

Lecithin - Bleached

Handling/Processing

Identification of Petitioned Substance

Chemical Name:

Lecithin
Phosphatidylcholine

CAS Number:

8002-43-5

Other Names:

Lecithol
Vitellin
Kelecine
Granulestin

Other Codes:

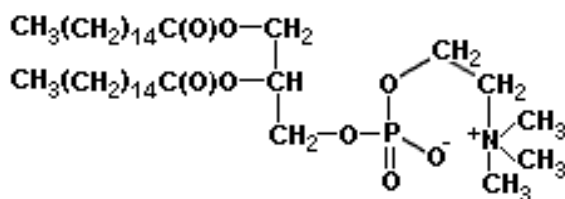
EINECS 232-307-2
RTECS OG 7565000

Characterization of Petitioned Substance

Composition of the Substance:

Lecithin was discovered in 1850 by Maurice Gobley, who isolated it (as an orange-colored substance) from egg yolks and identified it as the substance that allowed oil and water to mix. The name is derived from the Greek word lekithos, which means "yolk of egg." Lecithin is a naturally occurring fatty substance found in several foods including soybeans, whole grains, and egg yolks.

Commercially, lecithin is predominantly extracted from soybeans. The term 'lecithin' as used in the trade refers to the ordinary commercial lecithin, which is a mixture of phospholipids with a carrier of about 1/3 vegetable oil (ScoCCA, 1976). A typical phospholipid composition for a crude lecithin is phosphatidyl choline (PC), 15%; phosphatidyl ethanolamine (PE), 13 %; phosphatidyl inositol (PI), 9%; phosphatidic acid (PA), 5%; and phosphatidyl serine (PS), 2%; plus minor amounts of plant sugars and sterol glycosides. Phosphatidyl choline (usually referred to as pure lecithin) is a mixture of diglycerides of fatty acids linked to the choline ester of phosphoric acid, see below.



Pure Lecithin Chemical Structure

Phosphatides are the major functional ingredient in soybean lecithin. The ratio of the phospholipid is important for functionality. For example, high PC favors oil-in-water (o/w) emulsions, whereas high PI favors water-in-oil (w/o). Processing factors, either deliberate or unintentional, can affect lecithin's performance as an emulsifier (SzuHaj, 1983).

According to the petition's Lecithin Fact Sheet, commercial lecithin has an acetone insoluble (AI) content of 64-68%, an acid value (AV) of 24 -28, and a moisture content of less than 1%. The AI is the amount of phospholipids in the lecithin product determined by acetone insoluble gravimetric analysis. The AV is the titratable acidity from the phospholipids and added fatty acids.

Properties of the Substance:

Physical and Chemical Properties (Merck, 2006)

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49	Physical State: Waxy mass when the acid value is about 20, thick fluid when the acid value is around 30
50	Appearance: Light yellow to brown transparent sticky liquid, or white to light brown powder or
51	granules.
52	Specific Gravity: 1.0305 at 24 °C referred to water at 4 °C
53	Hygroscopicity: Swelling up in water and in NaCl solution forming a colloidal suspension
54	Solubility: Soluble in alcohol, ether, chloroform, petroleum ether, mineral oils and fatty acids;
55	insoluble in acetone, practically insoluble in cold vegetable and animal oils.
56	Iodine Value: 96
57	Saponification Value: 196

Specific Uses of the Substance:

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Lecithin has a wide range of food application, which includes emulsification, release properties, wetting, dispersing and texturization. The major applications for lecithin include margarine, chocolates, instantizing powders, release sprays, and baked goods. It is used as a natural surfactant between oil and water systems as seen in margarine products. Lecithin also helps modify chocolates for better enrobing and reduces crystallization of cocoa fat. In release applications, lecithin modifies the cooking surface to allow products to be more easily removed. As an instantizing agent, lecithin reduces the hydration properties of powders that would otherwise clump during dispersion in water and milk products. In baking, the lecithin provides a multifunction application by emulsifying the fat and water and as an anti-staling agent by inhibiting starch retrogradation. Actually, lecithin enhances the quality of baked goods by improving water absorption and the handling of the dough, increasing volume and shelf life, and improving uniformity of the products. It is also used as a packaging aid and directly on processing equipment as a lubricant.

