

Alginic Acid

Handling/Processing

Identification of Petitioned Substance

Chemical Names:

Alginic Acid

CAS Numbers:

9005-32-7

Other Name:

Algin

Other Codes:

8192143 (Beilstein Registry Number)

Trade Names:

Kelacid

232-680-1 (EINECS Number)

Landalgine

E400 (Sinclair 1998)

Polymannuronic acid

Satialginic UH8 EP

Norgine

Sazzio or Sazio

Summary of Petitioned Use

Alginic acid is currently listed in 7 CFR Section 205.605(a) as a nonagricultural (nonorganic), nonsynthetic substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” in the National List of Allowed and Prohibited Substances (hereafter referred to as the National List) (USDA National Organic Program 2014).

Characterization of Petitioned Substance

Composition of the Substance:

Alginic acid is defined by the Food and Drug Administration (FDA) as a “colloidal, hydrophilic polysaccharide obtained from certain brown algae by alkali extraction (FDA 2014)” and is classified as a food hydrocolloid along with other materials such as gum arabic, guar gum and carrageenan (Imeson 2010). Alginic acid is “a hydrophilic, colloidal polysaccharide obtained from seaweeds,” which means it is a water loving multi-chain carbohydrate (it can absorb 200-300 times its weight of water and salts) whose insoluble particles are dispersed throughout another substance, in this case water (Merck and Co., Inc. 1976). A natural polysaccharide, alginic acid is an unbranched binary copolymer consisting of (1,4)-linked β -D-mannuronic acid and α -L-guluronic acid, which are often referred to as M and G blocks respectively when found in consecutive units and MG blocks when found in alternating sequences (Liu, et al. 2006). Alginic acid is able to absorb and chemically bind sodium and other cations when prepared or ingested (Merck and Co., Inc. 1976; R.E. Gosselin 1976; FAO 2003). The chemical formula for alginic acid is $(C_6H_8O_6)_n$ where n is the number of repeated molecular units to form the saccharide chain. The melting point of the substance is 300 °C (Sigma-Aldrich Co. LLC 2014).

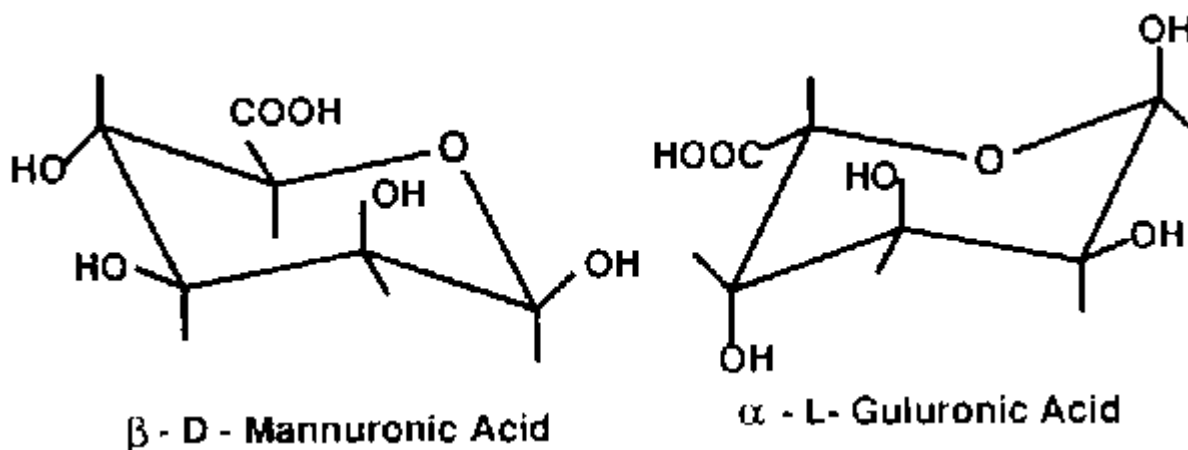
Source or Origin of the Substance:

Alginic acid is derived from brown seaweeds and is extracted primarily through maceration, alkali treatment, water dilutions, acid precipitation and dewatering (FAO 2003; OMRI 2014; Green 1934). Soda ash (sodium carbonate) is the most commonly used material for alkali treatment on an industrial scale, although literature also reports the use of sodium phosphate and basic solutions of ammonium, potassium, or sodium salts (Green 1934; Hernandez-Carmona, McHugh and Lopez-Gutierrez 1999b). Sodium salts are most often used for alkali treatment in order to create crude, soluble sodium alginate solutions. This crude sodium alginate solution is then used for alginic acid production, and later in the production of refined

