United States Department of Agriculture
Agricultural Marketing Service | National Organic Program
Document Cover Sheet
https://www.ams.usda.gov/rules-regulations/organic/petitioned-substances

Document Type:

☐ **National List Petition or Petition Update**

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

☒ **Technical Report**

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

# Potassium Carbonate

## Handling/Processing

**Potassium Carbonate**

**Chemical Names:**
Carbonate of potash; Carbonic acid, dipotassium salt; Carbonic acid, potassium salt (1:2); Dipotassium carbonate

**Other Names:**
K carbonate; Pearl ash; Potash; Salt of tartar; Salt of wormwood

**Trade Names:**
DCAD Plus; PX 1390-1; Sorb KX 35

**CAS Numbers:**
584-08-7

**Other Codes:**
U.S. EPA PC Code: 073504
INS number: 501(i)
NIOSH number: TS7750000
EC number: 209-529-3

**Summary of Petitioned Use**

Potassium carbonate is currently included on the National List at 7 CFR 205.605(b) for use as a synthetic, nonagricultural ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))," without annotation. This Technical Report supports the National Organic Standards Board (NOSB) review of potassium carbonate, which has a sunset date on June 22, 2025. The last report written for the NOSB on the material was in 1995 (NOP, 1995b). Potassium carbonate will be referred to as KC throughout this report.

**Characterization of Petitioned Substance**

**Composition of the Substance:**

KC is the dipotassium salt of carbonic acid, shown in Figure 1 (PubChem, 2022a).

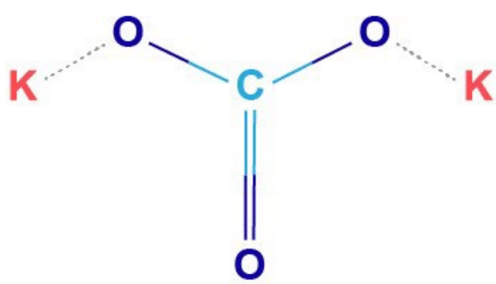


**Figure 1: The molecular structure of potassium carbonate. Illustration modified from PubChem (2022a)**

KC has the following molecular formulae (PubChem, 2022a; Schultz et al., 2000):

- Anhydrous[1]: $K_2CO_3$ or $CK_2O_3$
- Hydrated[2]: $K_2CO_3 \cdot nH_2O$ (n = 1.5 between 0-110°C)

[1] Without water molecules within crystals of the material ((Merriam-Webster, 2022a))
[2] Containing water molecules within the crystalline structure of the material. Sometimes referred to as "water of crystallization" or "water of hydration" (Merriam-Webster, 2022b).

Despite containing carbon, it is considered an inorganic compound[3] (Nelson, 1983; PubChem, 2022a). It can be found as a white, anhydrous or sesquihydrate[4] solid, or in concentrated solution (PubChem, 2022a).

**Source or Origin of the Substance:**

KC is one of several potassium-containing compounds that may be referred to as potash[5] (Garrett, 2012). Traditionally, potash was created by leaching wood ashes with water, which extracted a crude form of KC (Schultz et al., 2000). This type of KC, and its more refined by-product, pearl ash, have been utilized for millennia, with applications in baking and glassmaking. Following the discovery of naturally occurring potassium salts (e.g., potassium chloride or potassium sulfate) in the 1860s, wood ash-derived KC was replaced by mineral potassium salts obtained through shaft mining, dissolution mining, and evaporation methods (Ciceri et al., 2015). Potash mining is active worldwide, and commercial production of KC depends primarily on potassium chloride brines, which are derived from potassium chloride salts that are found in mineral potash (Schultz et al., 2000).

Modern, commercial production of KC occurs through the reaction of potassium hydroxide with carbon dioxide, or $CO_2$-containing off-gases from other industrial processes (Schultz et al., 2000). This manufacturing process, along with alternative processes, is described in greater detail in *Evaluation Questions #1* and *#2*. There are a limited number of natural sources of KC, which are discussed in greater detail in *Evaluation Question #3*.

**Properties of the Substance:**

KC is a dipotassium salt, available as a white powder (bulk density of 37 lb/ft[3]), granular crystals (bulk density of 75 - 84 lb/ft[3]), or a concentrated solution (47% potassium carbonate) (Armand Products Company, 2021; PubChem, 2022a). The powder and crystal forms are hygroscopic[6], and will liquefy in humid conditions (PubChem, 2022a, 2022b). Specific chemical and physical properties of potassium carbonate are listed in Table 1.

**Table 1: Properties of potassium carbonate**

| Property | Values – Potassium Carbonate |
|---|---|
| Physical State at 20°C | White, hygroscopic powder or crystals |
| Odor | Odorless |
| Color | White/Colorless |
| Molecular Formula | $K_2CO_3$ |
| Molecular Weight (g/mol) | 138.21 |
| Density (g/cm³) at 25°C | 2.29 |
| Water Solubility (g $K_2CO_3$/100 g $H_2O$) at 20°C | 110.5 |
| Dissociation Constants at 25°C | 6.35 (pKa1) and 10.33 (pKa2), 3.67 (pKb1) and 7.65 (pKb2) |
| Melting Point (°C) | 899°C |
| pH in aqueous solution | 11.6 |
| Stability | Deliquesces in high humidity or contact with moisture |
| Reactivity | Incompatible with chlorine trifluoride and magnesium |
| Flavor | Alkaline |

*Sources: (ChEBI, 2020; ECHA, 2022; PubChem, 2022a; Schultz et al., 2000)*

[3] Carbonates are considered inorganic compounds, as they are generally derived from alkali-earth metals that have been released from geologic parent material into soils (Nelson, 1983).
[4] Sesquihydrate refers to a compound which crystallizes with 1.5 times its quantity in water. In the case of potassium carbonate sesquihydrate, the molecular formula is: $K_2CO_3 \cdot 1.5H_2O$ (Duan et al., 2012).
[5] Other substances called potash include potassium chloride, potassium sulfate, potassium hydroxide, and potassium nitrate
[6] Tending to draw moisture in from the air (PubChem, 2022a).

**Specific Uses of the Substance:**

KC is both a carbonate salt and a potassium salt, with many historical and modern applications in food processing, agricultural production, and manufacturing (ChEBI, 2020; PubChem, 2022a; Schultz et al., 2000).

In 1995, the NOSB reviewed KC for addition to §205.605 for use as an ingredient (NOP, 1995b). Following this review, on April 26, 1995, at a full board meeting in Orlando, FL, the NOSB voted that potassium carbonate was synthetic and recommended that it be added to the National List (NOP, 1995a). KC was included on the original National List, at §205.605(b)(USDA AMS, 2000).

*Processing and handling applications*

Concerns about the health implications of sodium intake associated with various sodium salts led to the use of KC in doughs (Fu, 2008; Jia et al., 2021). Specifically, KC is utilized in the production of yellow, alkaline wheat noodles found in both Chinese and Japanese cuisines (Fu, 2008; Han, 2020; Jia et al., 2021).

In cocoa production, the "Dutching" process is valued for the production of cocoa with a characteristic dark brown color. The process utilizes KC and other alkaline carbonates to restore the desired dark pigmentation, which is partially lost during the removal of cocoa butter from cocoa powder (Bloomberg, 1918). In this process, KC is dissolved in water and applied to the fermented cocoa beans or to the partially roasted cocoa nibs, after which the roasting process is continued until the water has entirely evaporated (Bloomberg, 1918; Mohamadi Alasti et al., 2019).

In raisin production, KC can be used as a drying agent to decrease drying time (Doymaz & Pala, 2002). Open air drying can result in contamination and spoilage if the drying occurs too slowly (Doymaz, 2006; Peacock et al., 2006). Although solar dryers can be effective, the demand during peak season can exceed capacity, thus a number of drying agents may be used (Doymaz, 2006). KC has a long history of use as a drying agent in raisin production, with historical practices incorporating wood ash and olive oil into the process (Peacock et al., 2006). In modern production, KC is applied as a pre-harvest spray onto fruit, or as a pre-drying dip at an optimal 0.6% concentration, along with either olive oil or ethyl oleate (Doymaz & Pala, 2002; Peacock et al., 2006).

