

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.

# Calcium Carbonate

## Handling/Processing

1

2

### Identification of Petitioned Substance

3 **Chemical Names:**

4 Calcium carbonate

5 Marble

6 Limestone

7 Vaterite

8 Calcite

9 Carbonic acid, calcium salt

10 Chalk

11

12 **Other Name:**

13 E 170

14 Aragonite

15 Dolomite

16 Calcium milk

17

18 **Trade Names:**

19 Caltrate

20 Maalox

21 Tums

22 Oyster Shell Calcium

23 Alcalak

24

**CAS Numbers:**

471-34-1 (calcium carbonate)

308068-21-5 (marble)

1317-65-3 (limestone)

13701-58-1 (vaterite)

13397-26-7 (calcite)

72608-12-9 (carbonic acid, calcium salt)

13397-25-6 (chalk)

**Other Codes:**

CI: 77220 (calcium carbonate)

INS: 170(i) (calcium carbonate)

ICSC: 1193 (calcium carbonate)

UNII: H0G9379FGK (calcium carbonate)

EC: 207-439-9 (calcium carbonate)

EC: 215-279-6 (limestone)

EC: 603-785-3 (calcite)

EC: 615-782-4 (carbonic acid, calcium salt)

EC: 603-784-8 (chalk)

25

### Summary of Petitioned Use

26

27 Calcium carbonate is currently allowed under the National Organic Program (NOP) regulations at 7 CFR

28 205.605(a) as a nonagricultural nonsynthetic substance that may be used as an ingredient in or on

29 processed products labeled "organic" or "made with organic (specified ingredients or food group(s))."

30 Within food production, calcium carbonate has many applications including use as a coloring agent,

31 acidity regulator (pH), food stabilizer, anticaking agent, and for nutritional fortification (EFSA, 2011c).

32

33

### Characterization of Petitioned Substance

34

35 **Composition of the Substance:**

36 Calcium carbonate is an inorganic salt of natural (nonsynthetic) origin found in mineral deposits such as

37 limestone and chalk. Calcium carbonate is among the most abundant matter in the earth's crust, with a

38 composition of approximately 10% of sediments (Al Omari et al., 2016). Calcium carbonate is commercially

39 available as a white microcrystalline powder of varying particle sizes, with a purity  $\geq 98\%$  (EFSA, 2011c).

40

41 **Source or Origin of the Substance:**

42 Calcium carbonate is isolated from natural mineral formations, primarily limestone and chalk, and from

43 oyster shells. Calcium carbonate is isolated from raw minerals by calcination, a process of "heating to high

44 temperatures in air or oxygen," during which the calcium carbonate ( $\text{CaCO}_3$ ) is converted to calcium oxide

45 ( $\text{CaO}$ ), with carbon dioxide ( $\text{CO}_2$ ) gas being released during the process (Al Omari et al., 2016; IUPAC,

46 2014). Calcination is followed by slaking, a process in which the calcium oxide ( $\text{CaO}$ ) is hydrated through

47 the addition of water ( $\text{H}_2\text{O}$ ) to form the more stable form of lime, calcium hydroxide ( $\text{Ca(OH)}_2$ ) (Hassibi,

48 1999). Finally, calcium carbonate is reformed in a purified state through the process of carbonation, in

49 which carbon dioxide ( $\text{CO}_2$ ) gas is bubbled through an aqueous slurry of calcium hydroxide ( $\text{Ca(OH)}_2$ ),

50 resulting in the formation and precipitation of calcium carbonate (CaCO<sub>3</sub>) (Domingo et al., 2004; EFSA,  
51 2011c). Calcium carbonate may also be produced by crystallization of CaCO<sub>3</sub> formed via a salt metathesis  
52 reaction (Weiss et al., 2014).

