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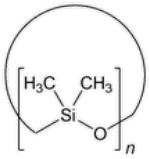
Cyclomethicone



$(C_2H_6OSi)_n$
Cyclopolydimethylsiloxane;
Cyclic polydimethylsiloxanes;
Cyclodimethicone
CAS RN®: 69430-24-6.

DEFINITION

Cyclomethicone is a fully methylated cyclic siloxane containing repeating units of $[-(CH_3)_2SiO-]_n$, in which *n* is 4, 5, 6, or a mixture of them. It contains NLT 98.0% of $(C_2H_6OSi)_n$, calculated as the sum of cyclomethicone 4, cyclomethicone 5, and cyclomethicone 6, and NLT 95.0% and NMT 105.0% of the labeled amount of any one or more of the individual cyclomethicone components.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197S**▲ (CN 1-May-2020)

Sample: Use neat liquids.

Acceptance criteria: The IR absorption spectrum exhibits maxima only at the same wavelengths as that of a similar preparation of USP Cyclomethicone 4 RS, USP Cyclomethicone 5 RS, or USP Cyclomethicone 6 RS.

ASSAY

• **Procedure**

Standard solution A: USP Cyclomethicone 4 RS (neat)
Standard solution B: USP Cyclomethicone 5 RS (neat)
Standard solution C: USP Cyclomethicone 6 RS (neat)
Sample solution: Cyclomethicone (neat)
Chromatographic system
(See *Chromatography ⟨621⟩, System Suitability*.)
Mode: GC
Detector: Flame ionization
Column: 0.32-mm × 60-m fused silica; coated with a 1.0-µm film of phase G1
Temperatures
Injection port: 250°
Detector: 300°
Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
60	—	60	5
60	10	200	15
200	5	225	5

Carrier gas: Helium

Flow rate: 1 mL/min

Injection volume: 1 µL

Injection type: Split ratio 1:20

System suitability

Samples: *Standard solution A*, *Standard solution B*, and *Standard solution C*

[NOTE—See *Table 2*.]

Table 2

Name	Relative Retention Time
Cyclomethicone 4	0.9
Cyclomethicone 5	1.0
Cyclomethicone 6	1.2

Suitability requirements

Relative standard deviation: NMT 2.0% for cyclomethicone 4, *Standard solution A*; NMT 2.0% for cyclomethicone 5, *Standard solution B*; NMT 2.0% for cyclomethicone 6, *Standard solution C*

Calculate the percentage of cyclomethicone 4, cyclomethicone 5, and cyclomethicone 6 by dividing 100 times the response of each peak at the retention time of the corresponding reference standard by the sum of all of the responses in the chromatogram. The percentages obtained from duplicate injections agree to within 1.0%.

Analysis

Samples: *Standard solution A, Standard solution B, Standard solution C,* and *Sample solution*

Calculate the percentage of cyclomethicone 4 (cyclomethicone 5 or cyclomethicone 6) in the portion of Cyclomethicone taken:

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

r_U = peak response of cyclomethicone 4 (cyclomethicone 5 or cyclomethicone 6)

r_T = sum of all the peak responses

Calculate the percentage purity by adding the percentages of cyclomethicone 4, cyclomethicone 5, and cyclomethicone 6.

Acceptance criteria

Sum of cyclomethicone 4, cyclomethicone 5, and cyclomethicone 6: NLT 98.0% of $(C_2H_6OSi)_n$

Labeled amount: 95.0%–105.0% of the labeled amount of any one or more of the individual cyclomethicone components

IMPURITIES

• **LIMIT OF NONVOLATILE RESIDUE**

Sample: 2.0 g

Analysis: Transfer the *Sample* into an open, tared aluminum dish, and evaporate in a circulating air oven at 150° for 2 h. Allow to cool in a desiccator, and weigh.

Acceptance criteria: NMT 3.0 mg, corresponding to NMT 0.15% (w/w)

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers. Avoid exposure to excessive heat.

• **Labeling:** Label it to state, as part of the official title, the *n*-value of the Cyclomethicone. Where it is a mixture of two or three such cyclic siloxanes, the label states the *n*-value and percentage of each in the mixture.

• **USP Reference Standards** ⟨11⟩
USP Cyclomethicone 4 RS
USP Cyclomethicone 5 RS
USP Cyclomethicone 6 RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CYCLOMETHICONE	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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