

Calcium Stearate Processing

Executive Summary¹

A petition is under consideration with respect to NOP regulations subpart G §205.605, governing the use of substances in processed products:

Petitioned: Inclusion of calcium stearate on National List of nonagricultural substances allowed in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

Calcium stearate is a compound of calcium with a mixture of solid organic acids obtained from edible sources. It is generally used as a solid-phase lubricant that reduces friction between particles of the substance to which it is added. The Petitioner’s intended use is “as a free-flowing agent to be used in processed food ingredients.” Specifically, calcium stearate is to be used “as an anti-caking agent and flow ingredient in dry blends sold to bakeries” (NOSB Petition). The NOP has no prior listing or ruling on the substance.

The TAP reviewers were divided over the use of calcium stearate in foods labeled as “organic.” Two of the reviewers felt it should not be added to the List, while one reviewer favored its inclusion. The reviewers who voted to restrict its use indicated that more information was needed on the nature of the substance and its potential applications. All three reviewers agreed that the substance should be allowed for use in products labeled as “made with organic...”, without annotations. Two of the reviewers felt that the substance should be considered synthetic based on its method of production for commercial use.

Summary of TAP Reviewer Analyses

Products considered "organic" (>95%)

Synthetic/ Nonsynthetic	Allowed or Prohibited	Notes/suggested annotations:
Synthetic (2) Nonsynthetic (1)	Allowed (1) Prohibited (2)	<i>Reviewer 1: Prohibited until more information becomes available on its production and range of application</i> <i>Reviewer 2: Allowed, no annotation</i> <i>Reviewer 3: Prohibited, no annotation</i>

Products considered "made with organic (specified ingredients or food group(s))" (>70%)

Synthetic/ Nonsynthetic	Allowed or Prohibited	Notes/suggested annotations:
Synthetic (2) Nonsynthetic (1)	Allowed (3) Prohibited (0)	<i>Reviewer 1: Allowed, no annotation</i> <i>Reviewer 2: Allowed, no annotation</i> <i>Reviewer 3: Allowed, no annotation</i>

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

Identification

Chemical name:	calcium stearate	International Numbering System for Food Additives:
Other names:	stearic acid calcium salt, octadecanoic acid calcium salt	Not listed
CAS Number:	1592-23-0	Other: None found.

Characterization

Composition:

Ca(C₁₈H₃₅O₂)₂

Physical Data:

Molecular wt.:	607.03
Melting point:	179°C
Specific gravity:	1.04
Solubility:	Practically insoluble in water (0.04g/L H ₂ O @ 15°C), ether, chloroform, acetone, and cold alcohol Slightly soluble in hot alcohol, hot vegetable and mineral oils Quite soluble in hot pyridine
Stability:	Stable under ordinary conditions of use and storage
Hazardous polymerization:	Will not occur

Properties:

Calcium stearate is a compound of calcium with a mixture of solid organic acids obtained from edible sources, and consists chiefly of variable proportions of calcium stearate and calcium palmitate (NAS 1996). It occurs as a fine, white to yellowish white, bulky powder having a slight, characteristic fatty odor.

Action:

Calcium stearate is a solid-phase lubricant that reduces friction between particles of the substance to which it is added.

How Made:

Traditionally, calcium stearate is made by reacting calcium chloride, sodium stearate, and other salts of mixed fatty acids in an aqueous solution, then isolating the precipitate (Kebrich and Petrot 1953). According to the Petitioner, this method is not practical for large-scale production, and instead the substance is derived from a dry fusion process in which stearic acid is reacted with calcium oxide. Stearic acid is a naturally occurring organic acid present in the glycerides of animal fats and most vegetable oils, and is derived from palm oil, soybean oil, or edible tallow. The finished product is composed of calcium with variable proportions of stearic and palmitic acids, and contains the equivalent of 9-10.5% calcium oxide (Osol and Hoover 1975). It is available in technical and food grades (Hawley 1977). No organic solvents are used in the dry fusion process.²

Uses:

Extremely low solubility makes calcium stearate a very versatile substance. Generally, it is used for waterproofing, as a releasing agent for plastic molding powders, as a stabilizer for polyvinyl chloride resins, lubricant, and a conditioning agent in various food and pharmaceutical products. Food grade calcium stearate is used as an anti-caking agent, emulsifier, flavoring agent, stabilizer, release agent, thickening agent (Merck 2001). Calcium stearate is a nonagricultural product.

