

# Magnesium Aluminum Silicate

## 1 Nonproprietary Names

BP: Aluminium magnesium silicate  
PhEur: Alumini magnesi silicas  
USPNF: Magnesium aluminum silicate

## 2 Synonyms

Aluminosilicic acid, magnesium salt; aluminum magnesium silicate; *Carrisorb*; *Gelsorb*; *Magnabite*; magnesium aluminosilicate; magnesium aluminum silicate, colloidal; magnesium aluminum silicate, complex colloidal; *Neusilin*; *Pharmsorb*; silicic acid, aluminum magnesium salt; *Veegum*.

## 3 Chemical Name and CAS Registry Number

Aluminum magnesium silicate [12511-31-8]  
Magnesium aluminum silicate [1327-43-1]

## 4 Empirical Formula Molecular Weight

A polymeric complex of magnesium, aluminum, silicon, oxygen, and water. The average chemical analysis is conventionally expressed as oxides:

|                      |       |
|----------------------|-------|
| Silicon dioxide      | 61.1% |
| Magnesium oxide      | 13.7% |
| Aluminum oxide       | 9.3%  |
| Titanium dioxide     | 0.1%  |
| Ferric oxide         | 0.9%  |
| Calcium oxide        | 2.7%  |
| Sodium oxide         | 2.9%  |
| Potassium oxide      | 0.3%  |
| Carbon dioxide       | 1.8%  |
| Water of combination | 7.2%  |

## 5 Structural Formula

The complex is composed of a three-lattice layer of octahedral alumina and two tetrahedral silica sheets. The aluminum is substituted to varying degrees by magnesium (with sodium or potassium for balance of electrical charge). Additional elements present in small amounts include iron, lithium, titanium, calcium, and carbon.

## 6 Functional Category

Adsorbent; stabilizing agent; suspending agent; tablet and capsule disintegrant; tablet binder; viscosity-increasing agent.

## 7 Applications in Pharmaceutical Formulation or Technology

Magnesium aluminum silicate has been used for many years in the formulation of tablets, ointments, and creams. It is used in oral and topical formulations as a suspending and stabilizing agent either alone or in combination with other suspending agents.<sup>(1-3)</sup> The viscosity of aqueous dispersions may be greatly increased by combination with other suspending agents, such

as xanthan gum, owing to synergistic effects, *see* Xanthan Gum. In tablets, magnesium aluminum silicate is used as a binder and disintegrant in conventional or slow-release formulations.<sup>(4,5)</sup> *See* Table I.

Magnesium aluminum silicate may cause bioavailability problems with certain drugs, *see* Section 12.

**Table I:** Uses of magnesium aluminum silicate.

| Use                           | Concentration (%) |
|-------------------------------|-------------------|
| Adsorbent                     | 10–50             |
| Binding agent                 | 2–10              |
| Disintegrating agent          | 2–10              |
| Emulsion stabilizer (oral)    | 1–5               |
| Emulsion stabilizer (topical) | 2–5               |
| Suspending agent (oral)       | 0.5–2.5           |
| Suspending agent (topical)    | 1–10              |
| Stabilizing agent             | 0.5–2.5           |
| Viscosity modifier            | 2–10              |

## 8 Description

The USPNF 20 describes magnesium aluminum silicate as a blend of colloidal montmorillonite and saponite that has been processed to remove grit and nonswellable ore components. Four types of magnesium aluminum silicate are defined: types IA, IB, IC, and IIA. These types differ according to their viscosity and ratio of aluminum and magnesium content, *see* Table II.

The PhEur 2002 describes magnesium aluminum silicate (aluminum magnesium silicate) as a mixture of particles with colloidal particle size of montmorillonite and saponite, free from grit and nonswellable ore.

