Interim Revision Announcement
Official: November 1, 2020

Stearyl Alcohol

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$C_{18}H_{38}O$ 270.49
1-Octadecanol;
Octadecan-1-ol [112-92-5].

DEFINITION

Stearyl Alcohol contains NLT 90.0% and NMT 102.0% of stearyl alcohol ($C_{18}H_{38}O$), 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 stearyl alcohol peak of the *System suitability solution*.

Change to read:

ASSAY

▲[Note—If 1-pentadecanol is one of the related alcohols in stearyl alcohol derived from animal sources, the *Assay* and *Organic Impurity Test 1, Limit of Related Fatty Alcohols* are not suitable.]▲ (IRA 1-Nov-2020)

- **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*. 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 Stearyl Alcohol RS in *Internal standard solution*, and heat the solution in a sealed container in a 50° water bath until stearyl alcohol is dissolved. Allow the solution to cool to room temperature, and mix well.

Sample solution: Prepare 1.0 mg/mL of Stearyl Alcohol in *Internal standard solution*. Heat the solution in a sealed container in a 50° water bath until stearyl 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

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, 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	1.09
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 and oleyl alcohol peaks, *System suitability solution*

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

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of stearyl alcohol ($C_{18}H_{38}O$) in the portion of Stearyl Alcohol taken:

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

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

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

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

C_U = concentration of Stearyl 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 each of USP Lauryl Alcohol RS, USP Myristyl Alcohol RS, USP Cetyl Alcohol RS, USP Stearyl Alcohol RS, USP Oleyl Alcohol RS, USP Linolenyl Alcohol RS, and USP Arachidyl 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 obtain 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, USP Oleyl Alcohol RS, USP Linolenyl Alcohol RS, and USP Arachidyl Alcohol RS.

Sample solution: 1 mg/mL of Stearyl Alcohol in ethanol. Heat the solution in a sealed container in a 50° water bath until stearyl 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

Component	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▲[a]▲ (IRA 1-Nov-2020)	1.09
Stearyl alcohol▲[c]▲ (IRA 1-Nov-2020)	1.25
Oleyl alcohol▲[a]▲ (IRA 1-Nov-2020)	1.28
Linolenyl alcohol▲[a]▲ (IRA 1-Nov-2020)	1.36
Arachidyl alcohol▲[a]▲ (IRA 1-Nov-2020)	1.44

[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 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 Stearyl 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, USP Oleyl Alcohol RS, USP Linolenyl Alcohol RS, and USP Arachidyl 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 obtain 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, USP Oleyl Alcohol RS, USP Linolenyl Alcohol RS, and USP Arachidyl Alcohol RS.

Sample solution: 1 mg/mL of Stearyl Alcohol in ethanol. Heat the solution in a sealed container in a 50° water bath until stearyl 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

Component	Relative Retention Time
n-Octadecane[a]	0.77
Lauryl alcohol[b]	0.79
n-Nonadecane[a]	0.84
n-Eicosane[a]	0.92

Component	Relative Retention Time
Myristyl alcohol[b]	0.93
n-Heneicosane[a]	0.98
1-Pentadecanol[c]	1.00
Branched docosanes[a]	1.00–1.03
n-Docosane[a]	1.05
Cetyl alcohol[b]	1.09
4-Octadecanol or 5-Octadecanol[d]	1.12
3-Octadecanol[d]	1.14
2-Hexyl-1-dodecanol or 2-Octyl-1-decanol[e]	1.15
2-Butyl-1-tetradecanol[e]	1.16
Unsaturated octadecanols[f]	1.17–1.19
2-Ethyl-1-hexadecanol[e]	1.19
Nonadecanol[d]	1.20
Eicosanol[d]	1.22
Stearyl alcohol[g]	1.25
Oleyl alcohol[b]	1.28
Linolenyl alcohol[b]	1.36
Arachidyl alcohol[b]	1.44

[a] Alkane.

[b] Related linear chain fatty alcohol.

[c] Internal standard.

[d] Linear secondary fatty alcohol.

[e] Related branched-chain fatty alcohol.

[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 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, or any unidentified impurity in the portion of Stearyl Alcohol taken:

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

r_U = peak response of each related fatty alcohol and alkane (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-dodecanol, 2-octyl-1-decanol, 2-butyl-1-tetradecanol, 2-ethyl-1-hexadecanol, 4-octadecanol or **5-octadecanol, 3-octadecanol, nonadecanol, eicosanol):** NMT 5.0%

Related linear fatty alcohols (lauryl alcohol, myristyl alcohol, cetyl alcohol, oleyl alcohol, linoleyl alcohol, arachidyl alcohol): NMT 1.0%

Related alkanes (octadecane, nonadecane, eicosane, heneicosane, docosane, branched docosanes): NMT 2.0%

Related unsaturated alcohols: NMT 1.0%

Sum of unidentified impurities: NMT 2.0%

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*: 195–220
- **Fats and Fixed Oils** ⟨401⟩, *Procedures, Iodine Value*: NMT 2

Change to read:

- **Water Determination** ⟨921⟩, *Method I,* ▲*Method Ia*:▲ (IRA 1-Nov-2020) NMT 0.5%, ▲using titrant: hydranal-composite 2 and solvent: hydranal-lipoSolver MH▲ (IRA 1-Nov-2020)

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

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