

Magnesium Sulfate

Handling/Processing

Identification of Petitioned Substance

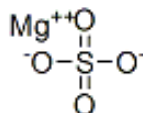
1	Chemical Names:	11	CAS Numbers:
2	Magnesium sulfate	12	7487-88-9 (magnesium sulfate anhydrous)
3		13	18939-43-0 (sulfuric acid magnesium salt)
4	Other Name:	14	14168-73-1 (monohydrate)
5	Epsom salts	15	10034-99-8 (heptahydrate)
6	Bitter salts		
7	Magnesium sulfate anhydrous		Other Codes:
8	Sulfuric acid, magnesium salt	16	050503 (USEPA PC Code [U.S. EPA 2010])
9		17	231-298-2 (EINECS)
10	Trade Names:		
	None		

Characterization of Petitioned Substance

Composition of the Substance:

The compound magnesium sulfate (anhydrous) contains magnesium, sulfur, and oxygen, MgSO_4 . Magnesium sulfate also occurs in hydrated forms ($\text{MgSO}_4 \cdot x\text{H}_2\text{O}$), including monohydrate and heptahydrate. The monohydrate and heptahydrate forms contain one and seven H_2O molecules, respectively (ChemIDplus Lite, 2011; Kawamura and Rao, 2007). Magnesium sulfate is considered ionic because a metal (magnesium) and a non-metal (sulfate) are bonded. Within the sulfate molecule, there is a covalent bond between the sulfur and oxygen atoms. The molecular structure of anhydrous magnesium sulfate is shown in Figure 1.

Figure 1. Molecular Structure of Magnesium Sulfate (Anhydrous)



Properties of the Substance:

Magnesium sulfate is an odorless solid that is generally found as needle-like colorless crystals or as a white crystalline powder (Kawamura and Rao, 2007). The substance is considered very soluble in boiling water. Different forms of magnesium sulfate have different molecular weights and differ in their solubility in water. The physical and chemical properties of magnesium sulfate are presented in Table 1. The properties presented in Table 1 apply to all three forms of magnesium sulfate (ie. monohydrate, heptahydrate, and anhydrous) unless specifically noted.

Specific Uses of the Substance:

Magnesium sulfate has a wide variety of uses in agriculture, food processing, personal care products, and medicine. In agriculture, magnesium sulfate is added to soil to correct for magnesium deficiency (Kawamura and Rao, 2007) or to improve the uptake of nitrogen and phosphorous by crops (Epsom Salt Council, 2009). Crops that heavily depend on magnesium-rich soil include potatoes, peppers, tomatoes, and roses. Magnesium sulfate also is commonly added to potted plants. The high solubility of magnesium sulfate makes it an ideal compound for adding magnesium to the soil.

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Table 1. Physicochemical Properties of Magnesium Sulfate

Physical or Chemical Property	Value
Physical State	Solid
Appearance	White crystalline powder or needle-like colorless crystals
Odor	Odorless
Taste	Bitter, salty, cooling
Molecular Weight	120.36 (anhydrous); 138.38 (monohydrate); 246.47 (heptahydrate)
Boiling Point	NA
Melting Point	2,055 °F or 1124 °C
Solubility in Water	anhydrous: 269 g/L (0 °C), 255 g/L (20 °C) heptahydrate: 710 g/L (20 °C)
Vapor Pressure	< .01 mm Hg at 20 °C
Density	2.66 g/cm ³ (anhydrous); 2.445 g/cm ³ (monohydrate); 1.68 g/cm ³ (heptahydrate)

Source: Chemical Book, 2010

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56 In food processing, magnesium sulfate is used as a flavor enhancer in bottled water and as a firming agent
57 in soybean curd. Magnesium sulfate also is used as a nutrient, primarily in salt-replacer products, dietary
58 supplements, carbonated diet soft drink beverages, sports drinks, and enhanced (fortified) water
59 beverages. It is used as a fermentation and malting aid in beer, ale, and other malt beverages (Kawamura
60 and Rao, 2007).