46 sodium alginate, the sodium salt of alginic acid (Green 1934; Hernandez-Carmona; McHugh and Lopez-
47 Gutierrez 1999b; FAO 2003). The amount of alkali used will vary depending on the brown seaweed species
48 and production method used but generally the target pH is 10 (Green 1934; Hernandez-Carmona, McHugh
49 and Lopez-Gutierrez 1999b). These processes isolate the naturally occurring alginic acid from the cell walls
50 of brown seaweeds (OMRI 2014, Green 1934; Hernandez-Carmona, McHugh and Lopez-Gutierrez 1999b ;
51 FAO 2003).

52 53 **Properties of the Substance:**

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55 Alginic acid is an odorless, white to yellowish-white fibrous powder that is insoluble in water and organic
56 solvents, and slightly soluble in alkali solutions (Remington, et al. 1975; FAO 2003). A tasteless substance,
57 alginic acid carries a pH between 2.0 and 3.4 in a 3% solution (Merck and Co., Inc. 1976).



60
61
62 Figure 1. Image of alginic acid showing the two monomeric units, β -D-mannuronic acid (M) and α -L-
63 guluronic acid (G) (FAO 1987).

64 65 **Specific Uses of the Substance:**

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67 The FDA has identified alginic acid as Generally Recognized as Safe (GRAS) and allowed for use only as an
68 emulsifier, emulsifier salt, formulation aid, stabilizer and thickener (FDA 2014). The use of alginic acid is
69 limited to soups and soup mixes (FDA 2014). Any use of alginic acid outside of these limitations would
70 require additional rule making either through a food additive regulation or amendment to the GRAS
71 affirmation regulation. Alginic acid is insoluble in water and is not often added directly to food, but it is
72 used extensively for non-food uses in the pharmaceutical industry as a tablet disintegrant due to its ability
73 to swell in water (Saltmarsh, Barlow and eds. 2013).

74 75 **Approved Legal Uses of the Substance:**

76
77 Alginic acid is a nonagricultural (nonorganic), nonsynthetic substance allowed as an ingredient in or on
78 processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" in
79 the National List (USDA National Organic Program 2014).

80
81 Alginic acid is listed at 21 CFR 184.1011 as a direct food substance affirmed as GRAS with specific
82 limitations for use as an emulsifier, emulsifier salt, formulation aid, stabilizer and thickener in soups and
83 soup mixes (FDA 2014).

84
85 Alginic acid is listed by the EPA as both an inert material approved for use in non-food use pesticides (EPA
86 2010) and as a former List 3 inert of unknown toxicity as included on the list of inert ingredients last
87 updated in August of 2004 (EPA 2004).

88

Action of the Substance:

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91 Due to its hydrophilic nature and high insolubility in water, alginic acid is used to manufacture
92 pharmaceutical tablets that deliver probiotics and drugs (Saltmarsh, Barlow and eds. 2013). Alginic acid is
93 also used as an emulsifier, emulsifier salt, formulation aid, stabilizer or thickener according to FDA
94 limitations described earlier (Saltmarsh, Barlow and eds. 2013; FDA 2014). It is not often added directly to
95 food, however, but rather is created *in situ* when sodium alginate is added to acidic foods (Saltmarsh,
96 Barlow and eds. 2013), with the lower pH causing alginic acid to precipitate from the solution (FAO 2003;
97 Green 1934). The newly created alginic acid will form a gelatinous film due to its insolubility in water
98 (Saltmarsh, Barlow and eds. 2013).

99

100 The action of alginic acid is directly related to the amounts of M, G and MG blocks present in the co-
101 polymer (Kloareg and Quatrano 1988). Alginic acid with low M/G ratio and high guluronic acid content
102 form strong and rigid gels (Kloareg and Quatrano 1988; Kim 2011). Alternatively, alginic acids with high
103 M/G ratio and low guluronic acid content will form soft, elastic gel (Kloareg and Quatrano 1988; Kim
104 2011).

