Tartaric Acid
Handling

Identification of Petitioned Substance

Chemical Names:
2,3-dihydroxybutanedioic acid

Other Name:
2,3-dihydroxysuccinic acid
Thearic acid
Uvic acid
L(+) tartaric acid
D(-) tartaric acid
Mesotartaric acid
Racemic acid

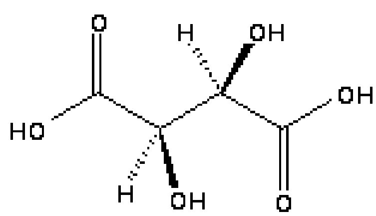
Trade Names:
None

CAS Numbers:
L(+) tartaric acid: 87-69-4
D(-) tartaric acid: 147-71-7
Mesotartaric acid: 147-73-9
Racemic acid: 133-37-9

Other Codes:
L(+) tartaric acid: 205-695-6
D(-) tartaric acid: 201-766-0
Mesotartaric acid: 205-696-1
Racemic acid: 205-105-7

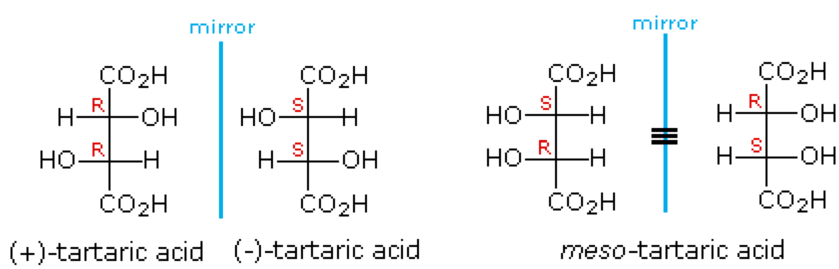
Characterization of Petitioned Substance

Composition of the Substance:
Tartaric acid [HOOCCH(OH)CH(OH)COOH; $C_4H_6O_6$] is a four-carbon, organic acid with two OH groups on the second and third carbon atoms, and two carboxylic acid (COOH) groups involving the first and fourth carbons. The chemical structure of L(+) tartaric acid is shown below:



Source: Reusch, 1999

Tartaric acid exists in three distinct isomeric forms, as shown in the Fisher projection formulas below. Two forms are chiral isomers, which means that the molecules are non-superimposable on their mirror images. The form of tartaric acid found naturally in grapes and often produced synthetically for use in handling is the L(+) tartaric acid isomer. This form is generally referred to as the 'dextro form' (Church and Blumberg, 1951). The D(-) form of tartaric acid is less common in nature and has almost no practical uses. The third form is an achiral isomer, mesotartaric acid, that also can be manufactured (Reusch, 1999).



Source: Reusch, 1999

Properties of the Substance:
An organic acid, tartaric acid is an odorless, white crystalline solid (Smith and Hong-Shum, 2008). The substance has a strong, tart taste and contributes to the flavors of many fruits (Furia, 1972). It has a high Ka (acid-dissociation equilibrium constant; measure of the strength of acidity) and possesses microbial stability. It is found naturally in plants including grapes, bananas, and tamarinds (The Chemical Company, 2010).

The physical and chemical properties of the tartaric acid are provided in Table 1.

Table 1. Physical and Chemical Properties of Tartaric Acid

Physical or Chemical Property:	Value:
Physical State	Solid
Appearance	White
Odor	None
Taste	Extremely tart
Molecular Weight	150.09
Boiling Point	N/A
Melting Point	168° C – 170° C
Solubility	Easily soluble in cold water, hot water, methanol, glycerol.
Vapor Pressure	N/A
Relative Density	1.76 (water = 1)

Source: Furia, 1972; Sciencelab.com, Inc., 2010

Specific Uses of the Substance:
Tartaric acid is a natural organic acid that is in many plants especially grapes, bananas, and tamarinds. Tartaric acid can be used to create several different salts, including tartar emetic (antimony potassium tartrate), cream of tartar (potassium hydrogen tartrate), and Rochelle salt (potassium sodium tartrate). The primary uses of tartaric acid are associated with its salts (The Chemical Company, 2010).

