# Potassium Chloride

## Handling/Processing

### Identification of Petitioned Substance

**Chemical Names:**
monopotassium chloride; KCl; hydrochloric acid, potassium salt (1:1); sylvite

**Other Names:**
kaliumchlorid [German]; chlorure de potassium [French]; cloruro potásico [Spanish]; muriate of potash; MOP; potash; salt substitute; E508; sylvine

**Trade Names:**
NoSalt; Salt Substitute; Lite Salt; Nu-Salt; Zea Salt; Potassium Pro; KaliSel

**CAS Numbers:**
7447-40-7: potassium chloride
14336-88-0: sylvite

**Other Codes:**
UNII: 660YQ98I10
EC number: 231-211-8
NIOSH RTECS number: TS8050000

### Summary of Petitioned Use

The National Organic Standards Board (NOSB) recommended that potassium chloride be added to the National List of Allowed and Prohibited Substances as a processing material in 1995 (NOSB, 1995). Potassium chloride was included in the final rule at 7 CFR 205.605(a), published in 2000 (NOP, 2000), where it has remained since.

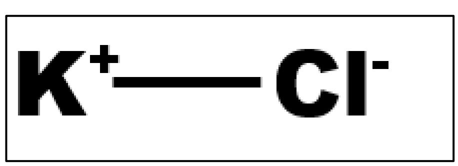
> **§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."**
>
> The following nonagricultural substances may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.
>
> (a) *Nonsynthetics allowed*:
> …
> Potassium chloride

This report serves to support the sunset review of potassium chloride.

### Characterization of Petitioned Substance

**<u>Composition of the Substance:</u>**
Potassium chloride is a metal halide salt composed of one potassium cation and one chloride anion with the formula KCl (National Center for Biotechnology Information, n.d.). Chemically, potassium chloride is defined as a binary ionic compound formed from the reaction of an alkali metal ion and a halogen ion (Zumdahl & DeCoste, 2017). Potassium chloride is similar to sodium chloride, or common table salt, in terms of crystal structure (Zumdahl & DeCoste, 2017).

**Figure 1. Chemical Structure Depiction of Potassium Chloride**



Potash is a generic term referring to several soluble potassium salts (naturally occurring or chemically produced) that provide plant-available potassium ($K_2O$). These soluble salts include potassium chloride (muriate of potash, MOP), potassium sulfate (sulfate of potash, SOP), and potassium magnesium sulfate (sometimes known as sulfate of potash magnesia, SOPM, or langbeinite) (USGS, 2020). Muriate of potash typically refers to an agricultural grade of potassium chloride which might contain up to 5% sodium chloride (USGS, 2020). Potassium chloride made up approximately 20% of total potash production in the United States in 2019 (USGS, 2020).

Several grades of potassium chloride are produced, mostly designated by grain size (Kafkafi et al., 2001):

- Granular or coarse: 0.595-3.36 mm particle size. Granular grade potassium chloride is suitable for single-nutrient applications, or for mechanical blending with other fertilizer materials.
- Standard: 0.210-1.19 mm particle size. Standard grade is suitable for single-nutrient application, hand blending, or granulated mixed fertilizer blends.
- Fine: 0.105-0.420 mm particle size. Fine grade is typically useful in the production of granulated blended fertilizers or for production of potassium sulfate.
- Soluble/suspension: 0.105-0.420 particle size. Soluble/suspension grade has the same grain size range as fine grade, but is a purer product suitable for fully dissolved liquid fertilizer blends, in single-nutrient liquid applications, of for the production of potassium sulfate.
- Industrial/chemical; this grade does not carry a size designation, and is a nearly pure product only manufactured by a few producers. Only about 4-5% of all potash produced is industrial grade.

Extremely high-purity food and pharmaceutical grade potassium chloride (>99%) is also manufactured, but its percentage in the total market is relatively minuscule (Rahm, 2017).

**<u>Source or Origin of the Substance:</u>**
The average concentration of potassium in the Earth's crust is approximately 25,000 ppm, almost wholly locked in aluminum silicate minerals like feldspar and mica (Kafkafi et al., 2001). Only about 2% of potassium in the crust is in exchangeable forms in soils. Crustal chloride (including potassium chloride, other chloride-containing minerals, and chloride dissolved in surface waters) concentrations are approximately 1,500 ppm, but the level is elevated in the oceans due to chloride's tendency to weather and solubilize from minerals easily (Kafkafi et al., 2001).

The naturally occurring mineral form of potassium chloride is known as sylvite, but it typically occurs in mixed salt deposits consisting of various other minerals including sylvinite (a sylvite and halite, NaCl, mixture); carnallite (a hydrated double salt of potassium chloride and magnesium chloride with the formula $KCl \cdot MgCl_2 \cdot 6H_2O$); kainite (a hydrated potassium and magnesium sulfate chloride with formula $KMg(SO_4)Cl \cdot 3H_2O$); and langbeinite (potassium magnesium sulfate, with formula $K_2Mg(SO_4)_3$) (Patnaik, 2003; Schultz et al., 2000).

As natural saltwater solutions evaporate, certain salt minerals precipitate in a specific order depending on their thermodynamic properties and concentrations. In general, first calcium carbonates form, then calcium sulfate (gypsum) crystallizes, depleting all of the calcium in the brine, followed by sodium chloride salt (Drever, 1997; Schultz et al., 2000). Finally, chlorides and sulfates of potassium and magnesium crystallize (Broughton, 2019; Drever, 1997; Schultz et al., 2000).[1]

The ultimate source of potassium ions in the oceans is the result of the weathering of potassium-bearing rocks like feldspars and micas (Schultz et al., 2000). Large amounts of chloride ions in seawater are thought to arise from chlorine released by undersea mid-ocean ridge volcanism, or by continental or "hotspot"

[1] This sequence of mineralization is simplified (Drever, 1997). A large number of factors can affect the sequence depending on environment and other minerals present (Drever, 1997). The general mineralization cycle is known as the Hardie-Eugster model and assumes a single stage, complete evaporation event (Drever, 1997; Hardie & Eugster, 1970). In nature, cyclic wetting and drying events also greatly complicate the system (Drever, 1997).

volcanic processes and subsequent transport back to oceans by sedimentation and erosion (Schilling et al., 1978).

In the United States, approximately 50% of potash production occurs at operations in New Mexico (as of 2019), but significant deposits occur in Utah, Montana, North Dakota, Arizona, and Michigan (USGS, 2020). Globally, the largest potash-producing countries are Canada, Russia, Belarus, China, Germany, and Israel (USGS, 2020). Canada, the largest producer, is estimated to hold 50% of the world's potash reserves (Warren, 2010). Potassium ores, at current extraction rates of known deposits, are expected to last another 400 years (Ciceri et al., 2015).

Three geologic environments contain the majority of extractable potassium chloride: 1) evaporites, 2) brines, and 3) seawater.

