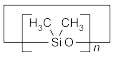
• **USP REFERENCE STANDARDS** ⟨11⟩
USP Alpha Cyclodextrin RS
USP Beta Cyclodextrin RS
USP Dextrose RS
USP Gamma Cyclodextrin RS

Cyclomethicone



$(C_2H_6OSi)_n$
Cyclopolydimethylsiloxane.
Cyclomethicone [69430-24-6].

» Cyclomethicone is a fully methylated cyclic siloxane containing repeating units of the formula:

$$[-(CH_3)_2SiO-]_n$$

in which *n* is 4, 5, or 6, or a mixture of them. It contains not less than 98.0 percent of $(C_2H_6OSi)_n$, calculated as the sum of cyclomethicone 4, cyclomethicone 5, and cyclomethicone 6, and not less than 95.0 percent and not more than 105.0 percent of the labeled amount of any one or more of the individual cyclomethicone components.

Packaging and storage—Preserve in tight containers.

Labeling—Label it to state, as part of the official title, the *n*-value of the Cyclomethicone. Where it is a mixture of 2 or 3 such cyclic siloxanes, the label states the *n*-value and percentage of each in the mixture.

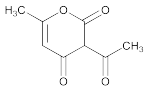
USP Reference standards ⟨11⟩**—**
USP Cyclomethicone 4 RS
USP Cyclomethicone 5 RS
USP Cyclomethicone 6 RS

Identification—Proceed as directed under ⟨197S⟩, except to use neat liquids. The IR absorption spectrum, determined in a 0.1-mm cell, 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.

Limit of nonvolatile residue—Evaporate 2.0 g in an open, tared aluminum dish in a circulating air oven at 150° for 2 hours, allow to cool in a desiccator, and weigh: the weight of the residue so obtained does not exceed 3.0 mg, corresponding to not more than 0.15% (w/w).

Assay—The gas chromatograph is equipped with a thermal conductivity detector and a suitable recorder, and contains a 3.66-m × 3-mm column packed with 20% liquid phase G1 on 60- to 80-mesh packing S1A (see *Gas Chromatography* under *Chromatography* ⟨621⟩). The column is temperature-programmed at a rate of about 8° per minute from 125° to 320°, the injection port is maintained at a temperature of about 300°, and the detector block is maintained at a temperature of about 350°. Helium is used as the carrier gas, flowing at a rate of about 20 mL per minute. Separately inject about 1 µL of USP Cyclomethicone 4 RS, USP Cyclomethicone 5 RS, and USP Cyclomethicone 6 RS into the gas chromatograph, record the chromatograms, and note the retention times of the peaks. Similarly inject about 1 µL of Cyclomethicone, record the chromatogram, and measure the responses of the major peaks. 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%. Calculate the percentage purity by adding the percentages of cyclomethicone 4, cyclomethicone 5, and cyclomethicone 6.

Dehydroacetic Acid



$C_8H_8O_4$ 168.15
Keto form: 2*H*-Pyran-2,4(3*H*)-dione, 3-acetyl-6-methyl-.
3-Acetyl-6-methyl-2*H*-pyran-2,4(3*H*)-dione [520-45-6].
Enol form: 2*H*-Pyran-2-one, 3-acetyl-4-hydroxy-6-methyl-.
3-Acetyl-4-hydroxy-6-methyl-2*H*-pyran-2-one [771-03-9].

» Dehydroacetic Acid contains not less than 98.0 percent and not more than 100.5 percent of $C_8H_8O_4$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers. No storage requirements specified.

USP Reference standards ⟨11⟩**—**
USP Dehydroacetic Acid RS

Identification, *Infrared Absorption* ⟨197K⟩.

Heavy metals, *Method II* ⟨231⟩**:** not more than 0.001%.

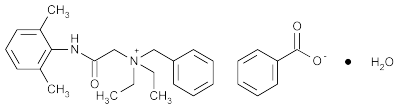
Loss on drying ⟨731⟩**:** Dry it at 80° for 4 hours: it loses not more than 1.0% of its weight.

Melting range, *Class I* ⟨741⟩**:** between 109° and 111°.

Residue on ignition ⟨281⟩: not more than 0.1%.

Assay—Transfer about 500 mg of Dehydroacetic Acid, accurately weighed, into a 250-mL conical flask, dissolve it in 75 mL of neutralized alcohol, add phenolphthalein TS, and titrate with 0.1 N sodium hydroxide VS to a pink endpoint that persists for not less than 30 seconds. Each mL of 0.1 N sodium hydroxide is equivalent to 16.82 mg of $C_8H_8O_4$.

Denatonium Benzoate



$C_{28}H_{34}N_2O_3 \cdot H_2O$ 464.60
Benzenemethanaminium, *N*-[2-[(2,6-dimethylphenyl)amino]-2-oxoethyl]-*N*,*N*-diethyl-, benzoate, monohydrate.
Benzyldiethyl[(2,6-xylylcarbamoyl)methyl]ammonium benzoate monohydrate [86398-53-0].
Anhydrous 446.59 [3734-33-6].

» Denatonium Benzoate, dried at 105° for 2 hours, contains one molecule of water of hydration or is anhydrous. When dried at 105° for 2 hours, it contains not less than 99.5 percent and not more than 101.0 percent of $C_{28}H_{34}N_2O_3$.

Packaging and storage—Preserve in tight containers.

Labeling—Label it to indicate whether it is hydrous or anhydrous.

USP Reference standards ⟨11⟩**—**
USP Denatonium Benzoate RS