Magnesium aluminum silicate occurs as off-white to creamy white, odorless, tasteless, soft, slippery small flakes, or as a fine, micronized powder. Flakes vary in shape and size from about 0.3 × 0.4 mm to 1.0 × 2.0 mm and about 25–240 μm thick. Many flakes are perforated by scattered circular holes 20–120 μm in diameter. Under dark-field polarized light, innumerable bright specks are observed scattered over the flakes. The powder varies from 45 to 297 μm in size.

**Table II:** Magnesium aluminum silicate types defined in the USPNF 20.

| Type | Viscosity (mPa s) | Al content/Mg content |
|------|-------------------|-----------------------|
| IA   | 225–600           | 0.5–1.2               |
| IB   | 150–450           | 0.5–1.2               |
| IC   | 800–2200          | 0.5–1.2               |
| IIA  | 100–300           | 1.4–2.8               |

## 9 Pharmacopeial Specifications

*See* Table III.

**Table III:** Pharmacopeial specifications for magnesium aluminum silicate.

| Test                          | PhEur 2002 | USPNF 20     |
|-------------------------------|------------|--------------|
| Identification                | +          | +            |
| Characters                    | +          | —            |
| Viscosity (5% w/v suspension) | —          | See Table II |
| Microbial limits              | +          | +            |
| pH (5% w/v suspension)        | 9.0–10.0   | 9.0–10.0     |
| Acid demand                   | —          | +            |
| Loss on drying                | ≤ 8.0%     | ≤ 8.0%       |
| Arsenic                       | ≤ 3 ppm    | ≤ 3 ppm      |
| Lead                          | ≤ 15 ppm   | ≤ 0.0015%    |
| Assay for Al and Mg content   | 95.0–105.0 | +            |

## 10 Typical Properties

**Acid demand:** 6–8 mL of 0.1 N HCl is required to reduce the pH of 1 g to pH 4.

**Density:** 2.418 g/cm<sup>3</sup>

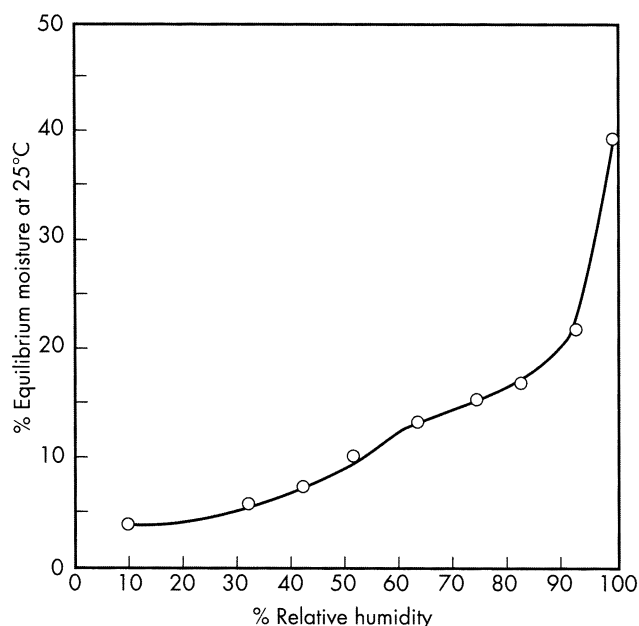
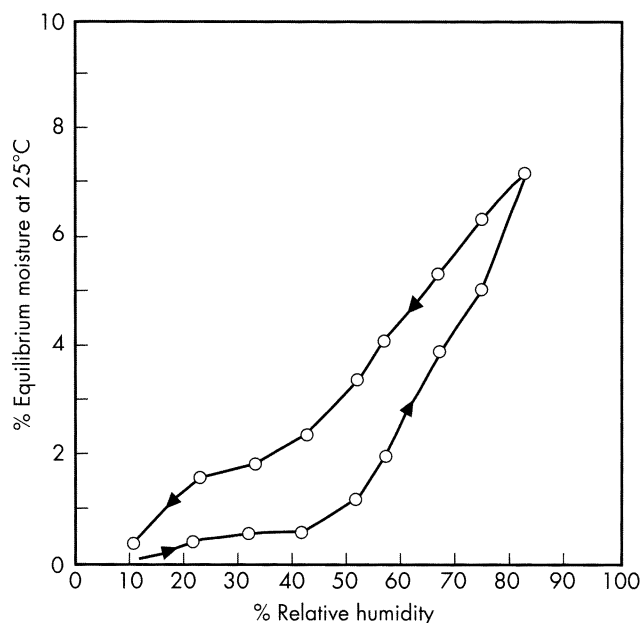
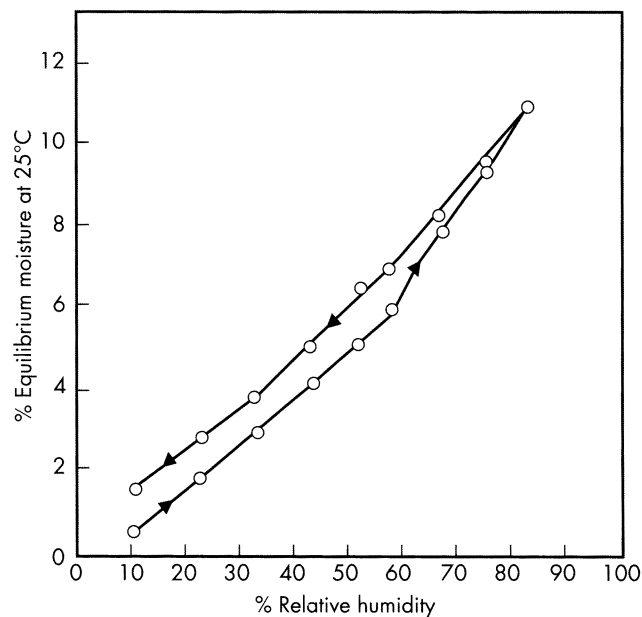
**Moisture content:** 6.0–9.98%.<sup>(6)</sup> See also Figures 1–3.<sup>(6)</sup>

