Interim Revision Announcement
Official: November 1, 2020

Cetyl Alcohol

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$C_{16}H_{34}O$ 242.44
1-Hexadecanol [36653-82-4].

DEFINITION

Cetyl Alcohol contains NLT 90.0% and NMT 102.0% of cetyl alcohol ($C_{16}H_{34}O$), the remainder consisting chiefly of related alcohols. It is obtained from sources of vegetable, animal, or synthetic origin.

IDENTIFICATION

- **A. Chromatographic Identity**

System suitability solution, Sample solution, and 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 cetyl 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: Prepare 1.0 mg/mL of USP Cetyl Alcohol RS in *Internal standard solution*, and heat the solution in a sealed container in a 50° water bath until cetyl alcohol is dissolved. Allow the solution to cool to room temperature, and mix well.

Sample solution: Prepare 1.0 mg/mL of Cetyl Alcohol in *Internal standard solution*, and heat the solution in a sealed container in a 50° water bath until cetyl 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

Injection port: 270°

Detector: 280°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)

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

Name	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 cetyl alcohol and 1-pentadecanol peaks, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cetyl alcohol ($C_{16}H_{34}O$) in the portion of Cetyl Alcohol taken:

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

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

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

C_S = concentration of USP Cetyl Alcohol RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–102.0%

IMPURITIES

- **Residue on Ignition** ⟨281⟩**:** NMT 0.1%, determined on 2 g

Change to read:

▲[Note—On the basis of the manufacturing route, perform either *Organic Impurity Test 1* (vegetable or animal sources) or *Organic Impurity Test 2* (synthetic sources).]▲ (IRA 1-Nov-2020)

Change to read:

- **▲Organic Impurity Test 1:▲ (IRA 1-Nov-2020) Limit of Related Fatty Alcohols**

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

Resolution solution: Prepare 1 mg/mL of USP Lauryl Alcohol RS, 1 mg/mL of USP Myristyl Alcohol RS, 1 mg/mL of USP Cetyl Alcohol RS, 1 mg/mL of USP Stearyl Alcohol RS, and 1 mg/mL of USP Oleyl 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 have 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, and USP Oleyl Alcohol RS.

Sample solution: Prepare 1.0 mg/mL of Cetyl Alcohol in ethanol, and heat the solution in a sealed container in a 50° water bath until cetyl 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 split ratio.

Injection type: Split; split ratio, 5:1

System suitability

Sample: *Resolution solution*

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

Table 3

Name	Relative Retention Time
Lauryl alcohol▲[a]▲ (IRA 1-Nov-2020)	0.79
Myristyl alcohol▲[a]▲ (IRA 1-Nov-2020)	0.93
1-Pentadecanol▲[b]▲ (IRA 1-Nov-2020)	1.00
Cetyl alcohol▲[c]▲ (IRA 1-Nov-2020)	1.09
Stearyl alcohol▲[a]▲ (IRA 1-Nov-2020)	1.25
Oleyl alcohol▲[a]▲ (IRA 1-Nov-2020)	1.28

[a] Related linear chain fatty alcohol.

[b] Internal standard.

[c] Sample.

Suitability requirements

Resolution: NLT 15 between the myristyl alcohol and 1-pentadecanol peaks; NLT 30 between the cetyl alcohol and stearyl alcohol peaks; NLT 2.0 between the stearyl alcohol and oleyl alcohol peaks

Analysis

Samples: *Resolution solution* and *Sample solution*

Identify each related fatty alcohol peak in the *Sample solution* based on those in the *Resolution solution*.

Calculate the percentage of each related fatty alcohol or ▲any unidentified▲ (IRA 1-Nov-2020) impurity in the portion of Cetyl Alcohol taken:

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

r_U = peak response of each related fatty alcohol (or any ▲unidentified▲ (IRA 1-Nov-2020) 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 peaks that are less than 0.05% for any ▲unidentified▲ (IRA 1-Nov-2020) impurities and any peaks due to solvent.

Sum of ▲unidentified▲ (IRA 1-Nov-2020) impurities: NMT 1%

Sum of related fatty alcohols and ▲unidentified▲ (IRA 1-Nov-2020) impurities: NMT 10.0%

Add the following:

▲● Organic Impurity Test 2: Limit of Branched-Chain Fatty Alcohols, Related Linear Fatty Alcohols, and Related Unsaturated Alcohols and Alkanes

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, and USP Oleyl 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 have 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, and USP Oleyl Alcohol RS.

