Alginates
Handling/Processing

Identification of Petitioned Substance

Chemical Names:
1. Ammonium alginate
2. Calcium alginate
3. Potassium alginate
4. Propylene glycol alginate (PGA)
5. Sodium alginate

Other Names:
6. Alginate
7. Algin gum
8. CA 33
9. Calginate
10. Combinace
11. Kaltostat
12. propanediol alginate (PGA)
13. Alginate acid, ammonium salt
14. Alginate acid, calcium salt
15. Alginate acid, potassium salt
16. Alginate acid, sodium salt

Trade Names:
17. Protanal
18. Protanal Ester
19. Profoam

CAS Numbers:
20. 9005-34-9 (Ammonium alginate)
21. 9005-35-0; 9019-42-5; 9019-43-6; 9060-20-2; 37228-92-5 (Calcium alginate)
22. 9005-36-1 (Potassium alginate)
23. 9005-37-2 (PGA)
24. 9005-38-3 (Sodium alginate)

Other Codes:
25. E401 (Sodium Alginate)
26. E402 (Potassium alginate)
27. E403 (Ammonium alginate)
28. E404 (Calcium alginate)
29. E405 (PGA)
30. 130239 (HS Code: PGA)

Summary of Petitioned Use

Classified as a synthetic substance, alginates are currently listed at 7 CFR Section 205.605(b) as nonagricultural (nonorganic) substances that are allowed as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” (USDA National Organic Program 2014). This technical report covers ammonium, calcium, potassium, and sodium alginate and propylene glycol alginate (PGA). Although the 1995 Technical Advisory Panel (TAP) Report did not include PGA (Taylor and Theuer 1995), because PGA is FDA approved as a food ingredient (21 CFR §172.858), it is included in this technical report. At the time of this report, no organic products were found that contained PGA as an ingredient.

Characterization of Petitioned Substance

Composition of the Substance:

Alginates are complex carbohydrates known as polysaccharides. These carbohydrate polymers are derived from brown seaweeds of the Class Phaeophyceae (Pawar 2012, Holdt and Kraan 2011, Mabeau and Fleurence 1993). Phycocollid is another term for polysaccharides (e.g., agar, alginates and carrageenan) that are derived from seaweeds (Zemke-White and Ohno 1999). Similar to the structure forming components of cellulose in terrestrial plants, alginates give brown algae, including brown seaweed species, both mechanical strength and flexibility (Draget, Smidsrød and Skjåk-Bræk 2005). The main cell wall components of seaweed are anionic polysaccharides: alginates and fucoidans (Michel, et al. 2010). Algal polysaccharides differ from cellulose in their high sulfate group content, high solubility in water and high content of ionic groups (Alves, Sousa and Reis 2013). The algin found in brown algae is present as a mixed salt (sodium and/or potassium, calcium, magnesium) of alginic acid (McHugh 2003). Alginates are
derivatives of alginic acid. Alginate is the conjugate base of alginic acid. Through processing, the water insoluble alginic acid is extracted and various water-soluble alginates can be produced (McHugh 2003). When extracted from the cell walls of brown algae, alginate forms a gum that is used by the food industry to increase viscosity, as a food thickener and stabilizer, and as an emulsifier (McHugh 2003).

Polysaccharides are polymers consisting of chains of carbohydrates joined together by glycosidic bonds. Alginates are comprised of two uronate sugars and the salts of mannuronic and guluronic acid derived from alginic acid (Pawar 2012). During extraction of alginates from harvested seaweed, the uronic acids are converted into the salt forms mannuronate (M) and guluronate (G) through a neutralization step (Pawar 2012). Alginate is a block copolymer composed of long chains of M or G blocks. These blocks can be homogeneous (GG, MM) or heterogeneous (MG, GM) (Draget, Smidsrød and Skjåk-Bræk 2005). Figure 1 illustrates the chemical structure of alginate and demonstrates how G and M blocks connect in sequence (Draget, Smidsrød and Skjåk-Bræk 2005). The proportion, distribution and length of the block types determine the chemical and physical properties of the alginate, such as the relative stiffness or flexibility of the gels formed in the presence of metallic ions (salts) (Yang, Ying-Jian and Wen 2011).

![Figure 1](image1.png)

**Figure 1.** Structural characteristics of alginates: a) alginate monomers, b) chain conformation, c) block distribution (Draget, Smidsrød and Skjåk-Bræk 2005).

**Propylene glycol alginate:**

Propylene glycol alginate (PGA) is an ester of alginic acid (World Health Organization 1997) where some of the carboxyl groups are esterified with propylene glycol, some are neutralized with an appropriate alkali, and some remain free. Figure 2 illustrates the reaction of propylene oxide and alginic acid to form PGA (World Health Organization 1997). Used as an emulsifier, thickener and stabilizer in food applications, PGA is functional in acidic conditions (Draget, Smidsrød and Skjåk-Bræk 2005).

![Figure 2](image2.png)

**Figure 2.** Propylene glycol alginate is formed from the reaction of propylene oxide with alginic acid (World Health Organization 1997).
Source or Origin of the Substance:

Marine algae and brown seaweeds such as kelp contain large amounts of polysaccharides that are extracted by the hydrocolloid industry: alginate from brown seaweeds, and carrageenan and agar from red seaweeds (Holdt and Kraan 2011, Mabeau and Fleurence 1993). Table 1 illustrates the variety of polysaccharides present in different types of seaweed and their functional role in the plant. Seaweed species are classified based on their photosynthetic pigments and vary by polysaccharide constituents and cell wall biology (Alves, Sousa and Reis 2013). Comprising up to 40% of the dry matter of algae, alginate is the structural component in the cell walls of these marine plants (Draget, Smidsrød and Skjåk-Bræk 2005). Alginates occur naturally in seaweed mainly in the form of sodium, potassium, calcium and magnesium salts of alginic acid (Saltmarsh, Barlow and eds. 2013). “Extraction involves ion exchange in an alkaline medium followed by precipitation, purification, recovery of alginic acid and conversion to the appropriate salt” (Saltmarsh, Barlow and eds. 2013). For example, ammonium alginate is the ammonium salt of alginic acid; potassium alginate is the potassium salt of alginic acid; sodium alginate is the sodium salt of alginic acid (World Health Organization 1997).

Alginates also occur as capsular polysaccharides (exopolysaccharides) in soil bacteria, including Pseudomonas aeruginosa (Draget, Smidsrød and Skjåk-Bræk 2005, Pawar 2012). While alginates can be derived from bacteria and algae, commercially available alginates are currently only derived from algae. Alginates are extracted from multiple brown seaweed species: Ascophyllum, Macrocystis, Lessonia, Durvillea, Ecklonia, Sargassum and Laminaria (Saltmarsh, Barlow and eds. 2013, Pawar 2012). The majority of commercially produced alginates are extracted from cultivated brown seaweeds with an estimated annual production of 30,000 metric tons (Hay, Rehman and Moradali, et al. 2013).

Table 1. Polysaccharides derived from seaweeds (Mabeau and Fleurence 1993).

<table>
<thead>
<tr>
<th>Seaweed Type</th>
<th>Cell-Wall polysaccharides</th>
<th>Storage polysaccharides</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brown Seaweeds (Phaeophyceae)</td>
<td>Alginate ( guluronic acid, mannuronic acid);</td>
<td>Laminarin (glucose)</td>
</tr>
<tr>
<td></td>
<td>Fucans ( sulfated fucose)</td>
<td></td>
</tr>
<tr>
<td>Red Seaweeds (Rhodophyceae)</td>
<td>Carrageenans (galactose, sulfate);</td>
<td>Floridean starch (glucose)</td>
</tr>
<tr>
<td></td>
<td>Agar (galactose);</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cellulose;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Xylan</td>
<td></td>
</tr>
<tr>
<td>Green Seaweeds ( Chlorophyceae)</td>
<td>Cellulose;</td>
<td>Starch</td>
</tr>
<tr>
<td></td>
<td>Xylan; Mannan;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Glucuronoxylorhamnan (sulfated)</td>
<td></td>
</tr>
</tbody>
</table>

The wide industrial application of the three main phycocolloids—agar, alginites and carrageenan—is based on their particular properties to form gels in aqueous solution (Zemke-White and Ohno 1999). Phycocolloids are hydrophilic, which means water loving (Khotimchenko, et al. 2001). In water, phycocolloids swell, causing the solution to thicken and increasing its viscosity (Khotimchenko, et al. 2001). Approximately 101 species of seaweeds are used for phycocollloid production as a source of agar, alginate and carrageenan (Zemke-White and Ohno 1999). Phycocolloid content varies between species, and according to growing season and environmental conditions. Table 2 presents the seaweed species used for alginate production and the countries in which they are cultivated. Of the species in the class of brown seaweeds, Phaeophyceae, 41 species are used for extracting alginates (Zemke-White and Ohno 1999).

