, dry place.

## 12 Incompatibilities

Incompatible with strong oxidizing agents.

## 13 Method of Manufacture

Historically, stearyl alcohol was prepared from sperm whale oil but is now largely prepared synthetically by reduction of ethyl stearate with lithium aluminum hydride.

## 14 Safety

Stearyl alcohol is generally considered to be an innocuous, nontoxic material. However, adverse reactions to stearyl alcohol present in topical preparations have been reported. These include contact urticaria and hypersensitivity reactions, which are possibly due to impurities contained in stearyl alcohol rather than stearyl alcohol itself.<sup>(11–15)</sup>

The probable lethal oral human dose is greater than 15 g/kg.

LD<sub>50</sub> (rat, oral): 20 g/kg<sup>(16)</sup>

## 15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection and gloves are recommended. Stearyl alcohol is not a fire hazard, although it will burn and may give off noxious fumes containing carbon monoxide.

## 16 Regulatory Status

Included in the FDA Inactive Ingredients Guide (tablets, topical, and vaginal preparations). Included in nonparenteral medicines licensed in the UK.

## 17 Related Substances

Cetostearyl alcohol; cetyl alcohol.

## 18 Comments

The EINECS number for stearyl alcohol is 204-017-6.

## 19 Specific References

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## 20 General References

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## 21 Author

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## 22 Date of Revision

30 May 2002.