KC is utilized to raise the pH in the deacidification of wine. The compound neutralizes acidity, and leads to the precipitation of tartrate (Mattick et al., 1980). Tartrate occurs naturally as a salt of tartaric acid in fruit (Kliewer et al., 1967).

The U.S. Food and Drug Administration (FDA) notes KC as an allowed substance in the production of modified hop extract, as listed at 21 CFR 172.560. The bitter flavor for which hops are valued is attributed to a number of naturally-occurring soft resins in the hop cone, the predominant of which is α-acid (Laws et al., 1977; O'Rourke, 2003). During the brewing process, α-acid content drops with yeast consuming some of it during the brewing process, and some of it precipitating from solution due to its low solubility (O'Rourke, 2003). Brewers may add more soluble forms (isomers) of α-acid, before or after fermentation, to alter flavor and other beer properties as desired (Kunimune & Shellhammer, 2008; O'Rourke, 2003). KC or other alkali metal carbonates are used to produce the more soluble forms of α-acid, following its initial extraction from the hops (O'Rourke, 2003; U.S. FDA, 2022a).

Meat processors are exploring the use of KC as a replacement for phosphates in processed meat products, along with a number of other alternatives (Thangavelu et al., 2019). One study found that KC, when applied at 0.3% or 0.5%, maintained the color of fresh pork, preserved tenderness, and reduced cooking loss[7] when compared with an industry standard, sodium tripolyphosphate (LeMaster et al., 2019).

KC is approved for use as a boiler additive in the preparation of steam that will come in direct contract with food (U.S. FDA, 2022d). The addition of an alkali to boiler water helps to reduce acid corrosion that

[7] Cooking loss refers to the volumetric decrease in a food following exposure to heat during cooking (Offer & Trinick, 1983). This may refer to any number of foods, including processed grains and meat (LeMaster et al., 2019; Rombouts et al., 2014).

may occur with water sources with a low pH (NOP, 2001). KC is among several other substances on the National List that can be used for this purpose, including sodium carbonate, sodium hydroxide, sodium bicarbonate, and potassium hydroxide (NOP, 2001).

KC is utilized as a potassium fertilizer and a livestock nutrient supplement (Fraley et al., 2015; Taha et al., 2014; Teeter & Smith, 1986). KC is not generally used for potassium supplementation in humans (Karp et al., 2009).

*Other agricultural applications*
In one study, KC was successfully used as a fungicide in a post-harvest handling application to reduce the presence of blue and green molds in 'Valencia' oranges (Youssef & Hussien, 2020). Other studies found KC to be less effective than other carbonates and bicarbonates as a post-harvest handling fungicide used on lemons, oranges, and papaya (Sivakumar et al., 2002; Smilanick et al., 1999).

One study found KC, when applied in combination with potassium sorbate, successfully reduced drying time in alfalfa hay in comparison with untreated hay (Jaster & Moore, 1992). Another study comparing KC, magnesium chloride, sodium iodide, and a commercial product in the desiccation of corn found KC to be the most effective treatment for reducing drying time without over-drying or leaching nutrients (Mora et al., 2019).

In the context of crop agriculture, potassium salts, including KC but mostly potassium chloride, are often applied to fields to boost potassium content (Prakash & Verma, 2016). Potassium chloride is more commonly applied as a fertilizer than other potassium salts (Prakash & Verma, 2016; Schultz et al., 2000). One study explored the use of refined KC and other potassium compounds to boost yield and quality in mango production, finding KC and potassium citrate to be most effective (Taha et al., 2014).

**<u>Approved Legal Uses of the Substance:</u>**

*FDA*
The U.S. Food and Drug Administration (FDA) considers KC to be a *Generally Recognized as Safe* (GRAS) substance, as listed at 21 CFR 184.1619, provided that it "is used in food at levels not to exceed current good manufacturing practice," and is used in one of the following applications:

- "As a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter."
- "As a nutrient supplement as defined in § 170.3(o)(20) of this chapter."
- "As a pH control agent as defined in § 170.3(o)(23) of this chapter."
- "As a processing aid as defined in § 170.3(o)(24) of this chapter."

Beyond GRAS statuses, the FDA has issued specific approval for KC:

- In the production of caramel color, which is a food color additive "exempt from certification" listed at §173.85.
- In the production of modified hop extract, which is a "flavoring agent" and "food additive permitted for direct addition to food for human consumption" listed at § 172.560.
- As an alkali ingredient in "specific standardized cocoa products" including cacao nibs listed at § 163.110, chocolate liquor at § 163.111, and breakfast cocoa at § 163.112.
- As a boiler water additive that "may be safely used in the preparation of steam that will contact food," provided that the "amount of additive is not in excess of that required for its functional purpose, and the amount of steam in contact with food does not exceed that required to produce the intended effect in or on the food," as listed at § 173.310.

*EPA*
The United States Environmental Protection Agency (EPA) lists KC as one of the approved "inert ingredients used pre-harvest" that is exempt from "the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops," as listed at 40 CFR 180.920.

The EPA lists KC under the name "carbonic acid, dipotassium salt" on the now obsolete Categorized Lists of Inert Ingredients. KC is specifically listed as a substance on *List 4B - Other ingredients for which EPA has sufficient information to reasonably conclude that the current use pattern in pesticide products will not adversely affect public health or the environment*.

**Action of the Substance:**

KC is a moderately strong base (pKb1=3.67, pKb2=7.65), a 0.1M aqueous solution of which has a pH of 11.5-11.6 (ECHA, 2022), and is thus useful as an alkali in processing and handling applications, including:

- As a flavoring agent or adjuvant in dough and other products (Jia et al., 2021).
- As a pH control agent in wine or mead production (Comuzzo & Battistutta, 2019).
- In the Dutching process for cocoa production (Puchol-Miquel et al., 2021).
- In the manufacture of raisins (Patidar et al., 2021).
- As an adjuvant in the production of extracts and concentrates such as caramel color and modified hop extract (U.S. FDA, 2022b, 2022a).

Unlike many other carbonates, KC is highly soluble in water, permitting the alkaline properties of the carbonate anion to be readily accessible (Eaton, 1950; PubChem, 2022a).

Noodle manufacturers use KC as a conditioner when making dough (Ding et al., 2021). KC directly acts on wheat gluten to improve strength and texture (Han, 2020). Alkaline substances including KC help disulfide bonds form between gluten proteins (Han, 2020; Rombouts et al., 2014). In an alkaline environment, oxidation of the gluten proteins leads to new disulfide bonds (Fan et al., 2018; Han, 2020; Rombouts et al., 2014). This environment also supports the restructuring of existing disulfide bonds, called the SS bond interchange, in a manner that increases dough strength and elasticity (Fan et al., 2018; Han, 2020; Rombouts et al., 2014).

Winemakers use KC to neutralize tartaric acid in wine (Comuzzo & Battistutta, 2019). After the neutralization reaction, potassium ions react with the tartaric acid to form an insoluble material (potassium acid tartrate), which precipitates. This precipitate is then removed (Comuzzo & Battistutta, 2019).

The increase in pH induced by the application of KC or other alkalis to cocoa has the following effects:

- It suppresses a number of naturally-occurring flavanols associated with bitter flavor (Miller et al., 2008; Mohamadi Alasti et al., 2019).
- It increases non-enzymatic browning in Maillard reaction during cocoa roasting (Ajandouz et al., 2001; Taş & Gökmen, 2016).
- It increases the solubility and suspension of cocoa in aqueous solution (Taş & Gökmen, 2016).

The changes to the cocoa produce a powder that:

- Is dark in color, compared to the raw cocoa powder after the removal of cocoa butter (Bloomberg, 1918).
- Has a balanced flavor, with reduced bitterness (Miller et al., 2008; Mohamadi Alasti et al., 2019).
- Has a degree of solubility that allows for the use of the product in drinks, such as hot cocoa, without the powder sinking (Taş & Gökmen, 2016).

In the production of raisins, KC is thought to effectively reduced drying time by removing the waxy layer on the grape surface to allow for faster moisture removal (Patidar et al., 2021).

