

**Sunset 2023**  
**Meeting 1 - Request for Public Comment**  
**Livestock Substances § 205.603 & § 205.604**  
**April 2021**

### **Introduction**

As part of the [Sunset Process](#), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List which must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, annotation, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the [Petitioned Substances Database](#).

### **Request for Comments**

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2021 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2021 public meeting. Comments should be provided via Regulations.gov at [www.regulations.gov](http://www.regulations.gov) on or before April 5, 2021, as explained in the meeting notice published in the Federal Register.

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (see [7 U.S.C. 6518\(m\)](#)) and the USDA organic regulations ([7 CFR 205.600](#)). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review, which demonstrated that the substances were: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should clearly indicate the commentor's position on the allowance or prohibition of substances on the National List and explain the reasons for the position. Public comments should focus on providing relevant new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance (e.g. scientific, environmental, manufacturing, industry impact information, etc.). Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

### **For Comments that Support the Continued Use of §205.603 Substances in Organic Production:**

If you provide comments supporting the allowance of a substance at §205.603, you should provide information demonstrating that the substance is:

1. not harmful to human health or the environment;
2. necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
3. consistent with organic livestock production.

### **For Comments that Do Not Support the Continued Use of §205.603 Substances in Organic Production:**

If you provide comments that do not support a substance at §205.603, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

1. harmful to human health or the environment;
2. unnecessary because of the availability of alternatives; and/or
3. inconsistent with organic livestock production.

**For Comments that Support the Continued Prohibition of §205.604 Substances in Organic Production:**

If you provide comments supporting the prohibition of a substance on the §205.604 section of the National List, you should provide information demonstrating that the substance is:

1. harmful to human health or the environment;
2. unnecessary because of the availability of alternatives; and
3. inconsistent with organic livestock production.

**For Comments that Do Not Support the Continued Prohibition of §205.604 Substances in Organic Production:**

If you provide comments that do not support the prohibition of a substance at §205.604, you should provide reasons why the use of the substance should no longer be prohibited in organic production. Specifically, comments that support the removal of a substance from the §205.604 section of the National List should provide new information since its last NOSB review to demonstrate that the substance is:

1. not harmful to human health or the environment; and/or
2. consistent with organic livestock production.

**For Comments Addressing the Availability of Alternatives:**

Comments may include information about the viability of alternatives for a substance under sunset review.

Viable alternatives include, but are not limited to:

- Alternative management practices that would eliminate the need for the specific substance;
- Other substances that are on the National List that are better alternatives, which could eliminate the need for this specific substance; and/or
- Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include: product or practice descriptions, performance and test data, reference standards, names and addresses of organic operations who have used the alternative under similar conditions and the date of use, and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review.

Written public comments will be accepted through April 5, 2021, via [www.regulations.gov](http://www.regulations.gov). Comments received after that date may not be reviewed by the NOSB before the meeting.

**§205.603 Sunsets: Synthetic substances allowed for use in organic livestock production:**

- [Activated charcoal](#)
- [Calcium borogluconate](#)
- [Calcium propionate](#)
- Chlorine materials
  - [\(i\) Calcium hypochlorite](#)
  - [\(ii\) Chlorine dioxide](#)
  - [\(iii\) Hypochlorous acid—generated from electrolyzed water](#)
  - [\(iv\) Sodium hypochlorite](#)
- [Kaolin pectin](#)
- [Mineral oil](#)
- [Nutritive supplements \(Injectable trace minerals, vitamins, and electrolytes\)](#)
- [Propylene glycol](#)
- [Sodium chlorite, acidified §205.603\(a\)\(28\); and Sodium chlorite, acidified §205.603\(b\)\(9\)](#)
- [Zinc sulfate](#)

**§205.604 Sunsets: Nonsynthetic substances prohibited for use in organic livestock production:**

- None

## Activated charcoal

**Reference:** §205.603 (a)(6) Activated charcoal (CAS # 7440-44-0) - must be from vegetative sources.

**Technical Report:** [2002](#); [2021 TR Pending](#)

**Petition(s):** [2002](#)

**Past NOSB Actions:** [2002 recommendation/vote](#)

**Recent Regulatory Background:** Added to NL effective 1/28/2019 ([83 FR 66559](#))

**Sunset Date:** 1/28/2024

### Subcommittee Review

#### Use

The principal veterinary use for activated charcoal is as an antidote to toxic substances—and analogous medical applications include use as a detoxifier. According to the 2002 TAP Review, it is regarded as the poison antidote of choice and the universal antidote to toxic substances. There is no reported overdose or acute toxicity. Activated charcoal is highly effective against both natural and synthetic toxins. Studies show activated carbon to be effective in removing various mycotoxins, such as aflatoxin, fumonisins, ochratoxin A, trichothenes, and zearalenone. Natural toxins from plants are also removed or attenuated by activated charcoal treatment or supplementation.

Activated carbon can also be used to remove synthetic pesticides from animals that might contaminate milk or meat. Treatment with activated carbon when using certain parasiticides can help reduce the residual levels in flesh and fatty tissue. However, it should be noted that use of such substances and withdrawal from milk or meat production is subject to the applicable USDA organic regulations.

Activated charcoal is used to treat animals for drug overdoses, with efficacy established on pigs, dogs, and rabbits.

#### Manufacture

Activated charcoal of vegetative origin can be made from a large variety of sources such as hardwoods, grain hulls, corn cobs, and nut shells. The material undergoes pyrolysis at a very high heat. These agricultural byproducts may be chemically activated using a variety of acids and bases. Acids may be acetic acid, and potassium hydroxide and sodium hydroxide are possible bases. The charcoal may also be activated through exposure to oxygenated gas or steam.

#### International Acceptance

*Canadian General Standards Board Permitted Substances [List](#)*

Table 5.3 of the Permitted Substances List includes activated charcoal, stating “shall be of plant origin.”

*European Economic Community (EEC) Council Regulation, EC No. [834/2007](#) and [889/2008](#)*

While there is no specific listing for activated charcoal, Article 14 notes that “suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.” The regulation further notes “disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined.”

*CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods ([GL 32-1999](#), Part B, Section 22)*

While there is no specific listing for activated charcoal (carbon), the Guidelines state the following:

The use of veterinary medicinal products in organic farming shall comply with the following principles:

- a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted;
- b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended;
- c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours;
- d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited.

#### *International Federation of Organic Agriculture Movements (IFOAM) Norms*

While activated charcoal is not specifically listed, the general principles state management practices should be directed to the well-being of animals, achieving maximum resistance against disease, and preventing infections. Sick and injured animals must be given prompt and adequate treatment. Further, the standards note the well-being of the animals is the primary consideration in the choice of illness treatment. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation.

#### *Japan Agricultural Standard (JAS) for Organic [Production](#)*

While activated charcoal is not specifically listed, the standard states that when veterinary drugs are used, the withholding period shall be twice the period of conventional standards.

#### **Environmental Issues**

Activated charcoal has minimal impact on human health and the environment. It may cause respiratory problems for those who handle it, especially as the particle size decreases. Its use in processing doesn't generally have an effect or chemical interaction in the agroecosystem. The greatest impact of activated charcoal from vegetative sources is the removal of organic matter from the system.

Because of concern regarding the use of certain acids in manufacture, during the 2021 sunset review for activated charcoal listed at §205.605(b), some stakeholders commented that they would like to see use limited to sources derived solely from steam activation.

#### **Discussion**

This substance was among 35 NOSB recommendations on amendments to the National List, made from November 2000 to November 2016, that were acted upon in a final rule published in December 2018. Because of this recent addition, this is the first sunset review of activated charcoal at this listing.