61

62 Magnesium sulfate has many human medicinal uses. Injections of magnesium sulfate can be used as an
63 anticonvulsant to control and prevent seizures in children suffering from acute nephritis. Magnesium
64 sulfate injections can help lower the blood pressure of pregnant females suffering from preeclampsia and
65 prevent pre-term labor. Asthma attacks can be treated with magnesium sulfate. When taken
66 intravenously, it reduces the resistance within the airways and facilitates normal airflow. Magnesium
67 sulfate can act as a laxative when taken orally and is used to relieve constipation (Adnani, 2010).

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69 Epsom salt, a common form of magnesium sulfate, is easily dissolved in water and is used to relieve
70 muscle aches and pains as well as to reduce itching and inflammation. It is commonly added to bath water
71 and used by individuals suffering from joint pain (Epsom Salt Council, 2009).

72

73 Magnesium sulfate also has a number of veterinary uses. It acts as an anticonvulsant, laxative,
74 bronchodilator, electrolyte replacement aid with hypomagnesaemia, and may be used to treat cardiac
75 arrhythmias. Specifically in swine, magnesium sulfate is administered to treat malignant hypothermia
76 (Dodman, 2010).

77

78 Magnesium sulfate can be added to livestock feed to treat conditions stemming from a magnesium
79 deficiency.¹ Lactation tetany or grass tetany occurs when ruminants graze on grasses low in magnesium or
80 suffer from a low level of magnesium in their diet. The condition is often realized after cases of sudden
81 death in cattle. Clinical signs include convulsions and muscular spasms, and death may occur due to
82 respiratory failure (Organic Livestock Research Group, 2000). If livestock are feeding on pastures with
83 high potassium levels, which interfere with the uptake of magnesium by grasses, supplemental magnesium
84 sulfate may be needed (Epsom Salt Council, 2009).

85

¹There are two types of veterinary hypomagnesaemia (i.e., magnesium deficiency) recognized clinically – hypomagnesaemic tetany in calves, which appears to be due to a straightforward deficiency of magnesium in the diet, and lactation tetany (or grass tetany), where there may be a partial dietary deficiency but in which nutritional and metabolic factors reduce the availability or increase the body loss of magnesium (Organic Livestock Research Group, 2000).

86 Magnesium capsules can be inserted into the rumen of livestock and after a one-week stabilization period,
87 the capsule begins to release magnesium for up to 80 days. This capsule is recommended for use in high-
88 risk or valuable animals. It is advised that, in addition to the capsule, the livestock be fed hay in order to
89 increase absorption of the magnesium (Champness, 2007). If immediate treatment for magnesium
90 deficiency is needed, magnesium sulfate can be administered intravenously (Papich, 2007).

91
92 A magnesium lick can also be provided for livestock to increase the amount of magnesium in the diet.
93 Because magnesium sulfate is not palatable, molasses is added to the magnesium lick to encourage cattle's
94 use. Licks are generally 80 percent molasses and 20 percent magnesium sulfate and are considered to be
95 less reliable than supplementing feed with magnesium (Harris, 2005).

96
97 Magnesium sulfate, as Epsom salts, can be used to treat inflammation and abscesses in livestock. Soaking
98 the affected area in a mixture containing Epsom salt and water can reduce signs of inflammation (Epsom
99 Salt Council, 2009).

100

101 **Approved Legal Uses of the Substance:**

102

103 Magnesium sulfate is currently included on the National List as a synthetic substance allowed for use in
104 organic crop production as a soil amendment if a magnesium deficiency is documented (7 CFR 205.601).
105 Magnesium sulfate is also included on the National List as a synthetic substance allowed for use in
106 livestock production when used as a disinfectant, sanitizer, or in medical treatments as applicable (7 CFR
107 205.603). In addition, the National List states that magnesium sulfate is allowed for use as a nonsynthetic
108 ingredient "in or on processed products labeled as 'organic' or 'made with organic (specified ingredients or
109 food group[s])' (7 CFR 205.605).

