Hydrated Lime

Livestock

Identification of Petitioned Substance

Chemical Names:
Calcium Hydroxide
Calcium Hydrate

Other Name:
Hydrated Lime
Slaked Lime
Caustic Lime

Trade Names:
Hydrated Lime

CAS Numbers:
1305-62-0 (calcium hydroxide)

Other Codes:
215-137-3 (EINECS No, calcium hydroxide)

Summary of Petitioned Use

The National Organic Program (NOP) final rule currently permits the use of hydrated lime for plant disease control in crop production (7 CFR §205.601(i)(4)) and external pest control in livestock production (7 CFR §205.603(b)(5)). Regarding livestock applications, the final rule states that hydrated lime may not be used to cauterize physical alterations (medical treatment) or deodorize animal wastes. This report provides targeted technical information to augment the 1995 (livestock) and 2002 (crops) technical advisory panel reports of hydrated lime in support of the National Organic Standards Board's sunset review of the substance used for parasitic mite control in sheep, goats, cattle and other livestock.

Characterization of Petitioned Substance

<u>Composition of the Substance:</u>

Hydrated or "slaked" lime consists primarily of calcium hydroxide [$Ca(OH)_2$] and magnesium hydroxide [$Mg(OH)_2$] at 50 – 95% and 0 – 50% of the substance, respectively (Lafarge, 2011). High purity forms of the substance contain greater than 90% calcium hydroxide (Santosh, 2005; Chemical Lime, 2008). In addition, smaller amounts of silicon (e.g., SiO_2), iron (e.g., Fe_2O_3), aluminum (e.g., Al_2O_3) and magnesium (e.g., MgO) oxide compounds, as well as calcium and magnesium carbonates ($CaCO_3$ and $MgCO_3$), are frequently observed in hydrated lime samples (Lafarge, 2011; Santosh, 2005). These trace components originate from the limestone starting material, which contains predominantly calcium carbonate ($CaCO_3$) with minor quantities of magnesium, silicon, aluminum and iron compounds (Oates, 2010). Due to the minimal contribution of other metallic species, the current technical report will focus on the properties of pure calcium hydroxide when specific information for hydrated lime is unavailable.

$$OH^{-} \quad Ca^{2+} \quad OH^{-}$$

Figure 1. Structural formula for calcium hydroxide [$Ca(OH)_2$]

<u>Source or Origin of the Substance:</u>

As discussed above, hydrated lime is ultimately derived from naturally derived limestone. The first step of lime sulfur production involves heating limestone—which consists primarily of calcium carbonate ($CaCO_3$)—to form solid quicklime (calcium oxide, CaO) and gaseous carbon dioxide (CO_2). Hydrated lime is produced from the slow addition of water to crushed or ground quicklime. Different grades of hydrated lime may be produced depending on the parent rock source; cleaner sources may contain 0.5–2.0%

magnesium oxide in the final product (USDA, 2002a). See the response to Evaluation Question #2 for additional information regarding the commercial production of hydrated lime.

Properties of the Substance:

Commercial sources of hydrated (slaked) lime generally consist of ≥ 90% calcium hydroxide [$Ca(OH)_2$]. The substance exists as colorless crystals or a soft white crystalline powder, and forms highly alkaline solutions (pH 12.4 at 25 ºC) when dissolved in water. Table 1 below summarizes the chemical and physical properties of hydrated lime/calcium hydroxide.

Table 1. Chemical and Physical Properties for Calcium Hydroxide [$Ca(OH_2)$]

Property	Description
Molecular formula	$Ca(OH)_2$
Molecular weight	74.1
Color	Colorless, white or gray
Form	Crystals, soft granules and/or powdery solid
Odor	Odorless
Boiling point	>1,000 ºC (decomposes)
Melting point	580 ºC (decomposes through loss of water)
Density	2.2 g/cm^3
pH	12.4 (aqueous solution saturated at 25 ºC)
Water solubility	1,730 mg/L (at 20 ºC)
Other solubilities	Insoluble in alcohol (i.e., ethyl alcohol); dissolves in acid with evolution of heat
Reactivity in air	Readily absorbs carbon dioxide (CO_2) from the air, forming $CaCO_3$
Stability	Stable; incompatible with strong acids, ammonium salts and aluminum metal

Data Sources: HSDB, 2014; Chemical Lime, 2008; Lafarge, 2011.

Specific Uses of the Substance:

According to the 1995 TAP report, hydrated lime can be used in livestock production as a cleaning agent for barns, stables and other living areas; disinfectant in footbaths; topical disinfectant on wounds; and sheep dip, often in combination with sulfur (i.e., producing lime sulfur) for effective control of mange and scabies mites on sheep (USDA, 1995a). Under the USDA organic regulations for livestock production, hydrated lime is only permitted for use as an external parsiticide (7 CFR 205.603(b)(5)).

The NOSB sunset review of hydrated lime pertains to applications of the substance for parasitic mite control in sheep, goats, cattle and other livestock. Mange caused by parasitic mites is highly irritating for animals, and can result in economic losses from wool damage (lamb and sheep) and reduced production of meat products (McNeal, 1999). Sheep scab—caused by the parasitic mite *Psoroptes ovis*—is a contagious, highly pruritic (i.e., itching) disease that results in the development of large, yellowish, scaly, crusted lesions, accompanied by damage to wool and hide. Although severe psoroptic mange was documented in one U.S. population of wild bighorn sheep in 1978, reports indicate that sheep scab has been eradicated from the United States, Canada, Australia, New Zealand and Scandinavia (CFSPH, 2009). Chorioptic and psorergatic mange of sheep and goats have also been eradicated in the U.S., while sarcoptic and demodectic mange remain problematic for producers of sheep and goats (Losson, 2011). In U.S. cattle production, sarcoptic mange (scabies), psoroptic mange, chorioptic mange, demodectic mange and psorergatic mange (itch mite) continue to be problematic skin diseases. Dips consisting of 2% hot lime sulfur (i.e., hydrated lime, elemental sulfur and water) are recommended as treatments for parasitic mites associated with these diseases (Losson & Mignon, 2011).