105

Combinations of the Substance:

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108 While alginic acid is extracted from alginates, it can also be used as a precursor to alginate salts (alginates)
109 identified on the National List at Section 205.605(b). Alginate salts can either be manufactured as stand
110 alone materials or formed *in situ* when alginic acid is added to dairy products such as whipping or ice
111 cream (Saltmarsh, Barlow and eds. 2013).

112

113 The purity of alginic acid is reported in the Food Chemicals Codex to be between 91% and 104.5% alginic
114 acid recorded on a dry basis (Food Chemicals Codex 2003). Nothing in the literature indicates the use of
115 additional ingredients such as stabilizers, preservatives, carriers or anti-caking agents in combination with
116 alginic acid. The precipitated alginic acid powder therefore contains mostly alginic acid along with
117 impurities such as arsenic, lead, ash and insoluble materials (Food Chemicals Codex 2003).

118

Status

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123 The National Organic Standards Board (NOSB) voted in April 1995 to allow alginic acid as a nonsynthetic
124 material for use in organic food processing (NOSB 1995), and alginic acid was included in the USDA
125 organic regulations published in December 2000 (USDA 2000). In its previous sunset review of alginic acid,
126 the NOSB voted to recommend continuing its listing at section 205.605(a) (USDA 2010).

127

Organic Foods Production Act, USDA Final Rule:

128

129

130 Alginic acid is currently included in section 205.605(a) as a nonagricultural (nonorganic), nonsynthetic
131 substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic
132 (specified ingredients or food group(s))” (USDA National Organic Program 2014). Alginic acid does not
133 specifically appear in the Organic Foods Production Act (OFFPA; USDA 1990).

134

International

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

145 Alginic acid is included in the CODEX Alimentarius Commission, Guidelines for the Production,
146 Processing, Labelling and Marketing of Organically Produced Foods as a food additive of nonagricultural
147 origin in Table 3. The CODEX Alimentarius Commission Guidance identifies alginic acid by its INC
148 number (400) and states that alginic acid, as a food additive, is permitted in foods of plant origins, although
149 exclusions of the General Standard for Food Additives (GSFA) still apply (FAO and WHO 2014).
150 Specifically, the GSFA lists many provisions for alginic acid that are not identified by the FDA including
151 use as a bulking agent, carrier, foaming agent, gelling agent, glazing agent, humectant, and sequestrant in
152 many food types (FAO and WHO 2014).

153
154 **European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008**

155 Alginic acid is listed as an approved food additive for use in the production of processed organic food in
156 Section A of the Commission Regulation (EC) No 889/2008 (The Council of the European Union 2008).
157 Alginic acid is approved for use in the preparation of foodstuffs of both plant and animal origin but is
158 restricted to only milk-based products when used in products of animal origin (The Council of the
159 European Union 2008). Alginic acid is classified as nonagricultural in the EU Organic Regulations (The
160 Council of the European Union 2008). The use of alginic acid in the production of processed organic food
161 was originally authorized under Regulation (EEC) No 2092/91. It was renewed and is present in Article
162 21(2) of regulation (EC) No 834/2007.

163
164 **Japan Agricultural Standard (JAS) for Organic Production**

165 The JAS for Organic Processed Foods, Table 1, identifies alginic acid as an allowed food additive limited to
166 use only in processed foods of plant origin (The Japanese Organic Standard 2005).

167
168 **International Federation of Organic Agriculture Movements (IFOAM)**

169 Alginic acid is recognized by IFOAM as an approved additive used in an organic processed product
170 without annotation in Appendix 4-Table 1 in the Organic NORMS for Organic Production and Processing
171 (IFOAM 2014).

172
173 **Evaluation Questions for Substances to be used in Organic Handling**

174
175 **Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the**
176 **petitioned substance. Further, describe any chemical change that may occur during manufacture or**
177 **formulation of the petitioned substance when this substance is extracted from naturally occurring plant,**
178 **animal, or mineral sources (7 U.S.C. § 6502 (21)).**