#### **Questions to our Stakeholders**

1. Is activated charcoal essential to organic livestock health care and production?

## Calcium borogluconate

**Reference:** §205.603 (a)(7) Calcium borogluconate (CAS # 5743-34-0) - for treatment of milk fever only.

**Technical Report:** [2000 TAP](#)

**Petition(s):** N/A

**Past NOSB Actions:** [2000 recommendation/vote](#)

**Recent Regulatory Background:** Added to NL effective 1/28/2019 ([83 FR 66559](#))

**Sunset Date:** 1/28/2024

### Subcommittee Review

#### Use

Calcium borogluconate is used for treatment of hypocalcemia (also called parturient paresis and commonly called milk fever) in cattle, sheep, and goats. Milk fever is the result of metabolic stress occurring only at or near parturition (giving birth). The mother mobilizes large amounts of calcium to produce milk to feed its newborn, and blood calcium levels can drop below the point necessary for impulse transmission along the nerve tracts. There are three discernable stages of milk fever for cows: in stage one, cows are able to stand but show signs of hypersensitivity and excitability. In stage two, cows are unable to stand. In stage three, cows lose consciousness progressively to the point of coma.

#### Manufacture

Calcium borogluconate is prepared by the reaction of five parts calcium gluconate to one-part boric acid in an aqueous solution. Boric acid esterifies the alcohol groups on the gluconate. Excess boric acid is removed by distillation with ethanol.

Calcium gluconate is prepared by several methods, including the reaction of gluconic acid with calcium hydroxide. Calcium hydroxide was also reviewed by the NOSB for processing and was classified as synthetic and allowed. Gluconic acid is most commonly produced in the U.S. by fermentation.

#### International Acceptance

*Canadian General Standards Board Permitted Substances [List](#)*

Table 5.3 of the Permitted Substances List includes calcium borogluconate “[f]or milk fever. No withdrawal period required.”

*European Economic Community (EEC) Council Regulation, EC No. [834/2007](#) and 889/2008*

While there is no specific listing for Calcium borogluconate, Article 14 notes that “suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.” The regulation further notes “disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular, restrictions with respect to courses of treatment and withdrawal periods shall be defined.”

*CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods ([GL 32-1999](#), Part B, Section 22)*

While there is no specific listing for calcium borogluconate, the Guidelines state the following:

- The use of veterinary medicinal products in organic farming shall comply with the following principles:
- a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted;

- b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended;
- c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours;
- d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited.

#### *International Federation of Organic Agriculture Movements (IFOAM) Norms*

While calcium borogluconate is not specifically listed, the general principles state management practices should be directed to the well-being of animals, achieving maximum resistance against disease, and preventing infections. Sick and injured animals must be given prompt and adequate treatment. Further, the standards note the well-being of the animals is the primary consideration in the choice of illness treatment. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation.

#### *Japan Agricultural Standard (JAS) for Organic [Production](#)*

Calcium borogluconate is not specifically listed.

### **Environmental Issues**

The TAP review did not discuss environmental issues related to the manufacture of calcium borogluconate. The review noted, “[t]he material is metabolized by the animal, with the calcium entering the blood stream and some being expressed as milk. The animal’s urine and feces may contain higher levels of boron as a result, but none of the literature reviewed partitioned the fate. Some claim that introduction of boron and sugar is either unnecessary or causes complications, but these are not specified.”

### **Discussion**

This substance was among 35 NOSB recommendations on amendments to the National List, made between November 2000 and November 2016, that were acted upon in a final rule published in December 2018. This is the first sunset review of calcium borogluconate at this listing.

Calcium borogluconate is also classified on the National List under electrolytes which are currently listed at §205.603 as synthetic substances allowed for organic livestock production when they do not contain antibiotics. According to the TR, electrolytes are needed in organic livestock production to restore ionic balance, thus treating metabolic conditions such as hypocalcemia, scours, dehydration, milk fever, erratic heartbeat, loss of muscle control, mastitis, ketosis, alkalosis, acidosis, difficulty in labor and prostration.

### **Questions to our Stakeholders**

1. The National List references multiple substances for the treatment of ketosis and milk fever, including propylene glycol, calcium propionate, calcium borogluconate and electrolytes. Are they equally necessary and effective? Do organic producers have the correct tools for treatment of all stages of the development of these related conditions?
2. Calcium borogluconate also appears on the National List under allowed electrolytes. Please describe the history and the importance of calcium borogluconate’s consideration by organic systems as a stand-alone substance.

## Calcium propionate

**Reference:** §205.603 (a)(8) Calcium propionate (CAS # 4075-81-4) - for treatment of milk fever only.

**Technical Report:** [2002 TAP](#); [2015 TR \(Electrolytes\)](#)

**Petition(s):** [2002](#)

**Past NOSB Actions:** [2002 recommendation/vote](#); [2002 position paper](#)

**Recent Regulatory Background:** Added to NL effective 1/28/2019 ([83 FR 66559](#))

**Sunset Date:** 1/28/2024

### Subcommittee Review

#### Use

Calcium propionate is used for treatment of hypocalcemia (also called parturient paresis and commonly called milk fever). Milk fever is the result of metabolic stress occurring only at or near parturition (giving birth). The mother mobilizes large amounts of calcium to produce milk to feed its newborn, and blood calcium levels can drop below the point necessary for impulse transmission along the nerve tracts. There are three discernable stages of milk fever for cows: in stage one, cows are able to stand but show signs of hypersensitivity and excitability. In stage two, cows are unable to stand. In stage three, cows lose consciousness progressively to the point of coma.

Calcium propionate was originally petitioned as both a mold inhibitor and as a treatment for livestock for milk fever but was approved with an annotation limiting the use as a treatment for milk fever.

Calcium propionate is an electrolyte that is needed in organic livestock to restore ionic balance, thus treating metabolic conditions such as milk fever (hypocalcemia), scours, dehydration, erratic heartbeat, loss of muscle control, mastitis, ketosis, alkalosis, acidosis, difficulty in labor and prostration. Lack of treatment can often result in death. The FDA considers electrolyte formulations to be animal drugs, but many of the formulations have not been formally approved by the FDA. Often this is because they are non-proprietary, general use materials, and no company has applied for a New Animal Drug Approval (NADA) (OMRI 2013; USDA 2005b)

Propionate is used by the liver to make glucose, which is used by the cow to make lactose, the sugar in milk. Milk production is very closely related to the total glucose supply at the udder. Propionate's second function involves the cow's fat metabolism. When the cow's energy demands for milk production exceed the amount of energy she is eating, she begins to break down some of her body fat stores. Fats are first broken down into smaller pieces, called non-esterified fatty acids (NEFA's), and carried to the liver. At the liver, they are broken down to form acetate to generate energy. Acetate is broken down to carbon dioxide and water to yield more energy; however, this process requires Propionate. If there is not enough propionate available (which is often the case when cows are making a lot of milk sugar), the excess acetate builds up in the liver, then acetate molecules combine to make acetone, acetoacetate, and beta-hydroxybutyrate. These products are released from the liver into the cow's bloodstream, causing the ketosis symptoms.

When lactation starts, milk fever can be treated by intravenous administration of electrolytes containing calcium to the animal. Calcium can be added by oral boluses, pastes, or drenching if the animal is still standing, but when the animal is down, intravenous injection is needed. Oral doses of calcium chloride can be effective, but it is caustic, causing ulcerations. It can also lead to acidosis. Calcium propionate is less caustic, does not cause acidosis, and the propionate fatty acid is glucogenic. One dose is given at calving, and another 24 hours later.



## **Manufacture**

Electrolytes are mostly synthetic materials produced by chemical processes. Since many are salts, they are often produced by acid-base reactions. Calcium propionate is produced by reacting propionic acid with an aqueous solution of calcium hydroxide. It is also produced by reacting calcium hydroxide with propionitrile.

## **International Acceptance**

*Canadian General Standards Board Permitted Substances [List](#)*

In Canada, the Permitted Substances List for Organic Animal Production allows electrolytes as part of Table 5.3 'Health Care Products and Production Aids.' Electrolytes without antibiotics are permitted, and electrolyte solutions 'with no added active ingredients' are permitted (Canadian Standards 2011). No withdrawal period required.