Tartaric acid and its salts have a very wide variety of uses. These include use as an acidulant, pH control agent, preservative, emulsifier, chelating agent, flavor enhancer and modifier, stabilizer, anti-caking agent, and firming agent. It has been used in the preparation of baked goods and confectionaries, dairy products, edible oils and fats, tinned fruits and vegetables, seafood products, meat and poultry products, juice beverages and soft drinks, sugar preserves, chewing gum, cocoa powder, and alcoholic drinks (Smith and Hong-Shum, 2003; The Chemical Company, 2010).

As an acidulant and flavoring agent, tartaric acid is known to enhance the flavors of the fruits in which it is a natural derivative. Tartaric acid is commonly used to enhance grape flavors and to enhance flavors associated with raspberry, oranges, lemon, gooseberry, and currant (Hui, 2006a; Furia, 1972; Heath, 1981).

Tartaric acid and its immediate byproducts are particularly useful in baking. Due to its acidic properties, tartaric acid is used in baking powder in combination with baking soda (sodium bicarbonate). When tartaric acid reacts with sodium bicarbonate, carbon dioxide gas is produced, causing various baking products to 'rise' without the use of active yeast cultures. This action alters the texture of many foods. Tartaric acid and its salts are used in pancake, cookie, and cake mixes because of these properties (Hui, 2006b). Cream of tartar is used to make cake frosting and candies (The Chemical Company, 2010).

In the winemaking process, tartaric acid is used to alter acidity. Tartaric acid is a natural component of grapes, which are frequently used in the production of wine. However, some wines are not made with grapes and a tablet of nonsynthetic or synthetic tartaric acid is added to wine to increase the mixture's acidity. In addition, organic acids, such as tartaric acid, are known to have antimicrobial properties which make them an important component in wine and other foods. These antimicrobial properties are associated with the natural acidity of tartaric acid, which creates an unfavorable environment for microorganisms to survive and grow. The typical concentrations of tartaric acid in wines range 1500 to 4000 mg/L. Higher levels may cause an unpleasant and sour taste (Bastos et al., 2009; Waite and Daeschel, 2007).

Industrial and manufacturing uses of tartaric acid and its derivatives include leather tanning, mirror silvering, ceramics, photography, and blue printing (ferric tartarate serves as a source of blue ink). Diethyl tartarate and dibutyl tartrate are common esters of tartaric acid and are used in dyeing textiles and the manufacture of lacquer (The Chemical Company, 2010).

Tartaric acid is used in several medical applications including the manufacture of solutions that are used to determine glucose levels. Rochelle Salt is occasionally used as a laxative. Tartaric acid also acts as a skin coolant and cream of tartar is an effective cleansing agent. In non-permanent hair dyes, tartaric acid acts as a mild acid (The Chemical Company, 2010).

Approved Legal Uses of the Substance:

Since 2003, tartaric acid has been included on the National List of Allowed and Prohibited Substances (hereafter referred to as the National List) as a nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." This material is listed both as a nonsynthetic allowed substance if made from grape wine (i.e. L(+) tartaric acid) [7 CFR §205.605 (a)] and a synthetic allowed (7 CFR §205.605 (b)) substance if made from malic acid (i.e. a synthetic form of L(+) tartaric acid). Following review of data detailing the manufacture of synthetic L(+) tartaric acid, it has been determined that the regulatory language (7 CFR §205.605 (a); 7 CFR §205.605 (b)) referring to synthetic L(+) tartaric acid should be altered to say 'made from maleic acid' rather than 'made from malic acid.' Data included in the U.S. Food and Drug Administration (FDA) Generally Recognized as Safe (GRAS) notice for synthetic L(+) tartaric acid (discussed in more detail below) supports this conclusion (FDA, 2009).

