

Calcium Acid Pyrophosphate

Handling/Processing

Identification of Petitioned Substance

Chemical Name:	CAS Number:
Calcium dihydrogen diphosphate	14866-19-4
Other Names:	Other Codes:
Calcium acid pyrophosphate	EINECS 238-933-2
Monocalcium dihydrogen diphosphate	INC 450(vii)
Monocalcium dihydrogen pyrophosphate	
Acid calcium pyrophosphate	

Characterization of Petitioned Substance

Composition of the Substance:

Calcium acid pyrophosphate (CAPP) is an anhydrous phosphate salt. It contains no more than 1% of water (determined by heating at 105° C for 4 hours). CAPP is expressed by the formula $\text{CaH}_2\text{P}_2\text{O}_7$ and made up of one molecule of calcium oxide and one molecule of phosphorous pentoxide (P_2O_5). Its assay contains not more than 64% P_2O_5 expressed on a dry weight basis (JFCFA, specification, 2006).

Properties of the Substance:

Physical and Chemical Properties

Color	White
Appearance	Powder
Odor	Odorless
Molecular weight (g/mol)	216.04
Solubility	Insoluble in water; soluble in dilute hydrochloric and nitric acids
pH	3*
Neutralizing value¹	67

Source: Food Chemicals Codex, 2010-2011; Lampila and Goober, 2002.

* The pH value is for a 1% aqueous solution.

Specific Uses of the Substance:

This petition requests that CAPP be added to the National List for use as a leavening agent in baked goods. The petition states, "The intended purpose of calcium acid pyrophosphate is as leavening acid in baked products... the use of calcium acid pyrophosphate has risen in popularity due to health benefits afforded by "low sodium" products..."

CAPP can be functioned as a leavening agent and a nutrient (FCC, 2010-2011). While fermentation of bread dough is traditionally carried out by the action of yeast cells on fermentable sugars, bread dough can be leavened using chemical leavening agents alone or in combination with the yeast (Bellido et al., 2008). CAPP is useful for doughs that are subject to refrigeration or frozen storage purposes (Heidolph and Gard, 1995). In addition, it may aid in strengthening dough systems via calcium-protein interactions (Foster,

¹ Defined as the parts by weight of sodium bicarbonate that 100 parts by weight of leavening acid will neutralize, i.e. release all of the carbon dioxide. It is the measure of the acid required within a specific bakery formulation.

39 2007). Therefore, CAPP can be used in baking powder, cakes, muffins, biscuits, pancakes, waffles, donuts,
40 whole grain bread, crackers, refrigerated and frozen (yeast) doughs, and for dough strengthening.

41
42 In addition, CAPP can be used as a poultry scald agent to remove feathers from poultry carcasses (FSIS
43 Directive 7120.1, Revision 3). According to the specification of calcium dihydrogen diphosphate prepared
44 by the Joint FAO/WHO Expert Committee on Food Additives (Monograph 1, 2006), it can also be used as
45 stabilizer and emulsifier.

47 Approved Legal Uses of the Substance:

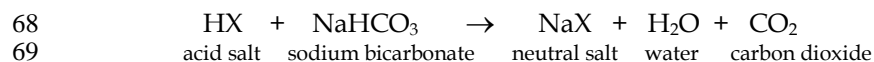
48
49 EPA – Not listed.

50 FDA – Not listed. [Note: FDA has several lists of generally recognized as safe (GRAS) substances, but
51 these lists are not all-inclusive. See the statement, below, under Section “Status” of this report.]

52 FSIS – CAPP is listed in FSIS Directive, 7120.1 (Revision 3), Safe and Suitable Ingredients Used in the
53 Production of Meat, Poultry, and Egg Products. CAPP is used as a poultry scald agent; the amount of
54 usage is stated as “sufficient for purpose”.