In addition, lecithin is used in pharmaceuticals (as dietary supplements, emulsifying agent for intravenous injections, and dispersant for vitamins); in cosmetics (as emulsifier and emollient in hair and make-up preparations, creams, and oils); and in animal feeds (as a nutritional ingredient, emulsifier, and wetting aid in calf milk replacers, pet foods, and many other types of feeds required high fat and oil contents). Other industrial applications include improving plasticity of industrial sealing compounds, in textile processing and dyeing operations, in the manufacture of masonry and asphalt products, paints and pigmented coatings, as well as in the production of plastic and rubber compounds.

Bleached lecithin is used in applications where a lighter color is deemed important. Unbleached fluid lecithin has a dark brown color which does not permit high use levels in white or very light colored products; however, in some formulations, brown fluid lecithin can be use effectively at low concentrations (Scocca, 1976).

Dry lecithin is used in commercial applications of food systems where liquid lecithin is more difficult to handle and the powdered or granular lecithin is more easily incorporated.

Approved Legal Uses of the Substance:

The U.S. Food and Drug Administration (FDA) approved lecithin under 21 CFR Part 184 — Direct Food Substances Affirmed as Generally Recognized as Safe (GRAS), §184.1400.

The U.S. Environmental Protection Agency (EPA) approved lecithins under 40 CFR Part 180 — Tolerances and Exemptions from Tolerances for Pesticide Chemicals in Food, §180.950 Tolerances exemptions for minimal risk active and inert ingredients, Subsection (e) Specific chemical substances.

The U.S. Department of Agriculture, National Organic Program listed “Lecithin-bleached” under 7 CFR §250.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products

101 labeled as “organic” or “made with organic (specified ingredients or food group(s)).” Subsection (b)
102 Synthetics allowed.

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104 **Action of the Substance:**

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106 Lecithin functions as a natural surfactant between oil and water phases. Lecithin is structurally like fats
107 but contains phosphoric acid. Most important, lecithin has an electrically charged or polar end (the
108 positive ‘+’ and the negative ‘-’) and a noncharged or nonpolar end, see above chemical structure (on page
109 1). The polar end of this and similar molecules is hydrophilic (water-loving) and wants to be dissolved in
110 water. The nonpolar end is lipophilic (fat-loving) and wants to be dissolved in fat or oil. The result in a
111 water-oil mixture is that the emulsifier dissolves part of itself in water and the other part in oil. If the oil is
112 shaken in an excess of water the oil will form small droplets. Then the nonpolar ends of lecithin molecule
113 orient itself within the fat droplets and the polar ends stick out from the surface of the droplets into the
114 water phase. This has the effect of surrounding the oil droplets with an electrically charged surface. Such
115 droplets repel one another rather than having a tendency to coalesce and separate as an oil layer. The
116 emulsion is thus stabilized (Potter, 1973).

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118 Lecithin reduces the surface tension of oil in contact with water, and the bleached lecithin can provide
119 specific benefits in products requiring special emulsifying action. One example of this is either the dry or
120 wet type whipped topping, such as a non-dairy whipped cream. In this application, a dark brown
121 unbleached fluid lecithin would probably result in a slight color in the finished product, but the bleached
122 lecithin would have no effect on the color (Scocca, 1976).

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Status

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126 **Domestic:**

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128 Food and Drug Administration (FDA) — Lecithin, including bleached lecithin, is an approved food
129 additive for use in food with no limitation other than current good manufacturing practice.

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131 Environmental Protection Agency (EPA) — Residues resulting from the use of lecithin as either an inert or
132 an active ingredient in a pesticide chemical formulation (including antimicrobial pesticide chemicals) is
133 exempted from the requirement of a tolerance, if such use is in accordance with good agricultural or
134 manufacturing practices.