*Evaporites*

Major potash deposits are invariably of marine origin (Schultz et al., 2000). As large bodies of seawater are isolated from the ocean by tectonic movements and sea level changes, the salt concentration increases through solar evaporation, sometimes becoming saturated and precipitating salt beds on the shore or lake bottom (Broughton, 2019; Warren, 2010). Climate adjustments over geologic time scales provide more or less atmospheric water, resulting in redissolution or later precipitation of salt beds as the saturation levels change, which leads to numerous salt deposits between clay layers (Schultz et al., 2000; Warren, 2010). In arid environments, eventually little to no water remains and mineral deposits are left behind (Schultz et al., 2000; Warren, 2010). These interbedded deposits are often significant and they are responsible for the massive potassium reserves found beneath the Canadian prairie, in Belarus, Russia, and New Mexico USA (Broughton, 2019; Warren, 2010).

Due to the lack of notable deposits of potassium and magnesium chlorides forming in the present day, it is thought that some change to seawater chemistry occurred over hundreds of millions of years (Broughton, 2019; Lowenstein et al., 2001).[2] In the past, calcium carbonate and potash deposits were commonly associated with evaporation of seawater, whereas today evaporites are more calcium sulfate (gypsum) rich (Broughton, 2019).

*Brines*

Brines may exist on the surface in inland lakes, such as the Great Salt Lake in Utah, or underground as groundwater beneath dry salt playas, such as the Great Salt Lake Desert west of the lake (Boden et al., 2016; Rupke, 2012). For surface lakes, various methods based on solar evaporation and beneficiation are used to isolate potassium salts (Schultz et al., 2000). In subsurface deposits, groundwater becomes enriched with potassium by the dissolution of solid beds of evaporite salts (Rupke, 2012). These brines can be exploited through well pumping (Rupke, 2012; USGS, 2020).

For very deep evaporite deposits, it may not be feasible to extract solid salts, necessitating solution mining techniques (Broughton, 2019). Fresh water is injected into the ore zones to dissolve the salts, followed by the injection of sodium chloride brine. The resulting super-saturation of sodium chloride causes precipitation of halite in the chamber and preferentially dissolves the potassium chloride in the ore, which can be retrieved (Broughton, 2019).

As solid subterranean salt deposits are extracted, groundwater may also flood the chambers, sometimes making them impossible to mine with conventional methods, as in some areas of the Canadian prairie evaporite zones (Broughton, 2019). These flooded mines are sometimes converted to solution mining operations where brine is the target (Broughton, 2019).

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[2] Research with mineral fluid inclusions indicates that substantial changes to dissolved ion concentrations in the oceans occurred throughout the Phanerozoic Eon (about 541 million years ago to the present), particularly during the Cambrian (541 million years ago to 485.4 million years ago), Silurian (444 million years ago to 419.2 million years ago), and Cretaceous (145 million years ago to 66 million years ago) periods, likely associated with periods of high volcanic activity and high sea levels (Lowenstein et al., 2001).

*Seawater*

Potassium and chloride ions make up a significant portion of the dissolved elements in seawater, sixth and first in abundance, respectively (Drever, 1997). Compared to evaporite and brine deposits, however, the potassium content in seawater is not great enough to currently make economical extraction possible (Ciceri et al., 2015; Schultz et al., 2000).[3] The prevalence of seawater evaporation-derived potash deposits in geologic history does not necessarily indicate that potassium was more concentrated in ancient seas. Instead, the crystallization sequence is affected by relative concentrations of magnesium, calcium, sodium, and carbonate in seawater through complex thermodynamic equilibria (Lowenstein et al., 2001).

See *Evaluation question #1* for further information on potassium chloride production and refining.

**Properties of the Substance:**

Potassium chloride is freely soluble in water, soluble in ether, glycerol, and alkalies, and slightly soluble in alcohol (Patnaik, 2003). Pure potassium chloride forms cubic crystals resembling common table salt (National Center for Biotechnology Information, n.d.). Natural potassium chloride (sylvite) minerals may occur as massive rock crystals in a variety of colors resulting from impurities, most often reddish from iron oxide (National Center for Biotechnology Information, n.d.). See Table 1 for Physical and Chemical Properties.

Potassium chloride tends to cake and the crystals often crack during transport and handling, producing a dust nuisance (Kafkafi et al., 2001).

**Table 1: Physical and Chemical Properties of Potassium Chloride**

| Property | Value[a] |
|---|---|
| Physical State and Appearance | cubic crystals, powder, or granular crystalline mass |
| Odor | odorless |
| Taste | saline, bitter |
| Color | colorless, white, bluish, or yellowish red |
| Molecular Weight | 74.55 g/mol |
| Density | 1.98 g/cm$^3$ |
| pH | 7 |
| Solubility | almost completely water soluble |
| Boiling Point | 1500 °C (sublimes) |
| Melting Point | 770 °C |
| Stability | hygroscopic (prone to moisture absorption by air); incompatible with strong oxidizers and strong acids |
| Reactivity | not typically very reactive; reacts with sulfuric acid |

**[a]Source: (Dana, 1898; National Center for Biotechnology Information, n.d.; Royal Society of Chemistry, 2022)**

**Specific Uses of the Substance:**

Potassium chloride is used as a salt replacer or for potassium enrichment in baby formulas, cereals, cheese, bread, frozen entrees, meats, chips and crisps, sports drinks, soups, sauces, and snack/meal bars (Cargill, Inc., 2022; Greer et al., 2020). Several government health agencies worldwide have recently been calling for drastic reductions in sodium intake in the population due to the global medical issues associated with elevated blood pressure, a major risk factor for cardiovascular disease (Greer et al., 2020). Much research has been devoted to potassium chloride as a partial replacer of common sodium chloride salt in foods. However, different populations get excessive sodium from variable sources (Greer et al., 2020). It is estimated that in China, for example, 75% of sodium intake results from seasoning food while cooking, meaning that adding less discretionary salt (or partially replacing salt with other substitutes) can help alleviate health issues in the population (Greer et al., 2020). In the United States, however, 70% of sodium

[3] The concentration of chloride in seawater is approximately 19,350 ppm, and potassium is 399 ppm (Drever, 1997).

comes from prepared processed or restaurant foods, so formulation changes will be necessary to reach the same levels of benefit (Greer et al., 2020).

Salt plays many roles in the production of bread, beyond just flavoring effects (G. Chen et al., 2018). Sodium chloride provides elasticity and strength to dough during mixing, microbial growth control, and desirable bread texture (G. Chen et al., 2018). It is thought that salt controls the growth rate of yeast, allowing more bubbles to be trapped in the gluten, leading to “fluffier” textured bread (G. Chen et al., 2018). Potassium chloride has been shown to impart comparable effects during bread making, and the flavor difference is minimal when mixed with some sodium chloride, magnesium sulfate, and magnesium chloride (G. Chen et al., 2018).

While potassium chloride can impart some preservation effects and protection from pathogens in food, like sodium chloride salt, the effect is far less pronounced (Greer et al., 2020).

