United States Department of Agriculture
Agricultural Marketing Service | National Organic Program
Document Cover Sheet
https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned

Document Type:

☐ **National List Petition or Petition Update**

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

☒ **Technical Report**

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

# Magnesium Stearate

**Handling/Processing**

## Identification of Petitioned Substance

**Chemical Names:**
Magnesium stearate
Octadecanoic acid magnesium salt
Magnesium octadecanoate

**Other Name:**
Stearic acid magnesium salt
Magnesium distearate

**Trade Names:**
N/A

**CAS Numbers:**
557-04-0

**Other Codes:**
EC-No. 209-150-3
INS No. 470(iii)

## Summary of Petitioned Use

Magnesium stearate is used as a lubricant or anticaking agent in food processing and handling. Magnesium stearate is currently listed on the National List of Allowed and Prohibited Substances as a synthetic nonagricultural (nonorganic) substance allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" (7 Code of Federal Regulation (CFR) 205.605(b)). Magnesium stearate is permitted for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))" but is prohibited in agricultural products labeled "organic."

## Characterization of Petitioned Substance

**Composition of the Substance:**

Magnesium stearate is a fatty acid, salt-type anionic surfactant with its appearance being white powder with a creamy feeling. It is a compound of magnesium with a mixture of solid organic acids obtained from edible sources and consists chiefly of variable proportions of magnesium stearate and magnesium palmitate (Pharmacopeia 2010).

The Food Chemicals Codex (FCC) requires that the material assays with an acceptance criteria of not less than (NLT) 6.8% and not more than (NMT) 8.3% magnesium oxide (MgO) (Pharmacopeia 2010). The structure of magnesium stearate is shown in Figure 1.

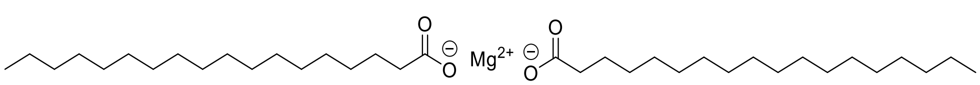


**Figure 1**. Structure of magnesium stearate.

**Source or Origin of the Substance:**

Magnesium stearate is produced by the reaction of sodium stearate with magnesium salts or by treating magnesium oxide with stearic acid (Nora 2005).

**Properties of the Substance:**

Physical and chemical properties of the substance are summarized in Table 1.

Table 1: Physical and Chemical Properties of Magnesium Stearate (Nora 2005).

| Property | Value |
|---|---|
| Chemical formula | $C_{36}H_{70}O_4Mg$ |
| Molar mass | 591.24 g/mol |
| Appearance | White fine powder |

| | |
|---|---|
| Solubility, water | Insoluble |
| Melting point | 200° C |
| Density | 1.028 $g/cm^3$ |

**Specific Uses of the Substance:**

The most common use of magnesium stearate in food handling and processing is as an anticaking agent in common salt; spices; vegetable, beverage, and fruit powders; powdered soups; powdered sauces; leavening agents; and confectionery such as hard candy (Luck 2005).

Magnesium stearate is often used as an antiadherent in manufacturing medical tablets, capsules and powders (Swarbrick 2001, Ritter 2008). In fact, magnesium stearate is the most commonly used lubricant for tablets, preventing ingredients from sticking to manufacturing equipment during the compression of chemical powders into solid tablets (Weiner 1999).

**Approved Legal Uses of the Substance:**

Magnesium stearate is currently listed on the National List of Allowed and Prohibited Substances as a synthetic nonagricultural (nonorganic) substance allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" (7 CFR 205.605(b)). Magnesium stearate is permitted for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))" but is prohibited in agricultural products labeled "organic."

Magnesium stearate is listed as Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration (21 CFR 184.1440). It is considered GRAS if it is produced as a white precipitate by adding an aqueous solution of magnesium chloride to an aqueous solution of sodium stearate which meets two key criteria: that it is derived from stearic acid obtained from edible sources and that it conforms to the requirements of 21 CFR 172. 860(b)(2). Magnesium stearate must also meet the specifications outlined in the Food Chemicals Codex, and it can be used in food with no limitation other than current good manufacturing practice (21 CFR 184. 1440(b)).

