

Sodium Acid Pyrophosphate

Handling/Processing

Identification of Petitioned Substance

Chemical Name:	CAS Number:
Sodium acid pyrophosphate	7758-16-9
Other Names:	Other Codes:
Disodium pyrophosphate	EINECS 231-835-0
Disodium diphosphate	INC 450(i)
Disodium dihydrogen pyrophosphate	
Acid sodium pyrophosphate	

Characterization of Petitioned Substance

Composition of the Substance:

Sodium acid pyrophosphate (SAPP) is a condensed phosphate, formed when sodium orthophosphate is heated to remove the water. It is expressed by the formula $\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$ and is composed of 20.72% Na, 0.91% H, 27.91% P, and 50.46% O (Merck, 2006). Its chemical structure is illustrated as following:

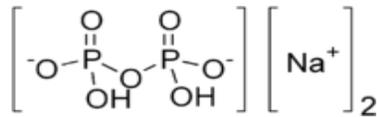


Figure 1. Chemical structure

Properties of the Substance:

Physical and Chemical Properties

Color	White
Appearance	Crystalline powder or granules
Odor	Odorless
Molecular weight	221.94
Decomposition	220° C
Relative density	1.86 g/cm ³
Solubility	Soluble in water
pH	4*

Source: Food Chemicals Codex, 2010-2011; the Merck Index, 2006.

* The pH value is for a 1% solution.

Specific Uses of the Substance:

The petitioner requests that SAPP be used as a sequestrant to maintain the appearance and texture of cooked and uncooked fruits and vegetables.

SAPP is a common food additive which serves more than one function. It is commonly used as:

- A chemical leavening agent in baked goods.
- A sequestrant/chelating agent in processed potatoes.
- An emulsifying agent in cheeses and related products.

- 39 • An inhibitor agent in canned tuna.
- 40 • A curing accelerator in processed meat and poultry products.

41
 42 Moreover, SAPP can be used in potable water treatment, animal feeds, and hog carcass scald and poultry
 43 carcass de-feathering agents. In petroleum production, it can be used as a dispersant in oil well drilling
 44 mud.

45
 46 **Approved Legal Uses of the Substance:**

47
 48 **EPA** – SAPP listed under 40 CFR §180.910 Inert ingredients used pre- and post-harvest; exemptions from
 49 the requirement of a tolerance. Its listed uses are as a surfactant, suspending agent, dispersing agent, and
 50 buffer. For potable water treatment, the maximum use level of SAPP is 12.0 mg/l.

51
 52 **FDA** – See Table 1.

53
 54 Table 1. FDA Regulation, 21 CFR

55

Regulatory Citations		Technical Effects	Status	Use Limits
SUBCHAPTER B – FOOD FOR HUMAN CONSUMPTION	Part 133 – Cheese and related cheese products. Subpart B – Requirements for specific standardized cheese and related products. §133.147, §133.169, §133.170, §133.171, §133.172, §133.173, §133.174, §133.179, §133.180.	Emulsifier	SAPP permitted as optional ingredient in a standardized food.	Not more than 3% of the weight of the finished food
	Part 137 – Cereal flours and related products. Subpart B – Requirements for specific standardized cereal flours and related products. §137.180 Self-rising flour.	Buffer and neutralizing agent	SAPP generally recognized as safe in foods but limited in standardized foods where the standard provides for its use.	Combined weight of acid-reacting substance and sodium bicarbonate is not more than 4.5 parts to each 100 parts of flour used
	Part 161 – Fish and shellfish. Subpart B – Requirements for specific standardized fish and shellfish. §161.190 Canned Tuna	Inhibitor (prevent struvite crystal formation)	SAPP permitted as optional ingredient in a standardized food.	Not in excess of 0.5% by weight of the finished food
	Part 182 – Substances Generally Recognized As Safe. Subpart B – Multiple Purpose GRAS Food Substances. §182.1087 Sodium acid pyrophosphate		GRAS	Good manufacturing practice
SUBCHAPTER E – ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS	Part 582 – Substances Generally Recognized As Safe. Subpart B – General Purpose Food Additives. §582.1087 Sodium acid pyrophosphate		GRAS	Good manufacturing or feeding practice

56
 57 **USDA** – Food Safety and Inspection Service (FSIS), Federal Register/Vol. 64, No. 246/Thursday,
 58 December 23, 1999/Rules and Regulations. Action: Final rule. SAPP is approved for use in preparation of
 59 meat and poultry products, see Table 2. In addition, SAPP is listed under NOP the National List of
 60 Allowed and Prohibited Substance. 7 CFR §205.605 (b) Synthetics allowed “Sodium acid pyrophosphate
 61 (CAS # 7758-16-9) – for use only as a leavening agent”.