110

111 Magnesium sulfate is considered by the Food and Drug Administration (FDA) as generally recognized as
112 safe (GRAS) when used as a nutrient or dietary supplement (21 CFR 184.1443). The Food and Nutrition
113 Board, an organization established by the Institute of Medicine that provides guidance to the public and
114 policy makers on nutrition and food sciences, has recommended that cereal grain products be fortified with
115 magnesium in response to the potential risk of deficiency among significant segments of the population
116 (FAQS, 2010).

117

118 Multiple products containing magnesium sulfate are approved by the FDA for medicinal use in humans.
119 Magnesium sulfate can be administered via injection or can be orally ingested (U.S. FDA, 2010). In 2010,
120 the FDA approved a product containing magnesium sulfate, which acts a colon cleanser in preparation for
121 a colonoscopy (Braintree Laboratories, 2010).

122

123 The FDA allows magnesium sulfate to be prescribed legally by veterinarians as an extra-label drug. An
124 extra-label drug is defined as the veterinary use of a drug in a manner for which it was not approved.² No
125 specific veterinary formulations of magnesium sulfate are available. The National Lists allows the addition
126 of magnesium sulfate to animal feed according to 7 CFR 205.603. Intravenous injection is used when
127 treatment is required immediately; however, adding magnesium sulfate to animal feed offers an alternative
128 in less urgent situations.

129

130 Under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the EPA exempts
131 residues of magnesium sulfate – used as a solid diluent, carrier, or safener – from the requirement of a
132 tolerance when used in accordance with good agricultural practices as inert (or occasionally active)
133 ingredients in pesticide formulations applied to pre- and post-harvest agricultural crops (40 CFR
134 180.1001[c]). No pesticide products containing magnesium sulfate as an active ingredient are currently
135 registered with the EPA.

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²Veterinarians may use drugs in an extra-label manner under authority of the Animal Medicinal Drug Use Clarification Act, which became effective in December 1996.

Action of the Substance:

Magnesium, found naturally in some foods, is an essential nutrient for health. Magnesium is essential for muscle and nerve function, heart rhythm and blood pressure, immune system health, bone strength, blood sugar level regulation, and energy metabolism and protein synthesis. Half of all magnesium in the body is found in the bone and only 1% is circulated in the blood. The remainder is contained in the cells and tissues. Magnesium sulfate is often added to food or produced in supplement form to provide additional magnesium to the majority of adults in the US that do not obtain the recommended amount from their diet (NIH, 2009).

Magnesium sulfate acts in a variety of ways in its various non-nutritive applications. It works as an enzyme stabilizer, coagulator, fermenting aid, water hardener, and flavor enhancer. These processes are described further in the Evaluation Questions section (Evaluation Questions 5, 6, and 7). For example, in tofu production, magnesium sulfate is added to soybean curd to ferment and firm the tofu (described in more detail in Evaluation Question 11).

Combinations of the Substance:

Magnesium sulfate is sometimes combined with other coagulants in the production of tofu. Natural nigari (derived from seawater) is a popular coagulant in Japan that contains magnesium sulfate and a number of other minerals. Nigari is predominantly magnesium chloride, with much smaller amount of magnesium sulfate, sodium chloride, potassium chloride, and other minerals. However, natural nigari is not approved by the FDA for use in the US and is not generally recognized as safe (GRAS). Dry mixtures of coagulants are sometimes found on the market as well (e.g., mixtures of lactone and magnesium sulfate) to combine the desirable effects of a number of coagulants (Shurtleff and Aoyagi, 2000).

Status

Historic Use:

Historically, magnesium sulfate has had a wide variety of uses in construction, manufacturing/processing, personal care products, food processing, medicine, and agriculture, and many of these uses are summarized by Giles Chemical (2008). As a building material, magnesium sulfate has been used as a setting agent and an extender in various adhesive products, as a component of cement for roofing panels and wallboard, and as an ingredient in flame retardant coatings and brick.

