Potassium Acid Tartrate

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
potassium acid tartrate
potassium bitartrate
potassium hydrogen tartrate
monopotassium tartrate
potassium; 2,3-dihydroxybutanedioic acid
$KC_4H_5O_6$

Other Names:
Cream of tartar

Trade Names:
Faccula
Faecula
Faccla
Faecla

CAS Number: 868-14-4

Other Codes:
INS 336 (includes dipotassium tartrate)
E336 (includes dipotassium tartrate)

Summary of Petitioned Use

Potassium acid tartrate is currently allowed under the National Organic Program (NOP) regulations at 7 CFR 205.605(b) as a nonagricultural, synthetic substance for use as an ingredient in or on processed products labeled "organic" or "made with organic (specified ingredients or food group(s))." The FDA authorizes using potassium acid tartrate in a variety of applications as a direct food substance, including as a leavening agent, a pH control agent, and an antimicrobial agent.

Characterization of Petitioned Substance

Composition of the Substance:

Potassium acid tartrate is the potassium acid salt of L-(+)-tartaric acid, and is also called potassium bitartrate or cream of tartar.

Food grade potassium acid tartrate, as defined at 21 CFR 184.1077, must meet the Food Chemicals Codex analytical specifications, including the "assay" (the percentage of potassium acid tartrate in the tested sample) specification of 99% minimum (U. S. Pharmacopeia 2010). A typical lot would test as 99.8% potassium acid tartrate (Spectrum Chemical Mfg Corp). Cream of tartar as sold in most grocery stores is likely to assay at 99.5% or more potassium acid tartrate (Havenhill 1903). Historically, though, cream of tartar was commercially available in several grades of purity, with varying proportions of calcium tartrate or calcium sulfate. The usual qualities were 95%, 98%, and 99-100% potassium acid tartrate, as determined by titration of acidity (Klapproth 1914).

When the National Organic Standards Board (NOSB) was originally tasked with reviewing this substance in 1995 for inclusion on the National List, the substance was referred to broadly as "potassium tartrate." However, the historical documentation of this review suggests that potassium acid tartrate was not the only substance considered in their review, thus confusing the issue. Additional details are discussed in the *OFPA/USDA Final Rule* section of this report. The rest of this report will focus only on the currently listed substance potassium acid tartrate, CAS Reg. No. 868-14-4.

Source or Origin of the Substance:

Potassium acid tartrate is a by-product of winemaking. Potassium acid tartrate occurs naturally in grapes, the major fruit used to produce wine. Tartaric acid is one of the two major food acids found in grapes (malic acid is the other). Potassium is the major cation (positively charged mineral ion) in grapes and other fruits (IOM (Institute of Medicine) 2005). Grapes and wine are slightly acidic, with a pH around 3.5 to 4.0. At this pH, tartaric acid is predominantly in the bitartrate ionic form. Potassium acid tartrate has very low cold water solubility and thus is prone to crystallization and sedimentation at several steps during the winemaking process and even in unfermented grape juice.

During the winemaking process, sediments form that must be removed to produce a clear wine. "Lees" is the name of the sediment consisting of dead yeast cells, grape pulp, seed, and other grape matter that accumulates during fermentation (Wine School of Philadelphia). "Argol" and "tartar" are synonyms used to describe the crust that builds up in wine vats and casks. Argol is defined as crude potassium hydrogen tartrate, deposited as a crust on the sides of wine vats (Collins English Dictionary). Tartar is defined as a substance consisting essentially of cream of tartar that is derived from the juice of grapes and deposited in wine casks together with yeast and other suspended matter as a pale or dark reddish crust or sediment (Miriam-Webster Dictionary). Argol (tartar) consists of about 80% potassium acid tartrate (Osol and Hoover 1976). Potassium acid tartrate is only slightly soluble in cold water but highly soluble in hot water (6.1g/100 mL at 100°C). Extracting wine lees with hot water dissolves the potassium acid tartrate. When the filtered extraction solution is cooled, potassium acid tartrate precipitates as very pure crystals (>99.5% pure). No other reagents or solvents are involved in the extraction. For more information on the manufacturing processes, see Evaluation Question #1.

Properties of the Substance:

Physical and chemical properties of the substance are summarized in Table 1.