179
180 Alginic acid is commercially extracted from alginates (e.g., sodium, potassium, calcium or magnesium
181 alginate) found in all brown seaweed species (Marcus 1961; Green 1934; Hernandez-Carmona, McHugh
182 and Lopez-Gutierrez 1999a; Thomas, Visakh and Matthews 2012). Major commercial sources are from
183 species that include *Ascophyllum* (North Atlantic), *Laminaria* and *Saccharina* (various northern hemisphere
184 oceans) and *Macrocystis* (California and Mexico), with lesser sources from *Lessonia* (South America),
185 *Durvilea* (Australia), *Ecklonia* (South Africa), *Sargassum*, and *Turbinaria* (Saltmarsh, Barlow and eds. 2013;
186 Kraan 2012). Alginates are the salts of alginic acid that provide the structural components of brown
187 seaweed. In order to extract alginic acid from these salts, ion exchange is induced in an alkali medium
188 followed by precipitation and purification (Saltmarsh, Barlow and eds. 2013; Green 1934; Marcus 1961;
189 Hernandez-Carmona, McHugh and Lopez-Gutierrez 1999a; FAO 2003). Formalin treatment is commonly
190 used to clean, wash and preserve raw seaweed (Vachel, et al. 2009; Hernandez-Carmona, et al. 1999a).

191
192 The process to extract alginic acid from brown seaweed species begins with the maceration,
193 demineralization (optional) and alkali treatment of seaweed using sodium carbonate or other alkali
194 material. Demineralization of macerated raw seaweed is usually accomplished through an acid treatment
195 (commonly hydrochloric acid or sulfuric acid is used) and subsequent dilutions with water (Green 1934;
196 Thomas, Visakh and Matthews 2012). The acid treatment, water dilutions and draining allows for the

197 removal of leached salts and water soluble organic materials which would otherwise interfere with
198 subsequent precipitation reactions (Green 1934; Thomas, Visakh and Matthews 2012).

199
200 The extraction of alginic acid relies heavily on ion exchange. These ion exchange processes are represented
201 below as reported by McHugh (1987). The calcium salt of alginic acid, the most abundant alginate salt in
202 brown seaweed species, is represented as $\text{Ca}(\text{Alg})_2$, the sodium cation as Na^+ , and mineral acid as H^+ :

203
204 Alkali treatment of seaweed without acid pre-treatment: $\text{Ca}(\text{Alg})_2 + 2\text{Na}^+ \rightarrow 2\text{NaAlg} + \text{Ca}^+$

205
206 When acid pre-treatment (demineralization) of seaweed is used: $\text{Ca}(\text{Alg})_2 + 2\text{H}^+ \rightarrow 2\text{HAlg} + \text{Ca}^{2+}$

207
208 Alkali treatment following acid pre-treatment: $\text{HAlg} + \text{Na}^+ \rightarrow \text{NaAlg} + \text{H}^+$

209
210 A formalin treatment can be used following acid demineralization to further remove phenolic compounds
211 that cause the dark color of the substance, and which might otherwise interfere with subsequent alkali
212 treatments (Le Gloahec and Herter 1938; Haug 1964; McHugh 1987). The demineralized, leached, chopped
213 and milled seaweed is alkali treated in the presence of a sodium salt such as sodium chloride or sodium
214 carbonate which yields a crude sodium alginate solution (OMRI 2014; Green 1934; FAO 2003). The crude
215 sodium alginate solution is then filtered using a filter press, centrifuge, vacuum filtering, sand bed
216 filtration or flotation method (Green 1934). The flotation method will most likely employ the use of a
217 flocculant such as polyacrylamide (McHugh 1987; Le Gloahec and Herter 1938). Diatomaceous earth or
218 carbon dioxide is used as a filtering aid or flocculant to assist in removing cellulose and other insoluble
219 materials (Green 1934; Andrade and Rojas 2012). After filtration, sodium alginate liquor is added to an
220 agitated solution of calcium chloride which yields fibers of an insoluble calcium salt of alginic acid, calcium
221 alginate (Green 1934; Andrade and Rojas 2012; McHugh 1987). Calcium alginate is then bleached with
222 sodium hypochlorite to whiten the end product (Green 1934; McHugh 1987; McHugh, Hernandez-
223 Carmona, et al. 2001).

224
225 Following bleaching, water is removed from the calcium alginate and the dewatered calcium alginate is
226 then added a number of times to a dilute HCl solution producing, via ion exchange, alginic acid from
227 calcium alginate salt that is free from Ca^+ ions (Green 1934; McHugh, Hernandez-Carmona, et al. 2001;
228 McHugh 1987). The fibrous alginic acid product is then dewatered using a filter press (McHugh 1987). The
229 process described above is known as the calcium alginate process (Andrade and Rojas 2012; FAO 2003).

