

Sunset 2023  
Meeting 2 - Review  
Handling Substances § 205.605(a), § 205.605(b), § 205.606  
October 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 scheduled for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that 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, use description, 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**

Written public comments will be accepted through September 30, 2021 via [www.regulations.gov](http://www.regulations.gov). Comments received after that date may not be reviewed by the NOSB before the meeting.

**§205.605(a) Sunsets: Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”:**

- Agar-agar
- Animal enzymes
- Calcium sulfate-mined
- Carrageenan
- Glucono delta-lactone
- Tartaric acid

**§205.605(b) Sunsets: Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”:**

- Cellulose
- Chlorine materials
  - (i) Calcium hypochlorite
  - (ii) Chlorine dioxide
  - (iii) Hypochlorous acid—generated from electrolyzed water
  - (iv) Sodium hypochlorite
- Potassium hydroxide
- Silicon dioxide
- Potassium lactate
- Sodium lactate

### Environmental Issues

There do not appear to be any human health concerns associated with potassium lactate as provided by the 2015 TR. There was an environmental issue raised about the amount of gypsum created in the manufacturing of lactic acid, the necessary precursor of potassium lactate. However, according to a report published by the EPA, lactic acid and its salts are readily biodegradable and have low potential to persist in the environment (Environmental Protection Agency 2008).

### Discussion

Many stakeholders view this listing as “enormously complicated” saying that it is the procedural history that is complicated and not the material itself. Potassium lactate has been allowed for use in organic handling since its approval in January of 2004. The decision to not require a petition for this material for inclusion to the National List was based on the fact that both of the materials used to produce potassium lactate (lactic acid and potassium hydroxide) were already approved on the National List. It was later determined that this decision was not consistent with previous NOSB recommendations on classification of materials and that the material needed to go through the petition process. Potassium lactate was added to the National List effective January 28, 2019. The Handling Subcommittee finds significant merit to keep potassium lactate on the National List at § 205.605 (b) with the annotation: for use as an antimicrobial agent and pH regulator only.

### Summary of Public Comments

A majority of public commenters was in support of relisting potassium lactate. A review of the “use tables” supplied by several associations indicate that potassium lactate is a widely used material. Some stakeholders asked why both potassium and sodium lactates are on the National List as they appear to be used nearly interchangeably. It was noted that there are certain uses, such as “low sodium” meat alternatives, that require potassium lactate specifically.

### Justification for Vote

The Subcommittee proposes removal of potassium lactate from the National List based on the following criteria in the Organic Foods Production Act (OPFA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

### Subcommittee Vote

Motion to remove potassium lactate from the National List

Motion by: Jerry D’Amore

Seconded by: Steve Ela

Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

### Silicon dioxide

**Reference:** §205.605(b) Silicon dioxide - Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.

**Technical Report:** [1996 TAP](#); [2010 TR](#)

**Petition(s):** [2010 petition to remove](#)

**Past NOSB Actions:** [09/1996 minutes and vote](#); [11/2005 recommendation](#); [12/2011 recommendation](#); [11/2016 recommendation](#)

**Recent Regulatory Background:** Added to NL 12/21/2000 ([65 FR 80548](#)); National list amended 05/28/2013 (effective 11/03/2013) ([78 FR 31815](#)); Sunset renewal notice effective 5/29/2018 ([83 FR 14347](#)).

**Sunset Date:** 5/29/2023

## Subcommittee Review

### Use

Synthetic amorphous silicon dioxide is used as a food additive for various functions including as:

- An anticaking agent in foods.
- A stabilizer in beer production, and filtered out of the beer prior to final processing
- An adsorbent in tableted foods.
- A carrier.
- A defoaming agent.

### Manufacture

Synthetic amorphous silicon dioxide can be manufactured by three methods: a vapor-phase hydrolysis process, a wet process, or a surface-modified treatment. According to FDA regulations, silicon dioxide (as a food additive) is manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect. Silicon dioxide can be produced as a nanomaterial, but for use in organic production such a material would have to be petitioned and placed on the National List. As stated in NOP Policy Memorandum from March 2015:

As with other substances, no engineered nanomaterial will be allowed for use in organic production and handling unless the substance has been

- 1) petitioned for use;
- 2) reviewed and recommended by the NOSB; and
- 3) added to the National List through notice and comment rulemaking.

Currently there is no silicon dioxide produced with nanotechnology on the National List.

### International Acceptance

#### Canadian General Standards Board Permitted Substances List

Silicon dioxide is listed in Table 6.3 Ingredients Classified as Food Additives, and Table 6.5 Processing Aids.

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

Silicon dioxide is listed in Annex VIII of the Commission Regulation, Section A Food Additives, Including Carriers for use in preparation of foodstuffs of plant origin as an anticaking agent for herbs and spices. Also listed as a gel or colloidal solution in Section B Processing Aids and Other Products, Which May Be Used for Processing of Ingredients of Agricultural Origin from Organic Production.

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

Silicon dioxide (Amorphous) is listed in Annex 2 Permitted Substances for the Production of Organic Foods, Table 3 Ingredients of Non-Agricultural Origin as an additive in foods of plant origin permitted for use in herbs, spices, seasonings, and condiments (e.g., seasonings for instant noodles). Also allowed as a processing aid in gel or colloidal solution.