62
 63 Table 2. The Usage of SAPP in Meat and Poultry Products
 64

Class	Purpose	Product	Amount
Curing accelerators (must be used only in combination with curing agents)	To accelerate color fixing or preserve color during storage	Frankfurters, wieners, vienna, bologna, garlic bologna, knockwurst, and similar products	Not to exceed alone or in combination with other curing accelerators for use in meat the following: 8 oz in 100 lb of meat, or meat and meat byproducts, content of the formula; nor 0.5% in the finished product.
Hog scald agents (must be removed by subsequent cleaning operations)	To remove hair	Hog carcasses	Sufficient for purpose
Miscellaneous	To decrease the amount of cooked out juices	Meat food products except where other prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations	For meat food products, 5% of phosphate in pickle at 10% pump level; 0.5% of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry products, 0.5% of total product.
Poultry scald agents (must be removed by subsequent cleaning operations)	To remove feathers	Poultry carcasses	Sufficient for purpose

65
 66 **Action of the Substance:**

67
 68 According to the petition, SAPP is used as a sequestrant on cooked or uncooked produce. A sequestrant is
 69 a food additive whose role is to improve the quality and stability of the food products. Sequestrants form
 70 chelate complexes with polyvalent metal ions, especially copper, iron, and nickel. They are also referred to
 71 as metal scavengers since they combine with trace metals (such as iron and copper) and remove them from
 72 solution. The trace metals when naturally occurring in foods become oxidation catalysts and induce many
 73 off-color reactions (Potter, 1973).

74
 75 Generally, chelation proceeds only if two general conditions are met: (1) the sequestrant must have the
 76 proper steric and electronic configuration in relation to the metal being complexed and (2) the surrounding
 77 environment (i.e., pH, ionic strength, solubility, etc.) must likewise conducive to complex formation.

78
 79 In the food processing, sequestrants are employed as additives to limit the participation of metal, as
 80 catalysts, in numerous deleterious reactions in food system. For example, SAPP and Na₂EDTA¹ are the

¹ ethylenediamine tetraacetic acid (EDTA)

81 sequestrants of choice to inhibit the after-cooking darkening for the potato processing in accordance with
82 Furia (1980).

83
84 Smith (1977) has reported that the most logical theory of the cause of after-cooking darkening appears to be
85 a reaction between certain types of orthodiphenols and certain forms of iron. Ferrous ions in potato
86 combine with an orthodiphenol forming a colorless or faintly colored compound which is oxidized when
87 exposed to air forming the deeply colored ferric compound. These chemicals (such as SAPP and
88 Na₂EDTA) have reduced darkening by sequestering or chelating the ferrous ions in potatoes so that it is
89 held in a nonionizable form and cannot react with orthodiphenol and, therefore, prevents the normal
90 formation of the dark colored pigment, a ferric-orthodiphenol compound (Smith, 1977).

91

92

Status

93

94 **Domestic:**

95

96 **EPA** – SAPP is listed under 40 CFR §180.910 Inert ingredients used pre- and post-harvest; exemptions
97 from the requirement of a tolerance. It is also listed in the List 4B - Other ingredients for which EPA has
98 sufficient information to reasonably conclude that the current use pattern in pesticide products will not
99 adversely affect the public health or the environment. Updated August 2004.

100

101 **FDA** – See the above, the Approved Legal Uses of the Substance section.

102

103 **USDA** – See the above, the Approved Legal Uses of the Substance section.

104

105 **International:**

106

107 **Codex** – Disodium pyrophosphate (INS: 450i) listed under phosphate group of the General Standard for
108 Food Additives. The specification prepared at the 41st Joint FAO/WHO Export Committee on Food
109 Additives (JECFA) meeting (1993), published in Food and Nutrition Paper (FNP) Series No. 52, Addendum
110 2 (1993) superseding specifications prepared at the 37th JECFA (1990), published in FNP 52 (1992). Metals
111 and arsenic specifications revised at the 55th JECFA (2000). A group maximum tolerable daily intake of 70
112 mg/kg body weight, expressed as phosphorus from all food sources, was established at the 26th JECFA,
113 1982. Functional Class: Food additives (raising agent, buffering agent, and sequestrant).