230
231 A secondary production method for producing alginic acid uses one less production step than the calcium
232 alginate process, yielding an alginic acid product that is far more difficult to handle and resulting in a loss
233 of overall alginic acid yield. Termed the "alginic acid method" (Andrade and Rojas 2012; FAO 2003;
234 McHugh 1987), this production method follows the same processes outlined above; however, instead of
235 treating the crude sodium alginate solution with calcium chloride, an acid is added directly to the sodium
236 alginate yielding an alginic acid gel (FAO 2003; Andrade and Rojas 2012; McHugh 1987). This gel contains
237 approximately 1-2% alginic acid and 98-99% water which must be removed (dewatered) (FAO 2003;
238 McHugh 1987). Dewatering is accomplished through centrifugation followed by a screw press. However,
239 this process yields only a fraction of the amount of alginic acid that is produced using the calcium alginate
240 method, which bypasses the creation of a highly viscous gel and instead produces a product that is high in
241 alginic acid that can be spray dried into a pure powder (Andrade and Rojas 2012; FAO 2003; McHugh
242 1987).

243
244 The production of alginic acid via microbial fermentation is also possible. However, only two bacterial
245 genera, *Pseudomonas* and *Azotobacter*, are known to carry the genes required for alginic acid biosynthesis
246 (Remminghorst and Rehm 2009). From these two genera, only the alginic acid synthesized by *Azotobacter*
247 *vinlandii* has a block copolymer structure similar to the structure of the substance when isolated from
248 marine sources (Thomas, Visakh and Matthews 2012). Considerable studies on the subject of alginic acid
249 biosynthesis pathways are published, beginning with the study of brown algae species, *Fucus gardneri* (Lin
250 and Hassid 1966), and later predominately related to the study of bacteria (Remminghorst and Rehm 2009;
251 Pindar and Bucke 1975). Large scale, industrial production of alginic acid currently uses marine sources

252 whose chemical components, such as the amounts of mannuronic (M) and guluronic (G) acid blocks, vary
253 depending on specific seaweed species and season, and require extensive post-harvest processing
254 (Remminghorst and Rehm 2009; Pindar and Bucke 1975). Alternatively, bacterial alginate products can be
255 manufactured with more consistency and are mainly being explored for their potential in medical
256 applications (Remminghorst and Rehm 2009).

257
258 **Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a**
259 **chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss**
260 **whether the petitioned substance is derived from an agricultural source.**

261
262 Alginic acids are found naturally in the cell wall components of brown seaweeds as the calcium salt of
263 alginic acid, and are biosynthesized through various pathways by two bacterial genera, *Pseudomonas* and
264 *Azotobacter* (Thomas, Visakh and Matthews 2012; Remminghorst and Rehm 2009; G. Hernandez-
265 Carmona, D. K. McHugh, et al. 1999a). Isolation from its salts and other organic materials occurs through
266 alkali treatment and subsequent purification steps (Thomas, Visakh and Matthews 2012; McHugh 1987;
267 Hernandez-Carmona, McHugh and Lopez-Gutierrez 1999b; G. Hernandez-Carmona, D. K. McHugh, et al.
268 1999a). Alginic acid is commercially derived from an agricultural source (wild harvested or cultivated
269 brown seaweeds) (USDA National Organic Program 2014).

270
271 As described in question 1, alginic acid is created by naturally occurring biological pathways in both brown
272 seaweeds and two bacterial genera. However, alginic acid is manufactured on an industrial scale through a
273 chemical separation process that involves the maceration, alkali treatment and acid precipitation of alginic
274 acid from brown seaweeds. In this process, alginic acid is isolated from its salts through a series of chemical
275 processes. The draft Classification of Materials Guidance (NOP 5033) states that a material may be
276 considered nonsynthetic (natural) if at the end of the extraction process:

- 277 • The material has not been transformed into a different substance via chemical change;
- 278 • The material has not been altered into a form that does not occur in nature; and
- 279 • Any synthetic materials used to separate, isolate, or extract the substance have been removed from the
280 final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no
281 technical or functional effect in the final product.