Greater than 90% of potassium chloride produced is used in fertilizer applications, as potassium chloride itself or after transformation into potassium sulfate (Patnaik, 2003; Schultz et al., 2000).

Other uses for potassium chloride (or other manufactured potash materials derived from potassium chloride) include components of soap or detergent, glass, ceramics, rubber, or industrial chemicals (Warren, 2010). Potassium chloride is sometimes used as a road deicer, and performs better than sodium or magnesium chloride at exceedingly low temperatures (down to -11°C, or 12.2°F) (Kafkafi et al., 2001). Water softening technology can also utilize potassium chloride as a recharging agent in ion exchange systems, working to exchange with calcium, magnesium, manganese, and iron in the resin bed (Kafkafi et al., 2001). Potassium chloride is used in some flame retardants, textiles, and dyes (Organisation for Economic Co-operation and Development (OECD), 2001).

**Approved Legal Uses of the Substance:**

*Food and Drug Administration (FDA)*

Potassium chloride is on the FDA list of “Direct Food Substances Affirmed as Generally Recognized as Safe” at 21 CFR §184.1622 with no limitation other than current good manufacturing practice when used as a flavor enhancer, flavoring agent, nutrient supplement, pH control agent, stabilizer, or thickener, and it may be used in infant formula. It is also considered “Generally Recognized as Safe” in animal feed at 21 CFR §582.5622.

In 2020, FDA issued a guidance indicating that potassium chloride could be referenced as “potassium salt” on product ingredient statements to make it clear to consumers that the substance was included in the formulation as a sodium chloride salt substitute (Center for Food Safety and Applied Nutrition, 2020).

*The Association of American Feed Control Officials (AAFCO)*

AAFCO lists potassium chloride as a mineral product in livestock feed, and it is included in the list of “Nutrients and/or Nutritional Supplements” at Subpart E (AAFCO, 2022).

*Environmental Protection Agency (EPA)*

Potassium chloride is exempt from the requirement of a tolerance as either an active or inert ingredient in pesticide formulations at 40 CFR 180.950, and is classified as List 4A, a minimal risk inert ingredient, on 2004 EPA List 4 (US EPA, 2004).

*United States Department of Agriculture (USDA)*

The Food Safety Inspection Service (FSIS) permits mixtures of sodium chloride, potassium chloride, and sodium gluconate for use in muscle meats and poultry for sodium reduction, and mixtures of sodium chloride, sodium ferrocyanide, potassium chloride, magnesium carbonate, sodium nitrite, medium chain triglycerides, and sodium gluconate for use in whole muscle meats, meat products, and poultry products for sodium reduction and curing at up to 3% of a product formulation (Food Safety Inspection Service, 2021).

**Action of the Substance:**

Potassium is the most abundant cation in the human body and is critical in the acid-base balance of fluids, the pressure gradient across cell membranes, and the balance of electrical charge gradients (Pavlech et al., 2021). Due to the prevalence of grains and processed foods in the modern diet, human dietary intake of potassium is typically lower than recommended, which may be linked to health problems (Römheld & Kirkby, 2010). Foods with significant potassium include many fruits, nuts, leafy and root vegetables, and meat (Pavlech et al., 2021). Biological potassium regulation primarily occurs in the kidneys (Pavlech et al., 2021). While severe hypokalemia, a major potassium deficiency, is rare as a result of reduced dietary intake, it can be a concern for those with certain diseases, those experiencing prolonged diarrhea and vomiting, or those on a variety of different diuretic, steroidal, antibiotic, or bronchodilating medications (Pavlech et al., 2021).

Chloride salts of potassium, magnesium, and calcium are essential nutrients involved in electrolyte balance, and necessary for proper cellular function in humans (EFSA Panel on Food Additives and Flavourings (FAF) et al., 2019). Chlorides are absorbed through the gastrointestinal tract, distributed to bodily tissues, and excreted in sweat, urine, and feces (EFSA Panel on Food Additives and Flavourings (FAF) et al., 2019).

**Combinations of the Substance:**

Since potassium chloride sometimes imparts an unpalatable bitter or metallic taste when used as a sodium replacement substance, it may be mixed with other flavoring agents like magnesium chloride, magnesium sulfate, calcium chloride, amino or food acids, umami substances, or spice mixtures (Greer et al., 2020). The EFSA Panel on Food Additives and Flavourings (2019) found in a survey of thousands of food products in Europe that it was rare for potassium chloride to be used alongside other non-sodium chlorides (calcium chloride, magnesium chloride, or hydrochloric acid) in the same product formulation, however. It may also be iodized like common sodium chloride salt (Greer et al., 2020). As a sodium replacement substance, potassium chloride is often found alongside potassium lactate and potassium phosphate in prepared low-sodium food formulations (Martínez-Pineda et al., 2021). Due to its tendency to absorb water, anti-caking agents such as tricalcium phosphate, sodium ferrocyanide, silicon dioxide, and magnesium carbonate may be included in some food-grade formulations to avoid "caking" (ICL Industrial Products, n.d.; Morton Salt, 2021).

Cruz-Romero et al. (2022) explored partial replacement of sodium chloride salt with a potassium chloride/tapioca starch mixture in breakfast sausages and found that the sensory differences (texture, color, juiciness, and saltiness) were negligible compared to full sodium content sausage at some tested replacement levels. Similarly, Lu et al. (2022) had success masking the bitter taste of potassium chloride at 50% salt replacement by mixing the potassium chloride with carrageenan. This replacement also preserved the fundamental textures and expected qualities of fries, ham, salted fish, chicken soup, and mushroom soup compared to potassium chloride replacement alone (Lu et al., 2022). Carrageenan also appears on the National List at §205.605(a). Akgün et al. (2019) found that formulations of tomato soup containing 60% of the normal sodium chloride content, 28% potassium chloride, and 12% lysine and glutamic acid (amino acids) were nearly undetectable by their human testers compared to full salt versions, but increased aerobic bacteria counts may result, which might increase pathogen contamination risks.

Synthetic potassium hydroxide (KOH) can be prepared from potassium chloride, and appears on the National List as such:

- §205.605(b), Synthetic materials permitted as nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)."Prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.
- §205.601(j)(1), As plant or soil amendments. Potassium hydroxide is permitted as an alkali extractant for aquatic plant products.
- §205.601(j)(3), As plant or soil amendments. Potassium hydroxide is permitted as an alkali extractant for humic acids.

Potassium hydroxide is produced by electrolysis of potassium chloride brine, creating hydrogen and chlorine gas as by-products (Kapusta, 1968; Patnaik, 2003).

Synthetic potassium carbonate also appears on the National List at §205.605(b) and is often produced from potassium chloride as a raw material (Schultz et al., 2000). Electrolysis of potassium chloride results in potassium hydroxide, which is then combined with carbon dioxide gas to produce potassium carbonate (Schultz et al., 2000).