Status

History of Use:

Calcium stearate was first isolated for commercial use in 1924 (Harrison). Its physical qualities and low toxicity made it a versatile additive in a wide range of products, some of which are listed in Table 2. It is also used in pharmaceuticals and cosmetics (Merck 2001).

Functionality

Calcium stearate is virtually nontoxic, and its unctuous properties make it ideal for use in food products (Osol and Hoover, 1975). The Petitioner's intended use is "as a free-flowing agent to be used in processed food ingredients." Specifically, calcium stearate is used "as an anti-caking agent and flow ingredient in dry blends sold to bakeries" (NOSB Petition). The substance may also be used as an anti-caking agent to prevent confectionery and baked goods from sticking to containers (Encycl. Chem. Tech. 2001). Commercially it is added to dry blends such as

Table 2. Sample Levels of Industry Additions of Calcium Stearate to Foods by Category

Food category	Weighted mean %
Baked goods, baking mixes	1.03
Fats and oils	0.06
Meat products	0.02
Poultry products	0.02
Eggs, egg products	0.02
Fish products	0.02
Soft candy	0.92
Soups, soup mixes	0.02
Snack foods	0.02
Gravies, sauces	0.03
Hard candy	0.08
Seasoning and flavors	0.64

NAS 1972

² Process as stated by Petitioner.

enrichment and dough conditioning products marketed to bakeries. Calcium stearate is also used to minimize airborne dust in operations where inhalation of particulate matter poses a health concern. According to the Petitioner, this is important for bakery workers who may experience harmful effects from bakery ingredient dust. Some flour conditioners contain potentially allergenic enzymes, and dust from certain vitamins (e.g. thiamin, a vasodilator) can be harmful (NOSB Petition). Calcium stearate is also used to reduce airborne dust particles in some mining operations (EPA 1994).

USDA Final Rule

The USDA has no prior ruling on the use/prohibition of calcium stearate, and currently there are no references to the substance in NOP regulations. NOP parameters specifically relating to the Petitioner’s request are as follows:

§ 205.301 Product Composition.

(b) Products sold, labeled, or represented as "organic." A raw or processed agricultural product sold, labeled, or represented as "organic" must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced, unless not commercially available in organic form, or must be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part.⁶ If labeled as organically produced, such product must be labeled pursuant to § 205.303.

(c) Products sold, labeled, or represented as "made with organic (specified ingredients or food group(s))." Multiingredient agricultural product sold, labeled, or represented as "made with organic (specified ingredients or food group(s))" must contain (by weight or fluid volume, excluding water and salt) at least 70 percent organically produced ingredients which are produced and handled pursuant to requirements in subpart C of this part. No ingredients may be produced using prohibited practices specified in paragraphs (1), (2), and (3) of § 205.301(f). Nonorganic ingredients may be produced without regard to paragraphs (4), (5), (6), and (7) of § 205.301(f). If labeled as containing organically produced ingredients or food groups, such product must be labeled pursuant to § 205.304.

Regulatory:

FDA regulates calcium stearate under Title 21 of the Code of Federal Regulations (CFR). Table 1 summarizes these references. In addition, regulations require that fatty acids and oils used in production of stearic acids must be free of chick edema factor (Rossoff 1974).

EPA List of Inert Pesticide Ingredients (2001) classifies calcium stearate on List 4B (Inerts which have insufficient data to substantiate they can be used safely in pesticide products).

NIEHS National Toxicity Program (NTP) Database does not list any regulatory limits for calcium stearate (NTP 2002).

OSHA does not regulate the substance as a carcinogen.

International Agency for Research on Cancer (IARC) does not regulate the substance as a carcinogen.

21 CFR	Section Heading	Annotation
169.179	Vanilla powder	Optional adjuvant for use as an anticaking ingredient in vanilla powder mixtures, not to exceed two percent of powder mixture by weight.
172.863	Salts of fatty acids	Lists parameters for use of salts of fatty acids in food components, including mixture composition and labeling of additives.
173.340	Defoaming agent	Optional adjuvant for use as a defoaming agent in processing beet sugar and yeast.
175.300	Resinous and polymeric coatings	Miscellaneous ingredient permitted for use in coating of food-contact surfaces of materials used in any aspect of processing or packing.
177.2410	Phenolic resins in molded articles	Optional adjuvant employed in the production of phenolic resins to confer lubricant qualities.
177.2600	Rubber articles intended for repeated use	Optional adjuvant for use as a plasticizer, not to exceed thirty percent of rubber product by weight.
178.1010	Sanitizing solutions	Optional adjuvant for preparation of sanitizing solution described in detail at (b)(41), not to exceed eight percent of preparation.
179.45	Packaging materials for use during the irradiation of prepackaged foods	Optional adjuvant for use in polyethylene film, not to exceed one percent of the polymer by weight, prepared from basic polymer described in 21CFR177.1520(a), and subjected to irradiation dose described in (10)(c).
178.2010	Antioxidants and/or stabilizers for polymers	Optional adjuvant for use as antioxidant/stabilizer in polymers used in articles intended for use in all aspects of food processing and packing.
181.29	Stabilizers	Classified as stabilizer, when migrating from food packaging material.
184.1229	Calcium stearate	GRAS when used in accordance with GMPs.