In pulp and paper manufacturing, magnesium sulfate acts as a stabilizing agent for oxygen and peroxide bleaching as well as for dyes. Magnesium sulfate precipitates heavy metals out of water during plating processes and acts as a coagulating agent in latex and rubber processing and a weighting agent in leather processing. In water treatment, magnesium sulfate removes heavy metals and acts as a water hardener (Giles Chemical, 2008).

In cosmetic hair products, magnesium sulfate acts as a hair wave neutralizer and as a product to increase hair density. In laundry detergents, magnesium sulfate is used as an anti-caking agent, foam stabilizer, viscosity control agent, and as a source for synthetic magnesium water hardness (Giles Chemical, 2008).

Fermentation processes are aided by magnesium sulfate, which is a source of magnesium ion in yeast and antibiotic production. Magnesium sulfate is an enzyme stabilizer in breweries and in cheese and high-fructose corn production (Giles Chemical, 2008).

Magnesium sulfate has many human medicinal uses (also discussed in Specific Uses of the Substance). Injections of magnesium sulfate can be used as an anticonvulsant to control and prevent seizures in children suffering from acute nephritis. Magnesium sulfate injections can also lower the blood pressure of pregnant females suffering from preeclampsia and prevent pre-term labor. Asthma attacks can be treated

192 with magnesium sulfate. When taken intravenously, magnesium sulfate reduces the resistance within the
193 airways and facilitates normal airflow. Magnesium sulfate can act as a laxative when taken orally and is
194 used to relieve constipation (Adnani, 2010).

195
196 Epsom salt, a common form of magnesium sulfate, is an analgesic soaking agent (Giles Chemical, 2008). It
197 is easily dissolved in water and is used to relieve muscle aches and pains as well as reduce itching and
198 inflammation. It is commonly added to bath water and used by individuals suffering from joint pain
199 (Epsom Salt Council, 2009).

200
201 In veterinary medicine, magnesium sulfate acts as an anticonvulsant, laxative, bronchodilator, electrolyte
202 replacement aid with hypomagnesaemia, and has been used for the treatment of cardiac arrhythmias.
203 Specifically in swine, magnesium sulfate is administered to treat malignant hypothermia (Dodman, 2010).

204
205 In accordance with 7 CFR 205.601, magnesium sulfate may be used in combination with synthetic or non-
206 synthetic crop fertilizers to act as a plant or soil amendment. Epsom salt, a synthetic form of magnesium
207 sulfate, is also used in this way (OMRI, 2010). For plants, magnesium sulfate improves nitrogen and
208 phosphorous uptake, helps seeds to germinate, increases chlorophyll production, and aids in the
209 production of flowering (Epsom Salt Council, 2009). In scenarios where immediate treatment is needed,
210 livestock may be injected intravenously with a solution of magnesium sulfate.

211
212 Magnesium sulfate is added as a source of magnesium to livestock feed, particularly for cattle and sheep.
213 Supplemental magnesium is necessary when livestock are feeding on pastures with high potassium levels;
214 high potassium interferes with the uptake of magnesium by grasses (Epsom Salt Council, 2009). It also
215 may be added to livestock feed for its laxative properties.

216 217 **OFPA, USDA National Organic Program Final Rule:**

218
219 Magnesium sulfate is currently included on the National List of Allowed and Prohibited Substances
220 (hereafter referred to as the National List) as a synthetic substance allowed for use in organic crop
221 production (25 CFR 205.601). Specifically, magnesium sulfate is approved for use as a plant or soil
222 amendment when soil deficiency has been documented. The National List also includes magnesium
223 sulfate as a synthetic substance allowed for use in organic livestock production as a disinfectant, sanitizer,
224 or in medical treatments as applicable (25 CFR 205.603). Non-synthetic sources of magnesium sulfate are
225 allowed as ingredients labeled as “organic” or “made with organic (specified ingredients or food
226 group[s])” (25 CFR 205.605).