Magnesium stearate is approved by FDA for the following applications:

- As a lubricant and release agent as defined in 21 CFR 170.3(o)(18); as a nutrient supplement as defined in 21 CFR 170.3(o)(20); and as a processing aid as defined in 21 CFR 170.3(o)(24)
- As a stabilizer for use as a prior-sanctioned food ingredient employed in manufacturing food-packaging materials (21 CFR 181.29)
- As a defoaming agent used in processing beet sugar and yeast (21 CFR 173.340 (a)(3))
- As a food additive permitted for direct addition to food for human consumption used or intended for use as a binder, emulsifier, and anticaking agent in food in accord with good manufacturing practice (21 CFR 172.863(b))

**Action of the Substance:**

Magnesium stearate performs several roles depending on its application. As an anticaking agent, it serves as a natural lubricant, repelling water due to its hydrophobic nature and preventing water from entering packaging to prevent clumping of the food products, supplements, or pharmaceutical ingredients. In the manufacturing process, the addition of magnesium stearate helps ensure that the composition of product mixtures is consistent.

As an anti-foaming agent, adding magnesium stearate retards negative changes and foaming height of a material when it is heated.

**Combinations of the Substance:**

Magnesium stearate is a common excipient (an inactive ingredient) added to active ingredients such as pharmaceuticals, supplements, and food products. As magnesium stearate is permitted for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))" but is prohibited in agricultural products labeled "organic," it is not typically used in combination with any substances on the National List for organic agricultural production.

## Status

**Historic Use:**

Per 7 CFR 205.605(b), magnesium stearate is not typically used in producing organic agricultural goods. In conventional agricultural production, it is routinely added during food handling/processing as an anticaking agent in common salt; spices; vegetable, beverage, and fruit powders; powdered soups; powdered sauces; leavening agents; and confectionery such as hard candy (Luck 2005).

**Organic Foods Production Act, USDA Final Rule:**

Magnesium stearate is currently listed on the National List of Allowed and Prohibited Substances as a synthetic nonagricultural (nonorganic) substance allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" (7 CFR 205.605(b)). Magnesium stearate is permitted for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))" but is prohibited in agricultural products labeled "organic."

**International**

The Canadian General Standards Board (CGSB) includes nonsynthetic sources (and synthetic sources provided that nonsynthetic sources are not commercially available) of magnesium stearate as a permitted substance for organic production systems under CAN/CGSB-32.311-2015 for use as an anticaking or releasing agent in products whose contents are ≥70% and <95% organic ingredients.

The Codex Alimentarius Commission's "Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods" lists magnesium stearate (INS No. 470(iii)) as a food additive that may be used in foods as an anticaking agent, emulsifier, or thickener under the conditions of good manufacturing practices (GL 32-1999).

Magnesium stearate was not found to be listed under any other international standard for organic handling and processing.

## Evaluation Questions for Substances to be used in Organic Handling

**Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).**

Magnesium stearate can be produced through the following procedure (Luck 2005):

First, sodium stearate is produced from the saponification of stearic acid and sodium hydroxide. The sodium stearate undergoes a double decomposition reaction with magnesium sulfate to yield the finished product. For example, in a prototypical reaction, stearic acid and water are added to the reactor and heated to 85° C, stirred until they dissolve, and then slowly added to a sodium hydroxide solution which is preheated to 75° C.

After the saponification reaction is completed, the reaction mixture is maintained at 72° C and slowly added to a preheated (55° C) magnesium sulfate solution. After this metathesis reaction, the water is removed through centrifugation. The filtered cake is then washed with water until sulfate ion requirements are met, and then the filtered cake is dried. In some instances, magnesium stearate is directly synthesized from the reaction of magnesium oxide and food-grade stearic acid.

Stearic acid is derived from natural animal and vegetable sources. Fats and oils rich in stearic acid are more abundant in animal fat (up to 30%) than in vegetable fat (typically <5%) (Beare-Rogers 2001). The important exceptions are cocoa butter and shea butter, where the stearic acid content (as a triglyceride) is 28–45%. Stearic acid is obtained from fats and oils by the saponification of the triglycerides using hot water (Anneken 2006). The resulting mixture is then distilled, and the resulting commercial stearic acid is often a mixture of stearic and palmitic acids, although purified stearic acid is available. Stearic acid is listed as GRAS by the U.S. Food and Drug Administration (21 CFR 184.1090) if it is produced commercially from hydrolyzed tallow derived from either edible sources or from hydrolyzed, completely hydrogenated vegetable oil derived from edible sources.

**<u>Evaluation Question #2:</u> Discuss whether the petitioned substance is formulated or manufactured by a chemical process or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.**

Magnesium stearate is formulated through a chemical process: either the reaction of sodium stearate with magnesium sulfate or the direct reaction of magnesium oxide with stearic acid. Stearic acid is readily derived from natural sources such as fats and oils derived from animal or vegetable fat, and is recognized as GRAS (21 CFR 184.1090). In addition, magnesium sulfate is usually obtained from natural sources as a hydrate salt (Seeger 2005) and is also recognized as GRAS (21 CRF 184.1443 and 582.5443). Magnesium oxide is produced through the calcination of magnesium carbonate ($MgCO_3$) or magnesium hydroxide (MgOH) at > 1400 °C (Seeger 2005), and it is recognized as GRAS (21 CFR 184.1321; 582.1431; 582.5431).