⁶Author’s note: Evaluation criteria for inclusion on National List are given below.

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

1. ***The potential of substance for detrimental chemical interactions with other materials used in organic farming systems.***
The intended use of the substance as a processing material precludes it from interacting directly with other materials used in organic farming.
2. ***The toxicity and mode of action of the substance, its breakdown products or contaminants, and their persistence and areas of concentration in the environment.***
Calcium stearate is considered to be nontoxic (GRAS) when used in accordance with GMPs (FASEB 1975, ACT 1982). No research was found regarding breakdown products, contaminants, or toxic interactions in the environment.
3. ***The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.***
See processing Criteria 2, below.
4. ***The effect of the substance on human health***
See Processing Criteria 3, below.
5. ***The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms, crop, and livestock.***
The Petition is for use as a processing material and thus are not applicable apply to agroecosystem interactions.
6. ***The alternatives to using the substance in terms of practices or other available materials.***
See Processing Criteria 1 and 7, below.
7. ***Its compatibility with a system of organic agriculture.***
See Processing Criteria 6, below.

Processing Criteria from the February 10, 1999 NOSB Meeting

1. ***The processing aid or adjuvant cannot be produced from a natural source and has no organic ingredients as substitutes***
No documentation was found referring to natural sources of food grade calcium stearate. Lecithin shares similar emulsification properties with calcium stearate, but may not be as versatile.
2. ***Manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA***
Traditional processes for manufacturing calcium stearate are outlined in the “How Made” section, above. The Petitioner does not supply information regarding its fusion process used for production. Stearic acids are naturally occurring organic acids and do not pose a significant risk to the environment (ACT 1982). Section 2119 OFPA U.S.C. 6513(e) states that “an organic handling plan shall contain provisions designed to ensure that agricultural products that are sold or labeled as organically produced are produced and handled in a manner that is consistent with the purposes of this title.” Specifically, a processor must keep an Organic Systems Plan on file with their certifier that provides a detailed description of how the operation will achieve, document, and sustain compliance with all applicable provisions of the NOP regulations. No information was found detailing adverse environmental effects of calcium stearate. Breads and bakery goods are common organic products, and the Petitioner’s intended use as a bakery dry blend additive appears to be consistent with GMPs as they pertain to organic processing.
3. ***The nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations***
Calcium stearate is considered non-toxic (ACT 1982). It is used in relatively small quantities (see Table 2, above), and the substance has not been shown to impact nutritional quality of food when used in accordance with GMPs (FASEB 1975). Stearic acid is commonly consumed as a glyceride component of fats in meat and table spreads. A survey of the food industry by a National Research Council subcommittee estimated 26,198kg of stearic acid were used by the food industry in 1970 (NAS 1972). Based on the numbers put forth in that report, estimates of intake of stearic acid are 0.35mg per capita daily. In the committee’s opinion, the daily intake of stearic acid and tallow that migrates to food from packaging materials is small compared to the intake of these substances from the food substances themselves. Stearic acid is considered non-carcinogenic in tests with mice (Van Duuren et. 1972).

Tallow appears to be easily absorbed in livestock. Absorption of tallow in animal feed by chicks at eight weeks was the same as adult hens (Renner & Hill 1960). In calves, the digestibility of tallow was 87.6 percent when fed at a level of five percent in an all-concentrate diet (Raven 1969). In contrast, the digestibility of stearic acid appears to be quite low. Stearic acid fed to adult rats as a mixture of calcium stearate and the free acid was less than when fed the free acid in semi-synthetic rations (Cheng et. al 1949). There is some evidence stearic acid is strongly thrombogenic (i.e., tending to attract clotting) when fed to rats at a rate of three to six percent (Renaud, S., 1969).