Sample solution: Prepare 1.0 mg/mL of Cetyl Alcohol in ethanol, and heat the solution in a sealed container in a 50° water bath until cetyl 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 split ratio.

Injection type: Split, split ratio, 5:1

System suitability

Sample: *Resolution solution*

[Note—See *Table 4* for the relative retention times.]

Table 4

Name	Relative Retention Time
n-Octadecane[a]	0.77
Lauryl alcohol[b]	0.79
n-Nonadecane[a]	0.84
Branched eicosanes[a]	0.86–0.88
n-Eicosane[a]	0.91
Myristyl alcohol[b]	0.93

Name	Relative Retention Time
4-Hexadecanol or 5-Hexadecanol[c]	0.96
3-Hexadecanol[c]	0.97
2-Hexyl-1-decanol or 2-Butyl-1-dodecanol[d]	0.99
1-Pentadecanol[e]	1.00
Unsaturated hexadecanol (1)[f]	1.01
Unsaturated hexadecanol (2)[f]	1.02
2-Ethyl-1-tetradecanol[d]	1.02
Unsaturated hexadecanol (3)[f]	1.03
Heptadecanol[c]	1.04
Unsaturated hexadecanol (4)[f]	1.05
2-Heptadecanol[c]	1.06
Octadecanol[c]	1.07
Cetyl alcohol[g]	1.09
Stearyl alcohol[b]	1.25
Oleyl alcohol[b]	1.28

[a] Alkane.

[b] Related linear chain fatty alcohol.

[c] Linear secondary fatty alcohols.

[d] Related branched-chain fatty alcohol.

[e] Internal standard.

[f] Related unsaturated alcohol.

[g] Sample.

Suitability requirements

Resolution: NLT 15 between the myristyl alcohol and 1-pentadecanol peaks; NLT 30 between the cetyl alcohol and stearyl alcohol peaks; NLT 2.0 between the stearyl alcohol and oleyl alcohol peaks

Analysis

Samples: *Resolution solution* and *Sample solution*

Identify each related fatty alcohol, alkane, and unsaturated alcohol peak in the *Sample solution* based on those in the *Resolution solution*.

Calculate the percentage of each related fatty alcohol, alkane, unsaturated alcohol, or any other unidentified related fatty alcohol or impurity in the portion of Cetyl Alcohol taken:

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

r_U = peak response of each related fatty alcohol, alkane, and unsaturated alcohol (or any unidentified 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 peaks that are less than 0.05% for any unidentified impurities and any peaks due to solvent.

Branched primary and linear secondary fatty alcohols (2-hexyl-1-decanol, 2-butyl-1-dodecanol, 2-ethyl-1-tetradecanol, 3-hexadecanol, 4-hexadecanol or 5-hexadecanol, heptadecanol, 2-heptadecanol, octadecanol): NMT 5.0%

Related linear fatty alcohols (lauryl alcohol, myristyl alcohol, stearyl alcohol, oleyl alcohol): NMT 1.0%

Related alkanes (octadecane, nonadecane, eicosane, branched eicosanes): NMT 1.0%

Related unsaturated alcohols: NMT 1.0%

Sum of unidentified impurities: NMT 1.5%

Sum of related fatty alcohols, alkanes, and unidentified impurities: NMT 10.0% ▲ (IRA 1-Nov-2020)

SPECIFIC TESTS

- **Fats and Fixed Oils** ⟨401⟩, *Procedures, Acid Value*: NMT 2
- **Fats and Fixed Oils** ⟨401⟩, *Procedures, Hydroxyl Value*: 218–238
- **Fats and Fixed Oils** ⟨401⟩, *Procedures, Iodine Value*: NMT 5

Change to read:

- **Water Determination** ⟨921⟩, *Method I,* ▲*Method Ia*: ▲ (IRA 1-Nov-2020) NMT 0.5%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed 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-Nov-2020) Label it to indicate whether it is derived from vegetable, animal, or synthetic sources.

- **USP Reference Standards** ⟨11⟩

USP Cetyl Alcohol RS
USP Lauryl Alcohol RS
USP Myristyl Alcohol RS
USP Oleyl Alcohol RS
USP Stearyl Alcohol RS

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