Table 2. Seaweed species in the class Phaeophyceae that are used for alginate production and the country where each species is predominately grown. Adapted from (Zemke-White and Ohno 1999).

<table>
<thead>
<tr>
<th>Species</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascophyllum nodosum</td>
<td>Ireland, Norway, UK</td>
</tr>
<tr>
<td>Cystoseira barbata</td>
<td>Egypt</td>
</tr>
<tr>
<td>Durvillaea potatorum</td>
<td>Australia</td>
</tr>
</tbody>
</table>
Properties of the Substance:

The physical and chemical properties of alginates render them useful in many food and industrial applications. These characteristics include: ability to retain water and water-holding capacity; gelling, viscosifying and stabilizing properties; emulsifying properties; and temperature-independent sol/gel transition in the presence of divalent cations, such as calcium (Draget, Smidsrød and Skjåk-Bræk 2005). Alginates bind easily with water and can produce high viscosity thickeners at low levels.

The chemical composition and resulting physical properties of an alginate varies according to seaweed species, structure and environmental conditions. “For example, some [species] may yield an alginate that gives a strong gel, another a weaker gel; one may readily give a cream/white alginate, another may give that only with difficulty and is best used for technical applications where colour does not matter” (McHugh 2003). Growing environments are influential as well; the ion composition of alginates is determined by the ion-exchange equilibrium with the seawater in which the algae plant grew (Pawar 2012). Another example, the amount of guluronate present in an alginate, is dependent on the seaweed sourced: the species, age at harvest, geographic location of harvest and plant part extracted (Fett and Wijey 1995).

Physical:

Alginate salts are odorless, white to yellowish-brown powders. Alginates have no discernable flavor.

Forming a viscous, colloidal solution, the salts of alginic acid formed with monovalent cations are soluble in water [sodium alginate, potassium alginate, ammonium alginate] (Kimica 2009). As a 1% solution, the resulting pH is between 5.0-7.5 (FMC BioPolymer 2006). Sodium alginate does not have a boiling or melting point. At temperatures greater than 392°F (>200°C), sodium alginate will auto ignite.

Alginates are block copolymers comprised of two uronic acids, mannuronic acid (M block) and guluronic acid (G block), of varying composition and sequence (Yang, Ying-Jian and Wen 2011). There is a correlation between the arrangement of the uronic acid blocks and the age of the plant and conditions of growth. The leaves of the same algae, L. hyperborea, have a very high content of guluronic acid when the plant grows in exposed coastal areas, compared to a lower G-content when the leaves float in placid waters (Draget, Smidsrød and Skjåk-Bræk 2005).

Chemical:

The solubility of alginates is influenced by the total ionic strength of the solution, the free calcium concentration, and pH of the solvent (van den Brink, et al. 2009). Sodium, potassium and ammonium alginates are soluble in hot and cold water (Saltmarsh, Barlow and eds. 2013, Kimica 2009). Table 3 outlines the solubility of different types of alginates in various solutions (Kimica 2009). Alginates formed with divalent cations are insoluble; calcium and magnesium alginates do not dissolve in water (McHugh 2003), but will swell when placed in water (Khotimchenko, et al. 2001). Ammonium, potassium and sodium alginates are insoluble in ethanol and ether (World Health Organization 1997). Calcium alginate is slightly soluble in ethanol and will dissolve slowly in sodium polyphosphate and sodium carbonate (World Health
Alginates selectively bind with divalent cations, especially calcium, making them insoluble in high calcium solutions such as milk or hard water with high calcium content (Table 3) (Draget, Smidsrød and Skjåk-Braek 2005). All of the alginate types listed in Table 3 are insoluble in fats, oils and organic solvents (Kimica 2009).

Alginates exhibit limited solubility at low pH. The soluble alginates will not hydrate in highly acidic systems (pH < 4.5). In more acidic conditions, alginic acid precipitates out of solution. The precipitation of alginic acid is caused by an abrupt decrease in pH below the pKa value of the alginate (Draget, Smidsrød and Skjåk-Braek 2005). Alginates with an alternating, heterogeneous structure (MG blocks) precipitate at lower pH compared with alginates containing a more homogeneous block structure (MM and GG) (Draget, Smidsrød and Skjåk-Braek 2005). Alginates are stable in alkaline conditions up to a pH of 10, beyond which depolymerization occurs (Saltmarsh, Barlow and eds. 2013).

Alginates form chemically induced gels (Truong, Walter and Giesbrecht 1995). The gel network is formed by inter-molecular association of divalent cations, such as calcium, with the polyguluronate sites of the alginate molecule (Truong, Walter and Giesbrecht 1995). The cross-linking between carboxyl groups and divalent cations is the basis for gel formation (Draget, Smidsrød and Skjåk-Braek 2005). Therefore, the sol/gel transition of alginates is not temperature dependent. Alginic gels can also be heated without melting (Draget, Smidsrød and Skjåk-Braek 2005).

Table 3. The solubility of alginates in various conditions (Kimica 2009).

<table>
<thead>
<tr>
<th>Type of Alginate</th>
<th>Acidic Conditions</th>
<th>Alkaline conditions</th>
<th>In solution with divalent cations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fruit juice, Liquor, Salad dressing, etc.</td>
<td>Kansui, etc.</td>
<td>Hard water, milk, etc.</td>
</tr>
<tr>
<td>Alginic acid</td>
<td>Insoluble</td>
<td>Soluble</td>
<td>Insoluble</td>
</tr>
<tr>
<td>Sodium alginate</td>
<td>Insoluble</td>
<td>Soluble</td>
<td>Insoluble</td>
</tr>
<tr>
<td>Potassium alginate</td>
<td>Insoluble</td>
<td>Soluble</td>
<td>Insoluble</td>
</tr>
<tr>
<td>Calcium alginate</td>
<td>Insoluble</td>
<td>Insoluble</td>
<td>Insoluble</td>
</tr>
<tr>
<td>Ammonium alginate</td>
<td>Insoluble</td>
<td>Soluble</td>
<td>Insoluble</td>
</tr>
<tr>
<td>PGA</td>
<td>Soluble</td>
<td>Soluble*</td>
<td>Soluble</td>
</tr>
</tbody>
</table>

* In neutral and alkaline conditions, PGA decomposes and forms an alginate salt.

Propylene glycol alginate:
Propylene glycol alginate is a white to yellowish brown substance that can be produced in filamentous, grainy, granular or powdered forms (FoodChem International Corporation 2014). Like alginates, PGA is soluble in water and will result in a viscous, colloidal solution (World Health Organization 1997). In a 1% solution, the pH ranges from 3.0-4.5 (FoodChem International Corporation 2014). Depending on the degree of esterification, which can be 280%, PGA is soluble in up to 60% aqueous ethanol (FoodChem International Corporation 2014). Most alginates exhibit limited solubility at low pH, but PGA is used as a food stabilizer under acidic conditions because PGA is soluble at a low pH (Draget, Smidsrød and Skjåk-Braek 2005).

Specific Uses of the Substance:
In 1881, alginic acid was first isolated and named by a Scottish scientist, Dr. E.C.C. Stanford (K. Draget 2009). Since then, alginic acid and its derivatives have been utilized as a hydrocolloid in a variety of applications such as food additives, pharmaceuticals, cosmetics and textile manufacturing (Kimica 2009).