Addition of KC during the α-acid extraction from hops results in the formation a potassium salt of iso-α-acid (O'Rourke, 2003). This α-acid isomer is more soluble in pre-fermentation liquid and may be added post-fermentation to beer, where it creates desired bitter flavors (O'Rourke, 2003; U.S. FDA, 2022a).

KC is useful as an adjuvant in the production of caramel color, where it functions as an alkaline substance that supports the development of the desired brown color that occurs when heating treated carbohydrates (Chappel & Howell, 1992).

**Combinations of the Substance:**

KC is commonly used in combination with sodium carbonate, in the food ingredient kansui that is used in noodle production (Ding et al., 2021). Additionally, it may be used in combination with fatty acid derivatives from plant oils, such as olive oil, in the acceleration of drying time in raisins (Peacock et al., 2006).

Substances that may be found in KC include the commonly reported impurities: sodium carbonate, silicic acid, sulfate, iron, and chloride (PubChem, 2022b; Schultz et al., 2000). See *Evaluation Question #8* for additional details on impurities found in KC.

## Status

**Historic Use:**

Wood ash-derived potash, and its primary constituent potassium carbonate, have recorded uses in a wide number of industries dating back to at least the 7th century B.C. (Schultz et al., 2000). Beginning in 1860, mined potash salts, predominantly containing potassium chloride, began to replace the wood ash-derived KC in a number of agricultural applications. Modern production of KC relies almost entirely on the reaction of potassium hydroxide with carbon dioxide (Schultz et al., 2000).

From the post-classical era through the early 20th century, pearl ash[8] was used as a gas-releasing (i.e., leavening agent) (Civitello, 2017; Gélinas, 2022; Schultz et al., 2000). This application generally fell from favor as its use creates a poor dough quality and flavor (Civitello, 2017; Gélinas, 2022). The application of KC as a drying agent for raisins is noted to have a long history, with wood ash traditionally being used in combination with olive oil (Peacock et al., 2006).

The USDA organic regulations have noted the use of KC as a food additive in organic processing and handling applications since its addition to the National List at 7 CFR 205.605(b), on December 21, 2000. There are numerous specific applications of the substance including use in:

- Dough conditioning in alkaline noodles (S. Jia et al., 2021).
- Wine deacidification (Comuzzo & Battistutta, 2019).
- Dutch processing of cocoa (Puchol-Miquel et al., 2021).
- Reduction of drying time in raisin production (Patidar et al., 2021).
- Modified hop extract production (O'Rourke, 2003).
- Meat color and texture retention (Jarvis et al., 2020).

In 2002, Maxicrop USA, Inc. petitioned for the addition of KC to the National List at §205.601, for "use as a plant or soil amendment as an aquatic plant extractant (hydrolyzed extract)," however the NOSB did not recommend the petitioned use for rulemaking (Maxicrop USA, Inc., 2002). Potassium carbonate is allowed in the extraction of humic acid under §205.601(j)(3).

**Organic Foods Production Act, USDA Final Rule:**

In 1995, KC was reviewed for addition to the National List as an allowed synthetic material for use as an ingredient in processing and handling applications (NOP, 1995a). The initial recommendation for addition to the National List included the annotation, "Potassium carbonate is allowed only for FDA-approved

[8] Pearl ash is an impure source of potassium carbonate that is produced by heating potash to high temperatures. This heating step removes a portion of the impurities that are found in wood ash-derived potash (Gélinas, 2022; Schultz et al., 2000).

applications where natural sodium carbonate is not an acceptable substitute"(NOP, 1995a). KC was added to the National list at 7 CFR 205.605(b) on December 21, 2000, without the aforementioned annotation (USDA AMS, 2000).

**International**

*Canada, Canadian General Standards Board – CAN/CGSB-32.311-2020, Organic Production Systems Permitted Substances List*
KC is listed in the Canadian General Standards Board Organic Production Systems Permitted Substances List (CAN/CGSB-32.311 - 2020) in the following locations:

- In Table 6.3, as a food additive, with no origin or usage annotations.
- In Table 6.5 as an allowed processing aid, with no origin or usage annotations.
- In Table 7.4 for allowed "cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory" with the annotation that "documentation shall demonstrate that effluent discharge was neutralized to minimize negative environmental impact."

*CODEX Alimentarius Commission – Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)*
KC is listed in the CODEX (GL 32-1999) guidelines in Table 3.1 as a *"food additive, including carriers"* for specific use in *"cereals/cakes & biscuits/confectionary."* It is also listed in Table 4 as *"processing aids which may be used for the preparation of products of agricultural origin referred to in section 3 of these guidelines"* and specific use for the *"drying of grape raisins."*

*European Economic Community (EEC) Council Regulation – EC No. 834/2007, 889/2008 and 2021/1165*
KC is listed in (EC) No 889/2008 under *"Section A – Food Additives, Including Carriers"* as an allowed substance for the *"preparation of foodstuffs of plant origin."* It is also listed under *"Section B – Processing Aids and Other Products, Which May Be Used for Processing of Ingredients of Agricultural Origin from Organic Production"* as allowed for the *"preparation of foodstuffs of plant origin,"* and specifically for drying of grapes.

EU organic standards have been updated since 2008. (EU) 2018/848 is the current regulation. Its Article 24(2)(a) authorizes certain products and substances for use in the production of processed organic food as noted in restrictive lists. These lists are currently codified in (EU) 2021/1165. Part A of Annex V lists food additives and processing aids. Potassium carbonates, E 501, appear in *"Section A1 - Food Additives, Including Carriers"* for addition to products of plant origin. KC also appears in *"Section A2 – Processing Aids and Other Products, Which May Be Used for Processing of Ingredients of Agricultural Origin from Organic Production,"* authorized only for the processing of organic grapes as a drying agent.

*Japan Agricultural Standard (JAS) for Organic Production*
KC is listed in the Japanese Agricultural Standard for Organic Processed Foods under the "Appended Table 1 Additives," where it is stated to be *"limited to the use in the drying of processed fruit products or in processed grain products, sugar, products containing legumes, noodles, bread, or confections."*

*IFOAM - Organics International*
KC is listed in the IFOAM Norms under the Standard for Organic Production and Processing in Appendix 4 – Table 1: List of Approved Additives and Processing/Post-Harvest Handling Aids for use as both an additive and a processing/post-harvest handling aid, without any limitation note.

## Evaluation Questions for Substances to be used in Organic Handling

**<u>Evaluation Question #1</u>: 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 predominant manufacturing method for KC involves the reaction of potassium hydroxide (KOH) with carbon dioxide ($CO_2$) (Schultz et al., 2000; U.S. FDA, 2022c). This manufacturing process involves the electrolysis of potassium chloride (KCl) to produce KOH, and the electrolysis step may occur prior to the manufacture of KC or may be vertically-integrated into the process (Occidental Chemical Corporation, 2013; U.S. EPA, 2022a).

*Production from potassium hydroxide and carbon dioxide*
The reaction of potassium hydroxide (KOH) and carbon dioxide or $CO_2$-rich off-gases from flues or lime kilns to produce KC often occurs as part of carbon capture and storage (CCS) processes (Huang et al., 2020; Schultz et al., 2000). For this method, the initial reaction of KOH and $CO_2$ produces potassium carbonate hydrate (see Figure 2), which is then crystallized into the anhydrous salt through a number of processes, as described in greater detail below (Schultz et al., 2000).