4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law*

Uses of calcium stearate in food products are listed Title 21 CFR and are summarized in Table 1, above. The primary intended purpose stated in the Petition is not as a preservative. The Petitioner classifies use of the substance as an emulsifier, flavoring agent, and thickening agent. The Petitioner does not clearly state whether these qualities should be considered secondary to the qualities the substance confers as a “free flowing agent.”

5. *It is Generally Recognized as Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP) and contains no residues of heavy metals or other contaminants in excess of FDA tolerances*

Calcium stearate is considered GRAS as a multiple purpose ingredient with no use limitation other than current GMP (21 CFR 184.1229). It contains no heavy metal residues or other contaminants regulated by the FDA.

6. *Its use is compatible with the principles of organic handling.*

The NOSB has no history of ruling on the use of calcium stearate. The justification section of the Petition focuses on the use of calcium stearate in dry blends of bakery products. This use does not appear to incorporate processing methods “that compromise the integrity and quality of finished products,” a principle of organic handling proposed by the NOSB. However, the intended use of the substance as stated by the Petitioner is “as a free-flowing agent to be used in processed food ingredients,” and thus, if granted, would not be limited to use in bakery products. No information was found describing other uses of calcium stearate in food processing, and hence compatibility with other processing methods remains in question.

7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.*

As mentioned previously, it is possible that lecithin may confer similar emulsification properties as calcium stearate. Beyond that use, the uniqueness of the effects of calcium stearate in food processing is not known. Calcium stearate does not act as a preservative or add significant nutritional value to the products to which it is added. The amounts required for the intended use, combined with economic considerations, would lead one to assume that the substance would not be used in excessive amounts.

TAP Reviewer Discussion

Reviewer 1 [Organic food industry certification specialist, MS Health Education, western US]

Evaluation of Calcium Stearate

1. *It cannot be produced from a natural source and has no organic ingredients as substitutes*
While the sources of the chemicals used to manufacture calcium stearate are stated as derived from tallow and palm, the process is a chemical process. There is no mention of the processing aids used to manufacture the product and there is no clear explanation of the “dry fusion” process. The stated action of the material is as a lubricant, anti-caking agent. To properly gauge substitutes, the intended use should be very clear. In reading the TAP review, the primary mention made of the intended use is: “Calcium stearate is used as an anti-caking agent and flow agent ingredient in dry blends sold to bakeries.” The flow of dry material can be managed through appropriate storage and other methods. In addition, oil and flour are clearly organic solutions for baked goods sticking to pans.
2. *Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA*
Statement supporting this claim are clear that “there is no research” to support non-negative findings for EPA, FDA, OSHA or the IARC. This is one way of looking at it. I do not subscribe to the notion that just because no research has been done on a material, that the material is automatically benign. This material has been used for many years and there do not appear to be any negatives associated with it. That is as positive as it gets.
3. *The nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations*
This statement appears to be true.
4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law*
This is difficult to gauge given the lack of specific application intended by the applicant.
5. *It is Generally Recognized as Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP) and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.*
See response to statement # 2.
6. *Its use is compatible with the principles of organic handling.*
This statement is not clearly true. One effect of organic handling has been to expand label clarity. Since this is a material that can (potentially) come from animal sources and yet this fact is not stated on the label, I do not believe it is compatible with the intention of organic handling. Further – it is clear that not all products can achieve “organic” status. This may be just such a product.
7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process*
The above statement is not true when considering that certified organic bakery products have been on the shelf for many years.

Additional references?

No additional sources.

Are there any other organically approved ingredients that can achieve similar results as calcium stearate?

Lecithin, oil, and other flow agents appear to be possibilities.

There seems to be very little information regarding calcium stearate in food processing. Besides the Petitioner’s stated intended use, in what other ways might the substance be used? Are there methods of potential use that are not compatible with the principles of organic handling?

While researching this subject, I found a number of other MSDS sheets. One clearly states that calcium stearate can be harmful when inhaled. This petition indicates that the material solves the problem of particulate matter in air. I suggest that other MSDS sheets for multiple applications and from multiple manufacturers are in order.

Recommendations to the NOSB:

- a) Calcium stearate is **synthetic**.
- b) Calcium stearate should be **prohibited in processed products labeled as “organic”** until more information is available about its production and the range of applications it might be used for.
- c) Calcium stearate should be **allowed in processed products labeled as “made with organic (specified ingredients or food group(s))”** to be consistent with 205.301 (c).