114

115 **European Union** – ‘E 450 (i) DISODIUM DIPHOSPHATE’ listed in Commission Directive 2002/82/EC of
116 15 October 2002, amending Directive 96/77/EC laying down specific purity criteria on food additives other
117 than colors and sweeteners.

118

119 **Canada** – Disodium pyrophosphate listed in the Natural Health Products Ingredients Database.
120 Maximum Tolerable Intake: up to 70 mg/kg body weight daily for phosphorus from all sources. Purposes:
121 buffering agent, emulsifying agent, emulsion stabilizer, gelling agent, pH adjuster, sequestering agent, and
122 thickening agent.

123

124 **Japan** – ‘Disodium Dihydrogen Pyrophosphate (Acidic) Disodium Pyrophosphate (266)’ listed on Table 1
125 related to Articles 12 and 21 of the Food Sanitation Law Enforcement Regulations. Last amendment
126 November 29, 2005. Ministry of Health, Labor, and Welfare Ordinance No. 166.

127

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

130

131 **Canada** – SAPP (for use as a leavening agent only) listed under Subsection 6.3 (*Non-organic Ingredients*
132 *Classified as Food Additives*) of Section 6 (*Permitted Substances Lists for Processing of the Organic Production*
133 *System Permitted Substances Lists*). Amended October 2008 and December 2009.

134

135 **European Union** – Not listed under the Organic Regulations, Commission Regulation (EC) No 889/2008
136 of September 5, 2008.
137

Evaluation Questions for Substances to be used in Organic Handling

139
140 **Evaluation Question #1:** Discuss whether the petitioned substance is formulated or manufactured by a
141 chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).
142

143 According to the petition, SAPP is manufactured by (1) partial neutralization of phosphoric acid (H_3PO_4)
144 with sodium hydroxide (NaOH) or sodium carbonate (Na_2CO_3) to form monosodium phosphate
145 (NaH_2PO_4) and then (2) dehydration of monosodium phosphate at approximately 250°C to form SAPP
146 ($\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$). The process is shown in Equation 1.
147



Equation 1. Chemical reaction of SAPP

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155
156 In the Hazardous Substances Data Bank (HSDB) of the Toxicology Data Network (TOXNET), it states that
157 manufacturing method of disodium pyrophosphate is a reaction of sodium carbonate with phosphoric
158 acid, followed by heating of the resulting monosodium phosphate to 220°C .
159

160 **Evaluation Question #2:** Describe the most prevalent processes used to manufacture or formulate the
161 petitioned substance. Further, describe any chemical change that may occur during manufacture or
162 formulation of the petitioned substance when this substance is extracted from naturally occurring plant,
163 animal, or mineral sources. (7 U.S.C. § 6502 (21))
164

165 The prevalent process used to manufacture SAPP is stated above in Evaluation Question #1 (EQ #1).
166 Phosphoric acid and sodium carbonate are the feedstock for producing SAPP.
167

Phosphoric acid

168
169
170 Phosphoric acid is produced by two commercial methods: wet process or thermal process. Wet process
171 produced phosphoric acid is used in the fertilizer production. Thermal process produced phosphoric acid
172 has a higher purity and is used to manufacture high grade chemicals, pharmaceuticals, food products,
173 beverages, and other nonfertilizer products (EPA AP-42, 1995). Raw materials used for the thermal process
174 are elemental (yellow) phosphorus, air, and water.
175

176 Phosphoric acid (H_3PO_4) manufactured by thermal process involves three major steps:

- 177 1) Combustion – liquid elemental phosphorus is burned (oxidized) in ambient air in a combustion
178 chamber at temperatures of 1650 to 2760°C (3000 to 5000°F) to form phosphorus pentoxide.
- 179 2) Hydration – phosphorus pentoxide is then hydrated with diluted H_3PO_4 or water to produce strong
180 phosphoric acid liquid.
- 181 3) Demisting – the final step removes the phosphoric acid mist from the combustion gas stream before
182 release to the atmosphere. This is usually done with high-pressure drop demisters.
183

184 The concentration of H_3PO_4 produced from the thermal process normally ranges from 75 to 85 percent.
185 This high concentration is required to manufacture high grade chemical production and other nonfertilizer
186 products (including foods and beverages). Efficient plants convert about 99.9 percent of elemental
187 phosphorus to phosphoric acid (EPA AP-42, 1995).
188

Sodium carbonate

Sodium carbonate (Na_2CO_3), commonly referred to as soda ash, may be manufactured synthetically or from naturally occurring raw materials such as ore. In the U.S., only one facility recovers small quantities of Na_2CO_3 as a byproduct of cresylic acid production. Over 85% of soda ash originates in Wyoming, with the remainder coming from Searles Valley, California (EPA AP-42, 1995).