Table 1: Reported Physical and Chemical Properties of Potassium Acid Tartrate (Budavari 1996; U. S. Pharmacopeia 2010; Hodgman, Weast, and Selby 1959)

Property	Value
Chemical formula	$KC_4H_5O_6$
Molar mass	188.177
Appearance	white crystalline powder or colorless or slightly opaque crystals
Density	1.05 g/cm3 (solid)
Solubility in water	100 °C 6.1 g/100 mL (1 gram in 16 mL) 25°C 0.6 g/100 mL (1 gram in 165 mL) 20 °C 0.37 g/100mL (1 gram in 270 mL)
Solubility	soluble in acid, alkali; insoluble in acetic acid, alcohol
Refractive index (nD)	1.511
pH[1]	~ 3.6

Specific Uses of the Substance:

The most prevalent uses of potassium acid tartrate are as a component of leavening agents ("baking powder"), as a pH control agent, and as an antimicrobial agent. Other uses that are permitted by the FDA at 21 CFR 184.1077(c) in food processing include as an anticaking agent, a formulation aid, a humectant, a processing aid, a stabilizer and thickener, and a surface-active agent.

[1] A saturated aqueous solution of potassium acid tartrate at 25°C is used as a standard pH reference. This solution has a pH of precisely 3.57 ± 0.02 (Lingane 1947).

The uses cited in the 1995 Technical Advisory Panel review -"as part of aluminum-free baking powder" and "for baking non-yeast breads" - reflect the FDA allowance of potassium acid tartrate as a leavening agent in baked goods.

Approved Legal Uses of the Substance:

The FDA authorizes using potassium acid tartrate in a variety of applications as a direct food substance, at 21 CFR 184.1077, in artificially sweetened jelly and preserves at 21 CFR 150.141 and 150.161, and for use in animal feeds at 21 CFR 582.1077.

The EPA makes no mention of potassium acid tartrate in 40 CFR 180 (tolerances and exemptions from tolerances for pesticide chemicals in foods). The USDA Food Safety Inspection Service (FSIS) permits the use of the sodium tartrate and sodium potassium salts of L-tartaric acid to acidify margarine and oleomargarine at 9 CFR 424.21(c), but not potassium acid tartrate.

Action of the Substance:

Antimicrobial agent: A pure solution of potassium acid tartrate has a pH of about 3.6 (Lingane 1947). Using this source of acidity can help maintain food pH below 4.6, where botulinum spores do not grow.

pH Control agent: Potassium acid tartrate has a pH of about 3.6 when it dissolves in water (Lingane 1947). It acts as a "pH buffer," since it can neutralize acidity with partial conversion to tartaric acid, or neutralize alkalinity with partial conversion from bitartrate to tartrate, in the pH range of 2.5 to 5.0, without a significant change in pH (Lu et al. 2008).

Leavening agent in baked goods: A dry mix of potassium acid tartrate and sodium bicarbonate is stable (EatByDate LLC 2012). When wetted with water, such as in a dough, the acidic potassium acid tartrate and the alkaline sodium bicarbonate dissolve and react, releasing carbon dioxide gas and giving baked goods an 'airy' texture. As the temperature of the dough increases during the baking process, the solubility of potassium acid tartrate in water increases, accelerating the reaction. The reaction of potassium acid tartrate and sodium bicarbonate in water can be described by the following chemical equation:

$$K^+H^+\text{tartrate}^{-2} + Na^+H^+CO_3^{-2} \rightarrow Na^+K^+\text{tartrate}^{-2} + H_2O + CO_2\ (\text{gas})$$

Sodium potassium tartrate, the other product of this reaction, is itself an affirmed GRAS food ingredient listed at 21 CFR 184.1804.

Combinations of the Substance:

The industrial material sold as a food ingredient, "Potassium Acid Tartrate, Powder, FCC," is at least 99% pure as required by the Food Chemicals Codex (U. S. Pharmacopeia 2010). The "cream of tartar" sold in grocery stores declares only potassium acid tartrate on the ingredient list.