*European Economic Community (EEC) Council Regulation, EC No. [834/2007](#) and [889/2008](#)*

Electrolytes are not mentioned specifically in 834/2007. However, Annex V, Feed Materials of Mineral Origin (EU EEC 2008, Article 14 Section 1 (e) (ii) states "chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions" (EU EEC 2007). In 889/2008 many of the electrolyte salts are permitted as feed additives.

While there is no specific listing for calcium propionate, Article 14 notes that "suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter." The regulation further notes "disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined."

*CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods ([GL 32-1999](#), Part B, Section 22)*

Electrolytes are not specifically mentioned. However, under Health Care, Section 22 "where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted."

*International Federation of Organic Agriculture Movements (IFOAM) Norms*

In the IFOAM NORMS for organic production and processing version 2012, electrolytes are not specifically mentioned for organic animal production. In Section III (5) on Animal Husbandry, only natural sources are permitted for vitamins, trace elements, and supplements. Use of synthetic allopathic veterinary drugs or antibiotics will cause the animal to lose its organic status (IFOAM 2012). But many of the electrolyte substances are mentioned in Appendix 4 as additives and processing aids (IFOAM 2012).

While Calcium Propionate is not specifically listed, the general principles state management practices should be directed to the well-being of animals, achieving maximum resistance against disease, and preventing infections. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation.

*Japan Agricultural Standard (JAS) for Organic [Production](#)*

The Japanese Agricultural Standard (JAS) for Organic Production originally considered only crops and processing (JAS 2005). Later revisions included livestock. A summary in 2007 mentions that organic livestock must be fed organic feed, have exercise and access to pasture, and must not be fed antibiotics or GMOs. Electrolytes for organic animal production were not mentioned; therefore, it is unknown whether they are specifically allowed or prohibited (JAS 2007).

*Soil Association Standards, United Kingdom*

The Soil Association Standards at Section 10.10.22 specifically allow calcium borogluconate, magnesium and phosphorus salts for milk fever. Section 10.10.34 specifically allows glucose/electrolytes as oral rehydration therapy for scours. Antibiotics and other non-allowed substances cannot be used (Soil Association 2005).

### **Environmental Issues**

Electrolytes are used in animal production situations. Since electrolytes are usually added to correct deficiencies, concentrations in the environment due to excretion would be no more than a normal untreated animal with normal electrolyte balances. Most of these materials are produced by acid-base reactions. Environmental contamination from production of calcium propionate is unlikely for the salts, as reactions are simple neutralizations, producing the needed salt and water. Any problems would come from excess stocking rates. Excess stocking rates could lead to an excess of metabolic by-products in the immediate environment, plus adds extra stress to the animals.

### **Discussion**

The 2015 TR on electrolytes, including calcium propionate, discussed whether there were alternative non-synthetic materials or alternative practices that would make the use of calcium propionate unnecessary. The TR concluded that the electrolytes are on the list of allowed synthetics, and non-synthetic sources of electrolyte formulations are typically not commercially available.

Alternative practices that would make the use of calcium propionate less necessary for the prevention and treatment of milk fever (hypocalcemia) are low calcium prepartum diets, Dietary Cation Anion Difference (DCAD) diets (prior to parturition), and administration of oral electrolytes. Sometimes combinations of these treatments are used. DCAD diets involve adding electrolytes to food to provide an excess of strong anions or choosing food that will have this effect. Body condition should be managed in late lactation to prevent cows from becoming too fat, which adds to the risk of milk fever. Modifying diets of late lactation cows to increase the energy supply from digestible fiber and reduce the energy supply from starch may aid in partitioning dietary energy toward milk and away from body fattening.

### **Questions to our Stakeholders**

1. Are there any new practices or non-synthetic materials that would make the use of calcium propionate unnecessary?
2. Do our livestock stakeholders think the listing for calcium propionate is necessary at §205.603(a)(8) since electrolytes are listed as a group at §205.603(a)(11) *Electrolytes—without antibiotics*?

## Chlorine materials

**Reference:** §205.603 (a)(10) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

- (i) Calcium hypochlorite
- (ii) Chlorine dioxide
- (iv) Sodium hypochlorite

**Technical Report:** [2006 TR](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [05/2006 NOSB sunset recommendation](#); [10/2010 NOSB recommendation](#); [10/2015 sunset recommendation](#); [11/2017 Recommendation to add hypochlorous acid](#); [11/2017 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice 3/15/2017 ([82 FR 14420](#)); Sunset renewal notice effective 10/30/2019 ([84 FR 53577](#))

**Sunset Date:** 10/30/2024

### Subcommittee Review

#### Use

Sodium and calcium hypochlorite are chlorinated inorganic disinfectants used to control bacteria, fungi, and slime-forming algae that can cause diseases in people and animals (EPA, 1991, 1992). These disinfectants also are used in cleaning irrigation, drinking water, and other water and wastewater systems. Chlorine dioxide is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is also used in cleaning water systems and disinfecting public drinking water supplies (Agency for Toxic Substances and Disease Registry (ATSDR), CDC, 2004a). It also is used as a bleaching agent in paper and textile manufacturing, as a food disinfectant (e.g., for fruit, vegetables, meat, and poultry), for disinfecting food processing equipment, and treating medical wastes, among other uses (EPA, 2003a). Chlorine materials are currently used for disinfection of livestock facilities (NOP Guidance [5026](#)).

#### Manufacture

Calcium hypochlorite, sodium hypochlorite, and chlorine dioxide are all synthetic materials that are manufactured by chemical processes. Calcium hypochlorite is produced by passing chlorine gas over slaked lime. It is then separated from the coproduct, calcium chloride, and air dried or vacuumed. Generally, sodium hypochlorite is produced by reacting chlorine with a solution of sodium hydroxide (NaOH, also called lye or caustic soda). This method is used for most commercial productions of sodium hypochlorite. A more active, but less stable formulation of sodium hypochlorite can be produced by chlorinating a solution of soda ash (Na<sub>2</sub>CO<sub>3</sub>). Chlorine dioxide is formed by reacting sodium chlorate (NaClO<sub>3</sub>) and sulfuric acid (H<sub>2</sub>SO<sub>4</sub>) with sulfur dioxide (SO<sub>2</sub>), or chloric acid is reacted with methanol (CH<sub>3</sub>OH) (HSDB, 2005). Alternatively, chlorine dioxide can be formed with chlorine (Cl<sub>2</sub>) and sodium chlorite; sodium hypochlorite with hydrochloric acid; potassium chlorate with sulfuric acid; or by passing nitrogen dioxide through a column of sodium chlorate.

#### International Acceptance

*Canadian General Standards Board Permitted Substances* [List](#)

Bleach (not exceeding drinking water standards) is permitted in packaging and sanitation.

European Economic Community (EEC) Council Regulation, EC No. [834/2007](#) and [889/2008](#)  
Sodium hypochlorite (e.g., as liquid bleach) is authorized for the clearing and disinfecting of livestock buildings and installations.

### Environmental Issues

Information available from EPA and FDA on chlorine dioxide, sodium, and calcium hypochlorite, and hypochlorous acid indicates that there is no environmental contamination resulting from proper manufacture, use, or disposal.

### Discussion

Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food-safety regulations. The Livestock Subcommittee (LS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for livestock handling and processing. The LS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards. However, at this point in time, chlorine materials are an essential part for maintaining hygiene in livestock facilities.

### Questions to our Stakeholders

1. Are there alternatives to chlorine materials that are less toxic sanitizer options in livestock operations?
2. Should we be considering chlorine materials through a more holistic point of view and, as per the sanitizer panel during the Fall 2020 NOSB meeting, are there practices we should look to prior to using chlorine materials in livestock operations?
3. Are there practices we should look to prior to using chlorine materials in livestock operations?
4. Are there any new recommendations for how to rotate sanitizers to maintain maximum efficacy?