135

136 National Organic Standards Board (NOSB) — During Sunset Review in October 2006, the NOSB
137 recommended renewing lecithin-bleached under 7 CFR §205.605(b) Synthetics allowed. In the committee
138 summary, the board further recognized that there are “plentiful non-synthetic and organic alternatives to
139 synthetic bleached lecithin in liquid form” but that there is currently no such alternative for “bleached
140 lecithin in dry, de-oiled form”. Because the Sunset Review provided no opportunities to add annotations,
141 the board saw no alternative but to recommend renewal of bleached lecithin. In closing its summary, the
142 board invited a petition to restrict the use of bleached lecithin to dry forms only.

143

144 **International:**

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146 The Joint FAO/WHO Expert Committee on Food Additives— Lecithin (INS¹: 322) functional uses as
147 antioxidant and emulsifier agent. Acceptable daily intake is not limited.

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149 Canadian Organic Standards— Lecithin bleached form is allowed when unbleached form is not suitable.
150 From organic sources only. Lecithin is listed in the table of “Food Additives” of the “Non-organic
151 Ingredients” section under permitted substances lists for processing and sanitation

¹ A number assigned to a food additive in accordance with the Codex Class Names and the International Numbering System (INS) for Food Additives.

152
153 The EU Organic Regulation No 2092/91— The use of lecithin as (1) a fungicide, listed in the section
154 “Substances of crop or animal origin”, for plant protections; and (2) a food additive, listed in the subsection
155 “Food additives, including carriers” of the section “INGREDIENTS OF NON-AGRICULTURAL ORIGIN”,
156 for preparation of foodstuffs composed essentially of one or more ingredients of plant and/or animal
157 origin.

158
159 The Codex Guidelines for Organically Produced Foods— Lecithin used for pest and disease control need
160 recognized by the certification body or authority, e.g., volume, frequency of application, specific purpose,
161 etc. In addition, lecithin (obtained without bleaches and organic solvents) as a food additive is permitted
162 for use in foods of plant origin and certain foods of animal origin (such as dairy products and analogues,
163 fats and oils, fat emulsions, emulsified sauces, and infant formulae and follow-on formula).

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165 Evaluation Questions for Substances to be used in Organic Handling

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167 **Evaluation Question #1: Is the petitioned substance formulated or manufactured by a chemical process?**
168 **(From 7 U.S.C. § 6502 (21).)**
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170 Most commercial lecithin is obtained in the process of degumming crude soy oil extracted from soy flakes
171 with hexane. Crude soy oil contains an average of 1.8% hydratable compounds, primary lecithin
172 phosphatides. Roughly, 1% of live steam or warm water is added to the crude soy oil at about 70° C, in a
173 batch or continuous process. The emulsion is then agitated or stirred for 10–60 minutes as the phosphatides
174 hydrate and agglomerate, forming a heavy oil-insoluble sludge, which is separated from the oil by use of a
175 centrifuge. The sludge obtaining from degumming centrifuge, a lecithin and water emulsion containing
176 25-50% water, may then be bleached once or twice to reduce its color from brown or beige to light yellow.
177 Fluidizing additives such as soy oil, fatty acids, or calcium chloride can then be added to reduce the
178 viscosity to that of honey and prevent the end product, on cooling, from being a highly plastic solid.
179 Finally, the product is film or batch dried to reduce moisture to about 1%. Whether bleached or not, the
180 finished commercial product is called “unrefined” or “natural” lecithin, which contains 65-70%
181 phosphatides and 30-35% crude soy oil. The oil in unrefined lecithin can be removed by extraction with
182 acetone (phosphatides are insoluble in acetone) to give a dry granular product called “refined lecithin”
183 (Soyinfo, 2007).

184
185 For bleaching process, the color of soybean lecithin is removed by the action of hydrogen peroxide and/or
186 benzoyl peroxides. Preparation of single-bleached products in commercial operations entails the addition
187 of 0.3 to 1.5% of 30% hydrogen peroxide directly to the gums. Double-bleached lecithin is manufactured
188 by the use of benzoyl peroxide in conjunction with hydrogen peroxide. Benzoyl peroxide may be added to
189 the gums during hydrogen peroxide bleaching or added to the dried gums. Typical amounts of benzoyl
190 peroxide used for double bleaching range from 0.3 to 0.5% by weight of the gums (Flider, 1989).