To make a baking powder, potassium acid tartrate is dry-blended with "baking soda," pure sodium bicarbonate, a nonagricultural, nonsynthetic substance listed at 7 CFR 205.605(a). Cornstarch is the typical diluent. Potassium acid tartrate is very stable as long as it is dry, so baking powder containing these three ingredients remains potent as long as it is kept dry (EatByDate LLC 2012).

Status

Historic Use:

The most significant historical use of potassium acid tartrate has been in baking, where it has been used in combination with sodium bicarbonate as a leavening agent (Federation of American Societies for Experimental Biology. Life Sciences Research Office 1979).

Organic Foods Production Act, USDA Final Rule:

Potassium acid tartrate has been on the National List as an allowed nonagricultural synthetic substance used in processing organic foods since the National List was first established.

When this substance was reviewed by the NOSB in 1995, it was referred to simply as "potassium tartrate." However, the historical documentation of the review of this substance suggests that a substance other than potassium acid tartrate may have been included in the review.

The information packet generated for the original NOSB evaluation of "potassium tartrate" in 1995 included reviews by two Technical Advisory Panel (TAP) food chemistry and food processing experts who focused on the GRAS food ingredient potassium acid tartrate, with the chemical formula $KC_4H_5O_6$ and CAS Registration Number 868-14-4, the subject of this Technical Report. Both TAP reviewers characterized potassium acid tartrate as "isolated from wine or grape juice" and "nearly all is a product of the wine industry."

The 1995 information packet also included a source document labeled "NOSB Material Database" provided by the NOP which was totally focused on "potassium tartrate," with the chemical formula $K_2C_4H_4O_6$. This potassium tartrate is commonly described as "dipotassium tartrate" to avoid confusion with "potassium bitartrate." The CAS Registration Number of potassium tartrate (a.k.a. dipotassium tartrate) is 921-53-9. Potassium tartrate was declared to be "synthetic allowed" in this "NOSB Material Database" document. (It is noteworthy that potassium tartrate, CAS Reg. No. 921-53-9, is not a GRAS food ingredient in the United States.)

The discussion of these substances reported in the minutes of the October 1995 NOSB meeting was about the substance(s) identified as "potassium acid tartrate (or potassium tartrate made from tartaric acid)." The NOSB voted unanimously that "this material" was synthetic. The NOSB voted on an annotation – "shall be derived from tartaric acid from grapes" – but the motion failed. Significantly, the two previous materials evaluated by the NOSB at that meeting were "tartaric acid (made from grape wine)," which was unanimously decided to be nonsynthetic, and "tartaric acid (made from malic acid)," which was unanimously decided to be synthetic.

The original National List had two relevant listings at §205.605(b) (nonagricultural synthetic substances), one for "Potassium acid tartrate" and the other for "Potassium tartrate made from tartaric acid." The listing for "Potassium tartrate made from tartaric acid" was removed from §205.605(b) in October 2007. The substance "Potassium acid tartrate" was retained on the National List at §205.605(b) with no annotation. Retention of "potassium acid tartrate" on the National List was reaffirmed by the NOSB in April 2010 as part of the 2012 Sunset review process. Currently, "potassium acid tartrate" is on the National List at §205.605(b) as a nonagricultural synthetic with no annotation.

International

International guidance and regulations include the use of potassium acid tartrate (INS 336i) in organic processing, generally consistent with the limited uses described by FDA at 21 CFR 184.1077(c). The European-focused regulations and guidance – CODEX, IFOAM and the EU – additionally include potassium tartrate (dipotassium tartrate) (INS 336ii) as an allowed potassium tartrate.

Canadian General Standards Board Permitted Substances List, CAN/CGSB-32.311-2015

Potassium acid tartrate ($KC_4H_5O_6$) is a permitted processing substance listed in Table 6.3, ingredients classified as food additives, with the following annotation: "If the non-synthetic form is not commercially available, the synthetic form is permitted."

Japan Agricultural Standard (JAS) for Organic Production
Article 4, Table 1, Food Additives permits the food additive INS 336i, potassium acid tartrate, for limited use for grain processed foods or confectionary only.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
The Codex organic guidelines permit the use of potassium acid tartrate (INS 336i) and dipotassium tartrate (INS 336ii) in plant foods, specifically confectionary, flours and starches, and cakes, but not in animal foods.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Consistent with the Codex guidelines, the European Community regulation permits the use of the potassium tartrates (i.e., both potassium acid tartrate E 336i and dipotassium tartrate E 336ii) in processing organic foods of plant origin (EC No. 889/2008 Annex VIII, Section A Food Additives).