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

Silicon dioxide (amorphous) is listed in Appendix 4, Table 1 List of Approved Additives and Processing/Post-Harvest Handling Aids.

#### Japan Agricultural Standard (JAS) for Organic Production

Silicon dioxide listed in Attached Table 1 Food Additives, limited to be used for processed foods of plant origin as gel or colloidal solution.

## Ancillary Substances

None reported in the 2010 TR and none noted in public comment during the 2016 sunset review.

## Environmental Issues

The 2010 TR stated silica dust is produced during its manufacture and use, however at the time of writing there was no data on ambient air concentrations of amorphous silica and ambient levels are not well quantified for crystalline silica. Exposure levels are considered the highest in occupations involved with packing, weighing, reprocessing, and cleaning. While the Subcommittee recognizes the risk of exposure to crystalline silica dust during the mining, manufacture and processing of silica, there does not appear to be a great deal of study on the effects of amorphous silica as is used in the manufacture of silicon dioxide. Studies that have explored exposure to amorphous silica dust suggest such exposure may not lead to silicosis or fibrosis as can result from crystalline silica exposure. These existing studies point to the need for further work in this area ([Merget R, Bauer T, Küpper HU, Philippou S, Bauer HD, Breitstadt R, Bruening T. Health hazards due to the inhalation of amorphous silica. Arch Toxicol. 2002 Jan;75\(11-12\):625-34. doi: 10.1007/s002040100266. PMID: 11876495; McLaughlin JK, Chow WH, Levy LS. Amorphous silica: a review of health effects from inhalation exposure with particular reference to cancer. J Toxicol Environ Health. 1997 Apr 25;50\(6\):553-66. doi: 10.1080/15287399709532054. PMID: 15279029](#)).

The 2010 TR noted the EPA concluded that silicon dioxide and silica gel do not pose unreasonable risks to the environment, including non-target organisms, when used at their registered levels. This conclusion is based on the belief that silicon dioxide and silica gel are chemically unreactive in the environment, occur naturally in various forms, and are practically non-toxic to non-target organisms.

## Discussion

A 2010 petition to remove silicon dioxide was put forward by RIBUS, the manufacturer of a commercially produced rice-based certified organic alternative to silicon dioxide. In 2011, the NOSB did not move the petition to remove forward, and silicon dioxide remained on the list. Data was presented in the petition claiming that a reformulation of the rice-based alternative could be substituted for silicon dioxide at nearly 1:1 ratio. However, the Handling Subcommittee felt the data was limited, not published from a third-party source, and did not conclusively demonstrate its applicability in all products and processes.

The Subcommittee did however wish to acknowledge the availability of a natural alternative. Even though the Subcommittee did not vote to remove silicon dioxide, it passed a recommendation in 2011 to amend the annotation of silicon dioxide, resulting in its current listing which requires the use of organic rice hulls when commercially available. In its recommendation, the Subcommittee noted that additional information and clarification of processors' needs regarding silicon dioxide is needed for future deliberations by the NOSB.

In its last sunset review in 2016, public comment indicated that organic rice hulls are *not* a viable alternative for all current uses:

- As an anticaking agent in organic powders, including organic cheese powders.
- In organic dry flavors in which rice hulls have not adequately or evenly disbursed flavor actives and have taken up moisture.
- As an anticaking agent at a recommended 2% application rate, when instead the rice hull rate has been 15-50%.
- As a flow agent for rice syrup solids.
- As a clarifier in the production of beer.

### Summary of Public Comment

Most stakeholders were in favor of relisting based on essentiality. Public comments noted that alternatives, such as organic rice hulls, are not able to be used to achieve suitable functionality in all applications. There were a few comments that suggested the NOSB review the current annotation against the original annotation passed by the Board to ensure the intent of the original annotation is accurately conveyed.

### Justification for Vote

The Subcommittee proposes removal of silicon dioxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

### Subcommittee Vote

Motion to remove silicon dioxide from the National List

Motion by: Kyla Smith

Seconded by: Kim Huseman

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## Sodium lactate

**Reference:** §205.605(b) Sodium lactate - for use as an antimicrobial agent and pH regulator only.

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

**Petition(s):** [2004](#); [2014 NOP memo to NOSB](#)

**Past NOSB Actions:** [4/2016 recommendation](#)

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

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

### Subcommittee Review

#### Use

Sodium lactate comes as a liquid and may be added to meat as an antimicrobial ingredient. It is affirmed as generally recognized as safe (GRAS) at 21 CFR 184.1639. The FDA does not authorize its use in infant foods and formulas.

#### Manufacture

Sodium lactate is generally produced from natural (fermented) lactic acid which is then reacted with sodium hydroxide. Lactic acid is produced from the fermentation of natural food sources such as dextrose (from corn) and sucrose (from sugar cane or sugar beets) or starch.

#### International Acceptance

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

Sodium lactate and potassium lactate are not listed for use in processing. Lactic acid is allowed.

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

Sodium lactate is allowed for use in processing foodstuffs of animal origin only and is listed for use in: "Milk-based and meat products."

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Sodium and potassium lactates are not specifically listed in any of the appendices in the IFOAM, but the precursor, lactic acid, is allowed.