**Particle size distribution:** see Section 8.

**Solubility:** practically insoluble in alcohols, water, and organic solvents.

**Swelling capacity:** swelling properties are reversible. Magnesium aluminum silicate swells to many times its original volume in water to form colloidal dispersions and may be dried and rehydrated any number of times.

**Viscosity (dynamic):** dispersions in water at the 1–2% w/v level are thin colloidal suspensions. At 3% w/v and above, dispersions are opaque. As the concentration is increased above 3% w/v, the viscosity of aqueous dispersions increases rapidly; at 4–5% w/v, dispersions are thick, white colloidal sols, while at 10% w/v firm gels are formed. Dispersions are thixotropic at concentrations greater than 3% w/v. The viscosity of the suspension increases with heating or addition of electrolytes, and at higher concentrations with aging.

**Figure 1:** Equilibrium moisture content of magnesium aluminum silicate (Veegum HV).**Figure 2:** Sorption-desorption isotherm of magnesium aluminum silicate (Pharmasorb).**Figure 3:** Sorption-desorption isotherm of magnesium aluminum silicate (Pharmasorb colloidal).

## 11 Stability and Storage Conditions

Magnesium aluminum silicate is stable indefinitely when stored under dry conditions. It is stable over a wide pH range, has base-exchange capacity, absorbs some organic substances, and is compatible with organic solvents.