IFOAM – Organics International
The IFOAM Norms, Appendix 4, Table 1, permit the use of INS 336 (i.e., both potassium acid tartrate E 336i and dipotassium tartrate E 336ii) as an additive and also as a processing and post-harvest handling aid, without limitation.

Evaluation Questions for Substances to be used in Organic Handling

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

The FDA regulation requires that the food additive "potassium acid tartrate" must be obtained as a by-product of wine manufacture (21 CFR 184.1077). No alternative manufacturing processes are allowed for food uses.

Winemaking process
The process for converting grapes into wine has several steps (Hornsey 2007):

1. Harvesting ripe grapes: grapes should be picked when at optimum sugar, acid and pH levels.
2. Crushing grapes: grapes are crushed to form "must," a mixture of crushed grapes, juice and stems. The term "must" refers to this mixture from the time the grapes are crushed until the mixture is pressed.
3. Adding sulfites, when required, to kill unwanted 'wild' yeast strains that have limited ethanol tolerance so that they stop growing before consuming all of the grape sugar.
4. Adding ethanol-tolerant yeast that will convert sugar to alcohol.
5. Primary fermentation, in open vats, that converts about two-thirds of the grape sugars to alcohol, taking about a week or so.
6. Pressing grapes, to separate the wine from the skins, seeds, stems and sediment. (White wines may be pressed before primary fermentation.) The compressed skins, seeds, stems and sediment are collectively described as "press cake."
7. Secondary fermentation, in closed vats (anaerobic conditions), to convert the rest of the grape sugars to alcohol.
8. Racking, a process of siphoning wine from one vessel to another in order to remove the wine from insoluble deposits (lees and sediment) in the secondary fermentation vessels.

9. Aging for six months to a year with several rackings to eliminate more lees and sediment.
10. Cold stabilization: (optional) chilling wine to about 30°F (-1°C) so that potassium bitartrate crystals precipitate (to form lees that can be removed by filtration).

This continuous deposition of lees and tartar during the entire fermentation process is related to the increasing alcohol content of the wine. The solubility of potassium acid tartrate in water decreases as the alcohol content increases (Hornsey 2007; Berg and Keefer 1958).

Converting winemaking by-products to potassium acid tartrate

Sources of potassium acid tartrate in winemaking are the various residues described above: press cake, lees and sediment. Extracting press cake, lees and sediment with hot water dissolves potassium acid tartrate. Activated charcoal removes soluble colored impurities from the supernatant. Cooling the supernatant causes potassium acid tartrate to crystallize[2]. The crystals are easily separated and dried.

Water is the only solvent or reagent used to extract potassium acid tartrate from the sediment. No chemical changes occur during extraction.

All of the potassium and all of the tartrate that make up the composition of potassium acid tartrate originate in the grapes. Grapes contain high concentrations of tartrates. Nagel et al. (1972) analyzed musts (crushed grapes) and wines made from these musts for their total tartrate content. The musts contained 4,200 to 11,000 mg/L whereas the wines contained only 400 to 3,700 mg/L, indicating that 60% to 90% of the tartrate (25 to 50 mEq/L) is lost in the press cake and lees during the winemaking process.

The L-(+) stereoisomer of tartaric acid is the form of tartaric acid present in grapes (Federation of American Societies for Experimental Biology. Life Sciences Research Office 1979) and is the unique stereoisomer permitted in food grade potassium acid tartrate by the FDA regulation at 21 CFR 184.1077.

Grapes also contain high concentrations of potassium. The major positively charged electrolyte mineral in grapes is potassium. Raw grapes contain 1,910 to 2,030 mg of potassium per kg, or about 50 mEq/kg, a sufficient amount to combine with the tartrate moiety to form potassium acid tartrate.

