Executive Summary

Magnesium hydroxide was petitioned for use in organic livestock production. Magnesium itself does not occur naturally but in the form of the mineral brucite. Magnesium hydroxide is used as an antacid for temporary relief of an upset stomach and as a laxative for short-term relief of constipation. Magnesium hydroxide is also used as a flame retardant and smoke depressant. Organic farmers historically use Rumalax or Magnalax, for cattle, particularly, with digestive problems. Reusable solids (also called biosolids or sludge) are lime materials, particularly magnesium hydroxide, that are used as a cheap alternative to expensive chemical fertilizers.

The FDA first deemed magnesium hydroxide safe on April 5, 1985 (50 FR 13559). It was later amended on January 5, 1999 (64 FR 405). The Miscellaneous Food Additives Regulations, 1995, has deemed magnesium hydroxide suitable for general food use. The EPA has confirmed that magnesium hydroxide is not found in ground water supplies. Therefore, unless prodigious natural deposits of magnesium hydroxide are found in the actual soil, the exposure of such a compound will not be detrimental and will not affect systems of sustainable agriculture. Magnesium hydroxide and magnesium oxide are currently under review by the USDA. There is no official ruling at this time and are petitioned to be reviewed in September 2002.

The NOP says at section 205.238 that "the producer of an organic livestock operation must not: (2) administer any animal drub, other than vaccinations, in the absence of illness. Organic farmers are not allowed to give unnecessary medicines to livestock. As in section 205.600 of the NOP final rule, "any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria: (2) the substance's manufacture, used and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling." Magnesium hydroxide/oxide is not explicitly listed in section 205.603 as a synthetic substance allowed for use in organic livestock production nor is it listed in section 205.604 as a prohibited substance.

Summary of TAP Reviewer's Analyses¹

Synthetic/	Allow without restrictions?	Allow only with
Nonsynthetic		restrictions? (See
		Reviewers' comments for
		restrictions)
Synthetic(0)	Yes (1)	Yes (2)
Nonsynthetic (3)	No (2)	No (1)

Identification

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¹ This Technical Advisory Panel (TAP) review is based on the information available as of the date of this review. This review addresses the requirements of the Organic Foods Production Act to the best of the investigator's ability, and has been reviewed by experts on the TAP. The substance is evaluated against the criteria found in section 2119(M) of the OFPA [7 USC 6517(m)]. The information and advice presented to the NOSB is based on the technical evaluation against that criteria, and does not incorporate commercial availability, socio-economic impact, or other factors that the NOSB and the USDA may want to consider in making decisions.

Chemical names:

Magnesium Oxide/Magnesium Hydroxide

Chemical formula: Mg(OH)2-Magnesium Hydroxide

MgO- Magnesium Oxide

Molecular Weight: 58.32 (Magnesium Hydroxide)

40.32 (Magnesium Oxide)

CAS No: 1309-42-8 (Magnesium Hydroxide) 1309-48-4 (Magnesium Oxide)

Other Names:

Brucite; Nemalite; Milk of magnesia (MOM); magnesium hydrate; antacid; Magnalax; Rumalax

Characterization

Composition:

Properties

Magnesium Hydroxide

Melting point: 350 °C Density (g cm-3): 2.36 Water solubility: negligible

Color is white or colorless with shades of gray, blue and green. **Luster** is vitreous or waxy; cleavage surfaces have a pearly luster. **Transparency** Crystals are translucent and rarely transparent.

Crystal System is trigonal; bar 3 2/m

Crystal Habit is typically in flattened tabular crystals with rare rhombohedral terminations. Also found in lamellar and fibrous aggregates and as foliated masses.

Cleavage is perfect in one direction, basal.

Fracture is uneven. **Hardness** is 2 - 2.5

Specific Gravity is 2.4 (slightly below average)

Streak is white.

Other Characteristics: cleavage flakes and fibers are flexible but not elastic.²

Magnesium Oxide

Appearance: Bulky white powder.

Odor: Odorless.

Solubility: Insoluble in water. **Specific Gravity:** 3.58 @ 25C (77F)

pH: 10.3

% Volatiles by volume @ 21C (70F): 0

Boiling Point: 3600C (6512F) **Melting Point:** 2800C (5072F)

Vapor Density (**Air=1**): No information found. **Vapor Pressure** (**mm Hg**): No information found.

 $^{^2 \}quad Information \ was \ referenced \ from \ \underline{http://physchem.ox.ac.uk/MSDS/MA/magnesium_hydroxide.htm}$

Evaporation Rate (BuAc=1):

No information found.

Color is colorless, white, gray, yellow to brown or black

Luster is vitreous to adamantine.

Transparency crystals are transparent to translucent.

Crystal System is isometric; 4/m bar 3 2/m

Crystal Habits include the typical cubes and octahedrons as well as rounded indistinct grains.

Cleavage is perfect in three directions forming cubes.

Hardness is 5.5

Specific Gravity is 3.6 (slightly above average)

Streak is white.

Other Characteristics: Crystals may dull in humid air ³

How Made:

Magnesium hydroxide (Brucite) is found naturally in serpentine, chlorite or dolomitic schists, or in crystalline limestones as an alteration product of periclase (magnesium oxide). It is prepared by mixing sodium hydroxide with a water-soluble magnesium salt. It is also formed by the hydration of reactive magnesium oxide. Either case produces a white precipitate. ⁴ Four companies in California, Delaware, and Florida, three companies in Michigan, and two companies in Utah recovered magnesium oxide and similar compounds from seawater. Seawater extraction and natural brines account for 70% of the U.S. magnesium production. Worldwide, there are several million tons of brucite resources. ⁵

Specific Uses:

Magnesium hydroxide is used as an antacid for temporary relief of an upset stomach and as a laxative for short-term relief of constipation. Magnesium hydroxide is used as a flame retardant and smoke depressant for temperatures exceeding 400 degrees Fahrenheit. Magnesium hydroxide is also a general food additive used as a color-retention agent, drying agent, pH control agent, or processing aid. Magnesium hydroxide is also used as a fertilizer (in the form of lime) as a substitute for more expensive chemical fertilizers.