The FDA classifies nonsynthetic L(+) tartaric acid and its salts (i.e. L(+) potassium acid tartrate, L(+) sodium potassium tartrate acid) to be GRAS. The FDA has compiled consumer data and determined that 6 mg each of tartaric acid and potassium acid tartrate added to foods is ingested daily per capita (a total of about 0.2 milligrams (mg) per kilogram (kg) in an adult). These substances are not believed to be hazardous to the general public if used at used at levels that are now typical, or that might reasonably be expected in the future (FDA, 2011a). In 2006, the FDA ruled that a synthetic form of L(+) tartaric acid is also considered GRAS. Synthetic L(+) tartaric acid is produced by the conversion of maleic anhydride to tartaric acid through the enzymatic action of the enzyme cis-epoxisuccinate hydrolase contained in immobilized *Rhodococcus ruber* cells (FDA, 2009).

The FDA also regulates the use of L(+) tartaric acid as an agent for compensating for the natural acidity of the fruit juice ingredient in fruit jellies, jams, preserves, butters, or related products. According to 21 CFR 150.141 and 150.161, the quantity of tartaric acid used in these products must a reasonable quantity for adding to the overall acidity of the product. Additionally, the use of L(+) tartaric acid is permitted as a neutralizing agent in cacoa products, including chocolate liquor and breakfast cocoa (discussed in detail in 21 CFR 163). The total amount of tartaric acid permitted for use in cocoa products is not to exceed 1.0 part by weight (FDA, 2011b).

Action of the Substance:

Generally, only L(+) tartaric acid is used in food applications. Tartaric acid increases the acidity of a solution and acts as an anti-microbial agent to preserve a food. The addition of tartaric acid (or products already known to contain tartaric acid) lowers the pH of a solution. In fruit juices, tartaric acid helps to maintain the proper sugar/acid balance in fruit juices. By lowering the pH of a solution, the tartaric acid acts as an effective antimicrobial agent by creating an environment too acidic for most microorganisms to grow (Nagy et al., 1993; Waite and Daeschel, 2007).

Baking powder is used in many baking applications and tartaric acid produces carbon dioxide gas following reaction with sodium bicarbonate. This action causes baking products to 'rise' without the use of active yeast cultures. The use of baking powder containing tartaric acid alters the texture of many foods (Hui, 2006b).

As an emulsifier, tartaric acid acts by attaching to a surface and then links two repelling substances, such as oil and water. This action is useful in the production of dairy products including milk because fats settle on the surface of the milk (i.e. cream) and must be homogeneously mixed to create milk for drinking (Hansenhuettl and Hartel, 2008).

Tartaric acid acts as a chelating agent and is used in the production of canned fruit products (Belitz et al., 2009). Chelates are formed when an organic acid binds with a metal and prevents its reaction with another chemical. Chelating agents prevent enzymatic browning through the formation of a complex a free metal and inhibitors through an unshared pair of electrons in their molecular structures (Martín-Belloso and Fortuny, 2009).

Combinations of the Substance:
At the end of the winemaking process, L(+) tartaric acid is an unwanted component. In order to precipitate tartaric acid, winemakers add calcium hydroxide and potassium hydroxide to the mixture and then evaporate this solution, producing a white powder that contains calcium or potassium tartrate along with other chemical components. The powder is sold to manufacturing facilities that purify L(+) tartaric acid (Yalcin et al., 2008).

L (+) tartaric acid is used in combination with citric acid to impart tartness to many flavors, including wild cherry and sour apple flavors (Smith and Hong-Shum, 2003).

In food and beverages, L(+) tartaric acid us used a synergist to increase the antioxidant effect of other substances (Hui, 2006a).

Status

Historic Use:
The ancient Greeks and Romans first identified tartaric acid as a by-product of winemaking; however the product was not harnessed for use because wine was not traditionally stored in wooden casks or containers suitable for the sediment that contains the crude tartar. As the use of wooden casks for the collection of wine increased, so did the collection of crude tartar. Some winemakers began exclusively using wooden casks for the storage of wine so that crude tartar could be collected more efficiently (Royal Society of Arts, 1899).

In the 1400's, Paracelsus identified the use of tartar as a medicine, but was incorrect in his analysis of the chemical. The chemical was first isolated in the mid-1700's after cream of tartar was boiled with chalk and treated with sulfuric acid. Tartaric acid is used to restore acidity in foods that contain fruit juices and also acts as a neutralizer in cocoa products (FDA, 2011b). Additional food products made using tartaric acid include bakery products, gelatin, soft drinks, and confectionary products (The Chemical Company, 2010).