53

#### 54 **Properties of the Substance:**

55 The properties of calcium carbonate are summarized in Table 1.

56

57

**Table 1. Properties of Calcium Carbonate**

CAS Registry Number	471-34-1
Molecular Formula	CaCO <sub>3</sub>
Molecular Weight	100.09 g/mol
Appearance	A white or nearly white powder or microcrystalline powder
Bulk Density	ca. 400 - 1,400 kg/m <sup>3</sup>
Melting Point	825 °C (decomposition)
Water Solubility	0.14 g/L (20 °C)

58 Sources: PubChem 10112; Al Omari et al., 2016; Millipore-Sigma, 2015; EFSA, 2011c.

59

#### 60 **Specific Uses of the Substance:**

61 Calcium carbonate is used for a wide range of applications in the food and agriculture industries. These  
62 applications include use as a coloring agent, food stabilizer, anticaking agent, gelling agent, glazing and  
63 release agent, thickener, bulking agent, acidity regulator, dough conditioner, and nutritional fortification  
64 additive (Al Omari et al., 2016; EFSA, 2011c; NOSB, 1995; NOSB, 2015). In addition to being a nutritional  
65 additive to food, calcium carbonate is also used as a dietary supplement, and in antacids (EFSA, 2011c;  
66 NOSB, 2015; PubChem 10112).

67

68 Calcium carbonate is also used in agricultural practices for the treatment and conditioning of soils,  
69 primarily as a means of adjusting soil pH. These treatment and conditioning practices may use calcium  
70 carbonate in a variety of forms, ranging from the precipitated salt to ground limestone (USGS, 2008).  
71 Moreover, calcium carbonate has been used in formulations to protect trees and their fruits (in orchards)  
72 from browsing game damage, when applied as a liquid solution that hardens to form a protective coating  
73 (EFSA, 2011a, b).

74

#### 75 **Approved Legal Uses of the Substance:**

76 The United States Department of Agriculture (USDA) NOP has approved the usage of calcium carbonate at  
77 7 CFR 205.605(a) as a nonagricultural, nonsynthetic substance that may be used as an ingredient in or on  
78 processed products labeled “organic” or “made with organic (specified ingredients or food group(s)).”

79

80 The United States Environmental Protection Agency (EPA) allows the use of calcium carbonate as an “inert  
81 ingredient permitted in minimum risk pesticide products,” at 40 CFR 152.25. The EPA also allows calcium  
82 carbonate as an “inert ingredient applied to animals,” at §180.930.

83

84 The United States Food and Drug Administration (FDA) allows the use of calcium carbonate as a “color  
85 additive mixture for coloring drugs” at 21 CFR 73.1070, and as a “color additive mixture for coloring  
86 foods” at §73.70. The FDA allows the use of calcium carbonate in “lakes (Ext. D&C)” for “externally applied  
87 drugs and cosmetics,” at §82.2051. Calcium carbonate is also approved for use as a “colorant for polymers”  
88 at §178.3297. The FDA allows the use of calcium carbonate as a “component of the food-contact surface of  
89 paper and paperboard” at §176.170.

90

91 The FDA allows the use of calcium carbonate as an “active ingredient” in “antacid products for over the  
92 counter (OTC) human use” at §331.11. The FDA allows the use of calcium carbonate as a food stabilizer at  
93 §181.29 and §169.115. The FDA allows the use of calcium carbonate as a binding agent in meat and poultry  
94 pieces at §424.21.

95

96 The FDA has allowed the usage of calcium carbonate for the production of calcium citrate by the  
97 neutralization of citric acid at §184.1195, the production of calcium gluconate by the neutralization of  
98 gluconic acid at §184.1199, the production of calcium glycerophosphate by the neutralization of  
99 glycerophosphoric acid at §184.1201, the production of calcium lactate by the neutralization of lactic acid at  
100 §184.1207, and for the production of calcium oxide (CaO) by “calcination at temperatures of 1,700-2,450 °F”  
101 at §184.1210.