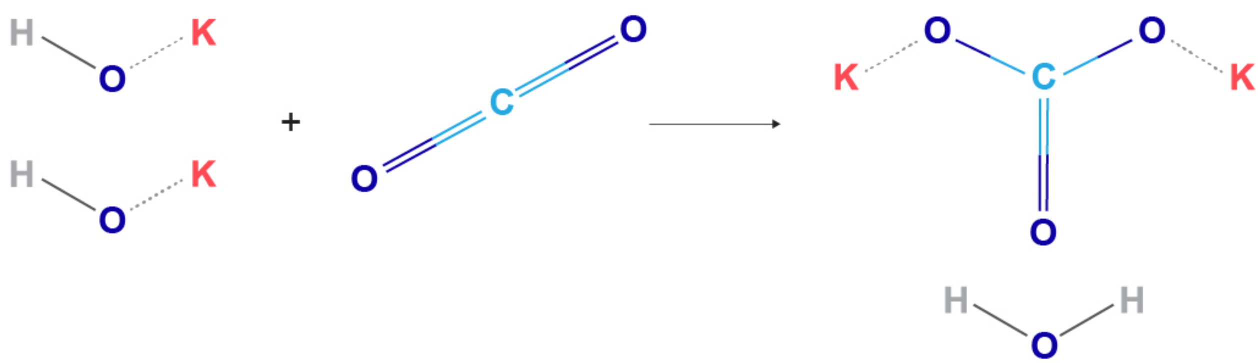

**Figure 2: Chemical reaction of potassium hydroxide with carbon dioxide, leading to the formation of potassium carbonate and water. Illustration modified from PubChem (2022a).**

Potassium hydroxide is almost exclusively manufactured through the electrolysis of potassium chloride (KCl), using either the diaphragm, membrane, or mercury processes (Schultz et al., 2000). Diaphragm and mercury electrolysis[9] were the predominant production methods prior to 1985, with mercury as the preferred method for achieving high purity of final products prior to concentration (Schultz et al., 2000). Both diaphragm and mercury production methods are subject to regulation regarding effluent from manufacturing points (U.S. EPA, 2022a).

Modern manufacturing is based on the membrane method, which uses electrolytic cells that contain polymeric membranes to produce a cell liquor with low chloride content and a KOH concentration of 32% (Lynch et al., 1983; Schultz et al., 2000). Irrespective of electrolytic cell type, all KOH products are evaporated to a concentration of 45-50% for the final product (Schultz et al., 2000).

High-purity sources of $CO_2$ gas are captured from industrial practices including electricity generation, cement production, ethanol fermentation, ammonia production, as well as iron and steel manufacturing (Bains et al., 2017; Ou et al., 2021). Although naturally occurring, distillation of $CO_2$ from ambient air is not economically viable at this time (Zhu et al., 2020).

[9] Electrolytic cells, including the diaphragm, mercury, and membrane versions, utilize an electrical current to induce a chemical reaction within an initial brine solution of KOH. All three methods utilize an initial brine containing KCl, which is reacted to form potassium hydroxide (Schultz et al., 2000).

*Crystallization of potassium carbonate*

Solid KC is produced through either the continuous crystallization process or the fluidized bed process (Schultz et al., 2000).

In the continuous crystallization process, the carbonate solution derived from the reaction between KOH and $CO_2$ is mixed with pre-existing mother liquor, then concentrated until a precipitate forms under vacuum and cooling (Schultz et al., 2000; Wang et al., 2017). The mother liquor is separated from the precipitate, filtered, and later reused (Schultz et al., 2000; Wang et al., 2017). The hydrated KC precipitate is then dried at 110-120ºC to form potash hydrate, or alternatively calcined at 200-350ºC to isolate KC with a purity of 98-100% (Schultz et al., 2000). When very pure KC is needed, manufacturers use a specific crystallizer, called a "mixed suspension mixed product removal" (or MSMPR) crystallizer (Schultz et al., 2000; Škrtić et al., 1989; Wang et al., 2017).

In the fluidized bed process, the reaction between KOH and $CO_2$ happens at the same time as the crystallization process (Schultz et al., 2000). Aqueous KOH is sprayed into a fluidized bed reactor chamber, where gaseous $CO_2$ is simultaneously introduced, leading to the production of aqueous KC (Huang et al., 2020; Schultz et al., 2000). Solid KC is then obtained within the same reactor, following a calcination step to produce KC prills (Huang et al., 2020; Schultz et al., 2000). The resulting prills are removed from the reactor and ground down. Granules of medium size are retained as the final product, while smaller and larger sizes are returned to the reactor to serve as crystallization seeds in subsequent reactions (Keith et al., 2018; Schultz et al., 2000). Due to the lack of mother liquor to siphon off impurities, purity of KC derived from the fluidized bed process is based on the purity of the raw materials (Gao et al., 2007; Schultz et al., 2000). This is discussed in greater detail in Evaluation Question #8.

*Alternative production methods*

There are a number of historic KC manufacturing processes that have fallen from significant use (Schultz et al., 2000). Either the products of these processes have reduced economic viability, or the processes themselves result in undesirable by-products (Schultz et al., 2000). In one alternative method, KCl is treated with $CO_2$ in the presence of an organic amine to produce potassium bicarbonate, which is then calcined to potassium carbonate (Schultz et al., 2000; Trypuć et al., 2001). The Engel-Precht method utilizes a salt, produced by the reaction of magnesium carbonate or magnesium oxide with KCl, in the presence of $CO_2$ and a pressurized environment (Schultz et al., 2000; Trypuć et al., 2001). In another process, an ion exchange system is created, where ammonium is washed with potassium chloride, after which ammonium carbonate is passed through the system (Berry et al., 1995). This process produces KC and ammonium chloride, the latter of which is subsequently recycled into ammonium carbonate for continuous use within the ion exchanger (Berry et al., 1995).

**<u>Evaluation Question #2:</u> 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.**

KC is on the National List at §205.605(b) as a nonagricultural synthetic substance (USDA AMS, 2022b). The substance is manufactured via chemical processes, predominantly through the reaction of potassium hydroxide (KOH) and carbon dioxide ($CO_2$) (Huang et al., 2020; Schultz et al., 2000). KC is classified as a synthetic material, in accordance with Guidance 5033-1 Decision Tree for Classification of Materials as Synthetic or Nonsynthetic (NOP, 2016). Following the decision tree, KC is determined to be synthetic in box 1, as it is not "manufactured, produced, or extracted from a natural source" (NOP, 2016).

Potassium hydroxide is synthesized through electrolysis of potassium chloride, typically using membrane-based electrolytic cell technology (Schultz et al., 2000; U.S. EPA, 2022a). Although naturally-occurring, the high-purity $CO_2$ used in production of KC is derived from industrial off-gases, such as those produced in the generation of electricity or through other manufacturing processes (Bains et al., 2017; Ou et al., 2021). Following the reaction of KOH and $CO_2$, solid KC is obtained through one of two crystallization processes which are discussed in *Evaluation Question #1*: continuous or fluidized-bed (Gao et al., 2007; Huang et al., 2020; Keith et al., 2018; Schultz et al., 2000). In either crystallization processes, the precipitate undergoes a calcination process to achieve a high purity final product (Huang et al., 2020; Schultz et al., 2000).

**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)).**

While historically derived from wood/plant-derived potash, commercially-available KC is a synthetic substance. KC can be derived from wood ashes or general plant ashes, or minerals found in potash salt deposits, the largest of which is located in Saskatchewan, Canada (Broughton, 2019; Kone et al., 2020; Schultz et al., 2000). Refined potash, sometimes referred to as pearl ash, contains potassium carbonate. To produce pearl ash from wood ash or minerals, the unrefined potash is dissolved in water or lye, boiled to evaporate the liquid, then heated in a pearling-oven to remove organic impurities (Hopkins, 1790; Jewett, 1866; Wentworth & Cleaveland, 1872). This process, specifically when the unrefined potash is dissolved in water, would produce pearl ash that would be nonsynthetic according to Guidance NOP 5033-1. There are no known commercially available sources of pearl ash produced in a manner that would be considered nonsynthetic.

**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.**

KC is listed as GRAS by the FDA at 21 CFR 184.1619 with no limitation provided that it "is used in food at levels not to exceed current good manufacturing practice."

KC is specifically listed as GRAS as:

- A food additive for use as a flavoring agent and adjuvant at § 170.3(o)(12).
- A nutrient supplement at § 170.3(o)(20).
- A pH control agent at § 170.3(o)(23).
- A processing aid at § 170.3(o)(24) (U.S. FDA, 2022m).