56 Action of the Substance:

57
58 Calcium acid pyrophosphate is an acid leavener, which is a component of the chemical leavening system in
59 bakery products. The chemical leavening system includes a source of soda (typically sodium bicarbonate,
60 but may be potassium or ammonium bicarbonate), one or more acid substances (phosphate salts, e.g.
61 CAPP), and gas (such as air that has been incorporated during the mixing process and water in the form of
62 steam) (Matz, 1992). After the soda dissolves in the aqueous dough or batter, it is ready to react with the
63 acid. As the acid dissolves, the hydrogen ion reacts with the bicarbonate ion, releasing carbon dioxide
64 (CO₂). This process is called chemical neutralization, where a bicarbonate source is neutralized by an acid
65 yielding CO₂; this process is demonstrated in Equation 1 (Heidolph, 1996). Furthermore, the acid-base (or
66 neutralization) reaction is a key to the effectiveness of leavening agents.



71 Equation 1. Leavening by chemical neutralization

72
73 Expansion of the dough or batter is based upon the evolution of CO₂, air, and steam. During the wet-
74 mixing of doughs or batters, bubble formation is achieved by entrapment of air and/or CO₂ evolved from a
75 chemical neutralization reaction whereby sodium bicarbonate reacts with a leavening acid (such as CAPP).
76 During bench time, additional CO₂ may evolve thus further expanding the dough or batter. Upon heating,
77 the final volume develops as a result of the CO₂ from any remaining active leavening agent; release of CO₂
78 dissolved in the aqueous portion; the generation of steam; and the thermal expansion of the gases.

79
80 There are a number of leavening acids to choose from in formulating a chemical leavening system. They
81 differ in the amount required to release completely all of the CO₂ in the soda, the speed with which they
82 release this leavening gas, and their effects on doughs, batters, and finished product characteristics.
83 Therefore, two important properties for using a leavening acid are neutralizing value and dough rate of
84 reaction (Matz, 1992):

- 85 • Neutralizing value (NV) describes the amount of leavening acid needed to react completely with the
86 amount of baking soda used in formulating a bakery product. If all of the soda reacts with the
87 leavening acid, the finished product should be close to neutral in pH, which is desired in most baked
88 products. Higher (alkaline) or lower (acidic) pH can be achieved, if desired, by adjusting the amount
89 of leavening acid and/or soda from the amount needed for complete reaction. The NV is defined as
90 the weight of soda neutralized by 100 parts of leavening acid.
- 91 • Dough rate of reaction (DRR) is a measure of the speed of reactivity of the leavening acid in a dough or
92 batter. DRR is determined by measuring the amount of CO₂ released from the dough over a period of
93 time, in other words the speed at which the CO₂ is evolved. This is important in controlling the

94 characteristics of the finished baked goods. If the acid reacts too rapidly with the soda, all of the CO₂
95 could be released during mixing and not be available to raise the product during the baking. The
96 finished product would be low in volume and dense in texture. On the other hand, if the acid reacts
97 with the soda too late in the baking process, the structure of the product will be 'set' by the heat of
98 baking, and the CO₂ cannot raise the product without causing cracks or splits.
99

100 Leavening acids are selected primarily on the bases of reactivity – how fast they react and at what
101 temperature. Reactivity depends mostly on solubility, which in turn depends on chemical composition,
102 particle size, and/or coating. According to Heidolph's report on *Designing Chemical Leavening Systems*
103 (1996), leavening acids can be grouped into categories based on their release characteristics:

- 104 • Nucleating agents (such as organic acids² and monocalcium phosphate) – they react with soda during
105 mixing or in the bowl. These leavening acids have essentially no delay in their reaction with the soda;
106 much of the CO₂ generated can be lost during forming, handling, and holding prior to baking and
107 expansion. In general, nucleating agents are not used as the sole leavening acid in formulations.
- 108 • Time-released agents (such as sodium acid pyrophosphate and CAPP) – they react after a period of
109 time. These leavening acids exhibit a wide range of reactivity; the amount of time delay can be from a
110 few minutes to as much as an hour or more.
- 111 • Heat-activated leavening agents (such as sodium aluminum phosphate and dicalcium phosphate
112 dihydrate) – they do not react significantly in the bowl or during holding and are triggered by heat.
113 These leavening acids are dependent on the dough or batter being heated to react with bicarbonate;
114 they begin to react at a specific temperature or range of temperatures.
115