## Status

**Historic Use:**

Potassium chloride was first determined to be a "Generally Recognized as Safe" (GRAS) substance by the FDA in 1983, for the uses described above under the *Approved Legal Uses of the Substance* section. See 21 CFR 184.1622.

In 2010, the Institute of Medicine (IOM), now known as the National Academy of Medicine (NAM), recommended that the FDA adopt new standards for the regulation of sodium content of foods due to the health problems associated with excess sodium intake, recognizing potassium chloride as the most common and effective sodium replacement substance (Murphy et al., 2021). In response, the FDA has organized foods into categories, targeting specific groups as good candidates for sodium reduction, but so far has only issued a voluntary draft guidance (Murphy et al., 2021). Morrison et al. (2021) warn that a voluntary system provides little transparency, and presents significant risk to those susceptible to hyperkalemia (potassium overdose) and those with chronic kidney disease.
The use of potash salts, including potassium chloride, as fertilizer during crop production has been common for centuries (Ciceri et al., 2015).

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

Potassium chloride is not mentioned specifically in the Organic Foods Production Act of 1990.

The National Organic Standards Board (NOSB) recommended that nonsynthetic potassium chloride be allowed in organic food processing in 1995 (NOSB, 1995). Potassium chloride was added to the National List of Allowed and Prohibited Substances in its first iteration in the year 2000, at §205.605(a), *Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))"* without annotation (NOP, 2000), where it has remained since.

Synthetic potassium compounds are also permitted by §205.605(b) due to their inclusion on 21 CFR 104.20, the FDA's *Nutritional Quality Guidelines For Foods.* During research for this report, we did not find any commercially available synthetic potassium chloride products that are not derived from concentrated and purified mined mineral sources.

Potassium chloride also appears on the National List of Allowed and Prohibited Substances at 7 CFR §205.602(e) of the National Organic Program (NOP) regulations, as a prohibited substance for organic crop production, with the following annotation:

> Potassium chloride – unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.

Potassium chloride is permitted as a nonsynthetic livestock feed additive or supplement by 7 CFR 205.237(a), *Livestock feed*, and is not prohibited by 7 CFR 205.604, *Nonsynthetic substances prohibited for use in organic livestock production*. Synthetic potassium chloride is permitted as a livestock feed additive used for enrichment or fortification by 7 CFR 205.603(d)(2), *Synthetic substances allowed for use in organic livestock production,* when FDA approved.

Synthetic potassium chloride is permitted as an inert ingredient for use with allowed active pesticide ingredients in organic crop production at 7 CFR 205.601(m)(1) due to its appearance on 2004 EPA List 4A, *Inerts of Minimal Concern* (US EPA, 2004).

## International

**Canada, Canadian General Standards Board—CAN/CGSB-32.311-2020, Organic Production Systems Permitted Substances List**

The Canadian Organic Standards (COS) permit the use of potassium chloride as a food additive (Canadian General Standards Board (CGSB), 2020b). The *Organic production systems Permitted Substances Lists, Table 6.3, Ingredients classified as food additives,* in CAN/CGSB-32.311-2020 state the following under the listing for "Potassium chloride" (Canadian General Standards Board (CGSB), 2020b):

> From mined sources such as sylvite, carnalite, and potash.

"Food additive" is defined in clause 3 of CAN/CGSB 32.310-2020 as such (Canadian General Standards Board (CGSB), 2020a):

> **Food additive (additif alimentaire)** has the same meaning as in B.01.001 of the *Food and Drug Regulations*.

The *Food and Drug Regulations* define a food additive (Government of Canada, 2022).

> *Food additive* means any substance the use of which results, or may reasonably be expected to result, in it or its by-products becoming a part of or affecting the characteristics of a food, but does not include
>
> (a) any nutritive material that is used, recognized or commonly sold as an article or ingredient of food;
> (b) vitamins, mineral nutrients and amino acids, other than those listed in the tables to Division 16,
> (b.1) supplemental ingredients;
> (c) spices, seasonings, flavouring preparations, essential oils, oleoresins and natural extractives;
> (d) agricultural chemicals, other than those listed in the tables to Division 16,
> (e) food packaging materials and components thereof; and
> (f) drugs recommended for administration to animals that may be consumed as food (additif alimentaire)

Potassium chloride also appears specifically under the "Yeast foods" entry of the *Permitted Substances List, Table 6.3* (Canadian General Standards Board (CGSB), 2020b):

> For use in alcoholic beverages:
>
> a) potassium chloride – permitted for ale, beer, light beer, malt liquor, porter, stout;

**CODEX Alimentarius Commission—Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)**

The Codex guidelines include potassium chloride, allowed for all food additive uses in organic production of foods of plant origin (FAO, 2007). The foods specifically listed aside this entry include fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, nuts and seeds, mustards, and non-emulsified sauces (e.g., ketchup, cheese sauces, cream sauces, brown gravy) (FAO, 2007). The guidelines also state that potassium chloride is not permitted as a food additive in food of animal origin.

**European Economic Community (EEC) Council Regulation—EC No. 834/2007, 889/2008, 2018/848, and 2021/1165**

The Commission Regulation (EC) No. 889/2008 permits "drinking water and salt (with sodium chloride or potassium chloride as basic components) generally used in food processing" in Article 27(e), *Use of certain products and substances in processing of food* (European Parliament, Council of the European Union, 2008).

Annex II of Regulation (EC) No 1333/2008, which regulates food additives by food group type, lists potassium chloride, calcium chloride, magnesium chloride, and hydrochloric acid at a "*quantum satis*" limit in an extensive list of food groups, meaning that the additives are simply allowed at the amount necessary for the food preparation (EFSA Panel on Food Additives and Flavourings (FAF) et al., 2019). Restrictions apply on specific food groupings. See the extensive study conducted by the EFSA Panel on Food Additives and Flavourings (2019) for additional information.

The European Union Commission Regulation requires that potassium chloride used as a food additive not exceed 3 ppm arsenic, 2 ppm lead, 1 ppm mercury, and 1 ppm cadmium (EFSA Panel on Food Additives and Flavourings (FAF) et al., 2019).

Part IV, *Processed food production rules* in the most current enforceable Regulations, (EU) 2018/848 of the European Parliament and of the Council (2018), also permits "drinking water and organic or non-organic salt (with sodium chloride or potassium chloride as basic components) generally used in food processing."

**Japan Agricultural Standard (JAS) for Organic Production**

Potassium chloride appears on *Appended Table 1 Additives* (Ministry of Agriculture, Forestry and Fisheries (MAFF), 2020). The use criteria are limited to use in processed vegetable products, processed fruit products, processed meat products, seasoning, or soup (Ministry of Agriculture, Forestry and Fisheries (MAFF), 2020).

**IFOAM – Organics International**

Appendix 4 of the IFOAM norms, *Table 1: List of Approved Additives and Processing/Post-Harvest Handling Aids*, includes potassium chloride as an additive, without further annotation (IFOAM Organics International, 2019). The introductory section for the appendix states that (IFOAM Organics International, 2019):

> Substances of certified organic origin must be used if commercially available. If organic sources are not available, natural sources must be used if commercially available. Only if organic and natural sources are not available, synthetic forms of the substances below may be used.