Conventional livestock producers use hydrated lime for additional purposes. Specifically, the substance is widely used to control animal manure odors and reduce vector attraction and proliferation in animal carcasses. It has also been used as whitewash to improve sanitation in animal enclosures and farm buildings (Curtis, undated). According to NCSU poultry extension specialists, lime products (including hydrated lime) are used to increase the pH of litter to destroy pathogens, reduce nitrogen content by increasing the volatilization of ammonia, and decrease the amount of soluble phosphorus, thus reducing runoff levels of these nutrients when poultry litter is applied to land (Shah, 2006; Extension, 2013). The available literature indicates that lime products effectively control poultry diseases, including avian influenza, Newcastle disease and ornithosis (Extension, 2013). Hydrated lime scattered in yards and pens is also effective in bacteria that causes foot rot. For this purpose, the substance is typically placed in and around areas where sheep congregate such watering areas, feed bunks or salt and mineral sources (Swartz, 1990). As an animal feed additive, hydrated lime breaks the bonds in corn stover cell walls, thus making the fiber more accessible to rumen microbes and improving overall digestibility of the stover (Tietz, 2013). Hydrated lime additions have also improved the digestibility of wheat straw for sheep (Djajanegara, 1985).

In addition to livestock uses, hydrated lime has a long history of use in crop production as a plant disease control agent, and is an essential component of lime sulfur (i.e., hydrated lime, elemental sulfur and water) and the Bordeaux mixture (i.e., hydrated lime, copper sulfate and water) (Curtis, undated; Broome & Donaldson, 2010). Field trials have demonstrated that hydrated lime is an effective insecticide; however, it may lead to plant damage in areas of treated vegetation (Boucher & Adams, 2012). Conventional crop producers also use lime products (limestone, quicklime or hydrated lime) to neutralize soil acidity and raise soil pH (Oates, 2010). As an adjuvant in spray solutions, hydrated lime helps to "fix" active ingredient as an insoluble hydroxide, thereby enabling prolonged release of the chemical agent (Curtis, undated).

Beyond agriculture, hydrated lime has a variety of other uses. Hydrated lime is used to adjust pH and to remove both carbonate and non-carbonate water hardness in water treatment. In addition, sewage treatment plants use hydrated lime to destroy pathogens, reduce odor and aid filtration. As an alkaline agent, hydrated lime is used to neutralize acid wastes and precipitate heavy metals and effluents from various industries. Beet sugar is treated with hydrated lime—generated in situ from quicklime (calcium oxide) and water—to precipitate organic and phosphoric acid calcium salts. When used in lime – cement – sand mortars, hydrated lime increases the plasticity and water retentivity of wet mortar, as well as the bond strength of mortar to the masonry, thus making the mortar less prone to cracking (Kenny & Oates, 2007). See the available substance reviews for a more detailed discussion of non-agricultural uses of hydrated lime and lime products (Kenny & Oates, 2007; Oates, 2010).

Approved Legal Uses of the Substance:

Hydrated lime is approved for use according to both US Environmental Protection Agency (US EPA) and Food and Drug Administration (FDA) regulations. US EPA has approved hydrated lime as a microbiocide or microbiostat agent that can be blended into a paint film or coating that resists deterioration, decay and odor caused by the growth of bacteria, mold, mildew, algae and fungi (US EPA, 2010). No agricultural pesticide products using hydrated lime as the active ingredient are currently registered with US EPA; however, one manufacturing use product consisting of approximately 96% calcium hydroxide is EPA-registered and commercially available (US EPA, 2014; Alistagen Corporation, 2003). This commercial product is labeled for use in the manufacture of or fabrication into antimicrobial pesticides; however, it not intended for use in or on coatings of other antimicrobial pesticides that will be used on contact with food or food preparation and processing surfaces. Calcium hydroxide is exempt from the requirement of a tolerance when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest (40 CFR 180.1001(c)). According to 21 CFR 184 and 21 CFR 582, calcium hydroxide is Generally Recognized As Safe (GRAS) by FDA when added directly to human food and livestock animal feed.

Action of the Substance:

Specific information concerning the miticidal mode of action of hydrated lime is limited. As microbiocides, lime products inhibit microbial pathogens by controlling the environment required for bacterial growth. The major component of hydrated lime (calcium hydroxide) creates aqueous solutions with pH levels as high as 12.4 when large amounts of the substance are dissolved in water (i.e., near the limit of solubility). These highly alkaline solutions are capable of destroying the cell membranes of harmful pathogens and other microorganisms. In addition, alkaline conditions create environmental conditions that are unfavorable for the growth of new pathogenic microorganisms (Alistagen Corporation, undated).

When mixed with elemental sulfur in water, hydrated lime forms calcium polysulfides (i.e., lime sulfur). This substance is insecticidal and miticidal, and provides effective control of insects and mites through the formation of toxic hydrogen sulfide gas (Venzon, 2013). In this context, calcium hydroxide primarily serves to enhance the solubility and penetrability of the active substance, elemental sulfur.