Alginates are the most widely produced polysaccharide (Brownlee, et al. 2005). They are used in food production and handling as an emulsifier or emulsifier salt, firming agent, flavor enhancer or flavor adjutant, formulation aid, processing aid, stabilizer or thickener, surface-active agent and texturizer (Truong, Walter and Giesbrecht 1995). Alginates are used in food applications at levels ranging from 0.5-1.5% (Brownlee, et al. 2005). “Given the large number of different applications, alginates must be regarded as one of the most versatile polysaccharides” (Draget, Smidsrød and Skjåk-Braek 2005). Table 4 outlines the major uses of alginates in food products as a percentage of total production.
Alginates are used to extend product shelf life and reduce risk of pathogen growth on food surfaces (Rößle, et al. 2011). Alginates are used as carriers of active or functional food ingredients (e.g., anti-browning agents, colorants, flavors, nutrients, spices, antimicrobial compounds) (Rößle, et al. 2011). As components of edible coatings or films, alginates act as a protective barrier to retard food spoilage and extend the effectiveness of an active ingredient (Datta, et al. 2008). Alginates are used in solid foods “to prevent water loss, syneresis1 and phase separation” (Saltmarsh, Barlow and eds. 2013). As selective barriers to moisture, oxygen, lipid oxidation and loss of volatile aromas and flavors, edible films increase the functionality of fresh-cut, pre-packaged fruits (Rößle, et al. 2011). Fresh apple wedges coated with alginate resulted in better retention of polyphenolic compounds than the uncoated wedges (Rößle, et al. 2011). Starch-alginate (SA) coatings are used to inhibit lipid oxidation and the formation of a “warmed-over flavor” in pre-cooked meats (Wu, et al. 2001). The barrier properties of SA-films improved with the addition of stearic acid. Starch-alginate-stearic acid (SAS) coatings were more effective in prohibiting moisture loss than lipid oxidation (Wu, et al. 2001).

Calcium alginate gels combined with antimicrobial agents have been used to preserve a wide variety of food products. When compared to the application of the antimicrobial agents alone, the use of the edible coating, calcium alginate gel, retained the effectiveness of two antimicrobial agents, nisin and oyster lysozyme, against Listeria monocytogenes and Salmonella anatum by 35 days (Datta, et al. 2008). Lactic acids added to calcium alginate gels reduced L. monocytogenes populations on lean beef tissue more than the acid treatment alone (Siragusa and Dickson 1992). The ability of alginates to instantly form gels, skins and fibers renders them useful for restructured foods (onion rings, pet-food chunks). Sodium alginate is commonly used as a stabilizer of ice cream to control the formation of ice crystals and improve flavor (Saltmarsh, Barlow and eds. 2013). Sodium alginate impedes the movement of water during melt/freeze cycles, thereby preventing the formation of ice crystals and fat clump growth in frozen products (Saltmarsh, Barlow and eds. 2013). Alginates are also used in many dairy products to prevent the attachment of food and packaging materials to foods such as refined cheese and cream cheese.

Sodium, potassium and ammonium alginates are soluble in cold water; these salts can be used interchangeably in food products for thickening, gelling, stabilizing, formation of films and controlled release applications (Saltmarsh, Barlow and eds. 2013). Their ability to make gels without the use of heat distinguishes alginates from other hydrocolloids that require high-temperature processes (i.e., gelatin, agar, carrageenan, locust bean gum). Alginates are useful when using heat sensitive ingredients (flavors, instant mixes).

Some examples of typical products that utilize alginates include sauces, salad dressings, desserts, fruit preparations, ice cream and water ices, onion rings, low-fat spreads, bakery filling creams, fruit pies, flavor capsules, icing and frostings (Saltmarsh, Barlow and eds. 2013). Alginates can be heated without melting, and therefore can be used in baking creams (Draget, Smidsrød and Skjåk-Bræk 2005). When used in combination, alginate-pectin gels exhibit a higher gel strength than either component alone, and alginate-pectin gels are heat reversible (Brownlee, et al. 2005). Ammonium alginate is used for can sealing due to its very low ash content (K. Draget 2009).

**Propylene glycol alginate:**

Propylene glycol alginate is used as a thickener, suspending agent and stabilizer; however unlike alginates, PGA does not form gels, insoluble films or fibers (Saltmarsh, Barlow and eds. 2013). Propylene glycol alginate is water-soluble and forms viscous solutions in hot and cold water. The chemical properties of PGA extend the applicability of alginates to lower-pH foods; PGA remains stable at pH down to 3. Propylene glycol alginate is more compatible with acidic foods and foods with high calcium content (Saltmarsh, Barlow and eds. 2013). Due to its stability at low pH levels, PGA is used in more applications than alginates; yet, the amount used is considerably less (Brownlee, et al. 2005). “Because of the relatively limited solubility of alginates at low pH, the esterified propylene glycol alginate is applied as a food stabilizer under acidic conditions” (Draget, Smidsrød and Skjåk-Bræk 2005). Its compatibility is due to the

---

1 The contraction of a gel accompanied by the exudation of liquid. The collection of whey on the surface of yogurt is an example of syneresis.
esterification of the reactive carboxylic acid groups, making PGA more acid stable and less sensitive to
calcium (Saltmarsh, Barlow and eds. 2013). However, PGA cannot dissolve in milk below the boiling point.
Grades of PGA with a high degree of esterification can interact with proteins and are used to stabilize beer
foam, meringues and noodles. Given its stability at low pH, PGA is frequently used in salad dressings to
stabilize oil-vinegar emulsion, in fruit drinks to prevent separation of pulp, and to flavor oils and fermented
milk drinks (Saltmarsh, Barlow and eds. 2013). Due to its unique suspension and foaming applications,
PGA is used in beer and soft drink production (Brownlee, et al. 2005).

Alginates are also used in culinary applications in the process of spherification. Alginate spheres consist of
a very thin, outer gel membrane with a liquid core (Lee and Rogers. 2012). Alginates are most commonly
used with calcium chloride to make spheres in the formation of faux caviar, egg dishes, gnocchi and ravioli.
Sodium alginate is added to a liquid, which is dropped into an aqueous solution of calcium chloride (Lee
and Rogers. 2012). The alginate at the surface of the droplet becomes a gel and forms a thin film around the
liquid inside (Cassi 2011). Calcium gluconoate and calcium lactate are also used as the source of calcium in
spherification (Lee and Rogers. 2012). The rate of gelation is greatest for calcium chloride (100 s) and
slowest for calcium gluconate (3000 s). Calcium chloride can lend a bitter taste to food, although it can be
masked by other flavors (Lee and Rogers. 2012).

The use of alginates is not limited to foods. Industrial applications use alginates to improve the
performance of products such as paper coating, textiles, adhesives, air freshener gels and ceramics (K.
Draget 2009). Alginates are also utilized in a variety of ways in the medical field. Examples include wound
dressings, surgical implants, pharmaceutical preparations, and as a source of dietary fiber (Brownlee, et al.
2005). Sodium alginate is used as a synthetic inert ingredient in crop pesticide products (OMRI 2014).
Propylene glycol alginate is used as an inert defoaming agent in pesticides and is allowed for application to
growing crops (pre-harvest) or to raw agricultural commodities after harvest; residues of PGA are exempt
from the tolerance limit when used in accordance with good agricultural practices (40 CFR 180.910).

Table 4. Common Uses of Alginates in Food Products (Brownlee, et al. 2005).