**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)).**

KC is not used as a preservative. KC is used as a pH adjuster and drying agent (see *Action of the Substance* and *Specific Uses of the Substance*, above). The FDA does not include KC as an antimicrobial agent at 21 CFR §170.3(o)(2), although it is listed as GRAS for other uses described in *Evaluation Question #4* (U.S. FDA, 2022m).

**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)).**

KC has a range of uses, including some that restore, improve, or maintain the flavor, color, texture, or nutritive values that are either lost in processing, or are further desired in a processed product. The *Specific Uses of the Substance* section above provides describes additional details regarding the application of KC for each of the following uses.

*Dough conditioning*

KC is an inorganic alkaline salt utilized in the production of several types of Chinese wheat noodles, typically occurring as part of a salt blend referred to as kansui (Obadi et al., 2022). When applied alone, or in combination with sodium bicarbonate (baking soda), KC strengthens gluten structure through disulfide bond formation (Han, 2020; Obadi et al., 2022). The resulting noodles are more elastic and firm, and assume a characteristic yellow color and alkaline flavor (F. Jia et al., 2019; Obadi et al., 2022). Research into the use of kansui in other noodle dough types, including buckwheat and chickpea-wheat composite doughs, indicates the valuable texture imbued by KC in wheat noodles may be transferrable into other dough compositions (Guo et al., 2017; F. Jia et al., 2019).

*Cocoa processing*

Modern manufacturing of cocoa beans frequently involves an alkalization step referred to as Dutch processing. This involves the addition of alkaline carbonates, frequently KC, to the cocoa beans, liquor, or powder prior to roasting, in order to obtain the desired pigment, flavor, and product performance when used in aqueous solutions (Bloomberg, 1918; Miller et al., 2008; Mohamadi Alasti et al., 2019). Natural cocoa ranges in appearance from light to medium brown, while alkalized cocoas may appear dark brown to black, or red brown to brick red, depending on the naturally occurring quantities of red pigment (Miller et al., 2008). The Dutching process is also attributed with developing the flavor and aroma of cocoa, although this change is associated with a loss of flavanols[10] and other valuable nutrients (González-Barrio et al., 2020; Taş & Gökmen, 2016). Alkalization alters the texture of the end product, insomuch that the cocoa becomes more soluble in solution and less prone to sinking following the treatment (Miller et al., 2008; Taş & Gökmen, 2016).

*Raisin production*

KC is utilized in combination with fatty acid derivatives, such as those found in olive oil, as a pre-treatment intended to accelerate drying time of grapes in raisin production (Doymaz, 2006). Application of KC along with a fatty acid produces raisins with lighter color and lower green-red/blue-yellow color ratios, which are both traits preferred by consumers (Doymaz & Pala, 2002).

Following pretreatment with KC, raisins appear to have the following (Doymaz & Pala, 2002; Foshanji et al., 2018):

- Higher soluble solids, indicative of greater sugar content.
- Higher total carbohydrate.
- Lower titratable acidity, indicative of acidity in flavor
- Lower crude fiber quantities.
- Higher antioxidant activity.
- Less non-enzymatic browning, which is generally associated with extended time in solar drying conditions.

*Wine deacidification*

Alkaline salts, including KC, are commonly utilized in the production of red wines to reduce acidity, facilitate the malolactic fermentation process, and to reduce astringent flavor associated with low pH (Benito et al., 2019; Comuzzo & Battistutta, 2019). In specific relation to flavor, KC initiates the precipitation of a tartaric acid salt, potassium acid tartrate (Comuzzo & Battistutta, 2019). Tartaric acid bears an astringent flavor that may be used as a food processing aid to create sour flavor, thus its removal may alter wine flavor to desired levels of acidity or astringency (Comuzzo & Battistutta, 2019; Sanyürek & Çakır, 2018).

*Modified hop extract production*

Alkali metals, and KC in particular, are allowed for use in the production of modified hop extract (U.S. FDA, 2022a). Modified hop extract is added to beer to improve flavor as well as the stability of foam (Kunimune & Shellhammer, 2008; U.S. FDA, 2022a). KC is added to acids extracted from hop cones to convert the α-acid constituent into a desired isomeric form (O'Rourke, 2003). This acid extract is then added into beer before or after fermentation to increase the characteristic bitter flavor associated with hops (O'Rourke, 2003). Additionally, the modified hop extract increases a number of beer foam attributes, including cling area and foam stability (Kunimune & Shellhammer, 2008).

[10] Flavanols are a category of naturally-occurring polyphenols that are found in cocoa and other foods (González-Barrio et al., 2020; Miller et al., 2008). They are considered antioxidants, and consumption of these compounds is associated with the prevention of cardiovascular and neurodegenerative diseases (González-Barrio et al., 2020).

*Meat color and texture retention*
Due to an expanding market for phosphate-free meat, processors have been seeking alternatives to sodium tripolyphosphate (STP) (Jarvis et al., 2020; LeMaster et al., 2019). KC is under study as a possible substitute (Jarvis et al., 2020; LeMaster et al., 2019). Application of KC to meat is found to increase redness of pork and chicken cuts, giving a fresh appearance (Jarvis et al., 2020; LeMaster et al., 2019). Additionally, the use of KC is effective in raising the pH of the meat cuts, which subsequently increases the water holding capacity of the products (Jarvis et al., 2020; LeMaster et al., 2019). This increase in water-holding capacity is directly tied to decreasing cooking loss, as well as an increased consumer perception of tenderness (LeMaster et al., 2019).

**<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)).**

Several applications of KC result in changes in the nutritional quality of food and/or feed.

The addition of kansui, or KC, to wheat noodles decreases the overall nutritional quality of the final product, through a decrease in lysine and an overall reduction in protein extractability (Obadi et al., 2022). Despite this, the addition of KC to dough increases extensibility and allows for the introduction of highly nutritious, non-cereal flours, such as those derived from chickpea and seeds, into dough without detriment to the final noodle texture (Ding et al., 2021; F. Jia et al., 2019).

As noted in *Evaluation Question #6*, following pre-treatment with KC and a fatty acid solution, sun dried raisins were found to have higher sugar content, higher total carbohydrate, lower crude fiber quantities, and higher antioxidant activity than untreated, sun dried raisins (Foshanji et al., 2018).

Hollenberg and Fisher (2007) describe cocoa powder and products that undergo heavy alkalization through KC application during the Dutching process as devoid of flavanol antioxidants. This assertion comes from research that shows the naturally-occurring flavanols in chocolate are oxidized and polymerized during the alkalization process (Miller et al., 2008). Although alkalization does destroy some portion of the flavanol content in raw cocoa, the amount destroyed varies with alkalization intensity (Miller et al., 2008). Up to 40% of the flavanol content may be retained in lightly alkalized products (Miller et al., 2008). Taş & Gökmen (2016) found that the Maillard reaction[11] that occurs in the Dutching process results in further loss of nutritional value in cocoa. This loss occurs as the amino acid lysine is reduced by both the roasting and alkalization processing steps (Taş & Gökmen, 2016).

Varo et al. (2022) explored the nutritional impacts of KC on blueberry wines, finding that the addition of KC did not affect beneficial health attributes of the wine such as Vitamin C or antioxidant contents.

**<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)).**

We found no reports of heavy metal or other contaminants in excess of FDA tolerances in KC. There are a number of commonly reported impurities in KC, including: sodium carbonate, silicic acid, sulfate, iron, and chloride (PubChem, 2022b; Schultz et al., 2000). None of these substances appear on the list for the FDA's Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed (U.S. FDA, 2021). Presence of poisonous and/or deleterious substances in KC is not reported in the literature, however industry specifications for food-grade KC do include monitoring of substances such as arsenic, lead, and mercury to remain in compliance with FDA action levels (Armand Products Company, 2022; Spectrum Chemical Mfg Corp, 2022).

[11] According to Ames (1992), the Maillard reaction is "a type of non-enzymatic browning which involves the reaction of carbonyl compounds, especially reducing sugars, with compounds which possess a free amino group, such as amino acids, amines and proteins." It most is most often induced by the application of heat to foods, during processing or cooking, and may result in the development of both desired and undesired flavors (Ames, 1992).