Non-hazardous for air, sea and road freight Avoid contact with the eyes May cause slight skin irritation

Action:

Magnesium hydroxide is mainly used in antacid or laxative tablets. Antacid tablets are used to relieve minor stomach pain caused by indigestion. Antacids are taken orally to relieve heartburn, acid indigestion, and hyperacidity. Antacids are occasionally taken with simethicone, which may relieve the symptoms of flatulence. Antacids taken alone or in conjunction with simethicone can also help relieve stomach or duodenal ulcers. A laxative effect will occur with greater doses of magnesium hydroxide, those exceeding doses for an antacid effect. Magnesium hydroxide is given orally as gel, tablets or syrup. Aluminum Hydroxide tab 0.84 gm; suspension 0.6g/10ml give sixth to eighth hourly. Magnesium Hydroxide suspension; 0.4 gm / 5 ml given every 6 to 8 hrs. Antacids do have the potential of causing problems during pregnancy. Sodium filled antacids have been linked with edema. Those on special low sodium diets should

 $^{^3 \} Information \ was \ referenced \ from \ \underline{http://mineral.galleries.com/minerals/oxides/periclas/periclas.htm}$

 $^{{\}small 4~Information~was~referenced~from~http://mineral.} \underline{galleries.com/minerals/oxides/brucite/brucite.htm}$

 $^{^{5} \ \}text{Information was referenced from } \underline{\text{http://minerals.usgs.gov/minerals/pubs/commodity/magnesium/401300.pdf}}$

take extra precautions because some antacids may have very high sodium contents. Antacids have also been linked to renal disease due to the high serum levels of aluminum, calcium, or magnesium caused by extensive use. It is possible for persons to experience allergic reactions to antacids. Antacids should not be used in small children nor should they be used extensively by expecting mothers. It is possible for aluminum, calcium or magnesium to be carried to the baby through breast milk. Those experiencing renal disease, persons with bone disorders, or Alzheimer's disease, should not use aluminum containing antacids. Magnesium hydroxide, or better known by farmers as Rumalax or Magnalax, is used for livestock with digestive problems. Dosage size of Rumalax should be administered based upon animal condition and size. The normal dosage is anywhere from two to four boluses. Humans consume antacids orally just as Rumalax is administered orally to cattle. A lubricant of some kind should be used before administering this drug to cattle or other such livestock.

Note- Three boluses are equivalent to about one quart of Milk of Magnesia.

Combinations:

Combination drugs of magnesium hydroxide include: 1) calcium rich Rolaids, 2) Di-Gel tablets, 3) Maalox, 4) Mylanta, and 5) Tempo tablets. Magnesium hydroxide may reduce absorption of dietary iron. Those with potassium deficiency problems or those with potential deficiency problems may experience low serum potassium levels in the body if taking magnesium hydroxide. In this case, potassium supplements should be taken while consuming antacids. Antacids have various drug interactions. They may reduce the potency of Fluoroquinolones and Cellulose Sodium Phosphate. Magnesium antacids may prevent either drug from acting effectively. Antacids should not be taken within one hour of taking Cellulose Sodium Phosphate. Aluminum containing antacids may react with Isoniazid and should not be taken within one hour of consumption. Antacids may decrease the effects of ketoconazole or methenamine; therefore these drugs should be taken 3 hours before antacid consumption. Antacids should not be taken within three or four hours of tetracylines (consumed orally as well). There are no known food interactions with magnesium hydroxide or more commonly with MOM. One should not use antacids or laxatives if they are experiencing lower abdominal pains or appendicitis. Persons with liver or kidney disease, bone disorders, hemorrhoids or intestinal bleeding, and expecting women should consult a doctor before taking either antacids or laxatives.

Status

Historic Use by Organic Farmers:

Organic farmers historically use Rumalax or Magnalax, for cattle, particularly, with digestive problems. Reusable solids (also called biosolids or sludge) are lime materials, particularly magnesium hydroxide, that are used as a cheap alternative to expensive chemical fertilizers. Farmers use biosolids to improve soil and crop quality. These biosolids are made with alkaline chemicals including potassium, calcium and magnesium. Magnesium is the most expensive chemical so it is used the most infrequently. Lime, a form of magnesium hydroxide, is used to prevent and cure sickness in livestock. Lime is widely used by farmers in agriculture. Effective sludge or lime materials should be formulated to reach and sustain a pH over 12. The longer the sludge reaction time (the longer it sits at pH greater than 12) the more lethal it becomes to bacteria; the easier it will be to fight off infection. Farmers use the sludge to kill off bacteria including Salmonella as well as the Poliovirus and Parvovirus. Magnesium is a critical nutrient for grain

Information was referenced from http://www.healthwell.com/healthnotes/Drug/Magnesium_Hydroxide
Information was referenced from http://shop.store.yahoo.com/animalmedicstore/rumbolbyag50.html

 $^{^{8} \} Information \ was \ referenced \ from \ \underline{http://www.healthwell.com/healthnotes/Drug/Magnesium_Hydroxide}$

⁹ Information was referenced from http://www.iwaponline.com/wio/2002/02/pdf/wio200202013.pdf

production. A good indicator if crops are experiencing a magnesium deficiency is leaf curling and mild yellowing, also known as intervenial chlorosis. Dolomitic lime (containing both calcium and magnesium) and magnesium oxide are common magnesium fertilizers. Soil testing and tissue analysis is carried out to see at what rate fertilizer should be applied, if needed at all. If no soil test data is available, 20-30 lb Mg/a is an acceptable amount. Farmers most commonly use dolomitic lime for fertilizing needs because is it generally safe. ¹⁰

Organic Materials and Practices List

603-025-0300

Livestock Production Materials and Practices

No supplements to regular feed shall be used in livestock production for a complying product other than:

- (e) Dolomite
- (j) Minerals, naturally occurring and synthetic. Bone meal is prohibited for use in animal feed;

Organic farmers may use magnesium in the dolomitic form for the production of livestock. Organic farmers use Rumalax to aid livestock with digestive problems. 11

OFPA, USDA Final Rule:

The NOP states in section 205.238 that "the producer of an organic livestock operation must not: (2) administer any animal drub, other than vaccinations, in the absence of illness. Organic farmers are not allowed to give unnecessary medicines to livestock. As in section 205.600 of the NOP final rule, "any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria: (2) the substance's manufacture, used and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling." Magnesium hydroxide/oxide is not explicitly listed in section 205.603 as a synthetic substance allowed for use in organic livestock production nor is it listed in section 205.604 as a prohibited substance.