Reviewer 2 [Ph.D., Food Biochemistry; specializing in effects of raw material quality and processing on color, flavor, texture and nutritional quality of fruit and vegetable products; prior experience in organics reviewing use of various processing aids; western US]

Evaluation of Calcium Stearate

Calcium stearate would appear to comply with the seven items required of a processing aid or adjuvant. It cannot be produced from a natural source; has no adverse effects on the environment or on nutritional quality of the food; it is not used primarily as a preservative—more to improve functionality; it is GRAS, compatible with organic handling and there is no alternative product.

Additional sources?

Unfortunately, I do not have any other references on calcium stearate.

Are there any other organically approved ingredients that can achieve similar results as calcium stearate?

I am not familiar with other organically approved ingredients that might replace it.

There seems to be very little information regarding calcium stearate in food processing. Besides the Petitioner's stated intended use, in what other ways might the substance be used? Are there methods of potential use that are not compatible with the principles of organic handling?

I would suggest contacting the American Institute of Baking or Kansas State University (where a lot of baking related research is done) for greater expertise on its use in baked products.

Recommendations to the NOSB:

- a) Calcium stearate is **non-synthetic**.
- b) Calcium stearate should be **allowed in processed products labeled as "organic."**
- c) Calcium stearate should be **allowed in products labeled as "made with organic (specified ingredients or food group(s))."**

Reviewer 3 [Ph.D., Agricultural & Environmental Chemistry; extension food toxicologist, emphasizing in naturally-occurring food toxins, western US]

Evaluation of Calcium Stearate

1. *Cannot be produced from a natural source*

The "How Made" discussion indicates that calcium stearate is synthesized from a reaction of calcium chloride, sodium stearate, and other salts of mixed fatty acids. All of these precursors for calcium stearate appear to be available from natural sources although their actual origins in the specific synthesis of calcium stearate are unknown. Interestingly, sodium stearate can be obtained from natural sources and has been listed as an anti-caking agent from various food additive sources such as the *Food Additives Handbook*, (Lewis, R.J., Van Nostrand Reinhold, New York, 1989, page 407. As for other organic ingredients that could be used as substitutes, the UC SAREP review mentions lecithin as a potential substitute. Another resource I encountered, <http://www.chemsoc.org/exemplarchem/entries/2001/anderson/anticakingagents.htm#1>, provided a detailed list of anti-caking agents, and included the following potential substitutes that are already on the allowed list of substances:

Calcium phosphates (mono-, di-, and tri-)
Magnesium carbonates
Bentonite
Silicon dioxide
Magnesium stearate

While these substances may not achieve the specific efficacy as anti-caking agents that calcium stearate could achieve, it is clear that organically-allowed substitutes are available.

2. *Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA*

Calcium stearate does not appear to pose environmental concerns.

3. *The nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations*

I concur that the small amounts of calcium stearate should not have any significant impact upon the nutritional quality of the food in the amounts in which it is considered for use.

4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law*

The draft review document lists several additional food additive functionalities of calcium stearate beyond its use as an anti-caking agent, including emulsifier, flavoring agent, stabilizer, release agent, and thickening agent. The *Food Additives Handbook* (see prior reference, page 114) also lists properties of binder and release agent for calcium stearate. While it seems clear that its *primary* use is as an anti-caking agent, its properties as a flavoring agent should at least be considered when making the determination as to its applicability under NOSB criteria.

5. *It is Generally Recognized as Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP) and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.*

Calcium stearate, when used in the proposed manner, is essentially innocuous and therefore presents no toxicological concern. Its manufacturing process should not result in heavy metal residues or other contaminants as it is produced and isolated as a non-water soluble precipitate.

6. *Its use is compatible with the principles of organic handling.*

The use of calcium stearate as an anti-caking agent for baking should not compromise the principles of organic handling.

7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process*

As discussed previously, sodium stearate is a naturally-occurring precursor for the synthetic production of calcium stearate and possesses its own anti-caking properties. Several other NOSB-approved substances also have been listed as anti-caking agents.

[The Reviewer did not reply directly to the questions regarding additional references, substitutes, and alternative manufacturing processes]

Recommendations to the NOSB:

- a) Calcium stearate should be considered **synthetic** based upon its method of production.
- b) Calcium stearate should be **prohibited in processed products labeled “organic”** on the basis of its chemical similarity to magnesium stearate which is prohibited in agricultural products labeled “organic.”
- c) Calcium stearate should be **allowed for use in processed products labeled as “made with organic (specified ingredients or food group(s))”** on the basis of its chemical similarity to magnesium stearate which is allowed in agricultural products labeled as “made with organic (specified ingredients or food group(s)).”

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