<table>
<thead>
<tr>
<th>Application of Alginate</th>
<th>% of total alginate food applications</th>
<th>Notes on application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premium beer foam stabilizer (PGA)</td>
<td>21.2</td>
<td>PGA provides better head retention &amp; prevents contamination</td>
</tr>
<tr>
<td>Restructured Foods</td>
<td>19.6</td>
<td>Renders food material product thermostability and desired consistency (e.g., onion rings, pimento pieces)</td>
</tr>
<tr>
<td>Additional uses of PGA</td>
<td>18.9</td>
<td>Due to acid stability and resistance to loss of viscosity, PGA is used in: soft drinks; dressings/condiments; milk drinks; sorbet; ice cream; noodles/pasta</td>
</tr>
<tr>
<td>Bakery Products</td>
<td>14.9</td>
<td>Bread and cake mixes: improves shelf life Bakery creams: provides freeze/thaw stability &amp; reduced syneresis Instant flan: provides cold solubility</td>
</tr>
<tr>
<td>Fruit Preserves</td>
<td>6.5</td>
<td>Jams, marmalades, fruit sauces: gelling, thickening, stabilizing agent Alginate-pectin gels</td>
</tr>
<tr>
<td>Ice Cream</td>
<td>3.8</td>
<td>Prevents crystallization and shrinkage Produces viscosity of ice cream Provides heat shock resistance Provides homogeneous melting without whey separation</td>
</tr>
<tr>
<td>Other</td>
<td>15.1</td>
<td>Desserts (mousses, instant puddings, ripple syrups) Emulsions and sauces (condiments, low fat dressings &amp; spreads) Extruded foods (noodles and pasta)</td>
</tr>
</tbody>
</table>
Approved Legal Uses of the Substance:

Alginates are classified as Generally Recognized as Safe (GRAS) in food according to good manufacturing processes. The FDA has outlined the specific uses and levels of concentration that are allowed for the different types of alginates (ammonium, calcium, potassium and sodium) in food products (21 CFR Regulations 184.1133, 184.1610, 184.1724, 184.1187). These uses are further described and addressed in Evaluation Question #4 and Table 5. In addition, sodium and propylene glycol alginate are permitted as ingredients per 21 CFR 133.178 and 133.179 in standardized pasteurized neufchatel and processed cheese spreads. PGA is also allowed as a coating for fresh citrus fruit per 21 CFR 172.210, as a defoaming agent in processed foods per 21 CFR 173.240, and as an indirect food additive (components of paper and paperboard) per 21 CFR 176.170.

Action of the Substance:

Alginates form chemically induced gels independent of temperature (Truong, Walter and Giesbrecht 1995, McHugh 2003). Once formed, the gels are thermostable and will not melt (Saltmarsh, Barlow and eds. 2013). The degree of thickening or gelling of alginates is determined by two factors:

1. the presence of monovalent or divalent cations in solution (Fernández-Martín, et al. 2009); and
2. the amount of guluronic present in the alginate, which is dependent on the algal species, age at harvest, geographic location of harvest and plant part extracted (Fett and Wijey 1995)

In the presence of monovalent cations, such as potassium and sodium, alginates do not form gels and can be used as thickening agents in foods. In the presence of divalent cations, such as calcium or magnesium, alginates form gels (Fernández-Martín, et al. 2009, Pawar 2012). The order of alginate affinity towards divalent ions is as follows: Pb > Cu > Cd > Ba > Sr > Ca > Co, Ni, Zn > Mn (Datta, et al. 2008). Calcium is the most commonly used cation for inducing alginate gel formation (Datta, et al. 2008). The cation acts as a crosslinker or bridge between the functional groups of the alginate chains (Yang, Ying-Jian and Wen 2011). “Alginate displays particular affinity for calcium, strontium and barium ions which induce a conformational transformation of the polyuronide chains into ‘eggboxes’ in which the cations are strongly chelated. Aggregation of alginate chains leads to the formation of gels” (Jimenez-Escrig and Sanchez-Muniz, F.J. 2000). Figure 3 illustrates the eggbox model of alginate gelling and the formation of divalent ion salt bridges (Lee and Rogers. 2012). Hydrogen bonds form between the oxygen (O) atoms and the metallic, divalent ion, and ionic bonds form between the carboxyl groups and the same metallic ion (Khotimchenko, et al. 2001).

The structure of alginates determines the stiffness and strength of the gel formed in the presence of divalent cations. The gelling effect of alginates increases as the ratio of guluronic to mannuronic units grows larger (Fernández-Martín, et al. 2009). Alginates with high concentrations of guluronic acid (G) are used for gelling; alginates with high levels of mannuronic acid (M) are used for thickening and stabilizing (Saltmarsh, Barlow and eds. 2013). Alginate gel is not formed if the guluronic acid content is less than 20-25% (Khotimchenko, et al. 2001). The molecular structure of alginates is arranged in varying proportions of these M and G acid units, as GG, MG and MM blocks (Draget, Smidsred and Skjåk-Bræk 2005). Alginate contains all four possible glycosidic linkages: diequatorial (MM), diaxial (GG), equatorial-axial (MG) and axial-equatorial (GM) (Yang, Ying-Jian and Wen 2011). Stiffness of the chain blocks increases in the order: MG < MM < GG. Mannuronic acid forms beta (1 → 4) linkages that result in a more flexible, linear conformation. Guluronic acid forms alpha (1 → 4) linkages that produce a steric hindrance around the carboxyl groups yielding a folded, rigid conformation (Yang, Ying-Jian and Wen 2011). The formation and resulting properties of the gel are determined by the interactions between G-blocks (Pawar 2012). In the presence of divalent cations, G-blocks bind with calcium more efficiently to form tightly held junctions that result in a stiff gel (Hay, Rehman and Ghafoor, et al. 2010). MG blocks also interact with divalent cations; however, these are weak junctions that form less stiff gels.
Figure 3. Chemical structure of monomeric units in alginate (G and M blocks) and representation of the “eggbox” model of alginate gelling: a) and b) illustrate the binding zones between alginate molecules; c) zooms into single binding zone showing two types of bonds: 1) hydrogen bond between OH groups and divalent ion (M$^{2+}$) (dotted line); and 2) ionic bond between carboxyl group and M$^{2+}$ (dashed line) (Khotimchenko, et al. 2001, Lee and Rogers. 2012).

Combinations of the Substance:

Additional ingredients are not commonly added to commercially available forms of alginates. Publically available specification sheets and ingredient lists did not report any ancillary substances (e.g., stabilizers, preservatives or anti-caking agents). Sodium alginate and PGA are commercially prepared as 100% freeze-dried material (FMC BioPolymer 2012).
The following substances are commonly used in combination with alginates. A divalent cation source is required to induce alginate gelling; calcium is most commonly used to produce stiff gels (Saltmarsh, Barlow and eds. 2013). Readily soluble in water, calcium acetate provides a soluble source of calcium for reaction with alginates. Calcium citrate effectively forms acid-based gels with alginates. The solubility of calcium citrate increases at lower pH values and decreases with increasing temperature. It effectively forms acid-based gels with alginates. Dicalcium phosphate and calcium chloride serve as a calcium sources to form gels with alginates (E400-403). Calcium chloride provides a source of calcium ions in solution and is commonly used to cross-link alginate gels. It is also used in the extraction of alginates from seaweed. In the production of ice cream, alginates are used in combination with other stabilizers to produce additional effects (Saltmarsh, Barlow and eds. 2013). To increase thickening and slow melting, alginates are combined with guar/locust bean gum (Brownlee, et al. 2005).

Composite polysaccharide films are increasingly used in the food industry to increase the shelf-life and reduce flavor loss in fresh fruit (Rößle, et al. 2011) and in precooked meats (Wu, et al. 2001). Sodium alginate coatings have been shown to inhibit lipid oxidation and the formation of a “warmed-over flavor.” In these applications, starch and alginate are combined at a 2.5:1 ratio and stirred into a water, ethanol and glycerin solution. The effectiveness of SA-films is increased with the addition of stearic acid. To create the starch-alginate-stearic acid (SAS) film, 20% stearic acid and 30% lecithin are added to the SA-film solution. Additionally, tocopherols can be added to produce tocopherol-coated SA and tocopherol-coated SAS films (Wu, et al. 2001).

Alginates are used to improve the texture of processed food. Tetrasodium pyrophosphate and calcium sulfate are used in combination with sodium alginate in texturized sweet potato puree (Truong, Walter and Giesbrecht 1995). Alginates are also used in dietary supplements. Fiber supplement formulations use alginates in combination with other fiber sources, psyllium seed and husk, flaxseed, guar gum and maltodextrin-soluble fiber, and cleansing agents bentonite, black walnut leaf, lactobacillus and beet root (Lifeplus 2014). The heavy metal binding property of alginates is utilized in dietary supplements; alginates are combined with milk thistle, silicon dioxide and rice flour in a hyпромелlose vegetable capsule (Rockwell Nutrition 2014).