## Chlorine materials – Hypochlorous acid – generated from electrolyzed water

**Reference:** §205.603 (a)(10) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(iii) Hypochlorous acid - generated from electrolyzed water

**Technical Report:** [2006 TR \(Chlorine materials\)](#); [2017 Limited Scope TR \(Hypochlorous Acid\)](#)

**Petition(s):** [2016 \(Hypochlorous Acid\)](#)

**Past NOSB Actions:** [11/2017 Recommendation to add hypochlorous acid](#);

**Recent Regulatory Background:** Hypochlorous acid added to NL effective 1/28/2019 ([83 FR 66559](#));

**Sunset Date:** 1/28/2024

### Subcommittee Review

#### Use

hypochlorous acid, as formulated via electrolyzed water, is effective as a sanitizer at a much lower chlorine

concentration and is safer for health and the environment than the currently listed chlorine sanitizers. Chlorine materials are currently used for disinfection of livestock facilities (NOP Guidance [5026](#)).

### **Manufacture**

Electrolyzed water (EW) is the product of the electrolysis of a dilute sodium chloride solution in an electrolysis cell containing a semi-permeable membrane that physically separates the anode and cathode but permits ions to pass through. In the process, hypochlorous acid, hypochlorite ion, and hydrochloric acid are formed at the anode, and sodium hydroxide is formed at the cathode. The solution formed on the anode side is acidic EW (pH 2 to 6), and the solution formed on the cathode side is basic EW (pH 7.5 to 13). Neutral EW, with a pH of 6 to 7.5 is produced by mixing the anodic solution with hydroxide, or by using a single-cell chamber for electrolysis. (TR lines 48-68).

### **International Acceptance**

*Canadian General Standards Board Permitted Substances [List](#)*

Bleach (not exceeding drinking water standards) is permitted in packaging and sanitation.

*European Economic Community (EEC) Council Regulation, EC No. [834/2007](#) and [889/2008](#)*

Sodium hypochlorite (e.g., as liquid bleach) is authorized for the clearing and disinfecting of livestock buildings and installations.

### **Environmental Issues**

Information available from EPA and FDA on chlorine dioxide, sodium, and calcium hypochlorite, and hypochlorous acid indicates that there is no environmental contamination resulting from proper manufacture, use, or disposal.

### **Discussion**

Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food-safety regulations. The Livestock Subcommittee (LS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for livestock handling and processing. The LS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards. However, at this point in time, chlorine materials are an essential part for maintaining hygiene in livestock facilities.

### **Questions to our Stakeholders**

1. Are there alternatives to chlorine materials that are less toxic sanitizer options in livestock operations?
2. Should we be considering chlorine materials through a more holistic point of view and, as per the sanitizer panel during the Fall 2020 NOSB meeting, are there practices we should look to prior to using chlorine materials in livestock operations?
3. Are there practices we should look to prior to using chlorine materials in livestock operations?
4. Are there any new recommendations for how to rotate sanitizers to maintain maximum efficacy?

## Kaolin pectin

**Reference:** §205.603 (a)(17) Kaolin pectin - for use as an adsorbent, antidiarrheal, and gut protectant.

**Technical Report:** [2002 TAP](#); [2021 TR Pending](#)

**Petition(s):** [2002](#)

**Past NOSB Actions:** [2002 recommendation/vote](#); [2002 Position Paper](#)

**Recent Regulatory Background:** Added to NL effective 1/28/2019 ([83 FR 66559](#))

**Sunset Date:** 1/28/2024

### Subcommittee Review

#### Use

Kaolin pectin is used in livestock for the same reasons that it is administered to humans: as an adsorbent, anti-diarrheal, and gut protectant. It may also be combined with vitamin A to treat bacterial diarrhea in calves.

#### Status

According to the 2002 TAP, the FDA has declared kaolin to be GRAS as an indirect food additive, and pectin to be GRAS as a direct food additive, both with the limitation that the levels in food are consistent with good manufacturing practices.

In addition to kaolin pectin having been placed on the National List as an allowed synthetic substance, kaolin and pectin are also separately allowed for use in organic systems.

In the 2002 TAP, there was some disagreement about whether kaolin pectin should be categorized as a synthetic or non-synthetic substance.

#### Manufacture

Both kaolin and pectin are formed naturally. Kaolin is a mineral dust formed by weathering of aluminum silicates. Pectin may be obtained for use by extraction into an aqueous medium from appropriate edible plant material, usually citrus fruits or apples. No organic precipitants are used other than methanol, ethanol, and isopropanol. In some types a portion of the methyl esters may have been converted to primary amides by treatment with ammonia under alkaline conditions. The commercial product is normally standardized with sugars and may be buffered with suitable food grade salts.

#### International Acceptance:

*Canadian General Standards Board Permitted Substances* [List](#)

Kaolin pectin not listed.

*European Economic Community (EEC) Council Regulation, EC No. [834/2007](#) and [889/2008](#)*

Kaolin pectin not listed.

Note that while there is no specific listing for kaolin pectin, the use of this substance is consistent with Article 14, which states that “suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.” The regulation further notes “disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined.”

*CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods* ([GL 32-1999](#))

Kaolin pectin not listed.

Note that while there is no specific listing for kaolin pectin, the use of this substance is consistent with the Guidelines, which state the following:

The use of veterinary medicinal products in organic farming shall comply with the following principles:

a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted;

b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended;

c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours;

d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited.

*International Federation of Organic Agriculture Movements (IFOAM) Norms*

Kaolin pectin not listed.

Note that while there is no specific listing for kaolin pectin, the use of this substance is consistent with IFOAM's general principles that state that "management practices should be directed to the well-being of animals, achieving maximum resistance against disease and preventing infections. Sick and injured animals must be given prompt and adequate treatment. Further, the standards note the well-being of the animals is the primary consideration in the choice of illness treatment. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation."

*Japan Agricultural Standard (JAS) for Organic [Production](#)*

Kaolin pectin in not listed.

### **Environmental Issues**

According to the 2002 TAP:

- There is no evidence that kaolin and pectin will contaminate environment.
- In the manner in which kaolin is to be used, in kaolin pectin, there is unlikely chance of environmental contamination. However, if workers are to be exposed to kaolin dust during manufacture, they must take appropriate precautions.

### **Discussion**

Under §6509 of OFPA ("Animal production practices and materials"), Section (d) ("Health care") states:

*(1) Prohibited practices*

*For a farm to be certified under this chapter as an organic farm with respect to the livestock produced by such farm, producers on such farm shall not—*

- (A) use subtherapeutic doses of antibiotics;
- (B) use synthetic internal parasiticides on a routine basis; or
- (C) administer medication, other than vaccinations, in the absence of illness.**

To the degree to which kaolin pectin is used to address actual livestock illnesses in the context of organic livestock production, its allowance is consistent with OFPA Section 6509.

Given that the TAP on kaolin pectin is from 2002 and a TR on kaolin pectin requested in 2020 is pending, the subcommittee should conduct another review of kaolin pectin once the TR becomes available, especially if it raises any significant concerns about the continued use of the substance in organic production.

#### Questions to our Stakeholders:

1. How widely used is kaolin pectin in organic livestock production?
2. Are there any equally effective non-synthetic/natural substances available that serve the same functions as kaolin pectin?
3. What problems/issues, if any, are there associated with the use of kaolin pectin in organic livestock production?
4. Is there any concern that organic livestock producers may be using kaolin pectin on a routine, prophylactic basis, rather than solely to address livestock illness?

## Mineral oil

**Reference:** §205.603 (a)(20) Mineral oil—for treatment of intestinal compaction, prohibited for use as a dust suppressant.

**Technical Report:** [2002 TAP](#); [2015 TR](#); [2021 Limited Scope TR Pending](#)

**Petition(s):** [2002 Petition](#)

**Past NOSB Actions:** [11/1995 NOSB minutes and vote](#); [2002 recommendation/vote](#); [5/2003 recommendation](#)

**Recent Regulatory Background:** Added to NL effective 1/28/2019 ([83 FR 66559](#))

**Sunset Date:** 1/28/2024

### Subcommittee Review

#### Use

The National Organic Program regulations currently permit the use of mineral oil in organic livestock production for treatment of intestinal compaction, prohibited for use as a dust suppressant in 7 CFR 205.603(a)(20). Mineral oil is also approved as a topical application and as a lubricant under 7 CFR 205.603(b)(7), but this sunset review is limited to 205.603(a)(20).