Combinations of the Substance:

Based on the available information, hydrated lime may be used alone or in combination with elemental sulfur for external pest control in conventional livestock production. The USDA final rule indicates that only the hydrated lime component may be used as an external parasiticide in organic livestock production (7 CFR 205.603(b)(5)). Lime sulfur is produced through reaction of boiling lime (calcium oxide) or hydrated/slaked lime (calcium hydroxide) and ground elemental sulfur (US EPA, 2005). As discussed in "Composition of the Substance," hydrated lime consists primarily of calcium hydroxide (> 90%) with smaller amounts of magnesium hydroxide (< 5%), magnesium oxide (< 5%), calcium carbonate (< 3%) and crystalline silica (< 2%) (Chemical Lime, 2008).

Status

Historic Use:

Hydrated lime and other lime products have a long history of use in agricultural and non-agricultural settings. Pesticide products containing calcium oxide or calcium hydroxide as the active ingredient were initially registered with US EPA in 1976; however, most of the historic registrations have been cancelled or withdrawn (US EPA, 2010). According to the 2006 NOSB recommendation, hydrated lime was recommended for addition to the National List as an external parasiticide following a technical advisory panel review in 1995 and renewed for this purpose in 2006 following an NOSB sunset review (USDA, 2006). In conventional livestock production, references citing the use of acaricidal (i.e., lethal to mites) hydrated lime treatments date back to the early twentieth century. The time period over which hydrated lime and related substances have been used to combat parasitic mites causing mange and other skin diseases in livestock remains uncertain.

Organic Foods Production Act, USDA Final Rule:

Synthetically produced livestock parasiticides are included in Section 2118 of the Organic Foods Production Act of 1990 (OFPA). Specifically, the OFPA states that the National List may allow the use of substances that would otherwise be prohibited under organic regulations (i.e., synthetics) if the substances contains an active ingredient in 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 cleaners" (OFPA 2118(c)(B)(i)).

The National Organic Program (NOP) final rule currently permits the use of hydrated lime for plant disease control in crop production (7 CFR §205.601(i)(4)) and external pest control in livestock production (7 CFR §205.603(b)(5)). For organic livestock applications, the final rule states that hydrated lime may not be used to cauterize physical alterations or deodorize animal wastes. In addition, calcium hydroxide is listed as an approved synthetic substance for use in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." (7 CFR 205.605(b)).

International

All of the international organizations reviewed have provided guidance on the use of hydrated/slaked lime (calcium hydroxide) products in organic production. Among these are regulatory agencies (Canada, EU and Japan) and independent organic standards organizations (Codex and IFOAM). International organic regulations and standards concerning hydrated lime are described in the following subsections.

Canadian General Standards Board

Canadian organic regulations permit the use of hydrated lime as a health care product and/or production aid in organic livestock production under Section 5.3 of the Permitted Substances Lists. According to this rule, hydrated lime is not allowed for use to cauterize physical alterations (medical treatment) or deodorize animal wastes. Hydrated lime is also listed in Section 4.3—Crop Production Aids and Materials—for use as a plant disease control agent only (CAN, 2011).

Codex Alimentarius Commission

The Codex Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (CAC/GL 32-1999) do not list hydrated lime/calcium hydroxide for use in organic livestock or crop production. However, calcium hydroxide is included in the list of "processing aids which may be used for the preparation of products of agricultural origin referred to in Section 3 of these guidelines" (Codex, 2013).

European Union

Organic regulations from the European Union do not permit the use of hydrated lime/calcium hydroxide as an external parasiticide in livestock production. However, Annex I of the European regulations allow "industrial lime from sugar production"—a byproduct of sugar production from sugar beet—as a fertilizer or soil conditioner. Calcium hydroxide may be used as a fungicide on fruit trees to control *Nectria galligena* in organic crop production under Annex II and as a processing aid in the production of processed organic foods of plant origin under Annex VIII (EC, 2008).

Japanese Ministry of Agriculture, Forestry and Fisheries

According to Table 4 of the Japanese agricultural standard for organic livestock products, slaked lime (calcium hydroxide) is an approved agent for cleaning or disinfecting of housing for livestock. Calcium hydroxide derived from calcium oxide (slaked lime) is also listed in Table 1 of the standard as an approved fertilizer and soil improvement substance (JMAFF, 2012). Hydrated lime is not explicitly approved as a miticide according to Japanese organic regulations.

International Federation of Organic Agriculture Movements

IFOAM Norms permit the use of "milk of lime" (i.e., hydrated/slaked lime, calcium hydroxide) for pest and disease control and disinfection in livestock housing and equipment (Appendix 5). Likewise, calcium hydroxide (slaked lime) is included in the "Indicative List of Equipment Cleansers and Equipment Disinfectants" (Appendix 4 – Table 2) for organic handling/processing. Calcium hydroxide is also listed as an approved food additive for maize tortilla flour and processing aid for sugar (Appendix 4 – Table 1). Lastly, application of calcium hydroxide (hydrated lime) is allowed on aerial plant parts only for plant disease control according to Appendix 3 of the IFOAM Norms (IFOAM, 2014). Hydrated lime is not explicitly listed as an approved miticide according to IFOAM.

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

Evaluation Question #1: Indicate which category in OFPA that the substance falls 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) Hydrated/slaked lime (calcium hydroxide) is used as an external parasiticide on livestock and an equipment cleanser in agricultural production.

(B) Calcium hydroxide is included on US EPA's 4B list of Minimal Risk Inert Ingredients (substances which have sufficient data to substantiate they can be used safely in pesticide products) (US EPA, 2004; US EPA, 2010). In addition, calcium hydroxide is exempt from the requirement of a tolerance when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest (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)).