191
192 Soybean lecithin can be classified into three broad types: unrefined or natural, refined, and chemically
193 modified. Unrefined or natural lecithin comes in six basic varieties, long defined by specifications of the
194 National Soybean Processors Association: plastic or fluid, each either unbleached, bleached, or double-
195 bleached. [Because fluid lecithin is easier to handle and dissolve more rapidly in various solvents, only
196 small amounts of plastic grade are now produced.] Refined lecithin, which has had the oil removed using
197 acetone, comes in three basic varieties: custom blended natural, oil-free phosphatides (as is or custom
198 blended), and alcohol-fractionated oil-free phosphatides (as is or custom blended). These latter special
199 refined grades, which may contain 60-99.7% phosphatidyl choline, are used mostly for pharmaceutical
200 applications and research. Chemically modified lecithin products, altered through selective chemical
201 treatment, improve lecithin's compatibility to certain systems (Soyinfo, 2007). Lecithin contains a number
202 of functional groups that may undergo hydroxylation, acetylation, hydrolysis, hydrogenation,
203 halogenation, phosphorylation, and sulfonation. However, with the exception of acetylated, hydroxylated,
204 and perhaps some hydrolyzed products, most of these are not employed on a commercial scale (List, 1989).
205 Summarized varieties of soybean lecithin as follows:

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TYPE	VARIETY
I. Unrefined or natural	A. Plastic <ul style="list-style-type: none"> • Unbleached • Single-bleached • Double-bleached B. Fluid <ul style="list-style-type: none"> • Unbleached • Single-bleached • Double-bleached
II. Refined	A. Custom blended natural B. Oil-free phosphatides <ul style="list-style-type: none"> • As is • Custom-blended C. Alcohol-fractionated oil-free phosphatides <ul style="list-style-type: none"> • As is • Custom -blended
III. Chemically modified	A. Acetylated B. Hydroxylated C. Enzymatically modified

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Szuhaj (1983), using another method of classification, has noted that in addition to the six basic types of natural or unrefined lecithin, there are six types of upgraded lecithin products, including clarified lecithins (filtered), fluidized lecithins, compounded lecithins, hydroxylated lecithin, deoiled lecithin (granular), and fractionated lecithin.

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Evaluation Question #2: Is the petitioned substance formulated or manufactured by a process that chemically changes the substance extracted from naturally occurring plant, animal, or mineral sources? (From 7 U.S.C. § 6502 (21).)

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As described above, most commercial lecithin is made from crude soy oil extracted from soy flakes. The crude soy oil is then treated with water or steam to precipitate the lecithin as gums. These wet gums are centrifuged, bleached (with hydrogen peroxide and/or benzoyl peroxide), and dried to become a bleached lecithin.

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The long chain fatty acid groups in the lecithin molecule, which provide the hydrophobic properties of lecithin, as well as the phosphoric acid-choline complex which provides the hydrophilic property of lecithin, are not adversely affected by the bleaching process (Scocca, 1976).

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Evaluation Question #3: Is the petitioned substance created by naturally occurring biological processes? (From 7 U.S.C. § 6502 (21).)

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Commercial lecithin is a naturally occurring mixture of the phosphatides of choline, ethanolamine, and inositol, with smaller amount of other lipids. It is isolated as a gum following hydration of solvent-extracted soy or other vegetable seed (such as corn, safflower, etc) oil. Lecithin is bleached by hydrogen peroxide and/or benzoyl peroxide and dried by heating. All of these are not naturally occurring biological processes.

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Evaluation Question #4: Is there a natural source of the petitioned substance? (From 7 CFR § 205.600 (b) (1).)