227 228 **International:**

229
230 The Canada Food Inspection Agency, Food and Drug Regulations (last modified in 2009), permit the use of
231 magnesium sulfate as a soil amendment and crop nutrient when a soil deficiency has been documented.
232 Acceptable forms of magnesium sulfate include mined kieserite and natural or synthetic Epsom salt.
233 Mined sources of magnesium sulfate are permitted for use in healthcare products and production aids.
234 Non-synthetic sources of magnesium sulfate are classified as a food additive. Sulfates produced using
235 sulfuric acid are prohibited (Canadian General Standards Board, 2009).

236
237 The European Economic Community (EEC) Council Regulation permits the use of non-synthetic
238 magnesium sulfate (kieserite) as a fertilizer and soil conditioner (Annex I, EC No. 889/2008). Non-
239 synthetic magnesium sulfate is also permitted as a feed material of mineral origin (Annex V, EC No.
240 889/2008). Magnesium sulfate is not listed as an approved organic processing agent.

241
242 International Federation of Organic Agriculture Movements (IFOAM) lists magnesium sulfate as a
243 permissible mineral for use as a fertilizer and soil amendment agent (KRAV, 2001). Approved mineral
244 fertilizers can only be applied in their natural form (i.e., without any further processing to increase
245 solubility, with the exception of grinding).

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Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Magnesium sulfate can be produced by recovery of the mineral kieserite (magnesium sulfate monohydrate) or epsomite (magnesium sulfate heptahydrate) from natural sources. Open-pit mines are used to recover mineral forms of magnesium sulfate. These products then undergo a process of dehydration to form anhydrous $MgSO_4$ and subsequent purification (HSDB, 2003). The substance is characterized as synthetic.

The synthetic form of magnesium sulfate is produced by a chemical reaction in which magnesite ore (consisting of $MgCO_3$) or magnesium hydroxide (obtained from seawater) is ignited to produce magnesium oxide. Magnesium oxide is then reacted with sulfuric acid, producing magnesium sulfate. To produce a high grade of purity, the magnesium sulfate is re-crystallized and separated from the parent solution (Kawamura and Rao, 2007).

Evaluation Question #2: Is the substance synthetic? Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).

Magnesium sulfate can be obtained from naturally-occurring sources or manufactured by a chemical process. OMRI-listed products are sold as either solid (crystal) or liquid forms of synthetic magnesium sulfate (OMRI, 2010).

Several mineral forms of magnesium sulfate are recovered from the ground. The magnesium sulfate generally found in nature is in the hydrated form (i.e., contains water). Specifically, magnesium sulfate monohydrate and magnesium sulfate heptahydrate occur in nature as the minerals kieserite and epsomite, respectively (Kawamura and Rao, 2007).

As discussed in the response to Evaluation Question #1, the synthetic form of magnesium sulfate is produced by a chemical reaction in which magnesite ore (containing $MgCO_3$) or magnesium hydroxide ($Mg(OH)_2$) is ignited to produce magnesium oxide. Magnesium oxide is then reacted with sulfuric acid, producing magnesium sulfate. To produce a high grade of purity, the magnesium sulfate is re-crystallized and separated from the parent solution (Kawamura and Rao, 2007).

Evaluation Question #3: Provide a list of non-synthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

Magnesium sulfate can occur naturally as the minerals epsomite ($MgSO_4 \cdot 7H_2O$) and kieserite ($MgSO_4 \cdot H_2O$).

Evaluation Question #4: Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status. What is the technical function of the substance?

Magnesium sulfate is categorized as generally recognized as safe (GRAS) when used as a nutrient or dietary supplement (21 CFR 184.1443).