### Historic Use:

The NOSB voted in April 1995 to allow alginates as synthetic materials for use in organic food processing (NOSB 1995), and they were included in the National Organic Program Rule published in December 2000. However, the 1995 Technical Advisory Panel (TAP) report did not include propylene glycol alginate (Taylor and Theuer 1995); PGA is included in this technical report, however, because PGA is FDA approved as a food ingredient per 21 CFR §172.858. Following the review of alginates in the 1995 TAP Report, the NOSB recommended the continued listing of alginates at § 205.605(b) (Agricultural Marketing Service 2010).

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

Alginates are currently listed as allowed synthetics at section 205.605(b) in the USDA organic regulations (USDA National Organic Program 2014). Alginates do not appear in the Organic Foods Production Act.

### International:

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

Certain alginates are permitted under the Canada Organic Regime due to their appearance in the section titled “Non-organic Ingredients Classified as Food Additives, of the Organic Production Systems Permitted...” (Saltmarsh, Barlow and eds. 2013). To increase thickening and slow melting, alginates are combined with guar/locust bean gum (Brownlee, et al. 2005).

**February 5, 2015**
Substances List.” In this section, alginates (alginic acid, sodium alginate and potassium alginate) are included in Table 6.3 (Canadian General Standards Board 2011).


Certain alginates are permitted. Only potassium (402) and sodium (401) alginates are listed as allowed food additives in Table 3.1 as an ingredient of nonagricultural origin in the CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (Codex Alimentarius Commission 2014).


Alginates (E401-E405) are permitted because they are included in the list of allowed food additives for use as thickeners and stabilizers (E400-E499). Alginates are classified as nonagricultural in the EU Organic Regulations (The Council of the European Union 2008). Sodium alginate (E 401) is listed as an approved food additive for use in certain unprocessed fruit and vegetables in an amendment to Annex II of the Commission Regulation (EC) No 969/2014 (The Council of the European Union 2014).

Japan Agricultural Standard (JAS) for Organic Production

Certain alginates are permitted. The JAS for Organic Processed Foods identifies sodium alginate as an allowed food additive limited to use only in processed foods of plant origin, INS number 401 (The Japanese Organic Standard 2005).

International Federation of Organic Agriculture Movements (IFOAM)

Certain alginates are permitted. Sodium and potassium alginate are recognized by IFOAM as approved additives for use in an organic processed products without annotation (IFOAM 2014) (Appendix 4: Table 1).

Evaluation Questions for Substances to be used in Organic Handling

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

Alginates are produced from algin and are usually extracted from the cell walls of brown algae. Commercial alginates are isolated mainly from the following algal species: Laminaria hyperborea, L. digitata, L. japonica, Ascophyllum nodosum, Macrocystis pyrifera, Eclonia maxima, Lessonia nigrescens, Durvillaea antarctica, and Sargassum spp (Draget, Smidsrød and Skjåk-Bræk 2005, Hay, Rehman and Ghafoor, et al. 2010). Alginic acid in brown seaweeds is mainly present as calcium, magnesium and sodium salts. The first step in the manufacture of alginate is to convert the insoluble calcium and magnesium alginate into soluble sodium alginate by ion exchange under alkaline conditions (World Health Organization 1997). Extraction involves ion exchange in an alkaline medium followed by precipitation, purification and conversion to the appropriate salt (Saltmarsh, Barlow and eds. 2013). “Commercial manufacturing of alginate almost always involves a purification step where an acid treatment precipitates the alginate as alginic acid” (Drageta, Skjak-Bræk and Stokke 2006). The extraction process renders alginates synthetic.

Extraction of alginates

The extraction of alginates follows the same manufacturing process as alginic acid (Pawar 2012). Alginic acid is obtained from brown seaweeds, which naturally contain calcium alginate. The seaweeds are mixed in water with sulfuric acid (OMRI 2014). This leaching converts the alginate in the seaweed into insoluble alginic acid. The insoluble alginic acid is solubilized by neutralization with an alkali, such as sodium carbonate (Na2CO3) or sodium hydroxide (NaOH). The demineralized seaweed is ground in the presence of sodium alkali. This converts the alginic acid into soluble sodium alginate. The insoluble components are removed; separation processes to remove particulate matter include sifting, flotation, centrifugation, flocculation, filtration or a combination of these (Hernandez-Carmona, McHugh and Lopez-Gutierrez 1999, February 5, 2015
Pawar 2012). The alginic acid is precipitated out of solution by adding sulfuric acid to the alginic solution. The precipitated alginic acid is then rinsed and dried (OMRI 2014). Sodium alginate is precipitated with an alcohol, sodium chloride (NaCl) or calcium chloride or a mineral acid (Pawar 2012). The dried product is milled and packaged (Pawar 2012, OMRI 2014). A filtration step is necessary for food grade alginates. Filtration aids include diatomaceous earth and perlite (Hernandez-Carmona, McHugh and Lopez-Gutierrez 1999). Alginates can be processed further by esterification to produce the propylene glycol ester, PGA (Saltmarsh, Barlow and eds. 2013). Alginates can also be recovered from brown seaweed via acid hydrolysis (Pawar 2012). The macerated seaweed is dissolved in sulfuric acid and heated to 110°C for four hours. The product is cooled and diluted with water (Pawar 2012).

The following technique is commonly used in the industry to isolate alginates from brown seaweed (Rahelivao, et al. 2013). Algae is ground and suspended in distilled water. Hydrochloric acid (HCl) is added to achieve a pH of 3. The mixture is stirred for 24 hours. The supernatant is eliminated by centrifugation. The seaweed residue is suspended in distilled water. Sodium carbonate and ethylenediaminetetraacetic acid (EDTA) are added to change the pH to 11. The alginate solution is kept at 80°C and stirred for 2 hours before filtering. The solution is acidified with HCl to pH of 3. The precipitate formed is collected by centrifugation and suspended in distilled water. Sodium hydroxide is added to adjust pH to 10. Sodium alginate is precipitated in presence of NaCl. The precipitate is washed with ethanol (Rahelivao, et al. 2013).

Achieving high yields of alginates from the raw algal material is important in industrial production. Alginate yield is lower in the absence of EDTA (10-13%) and higher in the presence of EDTA (~30%) (Rahelivao, et al. 2013). Higher temperatures and longer extraction times increase yield but decrease the viscosity of the product (Hernandez-Carmona, McHugh and Lopez-Gutierrez 1999). The type of alkali used, concentration in solution and duration of extraction have been manipulated in early patents and subsequent research to evaluate the most efficient extraction methods, which include but are not limited to the following: a) 4% Na₂CO₃ solution, 2 hours at 40°C; b) 5-7% Na₂CO₃ solution, 12 hours; c) Solution of algae to NaOH at a ratio of 1:50, with a pH below 7; d) 1.5% Na₂CO₃ at 50-60°C for 1.5 hours (Hernandez-Carmona, McHugh and Lopez-Gutierrez 1999).

**Biosynthesis**

Bacteria are capable of producing alginate as an exopolysaccharide, which can serve multiple functions (Hay, Rehman and Ghafoor, et al. 2010). *Pseudomonas* secretes a high volume of alginate to aid in formation of thick biofilms. In *Azotobacter*, alginates participate in the formation of desiccation resistant cysts. Pindar and Bucke proposed the first bacterial alginate biosynthesis pathway in 1975 in the species *Azotobacter vinelandii*. Biosynthesis “can be broken down into four stages: (i) precursor synthesis; (ii) polymerization and cytoplasmic membrane transfer; (iii) periplasmic transfer and modification; and (iv) export through the outer membrane” (Hay, Rehman and Ghafoor, et al. 2010).

The end product of bacterial fermentation is more consistent and can be customized (Draget, Smidsrød and Skjåk-Braek 2005). Alginates produced by bacteria are of high quality and are primarily used in medical applications. “Alginates with a very high content of guluronic acid can be prepared from old algal tissue of *L. hyperborea* by chemical fractionation or by enzymatic modification *in vitro* using mannuronan C-5 epimerases from *A. vinelandii*” (Draget, Smidsrød and Skjåk-Braek 2005). Alginates produced by *A. vinelandii* have higher concentrations of G-blocks that form stiffer gels. The isolation of alginates from bacteria results in alginates of more predictable, consistent composition, such as 100% mannuronate or guluronate versus a mixture of M and G blocks (Draget, Smidsrød and Skjåk-Braek 2005). Pharmaceutical grade alginates have defined molecular weights and M/G ratios. Figure 4 illustrates the steps of bacterial alginate biosynthesis; ultimately, the bacteria excrete the ‘mature alginate’ (Hay, Rehman and Moradali, et al. 2013).