282
283 In order to separate alginic acid from its salt form, it is subjected to numerous pH adjustments to promote
284 ion exchange. These chemical processes result in pure alginic acid. Since alginic acid is present in seaweeds
285 in its calcium, sodium, magnesium or other salt forms, and not in the free acid form, it is clear that the free
286 acid form does not appear in nature. Finally, the vast majority of materials used to adjust the pH during the
287 extraction of alginic acid are removed through ion exchange and have no technical effect in the final dried
288 powder. In its previous sunset review of alginic acid, the NOSB recommended the continued listing of
289 alginic acid as a nonsynthetic material at section 205.605(a) (USDA 2010).

290
291
292 **Evaluation Question #3: If the substance is a synthetic substance, provide a list of nonsynthetic or**
293 **natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).**

294
295 Alginic acid is currently considered a nonsynthetic substance. It occurs naturally in all brown seaweeds in
296 various salt forms (e.g., calcium, sodium, potassium, magnesium alginate) and is commercially produced
297 through alkali extraction of brown algal species, followed by numerous pH adjustments that facilitate ion
298 exchange. Alginic acid is also produced via biological pathways in the two bacterial genera, *Pseudomonas*
299 and *Azotobacter*. The widespread commercial use of alginic acid produced via fermentation is not yet
300 established and currently all commercial production uses brown algae species.

301
302 **Evaluation Question #4: Specify whether the petitioned substance is categorized as generally**
303 **recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR §**
304 **205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.**

305

306 Alginic acid is categorized as a direct food substance affirmed as GRAS and is approved for use as an
307 emulsifier, emulsifier salt, formulation aid, stabilizer, and thickener in soups and soup mixes at 21 CFR
308 184.1011 (FDA 2014).

309
310 **Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned**
311 **substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7**
312 **CFR § 205.600 (b)(4)).**

313
314 The FDA defines chemical preservative as, “any chemical that, when added to food, tends to prevent or
315 retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted
316 from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for
317 their insecticidal or herbicidal properties (FDA 2014).” The primary function of alginic acid is not as a
318 preservative but rather as an emulsifier, emulsifier salt, formulation aid, stabilizer and thickener. This
319 definition of chemical preservative is not applied to alginic acid from a regulatory standpoint.

320
321 The FDA, in listing alginic acid as a specific substance recognized as GRAS, notes that the functional uses
322 of alginic acid are as an emulsifier, emulsifier salt, formulation aid, stabilizer, and thickener (FDA 2014).
323 Emulsifiers and emulsifier salts are defined as, “substances which modify surface tension in the component
324 phase of an emulsion to establish a uniform dispersion or emulsion (FDA 1977).” Formulation aids are
325 defined as, “substances used to promote or produce a desired physical state or texture in food, including
326 carriers, binders, fillers, plasticizers, film-formers and tableting aids, etc. (FDA 1977).” Stabilizers and
327 thickeners are defined as, “substances used to produce viscous solutions or dispersions, to impart body,
328 improve consistency, or stabilize emulsions, including suspending and body agents, setting agents, jellying
329 agents, and bulking agents (FDA 1977).”

330
331 **Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate**
332 **or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)**
333 **and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600**
334 **(b)(4)).**

335
336 Alginic acid is primarily used to improve textures in soups and soup mixes as an emulsifier, formulation
337 aid, stabilizer and thickener (FDA 2014; Food Chemicals Codex 2003). The use of alginic acid for these
338 purposes is not a response to flavors, colors, textures or nutritive values lost in processing, but is used
339 instead to improve textures of soup and soup mixes as sold.

340
341 **Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or**
342 **feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).**

343
344 Studies have shown that calcium ions have a great affinity for alginic acid and, when combined, the two
345 components result in calcium alginate salts that bind calcium and can lead to reduced calcium solubility
346 and nutrient availability in the foods to which alginic acid is added (Bosscher, Micheline and Deelstra 2001;
347 Ha, et al. 1988; Burtin 2003). Further studies also have documented the potential cardioprotective nature of
348 alginic acid, with results suggesting that total and free cholesterol levels were suppressed in rats fed diets
349 containing increased levels of alginic acid (Nishide, Anzai and Uchida 1993; Ren, et al. 1994).