The raw material for Wyoming soda ash is mined trona ore. There are two processing methods (sesquicarbonate process and monohydrate process) used to produce natural soda ash (EPA AP-42, 1995).

- In the sesquicarbonate process, trona ore is first dissolved in water and then treated as brine. This liquid is filtered to remove insoluble impurities before the sodium sesquicarbonate is precipitated out using vacuum crystallizers. The result is centrifuged to remove remaining water, and can either be sold as a finished product or further calcined to yield soda ash with light to intermediate density.
- In the monohydrate process, crushed trona is calcined in a rotary kiln, yielding dense soda ash. CO_2 and water are byproducts. The calcined material is then combined with water to allow settling out or filtering of impurities such as shale. After that, it is concentrated by evaporators and/or mechanical vapor recompression crystallizers to precipitate out sodium carbonate monohydrate. Impurities such as sodium chloride and sodium sulfate remain in solution. The crystals and liquor are centrifuged, and the recovered crystals are calcined again to remove remaining water.

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

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

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))

The petitioned substance is regulated as GRAS when used in accordance with good manufacturing or feeding practices. SAPP uses as a multiple purpose GRAS food substance in food for human consumption are listed under 21 CFR §182.1087. In addition, it uses as a general purpose food additive in animal drugs, feeds, and related products are listed under 21 CFR §582.1087.

Evaluation Question #5: Describe whether the primary function/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 petitioned substance is used as a sequestrant. According to FDA's definitions, sequestrants are substances which combine with polyvalent metal ions to form a soluble metal complex, to improve the quality and stability of products (21 CFR §170.3 (o) (26)).

No information sources reviewed specifically address the primary function/purpose of SAPP as a preservative.

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))

SAPP would be applied to cooked or uncooked produce to maintain the appearance and texture of these foods in accordance with the petition.

244 The petitioned substance has been used for the potato industry to prevent after-cooking darkening of
245 cooked and oil-blanched French-fried potato for several decades. Smith and Davis (1960, 1961, and 1962)
246 found that the addition of SAPP at any one of various locations in the processing line increased the mealy
247 texture of reconstituted dehydrated potato, and prevented discoloration from after-cooking darkening in
248 cooked and many forms of processed products (such as dehydrated flakes and granules, oil-blanched
249 French fries, potato salad, peeled small frozen potatoes as well as in boiled or steamed whole or sliced
250 frozen potatoes). SAPP has also been used in potato products which have already developed after-cooking
251 darkening to reduce this dark color to an acceptable light color. In addition, sweet potatoes may be treated
252 with SAPP to inhibit discoloration (Lampila and Goober, 2002). Blanda et al. (2010) conducted a study of
253 off-odor and off-flavor development in boiled potatoes, and the effects of the use of food additives – after
254 cooking and before storage – were examined. They concluded that the best additive was SAPP since potato
255 slice flavor was almost unchanged during storage.

256
257 In the invention of US Patent No. 4647462 (Gogins and Smith, 1987), it states adding SAPP prevents
258 discoloration and stabilizes the texture and the taste properties of the frozen cauliflower pieces during
259 frozen storage. However, the use of SAPP alone in the retort process is ineffective to prevent discoloration
260 of the cauliflower. Moreover, Beck (1995) and Warren (1991) has patents using a mixture, which blended
261 SAPP and other chemicals, to prevent discoloration of produce during processing, handling and/or storage
262 (US Patent Nos. 5389389 and 5055313).

263
264 **Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or**
265 **feed when the petitioned substance is used. (7 CFR § 205.600 (b)(3))**
266

267 According to the Select Committee on GRAS Substances (SCOGS) Reviews on SAPP, it states that none of
268 the GRAS phosphates is intrinsically harmful and this use in foods does not present a hazard when the
269 total amount of phosphorus (P) ingested and the intakes of calcium (Ca), magnesium, vitamin D, and other
270 nutrients are satisfactory. The phosphorus supplied by GRAS phosphates, other than calcium phosphates,
271 added to foods is low in relation to the total amount of phosphorus naturally present in the diet. However,
272 the possibility that unreasonable increases in the usage of these phosphates in common foods could
273 significantly lower the Ca:P ration. Ingestion of excessive levels of phosphorus should be considered in
274 assessing the probability of a health hazard existing. The Select Committee has no evidence that the use of
275 any of these non-calcium phosphates as food ingredients at current levels is creating such a problem
276 (SCOGS, Report No. 32, 1975).