## 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)).**

*Raw material collection*

In solid potash deposits, mining methods differ based on the regional geology of the ore deposit (Schultz et al., 2000). In roughly horizontal deposits, the most common method for extraction is with heavy machinery (Schultz et al., 2000). Rooms are carved underground with pillars left in place to support the cavern (Broughton, 2019; Schultz et al., 2000). Cutting machines simply strip the ore which is transported by conveyer belt to trains, trucks, or processing facilities (Schultz et al., 2000). In steeply angled solid deposits, funnel-shaped channels are bored through the rock, then explosives are utilized to guide the rubble to certain areas by gravity, after which it is hauled out (Schultz et al., 2000).

Subsurface brines can also be directly pumped to the surface for processing or produced by injection of fluids into subterranean deposits (Schultz et al., 2000). In the case of very deep deposits (such as some deposits in Canada that are greater than 1000 meters deep), it is unfeasible to use conventional mining methods (Broughton, 2019; Schultz et al., 2000). Additionally, unintentional flooding of subsurface caverns that have been mechanically mined may necessitate conversion to solution mining techniques (Broughton, 2019; Schultz et al., 2000). Since mechanical mining only allows an extraction rate of 25-60%, depleted deposits are often converted to solution mining to maximize yield (Schultz et al., 2000). Extracted brine is typically stored in surface ponds (Schultz et al., 2000).

*Solid ore beneficiation and processing*

Raw solid ore is first crushed to a particle size of 4-5 mm or less (Schultz et al., 2000). The three primary mechanical treatment methods are flotation, electrostatic treatment, and leaching-crystallization, and all require a maximum of mineral separation into individual crystal grains, since ore rocks typically consist of deeply intergrown mixed salts (Schultz et al., 2000).

The majority of potassium chloride production, 75% as of 2004, utilizes flotation processes (Schultz et al., 2000; Titkov, 2004). In flotation, large tanks are filled with a saturated solution of sodium and potassium chloride, along with the finely ground ore material and a “collector,” commonly an aliphatic amine (Schultz et al., 2000; Titkov, 2004). Due to the high solubility of the salts, the solution must be previously saturated to keep the ore in a crystalline suspended state (Monte & Oliveira, 2004). The collector amines have an affinity for potassium chloride crystals and coat their surfaces (Schultz et al., 2000). Air bubbles are introduced which carry the amine-coated potassium chloride to the surface of the tank for skimming (Schultz et al., 2000). Additional chemicals, such as alcohols, are being investigated to improve flotation efficiency when combined with amine-based collectors (Monte & Oliveira, 2004).

The hot leaching process was the primary method to separate potassium chloride from ore material in the past, but is largely being replaced by flotation (Schultz et al., 2000). The ore material is mixed into a brine heated to just below boiling point, dissolving the sodium and potassium chloride (Schultz et al., 2000). The saturated hot solution is then fed to vacuum evaporators to cool, crystallizing sodium and potassium chloride crystals which are removed from the remaining liquor (Schultz et al., 2000). The two salts can be preferentially crystallized by the addition of more clean water to the evaporator liquor, or by temperature controls (Eatock, 1985; Schultz et al., 2000).

Electrostatic separation involves the use of conditioning agents added to the ground ore during drying to initiate an electric charge on the crystals (Schultz et al., 2000). The ore is then added to a free-fall separator containing electrodes, which attract the charged crystals before brushes remove them from the surface (Schultz et al., 2000). Electrostatic separation does not result in a satisfactorily pure product, so facilities typically combine this method with flotation or leaching (Schultz et al., 2000).

*Brine beneficiation and processing*

Surface brines, such as those occurring in the Great Salt Lake, Searles Lake (California), and the Dead Sea can be exploited by solar evaporation (Eatock, 1985). Evaporation ponds are constructed and the collected salts of sodium, potassium, and magnesium are separated by flotation methods (Eatock, 1985).

Deep deposits or mines that introduce other extraction challenges may employ solution mining (Eatock, 1985; Rahm, 2017). Bore holes are drilled to the salt deposits and hot water is pumped down, dissolving the ore body (Rahm, 2017). Following dissolution, hot brine is injected into the cavities to selectively dissolve the maximum amount of potassium chloride (Rahm, 2017). The potassium chloride-rich brine is cooled in surface ponds or in indoor crystallization apparatuses (Rahm, 2017). Though this method is energy intensive, it results in a product of high purity suitable for food and pharmaceutical applications; other methods sometimes result in a final product with a pink tint from iron oxide impurities (Rahm, 2017).

High-purity (62.5% $K_2O$) industrial and food grades of potassium chloride utilize vacuum crystallization processes in which saturated warm brines are cooled to form crystal slurries, dehydrated, and dried in hot air (Perucca, 2003; Tianjin Changlu Hanku Saltern Co. Ltd, 2014).

A novel method for production of high-purity potassium chloride from saturated brines, using a minimum of energy, has recently been investigated. Ji et al. (2022) tested the use of nanoporous metal oxide membranes combined with a relatively low heat to produce potassium chloride and recovered water. In their process, brine at 15% potassium chloride concentration is pumped through a hollow metal oxide membrane tube, and water is allowed to evaporate at 60°C until the solution reaches supersaturation (Ji et al., 2022). Narrow needles of potassium chloride form on the outside of the tube and clean water is recondensed (Ji et al., 2022). The authors propose that scaling up this method to industrial scales would reduce the environmental and monetary costs associated with current potassium chloride production technology (Ji et al., 2022).

**<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.**

Potassium chloride is most often produced by physical separation of naturally occurring mineral deposits, or from solar or forced evaporation of naturally occurring saltwater. The chemicals utilized in froth flotation, such as amines, alcohols, or other surfactants, do not crystallize together with the potassium chloride after washing and drying. While possible to produce potassium chloride from potassium metal or potassium hydroxide and hydrochloric acid, no reference was found to commercial products utilizing this chemical reaction, and we find it unlikely that this is at all prevalent due to the ready availability of mineral sources of potassium chloride.

Potassium chloride is not derived from an agricultural source. When compared to Guidance NOP 5033-2, *Decision Tree for Classification of Agricultural and Nonagricultural Materials for Organic Livestock Production or Handling*, step 1 results in a nonagricultural determination (National Organic Program (NOP), 2016).

1. Is the substance a mineral or bacterial culture as included in the definition of nonagricultural substance at section 205.2 of the USDA organic regulations? Yes; Nonagricultural.

Nonagricultural substance is defined at § 205.2 as:

> A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.

**<u>Evaluation Question #3:</u> If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR 205.600(b)(1)).**
Potassium chloride, as listed on the National List at §205.605(a), is a nonsynthetic material.

**<u>Evaluation Question #4:</u> 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.**
The FDA has categorized potassium chloride as GRAS at 21 CFR 184.1622. See *Approved Legal Use of the Substance* (above) for more information.