Status

117
118 **Domestic:**
119

120 The use of CAPP can be GRAS even if it is not listed by FDA. Because the use of a GRAS substance is not
121 subject to premarket review and approval by FDA, it is impracticable to list all substances that are used in
122 food on the basis of the GRAS provision (21 CFR §182.1).
123

124 CAPP is listed under *Poultry scald agents (must be removed by subsequent cleaning operations)* in USDA FSIS
125 DIRECTIVE, 7120.1 (Revision 3), SAFE AND SUITABLE INGREDIENTS USED IN THE PRODUCTION OF
126 MEAT, POULTRY, AND EGG PRODUCTS, dated 7/6/10.
127

128 **International:**
129

130 **Codex** – Calcium dihydrogen diphosphate listed in the General Standard for Food Additives. The
131 specification prepared at the 57th Joint FAO/WHO Expert Committee on Food Additives (JECFA) meeting
132 and published in Food and Nutrition Paper Series No. 52, Addendum 9. 2001. No acceptable daily intake,
133 but a group maximum tolerable daily intake of 70 mg/kg body weight, expressed as phosphorus from all
134 food sources, was established at the 26th JECFA, 1982. Functional Class: Food additives (emulsifier,
135 stabilizer, raising agent, and nutrient).
136

137 **European Union** – 'E 450 (vii) Calcium Dihydrogen Diphosphate' listed in Commission Directive
138 2002/82/EC of 15 October 2002, amending Directive 96/77/EC laying down specific purity criteria on food
139 additives other than colors and sweeteners.
140

141 **Canada** – Calcium Dihydrogen Diphosphate listed in the Natural Health Products Ingredients Database.
142 Maximum Tolerable Intake: up to 70 mg/kg body weight daily for phosphorus from all sources. Purposes:
143 emulsifying agent, stabilizing agent.
144

² Such as citric, fumaric, lactic, and tartaric acids

145 **Japan** – ‘Calcium Dihydrogen Pyrophosphate (Acidic Calcium Pyrophosphate) (265)’ listed on Table 1
146 related to Articles 12 and 21 of the Food Sanitation Law Enforcement Regulations.

147
148 **IFOAM** – Not listed under IFOAM Indicative List of Substances for Organic Production and Processing
149 dated on April 24, 2008.

150
151 **Canada** (organic) – Not listed under the Organic Production System Permitted Substances Lists.
152 Amended October 2008 and December 2009.

153
154 **European Union** (organic) – Not listed under the Organic Regulations, Commission Regulation (EC) No
155 889/2008 of September 5, 2008.

156

Evaluation Questions for Substances to be used in Organic Handling

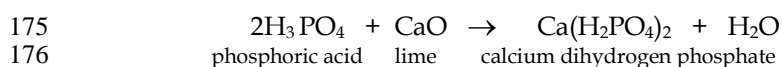
157
158
159 **Evaluation Question #1:** Discuss whether the petitioned substance is formulated or manufactured by a
160 chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).

161
162 According to the WHO Technical Report Series 909, calcium dihydrogen diphosphate is manufactured by
163 calcination of calcium orthophosphate at a temperature of about 270°C.

164
165 In US Patent 5409724, it states that CAPP can be made by the addition of monocalcium phosphate
166 monohydrate to an excess of phosphoric acid at elevated temperature, in the range of from 180 to 250° C,
167 whereby crystals of CAPP are formed. Usually, the crystal pattern of CAPP is platelet or tabular (Heidolph
168 and Gard, 1995).

169
170 The typical manufacturing method described by the petitioner states that food grade phosphoric acid
171 produced from phosphate rock is reacted with calcium oxide (lime) to precipitate calcium dihydrogen
172 phosphate. The calcium dihydrogen phosphate is filtered and undergoes calcinations at 270°C to form
173 CAPP. The material is then milled to a powder and packaged. The process is shown in Equation 2.

174



177



179

180

181 Equation 2. Chemical reaction of CAPP process

182

183 **Evaluation Question #2:** Describe the most prevalent processes used to manufacture or formulate the
184 petitioned substance. Further, describe any chemical change that may occur during manufacture or
185 formulation of the petitioned substance when this substance is extracted from naturally occurring plant,
186 animal, or mineral sources. (7 U.S.C. § 6502 (21))

187

188 The prevalent process used to manufacture CAPP is stated above in Evaluation Question #1 (EQ #1). As
189 described in EQ #1, phosphoric acid is a feedstock for producing CAPP.