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The most concentrated natural and unrefined sources of lecithin are soybeans (1.48 to 3.08% lecithin), peanuts (1.11%), calf liver (0.85%), oatmeal (0.65%), wheat (0.61%), and eggs (0.39%). Among refined substances, especially concentrated sources of lecithin include dehydrated (powdered) egg yolk (14-20%),

241 natural egg yolk (7-10%), wheat germ (2.82%), soy oil (1.8%), and butterfat (1.4%). Soy oil has the highest
242 lecithin and phosphatide content of any known oil; other vegetable oils average 0.5% lecithin. In plant
243 seeds, the phosphatides are largely associated with oil, but their content varies roughly with the protein
244 rather than the oil content. Moreover, all of the above indicates that phosphatides and lecithin appear to be
245 closely connected with the most important vital and reproductive organs and processes. In addition to the
246 spinal cord, brain, eggs, and seeds, they are also concentrated in the nerves, liver, kidneys, and sperm.
247 Actually, lecithin is found in the cell membranes of all human cells, and they tend to be most concentrated
248 where membrane functions are specialized. Lecithin compounds are also closely associated with fatty
249 acids in the body (Soyinfo, 2007).

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251 As mentioned before, bleached lecithin is obtained by bleaching process using hydrogen peroxide and/or
252 benzoyl peroxide.

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254 **Evaluation Question #5: Is there an organic agricultural product that could be substituted for the**
255 **petitioned substance? (From 7 CFR § 205.600 (b) (1).)**

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257 According to the petitioner, its plant has supplied organic lecithin since January 2004. Organic lecithin is
258 made from organic soybeans using the expeller press process to remove the crude soybean oil. Then, the
259 crude expeller soybean oil is hydrated with water or steam and the lecithin gums are removed by
260 centrifugation and dried.

261
262 The petition stated in part:

- 263 "... The world of organic ingredients has evolved to address the color issue with certified organic
264 solutions.
- 265 ○ Organic light-colored fluid lecithin: By reducing color pigments through selection of lighter
266 colored raw materials and reducing processing temperatures, organic processors can offer
267 100% organic light-colored lecithin that matches the industry color definition of "bleached
268 lecithin". In addition, color pigments can now be reduced by using filter media, which are
269 allowed in organic production. Either way, manufacturers can now find the same
270 functionality and similar color from an organic lecithin that is not bleached.
 - 271 ○ Organic fluid bleached lecithin: Using hydrogen peroxide allowed under 205.605(b) treating
272 organic fluid lecithin, organic processors now offer a bleached "organic" lecithin identical in
273 functional properties and color to the synthetic non-organic bleached lecithin currently
274 allowed.
 - 275 ○ Organic egg yolks: Organic egg yolks, which contain lecithin, are an effective emulsifier now
276 being used in organic products. These include organic ice creams, frozen yogurts, mayonnaise
277 and salad dressing products."

278
279 Currently, several companies— one in France, one in India, and two in US — supply organic lecithin.

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281 **Evaluation Question #6: Are there adverse effects on the environment from the petitioned substance's**
282 **manufacture, use, or disposal? (From 7 CFR § 205.600 (b) (2).)**

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284 Hexane is used to extract crude soy oil in soy flakes because it gives the highest yield. Then, hexane is
285 separated from the soybean oil in evaporators. The evaporated hexane is recovered and returned to the
286 extraction process. Hydrogen peroxide or benzoyl peroxide is used for bleaching process. Increased
287 environmental concerns on using these chemicals have resulted in legislation which could restrict oil
288 processing operations that use hexane.

289
290 In 1979, "Evaluation of the Health Aspects of Lecithin as a Food Ingredient" reported by the Federation of
291 American Societies for Experimental Biology contacted by FDA. This report concluded that there is no
292 evidence in the available information on lecithin and lecithin bleached with hydrogen peroxide that
293 demonstrates or suggests reasonable grounds to suspect a hazard to the public when they are used at levels
294 that are now current or that might reasonably be expected in the future.