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

**SEM: 1**

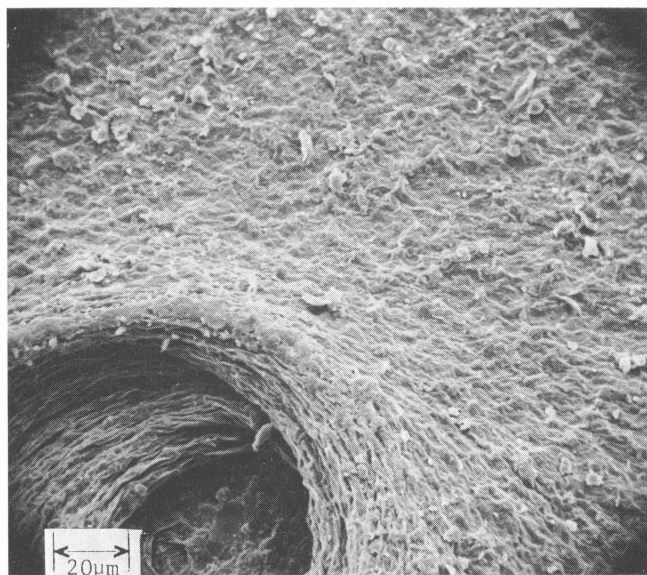
*Excipient:* magnesium aluminum silicate (*Veegum*)

*Manufacturer:* RT Vanderbilt Co., Inc.

*Lot No.:* 61A-1

*Magnification:* 600 $\times$

*Voltage:* 10 kV

**SEM: 3**

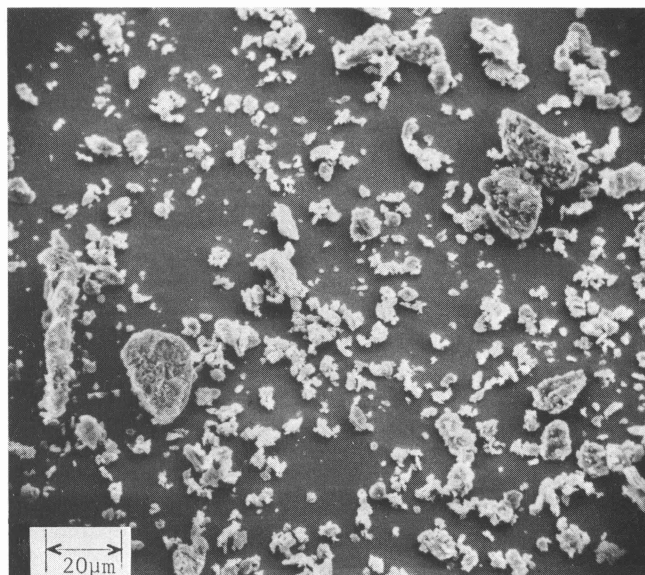
*Excipient:* magnesium aluminum silicate (*Veegum F*)

*Manufacturer:* RT Vanderbilt Co., Inc.

*Lot No.:* 61A-2

*Magnification:* 600 $\times$

*Voltage:* 10 kV

**SEM: 2**

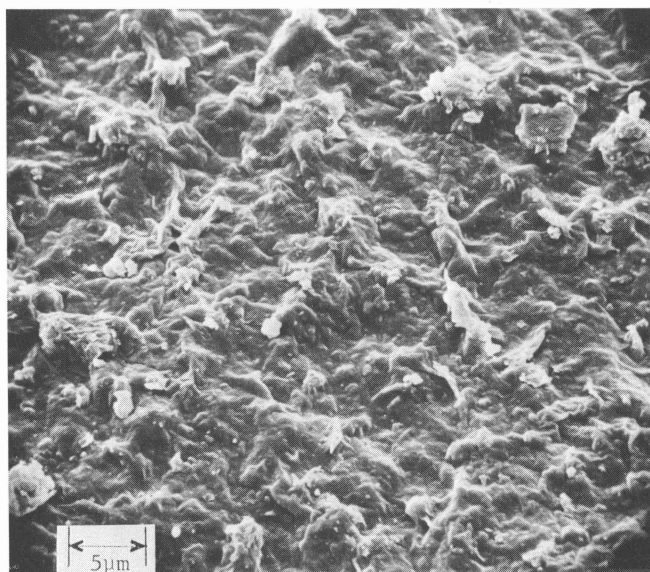
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*Manufacturer:* RT Vanderbilt Co., Inc.