The industrial production of hydrated/slaked lime involves two elementary reactions beginning with naturally occurring limestone deposits. In the first step, ground limestone—which contains predominantly calcium carbonate ($CaCO_3$) with smaller amounts of magnesium, silicon, aluminum and iron oxide compounds—is thermally transformed into quicklime (Oates, 2010). Specifically, heating raw or minimally processed limestone to temperatures in excess of 900 ºC results in conversion of the calcium carbonate content of limestone to calcium oxide (CaO) in a material known as quicklime (equation 1). This thermal transformation occurs with liberation of carbon dioxide (CO_2) gas. In the slaking process, quicklime reacts exothermically (releases heat) with two equivalents of water to produce hydrated/slaked lime consisting primarily of calcium hydroxide [$Ca(OH)_2$] (equation 2). The normal hydration process is carried out at atmospheric pressure and temperatures of approximately 100 ºC (Kenny & Oates, 2007). A variation of the normal hydration process involves reaction of quicklime and water under a high steam pressure of up to 1 MPa and at temperatures approaching 180 ºC to form hydrates. After hydration, the hydrated lime product is dried, milled, and air classified (Kenny & Oates, 2007). Equations 1 and 2 below provide molecular depictions of the overall synthetic process.

$$CaCO_3 \xrightarrow{heat} CaO + CO_2\ (g) \qquad \text{(equation 1)}$$

$$CaO + H_2O \rightarrow Ca(OH)_2 \qquad \text{(equation 2)}$$

Evaluation Question #3: 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)).

According to USDA organic regulations, the NOP defines synthetic as "a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources" (7 CFR 205.2). Hydrated lime [$Ca(OH)_2$] is produced through two sequential reactions: thermal decomposition of ground limestone ($CaCO_3$) to quicklime (CaO) followed by hydration of quicklime at elevated temperatures and/or pressures (Kenny & Oates, 2007; Oates, 2010). The limestone starting material is a naturally derived, non-synthetic substance. However, the NOSB classified calcium oxide (quicklime) as a synthetic substance due to the chemical change that occurs during the thermal reaction of natural limestone (USDA, 2002b). Hydrated lime is therefore produced through chemically changing a synthetic substance (quicklime). Based on NOP definitions, it is reasonable to conclude that hydrated lime used as an external parasiticide in organic livestock production is a synthetic substance. The NOSB has classified hydrated lime as synthetic since initially recommending addition of the substance to the National List for organic livestock production (USDA, 1995a).

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)).

Calcium hydroxide may be released to the environment through direct use of the substance and its inclusion in waste streams from use sites and production facilities (HSDB, 2014). The substance readily reacts with carbon dioxide (CO_2), forming an insoluble form of calcium carbonate ($CaCO_3$) (WSDE, 2005). When released to aqueous environments, calcium hydroxide will dissociate into calcium cations (Ca^{2+}) and hydroxide anions (OH^-). Dissolved carbonate (CO_3^{2-}) and/or carbon dioxide will react with the aqueous calcium ions to form calcium carbonate, which precipitates and deposits on sediments (Solvay, 2011). Indeed, calcium carbonate is a common constituent of natural soils. In addition to reactions with carbonate, calcium cations also form weak soluble complexes with free bicarbonate (HCO_3^-) and/or hydroxide (OH^-) anions when dissolved in natural waters. Calcium cations are also capable of binding to surfaces of mineral and colloidal fractions of suspended materials in aqueous media to various degrees, depending on pH and the levels of other ions present in water (US EPA, 2005). Calcium cations are less mobile in the environment than would be expected based on their solubility in water. In soils, calcium ions bind to cation exchange sites and therefore have limited mobility. Dissociated hydroxide anions will raise the pH of waters receiving calcium hydroxide (Solvay, 2011). Over time, the dissolved hydroxide ions will react with acidic species (sources of H^+) to form water, thus removing hydroxide from the system. Hydrated lime is non-volatile, and previous risk assessments indicate it is not transferred into the atmosphere (WSDE, 2005).

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)).

As associated substances, the chemistry and toxicology of calcium oxide and calcium hydroxide are interrelated. Calcium oxide is highly reactive with water, producing calcium hydroxide solutions. The formation of calcium hydroxide occurs when calcium oxide is in aqueous solutions of comes into contact with mucous membranes (US EPA, 2010). Therefore, the human and ecological toxicology data generated for one compound should be representative of both compounds. In some cases, the toxicology data for calcium oxide is used as a surrogate when data specific to calcium hydroxide is unavailable.

The hydroxide anions (OH^-) generated from dissolution of calcium hydroxide in water or other fluids is the main driver of toxicity for the substance. Calcium hydroxide solutions are alkaline (high pH), and are capable of exerting corrosive/caustic effects to exposed body surfaces and internal organs, such as the eyes, skin and respiratory tract. According to US EPA, these solutions can severely irritate/burn the eyes and cause blurred vision, ulceration, and dangerous formation of clumps in the conjunctival sac of the eye, sometimes resulting in a loss of vision (US EPA, 2010). Contact with the skin or mouth may cause caustic burns, and ingestion can cause a burning sensation, abdominal pain, vomiting and diarrhea. In extreme cases, individuals may experience esophageal and stomach perforation (US EPA, 2010). US EPA classified calcium hydroxide as highly toxic (Toxicity Category I) for acute eye and dermal irritation. While the substance is highly irritating, the systemic toxicity of calcium hydroxide is significantly lower. Indeed, the acute oral doses lethal to 50% of test animals (LD_{50} values) for rats (LD_{50} = 7,340 mg/kg-day) and mice (7,300 mg/kg-day) are consistent with US EPA Toxicity Category IV, or practically non-toxic (WSDE, 2005). Repeated exposure of rats to calcium hydroxide in water at concentrations of 50 and 350 mg/L led to aggression, restlessness, reduced food intake and blood changes, as well as internal changes to the liver, kidneys, stomach and intestine.