At present, production by fermentation is possible, but not economically feasible (Draget, Smidsrød and Skjåk-Braek 2005). It is significantly more expensive to produce alginates through bacterial biosynthesis pathway compared with alkali extraction from brown seaweed, at $100 \text{ g}^{-1}$ compared to $5 \text{ kg}^{-1}$, respectively (Hay, Rehman and Moradali, et al. 2013).
Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (2)). Discuss whether the petitioned substance is derived from an agricultural source.

Commercial manufacture of alginates utilizes the chemical process of alkali extraction of brown seaweed. The naturally occurring cell-wall polysaccharide present in brown seaweed is chemically altered during extraction and reacted with the appropriate salt to produce a synthetic alginate product. Produced by esterification of alginic acid, PGA is also a product of a chemical process.

While synthetic extraction is the most common commercial production, there is increasing attention and research into the biosynthesis of alginates via bacteria that produce alginate as an exopolysaccharide (Hay, Rehman and Moradali, et al. 2013). This method may be considered a ‘naturally occurring biological process’ as no further extraction or isolation is required of the alginate excreted by bacteria (Hay, Rehman and Moradali, et al. 2013).

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

There are no nonsynthetic forms of alginates. The polysaccharides that compose alginates are extracted from a nonsynthetic, natural source, brown algae; these algal polysaccharides are not found in any terrestrial plants (Holdt and Kraan 2011). The chemical process of alkali extraction renders alginates synthetic. Alginates are derived from alginic acid. Esterification of alginic acid produces PGA, which is also synthetic. Alginic acid does not exhibit the same chemical properties as alginate. For example, alginic acid is hydrophobic and is not soluble in water. Nor does alginic acid have as many food applications as alginates.

Alternatives to alginates include other nonsynthetic gelling and thickening agents derived from seaweed such as carrageenan and agar. However, these nonsynthetic gelling agents require high-temperature
processes for activation whereas alginates do not. See Evaluation Questions 12-13 below for more information on alternative substances to alginates.

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

Toxicological studies have shown that alginates are safe for use in food (McNeely and Kovacs 1975, Khotimchenko, et al. 2001, FDA 2014). Ammonium, calcium, potassium and sodium alginates are considered GRAS when used in accordance with good manufacturing practice as described in 21 CFR Regulation 184.1133, 184.1187, 184.1610, 184.1724 and 172.858 and as presented in Table 5. Propylene alginate glycol is approved for use by the FDA as a direct food additive (21 CFR 172.858 and 172.210). Ammonium, calcium and sodium alginates are listed at CFR 184, Subpart B, titled “Listing of Specific Substances Affirmed as GRAS” with maximum concentrations specified by food use category. Table 5 outlines the function and maximum allowance of alginates in specific food categories.

Produced by Inovo Biologic, Inc., the substance Polysaccharide Complex KAX is considered GRAS under the GRN 407 (FDA, GRAS Notices 2012). It is a polysaccharide complex of konjac glucomannan (konjac), sodium alginate and xanthan gum. It is allowed for use “at levels up to seven percent as an ingredient to provide dietary fiber or to provide thickening or a stabilizing effect in yogurts, milk shakes and fruit smoothie-type drinks, frozen yogurt, ice cream bars, puddings, white and whole wheat breads, cookies, breakfast bars, granola-type bars, noodles, whole wheat cereals, meatless lasagna and macaroni/cheese, fruit juices, fruit juice bars, cereal beverages, and medical foods.” The FDA had no questions regarding the substance (FDA, GRAS Notices 2012).

**Table 5.** Function and maximum allowable level of five different types of alginates in food. Each type of alginate can be used in food only within the following specific limitations. Blanks indicate that the alginate has not been approved for use in the specified food category by the FDA.

<table>
<thead>
<tr>
<th>Food Use Category</th>
<th>Ammonium alginate</th>
<th>Calcium alginate</th>
<th>Potassium alginate</th>
<th>Sodium alginate</th>
<th>Propylene glycol alginate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcoholic Beverages (170.3(n)(2))</td>
<td>0.4% a</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baked Goods (170.3(n)(1))</td>
<td>0.002% a</td>
<td></td>
<td></td>
<td>0.5% a,e,g</td>
<td></td>
</tr>
<tr>
<td>Cheeses (170.3(n)(5))</td>
<td></td>
<td>0.9% a,e,g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Condiments and relishes (170.3(n)(8))</td>
<td></td>
<td>1.0% a,b, except **</td>
<td></td>
<td></td>
<td>0.6% a,g</td>
</tr>
<tr>
<td>Confections and frostings (170.3(n)(9))</td>
<td>0.4% a</td>
<td>0.4% a</td>
<td>0.1% a</td>
<td>0.3% a</td>
<td>0.5% a</td>
</tr>
<tr>
<td>Egg Products (170.3(n)(11))</td>
<td>0.6% a</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fats and oils (170.3(n)(12))</td>
<td>0.5% a</td>
<td>0.5% a</td>
<td></td>
<td></td>
<td>1.1% a,g</td>
</tr>
<tr>
<td>Frozen dairy desserts (170.3(n)(26))</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.5% a</td>
</tr>
<tr>
<td>Gelatins and puddings (170.3(n)(22))</td>
<td>0.25% a</td>
<td>0.7% a</td>
<td>4.0% a,e,f</td>
<td>0.6% a,g</td>
<td></td>
</tr>
<tr>
<td>Gravies and sauces (170.3(n)(24))</td>
<td>0.4% a</td>
<td>0.4% a</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hard Candy (170.3(n)(25))</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10.0% a</td>
</tr>
<tr>
<td>Jams and jellies (170.3(n)(28))</td>
<td>0.4% a</td>
<td>0.5% a</td>
<td></td>
<td></td>
<td>0.4% a</td>
</tr>
<tr>
<td>Pimento Ribbon for Stuffed Olives</td>
<td></td>
<td><strong>6.0% a,b</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Processed Fruits and fruit juices (170.3(n)(35))</td>
<td></td>
<td></td>
<td>0.25% a</td>
<td>2.0% b,c</td>
<td></td>
</tr>
<tr>
<td>Seasonings and flavors (170.3(n)(26))</td>
<td>0.5% a</td>
<td>0.5% a</td>
<td></td>
<td></td>
<td>1.7% e</td>
</tr>
<tr>
<td>Sweet sauces (170.3(n)(43))</td>
<td>0.1% a,d</td>
<td>0.3% a</td>
<td>0.01% a</td>
<td>1.0% a,e,f,g,h,i</td>
<td>0.3% a,e,i</td>
</tr>
<tr>
<td>All other food categories</td>
<td>0.1% a,d</td>
<td>0.3% a</td>
<td>0.01% a</td>
<td>1.0% a,e,f,g,h,i</td>
<td>0.3% a,e,i</td>
</tr>
<tr>
<td><strong>21 CFR Regulation</strong></td>
<td><strong>184.1133</strong></td>
<td><strong>184.1187</strong></td>
<td><strong>184.1610</strong></td>
<td><strong>184.1724</strong></td>
<td><strong>172.858</strong></td>
</tr>
</tbody>
</table>
A chemical food preservative is defined under FDA regulations at 21 CFR 101.22(a) (5) as “any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties” (FDA, Title 21: Food and Drugs 2013). The primary function of alginates is not as a preserving agent. Rather, alginates are used in foods as gelling agents, thickeners, emulsifiers and flavor enhancers, which can have a secondary effect of stabilizing the food product over time.