OFPA, USDA Final Rule:
Both nonsynthetic and synthetic forms of tartaric acid are included on the National List as a nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." This material is listed both as a nonsynthetic allowed substance if made from grape wine (7 CFR §205.605 (a)) and a synthetic allowed (7 CFR §205.605 (b)) substance if made from malic acid. Attention has been focused on the accuracy of listing malic acid as the source of synthetic tartaric acid. A petition was submitted by a manufacturer of synthetic tartaric acid and was reviewed accordingly. Data on the manufacture and availability of synthetic tartaric acid was identified and evaluated for accuracy. The language contained in the current USDA Final Rule states the tartaric acid manufactured from malic acid is permitted for use in organic agriculture, but upon evaluation of the available data on the manufacture of synthetic L(+)tartaric acid, it has been determined that synthetic tartaric acid is typically manufactured from maleic acid. A synthetic form of L(+) tartaric acid

is listed as GRAS by the FDA and is described as 'produced by maleic anhydride' (FDA, 2009). No data on the synthesis of L(+) tartaric acid from malic acid was identified.

International

The use of tartaric acid ($C_4H_6O_6$; INS 334) is permitted for organic processing by the Canadian General Standards Board as a non-organic ingredients classified as a food additive in beverages. Use of the synthetic form is allowed only if the nonsynthetic form of tartaric acid is not commercially available. Tartaric acid derived from nonsynthetic sources is also permitted for use as a processing aid in beverages (the Canadian General Standards Board, 2011).

The European Economic Community (EEC) permits the use of tartaric acid as a food additive in organic food if derived from a plant source, which is presumably grapes (EEC 889/2008, 2008).

The CODEX Alimentarius Commission describe the functions of tartaric acid as an acidity regulator, adjuvant, anticaking agent, antioxidant, bulking agent, emulsifier, flour treatment agent, humectant, preservative, raising agent, sequestrant, stabilizer, and. Tartaric acid from a plant source (i.e. nonsynthetic L(+) tartaric acid) is permitted for use as a food additive in organic food production (although exclusions of the GFSA still apply). Tartaric acid is listed as an acceptable acidity regulator in the *Codex General Standard for Food Additives* (CODEX STAN 192-1995; CODEX Alimentarius Commission, 2011).

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)).

Both nonsynthetic and synthetic forms of L(+) tartaric acid (referred to simply as 'tartaric acid') are available for commercial use.

The nonsynthetic form of L(+) tartaric acid is isolated from the undesirable wastes created during the winemaking process. These unwanted materials include grape pomace, grape stalks, grape seeds, and vine prunings, which naturally contain a significant amount of tartaric acid (Yalcin et al., 2008). An excess of tartaric acid is generally unwanted in winemaking because it creates a sour and undesirable taste (Bastos et al., 2009). The available excess tartaric acid is precipitated using potassium hydroxide or calcium hydroxide in order to create a wine with the desired taste. Then the resulting waste mixture is evaporated. This process produces a powder containing calcium or potassium tartrate and additional substances including polyphenols and tannins. The powder is then sold to facilities that purify tartaric acid (Yalcin et al., 2008). The process for extracting tartaric acid from waste materials is similar to the processing of excess tartaric acid in that potassium hydroxide is added to the waste mixture. Activated carbon is also added to remove unwanted pigmentation. The potassium tartrate is precipitated by adding saturated pure tartaric acid solution and then the precipitate is redissolved with acidic water at 70° C. Potassium and sulfate ions must be removed from the remaining solution so cation exchanges are performed followed by evaporation. The solution is then crystallized at 4° C (Yalcin et al., 2008).

A synthetic process for producing large quantities of L(+) tartaric acid for commercial use was described by Church and Blumberg (1951). In this process, maleic acid anhydride is dissolved in water, and a catalyst solution containing tungstic oxide (a metallic catalyst) is added along with hydrogen peroxide. The solution is held in a reaction vessel that is set to a temperature of 70° C for 12 hours. The reaction mixture is then cooled, causing the acid to crystallize. Centrifugation is used to separate out tartaric acid crystals from the mixture. The tartaric acid is of a sufficient level of purity and does not require an additional purification step (Church and Blumberg, 1951).

