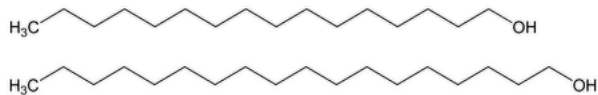


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Cetostearyl Alcohol

Change to read:



▲ Mixture of cetyl and stearyl alcohols ▲ (NF 1-Dec-2023)
CAS RN®: 67762-27-0.

DEFINITION

Cetostearyl Alcohol contains NLT 40.0% of stearyl alcohol (C₁₈H₃₈O), and the sum of the stearyl alcohol content and the cetyl alcohol (C₁₆H₃₄O) content is NLT 90.0% and NMT 102.0%. It is obtained from sources of vegetable, animal, or synthetic origin.

IDENTIFICATION

• A. CHROMATOGRAPHIC IDENTITY

Analysis: Proceed as directed in the Assay.
Acceptance criteria: The retention times of the major peaks of the *Sample solution*, excluding the solvent and internal standard peaks, correspond to the cetyl alcohol and stearyl alcohol peaks of the *System suitability solution*.

ASSAY

• PROCEDURE

Internal standard solution: 1 mg/mL of 1-pentadecanol (internal standard) in ethanol
System suitability solution: Prepare 1 mg/mL each of [USP Cetyl Alcohol RS](#), [USP Stearyl Alcohol RS](#), and [USP Oleyl Alcohol RS](#) in the *Internal standard solution*. Heat the solution in a sealed container in a 50° water bath until all fatty alcohols are dissolved. Allow the solution to cool to room temperature, and mix well.
Standard solution: To match the cetyl alcohol and stearyl alcohol ratio in the test sample, prepare the sum of 2.0 mg/mL of [USP Cetyl Alcohol RS](#) and [USP Stearyl Alcohol RS](#) in the *Internal standard solution*. Heat the solution in a sealed container in a 50° water bath until cetyl alcohol and stearyl alcohol are dissolved. Allow the solution to cool to room temperature, and mix well.
Sample solution: Prepare 2.0 mg/mL of Cetostearyl Alcohol in the *Internal standard solution*, and heat the solution in a sealed container in a 50° water bath until the cetostearyl alcohol is dissolved. Allow the solution to cool to room temperature, and mix well.

Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)
Mode: GC
Detector: Flame ionization
Column: 0.25-mm × 30-m fused-silica capillary; coated with a 0.25-µm layer of phase [G7](#)
Temperatures
Detector: 280°
Injection port: 270°
Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
60	20	180	—
180	10	220	5

Carrier gas: Hydrogen
Flow rate: 2.0 mL/min, constant flow mode

Injection volume: 1 µL

Injection type: Split, split ratio 100:1

Liner: Single taper, low pressure drop liner with deactivated wool

Run time: 15 min

System suitability

Samples:

System suitability solution and Standard solution

[NOTE—See [Table 2](#) for the relative retention times.]

Table 2

Component	Relative Retention Time
1-Pentadecanol (internal standard)	1.00
Cetyl alcohol	1.09
Stearyl alcohol	1.25
Oleyl alcohol	1.28

Suitability requirements

Resolution: NLT 30 between the cetyl alcohol and stearyl alcohol peaks; NLT 2.0 between the stearyl alcohol and oleyl alcohol peaks,
System suitability solution

Tailing factor: 0.8–1.8 for the stearyl alcohol and 1-pentadecanol peaks, *Standard solution*

Relative standard deviation: NMT 1%, using the area ratio of stearyl alcohol to 1-pentadecanol, *Standard solution*

Analysis

Samples: *Standard solution and Sample solution*

Calculate the percentages of cetyl alcohol ($C_{16}H_{34}O$) or stearyl alcohol ($C_{18}H_{38}O$) in the portion of Cetostearyl Alcohol taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of cetyl alcohol (or stearyl alcohol) to the internal standard from the *Sample solution*

R_S = peak response ratio of cetyl alcohol (or stearyl alcohol) to the internal standard from the *Standard solution*

C_S = concentration of [USP Cetyl Alcohol RS](#) (or [USP Stearyl Alcohol RS](#)) in the *Standard solution* (mg/mL)

C_U = concentration of Cetostearyl Alcohol in the *Sample solution* (mg/mL)

Acceptance criteria

Stearyl alcohol ($C_{18}H_{38}O$): NLT 40.0%

Sum of stearyl alcohol ($C_{18}H_{38}O$) and cetyl alcohol ($C_{16}H_{34}O$): 90.0%–102.0%

IMPURITIES

- **RESIDUE ON IGNITION (281):** NMT 0.1%, determined on 2 g

Change to read:

- **LIMIT OF RELATED FATTY ALCOHOLS**

Solution A: 1 mg/mL of 1-pentadecanol in ethanol

Resolution solution: Prepare 1 mg/mL each of [USP Lauryl Alcohol RS](#), [USP Myristyl Alcohol RS](#), [USP Cetyl Alcohol RS](#), [USP Stearyl Alcohol RS](#), [USP Oleyl Alcohol RS](#), [USP Linoleyl Alcohol RS](#), [USP Linolenyl Alcohol RS](#), and [USP Arachidyl Alcohol RS](#) in *Solution A*.

Heat the solution in a sealed container in a 50° water bath until all fatty alcohols are dissolved. Allow the solution to cool to room temperature, and mix well. Dilute the solution with ethanol to obtain a solution containing 0.05 mg/mL each of [USP Lauryl Alcohol RS](#), [USP Myristyl Alcohol RS](#), [USP Cetyl Alcohol RS](#), 1-pentadecanol, [USP Stearyl Alcohol RS](#), [USP Oleyl Alcohol RS](#), [USP Linoleyl Alcohol RS](#), [USP Linolenyl Alcohol RS](#), and [USP Arachidyl Alcohol RS](#).

Sample solution: 1 mg/mL of Cetostearyl Alcohol in ethanol. Heat the solution in a sealed container in a 50° water bath until the cetostearyl alcohol is dissolved. Allow the solution to cool to room temperature, and mix well.

Chromatographic system: Proceed as directed in the Assay, except for the *Injection type*.

Injection type: Split; split ratio 5:1