*Lot No.:* 61A-1

*Magnification:* 2400 $\times$

*Voltage:* 10 kV

**SEM: 4**

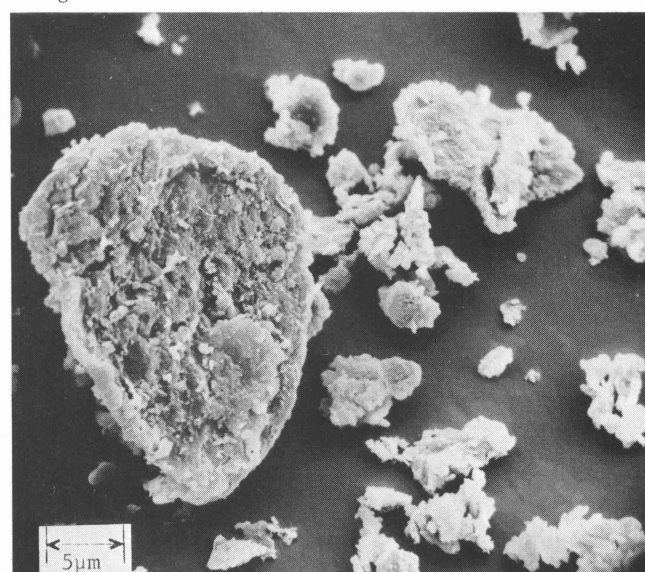
*Excipient:* magnesium aluminum silicate (*Veegum F*)

*Manufacturer:* RT Vanderbilt Co., Inc.

*Lot No.:* 61A-2

*Magnification:* 2400 $\times$

*Voltage:* 10 kV



## 12 Incompatibilities

Owing to its inert nature, magnesium aluminum silicate has few incompatibilities but is generally unsuitable for acidic solutions below pH 3.5. Magnesium aluminum silicate, as with other clays, may adsorb some drugs.<sup>(7,8)</sup> This can result in low bioavailability if the drug is tightly bound or slowly desorbed, e.g., amfetamine sulfate,<sup>(4)</sup> tolbutamide,<sup>(9)</sup> warfarin sodium,<sup>(10)</sup> and diazepam.<sup>(11)</sup>

## 13 Method of Manufacture

Magnesium aluminum silicate is obtained from silicate ores of the montmorillonite group, which show high magnesium content. The ore is blended with water to form a slurry to remove impurities and separate out the colloidal fraction. The refined colloidal dispersion is drum-dried to form a small flake, which is then micro-atomized to form various powder grades.

## 14 Safety

Magnesium aluminum silicate is generally regarded as non-toxic and nonirritating at the levels employed as a pharmaceutical excipient. Subacute animal feeding studies in rats and dogs fed magnesium aluminum silicate at 10% of the diet, for 90 days, were negative, including autopsy and histopathological examinations.<sup>(12)</sup>

LD<sub>50</sub> (rat, oral): > 16 g/kg<sup>(13)</sup>

## 15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection and gloves are recommended. Adequate ventilation should be provided and dust generation minimized.

## 16 Regulatory Status

Included in the FDA Inactive Ingredients Guide (oral granules, solutions, suspensions and tablets; rectal; and topical preparations). Included in nonparenteral medicines licensed in the UK.

## 17 Related Substances

Attapulgite; bentonite; kaolin; magnesium trisilicate; montmorillonite; saponite; talc.

### Montmorillonite

Empirical formula: Al<sub>2</sub>O<sub>5</sub>·4SiO<sub>2</sub>·4H<sub>2</sub>O

CAS number: [1318-93-0]

Comments: a naturally occurring silicate clay.

### Saponite

Empirical formula: Mg<sub>18</sub>(Al<sub>4</sub>Si<sub>21</sub>O<sub>66</sub>)·6H<sub>2</sub>O

CAS number: [1319-41-1]

Comments: a naturally occurring silicate clay.

## 18 Comments

The EINECS number for magnesium aluminum silicate is 215-478-8.

## 19 Specific References

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## 20 General References

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## 21 Author

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## 22 Date of Revision

19 June 2002.