Excluding large-volume spills of highly concentrated calcium hydroxide solutions to water bodies, it is unlikely that use or production of the substance will results in toxic effects for aquatic animals and plants. Studies of calcium hydroxide toxicity to fish species—including *Gambusia affinis* (western mosquitofish), *Clarius gariepinus* (African sharptooth catfish), *Micropterus sp.* (black bass) as well as goldfish, bass and sunfish—provided concentrations lethal to 50% of test organisms (LC_{50} values) ranging from 33.9 mg/L (96-hour LC_{50}) to 240 mg/L (24-hour LC_{50}). These data indicate that calcium hydroxide is practically non-toxic to slightly toxic to freshwater fish at low to moderate concentrations (WSDE, 2005). In a Canadian study, calcium hydroxide was dissolved in two eutrophic lakes at concentrations of 74 and 107 mg/L to determine the effects on macroinvertebrate species. It was found that water pH remained within its natural range (pH less than 10), and these calcium hydroxide concentrations had no significant impacts on macroinvertebrate density or biomass for up to two years after treatment (WSDE, 2005).

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)).

The primary environmental issues associated with production of hydrated lime include energy use and dust formation. Calcium oxide is obtained through the thermal decomposition of calcium carbonate (limestone) in fuel-powered kilns, a process that requires large amounts of energy (Kenny & Oates, 2007). Depending on the fuel source and efficiency of the kiln, the industrial production of quicklime and hydrated lime could have a substantial carbon footprint. Dust formation is another by product that must be closely monitored at various stages of limestone mining and processing. Specifically, the crushing and handling of limestone and the burning, processing and handling of quicklime and hydrated lime results in dust emissions (Kenny & Oates, 2007). Reverse-jet bag filters are widely used to capture and minimize the release of dust from the crushing, conveying, screening, storage, and grinding of quicklime. Likewise, bag filters are being increasingly used to control emissions from plants that produce hydrated lime from quicklime (Kenny & Oates, 2007). In addition to dust particles, Kenny & Oates (2007) indicated that the emission of sulfur dioxide (SO_2) and oxides of nitrogen (NO_X) can be an issue for rotary kilns, and for some shaft kilns used in the industrial production of quicklime from limestone. Indeed, the Research Triangle

Institute reported that gaseous pollutants—including carbon monoxide, carbon dioxide, nitrogen oxides and sulfur dioxide—are released through the production of lime (Beach, 2000).

Hydrated lime (calcium hydroxide) has a low environmental contamination potential. Indeed, the substance can be used as a liming treatment to ultimately improve the health of eutrophic lakes. Hydrated lime and other liming agents, such as calcium carbonate, have been used for lake rehabilitation for several decades (Murphy, 1988). In one experiment, the addition of hydrated lime at a rate of two kilograms per 100 liters of water effectively reduced the concentration of dissolved phosphorus that encourages the growth of various planktonic species and leads to algal and bacterial bloom development in freshwater ecosystems (Leoni, 2007). The greater efficacy of hydrated lime compared to other liming substances has been attributed to the dissociation of calcium hydroxide [$Ca(OH)_2$] into small, newly formed calcium carbonate ($CaCO_3$) crystals, which provide a large surface area for phosphorus absorption (Leoni, 2007). The addition of small to moderate amounts of hydrated lime that do not significantly alter water pH can beneficially impact the environment; however, large scale spills of the substance would likely result in impairment of the immediate environment.

In addition to spills of hydrated lime to surface waters, large-scale accidental releases of the chemical feedstock quicklime (calcium oxide) to natural waters or moist soils would raise the pH of the receiving medium. Aquatic species and soil organisms could be killed or damaged if quicklime were released in sufficient quantities. Reports of environmental contamination due to large-volume spills of hydrated lime, quicklime or waste materials containing these substances were not identified.

<u>Evaluation Question #7:</u> 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)).

According to material safety sheets, hydrated lime should not be mixed or stored with the following materials due to the potential for vigorous reaction and release of heat: acids (unless in a controlled process), reactive fluoridated compounds, reactive brominated compounds, reactive powdered metals, organic acid anhydrides, nitro-organic compounds, reactive phosphorus compounds, interhalogenated compounds (Chemical Lime, 2008). Aqueous solutions of hydrated lime are alkaline and incompatible with acids, ammonium salts and aluminum metal. The silicates in some hydrated lime materials react with powerful oxidizers such as fluorine, boron trifluoride (BF_3), chlorine trifluoride (ClF_3), manganese trifluoride (MnF_3) and oxygen difluoride (F_2O). Sources of hydrated lime that contain trace amounts of crystalline alumina can dissolve in hydrofluoric acid, producing corrosive silicon tetrafluroide (SiF_4) gas (Lafarge, 2011). With the exception of acidic species and ammonium salts, these chemical interactions should not occur during use of hydrated lime in organic production.

Regarding plant health, it is generally understood that various mineral species interact both synergistically and antagonistically in the process of absorption. Uptake of phosphate is essential for the absorption and translocation of calcium within the plant; however, high concentrations of calcium in the soil may lead to precipitation of less soluble calcium phosphates and associated phosphorus and calcium deficiency in plants (Jakobsen, 1993). As an alkaline substance, aqueous solutions of hydrated lime released to soils in significant amounts will raise the soil pH, thus altering the forms of calcium phosphate in the soil and potentially diminishing the uptake of calcium and phosphate by plants (Jakobsen, 1993). Hydrated lime is currently used as an external parasiticide in organically raised livestock, and therefore large amounts of the substance should not be released to soil.