In the case of “omasal impaction”, the ruminant’s third stomach (omasum) becomes tightly bound and compacted, resulting in severe pain for the affected animal. Omasal impaction is related to type II vagal indigestion (failure of omasal transport), which develops from any condition that prevents ingested material from passing through the omasal canal into the abomasum, the fourth and final stomach



compartment in cattle. In organic livestock production, operators orally administer mineral oil to lubricate the intestinal tract and dislodge intestinal obstructions in cattle and other ruminants.

In general, impactions in various segments of the gastrointestinal tract may develop in pregnant beef cows during cold winter months when cattle consume less water and are fed lower-quality roughage. Mineral oil may be applied as an oral drench at a rate of one to two gallons every 12 hours until the viscous mineral oil treatment lubricates the impaction. Abomasal impaction is treated using four liters (approximately one gallon) of mineral oil per day for three days. In the 2015 TR review it was noted that some livestock producers indicated that failure to regularly treat for omasal impaction often results in the need for surgery. In a related ailment known as “retained meconium” the baby calf’s first manure is blocked, thus rendering the animal unable to excrete normally. Mineral oil serves as an internal lubricant in conjunction with the administration of an enema to unblock the digestive obstruction.

In conventional cattle production, mineral oil is also commonly used to control bloat. Bloat generally occurs in animals after grazing young, lush pasture, particularly if the pasture contains significant amounts of legume species (clover, medics or lucerne). As a preventative measure in conventional systems, veterinary specialists suggest that cattle producers drench each animal twice daily with an anti-bloat preparation or oil when the pasture is conditions may be likely to cause bloat (i.e. young, lush pasture, and/or presence of significant amounts of legume species). However, this medical practice is not approved in organic production.

### **Manufacture**

Crude petroleum oil is the predominant source of mineral oil used in organic and conventional agriculture, as well as food for human consumption, cosmetic products, and drugs. Refined mineral oil is obtained through physical separation, such as distillation and solvent extraction, and chemical conversion processes, including cracking, hydrogenation, alkylation, isomerization and/or other chemical transformations. The composition of mineral oil is dependent upon the crude oil source (e.g., location of procurement) and the processing that occurs in the refinery, such as physical separations and chemical conversions. Because of the complexity of the mineral oil mixtures, refined mineral oil is identified using several CAS numbers depending on the treatment processes utilized and the intended use pattern of the mineral oil product. The mineral oil used in organic livestock production is hydrocarbon molecules containing 34 carbon atoms. These untreated mineral oil products may also contain small amounts of nitrogen- and sulfur containing compounds.

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). The industrial production of highly refined, food-grade mineral oil involves chemical processing and refinement using various chemical reagents and/or catalysts. Crude oil is desalted, distilled, and subjected to solvent extraction, de-aromatization with fuming sulfuric acid or sulfur trioxide, and/or catalytic hydrocracking treatments to reduce the concentration of polar constituents containing heteroatoms (nitrogen, oxygen and sulfur atoms) as well as polynuclear aromatic hydrocarbons (PAHs) and other aromatic compounds. Crude oil, itself, is considered an economically significant natural resource throughout the world, and would likely be classified as a naturally derived, non-synthetic substance according to NOP definitions. However, the production of mineral oil requires the alteration of crude oil through physical separation (distillation) followed by reactions/combination with synthetic substances and reagents (aromatic solvents, strong acids and/or catalysts). As such, the mineral oil is classified as a synthetic material on the National List.

### **International Acceptance**

*Canadian General Standards Board Permitted Substances [List](#)*

Canadian regulations permit numerous uses for mineral oil of varying purity. Mineral oil is allowed for external application only under Section 5.3 (health care products and production aids) of the permitted substances list for livestock production (CAN, 2011).

*European Economic Community (EEC) Council Regulation, EC No. [834/2007](#) and [889/2008](#)*

According to Annex II of the European Organic Regulation (EC) No 889/2008, mineral oil may be used as an insecticide and/or fungicide only in fruit trees, vines, olive trees and tropical crops (e.g., bananas). Mineral oil is not mentioned specifically in 834/2007 for the use in livestock. However, Annex V, Feed Materials of Mineral Origin (EU EEC 2008, Article 14 Section 1 (e) (ii) states “chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions” (EU EEC 2007). While there is no specific listing for mineral oil in livestock, Article 14 notes that “suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.” The regulation further notes “disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phyto-therapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined.”

*CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods ([GL 32-1999](#); Part B, Section 22)*

The Codex Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (CAC/GL 32-1999) indicate that mineral oil is only permitted for use in traps for organic crop production. Mineral oil is not specifically mentioned for livestock applications. However, under Health Care, Section 22 “where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted.”

*International Federation of Organic Agriculture Movements (IFOAM) Norms*

The IFOAM Norms permit the use of “light mineral oil (paraffin)” under Appendix 3 (crop protectants and growth regulators). There are no approved uses for mineral oil or related substances in organic livestock production under the IFOAM Norms (IFOAM, 2014).

*Japan Agricultural Standard (JAS) for Organic [Production](#)*

The Japanese Agricultural Standard (JAS) for Organic Production originally considered only crops and processing (JAS 2005) with later revisions including livestock. Japanese regulations for the organic production of livestock only mentions the use of “petroleum oil aerosol” and “petroleum oil emulsion” for plant pest and disease control (Table 2). Otherwise, it does not appear that Japanese organic regulations permit the use of mineral oil or related products in organic livestock production (JMAFF, 2012).

However, on July 16, 2020 USDA and Japan signed an Organic Livestock Equivalency. Livestock products include beef, eggs, etc., and processed products of animal origin include ham, cheese, chocolate milk, etc. The arrangement is limited to domestic animals (cattle, horses, sheep, goats, and pigs) or domestic poultry (chickens, quails, ostriches, ducks, and wild ducks. Due to this equivalency agreement, livestock treated with mineral oil would be allowed for export to Japan.

### **Environmental Issues**

In the 2007 risk assessment for mineral oil, the EPA indicated that most manufacturers are currently using modified refining and cleanup processes to remove the more toxic components and generate refined minerals largely devoid of PAHs as well as nitrogen and sulfur compounds. Because of their complexity, it is not possible to resolve mineral oil mixtures into individual components for quantification. Indeed, 46 classes of chemicals contained in crude and refined mineral oil mixtures have a wide variety of forms (isomers, carbon chain lengths, etc.) (EFSA, 2012).

Mineral oil may be classified as highly refined or mildly treated/untreated. The white mineral oil that is likely to be used to treat intestinal compaction in organic livestock production are highly refined oils that contain negligible quantities of toxic contaminants compared to untreated and mildly treated oils. Testing in laboratory animals has demonstrated that mineral oil is slightly to practically non-toxic to mammals on an acute exposure basis. Mineral oil is a mild irritant, classified as Toxicity Category IV (lowest toxicity) for skin irritation and Category III for eye irritation. Highly refined “white” mineral oil produced no sensitization reactions in guinea pigs repeatedly exposed to the substance.

The carcinogenicity and genotoxicity potential for mineral oil is generally dependent upon the degree of refinement and presence of PAHs in the mixture. White mineral oil—which has undergone the most severe acid, solvent, or hydrocracking treatment—showed no activity in a series of skin-tumor bioassays. Much like the mammalian studies, the results of avian and honeybee studies suggest that refined mineral oil is practically non-toxic to birds and honeybees via acute oral and contact exposure, respectively. Refined mineral oil is generally characterized as minimally toxic to aquatic organisms on an acute exposure basis.