The purity of KC is determined by input sources, including both KOH and $CO_2$, as well as the crystallization process utilized (Grant et al., 2014; Smith et al., 2009; Ye & Lu, 2014). Manufacturing processes that incorporate mother liquor to siphon off impurities are able to produce a higher purity KC than other processes (Gao et al., 2007; Schultz et al., 2000).

**Evaluation 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)).**

*Manufacture*

Specific resource consumption associated with KC production includes the production of KOH, $CO_2$ capture from industrial processes, transportation via truck or freight, water use, electricity use, and natural gas use (Maul et al., 2014). Emissions associated with manufacture include heat and $CO_2$ into air, as well as $K^+$ and $OH^-$ in water (Maul et al., 2014).

Two published life cycle assessments (LCAs) provide insight into the production demands and environmental fate of KC. One LCA compares the use of a KC-based $CO_2$ capture technology with other amine-based technologies (Grant et al., 2014). The other LCA is focused on potassium bicarbonate derived from KC, providing additional input into the energy demands and pollution associated with manufacture of the substance (Maul et al., 2014). Grant et al. (2014) found that the $CO_2$ equivalent tied to production of KC was predominantly due to electrolytic production of its precursor, potassium hydroxide (KOH). Similar conclusions were found by Maul et al. (2014), who identified KOH production and energy consumption during processing to be the most substantial negative impacts associated with KC manufacturing. The use of KC as a food additive or in other applications may result in less acidification and eutrophication than other synthetic compounds, however its use was still found to contribute to global warming, ozone depletion, and carcinogen production (Grant et al., 2014).

The prevailing manufacturing method for KOH involves electrolysis of potassium chloride (KCl) in a manner that is analogous to the chloralkali process for producing sodium hydroxide (NaOH) (Schultz et al., 2000; U.S. EPA, 2022a). Three forms of electrolysis have been used historically, however the predominant method for production is currently the membrane process (Schultz et al., 2000). The electricity demand associated with electrolytic processes position them as energy-intensive industrial processes, however exact numbers for energy consumption in KOH production are not publicly available (U.S. EIA, 2002, 2018).

The diaphragm and mercury-based electrolytic cells are point sources of pollution for mercury, chlorine, and suspended solids; as a result, this effluent is regulated by the EPA (U.S. EPA, 2022a).

Potassium hydroxide is considered a hazardous substance[12] under the Clean Water Act, due to its impact on pH and potassium levels in wastewater (U.S. EPA, 2022b). Although KOH is listed as a hazardous substance under the Clean Water Act, it is considered a GRAS substance when produced with good manufacturing practice and currently appears on the National List at §205.605(b) for use in processed products (U.S. EPA, 2022c; U.S. FDA, 2022l; USDA AMS, 2022a).

Although outside of the scope of processing and handling, KC is used as a livestock feed additive to provide supplemental potassium (Alfonso-Avila, Baumann, et al., 2017; Alfonso-Avila, Charbonneau, et al., 2017). Several studies have explored the use of KC as a potassium supplement for chickens, ducks, and quail, suggesting no or low toxicity in the superorder Galloanserae, or fowl birds (Andreatta Scottá et al., 2017; Chu et al., 1996; Joardar et al., 2020; Zarrin-Kavyani et al., 2018). The National Institute for Occupational Safety and Health (NIOAH) reports a LD50 of 100 mg/kg for oral consumption of KC by wild bird (NIOSH, 2018).

[12] According to the U.S. Environmental Protection Agency at 40 CFR 262.11, a hazardous substance "exhibits one or more hazardous characteristics as identified in subpart C of 40 CFR 261". This includes characteristics of ignitability, corrosivity, and reactivity (U.S. EPA, 2022d).

*Use*

As a food additive, KC is utilized in small quantities compared to its applications as a livestock feed supplement or in other industrial processes (Chu et al., 1996; Fraley et al., 2015; Jaster & Moore, 1992). Negative effects on biodiversity or the general environment have not been reported in relation to the use of KC as a food additive.

**<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)).**

KC is a GRAS substance, with a number of specifically allowed applications as a food additive, as discussed in previous sections (U.S. FDA, 2022k). There is limited information available related to negative health effects in humans resulting from the use of KC as a food additive, however there are some relevant studies related to potassium intake and toxicity.

Ingestion and inhalation are the primary routes of exposure, for which short-term risk is exclusively reported (ILO & WHO, 2021). The following acute hazards are reported (ILO & WHO, 2021):

- Sore throat and cough following inhalation.
- Redness and pain following contact with skin or eyes.
- Burning sensation in throat and chest following ingestion.

Borhani et al. (2015), Ghaedi et al. (2022), and Grant et al. (2014) all report KC as non-carcinogenic and non-genotoxic substance. However, NIOSH (2018) reported damaged nucleotide excision mechanisms via an unscheduled DNA synthesis assay[13] in rats following continuous oral ingestion of a dose of 504 g/kg bodyweight over a four-week period.

Ionic potassium is a critical cationic electrolyte, and its levels within the human body are held in a narrow homeostatic range (Zacchia et al., 2016). The ratio of internal (intracellular) to external (extracellular) cellular potassium is held within a narrow range to maintain cell membrane voltage. ATPase pumps, which are located in the cell membrane of most animal cells, are responsible for the regulation of the potassium ratio (Udensi & Tchounwou, 2017). Excess potassium ions are excreted from the body via the kidneys and urinary tract into waste water systems (Zacchia et al., 2016).

The addition of KC to food does raise potassium levels; however the current average potassium intake in the United States fails to reach the recommended levels for most individuals (Palmer & Clegg, 2016; Siddiqui et al., 2022; Zacchia et al., 2016). The FDA currently recommends the consumption of potassium salts as replacements for sodium salts to increase potassium intake and reduce the sodium-related risk for cardiovascular mortality (U.S. FDA, 2019). Superfluous potassium in extracellular plasma, resulting either from high dietary potassium intake, ineffective excretion by the renal system, or a combination of the two, may lead to a life-threatening electrolyte imbalance called hyperkalemia (Palmer & Clegg, 2016; Zacchia et al., 2016). Udensi & Tchounwou (2017) report that potassium infusions or long term fasting may also lead to hyperkalemia.

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

As reviewed in *Specific Uses of the Substance*, a number of food and beverage products incorporate the use of KC, including noodles, raisins, meat, and wine (see *Specific Uses of the Substance*, above). A summary of the availability of alternative practices is outlined in Table 2, below.

[13] The unscheduled DNA synthesis assay is used to determine the functionality of nucleotide excision repair mechanisms within a given cell (Kelly & Latimer, 2005). Practically speaking, this provides insight into whether a cell can effectively remove damaged lesions within a DNA strand (Kelly & Latimer, 2005).

**Table 2. Alternative practices available to replace the use of KC in handling/processing applications.**

| Primary Use | Alternative Practices | Reference |
|---|---|---|
| Alkaline noodle production | Limited availability of alternative practices | (Fu, 2008; S. Jia et al., 2021) |
| Dutch processing of cocoa | Ion exchange chromatography for natural alkalization | (Andruszkiewicz, 2019) |
| Raisin drying time reduction | High-humidity hot air impingement blanching (HHAIB) | (Bai et al., 2013) |
| | Pulsed vacuum drying (PVD) | (Xie et al., 2017) |
| | Mechanical abrasion | (Adiletta et al., 2015) |
| | Microwave treatment | (Patidar et al., 2021) |
| | Ultrasound wave treatment | (Patidar et al., 2021) |
| Boiler additive to reduce acid corrosion | Limited availability of alternative practices | (Daneshvar-Fatah et al., 2013) |
| Deacidification of wine | Planting hybrid wine cultivars with low to moderate titratable acidity | (Atucha et al., 2018) |
| | Utilizing rootstock cultivars that are indicated to produce lower titratable acidity | (Oliveira et al., 2020) |
| | Organic mulching, cover cropping, and reduced tillage | (Susaj et al., 2013) |
| | Avoidance of water stress before veraison | (Jackson & Lombard, 1993) |
| Modified hop extract production | Brewing with whole or pelletized hops | (O'Rourke, 2003) |
| Phosphate replacement in meat products | Power ultrasound treatment | (Thangavelu et al., 2019) |
| | High pressure processing | (Hygreeva & Pandey, 2016) |

*Noodles*

Alkaline noodles are a popular and traditional food throughout China and Southeast Asia (Fu, 2008). Their production method is dependent on the alkalization of dough using KC or sodium carbonate in order to achieve the specific color, texture, and flavor profile associated with traditional alkaline noodles (Fu, 2008). The inherent need to use alkaline salts in the noodles eliminates the possibility of alternative practices that would avoid their use, although other alkaline salts aside from KC may be used (Fu, 2008; Jia et al., 2021).