102  
103 The Alcohol and Tobacco Tax and Trade Bureau (TTB) of the United States Department of the Treasury  
104 allows the use of calcium carbonate for the “treatment of wine and juice” at 29 CFR 24.246(2b).  
105

#### 106 **Action of the Substance:**

107 Calcium carbonate has several uses, with the primary applications being for regulation of acidity and for  
108 nutritional fortification of foods. In terms of regulation of acidity, there are several venues for this  
109 application, including the regulation of the gastrointestinal pH of humans, the acid contents in food and  
110 beverages (e.g., wine), and the pH of soils. In these applications, the carbonate anion acts as a base, which  
111 is able to neutralize both strong and weak acids, resulting in the formation of a new calcium salt and  
112 carbon dioxide (CO<sub>2</sub>) gas (Al Omari et al., 2016; EFSA, 2011c; Holman and Stone, 2001; Oates, 1998).  
113 Although calcium carbonate has very low water solubility, the ionic compound is broken up by acids,  
114 greatly increasing the solubility of the calcium cation, and providing access to the basic properties of the  
115 carbonate anion (EFSA, 2011c; Oates, 1998).  
116

117 Calcium carbonate is also used for nutritional fortification of food, as well as a dietary supplement. When  
118 used in this capacity, the water insoluble calcium carbonate is broken into its corresponding ions by  
119 stomach acid, as described above in acid regulation. Once the calcium ion has been liberated from the  
120 carbonate anion, it can be absorbed by the body via both active transport and passive diffusion, with the  
121 remainder of the ion being excreted in feces (Heaney, 2002). Once absorbed by the body, the majority of  
122 calcium is stored in the skeleton (EFSA, 2011c).  
123

#### 124 **Combinations of the Substance:**

125 Calcium carbonate is commercially available as a white or nearly white powder or microcrystalline powder  
126 without additional substances (e.g., inert ingredients, stabilizers, preservatives, carriers, anticaking agents,  
127 or other materials), with a purity ≥98%. When sold as ground limestone, the majority of the product is  
128 comprised of calcium carbonate (≥94%), although it has been noted that due to the natural formation of  
129 limestone, other minerals, including aluminum and magnesium, may be present in variable amounts (Al  
130 Omari et al., 2016; EFSA, 2011c; USGS, 2008).  
131

132 Calcium carbonate is also a precursor to the substance calcium citrate, which is identified on the National  
133 List. As described above in **Approved Legal Uses of the Substance**, calcium citrate is formed by the  
134 neutralization of citric acid by the base calcium carbonate, as outlined at 21 CFR 184.1195.  
135

136 <b>Status</b>
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#### 137 138 **Historic Use:**

139 Calcium carbonate has been used in organic agricultural production with a range of applications. These  
140 include its use as an acidity regulator (both in food and in soil), as a stabilizer, and for general use in the  
141 processing and preparation of foods.  
142

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

144 Calcium carbonate is not listed in the Organic Foods Production Act of 1990.  
145

146 Calcium carbonate is listed at 7 CFR 205.605(a) as a nonagricultural nonsynthetic substance that may be  
147 used as an ingredient in or on processed products labeled “organic” or “made with organic (specified  
148 ingredients or food group(s),” and is also allowed for use in organic crop and livestock production at  
149 §205.105.  
150

**151 International**

152 **Canada** - Canadian General Standards Board Permitted Substances List.

153  
154 Calcium carbonate is listed in the Canadian General Standards Board Permitted Substances List  
155 (CAN/CGSB-32.311-2015) in Table 4.2 as allowed for "soil amendments and crop nutrition," with the  
156 exception that the calcium carbonate must be "mined," and from a "non-synthetic source." Calcium  
157 carbonate is also described as being allowed to "protect plants from harsh environmental conditions, such  
158 as frost and sunburn, infection, the buildup of dirt on leaf surfaces, or injury by a pest."

159  
160 The Canadian General Standards Board Permitted Substances List (CAN/CGSB-32.311-2015) also identifies  
161 calcium carbonate in Table 6.3 as a "food additive," with the exception "prohibited for use as a colouring  
162 agent," and in Table 6.5 as a "processing aid." Calcium carbonate is also described as being in the form of  
163 lime as a "cleaner, disinfectant and sanitizer permitted on organic product contact surfaces for which a  
164 removal event is mandatory."

