Magnesium Sulfate

Livestock

Identification of Petitioned Substance

Chemical Names:
Magnesium sulfate

Other Name:
Epsom salt
Bitter salts
Magnesium sulfate anhydrous
Sulfuric acid, magnesium salt

Trade Names:
None

CAS Numbers:
7487-88-9 (magnesium sulfate anhydrous)
18939-43-0 (sulfuric acid magnesium salt)
14168-73-1 (monohydrate)
10034-99-8 (heptahydrate)

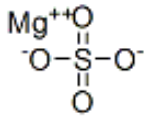
Other Codes:
050503 (USEPA PC Code [U.S. EPA 2010])
231-298-2 (EINECS)

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 ($MgSO_4xH_2O$), 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 (i.e., monohydrate, heptahydrate, and anhydrous), unless specifically noted.

Table 1. Physicochemical Properties of Magnesium Sulfate

Physical or Chemical Property	Value[a]
Physical state	Solid
Appearance	White crystalline powder or needle-like colorless crystals
Odor	Odorless
Taste	Bitter, salty, cooling
Molecular weight (g/mol)	120.36 (anhydrous); 138.38 (monohydrate); 246.47 (heptahydrate)
Boiling point	NA
Melting point	2,055°F or 1,124°C
Solubility in water (g/L)	anhydrous: 269 (0°C); 255 (20°C) heptahydrate: 710 (20°C)
Vapor pressure (mm Hg)	< 0.01 (20°C)
Density (g/cm^3)	2.66 (anhydrous); 2.445 (monohydrate); 1.68 (heptahydrate)

Source: Chemical Book, 2010

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.

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

Magnesium sulfate has many human medicinal uses. 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 help lower the blood pressure of pregnant females suffering from preeclampsia and prevent pre-term labor. Asthma attacks can be treated with magnesium sulfate. When taken intravenously, it reduces the resistance within the airways and facilitates normal airflow. Magnesium sulfate can act as a laxative when taken orally and is used to relieve constipation (Adnani, 2010).

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

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

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

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

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

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

Approved Legal Uses of the Substance:

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

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

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

The FDA allows magnesium sulfate to be prescribed legally by veterinarians as an extra-label drug. An extra-label drug is defined as the veterinary use of a drug in a manner for which it was not approved.[2] No

[1]There 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).

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

specific veterinary formulations of magnesium sulfate are available. The National List allows the addition of magnesium sulfate to animal feed according to 7 CFR 205.603. Intravenous injection is used when treatment is required immediately; however, adding magnesium sulfate to animal feed offers an alternative in less urgent situations.

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

Action of the Substance:

Magnesium is necessary for all reactions in the body that require energy. As the second most abundant intracellular cation, magnesium acts as an activator or catalyst in enzymatic reactions. Magnesium forms a complex with adenosine triphosphate (ATP), a molecule that produces and transfers energy within cells in the body. Bone and skeletal muscle contain the highest levels of magnesium of any organ system. Low levels of magnesium are also stored in the blood. In the blood, magnesium is in free form or is bound to serum proteins (mostly albumin), citrates, phosphates, or other compounds (Cornell University, 2006).

A balance between intestinal absorption and renal excretion is important in preventing levels of magnesium from becoming too high in the body. Serum magnesium levels are controlled by the kidneys, and the glomerulus within the kidney filters 70–80% of plasma magnesium. Reabsorption of magnesium depends on many factors, including hormone levels (e.g., parathyroid hormone [PTH], antidiuretic hormone [ADH], calcitonin, thyroxine), serum levels of calcium and magnesium, and an individual's dietary content. Magnesium is also secreted in the saliva of ruminants and in the sweat of horses (Cornell University, 2006).

Hypomagnesaemia is the result of an insufficient intake of magnesium. Clinical signs include convulsions and muscular spasms, and death may occur due to respiratory failure. In order to increase the uptake of magnesium, livestock feed can be supplemented with magnesium sulfate. In scenarios where immediate treatment is needed, livestock can be injected intravenously with a solution of magnesium sulfate (Organic Livestock Research Group, 2000).

Combinations of the Substance:

Dairy cows and other livestock suffering from hypocalcaemia (or milk fever; characterized by reduced levels of calcium in the blood) are usually deficient in calcium as well as magnesium. Combined treatments of calcium borogluconate and magnesium sulfate have been observed to be effective (Organic Livestock Research Group, 2000).

Epsom salt, a common form of magnesium sulfate, is easily dissolved in water and is used to relieve muscle aches and pains as well as to reduce itching and inflammation. For humans, it is commonly added to bathwater and used by individuals suffering from joint pain (Epsom Salt Council, 2009). Epsom salt can be used to treat inflammation and abscesses in livestock as well (Clarkson, 2007). Ingestion of a large volume of water containing magnesium sulfate is not recommended as magnesium sulfate is known to have laxative effects (Epsom Salt Council, 2009).

