



## TECHNICAL DATA SHEET

010421-TDS-ENG-2022

MAGNESIO SULFATO HEPTAHIDRATADO		
DESCRIPTION DCI: MAGNESIUM SULFATE		DESCRIPTION DOE: MAGNESIO SULFATO
CAS N°: 10034-99-8	EC N°: 231-290-2	AEMPS CODE: ---
MOL. WEIGHT: 246.48	MOL. FORMULA: MgSO <sub>4</sub> ·7H <sub>2</sub> O	ARTICLE CODE: 010421

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder or brilliant, colourless crystals.
Solubility	Freely soluble in water, very soluble in boiling water, practically insoluble in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and colourless
Acidity or alkalinity	= < 0.2 mL of HCl 0.01 M or NaOH 0.01M
Chlorides	= < 300 ppm
Iron	= < 20 ppm
Loss on drying	48.0 - 52.0 %
Assay	99.0 - 100.5 %

### COMPLIES WITH

European Pharmacopeia 10.3

### STORAGE

Keep the container tightly closed. Store in a cool, dry and well ventilated place.

### REMARKS

Magnesium Sulfate Heptahydrate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

The product is not of animal origin and no animal product is used in its production, so it is risk-free BSE/TSE.

The product is not derived from GMO. No genetically modified organism is used in its production and no GMO product comes in contact with the product during any stage of production.

### Properties and uses

Magnesium is the second most abundant cation in the body, and is an essential electrolyte that participates as an enzymatic cofactor.

It is absorbed in the intestine slowly. It binds to plasma proteins in 25 - 30%. It is eliminated by urine and feces. It crosses the placental barrier, and small amounts pass into breast milk.

It is found mostly in nuts, whole grains, and green vegetables. The human requirements are of approx. about 200 - 300 mg / day.

MAGNESIUM SULFATE is a salt of magnesium used mainly in states of deficiency of this ion and hypomagnesemias.

It also has a saline laxative effect.

Topically it has been used in the treatment of certain local inflammations, as in cases of pimples on the skin and in anthrax, but its prolonged application can damage the surrounding areas. The saturated aqueous solutions are used in baths for the therapy of osteoarthritis and for erysipelas.

### Dosage

In cases of mild magnesium deficiency, at a dose of about 50 mmol / day of magnesium.

As a saline or laxative laxative, at a dose of 5 - 15 g / day.

Topically, in saturated solutions for baths or in cold wet compresses.

### Side effects

All methods are validated by the official pharmacopeias and/or by the authorized manufacturer

A080.02.ENG



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In general, magnesium salts are absorbed very little orally, but in individuals with renal insufficiency, sufficient amounts can accumulate to produce toxic effects.

An excessive administration of magnesium can lead to the appearance of hypermagnesemia, which occurs with nausea, vomiting, hot flushes, thirst, hypotension due to peripheral vasodilation, drowsiness, confusion, loss of tendon reflexes due to a neuromuscular block, muscular asthenia, respiratory depression, cardiac arrhythmias, coma and cardiac arrest. Acute ingestion can cause gastrointestinal irritation and diarrhea.

### Precautions

It should be used with caution in patients with renal insufficiency, who receive a treatment with digitalis glycosides, and in pregnancy.

### Interactions

Magnesium salts administered orally decrease the absorption of tetracyclines and bisphosphonates.

### Incompatibilities

Polymyxin B sulfate, tartrates, phosphates, arsenates, carbonates, and bicarbonates. Magnesium salts have been described as incompatible with many drugs.

### Other observations

It is hygroscopic.

### Compounding examples

#### *Purifying saline water*

MAGNESIUM SULFATE - **20 g**

Sodium sulfate dry - **100 g**

Purified water - **100 g**

#### *Sedlitz water*

MAGNESIUM SULFATE - **30 g**

Sodium bicarbonate - **4 g**

Tartaric acid - **4 g**

Purified water - **650 g**