OFPA, 1990, states:

6508 PROHIBITED CROP PRODUCTION PRACTICES AND MATERIALS

- (b) **Soil Amendments**. For a farm to be certified under this chapter, producers on such farm shall not
- (1) use any fertilizers containing synthetic ingredients or any commercially blended fertilizers containing materials prohibited under this chapter or under the applicable State organic certification program; ¹³

¹⁰ Information was referenced from http://www.ces.ncsu.edu/resources/crops/ag580/limepho.htm

¹¹ Information was referenced from http://www.efn.org/~forestry/standards.html

¹² This information was referenced from http://www.ams.usda.gov/nop/regtext.htm

¹³ Information was referenced from http://www.ams.usda.gov/nop/orgact.htm

This section of the Organic Farmers Protection Act of 1990 says that certified farmers are prohibited from using any fertilizers that contain synthetic materials or any commercially blended fertilizers. Magnesium hydroxide occurs naturally and is better known as brucite in its natural state. The use of magnesium hydroxide in fertilizers does not violate this act and is deemed safe for organic farming use.

Magnesium hydroxide and magnesium oxide are currently under review by the USDA. There is no official ruling at this time and are petitioned to be reviewed in September 2002. ¹⁴

Regulatory: EPA/NIEHS/Other Sources

FDA:

On March 27, 1991, the FDA issued a report recalling 50 Magnesium Oxide Bolus Jars for use in cattle. The recall was attributed to deviations in good manufacturing practices. The distribution was nationwide. The FDA first deemed magnesium hydroxide safe on April 5, 1985 (50 FR 13559). It was later amended on January 5, 1999 (64 FR 405). The Miscellaneous Food Additives Regulations, 1995, has deemed magnesium hydroxide suitable for general food use. As found in part 184, the FDA has deemed magnesium hydroxide safe as of April 1, 2001. The code of federal regulations, title 21, which concerns food and drugs states:

Part 184-Direct food substances affirmed as generally recognized as safe

Sec. 184.1428 Magnesium hydroxide.

Sec. 184.1431 Magnesium oxide.

Sub Part B-Requirements for specific standardized cereal flours and related products

Sec. 155.170 Canned peas. (magnesium oxide, magnesium hydroxide, magnesium carbonate)

Part 582-Substances generally recognized as safe

Sub Part B-General purpose food additives

Sec. 582.1428 Magnesium hydroxide.

Sec. 582.1431 Magnesium oxide. 17

"November 12, 1996

FDA PUBLISHES FINAL RULE ON EXTRALABEL DRUG USE IN ANIMALS

In the November 7, 1996 *Federal Register*, FDA published a final rule to allow veterinarians to prescribe extralabel uses of certain approved animal drugs and approved human drugs for animals under certain conditions. This action implements the Animal Drug Use Clarification Act of 1994 (AMDUCA). This

17 Information was referenced from

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/ShowCFR.cfm?FR=184.1428

 $^{^{14} \} Information \ was \ referenced \ from \ \underline{www.ams.usda.gov/nop/MaterialsMay2002}$

¹⁵ Information was referenced from http://www.fda.gov/bbs/topics/ENFORCE/ENF00023.html

¹⁶ Information was referenced from http://www.hmso.gov.uk/si/si1995/Uksi 19953187 en 3.htm

regulation provides veterinarians with greater flexibility in the use of approved drugs in animals. These regulations put AMDUCA into effect on December 9, 1996.

The notice of proposed rulemaking published in the *Federal Register* on May 17, 1996. FDA received and considered approximately 110 comments in preparing the final rule.

Prior to the enactment of AMDUCA, the Federal Food, Drug, and Cosmetic Act (the Act) required users of approved new animal drug products to follow the exact directions on the labeling of the drug. This extralabel use restriction precluded use of an approved drug in species or for indications (disease or other conditions) not listed in the labeling, use of an approved drug at dosage levels higher than those stated on the label, and other extralabel purposes. In addition, the Act did not provide for the use of human drugs for treating animals.

Because of AMDUCA, the Federal Food, Drug, and Cosmetic Act will now permit veterinarians, like physicians, to prescribe extralabel uses of approved drugs for their patients. Although certain restrictions have been placed on veterinarians prescribing animal and human drugs in an extralabel manner, these restrictions generally apply only to the use of drugs extralabelly in food-producing animals. The key constraints are that any extralabel use must not result in violative residues in food-producing animals, the use must be by or on the order of a veterinarian within the context of a veterinarian-client-patient relationship, and the use must be in conformance with the new regulations.

AMDUCA includes a number of provisions that permit the Agency to restrict extralabel use in certain circumstances. For example, if there is a finding that there is a reasonable probability that an extralabel use may present a risk to public health from drug residues in animal-derived food, the Agency may establish a safe level for a residue for such extralabel use by regulation or order and may require the development of analytical methods for residue detection. If, after affording an opportunity for public comment, FDA finds that an extralabel animal drug use presents a risk to public health or that no analytical method has been developed and submitted, the Agency may prohibit such extralabel use. The following prohibitions currently apply to the uses of drugs in food-producing animals:

Chloramphenicol
Clenbuterol
Diethylstilbestrol (DES)
Dimetridazole
Ipronidazole
Other nitroimidazoles
Furazolidone (except for approved topical use)
Nitrofurazone (except for approved topical use)
Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine and sulfaethoxypyridazine)

Neither AMDUCA nor the implementing regulations are intended to lessen the responsibility of the manufacturer, the veterinarian, or the food producer with regard to drug residues. Under AMDUCA, any amount of residue resulting from an extralabel use would constitute a violation of the Act if a safe level or tolerance has not been established.