At the pH of grapes and wine, the primary tartrate species in these foods is potassium acid tartrate, and the predominant ionic form of tartaric acid is the "bitartrate" form. The pH of most wines falls around 3 to 4; about 3.0 to 3.4 is desirable for white wines, while about 3.3 to 3.6 is best for reds (Wine Spectator 2016). Tartaric acid has two carboxylic acid groups. A 0.1 N (7.5 g/L) solution of unneutralized tartaric acid has a pH of 2.2 (Budavari 1996). A saturated solution of potassium acid tartrate, which has one of these carboxyl groups neutralized with a potassium ion, has a pH of about 3.6. Dipotassium tartrate has both carboxyl groups neutralized with potassium ions; an aqueous solution of dipotassium tartrate has a pH between 7 and 8 (Budavari 1996).

Detartration during grape juice processing

Cream of tartar is also commercially produced as a by-product of grape juice processing. Wine, especially artisanal and homemade wine, can be produced by fermenting grape juice, either single strength juice or juice concentrate. Some kits for home winemaking rely on juice concentrates. Processors of grape juice and grape juice concentrate routinely cold stabilize these products to remove excessive potassium acid tartrate (Bates, Morris, and Crandall 2001). This improves the appearance of the wine and the perception of its quality.

> "Grape juice is cooled to precipitate potassium acid tartrate prior to bottling, in order to prevent precipitation in the retail juice product. Grapes are unique from other fruits in that, after juice extraction, the argols (potassium bitartrate, tartar in crude form) and tartrates must be precipitated. Otherwise, the argols will settle out upon cooling or even when filtered juice is refrigerated. These

[2] A YouTube video demonstrates how commercial cream of tartar is converted into chemically pure potassium acid tartrate: https://www.youtube.com/watch?v=nsrFv0I9hRA

> crystals, although harmless, are aesthetically unpleasant and can be mistaken for glass fragments. Thus to accomplish detartration (cold stabilization), the filtered juice is flash-heated at 80 to 85°C in a tubular or plate-type heat exchanger, rapidly cooled in another heat exchanger to -2.2°C and placed in tanks for rapid settling of argols. Seeding with bitartrate crystals and ion exchange methods exist to accelerate the cold stabilization step. The final processing into a single-strength juice or concentrate can occur once the argols have settled and the juice is racked off. The sediment can be filtered, resterilized and stored to allow the argols to settle again for optimal recovery of juice." (Bates, Morris, and Crandall 2001)

Joslyn and Tucker (Joslyn and Tucker 1930) were able to remove potassium tartrate (cream of tartar) more efficiently from grape juice by freezing the juice.

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

As noted in the response to Evaluation Question #1, potassium acid tartrate is present in raw grapes and is created by the naturally occurring reaction of the tartaric acid and potassium present in the grapes. The extraction process to isolate pure potassium acid tartrate from the potassium acid tartrate-containing lees, sediment, and press cake is very simple: mix these by-products with hot water to dissolve the potassium acid tartrate; separate the hot water supernatant from any undissolved residue; cool the supernatant so the potassium acid tartrate forms crystals; isolate the crystals; and dry them. No chemical changes occur during extraction. Nevertheless, potassium acid is classified as synthetic as indicated by its listing at §205.605(b) as an allowed *synthetic* nonagricultural substance.

Potassium acid tartrate is a precursor to tartaric acid, which is another substance that is listed on the National List. Tartaric acid, with the annotation "made from grape wine," is listed at §205.605(a) as an allowed *nonsynthetic*, nonagricultural (nonorganic) substance. Tartaric acid is produced by reacting potassium acid tartrate, the subject of this Technical Report, with hydrochloric acid to convert the bitartrate ion into soluble tartaric acid; adding calcium (as calcium hydroxide) to precipitate the tartaric acid as calcium tartrate; isolating the calcium tartrate precipitate; and then reacting calcium tartrate with sulfuric acid to form tartaric acid and insoluble calcium sulfate ("gypsum") (Budavari 1996). This isolation process is similar to how citric acid is recovered from lemons or from fermentation media. In 1995, the NOSB voted that tartaric acid made from by-products of winemaking was nonsynthetic. The FDA specification for tartaric acid at 21 CFR 184.1099 requires it to be a by-product of winemaking.

Interestingly, tartaric acid from grape wine is classified as nonsynthetic, whereas the precursor of tartaric acid, potassium acid tartrate from grape wine, is classified as synthetic.