350
351 The GRAS listing for alginic acid at 21 CFR part 184.1011 does not include uses as a nutrient supplement or
352 nutritive sweetener as defined at 21 CFR part 170.3 (FDA 2015). Under its allowed uses as defined by the
353 FDA, alginic acid is not added to improve the nutritional quality of foods.

354
355 Alginic acid is considered a low calorie ingredient (Saltmarsh, Barlow and eds. 2013). This consideration is
356 attributed to the human body’s inability to absorb alginic acid. Since alginic acid is a hydrophilic
357 polysaccharide, it is considered a potential source of dietary fiber with high water holding capabilities
358 (Saltmarsh, Barlow and eds. 2013; Gómez-Ordóñez, Jiménez-Escrig and Rupérez 2010).

359

360 **Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of**
361 **FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600**
362 **(b)(5)).**
363

364 No reported residues of heavy metals in excess of FDA tolerances for alginic acid were identified. Alginic
365 acid meets the specifications for heavy metals tolerances as found in the Food Chemicals Codex (FDA
366 2014). Specifically, these specifications for alginic acid include threshold of tolerances of no more than
367 3mg/kg of arsenic and not more than 5mg/kg lead (Food Chemicals Codex 2003).
368

369 Many studies focus on seaweed as a low-cost biological material which may be used to capture heavy
370 metal pollutants, including cadmium, copper, zinc, lead, chromium and mercury from the environment
371 (Figueira, et al. 2000; Davis, Volesky and Vieira 2000; Volesky and Holan 1995; Davis, Volesky and Mucci
372 2003). Brown seaweeds in particular are highly effective bio accumulators of heavy metals (Vieira and
373 Volesky 2010; Fourest and Volesky 1997), which is accomplished through ion exchange (Figueira, et al.
374 2000; Davis, Volesky and Vieira 2000; Vieira and Volesky 2010). The use of brown seaweed species in
375 industrial scale heavy metals remediation can occur at industrial effluent discharge sites, where biosorbent
376 particles are packed in sorption columns (Vieira and Volesky 2010). In the case of brown seaweeds, these
377 biosorbent particles are the alginates found within algal cell walls.
378

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

382 The majority of brown seaweed species harvested for production of alginic acid are wild harvested. These
383 species of brown seaweed are mostly found in cold waters with temperatures up to 20°C, and therefore
384 their production is not subject to the negative environmental issues that may be experienced in tropical
385 production areas such as high nutrient loads and farm fishery effluents (Kraan 2012; Philips 1990).
386 However, seaweed cultivation is practiced by countries such as China and Japan where large scale
387 production of *Saccharina japonica* (basonym *Laminaria japonica*) can affect coastal waterways (Kraan 2012;
388 Philips 1990; Lane, et al. 2006). This potential effect on coastal waterways can lead to increased
389 sedimentation, but can also have a positive effect on erosion control (Philips 1990). Large scale seaweed
390 farming can lead to the depletion of nutrients in the coastal waters where the seaweed grows, which can
391 affect primary food sources such as phytoplankton and may also affect the long term viability of the
392 seaweed production operation as a whole (Philips 1990; Scoggan, Zhimeng and Feijiu 1989). In order to
393 address nutrient depletion in the coastal waters supporting commercial seaweed operations, the practice of
394 adding both inorganic and organic (manure) nutrient sources is used when nitrate levels fall below 20ug/l
395 (Philips 1990; Scoggan, Zhimeng and Feijiu 1989). The effect of this practice is unclear.

396 Concern over the introduction of non-native aquatic plant species in commercial kelp production is also
397 documented in literature (Philips 1990). The recommended best practices that address these concerns are
398 provided in the ICES Code of Practice on the Introductions and Transfers of Marine Organisms
399 (International Council for the Exploration of the Sea 2005).
400

401 **Evaluation Question #10: Describe and summarize any reported effects upon human health from use of**
402 **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**
403 **(m) (4)).**
404

405 Alginic acid is recognized as GRAS by the FDA and is approved for human consumption. The Joint
406 FAO/WHO Expert Committee on Food Additives assessed the safety of alginic acid in 1992 and assigned
407 an Acceptable Daily Intake (ADI) of 'non-specified' ¹ (FAO 1992). There is risk of intestinal obstruction

¹ An ADI of 'non-specified' is assigned to food substances with low toxicity in consideration of both available data (chemical, biochemical, toxicological and other) and of the total dietary intake of the substance when used at levels required to achieve a desired affect. A numerical value of ADI is therefore not required when food substances both meet these criteria, and are manufactured to GMP standards (Joint FAO/WHO Expeert Committee on Food Additives 2001).