<u>Evaluation Question #8:</u> 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)).

Applications of hydrated lime in large amounts will primarily affect the agro-ecosystem by raising the pH of treated soils. Within certain limits, soil organisms—such as fungi, bacteria, earthworms and nematodes—can tolerate extremes in pH through maintenance physiological cellular pH (typically pH 7.0). Certain strains of bacteria can tolerate extreme pH levels (e.g., pH 1.0 or 11.0); however, larger soil organisms may be more sensitive to pH than these bacteria and other microorganisms (FAO, 2014). Relatively alkaline tolerant soil bacteria such as *Bacillus subtilis* cannot survive a sudden shift to pH levels greater than or equal to 9.3. A more modest shift to pH 9.0, however, typically results in growth arrest while the bacterium slowly acidifies the surrounding solution before resuming growth once a lower pH (i.e., pH 8.5 or lower) is achieved (Padan, 2005). Soft-bodied soil organisms such as earthworms are significantly more sensitive to soil pH, and rarely tolerate extreme pH conditions (i.e., pH greater than 8.0 or less than 4.0) (USDA, 2002).

Soil pH also directly affects the speciation and bioavailability of elements. For example, aluminum is more toxic at low (acidic) pH values because it is more soluble and thus available for uptake in plants (Delhaize & Ryan, 1995). Liming treatments to raise soil pH using hydrated lime could therefore protect plants from the phytotoxic effects of aluminum compounds when grown in contaminated soils. Essential minerals can also become unavailable at extreme pH levels. At high pH, the essential nutrients phosphorus and manganese can become increasingly unavailable for uptake in plants and soil microorganisms (FAO, 2014).

The available literature suggests that large-scale releases of hydrated lime resulting in extremely high soil pH will adversely affect the viability and reproduction of non-target soil organisms, including beneficial bacteria, fungi, nematodes and earthworms. Despite the inherent risks of these releases to soil, information was not identified on the potential or actual impacts of hydrated lime upon endangered species and the potential for measurable reductions in genetic, species or eco-system biodiversity.

Evaluation Question #9: Discuss and summarize findings on whether the use of 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)).

Hydrated lime is released to the environment through various industrial waste streams and according to its use in agricultural production (HSDB, 2014). Both calcium and hydroxide—the principal atomic/molecular subunits of hydrated lime—are abundantly present in natural waters (Solvay, 2011; WSDE, 2005); therefore, it is unlikely that small to moderate releases will adversely affect the aquatic or terrestrial environment. Large-volume accidental releases, however, could significantly raise pH of receiving waters and soils, resulting in toxic effects to non-target organisms. Hydrated lime is considered practically non-toxic to slightly toxic to freshwater fish and invertebrates when added in quantities that do not lead to significant changes in water pH (WSDE, 2005). While certain strains of soil bacteria can tolerate extreme pH levels (e.g., pH 1.0 or 11.0), larger soft-bodied soil organisms are significantly more sensitive to changes in soil pH. Earthworms, for example, can only survive in the physiological pH range of 4.0 to 8.0 (USDA, 2002). Changes in soil pH due to application of alkaline hydrated lime can also affect the bioavailability of toxic heavy metal contaminants as well as essential micronutrients (Delhaize & Ryan, 1995; FAO, 2014). It is highly unlikely that hydrated lime from livestock treatments will be released to nearby soils in sufficient quantities to adversely impact the environment. Industrial production of the chemical precursor, quicklime (CaO), uses considerable amounts of energy and may release dust into the atmosphere. The use of more efficient modern kilns and bag filters can minimize the environmental impact of this process (Kenny & Oates, 2007).

Treatment and disposal is a potential complication associated with the use of hydrated lime and other miticide treatments in large volumes. In some cases, operators have discharged spent dip directly into watercourses or allowed the chemicals to soak into the ground near the dip facility (PAN-UK, 1997). Livestock operators using hydrated lime dipping stations for external parasite control should ensure that the resulting highly alkaline waste solutions are properly treated and disposed of to minimize the likelihood of environmental contamination. Accordingly, regulatory best management guidelines for sheep dipping facilities do not condone the "soakaway" method for disposal of waste dip solutions (SEPA, 2006).

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)).

Acute irritation is the primary health concern for human exposure to calcium hydroxide. As highly alkaline substances, calcium hydroxide solutions are capable of exerting corrosive/caustic effects to exposed body surfaces and internal organs, such as the eyes, skin and respiratory tract. Indeed, these solutions can severely irritate/burn the eyes and cause blurred vision, ulceration, and dangerous formation of clumps in the conjunctival sac of the eye, sometimes resulting in a loss of vision (US EPA, 2010). Contact with the skin or mouth may cause caustic burns, and ingestion can cause a burning sensation, abdominal pain, vomiting and diarrhea. In extreme cases, individuals may experience esophageal and stomach perforation (US EPA, 2010). US EPA classified calcium hydroxide as highly toxic (Toxicity Category I) for acute eye and dermal irritation. Calcium hydroxide exhibits minimal systemic toxicity, and is therefore categorized as practically non-toxic to mammals via the oral route of exposure (WSDE, 2005). In light of the potential for extreme irritation, labels for commercial products containing calcium hydroxide carry the signals word "Danger" and the following precautionary statement (Alistagen, 2003):

> *Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles or face shield), clothing (long sleeve shirt, long pants), and gloves (gauntlet type). May be fatal if inhaled. Do not breathe dust. Wear a MSHA/NIOSH-approved dust/mist filtering respirator number TC-21C or a NIOSH-approved respirator with any N, R, P or HE filter. Harmful is absorbed through the skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.*