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

Potassium acid tartrate is present in grape juice and wine; it is extracted from natural sources: press cake, lees, and sediment recovered from winemaking. It is extracted with potable water and undergoes no chemical change during extraction or crystallization. Based on the decision tree in Draft Guidance NOP-5033-1, this manufacturing process could be considered nonsynthetic, although it is currently classified as a synthetic substance at §205.605(b).

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

Potassium acid tartrate is a GRAS food ingredient. In the 1970s, the Life Sciences Research Office of the Federation of American Societies for Experimental Biology, under contract from FDA, assembled qualified scientists to evaluate the health aspects of tartaric acid and those of its salts allowed as food additives. These consultants comprised the Select Committee on GRAS Substances (Federation of American Societies for Experimental Biology. Life Sciences Research Office 1979). Their report, "Evaluation of the Health Aspects of Potassium Acid Tartrate, Sodium Potassium Tartrate, Sodium Tartrate and Tartaric Acid as Food Ingredients," was published in 1979 (Federation of American Societies for Experimental Biology. Life Sciences Research Office 1979). The Select Committee concluded that:

> "There is no evidence in the available information of L(+) potassium acid tartrate, L(+) sodium potassium tartrate, L(+) sodium tartrate, and L(+) tartaric acid that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current, or that might reasonably be expected in the future."

As a result of this safety determination, the FDA moved these four GRAS substances from 21 CFR Part 182 – "Substances Generally Recognized As Safe" – to 21 CFR Part 184 – "Direct Food Substances Affirmed as Generally Recognized As Safe."

The FDA defines "potassium acid tartrate" at 21 CFR 184.1077(a): "Potassium acid tartrate (C4H5KO6, CAS Reg. No. 868-14-4) is the potassium acid salt of L-(+)-tartaric acid and is also called potassium bitartrate or cream of tartar. It occurs as colorless or slightly opaque crystals or as a white, crystalline powder. It has a pleasant, acid taste. It is obtained as a byproduct of wine manufacture."

No method of manufacture other than as a by-product of wine manufacture is encompassed by this regulation. The FDA definition of potassium acid tartrate would appear to require an agricultural source. Grapes and wine are agricultural products. The by-products that naturally settle out of grape juice and fermenting wine are used to make this food ingredient, with minimal processing (hot water extraction). However, the NOP regulation classifies potassium acid tartrate as nonagricultural at 7 CFR 205.605.

Specification of the L(+) form of tartaric acid is biologically significant, since this is the stereoisomer produced by fruits in nature (Federation of American Societies for Experimental Biology. Life Sciences Research Office 1979). The Food Chemicals Codex monographs for each of the four affirmed GRAS tartrate substances specify the L(+) configuration (U. S. Pharmacopeia 2010).

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

The FDA describes the technical functional effects for which direct human food additives may be added to foods at 21 CFR 170.3(o). Antimicrobial agents that preserve food by preventing growth of microorganisms and subsequent spoilage, including fungistats, mold and rope inhibitors, are considered 'preservatives.' The primary function of potassium acid tartrate is not as a preservative in this strict sense.

Potassium acid tartrate acts as an acidulant and as a buffer. These characteristics can facilitate maintenance of a low, 'safe' pH in processed foods. Thermally processed foods low in pH ("high acid foods") packaged in hermetically sealed containers are subject to the requirements of Title 21 CFR 113. "Low acid" foods, generally defined as foods with a finished equilibrium pH greater than 4.6 (21 CFR 113.3(n)), must undergo more vigorous processing to achieve sterilization.

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)).

Potassium acid tartrate is not used to recreate or improve flavor, color, texture or nutritive value lost in processing. Potassium acid tartrate can be used as the acidic component of baking powder. During the baking process, carbon dioxide is liberated from sodium bicarbonate (baking soda) by its reaction with potassium acid tartrate. The carbon dioxide leavens the baked good, creating an 'airy' texture.

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

Using potassium acid tartrate rather than sodium acid pyrophosphate as the acidulant in baking powder is nutritionally beneficial in that it increases dietary intake of potassium and reduces the dietary intakes of sodium and phosphorus. Intakes of sodium in the United States are generally considered to be excessive, as discussed in the Technical Report for Phosphates (Organic Materials Review Institute 2016).