165  
166 **CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing**  
167 **of Organically Produced Foods (GL 32-1999) -**

168 Calcium carbonate appears under CODEX GL 32-1999 guidelines as an allowed substance in "Table 1:  
169 Substances for use in Soil Fertilizing and Conditioning," without additional conditions, in "Table 3.1 Food  
170 additives, including carriers," without additional conditions, for use in "livestock and bee products," with  
171 specific conditions of "Milk products. Not as a colouring agent," and also for use in plant products,  
172 without additional conditions.

173  
174 **European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008**

175 Calcium carbonate is allowed under EC No. 889/2008 as a "fertilizer and soil conditioner," with the  
176 condition that it be "only of natural origin," as a "feed material of mineral origin," and as a "processing  
177 aid" for the "preparation of foodstuffs of plant origin," without specific conditions.

178  
179 **Japan Agricultural Standard (JAS) for Organic Production**

180 Calcium carbonate is listed in the Japanese Agricultural Standard for Organic Plants (notification no. 1605)  
181 in Table 1 as a "fertilizer and soil improvement substance," with the exception that it must be "derived  
182 from natural sources, or natural sources without the use of chemical treatment." Calcium carbonate as a  
183 "wetable powder" is listed in Table 2 as a "substance for plant pest and disease control," which is "limited  
184 to the use for preventing harmful effects of copper wettable powder."

185  
186 Calcium carbonate is listed in the Japanese Agricultural Standard for Organic Processed Foods (notification  
187 no. 1606) as a "food additive" in Table 1, with the exception that the substance is "limited to be used for  
188 dairy products (except for coloring) and for cheese as a coagulating agent."

189  
190 Calcium carbonate is listed in the Japanese Agricultural Standard for Organic Feeds (notification no. 1607)  
191 in Article 4 in the form of limestone as a "production method for organic feeds."

192  
193 **International Federation of Organic Agriculture Movements (IFOAM) -**

194 Calcium carbonate is listed in the IFOAM Norms in Appendix 4, Table 1, as an allowed "additive and  
195 processing/post-harvest handling aid" with a limitation of "not for coloring."

196  
197 **Evaluation Questions for Substances to be used in Organic Handling**

198  
199 **Evaluation Question #1:** Describe the most prevalent processes used to manufacture or formulate the  
200 petitioned substance. Further, describe any chemical change that may occur during manufacture or  
201 formulation of the petitioned substance when this substance is extracted from naturally occurring plant,  
202 animal, or mineral sources (7 U.S.C. § 6502 (21)).  
203

204 Calcium carbonate is a naturally occurring mineral which is prevalent in the earth's crust (approximately  
205 10%) and is found in all regions of the globe (Al Omari et al., 2016). Calcium carbonate is the major  
206 component of limestone and can be isolated and used as ground limestone. However, limestone is  
207 naturally occurring and may also contain other minerals (e.g., aluminum, magnesium, etc.) in varying  
208 amounts (Al Omari et al., 2016; EFSA, 2011c; USGS, 2008).

209 In the production of synthetic calcium carbonate, the ground limestone then undergoes a calcination  
210 process, during which the calcium carbonate limestone ( $\text{CaCO}_3$ ) is converted to calcium oxide quicklime  
211 ( $\text{CaO}$ ), with the loss of carbon dioxide ( $\text{CO}_2$ ) gas (Domingo et al., 2004). The quicklime is then slaked,  
212 through the controlled addition of water ( $\text{H}_2\text{O}$ ), resulting in the formation of calcium hydroxide slaked  
213 lime ( $\text{Ca}(\text{OH})_2$ ), which undergoes carbonation for the formation and precipitation of calcium carbonate  
214 ( $\text{CaCO}_3$ ) (Domingo et al., 2004).

215 According to the FDA at 21 CFR 184.1191, calcium carbonate can be prepared “(1) as a byproduct in the  
216 ‘Lime soda process;’ (2) by precipitation of calcium carbonate from calcium hydroxide in the ‘Carbonation  
217 process;’ or (3) by precipitation of calcium carbonate from calcium chloride in the ‘Calcium chloride  
218 process.’”