Results of laboratory studies in animals and epidemiological studies in humans indicate that hydrated lime is not a carcinogen, mutagen, or reproductive/developmental toxicant. Hydrated lime is not listed as a carcinogen by the International Agency for Research on Cancer (IARC) or the National Toxicology Program (NTP); however, the substance may contains trace amounts of crystalline silica, which is classified by IARC and NTP as a known human carcinogen (Lafarge, 2011; IARC, 2014). The acute irritation and toxicity associated with inhaling alkaline hydrated lime will likely limit the potential for a carcinogenic response related to the possible occurrence of crystalline silica impurities. Although hydrated lime is not considered a reproductive and developmental toxicant, concerns have been noted due to the adverse effects observed in the chronic rat study described in Evaluation Question #5 (WSDE, 2005). Retrospective epidemiological studies did not identify adverse effects for individuals working in lime factories for up to 40 years. Likewise, available epidemiological studies are considered insufficient to reach definitive conclusions regarding the association between cement dust exposure and stomach cancer (Health Council, 2004). According to 21 CFR 184.1205 and 21 CFR 582.1205, calcium hydroxide is Generally Recognized As Safe (GRAS) by FDA when added directly to food for human consumption and livestock animal feed.

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)).

A variety of control strategies are used to treat mange and mite infestations in sheep, goats, cattle and other forms of livestock. Most of the available treatments are performed through spray dipping or vat dipping, topical application of nonsystemic (no uptake and circulation in the body) acaricides, as well as oral, topical or injectable formulations of systemic drugs (Losson & Mignon, 2011). Although spray dipping is time consuming, the treatment method can be useful for small herds. Vat dipping, on the other hand, is time efficient, but fairly expensive and difficult to manage due the large volumes of water used and the disposal requirement for waste wash solutions (Losson & Mignon, 2011). The following treatment regimens are commonly used for conventionally produced cattle in the United States: two dippings in 0.3% coumaphos (synthetic miticide) with no withdrawal time*, two dippings in 0.2–0.25% phosmet (synthetic organophosphate insecticide/miticide) with a 21-day withdrawal time, and/or three dippings in 2% lime-sulfur (calcium polysulfides; formed through combination of hydrated lime and elemental sulfur) with no withdrawal time (Losson & Mignon, 2011). Only hot lime-sulfur is registered for use on lactating dairy cows. Injectible formulation of systemic parasiticides, including avermectins (i.e., ivermectin and doramectin) and milbemycins (moxidectin), are approved for control of psoroptic and sarcoptic mange at 200 μg/kg in non-lactating dairy cattle (Losson & Mignon, 2011). Likewise, sheep scab associated with various parasites can be treated with injections of ivermectin, doramectin or moxidectin, as well as acaricides administered as dips or sprays (CFSPH, 2009). The following paragraphs provide specific information for natural and synthetic materials used as external parasiticides in organic production.

Numerous natural, non-synthetic materials are used as mite repellents and/or miticides to control infestations of burrowing mites in organic livestock production. Vegetable oils may be applied to the skin of affected livestock to suffocate pests, including mites and insects. With the exception of mineral oil

* Withdrawal time is the time period between the last treatment and when the animal can be slaughtered for food.

(described below), petroleum based products such as kerosene and diesel are not allowed for use as external parasiticides (Macey, 2009). Mixtures of vegetable oils and essential oils (e.g., neem, anise, camphor, eucalyptus, pennyroyal, pine, rosemary and sassafras) are also used to control mites and lice on infested livestock (Macey, 2009; Pedretti, undated). Diatomaceous earth—a naturally occurring material composed of the fossilized remains of tiny, aquatic organisms called diatoms—is commonly used as an insecticidal and miticidal agent. The substance is not poisonous; rather, it absorbs the oils and fats from the cuticles of insect exoskeletons, causing the exposed insects to dry out and die (NPIC, 2013). Diatomaceous earth also has sharp, abrasive edges that pierce the exoskeletons of exposed insects, thereby accelerating the insecticidal process (Macey, 2009; NPIC, 2013). Topical treatments of garlic powder and addition of garlic tinctures (infusion of garlic in grain alcohol or water) to feed are also used to control mites. For small spots of mange, it is recommended that producers saturate the areas with garlic tincture and rub the substance into the skin (Macey, 2009). Botanical insecticides containing the natural substance pyrethrum (extracted from the flower head of the Chrysanthemum plant) without the synthetic synergist piperonyl butoxide may also provide effective parasite control in organically produced cattle (Macey, 2009).

Commercially available products formulated with naturally occurring, non-synthetic active insecticidal and/or miticidal substances are included on the Organic Materials Review Institute (OMRI) product list. OMRI-approved products formulated with the active ingredient pyrethrum include Clarke Merus™ and Merus™ 2.0, Evergreen® Pyrethrum Concentrate, Evergreen® Pyrethrum Dust, PyGanic® Crop Protection EC 1.4 II and EC 5.0 II, PyGanic® Livestock and Poultry Insecticide (OMRI, 2014). For example, the PyGanic® EC 1.4 II product—which contains pyrethrins as 1.4% of the formulation—is approved for use as a livestock and poultry spray to kill and repel flies, mosquitoes and gnats; for effective control of biting and sucking lice on cattle, horses, sheep, goats and hogs; to control poultry lice; to control bed bugs and mites on poultry and in poultry houses; to control sheep tick/sheep ked; to kill fleas and ticks on livestock and pets and to obtain protection against re-infestation; and to control adult darkling beetle (lesser meal worm) in poultry houses (MGK, 2006). In addition to pyrethrum products, Tickless™, Zig-Zag, Bijoux Natural Oils Insect Repellent, and Whiz Natural Oils Insect Repellent are also commercially available and may be applied to animals and around livestock housing areas to repel pest insects and mites (OMRI, 2014).