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

The primary purpose of potassium chloride is not for use as a preservative (see *Action of the substance,* above). According to the Food Chemicals Codex (Institute of Medicine, 1996), it is used as a:

- nutrient
- dietary supplement
- gelling agent
- salt substitute
- yeast food

The FDA's GRAS listing for potassium chloride at 21 CFR 184.1622 also includes pH control in its list of uses.

The FDA defines chemical preservatives as: "any chemical that, when added to food tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties" (FDA, 2020a). Similarly, the Codex Alimentarius (Joint FAO/WHO Codex Alimentarius Comission, 2021) defines preservatives as: "A food additive, which prolongs the shelf-life of a food by protecting against deterioration caused by microorganisms." The Codex groups materials by functional classes, which include "preservatives." Potassium chloride (INS 508) is not listed as a preservative (Joint FAO/WHO Codex Alimentarius Comission, 2021).

However, like sodium chloride, potassium chloride does have antimicrobial properties (a preservative function) (Inguglia et al., 2017; Greer et al., 2020). Inguglia et al. (2017) note that the two are roughly comparable, while Greer et al. (2020) note that potassium chloride is less effective than sodium chloride. The antimicrobial effect is due to its osmotic effects, which can cause a loss of water from bacterial cells (Inguglia et al., 2017).

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

Potassium chloride improves flavor by adding a "saltiness," as an alternative to table salt. FDA regulations at 21 CFR 184.1622 allow potassium chloride to be used as a flavor enhancer, as a flavoring agent, and as a nutrient supplement. According to the food corporation, Cargill, Inc. (2022), potassium chloride is primarily used as a salt replacer and for potassium enrichment. The FDA issued a guidance in 2020, that notified manufacturers that it would exercise discretion when reviewing the term "potassium salt" on product labels (FDA, 2020b). In other words, the FDA recognized "potassium salt" as an alternative name for potassium chloride.

Potassium chloride can be used to partially replace table salt (sodium chloride) in order to lower sodium levels in food (Inguglia et al., 2017). However, in some foods, only small potassium chloride substitutions can be made without negatively affecting flavor. The substance can impart a metallic flavor (Inguglia et al., 2017). In one study, at 40% substitution of potassium chloride and above, important flavor defects in fermented sausage and dry-cured pork loins were detected (Inguglia et al., 2017). In watery solutions, flavor defects can be detected at a 20% substitution rate (van Buren et al., 2016). In contrast, Grummer et al. (2013) were able to produce low sodium cheese (220mg sodium / 100g of cheese) by substituting potassium chloride that performed as well as a full sodium cheese (640mg sodium / 100g of cheese).

Several types of products can be added that in some cases may help to overcome the metallic flavor issues typical of potassium chloride (Grummer et al., 2013):

- flavor enhancers (monosodium glutamate, hydrolyzed vegetable protein, yeast extract, disodium inosinate, disodium guanylate)
- sweeteners (sucrose, taumatin, trehalose)

- bitter blocking compounds

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

Substituting potassium chloride for sodium chloride improves the nutritional quality of food. Potassium enrichment along with a reduction in dietary sodium has been shown to help reduce high blood pressure, and decrease the risk of cardiovascular disease (Ajenikoko et al., 2021). Studies show that the ratio of sodium to potassium (ideally a ratio of less than 1:1) may be more important for lowering blood pressure than the total levels of sodium or potassium alone (Ajenikoko et al., 2021).

In order for potassium chloride to cause negative health effects, the oral dose must be large enough to overcome the kidney's ability to excrete it (John et al., 2011). However, severe cases of dietary overdose in individuals with normal kidney function are extremely rare (John et al., 2011; Saxena, 1989). The kidneys are able to filter around 600-700 mmol of potassium ions per day, but the typical U.S. diet only contains 50 to 150 mmol per day (Saxena, 1989). The kidneys can become adapted to larger quantities of potassium if it is introduced slowly over time (John et al., 2011; Saxena, 1989).

Potassium overdose can occur in patients with kidney damage or those taking certain medications, such as certain diuretics, angiotensin receptor blockers, and angiotensin-converting enzyme inhibitors (John et al., 2011). This results in a condition called hyperkalemia, which can lead to muscle weakness, nausea, vomiting, paralytic ileus (impaired bowel activity), mucosal necrosis, and cardiac arrest. In one documented case, a 65 year old diabetic patient who had previously experienced heart failure began taking 8 teaspoons of salt substitute per day (containing potassium chloride), along with a prescribed potassium chloride medication. This lead to severe hyperkalemia causing muscle weakness, breathing difficulty, slow heartbeat, and eventually respiratory failure. However, severe cases of hyperkalemia are extremely rare. One of the reasons for this is that the kidneys are capable of maintaining homeostasis under normal potassium exposures. Additionally, the kidneys can become adapted to larger quantities of potassium over time, through increasing exposure (John et al., 2011). For more information related to human health, see *Evaluation Question #10*, below.

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

Unlike many other mined mineral substances, salts derived from evaporite deposits are not typically associated with significant concentrations of asbestos, radon, silica or heavy metals (Neumeyer-Gromen et al., 2009). Dean (1987) states that evaporite deposits can be some of the purest chemical compounds found in nature, in some cases surpassing the purity of reagent grade laboratory chemicals. Due to the significantly low levels of impurities in evaporites, there are few extensive studies into the subject (Dean, 1987).

Fano (1969) tested several purified potassium chloride salts for copper, lead, and zinc and the levels were in the range of thousandths of one ppm. While the FDA's Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed does set limits for lead, these restrictions apply only to cooking utensils and dishware (Center for Food Safety and Applied Nutrition, 2020). We found no studies regarding cadmium and mercury levels in potassium chloride, the two other toxic metals limited by the FDA.

In a study investigating the origin of an evaporite deposit in Laos, only trace values of several metals were detected (Li et al., 2018). This deposit was presumed to be altered from its original state by groundwater and atmospheric water infiltration (Li et al., 2018). Metals testing was conducted on core samples approximately every 5-15 meters, from 147.5 meters depth to 583.98 meters (Li et al., 2018). Zirconium, scandium, barium, lithium, tin, cesium, cobalt, and rubidium were typically below 1 ppm across the spectrum of depth (Li et al., 2018). The only metal occurring in appreciable amounts was titanium, ranging from 1-95 ppm (Li et al., 2018). Vanadium, chromium, nickel, copper, and zinc had a characteristic range between 1 and 5 ppm, and mostly on the lower end of that spectrum (Li et al., 2018). The purification process to manufacture industrial or food grade chloride salts would be expected to reduce the values of metals occurring in raw ore significantly.

**<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)).**

*Manufacturing:*
Food grade potassium chloride is made by purifying industrial grades (Tianjin Changlu Hanku Saltern Co. Ltd, 2014). The following information describes the environmental impacts of potassium chloride manufacturing overall.