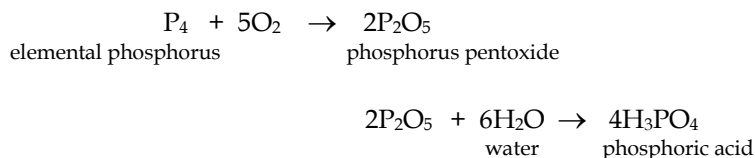
190

191 In general, phosphoric acid is produced by two commercial methods: wet process and thermal process.
192 Wet process phosphoric acid is used in fertilizer production. Thermal process phosphoric acid is of a
193 higher purity and is used in the manufacture of high grade chemicals, pharmaceuticals, food products,
194 beverages, and other nonfertilizer products (EPA AP-42, 1995). Raw materials for the thermal process are
195 elemental (yellow) phosphorus, air, and water.

196

197 Thermal process phosphoric acid (H_3PO_4) manufacture involves three major steps, see Figure 3:

- 198 1) Combustion— the liquid elemental phosphorus is burned (oxidized) in ambient air in a combustion
199 chamber at temperatures of 1650 to 2760 °C (3000 to 5000 °F) to form phosphorus pentoxide.
200 2) Hydration— the phosphorus pentoxide is then hydrated with diluted H₃PO₄ or water to produce strong
201 phosphoric acid liquid.
202 3) Demisting— the final step removes the phosphoric acid mist from the combustion gas stream before
203 release to the atmosphere. This is usually done with high-pressure drop demisters.



204
205
206
207
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210
211 Equation 3. Chemical reaction of thermal process of phosphoric acid

212
213 The concentration of H₃PO₄ produced from the thermal process normally ranges from 75 to 85 percent.
214 This high concentration is required for high grade chemical production and other nonfertilizer products
215 (including foods and beverages) manufacturing. Efficient plants recover about 99.9 percent of the
216 elemental phosphorus burned as phosphoric acid (EPA AP-42, 1995).

217
218 **Evaluation Question #3: Provide a list of non-synthetic or natural source(s) of the petitioned substance**
219 **(7 CFR § 205.600 (b) (1)).**

220
221 No information was indentified to suggest that there is a non-synthetic or natural source of the CAPP.

222
223 **Evaluation Question #4: Specify whether the petitioned substance is categorized as generally**
224 **recognized as safe (GRAS) when used according to FDA's good manufacturing practices. (7 CFR §**
225 **205.600 (b)(5))**

226
227 CAPP is not on the FDA GRAS substance lists. In the petition, under the regulatory status section, it states
228 "In the US, the FDA has deemed Calcium Acid Pyrophosphate as Generally Recognized As Safe (GRAS) by
229 a published regulation (21 CFR 182.8223). The safety of this substance was reviewed by the Select
230 Committee on GRAS Substances (SCOGS) review of GRAS substances conducted from 1972 to 1980,
231 wherein Calcium Acid Pyrophosphate was affirmed as GRAS with no limitations other than Good
232 Manufacturing Practices."

233
234 The following is the excerpt from the regulation 21 CFR Part 182 – Substances Generally Recognized As
235 Safe, Subpart I – Nutrients, cited by the petition:

236
237 §182.8223 Calcium pyrophosphate.

238 (a) *Product.* Calcium pyrophosphate.

239 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with
240 good manufacturing practice.

241
242 It does not contain any information related to calcium acid pyrophosphate (CaH₂P₂O₇).

243
244 Calcium pyrophosphate (Ca₂P₂O₇) and calcium acid pyrophosphate (CaH₂P₂O₇) are two different
245 substances with different chemical properties. Their CAS numbers are 7790-76-3 and 14866-19-4,
246 respectively. Furthermore, the SCOGS review on the safety of 'calcium acid pyrophosphate', mentioned by
247 the petitioner, could not be found through the literature search.