Magnesium sulfate is added as a source of magnesium to livestock feed when levels of magnesium are low in pastures. Dynamate® is a synthetic livestock feed supplement manufactured by the Mosaic Company as a combination of potassium and magnesium sulfates. Sulfur, potassium, and magnesium are considered to be dietary essentials for livestock. The Mosaic Company indicates that potassium will promote a more efficient uptake of magnesium when used in combination in livestock feed (Mosaic, 2009).

As discussed above (see **Specific Uses of the Substance**), a magnesium lick can be provided for livestock to increase the amount of magnesium in the diet. Because magnesium sulfate is not palatable, molasses is added to the magnesium sulfate—generally 80 percent molasses and 20 percent magnesium sulfate—to encourage cattle's use (Harris, 2005).

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

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

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

In accordance with 7 CFR 205.601, magnesium sulfate may be used in combination with synthetic or nonsynthetic crop fertilizers to act as a plant or soil amendment. Epsom salt, a synthetic form of magnesium sulfate, is also used in this manner (OMRI, 2010a). For plants, magnesium sulfate improves nitrogen and phosphorous uptake, helps seeds to germinate, increases chlorophyll production, and aids in the production of flowering (Epsom Salt Council, 2009).

Magnesium sulfate is added as a source of magnesium to livestock feed, particularly for cattle and sheep. Supplemental magnesium is necessary when livestock are feeding on pastures with high potassium levels; high potassium interferes with the uptake of magnesium by grasses (Epsom Salt Council, 2009). It also may be added to livestock feed for its laxative properties. In scenarios where immediate treatment is needed, livestock may be injected intravenously with a solution of magnesium sulfate.

The Organic Materials Review Institute (OMRI) has identified 14 products that contain magnesium sulfate as an active ingredient for use in organic production and processing. Currently manufactured products are sold as either solid (crystal) or liquid forms of magnesium sulfate. Most of the products listed contain synthetic forms of magnesium sulfate that are used in crop fertilizers and soil amendments. Only one product containing a mixture of magnesium sulfate and potassium sulfate (Dynamate®) is classified as a livestock feed ingredient (OMRI, 2010a).

OFPA, USDA National Organic Program Final Rule:

The National List includes magnesium sulfate as a synthetic substance allowed for use in organic livestock production as a disinfectant, sanitizer, or in medical treatments as applicable (7 CFR 205.603). Magnesium sulfate is also currently included on the National List as a synthetic substance allowed for use in organic crop production (7 CFR 205.601). Specifically,, magnesium sulfate is approved for use as a plant or soil amendment when soil deficiency has been documented. Nonsynthetic sources of magnesium sulfate are allowed as ingredients labeled as "organic" or "made with organic (specified ingredients or food group[s])" (7 CFR 205.605).

International

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

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

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

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

Evaluation Question #1: What category in OFPA does this substance fall under: (A) Does the substance contain an active ingredient in any of the following categories: copper and sulfur compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers? (B) Is the substance a synthetic inert ingredient that is not classified by the EPA as inerts of toxicological concern (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert ingredient which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part 180?

(A). Magnesium sulfate is considered a mineral.

(B). Some forms of magnesium sulfate can be considered as synthetic and as inert ingredients that are exempt from a requirement of tolerance (40 CFR 180.1001[c]).

Evaluation Question #2: 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 followed by dehydration to form anhydrous $MgSO_4$ (HSDB, 2003)..

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 #3: 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, 2010a).

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 #2**, 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 #4: Describe the persistence or concentration of the petitioned substance and/or its by-products in the environment (7 U.S.C. § 6518 (m) (2)).

Magnesium sulfate is discharged into water from various industrial sources, including mills, smelters, and mines. Weathering reactions (i.e., leaching) can also introduce magnesium sulfate to aquatic environments. Magnesium sulfate is highly soluble in water and is not expected to volatize or to undergo hydrolysis. In freshwater and saltwater, the magnesium sulfate complex acts as the primary source of total magnesium. An important removal process for magnesium sulfate in water is the ion exchange that occurs with calcium present in sediments. The uptake of magnesium by water is significant and results in sulfate reduction, meaning that aquatic contamination is unlikely (Bodek et al., 1988). One estimated dissociation constant (K_d) for magnesium sorption in river sediments is 1.3 m^3/kg, which indicates that magnesium ions are weakly sorbed on sediments. In seawater, high temperature areas act as sinks for magnesium (Pettine et al., 1994). Magnesium sulfate is not expected to be persistent in aquatic systems or bioconcentrate in the food chain (Pestell, 2007). Magnesium sulfate is considered as highly soluble and is not likely to be harmful to the aquatic environment because it is highly mobile.