The processes used to mine solid potassium chloride ore use large equipment that burns fossil fuels to extract and haul the material (Schultz et al., 2000). In some places, mining can cause the overlying ground to sink, as underground mining areas collapse. Potassium chloride can contain other mineral impurities. These are often separated through flotation methods, using liquids such as tetrabromoethane mixed with toluene, and aliphatic amines (containing an ammonium chloride chemical group).[4] Other processing aids such as foamers (substances that help create air bubbles) are made from oil and other synthetic compounds (Schultz et al., 2000).

According to Schultz et al., (2000), the primary environmental problem of the potash industry (including potassium chloride) is related to disposal of processing wastes. These wastes total approximately 200 million tons per year, consisting primarily of salts such as halite (rock salt, NaCl), kieserite ($MgSO_4$), and aqueous magnesium chloride. This waste may be either dumped, backfilled into mining sites, pumped into the ground, or discharged into waterways. Brines that drain off of dump sites are sometimes collected and returned to processing plants. Rainwater can create new brines from the potash wastes, which can leach into the environment, increasing the salinity of water and soils. Attempts to prevent leaching through covering wastes have been unsuccessful. In Canada, wastes are turned into a slurry and pumped to large lagoons that ultimately form flats. Wastes that are pumped into the ground can contaminate groundwater through leaks (Schultz et al., 2000).

The Werra River in Germany is an example of an area affected by waste from potash production (Arle & Wagner, 2013). Wastes from potash fertilizer production have been disposed of in the river for over 100 years, leading to a large increase in the concentration of dissolved ions (salinization). In 1976, researchers measured concentrations of up to 40,000 mg $Cl^-$/L in the river. Since then, the concentration of chloride ions has been reduced, but still greatly exceeds the threshold used for "good ecological status" of 200 mg $Cl^-$/L. As a consequence, the biodiversity in these areas has been severely impacted (Arle & Wagner, 2013). Similar issues exist for other potash mining areas, such as the Verkhne-Kamsk potash and magnesium salt mine in Russia (Lepikhin et al., 2012).

Heavy metals can be concentrated near potash production areas as well (Al-Khashman, 2012). For example, researchers found that zinc, cadmium, and lead were higher in the soil around a potash plant near the Dead Sea, as compared with soils found 1200 m away from the plant (Al-Khashman, 2012).

Potash (including potassium chloride) production is energy intensive (Parmenter et al., 2004). The energy requirements to produce, transport, package, and apply potash fertilizer are estimated to be 5,936 Btu/lb (13,800 kJ/kg). However, in comparison to synthetic nitrogen fertilizers which use 33,642 Btu/lb (78,230 kJ/kg), potash fertilizer energy use is relatively small (Parmenter et al., 2004).

Chen et al. (2018) found that the biggest environmental issue with potash production was its contribution to global warming. Using modelling software, Chen et al. performed a theoretical life cycle analysis for

[4] Tetrabromoethane, or TBE, is a metabolic poison which also decomposes into other toxic materials such as carbonyl bromide or hydrobromic acid (Hauff & Airey, 1980).

potassium chloride, and found that for every ton of $K_2O$ (1.67 tons KCl), the equivalent of 190kg of $CO_2$ are created (see Table 2, below). This was largely due to the energy needed to produce the substance.

**Table 2: Impact of producing 1 ton $K_2O$ (1.67 tons KCl) from brine in China, throughout the material's life cycle. Adapted from Chen et al., 2018.**

| Categories | Unit | Amount | Range due to uncertainty |
|---|---|---|---|
| Global warming | kg $CO_2$ eq. | 190 | 141 to 255 |
| Land occupation | hectare/year | 8.48 X $10^{-5}$ | 5.00 X $10^{-5}$ to 1.44 X $10^{-4}$ |
| Terrestrial acidification | kg $SO_2$ eq. | 0.295 | 0.215 to 0.406 |
| Aquatic eutrophication | kg $PO4^-$ eq. | 6.95 X $10^{-4}$ | 3.78 X $10^{-4}$ to 1.28 X $10^{-3}$ |
| Respiratory inorganics | kg $PM_{2.5}$ eq.[5] | 0.0545 | 0.0366 to 0.0812 |
| Respiratory organics | kg NMVOC eq.[6] | 0.281 | 0.183 to 0.433 |
| Ozone layer depletion | kg CFC-11 eq.[7] | 6.64 X $10^{-8}$ | 3.39 X $10^{-8}$ to 1.30 X $10^{-7}$ |
| Water depletion | $m^3$ | 8.13 | 6.66 to 9.92 |
| Metal depletion | kg Fe eq. | 0.151 | 0.0751 to 0.305 |
| Fossil depletion | kg oil eq. | 25.7 | 18.6 to 35.6 |
| Carcinogens | CTUh[8] | 3.40 X $10^{-7}$ | 1.53 X $10^{-7}$ to 7.54 X $10^{-7}$ |
| Non-carcinogenic toxins | CTUh | 2.32 X $10^{-5}$ | 1.03 X $10^{-5}$ to 5.23 X $10^{-5}$ |
| Freshwater ecotoxicity | CTUe[9] | 82.2 | 39.1 to 17.3 |
| Marine eutrophication | kg N eq. | 6.07 X $10^{-3}$ | 3.69 X $10^{-3}$ to 9.97 X $10^{-3}$ |

*Use*

The amount of potassium chloride used as a food additive is very small, in comparison with other uses (Schultz et al., 2000). No information was found that indicated that the use of potassium chloride as a food additive was harmful to the environment or biodiversity.

**<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)).**

The $LD_{50}$ value (the single dose at which the death of 50% of a population occurs) for potassium chloride has been measured at 3000 mg/kg body weight in rats (EFSA Panel on Food Additives and Flavourings (FAF) et al., 2019). This is considered to be a very low risk material for acute oral toxicity (EFSA Panel on Food Additives and Flavourings (FAF) et al., 2019).

While acute poisoning with potassium chloride has been reported in association with high consumption of salt substitutes or potassium supplements, few adverse effects have been observed by researchers (Steffensen et al., 2018). Rare and extreme symptoms include heart failure and cyanosis, a condition characterized by bluish skin and low blood oxygen levels (Steffensen et al., 2018). More common symptoms are gastrointestinal distress, shortness of breath, chest tightness, and general stomach irritation (Steffensen et al., 2018).