299 **Evaluation Question #5: Describe whether the primary function/purpose of the petitioned substance is**
300 **a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600**
301 **(b)(4)).**
302

303 This substance is not used as a preservative. It is used in food as a nutrient, coagulator, flavor enhancer,
304 fermentation and malting aid, and an enzyme stabilizer.
305

306 **Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate**
307 **or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)**
308 **and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600**
309 **(b)(4)).**
310

311 The addition of magnesium sulfate to food enhances flavors and textures and is also used for its nutritive
312 value. Magnesium sulfate is added to foods or produced as a nutritional supplement as a source of
313 magnesium. Magnesium, found naturally in some foods, is an essential nutrient for health; it helps with
314 muscle and nerve function, heart rhythm and blood pressure, immune system health, bone strength, blood
315 sugar level regulation, and energy metabolism and protein synthesis. Many adults in the US do not get the
316 recommended amount of magnesium through their diets (NIH, 2009). Magnesium sulfate is approved for
317 use as a flavor enhancer as defined in 170.3(o)(11); a nutrient supplement as defined in 170.3(o)(20); and a
318 processing aid as defined in 170.3(o)(24) of the Code of Federal Regulations for Food and Drugs (21 CFR
319 184.1443).
320

321 **Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or**
322 **feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).**
323

324 Magnesium sulfate supplements contain about 10% magnesium, as opposed to other magnesium
325 supplements (e.g., magnesium oxide), which can contain up to 60% magnesium. According to Morris et al.
326 (1987), magnesium sulfate administered orally has limited bioavailability that varies in individual people.
327 Magnesium sulfate has reduced bioavailability when it is covered in an enteric coating. Bioavailability of
328 magnesium from food sources also varies; absorption from almonds was considered equal to a soluble
329 magnesium acetate supplement (Fine et al., 1991). Based on this information, it appears the addition of
330 magnesium sulfate to food products provides a potential source of magnesium and inorganic sulfate to the
331 body, although the relative absorbed doses will vary based on the route of administration and inter-
332 individual variability.
333

334 The available literature identified only one reaction magnesium sulfate may have with food products. In
335 particular, magnesium compounds may bind with fiber and some fiber-associated compounds with
336 chelating ability (e.g., phytate, polyphenols and organic acids) (Kawamura and Rao, 2007).
337

338 **Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of**
339 **FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600**
340 **(b)(5)).**
341

342 Impurities in magnesium sulfate are reportedly limited to those in the raw material. Potential
343 contaminants include zinc, selenium, arsenic, iron, lead, and chloride; and small concentrations of other
344 acidic and alkaline materials including sulphites and oxides (Kawamura and Rao, 2007). Information on
345 the specific levels of these contaminants in the final product could not be obtained. However, the fact that
346 that magnesium sulfate meets the specifications of the Food Chemicals Codex suggests that levels do not
347 exceed the accepted reference standards for metals and other contaminants in food ingredients.
348

349 **Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the**
350 **petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i)**
351 **and 7 U.S.C. § 6517 (c) (2) (A) (i)).**
352

353 According to the U.S. Geological Survey (USGS), while there are sources of magnesium sulfate in the
354 United States, it is not mined in this country. Therefore, it does not appear that mining-related
355 environmental impacts are applicable in the United States (Kramer, 2001).
356

357 In industrial plants obtaining magnesium from seawater, the water is returned to the ocean after the
358 element is removed. According to the USGS, the effluent causes minimal changes to the ocean
359 environment and none of the discharges from either natural or synthetic magnesia plants has a noxious
360 quality (Kramer, 2001).
361

362 In the presence of water molecules, magnesium sulfate does not undergo hydrolysis, a process in which
363 water molecules split apart existing molecules into two parts (Bodek et al., 1988). This means that
364 magnesium sulfate will remain in the water in its original form.
365

366 **Evaluation Question #10: Describe and summarize any reported effects upon human health from use of**
367 **the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (ii) and 7 U.S.C. § 6518**
368 **(m) (4)).**
369

370 While dietary doses of magnesium generally do not pose health risks, pharmacologic doses may cause
371 adverse effects. Symptoms of hypermagnesemia from high doses of magnesium in supplements or medicines
372 are similar to magnesium deficiency and include mental changes, nausea, abdominal cramping, diarrhea,
373 appetite loss, muscle weakness, difficulty breathing, low blood pressure, and irregular heartbeat (NIH,
374 2009).
375