In soil, weathering removes magnesium sulfate by increasing its mobility through the soil. Weathering increases the solubility of magnesium sulfate. In acidic soils, high solubility prevents the persistence of magnesium minerals. In moist soils, volatilization of magnesium sulfate is not of concern because the compound is considered ionic and will not volatilize (Bodek et al., 1988).

In the atmosphere, magnesium sulfate will exist in the particulate phase. Removal from the ambient atmosphere is predicted to occur by wet and dry deposition (Bodek et al., 1988).

Evaluation Question #5: Describe the toxicity and mode of action of the substance and of its breakdown products and any contaminants. Describe the persistence and areas of concentration in the environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)).

Magnesium sulfate contains magnesium, which in mammals is required for many neurochemical transmissions, enzymatic reactions, and muscular excitability. The substance has a depressant effect on the central nervous system. Convulsions are controlled by administering magnesium sulfate, which blocks neuromuscular transmission and also decreases the amount of acetylcholine released by the motor nerve impulse (HOSPIRA, 2004).

When the level of magnesium in the blood plasma rises above threshold levels (i.e., 4 mEq/liter) and approaches 10 mEq/liter, the deep tendon reflexes are decreased and eventually disappear. Heart block can occur as well as respiratory paralysis (HOSPIRA, 2004).

Vasodilatation is produced when magnesium levels approach 10 mEq/liter. Sweating and flushing are symptoms of a lower dose of magnesium, and larger doses can cause the blood pressure to lower (HOSPIRA, 2004).

Before using magnesium sulfate, it is important to check that an individual's renal function is adequate as an accumulation of magnesium ions in body fluids can cause toxic effects, including heart changes, cyanosis, and flaccid paralysis (Gilman and Goodman, 1980).

Toxic effects have been observed in the neonates of women that have been administered an incorrect dose of magnesium sulfate for conditions such as preeclampsia. Effects include depression of cardiac function and of reflexes, flushing, sweating, hypotension, flaccid paralysis, hypothermia, and circulatory collapse. These symptoms can proceed to fatal respiratory paralysis (McEvoy, 2002). There is also an increased risk in blood loss in mothers administered magnesium sulfate injections (Kynczl-Leisure and Cibilis, 1996).

Evaluation Question #6: Describe any environmental contamination that could result from the petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)).

Both natural and synthetic forms of magnesium sulfate are used in crop production. If used as a foliar feed as directed by the manufacturer, environmental contamination is unlikely. Mining and additional manufacturing operations can produce runoff materials containing magnesium sulfate. However, magnesium sulfate is considered highly soluble and will not volatilize (Bodek et al., 1988). In the presence of water molecules, magnesium sulfate does not undergo hydrolysis, a process in which water molecules split apart existing molecules into two parts (Bodek et al., 1988). This means that magnesium sulfate will remain in the water in its original form.

In magnesia plants, based on seawater, the water used in the plant is returned to the ocean after the magnesia is removed. Due to recent technological innovations, the turbidity of the effluent has been decreased, which will result in minimal changes to the ocean environment. None of the discharges from either natural or synthetic magnesia plants has a noxious quality, and their appearance can be made acceptable with modern treatment methods (Kramer, 2002).

Evaluation Question #7: Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. Describe any environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)).

Dietary supplements containing magnesium sulfate are added to livestock feed as a source of magnesium when levels are low in pastures. Dynamate® is a synthetic livestock feed supplement manufactured by the Mosaic Company as a combination of potassium and magnesium sulfates, providing three essential nutrients to livestock—potassium, magnesium, and sulfur. The Mosaic Company indicates that potassium

will promote a more efficient uptake of magnesium when used in combination in livestock feed (Mosaic, 2009).

Magnesium and potassium interact with one another at a cellular level within the body. Magnesium is necessary for proper function of the sodium-potassium pump, a function that is essential for a cell's electrolyte homeostasis (Schroll, 2002; Bodek et al., 1988). The sodium-potassium pump provides active transport of potassium ions into and sodium ions out of cells. It occurs in all human cells, but is especially important in nerve and muscle cells. If a magnesium deficiency occurs, the function of the sodium-potassium pump could be impaired (Schroll, 2002).

Magnesium sulfate can act as a laxative when taken orally, so levels must be monitored carefully to prevent diarrhea and dehydration (Lenntech, Undated). Other symptoms of excessive magnesium intake include sluggish appearance and reduced digestibility of dry matter. In general, magnesium toxicity is not a problem with concentrations up to 0.4 percent being tolerated in beef cattle (Parish and Rhinehart, 2008).

Evaluation Question #8: Describe any effects of the petitioned substance on biological or chemical interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt index and solubility of the soil) crops, and livestock (7 U.S.C. § 6518 (m) (5)).