408 from the ingestion of large quantities of alginic acid (US Library of Medicine 2002). In addition, there is risk
 409 posed by inhalation which can result in chemical pneumonitis (US Library of Medicine 2002).

410
 411 **Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned**
 412 **substance unnecessary (7 U.S.C. § 6518 (m) (6)).**

413
 414 Alginic acid is a food hydrocolloid used in the food industry as an emulsifier, formulation aid, thickener
 415 and stabilizer (FDA 2014; Imeson 2010). There is heavy reliance on food hydrocolloids to manufacture
 416 processed food products that will look and feel the way the public expects (Imeson 2010; Saltmarsh, Barlow
 417 and eds. 2013). Alternative practices that would make the use of alginic acid unnecessary would most
 418 likely involve the use of other food hydrocolloids. Alternatives to the use of alginic acid are addressed in
 419 question 12 and 13 below.

420
 421 **Evaluation Question #12: Describe all natural (non-synthetic) substances or products which may be**
 422 **used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed**
 423 **substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).**

424
 425 Other food hydrocolloids may be used to obtain the desired emulsifying, stabilizing and thickening effects
 426 of alginic acid. Examples of such food hydrocolloids include agar, alginates, gum Arabic, carrageenan,
 427 cassia tora, gelatin, gellan gum, guar gum, karaya, konjac, locust bean gum, pectin, starches, tara,
 428 tragacanth, and xanthan gum (Imeson 2010). Currently agar agar, carrageenan, gellan gum, and xanthan
 429 gum are listed as nonagricultural (nonorganic) substances allowed as ingredients in or on processed
 430 products labeled as “organic” or “made with organic (specified ingredients or food group(s)),” although
 431 xanthan gum is currently classified as synthetic (USDA National Organic Program 2014). Of the food
 432 hydrocolloids allowed under the USDA organic regulations, xanthan gum and gellan gum are regularly
 433 available in the quantity needed and at a stable price (Imeson 2010). The price and supply variability of
 434 locust bean gum, guar gum and gum arabic are well known (Imeson 2010).

435
 436 **Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for**
 437 **the petitioned substance (7 CFR § 205.600 (b) (1)).**

438
 439 A list of certified organic food hydrocolloids that include gum arabic, guar gum, locust bean gum and
 440 inulin is included below, along with the number of sources as of January 2014. TIC Gums is also a supplier
 441 of organic food hydrocolloids and offers certified organic gum arabic, guar gum, inulin, and locust bean
 442 gum (TIC Gums, Inc. 2014). However, TIC Gums as a source of organic food hydrocolloid is not included
 443 in the table below since they are certified as a supplier of “bases, bulk.” Gum arabic, guar gum and locust
 444 bean gum are recognized as GRAS and are permitted in many food categories according to maximum
 445 usage levels permitted (FDA 2014). Guar gum, like alginic acid, is specifically permitted for use as an
 446 emulsifier and emulsifier salt, formulation aid, stabilizer and thickener in soups and soup mixes (FDA
 447 2014). Gum arabic and locust bean gum do not share the specific limitations placed on alginic acid. Guar
 448 gum, however, is allowed as an emulsifier and emulsifier salt, formulation aid, stabilizer and thickener in
 449 “all other food categories” up to 1%, and locust bean gum is allowed as a stabilizer and thickener in “all
 450 other food categories” up to 0.5% (FDA 2014). Inulin is approved as GRAS under two GRAS notifications
 451 (FDA 2013, FDA 2003), one of which allows for “use in food in general” and “as a bulking agent (FDA
 452 2003).”

453
 454 **Table 1.** List of available organic hydrocolloids certified to processing and handling standards as of 2013
 455 (National Organic Program 2014).

Certified organic product	# of Sources
Gum Arabic	4
Guar gum	6
Inulin	31
Locust bean gum	3

456 While from a regulatory standpoint it is clear that these certified organic hydrocolloids can be used in place
457 of alginic acid, it is unknown from an industry perspective whether these materials would be used in
458 practice as an alternative to alginic acid.
459

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