295

296 According to Material Safety Data Sheet (MSDS), it is not likely to produce degradation products with
297 hazard from lecithin in short term; however, degradation products may arise in long term. Dispose of
298 according to local, state, and federal environmental control regulations.
299

300 **Evaluation Question #7: Does the petitioned substance have an adverse effect on human health as**
301 **defined by applicable Federal regulations? (From 7 CFR § 205.600 (b) (3).)**
302

303 Lecithin is found in brain, nerve, liver, kidney, heart, blood, and other tissues. Because of its strong affinity
304 for water, it facilitates the passage of fats in and out of the cells; and it probably plays a role in fat
305 absorption from the intestine and transport of fats from the liver (Potter, 1973).
306

307 No acute exposure studies were found for soybean-derived lecithin in humans. According to MSDS, the
308 dust is predicated to be irritating to the eyes, skin, and respiratory tract from mechanical action. Inhalation
309 of lecithin aerosols may cause pulmonary edema; it may cause occupational asthma from pulmonary
310 sensitization. Acute ingestion may affect the liver (fatty liver degeneration). Safety glasses, lab coat, dust
311 respirator, and gloves are needed for personal protection.
312

313 Soy has also been recognized as one of the eight most common food allergens. During manufacture of
314 lecithin derived from soy, most, but not all, of soy protein is removed. Soy allergens, to the extent they are
315 present in lecithin, would be found in the protein fraction of the ingredient. Accurately measuring
316 lecithin's protein content presents challenges to current analytical methodology due to the ingredient's oily
317 matrix and low levels of protein.
318

319 **Evaluation Question #8: Is the nutritional quality of the food maintained when the petitioned**
320 **substance is used? (From 7 CFR § 205.600 (b) (3).)**
321

322 "Common food applications of lecithin include use as an emulsifier, a stabilizer, a dispersing aid, and an
323 incidental additive, such as a release agent for baked goods. Regardless of its food application, lecithin is
324 generally used in small amounts, with the result that it is, according to one lecithin manufacturer, present
325 in finished foods at levels rarely exceeding 1% by weight of the final food product." was stated in '*Guidance*
326 *on the Labeling of Certain Uses of Lecithin Derived from Soy Under Section 403(w) of the Federal Food, Drug, and*
327 *Cosmetic Act*' by FDA. The nutritional quality of the food is maintained when lecithin is used.
328

329 **Evaluation Question #9: Is the petitioned substance to be used primarily as a preservative? (From 7**
330 **CFR § 205.600 (b) (4).)**
331

332 Bleached lecithin is mainly used as an emulsifier, a release agent, and an instantizing agent in products
333 from foods to pharmaceuticals to other industrial applications.
334

335 **Evaluation Question #10: Is the petitioned substance to be used primarily to recreate or improve**
336 **flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g.,**
337 **vitamin D in milk)? (From 7 CFR § 205.600 (b) (4).)**
338

339 Lecithin is principally used as an emulsifying agent. It greatly speeds up dispersion of fatty and aqueous
340 compounds in a wide range of food applications, including margarine, confections, baked goods, and dairy
341 products. Bleached lecithin is used where a lighter color is deemed important. In addition, lecithin can be
342 used directly on processing equipment as a lubricant.
343

344 **Evaluation Question #11: Is the petitioned substance generally recognized as safe (GRAS) when used**
345 **according to FDA's good manufacturing practices? (From 7 CFR § 205.600 (b) (5).)**
346

347 Lecithin, including bleached lecithin, is affirmed as generally recognized as safe (GRAS) with no limitation
348 other than current good manufacturing practice by FDA in 21 CFR 184.1400.
349

350 **Evaluation Question #12: Does the petitioned substance contain residues of heavy metals or other**
351 **contaminants in excess of FDA tolerances? (From 7 CFR § 205.600 (b) (5).)47**
352

353 Commercial lecithin needs to meet the specifications of the Food Chemicals Codex (FCC), which is a result
354 of the work by the Committee of Codex Specifications of the Food and Nutrition Board² of the National
355 Research Council. The GRAS affirmation regulation specifies that the ingredient meet the specifications of
356 the FCC, 3d Ed. (1981), pp. 166–167. The FCC monograph stipulates that food grade lecithin contain not
357 more than 0.3% hexane-insoluble matter, not more than 1 ppm lead, etc.
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² The Food and Nutrition Board is not a regulatory agency of any government even though some governments may adopt the FCC for their use.

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