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

The food grade ingredient potassium acid tartrate complies with the Food Chemicals Codex standard for lead (< 4 ppm).

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

Potassium acid tartrate is produced by utilizing a waste product of winemaking to make a useful food ingredient, using the simple process of hot water extraction. This process is generally regarded as environmentally friendly because it recycles waste products and does not involve harmful chemicals. The supernatant water after cold crystallization can be reheated and used again to extract more potassium acid tartrate. The impurities removed from argol, lees and tartar to produce potassium tartrate are the soluble, biodegradable grape components such as colored pigments.

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

The estimated intake of potassium acid tartrate from ingestion of foods containing it as a food additive is 30 mg per day (Federation of American Societies for Experimental Biology. Life Sciences Research Office 1979). Potassium represents about 20% of the weight of potassium acid tartrate, so this amounts to only 6 mg/day against a Recommended Daily Intake of 4,700 mg/day. A 200-mL glass of wine is estimated to contain 400 mg of tartrate and thus about 500 mg of potassium acid tartrate (about 100 mg of potassium).

Voluntary overdose of potassium acid tartrate can lead to potassium toxicity. Cream of tartar has a long history of use as a purgative[3] (Rusyniak et al. 2013). Rusynaik et al. (2013) reported on an instance where two young men, who attempted to use cream of tartar as a purgative consumed six tablespoons of cream of tartar 3 to 5 times daily for one day. Each was hospitalized for potassium toxicity, the symptoms of which include electrolyte imbalance and effects on cardiac rhythm. Both recovered. Six tablespoons of cream of

[3] A "purgative" is an agent used for purging the bowels.

tartar were estimated to provide almost 17,000 mg of potassium, which is more than three times the Recommended Daily Intake.

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

Potassium acid tartrate is mentioned in 21 CFR 150 as an optional ingredient for use in fruit butters, jellies, preserves and related products. Virtually all of these products allow for the use of a buffering agent, an approved pH-adjusting function of potassium acid tartrate. Section 21 CFR 150.161(a)(3) spells out the many options: "sodium citrate, sodium acetate, sodium tartrate, monosodium phosphate, disodium phosphate, trisodium phosphate, sodium potassium tartrate, potassium citrate, potassium acid tartrate, or any combination thereof, in an amount not exceeding 2 ounces avoirdupois per 100 pounds of the finished food."

Potassium acid tartrate, under its common name "cream of tartar," competes with calcium monophosphate (anhydrous and monohydrate) and sodium acid pyrophosphate as the acidulant in baking powders. The two phosphates have advantages over cream of tartar in managing the release of carbon dioxide during the baking process, since they are less soluble in warm water (Edwards 2007). The nutritional advantages of potassium acid tartrate are (1) a metabolizable anion – tartrate – rather than a mineral anion – phosphate – which frequently is consumed at an undesirably high level in the diet (Organic Materials Review Institute 2016), and (2) a cation – potassium – which in most diets is present at suboptimal levels rather than the sodium cation contributed by sodium acid pyrophosphate (Organic Materials Review Institute 2015, 2016).

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

Nonsynthetic acids listed at §205.605(a) – citric, lactic, and tartaric made from grape wine – could be viable replacements for acidulation. Salts of these food acids, especially citric acid, with calcium hydroxide, potassium hydroxide or sodium hydroxide, can replicate the functional effects of potassium acid tartrate as a pH-adjusting agent, as noted at 21 CFR 150.161(a)(3), but these salts are classified as synthetic as indicated by their listing at §205.605(b) synthetic allowed (e.g., calcium citrate, sodium citrate, potassium citrate).

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

An alternative to potassium acid tartrate, currently classified as a synthetic nonagricultural substance, would be to isolate cream of tartar from organically grown grapes. Organically grown grapes were found to contain as much as or more tartaric acid than conventionally grown grapes (Henick-Kling 1995), depending on the degree of maturity of the grapes. Organic grapes used to produce wine consequently would be expected to create at least as much lees and argol during the winemaking process as conventionally grown grapes. Isolation of potassium acid tartrate from winemaking sediments can be accomplished using processes and substances permitted by the NOP regulations (e.g., water extraction; activated charcoal as filtering aid), thus raising the question of whether potassium acid tartrate could be eligible for organic certification.

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