### **Discussion**

Mineral oil was petitioned in 2002 to be used for treatment of intestinal compaction and topical application, and as a dust suppressant in organic livestock feedstuffs. After reviewing the 2003 TAP review, the Board recommended adding mineral oil for treatment of intestinal compaction. They did not recommend adding mineral oil as a dust suppressant additive in feedstuffs since they determined there were sufficient alternative supplies of other natural materials for that use that are not prone to rancidity. Some alternative products to mineral oil as a dust suppression include grapeseed, citrus, and certain other vegetable oils.

Following the NOSB recommendation of inclusion of mineral oil for use as a veterinary treatment for omasal impaction in organic livestock production other issues came to light. Based on consultations with the US Food and Drug Administration (FDA), the NOP was informed that mineral oil has not received approval through the FDA drug approval process to be authorized as a medical treatment in cattle, and the substance would not qualify for extra-label use by a licensed veterinarian. Animal drugs containing mineral oils—such as AgriLabs Mineral Oil Light and UNAVET Mineral Oil Light NF—are currently marketed for relief of obstruction or impaction of the intestinal tract in cattle, sheep, goats, swine, and horses. Because these animal drugs are not FDA approved, the labels carry the disclaimer: “this drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA.” FDA has yet to take regulatory action against these mineral oil products or require safety and efficacy testing for animal drugs containing mineral oil. The US Environmental Protection Agency (US EPA) deferred to FDA as the appropriate regulatory body for use of the substances.

Best management practices may prevent the development of omasal impaction in cattle, sheep, and other livestock under certain conditions. There are cultural practices that may decrease the incidence of intestinal compaction requiring treatment using natural and/or synthetic substances in organic livestock production. Omasal impaction generally occurs when the feed provided to cattle is tough and fibrous, particularly alfalfa stalks and cuttings from fodder trees, or under drought feeding conditions in sheep that are fed on the ground. The latter form of impaction in sheep is typically due to the accumulation of soil in the omasum.

In healthy animal stock, providing the necessary nutritional requirement for wintering pregnant beef cattle can prevent abomasal impaction. Producers using low-quality roughage should augment the ration with grain to meet energy and protein requirements, especially if laboratory analyses indicate these key nutrient parameters are low in the roughage alone. Adequate drinking water should be supplied continually for animal welfare, and to encourage proper digestion of feed and pasture materials. Omasal impaction may

be prevented through provision of rations containing 10–15% cut or chopped roughage mixed into the complete feed to ease the digestion of fibrous materials. The roughage should be a cereal, grain straw, grass hay, or equivalent, and grains should be rolled or cracked as opposed to finely ground.

### Questions to our Stakeholders

1. Are there new studies that indicate that the use of mineral oil as a treatment of intestinal compaction is no longer necessary?
2. Are there differences in interpretations by certifiers for allowed use of mineral oil as a treatment of intestinal compaction in livestock (7 CFR 205.603(a)(20))?
3. If there are differences in interpretations amongst certifiers for the use of mineral oil as a treatment of intestinal compaction in livestock, what clarification or guidance could be provided that would eliminate the differences in interpretation?

### Nutritive supplements – injectable trace minerals, vitamins, and electrolytes

**Reference:** §205.603 (a)(21) Nutritive supplements - injectable supplements of trace minerals per paragraph (d)(2) of this section, vitamins per paragraph (d)(3), and electrolytes per paragraph (a)(11), with excipients per paragraph (f), in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.

**Technical Report:** [1995 TAP \(\(a\)\(11\) electrolytes\)](#); [2015 TR \(\(d\)\(3\) vitamins\)](#); [2015 TR \(\(a\)\(11\) electrolytes\)](#); [2019 TR \(\(d\)\(2\) trace minerals\)](#);

**Petition(s):** [2009](#)

**Past NOSB Actions:** [05/2009 recommendation to add to NL](#)

**Recent Regulatory Background:** Added to NL effective 1/28/2019 ([83 FR 66559](#))

**Sunset Date:** 1/28/2024

### Subcommittee Review

#### Use

Nutritive supplements (Injectable trace minerals, vitamins, and electrolytes) are allowed to treat livestock ailments when administered or ordered by a licensed veterinarian.

#### Manufacture

Trace minerals used as feed additives are produced by chemical reactions resulting in inorganic forms of the mineral. Organic compounds are used for some of the trace minerals.

Vitamins can be extracted from foods or synthesized by chemical or biofermentation processes. Regarding the former, certain vitamins can be obtained from natural dietary sources in varying quantities. For example, Vitamin C (ascorbic acid) is a major nutritional component of citrus fruits and Vitamin D is a natural constituent nutrient of cold-water fish.

#### International Acceptance

*Canadian General Standards Board Permitted Substances [List](#)*

From the Permitted Substances List (CAN/CGSB-32.311- 459 2006), vitamins may be used for enrichment or fortification of livestock feed, and synthetic vitamins may be used if non-synthetic sources are not

commercially available (CAN, 2011b). Under no circumstances should vitamins be used to stimulate growth or production (CAN, 2011b).

*European Economic Community (EEC) Council Regulation, EC No. [834/2007](#) and 889/2008*

EC No. 834/2007 and 889/2008, state that “feed of mineral origin, trace elements, vitamins or provitamins shall be of natural origin. In case these substances are unavailable, chemically well-defined analogic substances may be authorized for use in organic production.” Specifically, vitamins are allowed nutritional additives for use in animal production under the following conditions: (1) Vitamins derived from raw materials occurring naturally in feedstuffs; (2) Synthetic vitamins identical to natural vitamins for monogastric animals and aquatic animals; (3) Synthetic vitamins A, D, and E identical to natural vitamins for ruminants with prior authorization of the Member States based on the assessment of the possibility for organic ruminants to obtain the necessary quantities of the said vitamins through their feed rations.

*CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods ([GL 32-1999](#))*

The Codex Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced 466 Foods (CAC GL 32-1999) provides criteria for feedstuffs and nutritional elements. Specifically, section 467 of these guidelines pertaining to livestock production states that “feedstuffs of mineral origin, trace minerals, vitamins, or provitamins can only be used if they are of natural origin. In case of shortage of these substances, or in exceptional circumstances, chemically well-defined analogic substances may be used” (Codex, 2013).

*United Kingdom Soil Association*

Nature identical synthetic vitamins may be used in the production of non-herbivores without permission, while producers of herbivores must seek approval to use nature identical synthetic vitamins A, D and E. Regarding the latter group, the operator must demonstrate nutritional deficiency of the animals’ feed. Soil Association standards do not permit the use of concentrated vitamins and minerals to encourage early maturity or high levels of production (Soil Association, 2014).

*Japan Ministry of Agriculture, Forestry, and Fisheries.*

The Japan Ministry of Agriculture, Forestry, and Fisheries Standard for Organic Feed does not specify the allowed or prohibited status of vitamins in organic livestock feed materials. However, the standard permits 493 natural feed additives: Feed additives (except for those produced by using antibiotic and recombinant DNA technology), which are natural substances or those derived from natural substances without being chemically treated. In case of a difficulty to obtain feed additives listed in 8, the use of similar agents to the described food additives are permitted only for supplementing nutrition and effective components in feeds. This statement suggests that synthetic vitamins may be allowed if naturally derived substitutes are not available (JMAFF, 2012).

### **Environmental Issues**

The potential exists for environmental contamination resulting from the industrial production of several vitamin compounds. In particular, materials safety data sheets (MSDS) for several feedstock chemicals and other chemical reagents used in the synthesis of calcium pantothenate (vitamin B5) and biotin (vitamin B7) indicate the potential for ecological damage if accidentally released into the environment. Isobutyraldehyde and cyanide salts used in the synthesis of calcium pantothenate as well as ethylene oxide used for choline chloride generation have shown toxicity toward fish and aquatic invertebrates. Further, hydrogen sulfide, which is used in the synthesis of biotin, is toxic to fish at low doses, and is therefore listed as very toxic to aquatic life. Strong acids (e.g., nitric acid, hydrochloric acid) used in the syntheses of numerous vitamins may alter the pH of aquatic systems if accidentally released to the environment. Strong acids and bases are also utilized in the extraction of tocopherols from vegetable oils and may lead to environmental impairment if accidentally released or improperly handled. Many of the vitamins

synthesized for supplements and feed fortification are derived from petroleum products or genetically modified crop materials.