277
278 **Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of**
279 **FDA tolerances that are present or have been reported in the petitioned substance. (7 CFR § 205.600**
280 **(b)(5))**
281

282 No information was indentified to suggest that SAPP contains residues of heavy metal or other
283 contaminants in excess of FDA tolerances. The petitioned substance is not listed as a commodity (the
284 applicable human food and animal feed products) under FDA's "Guidance for Industry: Action Levels for
285 Poisonous or Deleterious Substances in Human Food and Animal Feed".

286
287 According to the Food Chemical Codex (2010-2011) monograph on SAPP, it stipulates the impurities
288 acceptable criteria are not more than 3 mg/kg, 0.005%, and 2 mg/kg of arsenic, fluoride, and lead,
289 respectively.

290
291 **Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the**
292 **petitioned substance may be harmful to the environment. (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. §**
293 **6517 (c) (2) (A) (i))**
294

295 Sodium acid pyrophosphate

296
297 SAPP is listed in the EPA List 4B– Other ingredients for which EPA has sufficient information to
298 reasonably conclude that the current use pattern in pesticide products will not adversely affect the public

299 health or the environment. No data on toxicity, water pollution potential, and ecological toxicity of SAPP
300 were found in the Pesticide Action Network (PAN) Pesticides Database.

301
302 In the petition, it states SAPP is not expected to produce any significant environmental effects when
303 recommended use instructions are followed in accordance with the Material Safety Data Sheet (MSDS).
304 SAPP released into the soil, sub-surface or surface waters may be taken up by plants and used as essential
305 nutrients, such as temporary algae blooms. Phosphates may also form precipitates, usually with calcium or
306 magnesium. The resultant compounds (calcium phosphate and magnesium phosphate) are insoluble in
307 water and become part of the soil or sediment (ICL Performance Products LP, 2007).

308 309 **Phosphoric acid**

310
311 Elemental phosphorus, which is produced from phosphate rock, is used for synthesis of phosphoric acid by
312 thermal process. Phosphate rock may contain significant amounts of naturally occurring heavy metals.
313 Mining operations processing phosphate rock can leave tailings piles containing elevated levels of
314 cadmium, lead, nickel, copper, chromium, and uranium (Gnandil, et al., 2006). Unless carefully managed,
315 these waste products can leach heavy metals into groundwater or nearby estuaries. Uptake of these
316 substances by plants and marine life can lead to concentration of toxic heavy metals in food products
317 (Gnandil, et al., 2006).

318
319 According to EPA (AP-42, 1995), the major source of emission from the thermal process is phosphoric acid
320 mist contained in the gas steam from the hydrator. It is not uncommon for as much as half of the total
321 phosphorus pentoxide to be present as liquid phosphoric acid particles suspended in the gas stream.
322 Efficient plants are economically motivated to control this potential loss with various control equipment.
323 Phosphoric acid mist can be transported in air and dissolved in water.

324
325 In the Australian Government's National Pollutant Inventory, it states that "phosphoric acid has moderate
326 acute and chronic toxicity to aquatic life in the waters of low alkalinity." While small quantities of
327 phosphoric acid can be neutralized by the alkalinity in aquatic ecosystems, larger quantities can lower the
328 pH for extended periods of time, posing a potential risk to aquatic organisms. Phosphate (formed when
329 phosphoric acid is dissolved) is unlikely to bioaccumulate in most aquatic species.

330
331 When spilled onto soil, phosphoric acid will infiltrate downward, the rate being greater with lower
332 concentration because of reduced viscosity (TOXNET). During transport through the soil, phosphoric acid
333 will dissolve some of the soil material, in particular, carbonate-based materials. The acid will be
334 neutralized to some degree by soil. However, significant amounts of acid will remain for transport down
335 toward the groundwater table. Upon reaching the groundwater table, the acid will continue to move in the
336 direction of groundwater flow.