219 In the “Lime soda process,” a water softening procedure, slaked lime (calcium hydroxide ( $\text{Ca}(\text{OH})_2$ )) is  
220 reacted with soda ash (sodium carbonate ( $\text{Na}_2\text{CO}_3$ )) in a salt metathesis, from which calcium carbonate is  
221 precipitated (Britannica, 2018).

222  
223 In the carbonation of calcium hydroxide, slaked lime ( $\text{Ca}(\text{OH})_2$ ) is added to a solution of carbonic acid  
224 ( $\text{H}_2\text{CO}_3$ ), which has been prepared by the high-pressure injection of carbon dioxide ( $\text{CO}_2$ ) gas into water  
225 ( $\text{H}_2\text{O}$ ). Upon mixing, the solutions undergo a salt metathesis reaction, from which calcium carbonate is  
226 precipitated (Al Omari et al., 2016; Domingo et al., 2004; Brecevic and Kralj, 2007).

227  
228 In the “calcium chloride process,” calcium chloride ( $\text{CaCl}_2$ ) and magnesium chloride ( $\text{MgCl}_2$ ) solutions are  
229 adjusted to reach a pH of 7, at which point a solution of sodium carbonate ( $\text{Na}_2\text{CO}_3$ ) is mixed in, resulting  
230 in the formation and precipitation of calcium carbonate (Al Omari et al., 2016; Montes-Hernandez et al.,  
231 2007).

232  
233 Calcium carbonate may also be formed synthetically via a salt metathesis reaction, such as the combination  
234 of solutions of ammonium carbonate ( $(\text{NH}_4)_2\text{CO}_3$ ) and calcium acetate ( $\text{Ca}(\text{CH}_3\text{COO})_2$ ) under an  
235 atmosphere of carbon dioxide ( $\text{CO}_2$ ) gas (Al Omari et al., 2016; Weiss et al., 2014).

236  
237 **Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a**  
238 **chemical process or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss**  
239 **whether the petitioned substance is derived from an agricultural source.**

240  
241 The majority of isolated calcium carbonate is derived from marine life, as calcium carbonate is a major  
242 component of the shells of marine organisms, pearls, and egg shells (Beruto and Giordan, 1993). The  
243 mineral deposits of calcium carbonate are then composed of the “skeletal remains and other biological  
244 constituents that include fecal pellets, lime mud (skeletal), and microbially mediated cements and lime  
245 muds.” (Al Omari et al., 2016).

246  
247 Calcium carbonate is also naturally formed by biomineralization processes of photosynthetic microalgae.  
248 The biomineralization process is achieved by enzymatic fixation of carbon dioxide ( $\text{CO}_2$ ) gas, to form  
249 bicarbonate ions ( $\text{HCO}_3^-$ ), which are then converted to calcium carbonate ( $\text{CaCO}_3$ ) in the presence of  
250 calcium sources (Al Omari et al., 2016).

251  
252 Calcium carbonate is isolated from the natural mineral deposits described above, and then is processed  
253 according to one of the methods described above in **Evaluation Question #1**, for the precipitation of  
254 purified calcium carbonate for commercial uses.

255  
256

257 **Evaluation Question #3: If the substance is a synthetic substance, provide a list of nonsynthetic or**  
258 **natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).**  
259

260 Calcium carbonate is a natural, nonsynthetic substance, although it may also be manufactured via salt  
261 metathesis reactions, such as the combination of solutions of ammonium carbonate ((NH<sub>4</sub>)<sub>2</sub>CO<sub>3</sub>) and  
262 calcium acetate (Ca(CH<sub>3</sub>COO)<sub>2</sub>) to produce calcium carbonate as a precipitate, as described in **Evaluation**  
263 **Question #1** (Al Omari et al., 2016; Weiss et al, 2014).  
264

265 **Evaluation Question #4: Specify whether the petitioned substance is categorized as Generally**  
266 **Recognized as Safe (GRAS) when used according to FDA’s good manufacturing practices (7 CFR §**  
267 **205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.**  
268