*Cocoa*

Dutch process cocoa is produced through the addition of an alkali to cocoa beans, leading to changes in the final cocoa product that are desired by industry (Bloomberg, 1918; Puchol-Miquel et al., 2021; Taş & Gökmen, 2016). Recent work suggests that an additive-free alkalization is feasible. Andruszkiewicz (2019) developed a method to increase cocoa pH by using an ion-exchange chromatography resin which absorbed cations. Although not currently in use in commercial applications, the ion exchange chromatography method successfully raised the pH of cocoa nibs from 5.34 to 9.70 (Andruszkiewicz, 2019). The pH achieved in the ion exchange chromatography process is similar to that of the traditional method (Miller et al., 2008).

*Raisins*

Bai et al. (2013) cite concerns about chemical pretreatment, such as the use of KC, as the catalyst for developing alternative practices to reduce raisin drying time. One alternative is the high-humidity hot air impingement blanching (HHAIB) process. This process exposes grapes to temperatures of 110ºC for 90 seconds prior to air drying at 60ºC. It is found to decrease drying time without producing undesired enzymatic browning in the final product (Bai et al., 2013).

The use of far-infrared radiation in combination with pulsed vacuum pressure has also been shown to produce high quality raisins and other dried berries, such as goji berry (Bai et al., 2013; Xie et al., 2017).

Mechanically abrading grapes leads to variable results in non-chemical raisin production. This process reduces drying time in both white and red grapes, but results in a raisin color that does not meet industry standards (Adiletta et al., 2015; Patidar et al., 2021). New techniques, including microwave and ultrasound treatment, show promising results in reducing raisin drying time (Patidar et al., 2021). These approaches maintain appropriate pigmentation, although some loss of soluble solid has been reported under the application of ultrasound waves (Patidar et al., 2021).

*Boiler Water*

KC is utilized as an alkaline substance in boiler water to reduce corrosion caused by acidic water (U.S. FDA, 2022d). Alternative practices to reduce the corrosion are limited, however alternative alkalis exist, as discussed in *Evaluation Questions #12* and *#13* (Daneshvar-Fatah et al., 2013).

*Wine*

Cool temperatures can increase acidity in wine grapes (Atucha et al., 2018; Oliveira et al., 2020). Growers can plant hybrid wine cultivars that produce grapes with lower acidity compared to other cultivars when grown under cooler temperatures (Atucha et al., 2018). Hybrid cultivars are not available for the production of all types of wine at this time (Atucha et al., 2018). Another practice is to graft scions[14] from desired wine grape cultivars to rootstock that produces fruit with reduced acidity (Oliveira et al., 2020).

Water stress, caused by lack of water or salt stress, can increase undesirable traits in grapes including an increase in soluble solids and acidity (Jackson & Lombard, 1993; Susaj et al., 2013). One study found that maintaining an irrigation regime that eliminated water stress until the grapes were ripe, lowered acidity (Jackson & Lombard, 1993). Cultivation practices such as reduced tillage and the inclusion of organic mulches and cover crops are indicated as a means to lower grape acidity, increasing water availability through reduced weed competition and lower evaporation (Susaj et al., 2013).

*Beer*

KC is used in the production of stabilized iso-α-acids, which are the active flavor ingredient in modified hop extract (O'Rourke, 2003). Modified hop extract favorably improves beer flavor without complicating factors such as plant debris that must be removed or an overall loss of flavor during fermentation (O'Rourke, 2003). Whole or pelletized hop cones may replace hop extract in the fermentation process, if desired (O'Rourke, 2003).

*Meat*

Phosphates, particularly sodium triphosphate (STP), are used to produce desirable color, texture, and cooking performance in processed meat (Jarvis et al., 2020; LeMaster et al., 2019). Power ultrasound treatment utilizes high-intensity, low-frequency sound waves to treat meat (Thangavelu et al., 2019). This process improves meat tenderness, increases water-holding capacity (WHC), and increases processing time without the addition of any synthetic chemicals (Thangavelu et al., 2019).

High pressure processing is an alternative meat treatment that doesn't require the use of added chemicals. This process uses very high hydrostatic pressure to produce meat with higher WHC and improved emulsion stability (Hygreeva & Pandey, 2016).

**<u>Evaluation Question #12:</u> 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)).**

A number of nonsynthetic substances listed at §205.605(a) may be used in lieu of KC to achieve similar results to those described in *Specific Uses of the Substance*.

*Nonsynthetic Alternatives:*

<u>Calcium carbonate</u>

Calcium carbonate is a nonsynthetic alkaline salt that may be used in the deacidification of wine (NOP, 2018; Santos et al., 2016). When used in the deacidification of blueberry wine, Santos et al. (2016) found that

[14] Scions are the aboveground growing shoots that can be grafted onto rootstock of the same plant species in order to achieve a number of desired growth effects (Tworkoski & Miller, 2007).

calcium carbonate effectively reduced wine acidity and produced the most favorable wine in subsequent sensory tests.

Rebellato et al. (2021) added calcium carbonate to wheat noodle dough, effectively achieving the desired texture results that are typically associated with KC addition. The pH of the resulting noodle, however, was not as alkaline as is desired in a final product (Rebellato et al., 2021).

The European Food Safety Authority concluded that calcium carbonate poses no risk as a food additive when consumed in quantities close to recommended daily intake amounts for a given age group (EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), 2011). This determination was based on the natural abundance of calcium carbonate and data compiled on rodent toxicity, which found 1500 mg/kg bw/day to be the upper healthy limit for consumption (EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), 2011).

_Sodium carbonate and bicarbonate_

Kansui is a combination of KC and sodium carbonate (Ding et al., 2021)**.** It is one of the primary substances used in the production of alkaline noodles (Ding et al., 2021). Sodium carbonate is also commonly used independently to produce the alkaline noodles (Obadi et al., 2022). Sodium bicarbonate, another nonsynthetic, may also be used instead of kansui, KC, or sodium carbonate (Obadi et al., 2022). The quality of the noodles produced from either of these alternatives is characterized as lower than that produced by the addition of kansui or KC. Sodium bicarbonate produces a less desirable texture after cooking, while sodium carbonate produces a green-yellow noodle instead of bright yellow (Obadi et al., 2022).

The U.S. FDA outlines a number of substances that are allowed for use as boiler water additives in situations when the steam will subsequently come in contact with food (U.S. FDA, 2022d). Sodium carbonate is a nonsynthetic substance on the list. However, we found no information on the actual application and utility of the substance's use in boiler water in our review of the current literature.

Sodium carbonate can be used as a replacement for KC when combined with olive oil or other fatty acid derivatives to reduce drying time in raisins (Patidar et al., 2021).

Dutch processing of cocoa increases the material's pH to improve various characteristics. While KC is the predominant alkali used to do this, there are a number of alternatives available (Puchol-Miquel et al., 2021; Rodríguez et al., 2009). One study identified that nonsynthetic sodium bicarbonate can be used as a replacement for KC when only mild alkalization is desired (Puchol-Miquel et al., 2021). Another study explored the use of both sodium carbonate and sodium bicarbonate, finding that both sufficiently alkalized cocoa but also increased red pigment in the final product more than synthetic alkalis (Rodríguez et al., 2009).

