Magnesium Trisilicate

$2MgO \cdot 3SiO_2 \cdot xH_2O$(anhydrous) 260.86
Silicic acid ($H_4Si_3O_8$), magnesium salt (1:2), hydrate.
Magnesium silicate hydrate ($Mg_2Si_3O_8 \cdot xH_2O$) [39365-87-2].
Anhydrous [14987-04-3].

» Magnesium Trisilicate is a compound of Magnesium Oxide and silicon dioxide with varying proportions of water. It contains not less than 20.0 percent of magnesium oxide (MgO) and not less than 45.0 percent of silicon dioxide (SiO_2).

Packaging and storage—Preserve in well-closed containers.

Identification—

A: Mix about 500 mg with 10 mL of 3 N hydrochloric acid, filter, and neutralize the filtrate to litmus paper with 6 N ammonium hydroxide: the neutralized filtrate responds to the tests for *Magnesium* ⟨191⟩.

B: Prepare a bead by fusing a few crystals of sodium ammonium phosphate on a platinum loop in the flame of a Bunsen burner. Place the hot, transparent bead in contact with Magnesium Trisilicate, and again fuse: silica floats about in the bead, producing, upon cooling, an opaque bead with a web-like structure.

Water, *Method III* ⟨921⟩**—**Weigh accurately about 1 g in a tared platinum crucible provided with a cover. Gradually apply heat to the crucible at first, then strongly ignite to constant weight: it loses between 17.0% and 34.0% of its weight.

Soluble salts—Boil 10.0 g with 150 mL of water for 15 minutes. Cool to room temperature, allow the mixture to stand for 15 minutes, filter with the aid of suction, transfer the filtrate to a 200-mL volumetric flask, dilute with water to volume, and mix. Evaporate 50.0 mL of this solution, representing 2.5 g of the Trisilicate, in a tared platinum dish to dryness, and ignite gently to constant weight: the weight of the residue does not exceed 38.0 mg (1.5%).

Chloride ⟨221⟩**—**A 20-mL portion of the diluted filtrate prepared in the test for *Soluble salts*, representing 1 g of Magnesium Trisilicate, shows no more chloride than corresponds to 0.75 mL of 0.020 N hydrochloric acid (0.055%).

Sulfate—Treat the residue obtained in the test for *Soluble salts* with 2 mL of hydrofluoric acid, and evaporate on a steam bath to dryness. Mix the residue with water, transfer to a filter, and wash, using approximately 50 mL of water for the complete procedure. Heat the filtrate to boiling, and add 0.1 mL of hydrochloric acid and 5 mL of barium chloride TS. Maintain the mixture near its boiling point for 1 hour, filter, wash the precipitate thoroughly with water, dry, and ignite to constant weight: the weight of the residue does not exceed 30 mg (0.5%).

Free alkali—Add 2 drops of phenolphthalein TS to 20 mL of the diluted filtrate prepared in the test for *Soluble salts*, representing 1 g of the Trisilicate: if a pink color is produced, not more than 1.0 mL of 0.10 N hydrochloric acid is required to discharge it.

Arsenic, *Method I* ⟨211⟩: 8 ppm.

Heavy metals ⟨231⟩**—**Boil 2.67 g with a mixture of 50 mL of water and 5 mL of hydrochloric acid for 20 minutes, adding water to maintain the volume during the boiling. Add ammonium hydroxide until the mixture is only slightly acid to litmus paper. Filter with the aid of suction, and wash with 15 to 20 mL of water, combining the washing with the original filtrate. Add 2 drops of phenolphthalein TS, then add a slight excess of 6 N ammonium hydroxide. Discharge the pink color with dilute hydrochloric acid (1 in 100), then add 8 mL of dilute hydrochloric acid (1 in 100). Dilute with water to 100 mL, and use 25 mL of the solution for the test: the limit is 0.003%.

Acid-consuming capacity—Weigh accurately about 200 mg into a glass-stoppered, 125-mL conical flask. Add 30.0 mL of 0.1 N hydrochloric acid VS and 20.0 mL of water. Place the flask in a bath maintained at 37°, and shake the mixture occasionally during a period of 4 hours but leave the mixture undisturbed during the last 15 minutes of the heating period. Cool to room temperature. To 25.0 mL of the supernatant add methyl red TS, and titrate the excess acid with 0.1 N sodium hydroxide VS. One g of Magnesium Trisilicate, calculated on the anhydrous basis, consumes not less than 140 mL and not more than 160 mL of 0.10 N hydrochloric acid.

Assay for magnesium oxide—Weigh accurately about 1.5 g, and transfer to a 250-mL conical flask. Add 50.0 mL of 1 N sulfuric acid VS, and digest on a steam bath for 1 hour. Cool to room temperature, add methyl orange TS, and titrate the excess acid with 1 N sodium hydroxide VS. Each mL of 1 N sulfuric acid is equivalent to 20.15 mg of MgO.

Assay for silicon dioxide—Transfer about 700 mg of Magnesium Trisilicate, accurately weighed, to a small platinum dish. Add 10 mL of 1 N sulfuric acid, and heat on a steam bath to dryness, leaving the dish uncovered. Treat the residue with 25 mL of water, and digest on a steam bath for 15 minutes. Decant the supernatant through an ashless filter paper, with the aid of suction, and wash the residue, by decantation, three times with hot water, passing the washings through the filter paper. Finally transfer the residue to the filter, and wash thoroughly with hot water. Transfer the filter paper and its contents to the platinum dish previously used. Heat to dryness, incinerate, ignite strongly for 30 minutes, cool, and weigh. Moisten the residue with water, and add 6 mL of hydrofluoric acid and 3 drops of sulfuric acid. Evaporate to dryness, ignite for 5 minutes, cool, and weigh: the loss in weight represents the weight of SiO_2.

Ratio of SiO_2 to MgO—Divide the percentage of SiO_2 obtained in the *Assay for silicon dioxide* by the percentage of MgO obtained in the *Assay for magnesium oxide:* the quotient obtained is between 2.10 and 2.37.

Magnesium Trisilicate Tablets

» Magnesium Trisilicate Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $Mg_2Si_3O_8$.

Packaging and storage—Preserve in well-closed containers.

Identification—

A: Powder 1 Tablet, add 10 mL of 3 N hydrochloric acid and 5 drops of methyl red TS, heat to boiling, add 6 N ammonium hydroxide until the color of the solution changes to deep yellow, then continue boiling for 2 minutes, and filter: the filtrate so obtained responds to the tests for *Magnesium* ⟨191⟩.

B: Wash the solids on the filter obtained in *Identification* test *A* with hot ammonium chloride solution (1 in 50), add 10 mL of 3 N hydrochloric acid, and filter. Transfer the filter paper and contents to a small platinum dish, ignite, cool in a desiccator, and weigh. Moisten the residue with water, and add 6 mL of hydrofluoric acid. Evaporate to dryness, ignite for 5 minutes, cool in a desiccator, and weigh: a loss of more than 10% in relation to the weight of the residue from the initial ignition indicates SiO_2.

Disintegration ⟨701⟩: 10 minutes, simulated gastric fluid TS being substituted for water in the test.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Acid-neutralizing capacity ⟨301⟩**—**Not less than 5 mEq of acid is consumed by the minimum single dose recommended in the labeling.

Assay—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 1 g of magnesium trisilicate, to a beaker, add 20 mL of water, and slowly add 40 mL of 3 N hydrochloric acid, with mixing. Heat the mixture to boiling, cool, and filter into a 200-mL volumetric flask. Wash the beaker with water, adding