249 However, according to *FDA Guidance for Industry: Q&A about GRAS* (2004), the agency has several lists (e.g.
250 21 CFR Part 182³, Part 184⁴, Part 186⁵, and GRAS notices⁶) of GRAS substances, but these lists are not all-
251 inclusive. Because the use of a GRAS substance is not subject to premarket review and approval by FDA, it
252 is impracticable to list all substances that are used in food on the basis of the GRAS provision (21 CFR
253 §182.1). Therefore, CAPP may be a GRAS substance even if it is not listed by FDA (Q&A about GRAS,
254 2004).

255
256 **Evaluation Question #5: Describe whether the primary function/purpose of the petitioned substance is**
257 **a preservative. If so, provide a detailed description of its mechanism as a preservative. (7 CFR § 205.600**
258 **(b)(4))**

259
260 The petitioned substance serves as a chemical leavening acid (a leavening agent). For bakery application,
261 the chemical leavening is based upon the neutralization of common baking soda (such as sodium
262 bicarbonate) by acidic phosphate salts (such as CAPP) to generate carbon dioxide (CO₂). As the CO₂
263 expands, it provides volume and impacts texture and appearance of the baked goods. The purpose of a
264 leavening acid is to promote a controlled and nearly completed evolution of gas from a dough or batter in
265 which carbon dioxide in its dissolved or bound form (Matz, 1992).

266
267 **Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate**
268 **or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)**
269 **and how the substance recreates or improves any of these food/feed characteristics. (7 CFR § 205.600**
270 **(b)(4))**

271
272 No information sources reviewed specifically address that CAPP could be used primarily to recreate or
273 improve flavors, colors, textures, or nutritive values lost in processing. However, there is an indirect
274 impact on the texture of baked goods as CAPP neutralizes baking soda and CO₂ expands in the product
275 during the baking process.

276
277 **Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or**
278 **feed when the petitioned substance is used. (7 CFR § 205.600 (b)(3))**

279
280 The petition states “the use of calcium acid pyrophosphate has risen in popularity due to health benefits
281 afforded by “low sodium” products. CAPP is the calcium analog to Sodium Acid Pyrophosphate (CAS #
282 7758-16-9) which is already on “The National List of Allowed and Prohibited Substances” permitted for use
283 as a leavening agent in baked foods.”

284
285 When HHS and USDA issued the 2005 *Dietary Guidelines for Americans* encouraging the reduction of salt
286 and sodium in food, it recommended that people consume less than 2300 mg (approximately 1 teaspoon of
287 salt) of sodium per day. Based on doctor’s recommendations and the increased awareness of the negative
288 implications of sodium, such as for high blood pressure, consumers are looking to reduce the sodium in
289 their diet (NMI, 2006). In 2006, sodium reduction became a more prominent issue among consumers when
290 the American Medical Association (AMA) issued a statement that consumption of high-sodium foods
291 contributes to health problems, including heart disease and high blood pressure (Tanner, 2006).
292 Cardiovascular health concerns drove the AMA to request food manufacturers to produce food and
293 beverage offerings, where sodium is reduced by 50% versus current level (<2300 mg). In 2008, Congress
294 asked the Institute of Medicine (IOM) to recommend strategies for reducing sodium intake to levels

³ Containing the remnants of a list, which FDA established in its regulations shortly after passage of the 1958 Food Additives Amendment. The list is organized according to the intended use of these substances.

⁴ Containing a list of substances that FDA affirmed as GRAS as direct food ingredients for general or specific uses. This list derives from FDA’s 1970s comprehensive review of GRAS substances and from petitions that FDA received to affirm the GRAS status of particular uses of some food ingredients.

⁵ Containing a list of substances that FDA affirmed as GRAS for certain indirect food uses.

⁶ Containing a list of substances that have been the subject of a notice to FDA - i.e., when a firm has notified FDA about its view that a particular use of a substance is GRAS.