376 Magnesium sulfate has many human medicinal uses (see Specific Uses of the Substance). It has exhibited
377 laxative properties when ingested orally and is an effective anticonvulsant when administered via
378 injection. Before using magnesium sulfate, it is important to check that renal function is adequate as an
379 accumulation of magnesium ions in body fluids can cause toxic effects, including heart changes, cyanosis,
380 and flaccid paralysis (Gilman et al., 1980).
381

382 Toxic effects have been observed in the neonates of women that have been administered an incorrect dose
383 of magnesium sulfate for conditions such as preeclampsia. Effects include depression of cardiac function
384 and of reflexes, flushing, sweating, hypotension, flaccid paralysis, hypothermia, and circulatory collapse.
385 These symptoms can proceed to fatal respiratory paralysis (McEvoy, 2002). There is also an increased risk
386 in blood loss in mothers administered magnesium sulfate injections (Kynczl-Leisure et al., 1996).
387 Magnesium is known to cause vasodilation, which causes the symptoms of flushing and sweating in low
388 doses and circulatory collapse in higher toxic doses (Micromedex, 2010).
389

390 **Evaluation Information #11: Provide a list of organic agricultural products that could be alternatives for**
391 **the petitioned substance (7 CFR § 205.600 (b)(1)).**
392

393 No organic agricultural products are available as alternatives for the organic handling/processing uses of
394 magnesium sulfate allowed by the National List. The information provided below describes non-
395 agricultural (nonorganic) products that are potential alternative for these uses.
396

397 A number of alternative coagulants can be used in tofu production. Calcium citrate, calcium chloride
398 (from seawater), calcium sulfate (the mined form; also known as gypsum powder), and glucono-delta-
399 lactone (GDL; production with bromine water prohibited) all appear on the National List.
400

401 Research indicates that coagulants of different types will affect the texture, chewiness, color, and other
402 properties of the final tofu product. Although the property preferences may dictate the coagulant chosen,
403 some advocate that calcium chloride is the best option in American tofu because it has high calcium
404 content, the fastest reactant coagulation time, an excellent flavor, and it is generally recognized as safe

405 (GRAS). Calcium sulfate, another well-performing coagulant, is a popular tofu coagulant in Japan. It is
406 one of the least expensive coagulants in the U.S., producing the cheapest tofu. It is obtained from mining
407 and is not chemically processed or refined. Furthermore, it contains less than 10 ppm of heavy metal
408 contaminants and is generally recognized as safe (Shurtleff and Aoyagi, 2000). GDL is an acid coagulant
409 rather than a salt, and thus is best suited for soft, silken tofu. It is widely used for other applications in the
410 food industry. However, GDL is not on the GRAS list (Shurtleff and Aoyagi, 2000).

411
412 Two magnesium supplements appear on the National List: magnesium chloride and magnesium
413 carbonate. Magnesium hydroxide, magnesium oxide, and magnesium lactate also are used as magnesium
414 supplements, but these substances are not on the National List.

415
416 It is unclear if any of the dietary supplements of magnesium are more effective than magnesium sulfate.
417 The only information obtained regarding the comparison of magnesium supplements (NIH, 2009) did not
418 include magnesium sulfate supplements. However, research (National Heart, Lung, and Blood Institute, as
419 cited in NIH, 2009) has indicated that magnesium chloride performs superiorly (higher absorption and
420 bioavailability) to magnesium oxide and magnesium lactate (NIH, 2009).

421
422 Calcium sulfate can be used in beer processing as an alternative to magnesium sulfate to increase water
423 hardness (Hardwick, 1995). According to one source (Goldammer, 2008), calcium sulfate is more effective
424 at reducing pH than magnesium sulfate. Calcium sulfate (mined) is on the National List.

425
426 While many other flavor enhancers are on the National List, it is unclear if there any of these substances are
427 suitable alternatives to magnesium sulfate.

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