Title 21 of the *Code of Federal Regulations* is now amended to add a new part 530, titled "Extralabel Drug Use in Animals."¹⁸

Magnesium Hydroxide/Oxide is allowed for extralabel animal used in food-producing animals because it is not explicitly prohibited.

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¹⁸ Information was copied directly from http://www.fda.gov/cvm/index/amducca/amducatoc.htm

EPA:

The EPA has deemed magnesium hydroxide environmentally safe. This assessment is based on toxicology reports provided by the Center for Disease Control. Magnesium hydroxide is not listed on the EPA's list of regulated chemicals. ¹⁹

. The Certified Organic Management Standards (March 2002) require that soil fertility be evaluated and managed. Section 3.11.2 references that soil tests are required to know the exact amount of magnesium present. Section 6.6.2 of these standards allows limestone to be used as in aid in growing media.

NFPA Ratings: Health: **1** Flammability: **0** Reactivity: **0**

Livestock Medicines Act Loi sur les médicaments pour le bétail

REVISED REGULATIONS OF ONTARIO

REGULATION 730

Amended to O. Reg. 291/97

GENERAL

This Regulation is made in English only.

1. In this Regulation,

"biological" means a bacterin, vaccine, toxoid, antiserum or antitoxin prepared for use in the prevention or treatment of livestock diseases. R.R.O. 1990, Reg. 730, s. 1.

- **2.** Subject to the *Food and Drugs Act* (Canada) and the Food and Drug Regulations made thereunder, the drugs and classes of drugs designated in the Schedule are designated as livestock medicines for the purposes of the Act and this Regulation. R.R.O. 1990, Reg. 730, s. 2.
- **3.** (1) The following classes of licences are established:
- 1. Class 1.

2. Class 2.

R.R.O. 1990, Reg. 730, s. 3 (1); O. Reg. 291/97, s. 1 (1).

- (2) A livestock medicine set out in the Schedule is designated as a livestock medicine that may be sold by the holder of a Class 1 licence at the holder's established place of business.
- (3) A Class 2 licence authorizes the holder of a Class 1 licence to sell at a temporary place of business the livestock medicines that the holder is authorized to sell at the holder's established place of business. O. Reg. 291/97, s. 1 (2).

¹⁹ Information was referenced from a phone interview with George Prince, CDC, June 5, 2002.

- (4) Revoked: O. Reg. 291/97, s. 1 (2).
- **4.** (1) The applicant for a Class 1 licence shall send to the Director an application accompanied by payment of the fee of \$75.
- (2) A Class 1 licence is valid up to and including July 31 after it is issued. O. Reg. 291/97, s. 2.
- **5.** (1) The holder of a Class 1 licence may obtain a Class 2 licence by sending to the Director an application accompanied by payment of the fee of \$50.
- (2) A Class 2 licence is valid only for the period shown on it. O. Reg. 291/97, s. 2.
- **5.1** A licence is not transferable. O. Reg. 291/97, s. 2.
- **6.** (1) A licence is issued on the terms and conditions that the licensee,
- (a) shall continue to have an established place of business for the storage and sale of livestock medicines;
- (b) shall keep for sale or sell livestock medicines only at the established or temporary place of business described on the licence;
- (c) shall not keep for sale or sell any livestock medicines after the expiration date indicated by the manufacturer on the label thereof;
- (d) shall not repackage or relabel livestock medicines;
- (e) shall not deliver a livestock medicine except for dairy sanitizers, teat dips and udder washes to a livestock owner without an order from that owner authorizing the delivery evidenced by an invoice prepared by the licensee in advance of delivery;
- (f) shall keep refrigerated all livestock medicines that require refrigeration;
- (g) shall store in the manner prescribed by this Regulation all livestock medicines that do not require refrigeration; and

. . . .

- (i) shall not sell a livestock medicine to any person other than an owner of livestock or for any purpose other than the treatment of livestock. R.R.O. 1990, Reg. 730, s. 6 (1); O. Reg. 636/91, s. 2 (1, 2); O. Reg. 291/97, s. 3 (1).
- (2) A Class 2 licence shall be issued only for a temporary place of business that is located on premises where livestock are assembled in connection with an agricultural exhibition, a horse show or the holding of horse races. O. Reg. 291/97, s. 3 (2).
- **7.** (1) A licensee who maintains, handles or stores livestock medicines shall keep them in a refrigerator, cabinet or other storage facility that is used solely for that purpose.
- (2) A licensee shall ensure that livestock medicines, whether they require refrigeration or not, are maintained at the temperatures prescribed for them by the manufacturer and that they do not come in contact with food or medicine for human consumption. O. Reg. 636/91, s. 3.

- (3) The licensee shall maintain every refrigerator, cabinet or other storage facility in a clean and sanitary condition. O. Reg. 291/97, s. 4.
- 8. (1) Every licensee shall,
- (a) sell every livestock medicine in the container in which it is received by the licensee;
- (b) in the case of any livestock medicine bearing a warning or caution on the label, draw the attention of the purchaser to the warning or caution; and
- (c) immediately after the expiration date indicated by the manufacturer on the label of a livestock medicine, remove the livestock medicine from sale and keep it separate from other livestock medicines until it is disposed of in a manner approved by the Director.
- (2) No licensee shall engage in any practice by which a livestock medicine is held out as an inducement for the purchase of livestock medicines or other goods, or by which other goods are held out as an inducement for the purchase of livestock medicines.
- (3) No licensee shall store or permit to be stored any food or medicine for human consumption in a refrigerator, cabinet or facility used for the storage of livestock medicines. R.R.O. 1990, Reg. 730, s. 8.
- **9.** (1) Every licensee shall keep accurate records of the livestock medicines sold by the licensee, and the record of each sale shall include.
- (a) the date of the sale;
- (b) the name and address of the purchaser;
- (c) the brand name and quantity; and
- (d) the lot numbers of any biologicals.
- (2) Every record of a sale of livestock medicines shall be kept for a period of at least two years. R.R.O. 1990, Reg. 730, s. 9.
- **10.** No advertising in respect of livestock medicines by a licensee shall exceed the claims or information set out on the manufacturer's label. R.R.O. 1990, Reg. 730, s. 10.
- 11. (1) Where an inspector seizes, removes or detains any livestock medicine under clause 3 (5) (c) of the Act, the inspector shall,
- (a) attach thereto a tag bearing a serial number and the words "Ont. Detained";
- (b) forthwith thereafter notify the owner or the person who had possession thereof in writing of,
- (i) the seizure, and
- (ii) the grounds on which the seizure was made; and
- (c) direct that the livestock medicine be detained in the place where it was found or be removed to another place designated by him or her.