269 Calcium carbonate has been listed as GRAS by the FDA at 21 CFR 184.1191 “with no limitation other than  
270 good manufacturing practice.” Calcium carbonate has also been listed as GRAS as a “food additive,” by the  
271 FDA at §582.1191, and as a “nutrient and/or dietary supplement” at §582.5191. Furthermore, ground  
272 limestone has been given GRAS status by the FDA at §184.1409 as long as it is composed of “not less than  
273 94 percent” calcium carbonate.  
274

275 **Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned**  
276 **substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7**  
277 **CFR § 205.600 (b)(4)).**  
278

279 Calcium carbonate does not function as a preservative.  
280

281 **Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate**  
282 **or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)**  
283 **and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600**  
284 **(b)(4)).**  
285

286 Calcium carbonate has been used as a coloring or whitening agent, with applications including paints,  
287 soaps, paper, cement, cosmetic products (e.g., mouth washes, creams, lotions), and medical and food  
288 products (DDW, 2014; Oregon DHS, 1998). However, in historic organic food processing, both within the  
289 United States and internationally, calcium carbonate is not allowed for coloration purposes (see **Status**  
290 **section**).  
291

292 One of the major applications of calcium carbonate is for nutritional fortification, and it is also used directly  
293 as a dietary supplement for nutritional purposes. In this mode of action, the insoluble salt is broken down  
294 by stomach acid into its ions. Once in ionic form, the calcium cation (Ca<sup>2+</sup>) may be absorbed into the body  
295 via active transport and/or passive diffusion, where it is then stored primarily in the skeleton (Heaney,  
296 2002; EFSA, 2011c).  
297

298 **Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or**  
299 **feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).**  
300

301 The incorporation of calcium carbonate into food or feed will result in an enhancement of calcium ions  
302 (Ca<sup>2+</sup>), which is absorbed and stored in the skeleton, as described above in **Evaluation Question #6**.  
303

304 **Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of**  
305 **FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600**  
306 **(b)(5)).**  
307

308 No residues of heavy metals or other contaminants have been reported in the commercially available  
309 precipitated calcium carbonate. However, it has been noted that ground limestone (which is essentially  
310 calcium carbonate) may contain varying amounts of aluminum and magnesium (EFSA, 2011c; USGS, 2008).  
311

312 **Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the**  
313 **petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i)**  
314 **and 7 U.S.C. § 6517 (c) (2) (A) (i)).**  
315

316 The processing of calcium carbonate has the potential to provide negative environmental outcomes. These  
317 are largely centered on the resulting impacts to water systems, both above and below ground. Many  
318 mineral deposits containing calcium carbonate can serve as aquifers, which yield water to wells (USGS,  
319 2008). Their possible contamination may be the result of natural contaminants, or from spills or other  
320 contaminants produced in the mining process (USGS, 2001). The disruption to ground water may also  
321 result in the decline of the local water table, which can have far-reaching effects. If the quarry site is in  
322 contact with the water table, flooding of the operation may result, causing the water to be pumped out and  
323 rerouted (USGA, 2001).  
324

325 Mining may also have negative effects on biodiversity. As described above, mineral extraction efforts may  
326 result in the decline or reorganization of the water table and pumping of the sites may also change the state  
327 of surface water. These changes will result in a range of impacts to the surrounding ecosystems, depending  
328 on the scope and the identity of the ecosystem. There are also potential impacts to the disruption of  
329 subterranean environments (e.g., caves), which house species that may not be able to cope with habitat loss  
330 (USGS, 2001).  
331

332 **Evaluation Question #10: Describe and summarize any reported effects upon human health from use of**  
333 **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**  
334 **(m) (4)).**  
335