295 recommended in the *Dietary Guidelines for Americans*—currently no more than 2300 mg per day for persons
296 2 or more years of age. This amounts to about 1 teaspoon of salt per day, while the average American
297 consumes about 50 percent more than that, in other words, more than 3400 mg of sodium per day. The
298 IOM report on *Strategies to Reduce Sodium Intake in the United State* was released on April 20, 2010.
299

300 Heidolph (2008) has reported that CAPP is ideal for bakery products where sodium based leavening agents
301 are traditionally used, such as sodium acid pyrophosphate or sodium aluminum phosphate, but zero
302 sodium is desired. When CAPP is used to substitute for sodium-based leavening acid, it can provide
303 sodium reduction up to 26%, depending on the formulation and leavening acid that is being replaced. In
304 addition, CAPP contains about 19% calcium by weight. Heidolph (2008) stated that “Calcium acid
305 pyrophosphate (CAPP) is a unique leavening acid that has zero sodium and is a good source of calcium.”
306

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

310 No information was indentified to suggest that CAPP contains residues of heavy metals or other
311 contaminants in excess of FDA’s Action Levels for Poisonous or Deleterious Substances in Human Food.
312
313

314 The Food Chemical Codex (2010-2011) monograph stipulates that CAPP may contain not more than 3
315 mg/kg, 0.005%, and 2 mg/kg of arsenic, fluoride, and lead, respectively.
316

317 **Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the**
318 **petitioned substance may be harmful to the environment. (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. §**
319 **6517 (c) (2) (A) (i))**

320
321 The typical manufacturing method described by the petitioner in the petition states that food grade
322 phosphoric acid used to react with calcium oxide (lime) to precipitate calcium dihydrogen phosphate is
323 produced from phosphate rock. Phosphate deposits can contain significant amounts of naturally occurring
324 heavy metals. Mining operations processing phosphate rock can leave tailings piles containing elevated
325 levels of cadmium, lead, nickel, copper, chromium, and uranium (Gnandil et al., 2006). Unless carefully
326 managed, these waste products can leach heavy metals into groundwater or nearby estuaries. Uptake of
327 these substances by plants and marine life can lead to concentration of toxic heavy metals in food products
328 (Gnandil et al., 2006).
329

330 However, the thermal process phosphoric acid (as described in Evaluation Question #2) is a feedstock of
331 CAPP. According to EPA (AP-42, 1995), the major source of emissions from the thermal process is
332 phosphoric acid mist contained in the gas steam from the hydrator. It is not uncommon for as much as half
333 of the total phosphorus pentoxide to be present as liquid phosphoric acid particles suspended in the gas
334 stream. Efficient plants are economically motivated to control this potential loss with various control
335 equipment (EPA, AP-42, 1995). Phosphoric acid mist can be transported in air and dissolved in water.
336

337 In the Australian Government’s National Pollutant Inventory, it states that “phosphoric acid has moderate
338 acute and chronic toxicity to aquatic life in waters of low alkalinity.” While small quantities of phosphoric
339 acid can be neutralized by the alkalinity in aquatic ecosystems, larger quantities can lower the pH for
340 extended periods of time, posing a potential risk to aquatic organisms. Phosphate (formed when
341 phosphoric acid is dissolved) is unlikely to bioaccumulate in most aquatic species.
342

343 When spilled onto soil, phosphoric acid will infiltrate downward, the rate being greater with lower
344 concentration because of reduced viscosity (TOXNET). During transport through the soil, phosphoric acid
345 will dissolve some of the soil material, in particular, carbonate-based materials. The acid will be
346 neutralized to some degree with adsorption of the proton and phosphate ions also possible. However,
347 significant amounts of acid will remain for transport down toward the groundwater table. Upon reaching
348 the groundwater table, the acid will continue to move in the direction of groundwater flow.
349

350 Occupational exposure to concentrated levels of phosphoric acid may occur through inhalation of mist,
351 ingestion, eye, and skin contact in industries manufacturing and using phosphoric acid. According to the
352 OSHA standards, 29 CFR §1900.1000 Table Z-1 (8-hrs Time Weighted Average), permissible exposure limit
353 is 1 milligram per cubic meter. The general public may be exposed to small quantities of phosphoric acid
354 in the consumption of food and soft drinks and by using some cleaning agents.

355
356 According to the material safety data sheet of ICL Performance Products LP provided by the petitioner, it
357 states “on the basis of available information, this material is not expected to produce any significant
358 environmental effects when recommended use instructions are followed.”