337 338 **Sodium carbonate (soda ash)**

339
340 The principal air emissions from the sodium carbonate production methods are particulate emissions.
341 Particulate emissions are typically controlled by venturi scrubbers, electrostatic precipitators, cyclones or
342 baghouse filters. These control devices should be an integral part of the manufacturing process (EPA AP-
343 42, 1995).

344
345 Carbon monoxide, nitrogen oxides, sulfur dioxide, and carbon dioxide are other emissions of products of
346 combustion from direct-fired process. With the exception of carbon dioxide, which is suspected of
347 contributing to global climate change, available data are insufficient to quantify these emissions with a
348 reasonable level of confidence (EPA AP-42, 1995).

349
350 According to HSDB (TOXNET), the sesquicarbonate and monohydrate processes produce no large volume
351 of associated wastes. The major waste products – tailings, insoluble shale and minerals associated with
352 trona ore – are produced during processing. These solids along with purge liquors containing organic and

353 trace impurities should be sent to evaporation ponds where concentration of the aqueous stream is a first
354 step in the eventual recovery of residual alkali (TOXNET).

355
356 **Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the**
357 **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))**
358

359 In the SAPP report of SCOGS Reviews (Report No. 32, 1975), the Select Committee has weighed the
360 foregoing and concludes that there is no evidence in the available information on SAPP that demonstrates
361 or suggests reasonable grounds to suspect a hazard to the public when they are used at levels that are now
362 current or might reasonably be expected in the future.

363
364 OSHA has not established specific SAPP limits for occupational exposure limits. However, OSHA has
365 established limits for particulates not otherwise regulated and particulates not otherwise classified which
366 are the least stringent exposure limits applicable to dusts. Here are the OSHA Permissible Exposure
367 Limits: 15 mg/m³ (total dust) 8-hr Time Weighted Average (TWA) and 5 mg/m³ (repairable) 8-hr TWA.

368
369 According to the MSDS, the dry powder of SAPP may cause body irritation in some individuals.
370 Prolonged contact with the dry powder may cause drying or chapping of the skin. Workers exposed to the
371 dust of SAPP reported mild irritation of the nose and throat, with five of the eighteen workers reporting
372 nasal stuffiness and nosebleeds. High dust concentrations were reported to cause mild eye and skin
373 irritation (ICL Performance Products LP, 2007). Individuals handling SAPP should use suitable respiratory
374 equipment and wear appropriate protective clothing and eyewear. Hands and contaminated skin
375 thoroughly washed after handling SAPP.

376
377 The following toxicological information was excerpt from the MSDS (2007) provided by the petitioner:

378
379 "Data from ICL Performance Products LP single-dose (acute) animal studies with this material² are given
380 below:

381
382 Oral — rat LD₅₀ - 3,600 mg/kg; slightly toxic
383 Dermal — rabbit LD₅₀ - >7,940 mg/kg; practically non-toxic
384 Eye irritation — rabbit - 66.5/110; severely irritating
385 Skin irritation — rabbit - 0.7/8.0; slightly irritating
386 Inhalation — LC₅₀ - >0.58 mg/L, 4 hr. (rat) - maximum attainable concentration

387
388 No birth defects were reported in mice, hamsters, or rabbits given sodium acid pyrophosphate during
389 pregnancy. No adverse genetic effects were reported in standard tests using animals or bacterial or
390 yeast cells."

391
392 **Evaluation Question #11: Provide a list of organic agricultural products that could be substituted for**
393 **the petitioned substance. (7 CFR § 205.600 (b)(1))**
394

395 No information sources reviewed specifically address that an organic agricultural product could be
396 substituted for SAPP.

397
398 SAPP is listed on NOP the National List of Allowed and Prohibited Substance under §205.605
399 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as
400 "organic" or "made with organic (specified ingredients or food group(s))." (b) Synthetics allowed.
401 Currently, SAPP is only allowed for use as a leavening agent.