**<u>Evaluation Question #3:</u> If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).**

Magnesium stearate is a synthetic material solely manufactured by a chemical process, and is not extracted from naturally occurring plant, animal, or mineral sources. Magnesium stearate is produced by a chemical process from either the reaction of sodium stearate with magnesium sulfate or the direct reaction of magnesium oxide with stearic acid (Luck 2005).

**<u>Evaluation Question #4:</u> Specify whether the petitioned substance is categorized as Generally Recognized as Safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.**

Magnesium stearate is listed as Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration (21 CFR 184.1440). It is considered GRAS if it is produced as a white precipitate by adding an aqueous solution of magnesium chloride to an aqueous solution of sodium stearate which meets two key criteria: that it is derived from stearic acid obtained from edible sources and that it conforms to the requirements of 21 CFR 172. 860(b)(2). Magnesium stearate must also meet the specifications outlined in the Food Chemicals Codex (21 CFR 184. 1440(b)) and can be used in food with no limitation other than current good manufacturing practice.

**<u>Evaluation Question #5:</u> Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b)(4)).**

The primary technical function or purpose of magnesium stearate is for use as a processing aid in organic handling. Its intended uses are as an anticaking agent in common salt; spices; vegetable, beverage, and fruit powders; powdered soups; powdered sauces; leavening agents; and confectionery such as hard candy (Luck 2005). No published literature was located to suggest that the petitioned substance is being used primarily as a preservative.

**<u>Evaluation Question #6:</u> Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).**

There was no information found to suggest that magnesium stearate is used to recreate or improve flavors, colors, textures, or nutritive values lost in the processing of agricultural products. While magnesium stearate can provide a small amount of magnesium, an essential mineral, manufacturers primarily use magnesium stearate as an anticaking agent in the production of agricultural products, pharmaceuticals, and dietary supplements.

**<u>Evaluation Question #7</u>: Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).**

Magnesium stearate is listed as Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration (21 CFR 184.1440) and is expected to have no effect or potential effect on the nutritional quality of food when used according to good manufacturing practices.

**<u>Evaluation Question #8:</u> List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600 (b)(5)).**

In the process for the manufacturing of the petitioned substance, no heavy metals or other contaminants in excess of FDA tolerances have been reported. The Food Chemicals Codex recognizes lead as a potential inorganic impurity for magnesium stearate, and the lead concentration must assay with an acceptance criteria of not more than 5 milligrams/kilogram (mg/kg) (Pharmacopeia 2010).

**<u>Evaluation Question #9:</u> Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).**

The most common manufacturing process for magnesium stearate uses three ingredients: stearic acid, sodium hydroxide, and magnesium sulfate. Due to the properties of these compounds, there is limited potential for harmful effects to the environment or biodiversity.

To the best of the investigator's knowledge, there is limited toxicity research on stearic acid, focusing mostly on toxicity effects in food and cosmetic ingredients (ACT 1990). Based on its low acute toxicity, it would likely present a low risk to the environment if spilled.

Magnesium sulfate is a naturally occurring mineral, readily found in the environment as kieserite (magnesium sulfate monohydrate) or epsomite (magnesium sulfate heptahydrate) is highly soluble in water and is not expected to volatize or to undergo hydrolysis. In freshwater and saltwater, the magnesium sulfate complex acts as the primary source of total magnesium. An important removal process for magnesium sulfate in water is the ion exchange that occurs with calcium present in sediments. The uptake of magnesium by water is significant and results in sulfate reduction, meaning that aquatic contamination is unlikely (Bodek 1988). However, one study found that magnesium sulfate, and the magnesium ion in particular, can be toxic at concentrations in the low mg/L range to species that inhabit very low ionic strength surface waters (van Dam 2010). In seawater, high temperature areas act as sinks for magnesium(Pettine 1994). Magnesium sulfate is not expected to be persistent in aquatic systems or bioconcentrate in the food chain and is not likely to be harmful to the aquatic environment because it is highly mobile.

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

The hazard of sodium hydroxide for the environment is caused by the hydroxide ion, as it can have a strong pH effect (EPA 1988). A high concentration in water will result in toxic effects for aquatic organisms (e.g., fish). However, a low concentration in water will not result in effects on aquatic organisms because the sodium hydroxide will be neutralized by other substances present in water (for example dissolved carbon dioxide, organic acids) and thus the pH will not increase. Because sodium hydroxide is neutralized in the environment, the substance is not persistent and will not accumulate in organisms or in the food chain. Bioaccumulation also will not occur.