359
360 **Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the**
361 **petitioned substance. (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i) and 7 U.S.C. § 6518 (m) (4))**
362

363 Currently, there is no toxicology data or risk assessment on human health for use of CAPP (CAS No. 14866-
364 19-4). No information can be found in Toxicology Data Network, FDA, or EPA reports.

365
366 Two material safety data sheets (MSDS) are included in the petition. One is for the CAL-RISE™ product,
367 which is composed of CAPP (<75%) and monocalcium phosphate (>25%), and it contains toxicological
368 information based on animal studies — an acute LD₅₀ =2000 mg/kg (dermal, rabbit) and acute LD₅₀
369 ranging from 3986 -5000 mg/kg (oral, rabbit). The other MSDS submitted is for the Levona™ product,
370 which is composed of CAPP and tricalcium phosphate [there is no specific percentage given]. Under the
371 toxicological information section of its MSDS, it states “...has not conducted toxicity studies with this
372 material and no data was found in a reasonably extensive search of the literature.”

373
374 According to those MSDS, both products may cause skin, eye, and respiratory tract irritation. From an
375 occupational health perspective, workers are recommended to wear appropriate protective eyeglasses and
376 gloves and NIOSH/MSHA approved respiratory protection equipment.

377
378 Several sources⁷ (Food Product Design, Prepared Foods, Baking Management, and US Patent 5409724) refer
379 to the use of CAPP in baked products to reduce sodium levels, raise calcium levels, and address the
380 growing health concerns of consumers (Foster, 2007; Mannie, 2009; Seiz, 2005; and Heidolph and Gard,
381 1995). Also, see the Evaluation Question #7.

382
383 **Evaluation Question #11: Provide a list of organic agricultural products that could be substituted for**
384 **the petitioned substance. (7 CFR § 205.600 (b)(1))**
385

386 No information was indentified to suggest that an organic agricultural product could be substituted for
387 CAPP. Nevertheless, sodium acid pyrophosphate (CAS No. 7758-16-9) is a leavening acid and can be
388 substituted for CAPP. Sodium acid pyrophosphate is on the National List— § 205.605 Nonagricultural
389 (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made
390 with organic (specified ingredients or food group(s))”, (b) Synthetics allowed —for use only as a leavening
391 agent.

392 393 394 References

395
396 Bellido, G. G., Scanlon, M. G., Sapirstein, H. D., and Page, J. H. Use of pressuremeter to measure the
397 kinetics of carbon dioxide evolution in chemically leavened wheat flour dough. J. Agric. Food Chem. 2008,
398 56, 9855-9861.

399

⁷ Most information were provided by the ICL Performance Products LP manufacturing Levona™ and the Innophos producing CAL-RISE™.

- 400 Canadian Organic Production Systems Permitted Substances Lists. CAN/CGSB-32.311-2006. Amended
401 Oct. 2008 and Dec. 2009. [http://www.tpsgc-pwgsc.gc.ca/cgsb/on_the_net/organic/032_0311_2006-
403 e_Amended%20Oct%202008%20and%20Dec%202009.pdf](http://www.tpsgc-pwgsc.gc.ca/cgsb/on_the_net/organic/032_0311_2006-
402 e_Amended%20Oct%202008%20and%20Dec%202009.pdf)
- 404 Commission Directive 2002/82/EC of 15 October 2002, amending Directive 96/77/EC laying down
405 specific criteria on food additives other than colors and sweeteners. Official Journal of the European
406 Communities. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:292:0001:0028:EN:PDF>
407
- 408 EPA, AP-42, Ch 8.9 Phosphoric Acid. Compilation of Air Pollutant Emission Factors, 5th ed. Jan 1995.
409
- 410 FDA, Food, Guidance for Industry: Frequently Asked Questions About GRAS. December 2004.
411 [http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngr
413 edientsandPackaging/ucm061846.htm](http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngr
412 edientsandPackaging/ucm061846.htm)
- 414 FDA, Guidance for Industry: Action Level for Poisonous or Deleterious Substances in Human Food and
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