In 2006, an alternative method for the manufacture of synthetic L(+) tartaric acid was declared as GRAS by the FDA. Using this method, tartaric acid produced by the conversion of maleic anhydride to tartaric acid.

This conversion is facilitated by the enzymatic action of cis-expoxisuccinate hydrolase. This enzyme is contained in immobilized *Rhodococcus ruber* cells. *Rhodococcus ruber* cells are produced by fermentation and are subsequently immobilized by the addition of carrageenan, a commonly used food additive that comes from red seaweed. The reaction substrate is produced in the presence of a metallic catalyst and by the reaction of maleic anhydrate with hydrogen peroxide. The reaction product is then calcified, separated, and acidified to yield tartaric acid (FDA, 2009; Brenn-O-Kem Ltd., 2011). This is the process most commonly used in the manufacture of synthetic tartaric acid (Brenn-O-Kem Ltd., 2011).

Evaluation Question #2: Is the substance synthetic? 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)).

Both nonsynthetic and synthetic forms of L(+) tartaric acid are manufactured in commercially available quantities.

Synthetic tartaric acid is currently available for commercial use and is manufactured primarily by the conversion of maleic anhydride to tartaric acid using the enzymatic action of cis-eposxisuccinate hydrolase contained in immobilized *Rhodococcus ruber* cells (FDA, 2009). Details on this process are provided in Evaluation Question #1. Note that the D(-) form of tartaric acid is generally not used for practical applications (The Chemical Company, 2010).

Nonsynthetic tartaric acid is also available for commercial use and is produced following precipitation from sediment and wine wastes obtained during the production of grape wines. Tartaric acid is a naturally occuring organic acid found in grapes and it is estimated that the average concentration of tartaric acid in winery waste is approximately 50 to 75 kg/ton in grape pomace and approximately 100 to 150 kg/ton in yeast lees (Nerantzis and Tartaridis, 2006). Tartaric acid is observed at the end of the winemaking in the form of crystals. These crystals form after potassium and calcium present naturally in wine combine with tartaric acid and form the compounds potassium bitartrate and calcium tartrate, respectively. During fermentation, these compounds precipitate out and evidence of this action is noted in the formation of crystals (YSI Environmental, 2006).

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

L(+) tartaric acid is found as a secondary organic acid in many fruits including grapes, cherries, apples, mangos, raspberries, and strawberries. In tamarinds, tartaric acid is a predominant organic acid (Sortwell et al., 1996). The nonsynthetic form of tartaric acid used for many food and industrial applications is derived from the wastes associated with winemaking. Grape growers and wine makers produce a significant amount of waste materials and tartaric acid is contained in grape pomace and yeast lees. Tartaric acid can be precipitated out of wastes and the actual wine solution by adding potassium hydroxide or calcium hydroxide. After evaporation, tartaric acid in the form of crystals remains and can be sent for purification (Nerantzis and Tataridis, 2006). Nonsynthetic tartaric acid is commercially available from a large number of distributors throughout the world. Details on some of these distributors are provided below:

- Penta Manufacturing: 50 Okner Parkway, Livingston, NJ 07039
- Brenn-O-Kem (Pty) Ltd: P.O. Box 71, Wolseley, 6830, South Africa
- Randi Group: Via Spallanzani, 7, 48018 Faenza, Italy
- Australian Tartaric Products Pty. Ltd.: PMB 25, Red Cliffs Victoria, 3496. Australia
- Industria Chimica Valenzana: Viale dei Platani, 101, Partinico (PA), Palermo 90047, Italy

A manufacturer of synthetic tartaric acid produced from maleic anhydride has also been identified:

- Changmao Biochemical Engineering Co.: No. 1228, N. Changjiang Rd., Changzhou City, Jiangsu Province, P.R. China

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. What is the technical function of the substance?

Nonsynthetic L(+) tartaric acid and its salts (i.e. L(+) potassium acid tartrate, L(+) sodium potassium tartrate acid) are classified by the FDA to be GRAS. These substances are not believed to be hazardous to the general public if used at used at levels that are now current (a total of about 0.2mg per kg in an adult), or that might reasonably be expected in the future (FDA, 2011a).