402 References

403
404

² Contains SAPP >95% w/w

- 405 Blanda, G., Cerretani, L., Comandini, P., Toschi, T.G., and Lercker, G. Investigation of off-odour and off-
406 flavour development in boiled potatoes. Food Chemistry 118 (2010) 283-290.
407
- 408 Beck, G.B. Compositions and Methods for Inhibiting Browning on Processed Produce. US Patent No.
409 5389389. Feb. 14, 1995.
410
- 411 Canada Natural Health Product Ingredients Database. Disodium pyrophosphate. [http://webprod.hc-
412 sc.gc.ca/nhpid-bdipsn/ingredReq.do?id=157&lang=eng](http://webprod.hc-sc.gc.ca/nhpid-bdipsn/ingredReq.do?id=157&lang=eng)
413
- 414 Canadian Organic Production Systems Permitted Substances Lists. National Standard of Canada,
415 CAN/CGSB-32.311-2006. Amended Oct. 2008 and Dec. 2009. [http://www.tpsgc-
416 pwgsc.gc.ca/cgsb/on_the_net/organic/032_0311_2006-
417 e_Amended%20Oct%202008%20and%20Dec%202009.pdf](http://www.tpsgc-pwgsc.gc.ca/cgsb/on_the_net/organic/032_0311_2006-e_Amended%20Oct%202008%20and%20Dec%202009.pdf)
418
- 419 Commission Directive 2002/82/EC of 15 October 2002, amending Directive 96/77/EC laying down
420 specific purity criteria on food additives other than colors and sweeteners. Official Journal of the
421 European Communities. [http://eur-
422 lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:292:0001:0028:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:292:0001:0028:EN:PDF)
423
- 424 Commission Regulation (EC) No 889/2008 of 5 September 2008, laying down detailed rules for the
425 implementation of Council Regulation (EC) No 834/2007 on organic production and labeling of organic
426 products with regard to organic production, labeling and control. Official Journal of the European Union.
427 <http://tilth.org/files/certification/2008.pdf>
428
- 429 Disodium carbonate. In Toxicology Data Network (TOXNET), Hazardous Substances Data Bank (HSDB).
430 U.S. National Library of Medicine. <http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?/~fiXCcD:1>
431
- 432 Disodium pyrophosphate. In Toxicology Data Network (TOXNET), Hazardous Substances Data Bank
433 (HSDB). U.S. National Library of Medicine. <http://toxnet.nlm.nih.gov/cgi-bin/sis/search>
434
- 435 Disodium Pyrophosphate, specification, monograph 1 (2006). Joint FAO/WHO Expert Committee on Food
436 Additives (JECFA). <http://www.fao.org/ag/agn/jecfa-additives/details.html?id=527>
437
- 438 EPA, List 4B – Inert Ingredients Ordered Alphabetically by Chemical Name. US EPA, Office of Pesticide
439 Programs, List of Inert Pesticide Ingredients. Updated August 2004.
440 <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5067227>
441
- 442 EPA, AP 42, Phosphoric Acid. In Ch 8: Inorganic Chemical Industry. Compilation of Air Pollutant
443 Emission Factors, 5th ed., Vol. 1, Jan 1995.
444
- 445 EPA, AP 42, Sodium Carbonate. In Ch 8: Inorganic Chemical Industry. Compilation of Air Pollutant
446 Emission Factors, 5th ed., Vol. 1, Jan 1995.
447
- 448 EPA, 40 CFR §180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a
449 tolerance. http://edocket.access.gpo.gov/cfr_2004/julqtr/pdf/40cfr180.910.pdf
450
- 451 FDA, 21 CFR §170.3 Definitions. [http://ecfr.gpoaccess.gov/cgi/t/text/text-
452 idx?c=ecfr&sid=751f4dea735c7591898657fe37f0e058&rgn=div8&view=text&node=21:3.0.1.1.1.1.1.1&idno=2
453 1](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=751f4dea735c7591898657fe37f0e058&rgn=div8&view=text&node=21:3.0.1.1.1.1.1.1&idno=2)
454
- 455 FDA, Guidance for Industry: Action Level for Poisonous or Deleterious Substances in Human Food and
456 Animal Feed, August 2000.
457 [http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Chemical
458 ContaminantsandPesticides/ucm077969.htm](http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ChemicalContaminantsandPesticides/ucm077969.htm)