- (2) Where a livestock medicine is detained, no person shall,
- (a) remove the tag attached to it; or
- (b) sell, offer to sell, move or allow or cause to be moved such livestock medicine.
- (3) Where an inspector is satisfied that,
- (a) the licensee is not contravening the Act or this Regulation with regard to a livestock medicine that is detained; or
- (b) the person whose livestock medicine is detained is authorized to sell livestock medicines to owners of livestock for the treatment of livestock,

the inspector shall remove the attached tag and release the livestock medicine from detention.

- (4) Where,
- (a) after a hearing, the Director finds,
- (i) that there is a contravention of the Act or this Regulation by the licensee whose livestock medicine is detained, or
- (ii) that the person whose livestock medicine is detained is not authorized to sell livestock medicines to owners of livestock for the treatment of livestock; or
- (b) a person is convicted of an offence against the Act or this Regulation in respect of livestock medicine that is detained.

the Director may direct that the livestock medicine be destroyed or disposed of in such manner as he or she considers advisable.

- (5) Any proceeds realized from the disposal of livestock medicine under subsection (4) shall be paid to the Minister of Finance. R.R.O. 1990, Reg. 730, s. 11.
- **12.** Where a licence is refused, suspended or revoked, any livestock medicines in the possession of the applicant or licensee shall be removed and disposed of under the supervision of an inspector by,
- (a) their sale to a person authorized to sell livestock medicines;
- (b) their return to the supplier of the livestock medicines; or
- (c) any other method satisfactory to the Director. R.R.O. 1990, Reg. 730, s. 12.
- **13.** In addition to the grounds mentioned in section 6 of the Act, the Director may refuse to renew or may suspend or revoke a licence where the licensee sells any drug other than a livestock medicine. R.R.O. 1990, Reg. 730, s. 13. ²⁰

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²⁰ Copied directly from http://192.75.156.68/DBLaws/Regs/English/900730_e.htm

Status Among U.S. Certifiers

The Texas Department of Agriculture does have Magnesium hydroxide on their Organic Materials List. (Contact- Leslie McKinnon- Coordinator for Organic Certification) ²¹

Ohio is in accordance with OMRI criterion. Magnesium hydroxide is allowed but is restricted. It can be used as a feed additive. It can only be used for trace minerals. (Contact- Steve Sears- Certification Administrator) ²²

Oregon does not have specific limitations on materials used for crops and livestock. If the materials comply with USDA regulations, they are deemed acceptable for use in the state of Oregon. (Contact-Ron McKay) ²³

Pennsylvania is in accordance with guidelines proposed by OMRI. (Contact- Martha Melton) ²⁴

International

IFOAM: Basic standards 2002- not explicitly listed as approved food additive or processing aid²⁵ **CODEX:** Magnesium hydroxide meets the requirements set forth in the Food Chemical Codex, 3rd ed. Assuming good manufacturing practices, magnesium hydroxide is recognized as an acceptable, safe food ingredient

NORWAY: Norway has set up the Norwegian State Pollution Control Authority (SFT), which enforces permits for any drilling of fluids/muds. Norway acts in accordance with OSPAR regulations. Magnesium hydroxide is listed as a chemical requiring a much reduced discharge rate, despite the full known toxicology of the compound. The discharge of unused chemicals is strictly forbidden and enforced in Norway. ²⁶

<u>EU:</u> The European Union (EU) and the US vary greatly in their limitations on sludge and how it should be treated to prevent disease in livestock. The EU allows more freedom when considering how sludge will be used for treatment. The US requires disposal classification of the sludge before it can be used for treatment. BIO-GRO, New Zealand organic standards have approved magnesium limestone as an acceptable fertilizer. BIO-GRO states that the fertilizer is acceptable if it is from its natural origin. ²⁷ Various international eco-label programs including Blue Angel (Germany), Ecomark (India), Environmental Choice (Canada), European Union, Green Seal (United States), and Nordic Swan (Norway, Sweden, Denmark, Finland, Iceland) do site flame-retardants as chemicals to avoid. Even thought magnesium is a flame retardant, it is cited as an alternative *solution* to those you should avoid. Magnesium is deemed acceptable because it is a non-halogenated flame retardant. Other alternatives provided by eco-

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²¹ Information was referenced from email correspondence with Leslie McKinnon, Coordinator for Organic Certification, June 4, 2002.

²² Information was referenced from a phone interview with Steve Sears, Certification Administor, June 5, 2002.

²³ Information was referenced from a phone interview with Ron McKay, State Certifier, June 5, 2002.

²⁴ Information was referenced from a phone interview with Martha Melton, State Certifier, June 5, 2002

²⁵ This information was referenced from http://www.ifoam.org/standard/ibs_final02.html

 $^{26\} Information\ was\ referenced\ from\ \underline{http://www.offshore-environment.com/norway.html}$

²⁷ Information was referenced from http://www.biogro.co.nz/files/1010430_livestock.pdf

labeled programs include borates, boronic acids, and phosphorus based materials. ²⁸ Magnesium hydroxide/oxide are listed as permitted substances in the EU standards. ²⁹

JAPAN: not specifically listed in Japanese Rule ³⁰

Section 2119 OFPA U.S.C. 6518(m)(1-7) Criteria

1. The potential of the substance for detrimental interactions with other materials used in organic farming systems.

None if dolomitic lime is used as a fertilizer.