336 There are limited studies on the impact of calcium carbonate on humans. In the reported studies, increased  
337 intake of calcium can result in hypercalcemia and the formation of kidney stones when total daily calcium  
338 intake reaches levels at or above 2000 mg (Al Omari et al., 2016; EFSA, 2011c). The potential for  
339 hypercalcemia and alkalosis has been noted when subjects ingested calcium carbonate 2.0 to 16.5 g/day in  
340 the form of dietary supplements in concert with “large amounts” of milk or cream for the treatment of  
341 peptic ulcers (Martindale, 2002). Robson and Heading reported acute hypercalcemia and recurrent  
342 nephrolithiasis in three subjects that regularly ingested large quantities (7 to 15 g/day) of a calcium  
343 carbonate/sodium bicarbonate powder for 10 years (EFSA, 2011c; Robson and Heading, 1978). Bolland et  
344 al. report the increased risk of myocardial infraction in subjects whose intake calcium was above 805  
345 mg/day, although it was noted that there was no effect below this threshold (Bolland et al., 2010).  
346

347 **Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned**  
348 **substance unnecessary (7 U.S.C. § 6518 (m) (6)).**  
349

350 Due to the many applications of calcium carbonate, both in food and other industries, there are no  
351 alternative practices that reduce the value of calcium carbonate, which has become an integral part of  
352 agricultural production, processing, as well as human nutrition and health.  
353

354 **Evaluation Question #12: Describe all natural (nonsynthetic) substances or products which may be used**  
355 **in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances**  
356 **that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).**  
357

358 Sodium bicarbonate ( $\text{NaHCO}_3$ ) and sodium carbonate ( $\text{Na}_2\text{CO}_3$ ) are both natural substances that, like  
359 calcium carbonate, can be used for acid regulation (increasing pH). Sodium carbonate is a naturally-formed  
360 substance, which is found in the naturally occurring mineral trona, a mixture of hydrated sodium  
361 carbonate ( $\text{Na}_2\text{CO}_3$ ) and sodium bicarbonate ( $\text{NaHCO}_3$ ) (Solvay, 2014). Trona is a feedstock for the  
362 production of soda ash (sodium carbonate ( $\text{Na}_2\text{CO}_3$ )), and following extraction, the mineral is ground and  
363 calcined to produce sodium carbonate monohydrate ( $\text{Na}_2\text{CO}_3 \cdot \text{H}_2\text{O}$ ), which can undergo further  
364 calcination to remove the hydrate (water molecule) (Kirk-Othmer, 2012). Sodium bicarbonate can be  
365 formed from the isolated sodium carbonate by treatment with water ( $\text{H}_2\text{O}$ ) and a carbon dioxide ( $\text{CO}_2$ )  
366 source (PubChem 516892). Like calcium carbonate, both sodium carbonate and sodium bicarbonate are



367 effective acid regulators and are sometimes found in the same products and procedures for acid regulation  
368 (PubChem 10340).

369  
370 **Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for**  
371 **the petitioned substance (7 CFR § 205.600 (b) (1)).**

372  
373 Calcium hydroxide (Ca(OH)<sub>2</sub>) (listed as hydrated lime), sodium carbonate (Na<sub>2</sub>CO<sub>3</sub>), and potassium  
374 bicarbonate (KHCO<sub>3</sub>) are all listed as allowed nonsynthetic substances at 7 CFR 205.601. Calcium  
375 hydroxide provides the best alternative for calcium carbonate, as it provides both major functions of acid  
376 regulation (increasing pH), as well as a nutritional additive. (NOSB, 2002). However, calcium hydroxide  
377 has increased water solubility, and increased basicity compared to calcium carbonate, making it less  
378 desirable for some food processing applications (PubChem 6093208). Calcium hydroxide acts as a firming  
379 agent in addition to acid regulation (JECFA, 1965).

380  
381  
382 Sodium carbonate (Na<sub>2</sub>CO<sub>3</sub>) and potassium bicarbonate (KHCO<sub>3</sub>) can also be used for acid regulation  
383 (increasing pH). However, like calcium hydroxide, these bases have much higher water solubility than  
384 calcium carbonate, and therefore do not require the presence of an acid to become soluble and 'active,'  
385 making them less desirable for some applications (PubChem 10340; PubChem 516893; PubChem 6093208;  
386 PubChem 10112).

387

#### Report Authorship

389

390 The following individuals were involved in research, data collection, writing, editing, and/or final  
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397 All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11 – Preventing  
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