459
460 FDA, Listing of Food Additive Status Part I
461 [http://www.fda.gov/Food/FoodIngredientsPackaging/FoodAdditives/FoodAdditiveListings/ucm09104](http://www.fda.gov/Food/FoodIngredientsPackaging/FoodAdditives/FoodAdditiveListings/ucm091048.htm)
462 [8.htm](http://www.fda.gov/Food/FoodIngredientsPackaging/FoodAdditives/FoodAdditiveListings/ucm091048.htm)
463
464 FDA, Listing of Food Additive Status Part II, Sodium acid pyrophosphate.
465 <http://www.fda.gov/Food/FoodIngredientsPackaging/FoodAdditives/ucm191033.htm>
466
467 Furia, T.E. Ch. 6 Sequestrants in Food. In CRC Handbook of Food Additives, 2nd ed. 1980.
468
469 Gnandil, K., Tchangbedjil, G., Killil, K., Babal, G., Abbel, E. The Impact of Phosphate Mine Tailings on the
470 Bioaccumulation of Heavy Metals in Marine Fish and Crustaceans from the Coastal Zone of Togo. Mine
471 Water and the Environment 25 (1): 56–62, March 2006.
472
473 Gogins, K.A.Z. and Smith, D.J. Frozen Cauliflower Product and Treatment Method. US Patent No.
474 4647462, Mar. 3, 1987. <http://www.freepatentsonline.com/4647462.pdf>
475
476 International Federation of Organic Agriculture Movements (IFOAM) Indicative List of Substances for
477 Organic Production and Processing. Apr. 24, 2008.
478 http://www.ifoam.org/about_ifoam/standards/pdfs/20080423_IFOAM_Indicative_List.pdf
479
480 Japan Food Sanitation Law Enforcement Regulations. Last amendment Nov. 29, 2005. Ministry of Health
481 and Welfare Ordinance No.166. <http://www.jetro.go.jp/en/reports/regulations/pdf/food-e.pdf>
482
483 Lampila, L. E. and Goober, J. P. Ch. 25 Food Phosphates. Food Additives, edited by Branen A. L.,
484 Davidson, P. M., Salminen, S., and Thorngate III, J. H. 2nd Ed., 2002. Marcel Dekker, Inc.
485
486 Merck, 2006. Sodium acid pyrophosphate in The Merck Index an Encyclopedia of Chemicals, Drugs, and
487 Biologicals, 14th Ed., p. 1478 (Monograph No. 8572). Merck & Co., Inc., Whitehouse Station, NJ, 2006.
488
489 Ng, K.C. and Weaver, M.L. Effect of pH and Temperature on the Hydrolysis of Disodium Acid
490 Pyrophosphate (SAPP) in Potato Processing. Am. J. of Potato Research, vol. 56, no. 2, pp.63-69. Feb. 1997.
491
492 Organic Materials Review Institute. 2009. Standards Manual. Organic Materials Review Institute; Eugene,
493 Oregon.
494
495 Potter, N.N. Ch. 23 Food Additives, Wholesomeness, and Consumer Protection. In Food Science, 2nd ed.
496 1973. The AVI publishing company, Inc.
497
498 Smith, O. Ch. 19 Culinary Quality and Nutritive Value of Potatoes. In Potatoes: Production, Storing
499 Processing. 2nd ed. 1977.
500
501 Smith, O. and Davis, C.O. Preventing discoloration in cooked and French-fry potatoes. Am Potato J
502 37:352, 1960.
503
504 Smith, O. and Davis, C.O. Potato quality VIX. Preventing of graying in dehydrated potato products.
505 Potato Chipper 21, No. 3. 1961.
506
507 Smith, O. and Davis, C.O. Potato quality XIII. Preventing after-cooking discoloration in oil blanched
508 French fries. Am Potato J 39:45-56, 1962
509
510 Sodium Acid Pyrophosphate, Food Chemical Codex, 7th Ed., 2010-2011. U.S. Pharmacopeia.
511

512 Sodium acid pyrophosphate, Material Safety Data Sheet. ICL Performance Products LP. Reference No:
513 AST10051. Mar. 12, 2007.
514
515 Sodium acid pyrophosphate, PAN Pesticides Database-Chemical.
516 http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC34345
517
518 Sodium acid pyrophosphate, Report No. 32, the Select Committee on GRAS Substances (SCOGS) Reviews.
519 1975. <http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=scogsListing&id=278>
520
521 The use of phosphates for potable water treatment.
522 <http://www.phosphatesfacts.org/pdfs/Potable%20Water%20Treatment.pdf>
523
524 USDA, Food Safety and Inspection Service. 2005. Principles of Preservation of Shelf-Stable Dried Meat
525 Products. Page 161, Issued May 11, 2005.
526 http://www.fsis.usda.gov/PDF/FSRE_SS_7Principles.pdf
527
528 USDA, Food Safety and Inspection Service. Federal Register/Vol. 64, No. 246/Thursday, December 23,
529 1999/Rules and Regulations. <http://www.fsis.usda.gov/oppde/rdad/FRPubs/88-026F.pdf>
530
531 Warren, B.Z. Food Preservative Compositions. US Patent No. 5055313. Oct, 8, 1991.