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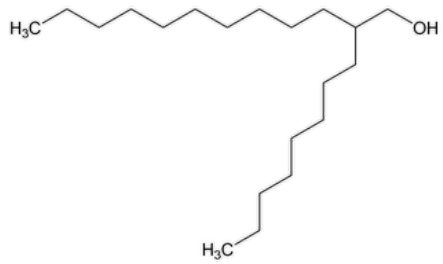
Octyldodecanol



$C_{20}H_{42}O$ 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

• **Organic Impurity Test 1: Limit of Related Fatty Alcohols and Alkanes**

System suitability solution: Prepare 1 mg/mL each of USP Stearyl Alcohol RS, USP Oleyl Alcohol RS, USP Linoleyl Alcohol RS, and USP Octyldodecanol RS in ethanol, 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. Dilute the solution with ethanol to obtain a solution containing 0.05 mg/mL each of USP Stearyl Alcohol RS, USP Oleyl Alcohol RS, USP Linoleyl Alcohol RS, and USP Octyldodecanol RS.

Sample solution: 1 mg/mL of Octyldodecanol in ethanol

Chromatographic system: Proceed as directed in the *Assay*, except use split injection with a split ratio of 5:1.

System suitability

Samples: *System suitability solution* and *Sample solution*

[Note—See *Table 3* for the relative retention times.]

Table 3

Component	Relative Retention Time
n-Nonadecane[a]	0.63
9-Methyl nonadecane[a]	0.65
2-Octyl-1-decanol or 2-hexyl-1-dodecanol[b]	0.87
Stearyl alcohol[c]	0.95
Oleyl alcohol[c]	0.96
Linoleyl alcohol[c]	0.99
Octyldodecanol[d]	1.00
2-Octyl-1-tetradecanol or 2-decyl-1-dodecanol[b]	1.17
Any other unspecified related fatty alcohol or impurity	—

[a] Alkane.

[b] Related branched chain fatty alcohol.

[c] Related linear chain fatty alcohol.

[d] Sample.

Suitability requirements

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

Analysis

Samples: *System suitability solution* and *Sample solution*

Identify *n*-nonadecane, 9-methyl nonadecane, and each of the linear chain fatty alcohols and branched chain fatty alcohols in the *Sample solution* according to *Table 3*.

Calculate the percentage of *n*-nonadecane (9-methyl nonadecane, each of the linear chain fatty alcohols and branched chain fatty alcohols, or any other unspecified related fatty alcohol or impurity) in the portion of Octyldodecanol taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of *n*-nonadecane (9-methyl nonadecane, each of the linear chain fatty alcohols and branched chain fatty alcohols, or any other unspecified related fatty alcohol or impurity) from the *Sample solution*

r_T = sum of all the peak responses, excluding peak responses due to solvent, from the *Sample solution*

Acceptance criteria: Disregard any unspecified peaks that are less than 0.05%, and any peaks due to solvent.

Sum of unspecified related fatty alcohols and impurities: NMT 1%

Sum of *n*-nonadecane, 9-methyl nonadecane, 2-octyl-1-decanol, 2-hexyl-1-dodecanol, 2-octyl-1-tetradecanol, and 2-decyl-1-dodecanol: NMT 1.5%

- **Organic Impurity Test 2: Limit of Branched Chain Fatty Alcohols and Branched Chain Aldehyde**

System suitability solution: Prepare 1 mg/mL each of USP Stearyl Alcohol RS, USP Oleyl Alcohol RS, USP Linoleyl Alcohol RS, and USP Octyldodecanol RS in ethanol, 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. Dilute the solution with ethanol to obtain a solution containing 0.05 mg/mL each of USP Stearyl Alcohol RS, USP Oleyl Alcohol RS, USP Linoleyl Alcohol RS, and USP Octyldodecanol RS.

Sample solution: 1 mg/mL of Octyldodecanol in ethanol

Chromatographic system: Proceed as directed in the *Assay*, except use split injection with a split ratio of 5:1 and run time of 30 min.

System suitability

Samples: *System suitability solution* and *Sample solution*

[Note—See *Table 4* for the relative retention times for branched chain fatty alcohols and branched chain aldehyde.]

Table 4

Component	Relative Retention Time
2-Octyl-1-decanol or 2-hexyl-1-dodecanol[a]	0.87
2-Octyldodecanal[b]	0.93
Stearyl alcohol[c]	0.95
Oleyl alcohol[c]	0.96
Linoleyl alcohol[c]	0.99
Octyldodecanol[d]	1.00
2-Octyl-1-tetradecanol or 2-decyl-1-dodecanol[a]	1.17
Any other unspecified fatty alcohol or impurity	—

[a] Related branched chain fatty alcohol.

[b] Branched aldehyde.

[c] Related linear chain fatty alcohol.

[d] Sample.

Suitability requirements

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

Analysis

Samples: *System suitability solution* and *Sample solution*

Identify each branched chain fatty alcohol peak and branched chain aldehyde peak in the *Sample solution* according to *Table 4*.

Calculate the percentage of each branched chain fatty alcohol (2-octyl-1-decanol, 2-hexyl-1-dodecanol, 2-octyl-1-tetradecanol, or 2-decyl-1-dodecanol), branched chain aldehyde (2-octyldodecanal), or any unspecified fatty alcohol or impurity in the portion of Octyldodecanol taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of each branched chain fatty alcohol (2-octyl-1-decanol, 2-hexyl-1-dodecanol, 2-octyl-1-tetradecanol, or 2-decyl-1-dodecanol), branched chain aldehyde (2-octyldodecanal), or any unspecified fatty alcohol or impurity from the *Sample solution*

r_T = sum of all the peak responses, excluding peak responses due to solvent, from the *Sample solution*

Acceptance criteria: Disregard any unspecified peaks that are less than 0.05%, and any peaks due to solvent.

Sum of unspecified fatty alcohols and impurities: NMT 5%

Branched chain fatty alcohols (2-octyl-1-decanol, 2-hexyl-1-dodecanol, 2-octyl-1-tetradecanol, and 2-decyl-1-dodecanol): NMT 5%

Branched chain aldehyde (2-octyldodecanal): NMT 2%

SPECIFIC TESTS

• **Fats and Fixed Oils** ⟨401⟩, *Procedures, Acid Value*: NMT 0.5

• **Fats and Fixed Oils** ⟨401⟩, *Procedures, Iodine Value*: NMT 8

• **Fats and Fixed Oils** ⟨401⟩, *Procedures, Peroxide Value*: NMT 5.0

• **Water Determination** ⟨921⟩, *Method I*: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **Labeling:** If a test for *Impurities* other than *Organic Impurity Test 1* is used, the labeling states the test with which the article complies. Label it to indicate whether it is derived from vegetable, animal, or synthetic sources.

• **USP Reference Standards** ⟨11⟩

USP Cetyl Alcohol RS
USP Linoleyl Alcohol RS
USP Octyldodecanol RS
USP Oleyl Alcohol RS
USP Stearyl Alcohol RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
OCTYLDODECANOL	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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