

Magnesium Trisilicate

1 Nonproprietary Names

BP: Magnesium trisilicate
PhEur: Magnesii trisilicas
USP: Magnesium trisilicate

2 Synonyms

E553(a); magnesium mesotrisilicate; silicic acid, magnesium salt (1:2), hydrate.

3 Chemical Name and CAS Registry Number

Magnesium trisilicate hydrate [39365-87-2]

4 Empirical Formula Molecular Weight

$Mg_2Si_3O_8 \cdot xH_2O$ 260.86 (anhydrous)

5 Structural Formula

$2MgO \cdot 3SiO_2 \cdot xH_2O$

6 Functional Category

Anticaking agent; glidant; therapeutic agent.

7 Applications in Pharmaceutical Formulation or Technology

Magnesium trisilicate is used in oral pharmaceutical formulations and food products as a glidant. It is also used therapeutically as an antacid, and also for the treatment of ciprofloxacin overdose or toxicity.⁽¹⁾

8 Description

The USP 25 describes magnesium trisilicate as a compound of magnesium oxide and silicon dioxide with varying proportions of water. It contains not less than 20% of magnesium oxide and not less than 45% of silicon dioxide. The PhEur 2002 similarly describes magnesium trisilicate as having a variable composition corresponding to the approximate formula $Mg_2Si_3O_8 \cdot xH_2O$. It contains not less than 29% of magnesium oxide and not less than the equivalent of 65% of silicon dioxide, both calculated with reference to the ignited substance.

Magnesium trisilicate 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 trisilicate.

Test	JP 2001	PhEur 2002	USP 25
Identification	+	+	+
Loss on ignition	≤34.0%	17.0–34.0%	—
Water-soluble salts	≤0.02g	≤1.5%	≤1.5%
Chloride	≤0.053%	≤500 ppm	≤0.055%
Sulfates	≤0.480%	≤0.5%	≤0.5%
Alkalinity	+	+	—
Arsenic	≤5 ppm	≤4 ppm	≤8 ppm
Heavy metals	≤30 ppm	≤40 ppm	≤0.003%
Water	—	—	17.0–34.0
Acid-absorbing capacity	140–160 mL	≤100.0 mL	140–160 mL
Assay of MgO	≥20.0%	≥29.0% ^(a)	≥20.0%
Assay of SiO ₂	≥45.0%	≥65.0% ^(a)	≥45.0%

^(a) With reference to the ignited substance.

10 Typical Properties

Moisture content: magnesium trisilicate is slightly hygroscopic. At relative humidities of 15–65%, the equilibrium moisture content at 25°C is 17–23% w/w; at relative humidities of 75–95%, the equilibrium moisture content is 24–30% w/w.

Solubility: practically insoluble in ethanol (95%) and water.

11 Stability and Storage Conditions

Magnesium trisilicate is stable if stored in a well-closed container in a cool, dry place.

12 Incompatibilities

Magnesium trisilicate, when taken with drugs such as mebeverine hydrochloride,⁽²⁾ sucralfate, and tetracycline, may cause a reduction in bioavailability via binding or chelation. The dissolution rate of folic acid,⁽³⁾ erythromycin stearate,⁽⁴⁾ paracetamol, and chloroquine phosphate⁽⁵⁾ may be retarded by adsorption onto magnesium trisilicate. Antimicrobial preservatives, such as the parabens, may be inactivated by the addition of magnesium trisilicate.⁽⁶⁾

Magnesium trisilicate is also readily decomposed by mineral acids.

13 Method of Manufacture

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

14 Safety

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

When administered orally, magnesium trisilicate is neutralized in the stomach to form magnesium chloride and silicon dioxide; some magnesium may be absorbed. Caution should be used when concentrations greater than 50 mEq of magnesium are given daily to persons with impaired renal function, owing to the risk of hypermagnesemia.

Therapeutically, up to about 2 g of magnesium trisilicate may be taken daily as an antacid.

Reported adverse effects include the formation of bladder and renal calculi following the long-term use of magnesium trisilicate as an antacid.^(7,8)

15 Handling Precautions

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

16 Regulatory Status

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

17 Related Substances

Calcium silicate; magnesium silicate; magnesium trisilicate anhydrous; talc.

Calcium silicate

Appearance: white to off-white-colored, free-flowing powder that remains free-flowing after absorbing relatively large amounts of water or other liquids.

Solubility: practically insoluble in water. Forms a gel with mineral acids.

Handling precautions: in the UK, the long-term (8-hour TWA) occupational exposure standards for calcium silicate are 10 mg/m³ for total inhalable dust and 4 mg/m³ for respirable dust.⁽⁹⁾

Comments: many different forms of calcium silicate are known such as CaSiO₃, Ca₂SiO₄, and Ca₃SiO₅. Usually these occur in the hydrated form and contain varying amounts of water of crystallization. Calcium silicate is used in pharmaceutical formulations as a glidant and anticaking agent.⁽¹⁰⁾ Also used in food products (GRAS listed). The EINECS number for calcium silicate is 215-710-8.

Magnesium trisilicate anhydrous

Empirical formula: Mg₂Si₃O₈

Molecular weight: 260.86

CAS number: [14987-04-3]

18 Comments

Magnesium trisilicate is regarded as a type of magnesium silicate. The EU food additive code E553(a) seems to have been applied to both. The EINECS number for magnesium trisilicate is 239-076-7.

19 Specific References

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- 2 Al-Gohary OMN. An *in vitro* study of the interaction between mebeverine hydrochloride and magnesium trisilicate powder. *Int J Pharm* 1991; 67: 89–95.
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- 4 Arayne MS, Sultana N. Erythromycin–antacid interaction. *Pharmazie* 1993; 48: 599–602.
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- 6 Allwood MC. The adsorption of esters of *p*-hydroxybenzoic acid by magnesium trisilicate. *Int J Pharm* 1982; 11: 101–107.
- 7 Joekes AM, Rose GA, Sutor J. Multiple renal silica calculi. *Br Med J* 1973; 1: 146–147.
- 8 Levison DA, Crocker PR, Banim S, Wallace DMA. Silica stones in the urinary bladder. *Lancet* 1982; I: 704–705.
- 9 Health and Safety Executive. *EH40/2002: Occupational Exposure Limits 2002*. Sudbury: Health and Safety Executive, 2002.
- 10 Asano T, Tsubuku S, Sugawara S, *et al*. Changes in volume and compression energy upon compression of calcium silicate tablets. *Drug Dev Ind Pharm* 1997; 23: 679–685.

20 General References

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

21 Author

AS Kearney.

22 Date of Revision

1 October 2002.