## Discussion

There can be times of stress when certain individual animals need high amounts of vitamins and minerals delivered to target tissues in a rapid manner. If for whatever reason animals are not eating, then they are not taking in the oral forms of vitamins and minerals. They may need nutritive supplementation best delivered by injection. Additionally, with the prohibition of the use of antibiotics in certified organic livestock, farmers and veterinarians need as many of the remaining tools as possible to prioritize animal health. Injectable forms of vitamins and minerals, allowed strictly on an as need basis, provide valuable support to an animal's immune system and is a method that works to assist livestock health, well-being and promotes animal welfare.

## Questions to our Stakeholders

1. Do advances in organic ration formulations change the need for injectable nutritive supplements?

## Propylene glycol

**Reference:** §205.603 (a)(27) Propylene glycol (CAS #57-55-6) - only for treatment of ketosis in ruminants.

**Technical Report:** [2007 TAP](#); [2021 TR Pending](#)

**Petition(s):** [2002](#)

**Past NOSB Actions:** [2002 Position Paper](#); [9/2002 recommendation to add to NL](#)

**Recent Regulatory Background:** Added to NL effective 1/28/2019 ([83 FR 66559](#))

**Sunset Date:** 1/28/2024

## Subcommittee Review

### Use

Propylene glycol is used as a drench for the treatment of ketosis in ruminants, and is considered GRAS, except when used in or on cat food. According to the TR, propylene glycol is used as an anticaking agent, emulsifier, flavor agent, formulation aid, humectant, processing aid, solvent and vehicle, stabilizer and thickener, surface-active agent, and as a texturizer.

### Manufacture

Propylene glycol is manufactured by treating propylene with chlorinated water to form chlorohydrin, which is then converted to glycol by treatment with sodium carbonate solution. Propylene glycol is also prepared by heating glycerol with sodium hydroxide and distilling the mixture.

### International Acceptance

*Canadian General Standards Board Permitted Substances [List](#)*

Propylene glycol listed in Table 5.3 as a permitted health care product/production aide for livestock, specifically limited to use as an ingredient in foot baths.

*European Economic Community (EEC) Council Regulation, EC No. [834/2007](#) and [889/2008](#)*

While there is no specific listing for propylene glycol, Article 14 notes that “suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.” The regulation further notes “disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict

conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular, restrictions with respect to courses of treatment and withdrawal periods shall be defined.”

*CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)*

While there is no specific listing for propylene glycol, the Guidelines state the following:

The use of veterinary medicinal products in organic farming shall comply with the following principles:

- a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted;
- b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended;
- c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours;
- d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited.

*International Federation of Organic Agriculture Movements (IFOAM) Norms*

While propylene glycol is not specifically listed, the general principles state management practices should be directed to the well-being of animals, achieving maximum resistance against disease, and preventing infections. Sick and injured animals must be given prompt and adequate treatment. Further, the standards note the well-being of the animals is the primary consideration in the choice of illness treatment. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation.

*Japan Agricultural Standard (JAS) for Organic [Production](#)*

While propylene glycol is not specifically listed, the standard states that when veterinary drugs are used, the withholding period shall be twice the period of conventional standards.

### **Environmental Issues**

The 2007 TAP review states; the intended use of propylene glycol as a drench treatment would not result in direct interaction with other materials used in organic farming systems. There is no indication of detrimental interactions from this application. Additionally, when released into the soil, this material is expected to readily biodegrade and leach into groundwater. When released into water, this material is expected to readily biodegrade. When released into the air, this material is expected to be readily degraded by reaction with photochemically produced hydroxyl radicals.

According to the TAP Review on propylene, also known as propene, is an unsaturated hydrocarbon. It is an important petrochemical feedstock. It is obtained as a by-product of gasoline manufacture by the fluid cracking of gas oils, or from ethylene in the steam cracking of hydrocarbons, in which a mixture of steam and hydrocarbon is passed through a tube heated to 600- 900°C (1110-1650°F). About 10% of the propylene that is manufactured is converted into propylene oxide, C<sub>3</sub>H<sub>6</sub>O, either by a reaction with hypochlorous acid, HOCl, followed by calcium hydroxide, or in a one-step reaction with hydroperoxide,

ROOH, in the presence of a molybdenum or vanadium catalyst. Propylene oxide is then hydrolyzed to propylene glycol or polymerized to polypropylene glycol, or used in the preparation of polyurethanes, detergents, hydraulic fluids, etc.

### Discussion

This substance was among 35 NOSB recommendations on amendments to the National List, made from November 2000 to November 2016, that were acted upon in a final rule published in December 2018. Because of this recent addition, this is the first sunset review of propylene glycol at this listing.

A TR is pending for propylene glycol. In the original TAP review, all three TAP reviewers found propylene glycol to be a synthetic material. Two reviewers supported allowance of the substance in livestock with restrictions, while the other supported allowance for all petitioned purposes and without restriction. Concerns included the consistency of the method of manufacturing of propylene glycol with organic practices, and the availability of other methods of treatment and prevention of ketosis.

### Questions to our Stakeholders

1. When preventative measures do not work, are there natural/non-synthetic alternative treatments for ketosis in ruminants since approval of the petition? Are there any alternative synthetic treatments on the NL that make this listing redundant?
2. Are there developments in manufacturing of propylene glycol that would require new evaluation of source materials?

## Sodium chlorite, acidified

**Reference:** §205.603 (a)(28) Sodium chlorite, acidified - allowed for use on organic livestock as a teat dip treatment only; and

§205.603 (b)(9) Sodium chlorite, acidified - allowed for use on organic livestock as a teat dip treatment only.

**Technical Report:** [2013 TR](#)

**Petition(s):** [2012](#); [2014 Addendum #1](#); [2014 Addendum #2](#)

**Past NOSB Actions:** [4/2015 recommendation](#)

**Recent Regulatory Background:** Added to NL effective 1/28/2019 ([83 FR 66559](#))

**Sunset Date:** 1/28/2024

### Subcommittee Review

#### Use

Acidified sodium chlorite is used as a disinfecting teat dip for organic livestock producers. Acidified sodium chlorite breaks down in the environment to water and salt and is more benign than other teat dip materials currently listed on the National List.

#### Manufacture

Acidified sodium chlorite solutions are made by mixing an aqueous solution of sodium chlorite with a food-grade acid, such as citric acid. Several industrial synthetic procedures are utilized in the production of sodium chlorite. As examples, the treatment of chlorine dioxide, sodium hydroxide, and a reducing agent (e.g., sodium sulfite) or reaction of chlorine dioxide with sodium peroxide (i.e.,  $\text{Na}_2\text{O}_2$  or an alkaline solution of hydrogen peroxide,  $\text{H}_2\text{O}_2$ ) are commercially utilized methods for the synthesis of sodium chlorite.



Generally Recognized as Safe (GRAS) acids, such as citric and lactic acids, are typically produced through fermentative means; however, these naturally occurring compounds may also be extracted from plant-based sources or generated using chemical synthetic methods.

### **International Acceptance**

*Canadian General Standards Board Permitted Substances [List](#)*

Acidified sodium chlorite is not specifically listed.

*European Economic Community (EEC) Council Regulation, EC No. [834/2007](#) and [889/2008](#)*

While there is no specific listing for acidified sodium chlorite, Article 14 notes that “suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.” The regulation further notes “disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined.”

*CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods ([GL 32-1999](#), Part B, Section 22)*

While there is no specific listing for acidified sodium chlorite, the Guidelines state the following:

The use of veterinary medicinal products in organic farming shall comply with the following principles:

- a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted;
- b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended;
- c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours;
- d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited.

