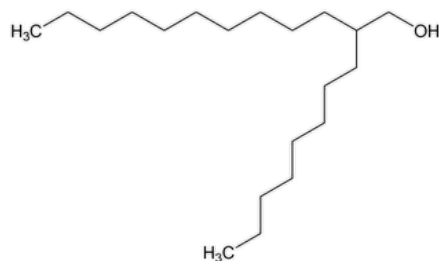


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Octyldodecanol



$C_{20}H_{42}O$ 298.55

1-Dodecanol, 2-octyl-;
 2-Octyldodecan-1-ol;
 2-Octyldodecanol;
 2-Octyldodecyl alcohol CAS RN®: 5333-42-6.

DEFINITION

Octyldodecanol contains NLT 90.0% and NMT 102.0% of 2-octyldodecan-1-ol ($C_{20}H_{42}O$), the remainder consisting chiefly of related alcohols. 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 time of the major peak of the *Sample solution*, excluding the solvent and internal standard peaks, corresponds to the octyldodecanol peak of the *Standard solution*.

• B. [FATS AND FIXED OILS \(401\)](#), [Procedures](#), [Hydroxyl Value](#): 175–190

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: Prepare 1.0 mg/mL of [USP Octyldodecanol RS](#) in *Internal standard solution*.

Sample solution: Prepare 1.0 mg/mL of Octyldodecanol 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

Injection port: 270°

Detector: 280°

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 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	1.08
Stearyl alcohol	1.25
Oleyl alcohol	1.27
Octyldodecanol	1.32

Suitability requirements

Resolution: NLT 10 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 octyldodecanol and 1-pentadecanol peaks, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of octyldodecanol ($C_{20}H_{42}O$) in the portion of Octyldodecanol taken:

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

R_U = peak response ratio of octyldodecanol to the internal standard (peak response of octyldodecanol/peak response of the internal standard) from the *Sample solution*

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

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

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

Acceptance criteria: 90.0%–102.0%

IMPURITIES

[NOTE—On the basis of the manufacturing route, perform either *Organic Impurity Test 1* or *Organic Impurity Test 2*.]

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