Like KC, sodium carbonate and sodium bicarbonate are also relatively safe for human consumption in small quantities. The U.S. Food and Drug Administration considers both sodium carbonate and sodium bicarbonate to be GRAS substances (U.S. FDA, 2022i, 2022h). Human patch tests indicate sodium carbonate is not an irritant, however the alkaline nature of the substance as an aqueous solution may lead to localized necrosis of the mucous membranes (PubChem, 2018b). Consuming large quantities of sodium carbonate may cause digestive system corrosion, circulatory collapse, and death; however, no acute poisonings have been reported in the literature to date (PubChem, 2018b). Likewise, sodium bicarbonate poses a number of acute and chronic risks to the gastric system, however there is little documentation of toxicity for the substance (PubChem, 2018a).

To reach a determination of nonsynthetic status using Guidance 5033-1, sodium carbonate and bicarbonate must be derived from the mined mineral, trona (Maul et al., 2014; NOP, 2016). There are a number of natural deposits of trona worldwide and use of its derivatives as food additives is not expected to pose any risk to the environment (EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), 2010; PubChem, 2018b). Sodium bicarbonate is also reported to hold low ecotoxicological risk (European Food Safety Authority (EFSA) et al., 2018). Although the use of sodium carbonate and bicarbonate in food does not explicitly pose a risk to the environment, trona mining is associated with methane emissions, as well as sodium chloride brine and tar that may seep into the surrounding area (U.S. EPA Coalbed Methane Outreach Program, 2016; Wiig et al., 1995).

Chloride salts

Calcium chloride and magnesium chloride are both salts that can be produced nonsynthetically and can be used in the production of modified hop extract (U.S. FDA, 2022a). Both salts perform similarly to KC, increasing the content of iso-α-acid in hop extract (O'Rourke, 2003).

Magnesium chloride and calcium chloride are both GRAS substances, and are authorized food additives in the European Union (EFSA Panel on Food Additives and Flavourings (FAF) et al., 2019; U.S. FDA, 2022e, 2022f). Both substances pose low acute oral toxicity risk and low genotoxicological risk (EFSA Panel on Food Additives and Flavourings (FAF) et al., 2019). The two chlorides have been explored as environmentally-favorable alternatives to salt-based road deicers, and the use of either substance in this application did not induce adverse effects in aquatic life in areas surrounding or downstream of treated roads (Baek et al., 2014; Goodrich et al., 2009; Snow, 2003).

Microbial products

There has been growing interest from wine makers to use non-*Saccharomyces* yeasts to alter and improve a variety of wine characteristics (Benito et al., 2019). Several species, including *Schizosaccharomyces pombe, Oenococcus oeni,* and *Zygosaccharomyces bailii*, have displayed an ability to deacidify wines, and may be alternatives to the use of potassium or calcium salts (Benito et al., 2019; Cioch-Skoneczny et al., 2021; Vicente et al., 2022). Although these yeasts are naturally occurring in wines, the deacidification process works best when these alternative yeasts are added in greater quantities prior to subsequent fermentation with *Saccharomyces cerevisiae* (Benito et al., 2019; Cioch-Skoneczny et al., 2021).

Non-*Saccharomyces* yeasts are added to wine at the beginning of the fermentation process to achieve targeted wine characteristics (Benito et al., 2019; Cioch-Skoneczny et al., 2021). Species such as *S. pombe* and *Z. bailii* have low to moderate resistance to alcohol, and in general the non-*Saccharomyces* taxa cannot survive once the fermenting wine reaches an alcohol level of 4%(*v/v*) (Benito et al., 2019). Human health and environmental effects associated with the use of these yeasts in wine are not reported; however, it is noted that the non-*Saccharomyces* species are used to avoid genetically modified *Saccharomyces* yeasts (Vicente et al., 2022).

Potassium chloride

Health concerns related to hypertension and high phosphate consumption drive the demand for non-phosphate NaCl salt replacements (Cruz-Romero et al., 2022; Erem & Razzaque, 2018). In part, these salts improve texture, by increasing water holding capacity in processed meat products (Cruz-Romero et al., 2022). Although KC shows promise, potassium chloride is the most common salt replacement in sodium reduction efforts (Desmond, 2006). Several studies indicate potassium chloride is capable of replacing NaCl, without negative sensory effects, if used at a replacement rate lower than 50% and in combination with substances like tapioca starch or onion (Cruz-Romero et al., 2022; Lilic et al., 2015). Replacement rates vary depending on the food product in which they are utilized, and excessive quantities may result in a metallic flavor (Inguglia et al., 2017). Replacement rates ranging from 40-65% show success in high-fat, solid foods, such as meat and cheese (Grummer et al., 2013; Inguglia et al., 2017). When used in watery products, replacement rates above 20% lead to off-flavor (van Buren et al., 2016). Full replacement of NaCl is not feasible with potassium chloride, as a bitter flavor will ultimately become apparent (Cruz-Romero et al., 2022; Lilic et al., 2015).

Potassium chloride is considered a GRAS substance (U.S. FDA, 2022g). Fatal hyperkalemia is unlikely to occur via consumption of potassium salts, but it is possible under some circumstances (PubChem, 2015; Steffensen et al., 2018). Acute poisoning with potassium chloride may occur when potassium is introduced via an IV and in rare cases oral overdose (EFSA Panel on Food Additives and Flavourings (FAF) et al., 2019; PubChem, 2015). Daily consumption above 40mg/kg bodyweight may result in gastrointestinal irritation, and aqueous solutions of potassium chloride with 60% or greater concentration may irritate skin

(EFSA Panel on Food Additives and Flavourings (FAF) et al., 2019; PubChem, 2015). No fetotoxic, teratogenic, and genotoxic effects are reported in mice, rats, or bacterial tests as a result of low to moderate doses of the substance (EFSA Panel on Food Additives and Flavourings (FAF) et al., 2019; PubChem, 2015). However, high concentrations have some genotoxicity towards mammalian cells cultured at low pH (EFSA Panel on Food Additives and Flavourings (FAF) et al., 2019; PubChem, 2015). Several tests of acute and chronic ecotoxicity tests indicate that potassium chloride is not considered a hazard to freshwater organisms (PubChem, 2015).

*Allowed Synthetic Alternatives:*

*Sodium hydroxide*

Sodium hydroxide is an effective alternative to KC for reducing drying time in raisin production (Patidar et al., 2021). It acts by producing microcracks in the grape skin. The resulting raisins may appear dull or pale in color (Patidar et al., 2021). This may be problematic, as one sensory study found bright color and appearance to be highly desired by consumers (Foshanji et al., 2018).

Sodium hydroxide may also be used as an alternative alkali in the Dutch processing of cocoa, producing a cocoa with a desirable color and sugar content (Rodríguez et al., 2009).

The U.S. FDA lists sodium hydroxide as an allowed substance for use as an alkali in boiler water that produces steam that may contact food (U.S. FDA, 2022d).

Sodium hydroxide is considered a GRAS substance that is useful as a pH control agent, when used in accordance with good manufacturing practices (U.S. FDA, 2022j). Human toxicity studies indicate the substance may:

- Cause caustic strictures of the esophagus following oral consumption (PubChem, 2012).
- Irritate skin when used in combination with sodium lauryl sulphate (PubChem, 2012).
- Irritate skin when applied independently at high doses (PubChem, 2012).
- Irritate the upper respiratory system following long-term exposure to sodium hydroxide dust (PubChem, 2012).
- Lead to pharyngeal and esophageal edema, asphyxia, and death, when orally ingested at high concentrations (PubChem, 2012).

Acute exposure studies in animals indicate sodium hydroxide is capable of causing a high degree of destruction of all tissue types studied, provided the contact window was sufficiently long (PubChem, 2012). Ecotoxicity studies indicate concentrations of 20-100mg/L are sufficient to kill aquatic organisms, and doses at the lower end of the range may also reduce fertility in fish (PubChem, 2012).

Aqueous solutions of sodium hydroxide at concentrations below 8% are reported to be an irritant to skin, eyes, and the respiratory tracts of dogs, cats, and ornamental fish, however they are still considered safe for use as an acidity regulator in animal feed when used at sufficiently low levels (EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), 2012).

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

As noted in *Historic Use*, it is possible to derive potash from an agricultural source, such as wood, however there are no known commercial sources of potash-derived KC (Schultz et al., 2000).

## Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:

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All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

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