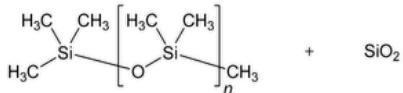


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## Simethicone



Simethicone;  
 $\alpha$ -(Trimethylsilyl)- $\omega$ -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  $38 \pm 2$  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 Polymethylsiloxane 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  $\mu$ m

**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  $\mu$ m. Determine the absorbances of the *Samples* at the wavelength of minimum absorbance at about 8.2  $\mu$ m, 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  $5.5 \pm 0.5$  cm and a wall height of  $2.5 \pm 1.0$  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  $\mu$ L 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  $13.3 \pm 0.4$  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  $300 \pm 30$  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 Polymethylsiloxane RS](#)

[USP Simethicone RS](#)

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

Topic/Question	Contact	Expert Committee
SIMETHICONE	<a href="#">Documentary Standards Support</a>	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM32020 Small Molecules 3

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