The FDA ruled in 2006 that a synthetic form of tartaric acid is also considered GRAS. This form of synthetic tartaric acid is produced by the conversion of maleic anhydride to tartaric acid through the enzymatic action of the enzyme cis-epoxisuccinate hydrolase contained in immobilized *Rhodococcus ruber* cells (FDA, 2009).

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)).

One of the many functions of L(+) tartaric acid is the ability to act as a preservative (Smith and Hong-Shum, 2003). The other primary functions of L(+) tartaric acid are discussed in more detail in the sections on Specific Uses and the Action of the Substance.

Tartaric acid acts as an effective preservative by controlling the pH of a variety of food products by altering the acidity and preventing the growth of spoilage microbes. The first dissociation constant or pK_1 of tartaric acid is equal to 2.98 and the second dissociation constant or pK_2 is equal to 4.34. Typically an acidic environment causes a loss in enzymatic function in spoilage microbes, thereby destroying them (Waite and Daeschel, 2007). Tartaric acid is used to alter the acidity of milk, margarine, meat and poultry products, fruit preserves, jellies, and jams, canned fruits, sherbets, beverages (including fruit juices), and soft drinks. A small amount of tartaric acid is added to a solution (1-3% of the total solution) that meat carcasses are dipped in for the reduction of microbial populations present on the carcass (Smith and Hong-Shum, 2003).

In wine and juices, tartaric acid acts as a preservative by reducing the pH. Tartaric acid is typically added prior to fermentation of grapes or after fermentation to correct the solution's overall acidity level (Smith and Hong-Shum, 2003; Waite and Daeschel, 2007).

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)).

L(+) tartaric acid is used to improve flavors, colors, and textures lost in food processing (Smith and Hong-Shum, 2009).

As an acidulant, tartaric acid is used to improve the taste and enhance flavors of fruit-flavored products and can add intensity to the sweetness of sucrose (Heath, 1981). A wide variety of products may contain tartaric acid, including fruit-flavored carbonated and noncarbonated beverages, dry beverage powders, low-calorie beverages, candies, fruit gums, and thermal processed fruits. Specifically, tartaric acid enhances lime, cranberry, and grape flavors (Hui, 2006a).

Tartaric acid is also considered a chelating agent and prevents discoloration that might occur during food processing. Chelating agents are capable of binding metal ions and in doing so improve color, aroma, and texture. Tartaric acid is added to canned fruit products because it increases the stability of the product's color and aroma (Belitz et al., 2009).

The texture of food is altered by the presence of tartaric acid or one of its salts, cream of tartar. Tartaric acid and cream of tartar are examples of fast-acting baking powders. Fast-acting baking powders contain acids that release a large amount of gas in a short amount of time during the mixing process or while a batter or other baking mixture is at rest. Tartaric acid and cream of tartar are important components of cookie, pancake, and cake mixes and are often sold as 'double-acting baking powder' (Hui, 2006b).

<u>Evaluation Question #7</u>*:* 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)).

No effects of L(+) tartaric acid on the nutritional quality of food have been identified.

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

No information on the report of residues of heavy metals or other contaminants has been identified for the substance.

<u>Evaluation Question #9:</u> 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)).

If appropriate use patterns and disposal recommendations are followed, it is unlikely that tartaric acid would cause harm to the environment. However, tartaric acid is an acidulant and its release to the environment in large quantities could alter the pH of aquatic and soil environments. If a large amount of an organic acid (i.e., tartaric acid) was released to the soil after improper disposal of excess tartaric acid or following improper use patterns, the increased acidity could create an environment incapable of supporting native soil organisms (Bickelhaupt, 2011).

A large release of tartaric acid to the aquatic environment is likely to have an effect on aquatic organisms. Many aquatic organisms would die if the pH of the waterbody became too low (Brenn-O-Kem Ltd., 2011).

Environmental persistence and degradability data are available for tartaric acid. The biodegradability of tartaric acid is 95% after 3 days and the substance is considered readily biodegradable. No bioaccumulation is to be expected (log P_{ow}[1] < 1) (Brenn-O-Kem Ltd., 2011; Fisher Scientific, 2008).

