

Magnesium Silicate

1 Nonproprietary Names

JP: Magnesium silicate
USPNF: Magnesium silicate

2 Synonyms

E553a; synthetic magnesium silicate.

3 Chemical Name and CAS Registry Number

Silicic acid, magnesium salt [1343-88-0]

4 Empirical Formula Molecular Weight

$\text{MgO} \cdot \text{SiO}_2 \cdot x\text{H}_2\text{O}$
See also Sections 5 and 17.

5 Structural Formula

Magnesium silicate is a compound of magnesium oxide and silicon dioxide. *See also* Section 17.

The JP 2001 states that magnesium silicate contains not less than 45.0% of silicon dioxide (SiO_2 ; molecular weight 60.08) and not less than 20.0% of magnesium oxide (MgO ; 40.30), and the ratio of percentage (%) of magnesium oxide to silicon dioxide is not less than 2.2 and not more than 2.5.

The USPNF 20 describes magnesium silicate as a compound of magnesium oxide (MgO) and silicon dioxide (SiO_2) that contains not less than 15.0% of MgO and not less than 67.0% of SiO_2 calculated on the ignited basis.

6 Functional Category

Anticaking agent; glidant.

7 Applications in Pharmaceutical Formulation or Technology

Magnesium silicate is used in oral pharmaceutical formulations and food products as a glidant and an anticaking agent.

8 Description

Magnesium silicate occurs as an odorless and tasteless, fine, white-colored powder that is free from grittiness.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for magnesium silicate.

Test	JP 2001	USPNF 20
Identification	+	+
pH (10% aqueous suspension)	—	7.0–10.8
Loss on drying	—	≤ 15%
Soluble salts	≤ 0.02 g	≤ 3%
Chloride	≤ 0.053%	—
Free alkali	+	+
Heavy metals	≤ 30 ppm	≤ 20 ppm
Arsenic	≤ 5 ppm	—
Sulfate	≤ 0.48%	—
Organic volatile impurities	—	+
Loss on ignition	≤ 34%	≤ 15%
Fluoride	—	≤ 10 ppm
Lead	—	≤ 0.001%
Acid-consuming capacity	+	—
Ratio of SiO_2 to MgO	2.2–2.5	2.5–4.5
Assay for MgO	≥ 20.0%	≥ 15%
Assay for SiO_2	≥ 45.0%	≥ 67%

10 Typical Properties

Moisture content: magnesium silicate is slightly hygroscopic.
Solubility: practically insoluble in ethanol (95%), ether, and water.

11 Stability and Storage Conditions

Magnesium silicate should be stored in a well-closed container in a cool, dry place.

12 Incompatibilities

Magnesium silicate may decrease the oral bioavailability of drugs such as mebeverine hydrochloride,⁽¹⁾ sucralfate, and tetracycline, via chelation or binding, when they are taken together. The dissolution rate of folic acid,⁽²⁾ erythromycin stearate,⁽³⁾ paracetamol, and chloroquine phosphate,⁽⁴⁾ may be retarded by adsorption onto magnesium silicate. Antimicrobial preservatives, such as parabens, may be inactivated by the addition of magnesium silicate.⁽⁵⁾

Magnesium silicate is readily decomposed by mineral acids.

13 Method of Manufacture

Magnesium silicate may be prepared from sodium silicate and magnesium sulfate. The silicate also occurs in nature as the minerals meerschau, parasepiolite, and sepiolite.

14 Safety

Magnesium silicate is used in oral pharmaceutical formulations and is generally regarded as an essentially nontoxic and nonirritant material.

Orally administered magnesium silicate is neutralized in the stomach to form magnesium chloride and silicon dioxide;

some magnesium is absorbed. Caution should be used when greater than 50 mEq of magnesium is given daily to persons with impaired renal function, owing to the risk of hypermagnesemia.

Reported adverse effects include the formation of bladder and renal calculi following the regular use, for many years, of magnesium silicate as an antacid.^(6,6,712,403,)

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection is recommended.

16 Regulatory Acceptance

GRAS listed. Accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Guide (oral tablets).

17 Related Substances

Magnesium aluminum silicate; magnesium metasilicate; magnesium orthosilicate; magnesium trisilicate; talc.

Magnesium metasilicate

Comments: magnesium metasilicate (MgSiO_3) occurs in nature as the minerals clinoenstatite, enstatite, and protoenstatite.

Magnesium orthosilicate

Comments: magnesium orthosilicate (Mg_2SiO_4) occurs in nature as the mineral forsterite.

18 Comments

The EINECS number for magnesium silicate is 215-681-1.

19 Specific References

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- 3 Arayne MS, Sultana N. Erythromycin-antacid interaction. *Pharmazie* 1993; 48: 599-602.
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- 7 Levison DA, Crocker PR, Banim S, Wallace DMA. Silica stones in the urinary bladder. *Lancet* 1982; i: 704-705.

20 General References

Anonymous. The silicates: attapulgite, kaolin, kieselguhr, magnesium trisilicate, pumice, talc. *Int J Pharmaceut Compound* 1998; 2(2): 162-163.

21 Author

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22 Date of Revision

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