2. The toxicity and mode of action of the substance and of its break down products or any contaminants, and their persistence and areas of concentration in the environment.

Although magnesium hydroxide is poorly absorbed, toxins may build up in the body of a renal impaired patient. High levels of toxins in the blood may cause flushed skin, extreme thirst, hypertension, respiratory depression, and the blocking of neuromuscular transmission. ³¹ The fatal dose of the magnesium ion in humans is approximately 30mg/kg which would raise serum magnesium levels in the body to 13-15 meq/L, a lethal level. The likelihood of such an occurrence is rare. Fatality is minimal. The prolonged use of Mg(OH) $_2$ may cause rectal stones comprised up Mg(CO) $_3$ and Mg(OH) $_2$. Systemically, magnesium can depress the central nervous system in the body, hinder reflexes, and finally cause death from respiratory paralysis. ³²

3. The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.

Aluminum and magnesium *phosphide* are very hazardous to the environment. Non-targeted water supplies and organisms aren't as high a risk as those species targeted by the pesticides. In the environment these pesticides, aluminum and magnesium phosphide, decompose rapidly into aluminum and magnesium hydroxide which decompose even faster. Aluminum and magnesium hydroxide pose little to no environmental risks specifically to water supplies. Magnesium hydroxide occurs naturally in the brucite form posing a negligible affect on the environment even if it should happen to be misused or discarded incorrectly. It degrades very quickly. Causmag TGM is a magnesium oxide product which is used in waste water treatments. It is extremely water soluble, ensuring a short operation time with little sludge disposal problems that may have adverse environmental effects. ³³

4. The effects of the substance on human health.

Generally speaking, humans should not have a problem with magnesium hydroxide if used as a laxative or an antacid as approved by the FDA. Magnesium hydroxide is a liming material. It is also used by farmers, in large quantities, for cattle. Farmers use what is called Rumalax Bolus. It is a drug administered orally which contains a large amount of magnesium hydroxide (27 g/bolus) as well as

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²⁸ Information was referenced from http://www.moea.state.mn.us/berc/dfe-materials.cfm#programs

²⁹ Referenced from http://www.foodstandards.gov.uk/multimedia/pdfs/elist_numbers.pdf

³⁰ Directly referenced from http://www.fas.usda.gov/gainfiles/200004/25647377.pdf

³¹ Information was referenced from http://www.paddocklabs.com/msdspdf/MILKOMAG.PDF

³² Information was referenced from http://toxnet.nlm.nih.gov/cgi-bin/sis/search

³³ Information was referenced from http://www.magnesiainternational.com/home.htm

ginger, capsium, and methyl salicylate. This large concentration is intended for cattle with digestive problems only. This is for animal use only and can affect human health if digested or misused. Magnesium hydroxide will irritate eyes and skin if exposed. ³⁴

MAGNESIUM HYDROXIDE

Human Health Effects:

Human Toxicity Excerpts:

PROLONGED USE OF MG(OH)2 MAY RARELY CAUSE RECTAL STONES COMPOSED OF MGCO3 & MG(OH)2.

[Gilman, A. G., L. S. Goodman, and A. Gilman. (eds.). Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan Publishing Co., Inc. 1980. 993]**PEER REVIEWED**

FATAL DOSE OF ABSORBED MAGNESIUM ION IS APPROX 30 MG/KG, AN AMT WHICH WOULD RAISE SERUM MAGNESIUM TO LETHAL LEVEL OF 13-15 MEQ/L... FATALITIES ARE RARE.

[Dreisbach, R. H. Handbook of Poisoning. 9th ed. Los Altos, California: Lange Medical Publications, 1977. 412]**PEER REVIEWED**

IF EVACUATION FAILS (BOWEL OBSTRUCTION OR ATONY), MUCOSAL IRRITATION & ABSORPTION OCCUR. SYSTEMICALLY MG PRODUCES CNS DEPRESSION, ABOLITION OF REFLEXES, & DEATH FROM RESP PARALYSIS.

[Gosselin, R.E., H.C. Hodge, R.P. Smith, and M.N. Gleason. Clinical Toxicology of Commercial Products. 4th ed. Baltimore: Williams and Wilkins, 1976.,p. II-88]**PEER REVIEWED** 35

MAGNESIUM OXIDE

CASRN: 1309-48-4

For other data, click on the Table of Contents

Human Health Effects:

Human Toxicity Excerpts:

EXAM OF 95 MEN EXPOSED TO MGO DUST REVEALED ONLY SLIGHT IRRITATION OF EYES & NOSE, ALTHOUGH MG LEVEL IN SERUM OF 60% OF THOSE EXAMINED WAS ABOVE NORMAL UPPER LIMIT OF 3.5 MG%... EXPTL METAL FUME FEVER IN MAN HAS HOWEVER, BEEN PRODUCED BY EXPOSURE TO EXCESSIVE CONCN OF FRESH MGO FUME...

[Patty, F. (ed.). Industrial Hygiene and Toxicology: Volume II: Toxicology. 2nd ed. New York: Interscience Publishers, 1963. 1078]**PEER REVIEWED**

...WORKERS OBSERVED...PRONOUNCED LEUKOCYTOSIS ANALOGOUS TO THAT CAUSED BY ZINC OXIDE /WITH REACTIONS OF METAL FUME FEVER CAUSED BY MGO EXPOSURE/. [Browning, E. Toxicity of Industrial Metals. 2nd ed. New York: Appleton-Century-Crofts, 1969. 210]**PEER REVIEWED**

 $^{34 \ \} Information \ was \ referenced \ from \ \underline{http://shop.store.yahoo.com/animalmedicstore/rumbolbyag50.html}$

³⁵ Copied directly from http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAcHa4XB:1

ACUTE MAGNESIUM TOXICITY CAUSES NAUSEA, MALAISE, GENERAL DEPRESSION, & PARALYSIS OF RESP, CARDIOVASCULAR, & CENTRAL NERVOUS SYSTEMS. TOXIC EFFECTS OF MAGNESIUM ON CNS ARE DUE TO DECR LIBERATION OF ACETYLCHOLINE @ NEUROMUSCULAR JUNCTION & SYMPATHETIC GANGLIA./MAGNESIUM/ [Luckey, T.D. and B. Venugopal. Metal Toxicity in Mammals, 1. New York: Plenum Press, 1977. 168]**PEER REVIEWED**