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

The available literature did not present a mechanism of alginates as substances used as preservatives. Rather, alginates are primarily used to produce or enhance the texture during processing of restructured foods, to stabilize or thicken food products, and as a flavor adjuvant or enhancer (Datta, et al. 2008). Alginate is a source of dietary fiber (Brownlee, et al. 2005) but there is no indication in the literature that alginates are added to processed foods in order to restore fiber lost in processing. As a component of edible coatings on fresh-cut fruits, alginates are used to maintain color and texture and extend the shelf life of the product by preventing moisture loss, oxidation and loss of aromas and flavors (Rößle, et al. 2011). The use of alginates in these applications is not intended to restore flavor.

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

The human body does not absorb alginates, making them a low-calorie ingredient that does not provide metabolic energy (Draget, Smidsrød and Skjåk-Bræk 2005, Saltmarsh, Barlow and eds. 2013). Multiple sources indicate the use of alginates in diet foods as sources of insoluble fiber (Brownlee, et al. 2005, Burtin 2003, Jimenez-Esrig and Sanchez-Muniz, F.J. 2000, MacArtain, et al. 2007) or as a means of appetite control (Paxman, et al. 2008). The indigestible fibers of alginates “can increase feelings of satiety and aid digestive transit through their bulking capacity” (MacArtain, et al. 2007). Alginates are frequently used in fiber supplements as a polysaccharide bulking agent (Anderson, et al. 1991, Mabeau and Fleurence 1993, Brownlee, et al. 2005). Seaweeds can provide up to 12.5% of the daily fiber needs in an 8 g serving (MacArtain, et al. 2007). Fiber supplement products use alginates in combination with other fiber sources: psyllium seed and husk, flaxseed, guar gum and maltodextrin-soluble fiber, and cleansing agents such as bentonite, black walnut leaf, lactobacillus and beet root (Lifeplus 2014). The binding nature of alginates affects the bioabsorption of heavy metals in the human system and has been linked to reduced mineral availability, namely iron (Bosscher, Caillie-Bertrand and Deelstra 2001, MacArtain, et al. 2007). Alginates
are used in dietary supplements, accompanied by marketing claims that they are “beneficial for those individuals exposed to environmental pollutants or toxins” (Rockwell Nutrition 2014).

Seaweeds have high mineral content (calcium, magnesium, phosphorus, potassium, sodium and iron); however, “the linkage of certain minerals with anionic polysaccharides (alginites, agar or carrageenan) might limit the absorption of these minerals” (Mabeau and Fleurence 1993). The type of linkage between the polysaccharide and the mineral determine the availability of the mineral. “The strong affinity of divalent cations (particularly calcium) for carboxylic polysaccharides limits the availability of associated minerals” (Mabeau and Fleurence 1993). Experiments in growing rats have shown substantial reductions in iron absorption with sodium alginate (Bosscher, Caillie-Bertrand and Deelstra 2001).

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

No reports of levels of heavy metals in alginates, including PGA, were found. Alginates do not exhibit heavy metal levels in excess of FDA tolerances (FDA 2014). Product specification sheets report minimal concentrations of heavy metals: <3ppm arsenic, <10ppm lead, ≤1 ppm mercury, <1.5ppm (FMC BioPolymer 2012) and <40ppm total heavy metals (FMC BioPolymer 2005). However, studies on bioremediation with seaweed and seaweed derivatives report their ability to absorb heavy metals (Aderhold, Williams and Edyvean 1996, Khotimchenko, et al. 2001). Alginates have a high binding capacity for heavy metals and can sequester metal ions such as arsenic, lead, zinc and copper. In the presence of high concentrations of nickel, copper, zinc, lead and cadmium, alginates caused a reduction in residual concentrations of all ions except zinc (Aderhold, Williams and Edyvean 1996).

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

Annually, more than 3.5 million tons of seaweeds are harvested for food consumption (60%) and phycocolloid production (40%) (LaHaye 2001); in general, the rate of seaweed harvest has continued to increase in the 21st century (Bixler and Porse 2011). However, the balance of seaweed supply and demand is increasingly more fragile due to rising seawater temperatures, erratic weather patterns and pollution (Bixler and Porse 2011). Many of the brown seaweed species used to extract alginates are wild harvested (McHugh 2003). Table 6 illustrates shifts in the last decade that have occurred in harvest location, species of seaweed harvested, chemical composition and total seaweed harvest for alginate production in dry tons (Bixler and Porse 2011). Higher quality species of brown seaweed are found in cold waters (20°C) (Kraan 2012). As the water temperature increases, the concentration of terpenes and other chemical compounds in the seaweed increases; these compounds are not desirable for alginites used in food production (Kraan 2012). Since the quality and quantity of alginites depend on the algae species, the type and age of tissues extracted and location of harvest, the structure and properties of alginites harvested from specific locations has been documented: Madagascar seacoast algae (Rahelivao, et al. 2013), brown seaweed species in Quebec’s Saint-Lawrence River (Rioux, Turgeon and Beauleiu 2007), substantial resources of *Ascophyllum nodosum* in Ireland, Scotland, Iceland, France and Canada (Bixler and Porse 2011), *Lessonia nigrescens* from Chile (Bixler and Porse 2011) and several species in the European temperate Atlantic waters (Holdt and Kraan 2011).

**Table 6.** Geographic harvest of seaweeds used for alginate production in 1999 and 2009 (Bixler and Porse 2011).

<table>
<thead>
<tr>
<th>Type</th>
<th>Harvest Location</th>
<th>Extract Type</th>
<th>1999 Harvest (dry t)</th>
<th>%</th>
<th>2009 Harvest (dry t)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laminae spp.</td>
<td>France, Ireland, United</td>
<td>Med/High G</td>
<td>5,000</td>
<td>6</td>
<td>30,500</td>
<td>32</td>
</tr>
<tr>
<td></td>
<td>Kingdom, Norway</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lessonia spp.</td>
<td>Chile, Peru</td>
<td>Med/High G</td>
<td>7,000</td>
<td>8</td>
<td>27,000</td>
<td>28</td>
</tr>
<tr>
<td>Laminaria spp.</td>
<td>China, Japan</td>
<td>Med G</td>
<td>13,000</td>
<td>16</td>
<td>20,000</td>
<td>21</td>
</tr>
<tr>
<td>Macrocystis</td>
<td>U.S., Mexico, Chile</td>
<td>Low G</td>
<td>35,000</td>
<td>42</td>
<td>5,000</td>
<td>6</td>
</tr>
</tbody>
</table>
Seaweed can replicate via vegetative (asexual) reproduction or sexual reproduction; the latter requires a cycle of alternating generations between a large sporophyte and a microscopic gametophyte (McHugh 2003). Many of the brown algae species used for alginate production cannot be propagated by taking cuttings from mature plants. In land-based facilities, it is challenging to manage precisely the water temperature, light and nutrient conditions necessary to facilitate the sexual reproductive cycle of brown algae species; it becomes cost prohibitive to supply the raw material for alginate production in this manner. “None of the usual seaweeds for alginate production are cultivated. This makes cultivated brown seaweeds too expensive when compared to the costs of harvesting and transporting wild seaweeds” (McHugh 2003).

Figure 5 illustrates the mechanical harvest of wild seaweeds at sea; each drag of the trawl harvests over 1 ton of fresh kelp in two minutes (Vea and Ask 2011). It is important to note that cultivation of low-grade industrial alginites is possible; wild harvested seaweed has higher levels of G-acid, yielding higher quality alginites that form stiff, hard gels (Bixler and Porse 2011). There is growing concern about overharvesting wild seaweed and depleting natural resources of seaweed (Vea and Ask 2011). Sustainable harvesting management plans have been implemented in Norway consisting of revolving 5-year harvest cycles, set harvest volumes for specific areas and monitoring of regrowth (Vea and Ask 2011).
recycled or disposed of properly (Zemke-White and Ohno 1999). Advancements in integrated farming of seaweed, fish, crustaceans and mollusks could resolve issues of nitrogen leaching and eutrophication from the seaweed system (Titlyanov and Titlyanova 2010). Another example of “integrated mariculture,” seaweeds can provide nutrient uptake from fish excrement in existing fish farms (Titlyanov and Titlyanova 2010). A significant problem of cultivated seaweed that would not be addressed by integrating systems is the introduction of non-native seaweed species. The potential introduction of non-native aquatic plant species from commercial kelp production is a serious bio-invasive risk for nearby marine communities (Chandrasekaran, et al. 2008). Since seaweed can reproduce asexually, fragments from cultivated seaweed can escape from seaweed farms and colonize new areas of coral or other features. If colonization occurs on dead coral reefs, the invasive algae can prevent the cycle of coral erosion and resettlement of coral, leading to reef degradation (Chandrasekaran, et al. 2008). Given the insurmountable challenges of managing non-native seaweed populations, some researchers claim that it is preferable to focus on sustainable wild harvest techniques with regard to mitigating environmental impact (Titlyanov and Titlyanova 2010).