*International Federation of Organic Agriculture Movements (IFOAM) Norms*

While acidified sodium chlorite is not specifically listed, the general principles state management practices should be directed to the well-being of animals, achieving maximum resistance against disease, and preventing infections. Sick and injured animals must be given prompt and adequate treatment. Further, the standards note the well-being of the animals is the primary consideration in the choice of illness treatment. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation.

*Japan Agricultural Standard (JAS) for Organic [Production](#)*

Acidified sodium chlorite is not specifically listed.

## **Environmental Issues**

While the manufacture and use of acidified sodium chlorite solutions have resulted in releases to the environment, the risk of environmental contamination from released acidified sodium chlorite is minimal. Certain manufacturing facilities have reported releases of chlorine dioxide, a portion of which was generated through reaction of chlorite with a strong acid, to air, water, and soil (ATSDR, 2004). Strong acids (e.g., hydrochloric acid) and bases (sodium hydroxide) are used in the commercial production of sodium chlorite, and their release due to improper handling/disposal could lead to serious environmental impairments. Likewise, the release of strong oxidizing agents in large quantities may lead to ecotoxicity in both terrestrial and aquatic environments. This is true of both the chemical feedstocks (e.g., hydrogen peroxide) used in the manufacture of acidified sodium chlorite precursors and the chemicals in acidified sodium chlorite solutions (i.e., chlorous acid, chlorine dioxide, chlorite). Regarding the former, several lower reactivity sulfur-containing and carbonaceous substances have been evaluated for the conversion of chlorine dioxide to sodium chlorite.

## **Discussion**

Acidified sodium chlorite was among 35 NOSB recommendations on amendments to the National List, made between November 2000 and November 2016, that were acted upon in a final rule published in December 2018. Because of this recent addition, this is the first sunset review of acidified sodium chlorite at this listing.

Preventive health care is an essential part of organic farming, and mastitis prevention through clean milking parlors and clean animals is always of paramount importance on a dairy farm. Organic farmers cannot use antibiotics and thus the use of pre milking and post milking teat dips is a normal practice and may be the most critical factor in preventing mastitis. Acidified sodium chlorite satisfies the criteria related to impact on humans and the environment and is compatible with organic agriculture. Iodine is widely used in teat dips. The technical report (TR) on iodine, received on January 7, 2015, provides recent research information and comparative data on iodine-based teat dips and on teat dips whose primary ingredient is acidified sodium chlorite. The following is excerpted from the iodine TR in its discussion of alternatives to iodine in teat dips: "Information regarding the availability of natural, non-synthetic agricultural commodities or products that could substitute for iodine and iodophor disinfectants is limited." Acidified sodium chlorite thus appears to be a potentially important ingredient in teat dips.

## **Questions to our Stakeholders**

1. Are there preferred alternatives to acidified sodium chlorite for preventative care in dairy cows?
2. Have there been changes in the availability of iodine that would reduce the need for acidified sodium chlorite?

## Zinc sulfate

**Reference:** §205.603 (b)(11) Zinc sulfate - for use in hoof and foot treatments only.

**Technical Report:** [2015 TR](#)

**Petition(s):** [2014](#)

**Past NOSB Actions:** [4/2015 recommendation](#)

**Recent Regulatory Background:** Added to NL effective 1/28/2019 ([83 FR 66559](#))

**Sunset Date:** 1/28/2024

### Subcommittee Review

#### Use

Zinc sulfate is allowed for use in organic livestock as a footbath for control of foot rot in livestock-- primarily dairy cattle, sheep, and goats.

#### Manufacture

Zinc sulfate is produced synthetically by combining zinc ash with aqueous sulfuric acid (TR line 53). Commercially, zinc sulfate is manufactured from zinc ore mined from underground or open pit mines (TR line 60).

#### International Acceptance

*Canadian General Standards Board Permitted Substances [List](#)*

Operators of organic livestock production facilities must establish a provision for prompt treatment for animals with detectable disease, lesions, lameness, injury, and other physical ailments. Where preventive practices and vaccines are inadequate to prevent sickness or injury and where disease and health problems require treatment, the use of biological, cultural, and physical treatments and practices is permitted, in accordance with CAN/CGSB-32.311, Organic Production Systems — Permitted Substances Lists, but maybe relaxed under veterinary supervision if listed substances fail to work. Products from sick animals or those undergoing treatment with restricted substances shall not be organic or fed to organic livestock (CGSB, 2011a). Sulfates of zinc may be used only to correct for deficiencies determined by soil or plant tissue testing. Sulfates produced using sulfuric acid are prohibited. Zinc sulfate may be used to correct a documented zinc deficiency (CGSB, 2011b). TR lines 216 – 225.

*European Economic Community (EEC) Council Regulation, EC No. [834/2007](#) and [889/2008](#)*

Disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. Restrictions with respect to courses of treatment and withdrawal periods are defined (EU, 2007); Animal health is based on prevention of disease, but treated livestock may not be sold as organic products if treatment involves an unapproved medication. Treated livestock must be submitted to the defined conversion periods. Zinc sulfate may be used as a trace element in the production of organic livestock. The maximum concentration for zinc in composted or fermented household waste to be used as fertilizer or soil conditioner is 200 milligrams per kilogram (EU, 240 2008). TR lines 231-240.

*CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods ([GL 32-1999](#))*

Where specific disease occurs, and no management practice exists, therapeutic use of veterinary drugs is permitted; Zinc can be used as a trace element supplement when the need is recognized by the certification body or authority. The use of zinc sulfate for control of foot rot in cattle sheep and goats has not been specifically addressed (Codex, 2007). TR lines 226-230

### *International Federation of Organic Agriculture Movements (IFOAM) Norms*

Organic animal management systems follow the principle of positive health, which consist of a graduated approach of prevention (including vaccinations and anti-parasite treatments only when essential), then natural medicines and treatment, and finally if unavoidable, treatment with allopathic chemical drugs. Organic animal management never withholds medical treatment considered necessary for the welfare of an animal to maintain the organic status of the animal (IFOAM, 2014). TR lines 245-250

### *Japan Agricultural Standard (JAS) for Organic [Production](#)*

Veterinary Drugs specified by Article 1. 1 of the Ministerial Ordinance for Handling by the Ministry of Health, Labor and Welfare (No.4 of 1961) are permitted. Zinc sulfate use is limited to the case where livestock is unable to grow normally because of its shortage as a trace element (MAFF, 2012). TR lines 241-244

### **Environmental Issues**

Excess applications of zinc sulfate could disrupt essential nutrient balances in soils and in extremes could become toxic to plants or animals. Zinc sulfate is toxic to fish and aquatic invertebrates. Direct application to water where these exist should be avoided. It should also be noted that the use of zinc sulfate should decrease the use of copper sulfate in treating foot diseases. The buildup of persistent copper in agricultural soils is a serious issue. While zinc sulfate can also accumulate in soils, its persistence is less certain due to the mode of attachment to soils. Zinc sulfate is therefore considered a more benign material compared to copper sulfate.

### **Discussion**

Copper sulfate and zinc sulfate are two of the most accepted treatments and are comparable in efficacy. Zinc sulfate has proven particularly effective at controlling the bacteria associated with foot rot, and is sometimes used in combination with other materials, including copper sulfate. The combination of zinc sulfate with sodium lauryl sulfate (as an excipient) has proven to be more effective than zinc sulfate with copper sulfate.

The Livestock Subcommittee will again seek public comments regarding the effectiveness of alternative methods for controlling foot rot, including management practices, and the use of hydrogen peroxide, peracetic acid or other materials. Further, the subcommittee will seek feedback on whether the availability of zinc sulfate for use in organic livestock production would likely reduce the use of copper sulfate for treatment of foot rot.

### **Questions to our Stakeholders**

1. Has the use of zinc sulfate reduced the use of copper sulfate in treating foot disease in livestock?