HYPOTENSION, CUTANEOUS VASODILATION, & CARDIAC ARREST ARE MAJOR MAGNESIUM TOXICITY SYMPTOMS OF CARDIOVASCULAR SYSTEM. DEPRESSION OF CARDIAC MUSCLE ACTIVITY & HYPOXIA, SECONDARY TO PARALYSIS OF RESP TISSUES, ARE RESPONSIBLE FOR LOCAL INTRASPINAL & GENERAL ANESTHETIC EFFECTS OF MAGNESIUM TOXICITY. /MAGNESIUM/

[Luckey, T.D. and B. Venugopal. Metal Toxicity in Mammals, 1. New York: Plenum Press, 1977. 168]**PEER REVIEWED**

...4 HUMAN SUBJECTS WERE EXPOSED @ MEASURED CONCN OF FRESHLY GENERATED MAGNESIUM OXIDE FUME. ALTHOUGH SLIGHT REACTIONS WERE OBSERVED AFTER LESS THAN 10 MIN OF EXPOSURE @ CONCN OF APPROX 400-600 MG/CU M, IT WAS BELIEVED THAT MORE SEVERE EXPOSURES WOULD LEAD TO MORE SEVERE REACTIONS. [American Conference of Governmental Industrial Hygienists. Documentation of the Threshold Limit Values for Substances in Workroom Air. Third Edition, 1971. Cincinnati, Ohio: AmericanConference of Governmental Industrial Hygienists, 1971. (Plus supplements to 1979) 147]**PEER REVIEWED**

MAGNESIUM SALTS ARE PRACTICALLY NONTOXIC BY ORAL ADMIN, SINCE EFFECTIVE HOMEOSTASIS OPERATES IN INTESTINAL ABSORPTION./MG SALTS/ [Luckey, T.D. and B. Venugopal. Metal Toxicity in Mammals, 1. New York: Plenum Press, 1977. 167]**PEER REVIEWED** ³⁶

5. The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms(including the salt index and solubility of the soil), crops and livestock

Several chemical reactions take place between lime, fertilizers, and the soil to which they both are applied. Soil particles have been layered with oxides and organic materials adding to the chemical reactions taking place when fertilizers are applied to the soil. Magnesium hydroxide is a type of fertilizer that can be used in helping crops grow. The positive charge from the magnesium (cation) reacts with the negative charge on the soil. The two charges are attracted to one another. Liming materials may be carbonates, oxides, or hydroxides. The finer the chemical form becomes, the faster the reaction time. Magnesium hydroxide and oxide are also known as hydrated lime and burned lime respectively. Hydroxides and oxides are more water-soluble thus greatly surpassing the reaction time of carbonates. For ideal crop grow, lime should be used as fertilizer to adjust the pH level of the soil. Magnesium hydroxide will only interact with the soil and will not be harmful to other soil surface organisms. It is the soil's negative charge reacting with the magnesium's positive charge. ³⁷

6. The alternatives to using the substance in terms of practices or other available materials.

37 Information was referenced from http://www.ca.uky.edu/agc/pubs/agr/agr5/agr5.htm

³⁶ Copied directly from http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAsqaybF:1

In Alberta, Canada, forestry plants burn saw dust, bark, etc. to generate electricity. The wood ash remnants have actually been documented as an excellent fertilizer, improving crop growth. Improved growth was noted especially in areas where windows were burned. Alberta Environment, in conjunction with the Alberta Forest Products Association and Alberta Agriculture is currently developing guidelines for wood ash use as a liming material. ³⁸ Other alternative liming agents, fertilizers, include calcium hydroxide, calcium oxide, and calcium limestone. Organic farmers may also use natural forms of phosphorous as a fertilizer. Animal manures are a good source of phosphorous, nitrogen, and other nutrients. One caveat about animal manures; they may contain high levels of nitrates and ammonia if used in their raw form. Animal manures cannot be used for foods intended for human consumption. They will be in violation of the OFPA of 1990.

6513 ORGANIC PLAN

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- (A) **Inclusion in Organic Plan**. An organic plan shall contain terms and conditions that regulate the application of manure to crops.
- (B) Application of Manure. Such organic plan may provide for the application of raw manure only to
- (i) any green manure crop;
- (ii) any perennial crop;
- (iii) any crop not for human consumptions

Organic farmers are prohibited from using ammonium sulphate as a soil additive but they may use zinc, iron, and potassium sulphates as suitable alternatives. ³⁹

7. Its compatibility with a system of sustainable agriculture.

The EPA has confirmed that magnesium hydroxide is not found in ground water supplies. Therefore, unless prodigious natural deposits of magnesium hydroxide are found in the actual soil, the exposure of such a compound will not be detrimental and will not affect systems of sustainable agriculture. 40

TAP Reviewer Discussion

<u>Reviewer 1</u> [Ph.D. Animal Science, M.S. Animal Science. Research and teaching activities related to dairy cattle nutrition and nutrient management on livestock farms. Southeast US]

Comments on petition

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³⁸ Information was referenced from http://www.agric.gov.ab.ca/agdex/500/534-2.html

³⁹ Information was referenced from http://www.ams.usda.gov/nop/orgact.htm

⁴⁰ Information was referenced from a phone interview with Don Henderson, EPA Librarian, June 5, 2002.

The petition is somewhat vague on the specific uses being proposed for magnesium hydroxide. While the use of magnesium hydroxide as a digestive aid is well-supported in the petition, significant evidence is produced indicating that it should not be approved for use as a soil amendment or preservative. There are many alternatives to this compound for agronomic use, and its use as a preservative is explicitly banned in the Federal Organic Food Production Act.

OFPA Criteria Evaluation

(1) The potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

I agree with the criteria evaluation in the petition.

(2) The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;

I agree with the criteria evaluation.