A limited number of synthetically derived miticides are permitted for use in organic livestock production. Iodine scrubs have been used to control infestations (Macey, 2009). In addition, mineral oil is approved for use as an external parasiticide in the United States (7 CFR 205.603(b)(6)), and should provide similar control of insects and mites by smothering exposed insects in a manner similar to vegetable oils and essential oils. Light treatments of mineral oil (or vegetable oils described above) should be applied regularly to effectively control mites, ticks, lice and other parasites (Pedretti, undated). Because soap removes the waxy cuticle that protects insects and mites from dehydrating, repeated soaping treatments will kill lice and mites on affected livestock (Macey, 2009; Pedretti, undated). Selected systemic parasiticides—including (i) fenbendazole, (ii) ivermectin and (iii) moxidectin—are allowed as emergency treatments for organically managed "dairy and breeder stock when organic system plan-approved preventative management does not prevent infestation" (7 CFR 205.603(a)(18)). Milk products from treated animals cannot be labeled as "organic" for at least 90 days following treatment with any of these animal drugs. Additionally, treatment cannot occur during the last third of gestation period in breeder stock intended for sale as organic, and must not be used during the lactation period for breeding stock. These substances are always prohibited for use in slaughter stock (7 CFR 205.603(a)(18)).

Other substances included in 7 CFR 205.603(b) are not intended for use in the same manner as hydrated lime, which is typically used to control mites, lice and ticks on large animals. Sucrose octanoate esters are approved as external parasiticides in organic livestock production specifically for *Varroa* mite control on honey bees (USDA, 2005). Copper sulfate is approved for use in footbaths to kill bacteria and fungi responsible for foot rot in large animals, and is therefore a viable alternative to hydrated lime for that use pattern in organic livestock production. The following is a full list of substances approved under 7 CFR 205.603(b) as topical treatments, external parasiticides and/or local anesthetics as applicable:

- Copper sulfate – Topical treatment, bactericide/fungicide in foot baths for treating foot rot.
- Formic acid (CAS number: 64-18-6) – For use as a pesticide solely within honeybee hives.
- Iodine – Antimicrobial substance used as a topical treatment.

- Lidocaine – As a local anesthetic; use requires a withdrawal period of 90 days after administration to livestock intended for slaughter and 7 days after administration to dairy animals.
- Lime, hydrated – As an external pest control; not permitted to cauterize physical alterations or deodorize animal wastes.
- Mineral oil – For topical use and as a lubricant; may be used as a spot treatment alternative to hydrated lime sprays and dips to kill external parasites on livestock.
- Procaine – As a local anesthetic; use requires a withdrawal period of 90 days after administration to livestock intended for slaughter and 7 days after administration to dairy animals.
- Sucrose octanoate esters (CAS numbers: 42922-74-7 and 58064-47-4) – In accordance with approved labeling, it may be used for *Varroa* mite control on honey bees.

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

Preventative measures and cultural control practices are commonly employed in organic livestock operations to reduce the risk of parasite infestation in large animals. Whenever possible, it is highly recommended that livestock producers exercise preventative measures to minimize the risk of mite and lice infestations in herds of cattle and other livestock. Livestock operators are generally encouraged to separate new arrivals for at least three weeks before introduction to the herd. During this time, it is important to check these animals closely for any signs of infestation and to treat when necessary (Pedretti, undated). Likewise, it is essential that livestock managers promptly separate animals displaying early signs of infestation. Providing high quality feed and reducing stress levels in the herd can also minimize the occurrence of widespread mite infestations (Pedretti, undated). The following is a summary of best practices for minimizing the occurrence of parasite infestation in large animal herds (Macey, 2009):

- keep animals outdoors as much as possible to ensure ample exposure to sunlight;
- avoid close confinement of animals;
- provide good quality feed to animals and "free choice" minerals and kelp to young stock during the winter months;
- maintain a stress free environment with ample space to allow for natural behavioral patterns in production animals;
- quarantine any affected animals, and check replacement animals brought into the herd (isolate from the herd and observe for three weeks before introduction);
- maintain a closed herd policy;
- minimize communal grazing with other herds to avoid transmission of lice and mites;
- provide a cattle back scratcher (without an insecticide reservoir) to help control chewing lice populations;
- select for resistance in the herd, and cull animals that are chronically infested with parasites.

Infestations of burrowing mites and lice are readily spread through direct contact between cattle or when straw bedding and other objects become contaminated with burrowing mites (Macey, 2009). Therefore, in addition to avoiding close confinement of animals, it may be necessary to clean livestock housing areas and frequently change bedding materials during times of intense pest pressure. Mite populations generally surge in fall and winter, with the heaviest infestations occurring in late winter and early spring (Macey, 2009). Likewise, operators should clean and disinfect pens, sheds and other infested areas before moving in animals that are free of mite infestations (Weinzierl & Jones, 2000). As with mite and lice prevention in cattle, the primary means of preventing the occurrence of sheep scab, mange and other mite infestations is for sheep producers to avoid exposing sheep to infected animals (McNeal, 1999). When mange is detected, the affected animals should be quarantined to prevent the spread of mites throughout the herd (CFSPH, 2009). In cases of severe infestation, it may be necessary to kill and destroy severely infested animals or market for slaughter the animals that are severely attacked (Weinzierl & Jones, 2000).

Research and technical recommendations regarding non-chemical control methods are lacking in the peer-reviewed and agricultural extension literature. Therefore, it is unlikely that existing infestations can be controlled without the use of natural (non-synthetic) or approved synthetic substances described in Evaluation Question #11.

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