Magnesium sulfate can act as a laxative when taken orally. Magnesium will be excreted by the kidney and may be present in feces if not already absorbed by the body (Mayo Clinic, 2011). In horses, a lot of magnesium is lost by sweating; excessive magnesium is excreted in the urine (Clarkson, 2007). Excess sulfur is excreted in the feces and urine (Lewis, 2005).

It can be assumed that livestock excrements will come in contact with the ground and enter the soil system. Because magnesium sulfate is a magnesium salt of sulfuric acid, it is a neutral salt. Aqueous solutions of magnesium sulfate are considered neutral or only very slightly acidic. Therefore, this addition of magnesium sulfate to soil is expected to have little or no effect on soil pH and microorganism survival (Brennan, 2010).

Evaluation Question #9: Discuss and summarize findings on whether the petitioned substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

If used in accordance with 7 CFR 205.603, it is unlikely that magnesium sulfate will cause harm to the environment.

Magnesium sulfate exists in the atmosphere as a particulate as is not likely to be released following most manufacturing processes. The substance is removed from the atmosphere by wet and dry deposition.

The physicochemical properties of magnesium sulfate make it an unlikely cause of contamination to the aquatic environment. Magnesium sulfate is considered highly soluble in water and also very mobile.

Magnesium is not likely to volatize in soil due to its ionic properties. Magnesium sulfate also undergoes ion exchange with calcium, which allows for its removal in sediments. The uptake of magnesium by rivers is significant and results in sulfate reduction, and its estimated K_d value for magnesium sorption in river sediments (1.3 m^3/kg) indicates that magnesium ions are weakly sorbed on sediments.

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

Magnesium sulfate has many human medicinal uses (see **Specific Uses of the Substance**). It is has exhibited laxative properties when ingested orally and is an effective anticonvulsant when administered via injection. Before using magnesium sulfate, it is important to check that an individual's renal function is adequate as an accumulation of magnesium ions in body fluids can cause toxic effects, including heart

changes, cyanosis, and flaccid paralysis (Gilman and Goodman, 1980). If humans intake too much magnesium sulfate and the level of magnesium in the blood plasma rises above the threshold level (i.e., 4 mEq/liter) and approaches 10 mEq/liter, the deep tendon reflexes are decreased and eventually disappear. Heart block can occur as well as respiratory paralysis (HOSPIRA, 2004).

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

Evaluation Question #11: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

An alternative source of magnesium that may be added to livestock feed is magnesium oxide. Magnesium oxide appears on the EPA's List 4A Inerts and is permitted for use in pesticide products (and can be used in FIFRA Section 25[b] products applied to food use and/or nonfood use sites) (U.S. EPA, 2004; U.S. EPA, 2010). However, only synthetic magnesium can be obtained from magnesium oxide for use in livestock feed ingredients and livestock healthcare (OMRI, 2010b) and, therefore, would not be considered a natural, nonsynthetic alternative.

Dolomite is a nonsynthetic form of magnesium that can be added as a supplement to the diet of livestock. Dolomite can be a less desirable alternative to magnesium sulfate because it is considered to have low bioavailability (Clarkson, 2007).

The following product is available for use as a nutritional additive in livestock feed and contains nonsynthetic dolomite as the active ingredient (OMRI, 2010c):

- Winnemucca Mud: 415 Wellington Street, Winnemucca, NV 89445

Evaluation Question #12: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

Grasses that are higher in magnesium content are being selectively bred for future planting (Organic Livestock Research Group, 2000). These grasses show potential to reduce the incidence of magnesium deficiency. An assessment of the efficacy of a cultivar of Italian ryegrass (Bb 2067) in impacting the incidence of magnesium deficiency in lactating ewes revealed that the grass was effective in controlling hypomagnesaemia (Moseley and Baker, 1991).

When a pasture has been identified as magnesium deficient, magnesium supplies must be replenished with approved soil amendments. Hay (which stimulates salivation and rumination) can also be added to the diet to aid in magnesium absorption and prevent excessive build-up of ammonia in the rumen (Organic Livestock Research Group, 2000).

Adult cattle that have been exposed to cold, wet, and windy weather have been observed to have reduced levels of serum magnesium. This phenomenon may be due to cattle's resistance to eat when exposed to adverse weather conditions. Cold weather stress can also increase the frequency of urinary excretion, thereby decreasing levels of magnesium in the body (Organic Livestock Research Group, 2000). In addition, stress and excitement (likely to occur during inclement weather) causes the release of adrenaline which can trigger the onset of hypomagnesaemia (Champness, 2007). Based on these factors, it is important that livestock have access to shelter to protect them from adverse weather conditions (and decrease the likelihood of hypomagnesaemia). A study conducted with cattle in Ontario, Canada

concluded that there was a significant relationship between hypomagnesaemia and lack of shelter. A lower incidence of hypomagnesaemia was reported in cattle that were kept in protective housing (Hidiroglou et al., 1981).

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