Magnesium stearate (i.e., octadecanoic acid, magnesium salt) is classified by the U.S. Environmental Protection Agency (EPA) on their List of Inert Pesticide Ingredients (List 4A) as a minimal risk inert ingredient and is expected to have a negligible impact on the environment or biodiversity.

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

Magnesium stearate is composed mainly of magnesium salts of stearic and palmitic acids, obtained from edible fats and oils. Magnesium stearate is currently classified as not being a hazardous substance and possesses no known hazards not otherwise classified (HNOC) or not covered by Globally Harmonized System (GHS) labels (Sigma-Aldrich 2016).

The Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) recently performed a safety evaluation of magnesium stearate, incorporating a range of published studies with genotoxicity testing (JECFA 2015). Under the acidic conditions of the stomach, magnesium stearate is converted into its constituent magnesium ion (cation) and stearic/palmitic acids (anions) upon digestion. The palmitic and stearic acids and their salts are constituents and products of the metabolism of edible oils and fats, for which the metabolic fate is well understood. Thus, these fatty acids were of no toxicological concern.

Acute and short-term toxicity studies in rats were determined to be not relevant, as extraordinarily large doses were required to observe a negative biological response. For example, the oral median lethal dose ($LD_{50}$) in rats was found to be greater than 10 grams/kilogram (g/kg) of body weight (bw), indicating that magnesium stearate is practically nontoxic. Similar studies were unable to suggest any genotoxicity potential or reproductive toxicity of magnesium stearate.

The Committee estimated the theoretical dietary exposure to magnesium stearate based on proposed maximum use levels, which results in a potential total dietary exposure to magnesium stearate of 44 mg/kg bw per day for children and 83 mg/kg bw per day for adults, corresponding to 2 and 4 mg/kg bw per day of magnesium respectively. This would contribute up to an additional 240 mg/day to the background exposure to magnesium from food of 180–480 mg/day. The Committee noted that the consumption of the food additive may lead to an additional dietary exposure to stearic and palmitic acids in the order of 5 g/day.

As an acceptable daily intake (ADI) of "not specified" has been established for a number of magnesium salts used as food additives, the Committee concluded that there are no differences in the evaluation of the toxicity of magnesium stearate compared with other magnesium salts and confirmed the ADI of "not specified" for magnesium stearate. However, the Committee did express concern that the use of magnesium salts in many food additives may result in combined exposure that may lead to a laxative effect.

**Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).**

The undesirable caking and deliquescence (i.e., absorption of moisture from the air to dissolve or become liquid) of bulk powders is a common problem in a number of industries, including the food industry (Zafar 2017). Bulk powder caking is a very challenging topic, as it is difficult to predict how a powder will behave.

According to Zafar (2017), there are number of approaches available that may reduce the caking propensity of a material without the addition of anticaking agents:

1. Decreasing the fines content of the powder
2. Minimizing moisture content
3. Identifying the major caking component and identifying if an alternative is available
4. Reducing temperature and humidity cycling where appropriate
5. Reducing consolidation load where appropriate.

**Evaluation Question #12: Describe all natural (nonsynthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).**

Naturally occurring carbonates of calcium, cellulose, and rice hull powder could be used as an all-natural (nonsynthetic) substitute for the petitioned substance. Calcium carbonate is currently listed on the National List. However, only synthetic forms of cellulose are listed on the National List (7 CFR 205.605).

There are several other, mainly synthetic, alternative products that could be substituted for the petitioned substance. With respect to the applications as a defoamer, silicon dioxide is listed as a synthetic allowed substance on the National List (7 CFR 205.605(b)). Cellulose can serve as an alternative anticaking agent to magnesium stearate and is included on the National List as a synthetic allowed substance for use in regenerative casings, as an anticaking agent (non-chlorine bleached), and as a filtering aid (7 CFR 205.605(b)). Calcium carbonate (nonsynthetic) and calcium phosphates (synthetic) are also possible anticaking alternatives included on the National List (7 CFR 205.605).

**Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b) (1)).**

There are several organic agricultural products that could be used as alternatives for the petitioned substance. Cellulose powder extracted from organic agricultural products, such as organically produced oat and soybean hulls, corn stalks, or sugar beets (Aubrey 2014). However, establishing supply chain systems to accumulate the plant materials is often cost-prohibitive. Rice hull powder from organically grown rice could also be used as an anticaking agent. Moreover, natural silica, or silicon dioxide, can be used as an anticaking agent and extracted from the plant cells of rice husk (Zakharov 1993). Powdered rice has also been demonstrated to be an effective anticaking agent in table salt and a concentration of 1% rice powder could take the place of other anticaking food additives in salt and spice production (Akay 2009).

## Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:


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- Anna Arnold, Technical Writer, Savan Group


All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

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