

- **LABELING:** Label it to state whether it is silica gel or precipitated silica.

Colloidal Silicon Dioxide

SiO ₂	60.08
Silica [7631-86-9].	

DEFINITION

Colloidal Silicon Dioxide is a submicroscopic fumed silica prepared by the vapor-phase hydrolysis of a silicon compound. When ignited at 1000° for 2 h, it contains NLT 99.0% and NMT 100.5% of SiO₂.

IDENTIFICATION

- **A. PROCEDURE**

Analysis: Transfer 5 mg to a platinum crucible, and mix with 200 mg of anhydrous potassium carbonate. Ignite at a red heat over a burner for 10 min, and cool. Dissolve the melt in 2 mL of freshly distilled water, warming if necessary, and slowly add 2 mL of ammonium molybdate TS to the solution.

Acceptance criteria: A deep yellow color is produced.

- **B. PROCEDURE**

[NOTE—Avoid contact with o-tolidine when performing this test, and conduct the test in a well-ventilated hood.]

Analysis: Place 1 drop of the yellow silicomolybdate solution from *Identification* test A on a filter paper, and evaporate the solvent. Add 1 drop of a saturated solution of o-tolidine in glacial acetic acid to reduce the silicomolybdate to molybdenum blue, and place the paper over ammonium hydroxide.

Acceptance criteria: A greenish blue spot is produced.

ASSAY

- **PROCEDURE**

Sample: 500 mg

Analysis: Ignite the *Sample* in a tared platinum crucible at 1000 ± 25° for 2 h, cool in a desiccator, and weigh. Add 3 drops of sulfuric acid, and add enough alcohol to just moisten the sample completely. Add 15 mL of hydrofluoric acid, and in a well-ventilated hood evaporate on a hot plate to dryness, using medium heat (95°–105°) and taking care that the sample does not spatter as dryness is approached. Heat the crucible to a red color with the aid of a Bunsen burner. Ignite the residue at 1000 ± 25° for 30 min, cool in a desiccator, and weigh. If a residue remains, repeat the *Analysis*, beginning with "Add 15 mL of hydrofluoric acid". The weight lost by the assay specimen, previously ignited at 1000 ± 25°, represents the weight of SiO₂ in the portion taken.

Acceptance criteria: 99.0%–100.5% on the previously ignited basis

IMPURITIES

Inorganic Impurities

- **Loss on Ignition** *(733)*: Ignite the portion of Colloidal Silicon Dioxide, retained from the test for *Loss on Drying*, at 1000 ± 25° to constant weight: the previously dried Colloidal Silicon Dioxide loses NMT 2.0% of its weight.

- **ARSENIC, Method 1** *(211)*

Sample solution: To 2.5 g add 50 mL of 3 N hydrochloric acid, and reflux for 30 min using a water condenser. Cool, filter with the aid of suction, and transfer the filtrate to a 100-mL volumetric flask. Wash the filter and flask with several portions of hot water, and add the washings to the flask. Cool, and dilute with water to volume.

Analysis: A 15.0-mL portion of *Sample solution*, to which 3 mL of hydrochloric acid has been added, meets the requirements of the test, the addition of the 7 N sulfuric acid being omitted.

Acceptance criteria: NMT 8 ppm

SPECIFIC TESTS

- **pH** *(791)*: 3.5–5.5, in a (1 in 25) dispersion
- **Loss on Drying** *(731)*: Dry in a tared platinum crucible at 105° for 2 h: it loses NMT 2.5% of its weight. Retain the dried specimen in the crucible for the test for *Loss on Ignition*.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

Simethicone—see *Simethicone General Monographs*

Simethicone Emulsion—see *Simethicone Emulsion General Monographs*

Soda Lime

» Soda Lime is a mixture of Calcium Hydroxide and Sodium or Potassium Hydroxide or both.

It may contain an indicator that is inert toward anesthetic gases such as Ether, Cyclopropane, and Nitrous Oxide, and that changes color when the Soda Lime no longer can absorb Carbon Dioxide.

Identification—

A: Place a granule of it on a piece of moistened red litmus paper: the paper turns blue immediately.

B: A solution in 6 N acetic acid responds to the tests for *Calcium* *(191)*. It also imparts a yellow color to a nonluminous flame that, when viewed through cobalt glass, may show a violet color.

Loss on drying *(731)*—Weigh accurately, in a tared weighing bottle, about 10 g, and dry at 105° for 2 hours: it loses between 12.0% and 19.0% of its weight.

Moisture absorption—Place about 10 g in a tared, 50-mL weighing bottle, having a diameter of 50 mm and a height of 30 mm, and weigh. Then place the bottle, with cover removed, for 24 hours in a closed container in which the atmosphere is maintained at 85% relative humidity by being in equilibrium with sulfuric acid having a specific gravity of 1.16. Weigh again: the increase in weight is not more than 7.5%.

Hardness—Screen 200 g on a mechanical sieve shaker (see *Particle Size Distribution Estimation by Analytical Sieving* *(786)*) having a frequency of oscillation of 285 ± 3 cycles per minute, for 3 minutes, to remove granules both coarser and finer than the labeled particle size. Proceed as directed in the test for *Hardness* under *Barium Hydroxide Lime*, beginning with "Weigh 50 g of the granules." The percentage of Soda Lime retained on the screen is not less than 75.0, and represents the hardness.

Carbon dioxide absorbency—Proceed as directed in the test for *Carbon dioxide absorbency* under *Barium Hydroxide Lime*. The increase in weight is not less than 19.0% of the weight of Soda Lime used for the test.

Other requirements—It meets the requirements for *Packaging and storage, Labeling, and Size of granules* under *Barium Hydroxide Lime*.