(3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance:

I agree with the criteria evaluation.

(4) the effect of the substance on human health;

I agree with the criteria evaluation.

(5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

I agree with the criteria evaluation.

- (6) the alternatives to using the substance in terms of practices or other available materials; and I agree with the criteria evaluation. As noted, there are several alternatives to magnesium hydroxide available for agronomic use, but no organic alternatives to its use in treatment of digestive upsets of livestock.
- (7) its compatibility with a system of sustainable agriculture. I agree with the criteria evaluation.

Reviewer 1 Conclusion.

The substance is not synthetic, as it is found naturally.

Reviewer 1 Recommendation Advised to the NOSB:

The substance is Not Synthetic

For Livestock, the substance should be Added to the National List with restrictions.

I recommend magnesium hydroxide be approved synthetic-allowed with restrictions on its use. It should be approved only for treatment of digestive upsets (upset stomach, constipation) in livestock. Landapplication of biosolids (which contain magnesium hydroxide) is explicitly banned in section 205.203 e.2 of the Federal Organic Food Production Act; this petition can not and should not supersede that agronomic ban. Likewise, use of compounds as a preservative is explicitly banned in section 205.600 b.4 of the Federal Organic Food Production Act. This petition can not and should not supersede the ban on use of preservatives.

When used to treat digestive upsets, there are no organic substitutes for magnesium hydroxide, and its manufacture, use, and disposal do not have adverse effects on the environment. The nutritional quality of food (milk, meat) is maintained when it is used and it does not have adverse effect on human health. It is listed as GRAS by FDA, is not proposed for use as a preservative, and is necessary to the production of

organically produced agricultural product. Listing this product with the limitation indicated is consistent with the action of individual states (Texas, Ohio).

Reviewer #2: [Ph.D. Food Science, Regents Professor and Director, Southeast U.S.]

Comments on Database

There are a few inconsistencies or inaccuracies in the database that should be corrected. These include:

- 1. In the "Specific Uses" section, lime is described as "any material that contains magnesium or calcium and will neutralize soil activity." In addition, in the "Historic Use by Organic Farmers" section lime is described as "a form of magnesium hydroxide." The scientific definition of lime is calcium oxide. Lime of commerce contains 90-95% free CaO. Magnesium hydroxide is not a major component of lime, hence the definition for lime included in the database is incorrect.
- 2. Also in the "Specific Uses" section, it is indicated that "magnesium hydroxide helps both crops and livestock by both preventing and curing diseases." This is not completely accurate because Mg(OH)₂ does not cure plant and animal diseases. Rather, it is used in cattle as a "pain reliever" to provide temporary relief of an upset stomach (antacid) and short-term relief of constipation (laxative). Magnesium hydroxide is used in crop production primarily as a source of minerals for the soil (fertilizer) and not to cure diseases in crops.
- 3. In the "Historic Use by Organic Farmers" section, there is considerable discussion regarding the use of lime in agriculture but this is irrelevant because lime (CaO) and magnesium hydroxide are entirely different chemicals.
- 4. In the "Action" section, there is considerable detail provided regarding the potential adverse effects of prolonged exposure to antacids. Antacids frequently contain other chemicals besides Mg(OH)₂ which may be primary contributors to the adverse reactions in humans to antacids. Information provided should be specific to Mg(OH)₂ and a better analysis of the facts needs to be provided if mixtures of chemicals are used.

OFPA Criteria Evaluation

1. The potential of such substances for detrimental interactions with other materials used in organic farming systems.

None if used as dolomite as a fertilizer or if used at recommended concentrations in livestock for digestive problems.

2. The toxicity and mode of action of the substance and its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.

The likelihood of magnesium toxicity from the use of magnesium hydroxide as a soil fertilizer or as a livestock treatment when used at recommended concentrations is remote.

3. The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.

Magnesium hydroxide occurs naturally as the mineral, brucite, which degrades very quickly and has no history of negative impact on the environment.

4. The effect of the substance on human health.

Exposure to concentrated magnesium hydroxide will irritate eyes and skin; however, at appropriate concentrations, it is used as a laxative or antacid in humans. As with most chemicals, ingestion at high concentrations (e.g., 30 mg/kg), Mg(OH)₂ can be fatal in humans, but rarely.

5. Effects of the substance on biological and chemical interactions in the agro ecosystem, including the physiological effects of the substance in soil organisms, crops and livestock.

I concur with the criteria evaluation.

6. Alternatives to using the substance in terms of practices or other available materials.

I concur with the criteria evaluation.

7. Its compatibility with a system of sustainable agriculture.

There appears to be no issues associated with the compatibility of $Mg(OH)_2$ with sustainable agriculture.

Reviewer 2 Recommendation to the NOSB

The substance is <u>nonsynthetic</u>.

For crops and livestock, the substance should be <u>added to the National List with</u> Restrictions.

Reviewer 3 [Ph.D. Chemistry, Professor, Department of Chemistry, Southwest US]

Comments on Database

The following information needs to be corrected or added to the database:

No additional information is required.

The Technical Advisory Panel's review of potassium sorbate, its chemistry and applications is adequate to understand how the compound would be useful in livestock production.

OFPA Criteria Evaluation/Summary

Magnesium hydroxide is not a synthetic material, as it occurs naturally in the form of a mineral. It is used for both medicinal (for digestive problems) and fertilizer purposes. The minerals of magnesium are very similar to those of calcium so many applications use a combination of both (e.g., dolomitic lime).

Medicinal uses are surely permitted. There is no mention of using magnesium hydroxide in various forms as a preventative measure.

Reviewer 3 Conclusion

It is a <u>non-synthetic</u> material. I see no reason not to use it an essentially an antacid. Fertilizers must not be synthetic nor blended commercially. Again, magnesium hydroxide is not synthetic.

Reviewer 3 Recommendation Advised to the NOSB

In summary, I see no reason not to allow magnesium hydroxide for all indicated uses. Magnesium hydroxide is a <u>non-synthetic</u> material.

For Livestock, the substance should be <u>Added to the National List without restrictions</u>.