Byproducts of industrial extraction of alginate are a potential source of pollution unless properly managed, utilized in another process, or repurposed as a substrate for another product (Fleury and Lahaye 1993). Dealginated seaweed waste has been shown to remove heavy metals from solution (Aderhold, Williams and Edyvean 1996). Rates of cadmium removal by dealginated seaweed have been found to be fast and effective (91% removal within 5 minutes) (Romero-Gonzalez, Williams and Gardiner 2001). Wastewater management is an important aspect of the manufacturing process. The first acidic-water effluent from the alginate manufacturing process contains fucose, uronic acid, sulfate, xylose and galactose. Several thousand cubic meters of liquid are produced annually. Fucans are sulfated polysaccharides that have nutritional and biological properties, such as antitumoral, antiviral and anticoagulant properties (Fleury and Lahaye 1993). The feasibility of using the substrate for methane production has been investigated but the suitability of the alginate byproducts for the production of gas remains unknown (Edyvean, Stanley and Stanley 1988).

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

Human endogenous enzymes in the gastrointestinal tract cannot digest algal polysaccharides (Mabeau and Fleurence 1993, MacArtain, et al. 2007). Seaweed polysaccharides are not metabolized; alginites are only partly degraded and lead to a substantial production of short chain fatty acids in the colon (Burtin 2003). Algal polysaccharides reach the large intestine where they are subsequently fermentable in the colon by gut bacteria (Burtin 2003). The resistance of alginites to bacterial and enzymatic degradation in the human gut is due to its high concentrations of fucose and sulfate (Jimenez-Escrig and Sanchez-Muniz, F.J. 2000). After 6 hours of fermentation and production of gas in the colon, only 65% of the degraded alginites were metabolized to short chain fatty acids. “Since algal fibre probably retains its physicochemical properties in the colon, its resistance to fermentation can lead to particular physiological effects” (Jimenez-Escrig and Sanchez-Muniz, F.J. 2000). Fermentation leads to the production of hydrogen, methane and short chain fatty acids, which can be a source of metabolic energy and discomfort (Burtin 2003).

Alginites that are not degraded by human enzymes are a source of dietary fiber (Burtin 2003). A study on the dietary effects of sodium alginate in humans concluded that the ingestion of high levels of sodium alginate caused “no effects other than those normally associated with a polysaccharide bulking agent” (Jimenez-Escrig and Sanchez-Muniz, F.J. 2000). Alginites slow digestion as a bulking agent (Anderson, et al. 1991, Jimenez-Escrig and Sanchez-Muniz, F.J. 2000). The water-holding and water-binding capacity of alginites decreases the transit time of digested food in the colon; this decrease in “colon transit time” is considered a positive factor in preventing colon cancer (MacArtain, et al. 2007). Dietary fiber from brown algae is essentially composed of four families of polysaccharides: laminarins, alginites, fucans and cellulose (Jimenez-Escrig and Sanchez-Muniz, F.J. 2000). Dietary fiber decreases the risk of coronary heart disease “due to its characteristics of dispersibility in water (water-holding capacity), viscosity, binding ability, absorptive capacity, faecal bulking capacity and fermentability in the alimentary canal. Indigestible viscous
seaweed polysaccharides such as alginates, carrageenans and funoran, which are capable of forming ionic colloids, have shown positive effects on serum lipid levels in rats. The capacity of seaweed polysaccharides to lower serum cholesterol levels seems to be due to their ability to disperse in water, retain cholesterol and related physiologically active compounds and inhibit lipid absorption in the gastrointestinal tract” (Jimenez-Éscrig and Sanchez-Muniz, F.J. 2000). Incorporation of alginates into foods or beverages has been shown to mimic the physiological effects of meal consumption, thereby reducing hunger and food intake while increasing satiety (Brownlee, et al. 2011). Results also demonstrate improved glycemic control and reduced fat absorption (Brownlee, et al. 2011).

Based on its high biocompatibility, abundance and availability of the algal sources and relatively low cost to produce, alginates are increasingly being used in the medical field (Brownlee, et al. 2005). Alginates are used for heartburn prevention (Caestecker 2001). Alginates serve the active ingredient in anti-reflux therapies (Brownlee, et al. 2005). “Alginate encapsulation has been used successfully as a method to orally deliver DNA based vaccines” (Hay, Rehman and Ghafoor, et al. 2010).

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

Alternatives to alginates include other gelling and thickening agents derived from seaweed such as carrageenan and agar, as well as xanthan gum (Imeson 2010). The ability of alginates to make gels without the use of heat distinguishes them from other hydrocolloids that require high-temperature processes (e.g., gelatin, agar, carrageenan, locust bean gum) (Saltmarsh, Barlow and eds. 2013). See questions below for more information on alternative substances to alginates.

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

Other food hydrocolloids may be used to obtain the desired emulsifying, stabilizing and thickening effects of alginates. Examples of such food hydrocolloids include alginic acid, agar agar, gum Arabic, carrageenan, cassia tora, gelatin, gellan gum, guar gum, karaya, konjac, locust bean gum, pectin, starches, tara, tragacanth and xanthan gum (Imeson 2010). Currently agar agar, carrageenan, gellan gum and xanthan gum are listed as nonagricultural (nonorganic) substances that are allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” (7 CFR §205.605(a) and (b)). The supply and price of xanthan gum and gellan gum are stable; the price and supply variability of locust bean gum, guar gum and gum Arabic are well known (Imeson 2010).

At the time of this report, there are no certified organic products available that contain PGA.

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

Food additives that may be used as alternatives to alginates to achieve a similar functionality include carrageenan, guar gum, gum Arabic, gelatin, locust bean gum and xanthan gum. Guar gum, gum Arabic, locust bean gum and gelatin are agricultural processing ingredients. They are listed under the USDA organic regulations section 205.606 as nonagricultural (nonorganic) substances that are allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))”. Nonorganic forms may be used only when the ingredient has been shown to be commercially unavailable in organic form. Xanthan gum is synthetic; however, it is allowed for use in organic processed products (7 CFR §205.605(b)).

Certified organic food hydrocolloids include gum Arabic, guar gum, locust bean gum and inulin (National Organic Program 2014). Table 7 includes the number of certified organic sources of these alternative hydrocolloids as of January 28, 2015. Products manufactured by TIC Gums are not included in the count; a search of the substance names on the Agricultural Marketing Services will not yield TIC Gums in the
results. TIC Gums manufactures hydrocolloids and stabilizers, including some certified organic products (http://www.ticgums.com/products.html).

Gum Arabic, guar gum and locust bean gum are considered GRAS; they are permitted in many food categories according to maximum usage levels permitted (FDA 2014). Guar gum is allowed as an emulsifier and emulsifier salt, formulation aid, stabilizer and thickener in “all other food categories” up to 1%. Locust bean gum is allowed as a stabilizer and thickener in “all other food categories” up to 0.5% (FDA 2014). Inulin is approved as GRAS under GRN No. 118 and GRN No. 477, allowing for use as “a bulking agent” and use “in food in general,” respectively (FDA 2003, FDA 2013).

Table 7. List of available organic hydrocolloids certified to processing and handling standards as of 2013 (National Organic Program 2014).

<table>
<thead>
<tr>
<th>Certified organic product</th>
<th># of Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gum Arabic</td>
<td>4</td>
</tr>
<tr>
<td>Guar gum</td>
<td>6</td>
</tr>
<tr>
<td>Inulin</td>
<td>31</td>
</tr>
<tr>
<td>Locust bean gum</td>
<td>3</td>
</tr>
</tbody>
</table>

References


OMRI. "OMRI Products Database." Eugene, OR, 12 03, 2014.

February 5, 2015