The United States National Academy of Sciences considers 4.7 g/day to be an upper limit of potassium chloride consumption, even in patients suffering diabetes, kidney disease, and heart disease. Normal consumption from food does not approach this value (Steffensen et al., 2018). Occasional case reports

[5] $PM_{2.5}$ eq. is a standardized way to refer to very small (2.5 micrometer) particulate matter in the air.
[6] NMVOC eq. is a standardized way to refer to "non-methane" volatile organic compounds.
[7] CFC-11 eq. is a standardized way to represent chlorofluorocarbons, equivalent to the effect of the chemical trichlorofluoromethane.
[8] CTUh or "Comparative Toxic Unit for humans" is a way of expressing the "estimated increase in morbidity in the total human population per unit mass of a chemical emitted (cases per kilogramme)" (European Commission, n.d.)
[9] CTUe or "Comparative Toxic Unit equivalent" is similar to CTUh, except that it applies to other species. "An estimate of the potentially affected fraction of species (PAF) integrated over time and volume, per unit mass of a chemical emitted" (USEtox International Center, 2022).

related to potassium supplements indicated that adverse effects could result from consumption of 5-7 g as a single dose (EFSA Panel on Food Additives and Flavourings (FAF) et al., 2019; Steffensen et al., 2018). Acute potassium intoxication of otherwise healthy persons has only been observed in those taking potassium supplements (Steffensen et al., 2018).

Extensive research has been conducted to evaluate the effect of sodium chloride on blood pressure elevation (hypertension) and subsequent stroke risk. Potassium chloride has been shown to have far lower risks than sodium chloride for cardiovascular diseases, and has shown no genotoxic or carcinogenic effects in animal testing (EFSA Panel on Food Additives and Flavourings (FAF) et al., 2019). Exposure to potassium chloride at the levels used in foods does not raise any safety concerns according to the EFSA Panel on Food Additives and Flavourings (2019).

Using risk assessment models, Marklund et al. (2020) explored the effect of a nationwide effort to partially replace sodium chloride with potassium chloride in China, where hypertension is a growing problem due to excessive sodium intake. Their models found that when using potassium enriched salt substitutes (average of 25% potassium chloride) approximately 450,000 deaths from cardiovascular disease (or 11% of the total), and 21,000 cardiovascular disease deaths in those with chronic kidney disease could be prevented. At the same time, the increased dietary potassium was expected to contribute to 11,000 additional deaths, nearly half of these related to hyperkalemia in those in kidney failure. The authors concluded that the net benefits of partial replacement of discretionary salt with potassium chloride outweigh the risks (Marklund et al., 2020; Morrison et al., 2021). In contrast, Steffensen et al. (2018) reported that the number of people that would face increased health risks is greater than those likely to benefit from a concerted national effort to replace sodium with potassium in Norway, due to the percentage of the population suffering from kidney disease, diabetes, or those taking potassium interfering medications.

In order to meet the World Health Organization's (WHO) goal to reduce global sodium intake by 30% by 2025, researchers advise mandatory food labeling of potassium to minimize risks to susceptible populations, such as those with chronic kidney disease (Marklund et al., 2020; Morrison et al., 2021).

**<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)).**

On a personal level, the least intrusive way to increase potassium intake while also reducing sodium intake (and subsequently the increased risk of cardiovascular diseases) in the diet is to replace processed salty foods with fresh fruits, vegetables, or dairy products already rich in potassium (Morrison et al., 2021). Salt is an integral flavoring component across the entire food industry, and potassium is an essential nutrient. We could find no alternative practices that would make the use of the substance unnecessary aside from not including salt in food formulations.

**<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)).**

*As a flavoring or sodium replacement substance*

Potassium chloride itself is largely a sodium replacement substance to reduce cardiovascular disease rates in the population. To achieve a salty flavor in foods, sodium chloride salt can replace potassium chloride. As a preservative substance, potassium chloride is comparable to sodium chloride in controlling foodborne pathogens but somewhat less effective (Greer et al., 2020; Inguglia et al., 2017).

As flavor enhancers, monosodium glutamate, yeast extracts, and hydrolyzed vegetable proteins are sometimes used as substitutes for salts (Scourboutakos et al., 2018). All three have a flavoring mode of action based on the glutamate molecule, which produces the savory umami flavor in foods (Scourboutakos et al., 2018).

Calcium chloride and lactate salts may also be used as salt replacements or flavor-enhancing substances (Scourboutakos et al., 2018). Calcium chloride appears on §205.605(a) as a permitted food ingredient in organic products.

*As a nutrient or dietary supplement*

Potassium acid tartrate, potassium bicarbonate, potassium carbonate, potassium citrate, potassium hydroxide, and dipotassium phosphate are relevant sources of potassium identified by the FDA as GRAS (NOP, 2015). Of these minerals, potassium acid tartrate is the only one that may qualify as a nonsynthetic material, and it appears on the National List at §205.606 as a nonorganic agricultural substance that can be used in organic products when organic versions are not commercially available (NOP, 2015). The other synthetic materials qualify as "nutrient vitamins and minerals" permitted at §205.605(b) on the National List, however.

*As a gelling agent, pH control agent, stabilizer, or thickener*

Several gelling agents and thickeners are available as an alternative to potassium chloride, many of which are included on the National List. Examples include xanthan gum, gum arabic, guar gum, locust bean gum, tragacanth gum, cornstarch, agar, carrageenan, pectin, gellan gum, gelatin, and alginates (Saha & Bhattacharya, 2010).

The FDA lists several potassium-based compounds in its Food Additive Status List, categorized by use (FDA, 2022). However, many of these substances are likely synthetic materials.

- Buffers and neutralizing agents (equivalent to pH control agents) – potassium acetate; potassium acid tartrate; potassium bicarbonate; potassium carbonate; and potassium hydroxide
- Stabilizers – potassium alginate
- Miscellaneous – potassium acid tartrate; potassium alum; potassium bicarbonate; potassium caprate; potassium caprylate; potassium carbonate; potassium caseinate; potassium citrate; potassium gluconate; potassium hydroxide; potassium lactate; potassium laurate; potassium myristate; potassium nitrate; potassium oleate; potassium palmitate; potassium salts of fatty acids; and potassium stearate

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

Though it may be possible to enhance savory flavors in food using seafood-based products, seaweeds, or products containing glutamates/glutamic acid, there is no feasible agricultural product that can completely replace salt as a flavoring agent.

Gum arabic, guar gum, locust bean gum, carob bean gum, and tragacanth gum are effective gelling agents and thickeners for food applications, such as in beverages, salad dressings, bakery products, sauces, dairy products, condiments, puddings, and cake mixes (Saha & Bhattacharya, 2010). The Organic Integrity Database lists several organic gum products. Several other gelling agents and thickeners appear on the National List as agricultural materials restricted for commercial availability of organic versions. Several organic cornstarches are available, but organic pectin, gelatin and tragacanth gum do not appear to be widely available. During the literature review for this report, we found very little reference to potassium chloride used as a gelling agent beyond the FDA allowance as a thickener, however.

As mentioned above, potassium acid tartrate is defined as an agricultural product on the National List. Potassium acid tartrate is a pH buffer like potassium chloride, but is significantly more acidic, so it would not act as a direct replacement for potassium chloride for pH adjustment/buffering uses (NOP, 2017). Similarly, potassium acid tartrate may be used as a leavening agent in bread dough, but serves a different purpose than potassium chloride (NOP, 2017). The acid reacts with baking soda in a neutralization reaction, resulting in rising dough (NOP, 2017). It is therefore not feasible as a potassium chloride substitute.

## 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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