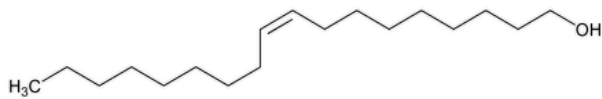


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Oleyl Alcohol



$C_{18}H_{36}O$ 268.48
9-Octadecen-1-ol, (Z)-;
(Z)-9-Octadecen-1-ol CAS RN®: 143-28-2.

DEFINITION

Oleyl Alcohol is a mixture of unsaturated and saturated high molecular weight fatty alcohols consisting of 75.0%–102.0% of oleyl alcohol ($C_{18}H_{36}O$) and its isomers. It is obtained from sources of vegetable, animal, or synthetic origin. It may contain suitable stabilizers.

IDENTIFICATION

• **A. CHROMATOGRAPHIC IDENTITY**

Analysis: Proceed as directed in the Assay.
Acceptance criteria: The retention time of the major peak of the *Sample solution*, excluding the solvent and internal standard peaks, corresponds to the oleyl alcohol peak 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 *Internal standard solution*, and 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: 1.0 mg/mL of [USP Oleyl Alcohol RS](#) in *Internal standard solution*
Sample solution: 1.0 mg/mL of Oleyl Alcohol in *Internal standard solution*
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 injection; split ratio is 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	1.08
Stearyl alcohol	1.25
Oleyl alcohol	1.27

Suitability requirements

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

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

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

Analysis

Samples: *Standard solution* and *Sample solution*

The peak of elaidyl alcohol, which is an isomer of oleyl alcohol, can be resolved from the oleyl alcohol peak with a resolution of about 1, and with a relative retention time with reference to oleyl alcohol of 0.995. An additional small peak that may be observed on the peak tail of oleyl alcohol can be assigned to another oleyl alcohol isomer. If elaidyl alcohol is observed, a combination of both peaks of elaidyl alcohol and oleyl alcohol is used to determine oleyl alcohol content.

Calculate the percentage of oleyl alcohol ($C_{18}H_{36}O$) or its isomers in the portion of Oleyl Alcohol taken:

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

R_U = peak response ratio of oleyl alcohol (or elaidyl alcohol) to the internal standard [peak response of oleyl alcohol (or elaidyl alcohol)/peak response of the internal standard] from the *Sample solution*

R_S = peak response ratio of oleyl alcohol to the internal standard (peak response of oleyl alcohol/peak response of the internal standard) from the *Standard solution*

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

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

Acceptance criteria: 75.0%–102.0% for oleyl alcohol and its isomers

IMPURITIES

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

• **LIMIT OF RELATED FATTY ALCOHOLS**

Resolution solution: Prepare 1 mg/mL each of [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 ethanol. 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.