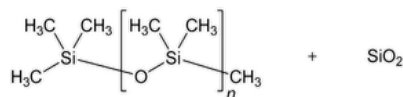


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Simethicone



Simethicone;
 α -(Trimethylsilyl)- ω -methylpoly[oxy(dimethylsilylene)], mixture with silicon dioxide
CAS RN[®]: 8050-81-5.

DEFINITION

Simethicone is a mixture of fully methylated linear siloxane polymers containing repeating units of the formula $[-(\text{CH}_3)_2\text{SiO}-]_n$, stabilized with trimethylsiloxy end-blocking units of the formula $[-(\text{CH}_3)_3\text{SiO}-]$, and silicon dioxide. It contains NLT 90.5% and NMT 99.0% of polydimethylsiloxane ($[-(\text{CH}_3)_2\text{SiO}-]_n$), and NLT 4.0% and NMT 7.0% of silicon dioxide.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197F.](#) ▲ (CN 1-MAY-2020) Meets the requirements

ASSAY

PROCEDURE

Standard stock solution: 2 mg/mL of [USP Polydimethylsiloxane RS](#) in toluene

Standard solution: Add 25.0 mL of *Standard stock solution* to a round, narrow-mouth, screw-capped, 120-mL bottle. Add 50 mL of dilute hydrochloric acid (2 in 5), close the bottle securely with a cap having an inert liner, and shake for 5 min, accurately timed, on a reciprocating shaker at a suitable rate (e.g., about 200 oscillations/min and a stroke of 38 ± 2 mm). Transfer the mixture to a 125-mL separator, and remove 5 mL of the upper organic (toluene) layer to a 15-mL, screw-capped test tube containing 0.5 g of anhydrous sodium sulfate. Close the tube with a screw-cap having an inert liner, agitate vigorously, and centrifuge the mixture until a clear supernatant is obtained.

Sample stock solution: Add 50 mg of Simethicone to a round, narrow-mouth, screw-capped, 120-mL bottle. Add 25.0 mL of toluene, and swirl to disperse.

Sample solution: Using the *Sample stock solution*, proceed as directed in the *Standard solution*, beginning with "Add 50 mL of dilute hydrochloric acid (2 in 5)".

Blank: Add 25 mL of toluene to a round, narrow-mouth, screw-capped, 120-mL bottle. Proceed as directed in the *Standard solution*, beginning with "Add 50 mL of dilute hydrochloric acid (2 in 5)".

Instrumental conditions

Mode: IR

Analytical wavelength: Wavelength of maximum absorbance at about $7.9 \mu\text{m}$

Cell: 0.5 mm

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the absorbance of the *Samples*, using the *Blank* to set the instrument.

Calculate the percentage of polydimethylsiloxane $[-(\text{CH}_3)_2\text{SiO}-]_n$ in the portion of Simethicone taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_s = concentration of [USP Polydimethylsiloxane RS](#) in the *Standard stock solution* (mg/mL)

C_u = concentration of Simethicone in the *Sample stock solution* (mg/mL)

Acceptance criteria: 90.5%–99.0%

OTHER COMPONENTS

• CONTENT OF SILICON DIOXIDE

Standard solution: Transfer 3.00 g of [USP Simethicone RS](#) to a screw-capped bottle, add 10.0 mL of *n*-hexane, and mix by shaking.

Sample solution: Transfer 3.00 g of Simethicone to a screw-capped bottle, add 10.0 mL of *n*-hexane, and mix by shaking.

Dimethicone solution: Transfer 3.00 g of dimethicone having a viscosity of 500 centistokes to a screw-capped bottle, add 10.0 mL of *n*-hexane, and mix by shaking.

Instrumental conditions

Mode: IR

Analytical wavelength: 7–9 μm

Cell: 0.1 mm

Blank: *n*-Hexane

Analysis

Samples: *Standard solution*, *Sample solution*, and *Dimethicone solution*

Record the absorbance spectra of the *Samples* between 7 and 9 μm . Determine the absorbances of the *Samples* at the wavelength of minimum absorbance at about 8.2 μm , observed in the spectrum obtained from the *Dimethicone solution*.

Calculate the percentage of silicon dioxide in the portion of Simethicone taken:

$$\text{Result} = [(A_u - A_d)/(A_s - A_d)] \times C$$

A_u = absorbance of the *Sample solution*

A_d = absorbance of the *Dimethicone solution*

A_s = absorbance of the *Standard solution*

C = designated percentage of silicon dioxide in [USP Simethicone RS](#)

Acceptance criteria: 4.0%–7.0%

SPECIFIC TESTS

• LOSS ON HEATING

Sample: 15 g

Analysis: Heat the *Sample* in an open, tared vessel having a diameter of 5.5 ± 0.5 cm and a wall height of 2.5 ± 1.0 cm at 200° in a circulating air oven for 4 h, and allow to come to room temperature in a desiccator before weighing.

Acceptance criteria: NMT 18.0%

• DEFOAMING ACTIVITY

Foaming solution: 1 g of octoxynol 9 in 100 mL of water

Sample solution: Transfer 200 mg of Simethicone to a 60-mL bottle, add 50 mL of tertiary butyl alcohol, cap the bottle, and shake vigorously. Warm slightly, if necessary, to dissolve.

Analysis

Samples: *Foaming solution* and *Sample solution*

For each test use a clean, unused, 250-mL glass jar. Add, dropwise, 500 μL of the *Sample solution* to the 250-mL glass jar, fitted with a 50-mm cap, containing 100 mL of the *Foaming solution*. Cap the jar, and clamp it in an upright position on a wrist-action shaker. Using a radius of 13.3 ± 0.4 cm (measured from the center of the shaft to the center of the bottle), shake for 10 s through an arc of 10° at a frequency of 300 ± 30 strokes/min. Record the time required for the foam to collapse. The time, in s, for foam collapse is determined at the instant the first portion of foam-free liquid surface appears, measured from the end of the shaking period.

Acceptance criteria: The defoaming activity time does not exceed 15 s.

ADDITIONAL REQUIREMENTS

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

• **USP REFERENCE STANDARDS (11).**

[USP Polydimethylsiloxane RS](#)

[USP Simethicone RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
SIMETHICONE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

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