<u>Evaluation Question #10:</u> 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)).

L(+) tartaric acid in both the nonsynthetic and synthetic forms and its salts (i.e., L(+) potassium acid tartrate, L(+) sodium potassium tartrate acid) have been classified by the FDA as GRAS (FDA, 2009, 2011a). While there are no known specific hazards to human health associated with normal use patterns of tartaric acid, acute effects associated with exposure are reported in Material Safety Data Sheets (MSDS) for L(+) tartaric acid. Brief contact with tartaric acid is noted to cause possible irritation to the eyes. However, scientific literature supporting these effects was not identified. One study reported no signs of irritation after humans were administered a dermal dose of hand lotion containing tamarind and 2 percent (w/w) tartaric acid for 30 minutes daily for 5 days under semi-occlusive patch (Maenthaisong et al., 2007).

An MSDS (Industria Chimica Valenzana, 2007) notes that prolonged contact with L(+) tartaric acid may cause irritation to the skin, upper respiratory tract, and mucous membranes. Ingestion of large quantities may cause irritation to the gastro-intestinal tract and could result in nausea or vomiting. Chronic toxicity is determined as low.

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[1] P_{ow} refers to the octanol water coefficient of a substance.

The oral LD_{50} of tartaric acid is between 3310 and 3530 mg/kg body weight in the rat and is 5000 mg/kg body weight in the dog. The acceptable daily intake of tartaric acid and its potassium and sodium salt is up to 30 mg/kg body weight for humans (Smith and Hong-Shum, 2008). The daily intake of tartaric acid that is added to foods is orders of magnitude below that which could be expected to cause human toxicity (FDA, 2011a).

Evaluation Information #11: Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b)(1)).

Tartaric acid has a variety of applications in food handling, including use in baking applications and as an acidulant, flavoring agent, preservative, pH adjuster, and chelating agent.

No organic agricultural products have been identified as appropriate alternatives for tartaric acid in food applications (including winemaking). However, other organic acids, including citric acid and malic acid, have demonstrated similar properties as tartaric acid with respect to its function as an acidulants, flavoring and chelating agent, pH adjuster, and preservative. Both citric and malic acids are included on the National List as non-organic, non-agricultural substances permitted for use in organic agriculture (7 CFR §205.605).

In baking, L(+) tartaric acid is a critical component of baking powder. Baking powder can be replaced with baking soda, but cream of tartar must be added to maintain the properties of baking powder. Therefore, no sound alternative is available for tartaric acid in many baking applications (Hui, 2006b).

When used as an acidulant and flavoring agent, citric acid can sometimes act as a replacement of tartaric acid (Smith and Hong-Shum, 2008). The National List includes nonsynthetic citric acid as permitted for use in organic food processing and handling.

Tartaric acid is a critical component in winemaking and cannot be replaced with an organic alternative. Although both malic acid and tartaric acid are natural components of grapes and are used to alter the acidity in wine and possess characteristics of a preservative, they generally cannot be used interchangeably because the substances contribute differently to the wine's overall taste. In addition, the concentration of malic acid in grapes is much smaller than tartaric acid. It is because of this phenomenon that additional malic and/or tartaric acid is added by winemakers in order to produce the desired taste and to obtain the proper pH for the wine solution. L-Malic acid (CAS # 97–67–6) is included on the National List as a nonorganic substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" (Volschenk et al., 2006).

When simply seeking to adjust pH, many organic acids can be used in place of tartaric acid. Citric acid and malic acid are useful replacements for tartaric acid; however it is important to note that these acids also have flavors associated with their presence in a substance. If seeking a purely grape flavor, then tartaric acid is the primary organic acid that should be used because malic acid adds and apple flavor to a product and citric acid adds many citrus flavors. These alternative flavors may not be desirable to the product's flavor profile (Hui, 2006a).

Citric acid is also known to be an effective chelator and could be used in place of tartaric acid for this purpose. Chelators are important in the processing of fruit and vegetables. Specifically, citric acid is used to prevent enzymatic browning because of its effectiveness at chelating copper (Hui, 2006a).

References:

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