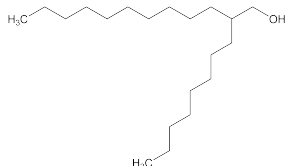


Octyldodecanol



C₂₀H₄₂O 298.55
 1-Dodecanol, 2-octyl-;
 2-Octyldodecan-1-ol;
 2-Octyldodecanol;
 2-Octyldodecyl alcohol [5333-42-6].

DEFINITION

Octyldodecanol contains NLT 90.0% and NMT 102.0% of 2-octyldodecanol, 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 2-octyldodecanol peak of the *Standard solution*.

ASSAY

Change to read:

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*. (IRA 1-Jan-2017)

Sample solution: Prepare 1.0 mg/mL of Octyldodecanol in *Internal standard solution*. (IRA 1-Jan-2017)

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
2-Octyldodecanol	1.32

Suitability requirements

Resolution: NLT 10 (IRA 1-Jan-2017) 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 2-octyldodecanol and 1-pentadecanol peaks, *Standard solution*

Relative standard deviation: NMT 1%, using the area ratio of 2-octyldodecanol to 1-pentadecanol, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*
 Calculate the percentage of 2-octyldodecanol (C₂₀H₄₂O) 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 2-octyldodecanol to the internal standard (peak response of 2-octyldodecanol/peak response of the internal standard) from the *Sample solution*

R_S = peak response ratio of 2-octyldodecanol to the internal standard (peak response of 2-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% of 2-octyldodecanol

IMPURITIES

Add the following:

• [NOTE—On the basis of the manufacturing route, perform either *Organic Impurity Test 1* or *Organic Impurity Test 2*.] (IRA 1-Jan-2017)

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

Change to read:

• **ORGANIC IMPURITY TEST 1:** (IRA 1-Jan-2017) **LIMIT OF RELATED FATTY ALCOHOLS AND ALKANES:** (IRA 1-Jan-2017)

2 Octyldodecanol

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. • (IRA 1-Jan-2017)

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 • (IRA 1-Jan-2017)

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

• Table 3

Component	Relative Retention Time
<i>n</i> -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.

• (IRA 1-Jan-2017)

Suitability requirements

Resolution: NLT 2.0 between the stearyl alcohol and oleyl alcohol peaks; NLT 2.0 between the linoleyl alcohol and 2-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 • (IRA 1-Jan-2017)

Acceptance criteria: Disregard • any unspecified peaks that are less than 0.05%, • (IRA 1-Jan-2017) and any peaks due to solvent.

Sum of unspecified • related fatty alcohols and impurities: • (IRA 1-Jan-2017) 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% • (IRA 1-Jan-2017)

Add the following:

• 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% (IRA 1-Jan-2017)

SPECIFIC TESTS

- **FATS AND FIXED OILS** <401>, *Acid Value:* NMT 0.5
- **FATS AND FIXED OILS** <401>, *Hydroxyl Value:* 175–190
- **FATS AND FIXED OILS** <401>, *Iodine Value:* NMT 8
- **FATS AND FIXED OILS** <401>, *Peroxide Value:* NMT 5.0
- **WATER DETERMINATION** <921>, *Method I:* NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.

Change to read:

- **LABELING:** If a test for *Impurities* other than *Organic Impurity Test 1* is used, the labeling states the test with which

the article complies. (IRA 1-Jan-2017) Label it to indicate whether it is derived from vegetable, animal, or synthetic sources.

Change to read:

• USP REFERENCE STANDARDS <11>

- (IRA 1-Jan-2017)
 - USP Cetyl Alcohol RS
 - USP Linoleyl Alcohol RS
 - USP Octyldodecanol RS
 - USP Oleyl Alcohol RS
 - USP Stearyl Alcohol RS