

Potassium Hydroxide

Handling/Processing

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Identification of Petitioned Substance

Chemical Names: Potassium hydroxide	14	Trade Names: Commonly sold as a generic commodity and not a brand name product.
Other Name: Caustic potash, potash lye, potassa, potassium hydrate, and lye (although this usually refers to sodium hydroxide or a combo of both); potasa cáustica (Spanish); potasse caustique (French); kaliumhydroxid (German)		CAS Numbers: 1310-58-3
		Other Codes: INS 525; RTECS: TT2100000; EINECS: 215-181-3; UN 1813 (dry), UN1814 (aqueous solution)

Summary of Petitioned Use

Potassium hydroxide (KOH) is currently allowed under the National Organic Program (NOP) regulations for use in inorganic handling and processing as a synthetic nonagricultural (nonorganic) substance listed at 7 CFR 205.605(b) for use as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" with the following annotation: "prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches." It is used as a direct food additive, formulation aid, pH adjuster, cleaning agent, stabilizer, thickener, and poultry scald agent.

Characterization of Petitioned Substance

Composition of the Substance:
Molecular formula: KOH
Elemental composition: K 69.68%, O 28.51%, H 1.80%

Source or Origin of the Substance:
Food grade potassium hydroxide sold in the U.S. is obtained commercially from the electrolysis of potassium chloride (KCl) solution in the presence of a porous diaphragm [21 CFR 184.1631(a)]. The manufacturing process is explained more fully under Evaluation Question #1.

Properties of the Substance:
Potassium hydroxide is a white to slightly yellowish solid that is highly deliquescent (prone to liquification). Commercial sources are marketed in several forms, including pellets, flakes, sticks, lumps and powders. When dissolved in water or alcohol, potassium hydroxide generates heat. When exposed to air, potassium hydroxide rapidly absorbs moisture and carbon dioxide and deliquesces. Potassium hydroxide is highly corrosive; it should be stored in a tight container when not in use, and should not be handled without protective gear.

The physical and chemical properties of potassium hydroxide are summarized in Table 1.

48 Table 1: Physical and Chemical Properties of Potassium Hydroxide

Property	Characteristic / Value	Source(s)
Molecular Formula:	KOH	(Merck 2015)
Molecular Weight:	56.11	(Merck 2015)
Percent Composition:	K 69.68%, O 28.51%, H 1.80%	(Merck 2015)
Physical State at 25°C / 1 Atm.	Liquid	(Merck 2015)
Color	White to slightly yellow	(Merck 2015)
Odor	Odorless	(Royal Society of Chemistry 2015)
Density / Specific Gravity	0.940-0.950	(Merck 2015)
Melting Point	250°C	(Schultz et al. 2006)
Boiling Point	380°C	(Merck 2015)
Solubility	Soluble in 0.9 part water, about 0.6 part boiling water, 3 parts alcohol, and 2.5 parts glycerol	(Merck 2015)
Vapor Pressure	1 mm Hg @ 714° C	(Royal Society of Chemistry 2015)
pH	13.5	(Merck 2015)
Corrosion Characteristics	Corrosive to metal and tissue	(Royal Society of Chemistry 2015)

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Specific Uses of the Substance:

Uses of potassium hydroxide that are Generally Recognized As Safe (GRAS) by the U.S. Food and Drug Administration (FDA) include use as a formulation aid, pH control agent, processing aid, stabilizer and thickener [21 CFR 184.1631(b)].

Potassium hydroxide's main food processing uses include use as a pH adjuster, cleaning agent, stabilizer, thickener, fruit and vegetable peeling agent, and poultry scald agent. It is used in dairy products, baked goods, cocoa, fruits, vegetables, soft drinks and poultry. The main foods processed with potassium hydroxide are chicken, cocoa, coloring agents, ice cream and black olives (Ash and Ash 1995).

Soft soap is manufactured with potassium hydroxide. Caustic potash is used by livestock producers to dehorn calves, dissolve scales and hair in skin scraping, and for wart removal. Industrial applications include electroplating, printing, wood mordant, and to manufacture cleaning agents, including some non-phosphate detergents (Merck 2015).

Approved Legal Uses of the Substance:

Potassium hydroxide is FDA GRAS when used in food with no limitation other than current good manufacturing practice [21 CFR 184.1631(c)]. Approved legal uses are as a formulation aid [21 CFR 170.3(o)(14)]; a pH control agent [21 CFR §170.3(o)(23)]; a processing aid [21 CFR 170.3(o)(24)]; and a stabilizer and thickener [21 CFR 170.3(o)(28)]. Approved legal uses are summarized in Table 2.

73 Table 2: Approved Food Uses of Potassium Hydroxide (EAFUS 2001; 21 CFR 184.1631; 9 CFR 424.21)

Use	Reference
Acrylate ester copolymer coating	21 CFR 175.210(b)
Chocolate and cocoa (<i>optional ingredient</i>)	21 CFR 163
Cacao nibs	21 CFR 163.110(b)(1)
Breakfast cocoa	21 CFR 163.112(b)(1)
Chocolate liquor	21 CFR 163.111(b)(1)
Caramel color	21 CFR 73.85(a)(2)(ii)
Defoaming agents used in the manufacture of paper and paperboard	21 CFR 176.210
Formulation aid	21 CFR 170.3(o)(14)
Paper and paperboard components in contact with dry food	21 CFR 176.180
pH control agent	21 CFR 170.3(o)(23)
Polyethylene resins, carboxyl modified	21 CFR 177.1600
Poultry scald	9 CFR 424.21
Processing aid	21 CFR 170.3(o)(24)
Stabilizer and thickener	21 CFR 170.3(o)(28)
Textiles and textile fibers	21 CFR 177.2800
Washing or peeling of fruits and vegetables	21 CFR 173.315(a)(1)

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76 **Action of the Substance:**77 Potassium hydroxide is a strong base that forms salts when combined with acids, is caustic to metals and
78 non-metals, and saponifies fatty acids. Potassium hydroxide is highly reactive.

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80 Lye or caustic peeling with potassium or sodium hydroxide is based on the principle that the cell and
81 tissue constituents of the peels have different solubility levels in a base solution. The pectin-forming middle
82 layer of the peel is particularly soluble in a base (Lindsay 1996). Elevated temperatures of 60-82°C (140-
83 180°F) and mild abrasion can accelerate the lye peeling process. Tomatoes that are lye peeled can either be
84 immersed in a lye bath or subjected to a lye spray (Luh and Kean 1988). Peeling tomatoes with potassium
85 hydroxide requires half the amount of caustic compared with sodium hydroxide peeling (Das and
86 Barringer 2006).

87

88 Peaches peeled for canning or pickling use a 1.5% solution of lye at a temperature slightly below 145°F
89 (<62°C) for about 60 seconds, followed by a wash and dip into a solution of 0.5-3.0% citric acid. Because hot
90 water cannot be used for freezing peaches, they require a higher solution – about 10% – and a treatment
91 time of about 4 minutes to be peeled. Lye is removed by thorough washing, and again citric acid is used to
92 neutralize the pH of the fruit (Woodroof 1986).

93

94 Potassium hydroxide is also used to make soap from the reaction with potassium salts of fatty acids. The
95 process of making soap is known as 'saponification.' Triglycerides derived from vegetable oils and animal
96 fats react with a strong base, such as potassium hydroxide. This reaction breaks the ester bond, which
97 releases the fatty acid salt and glycerol. The process is portrayed by the reaction in Figure 1.

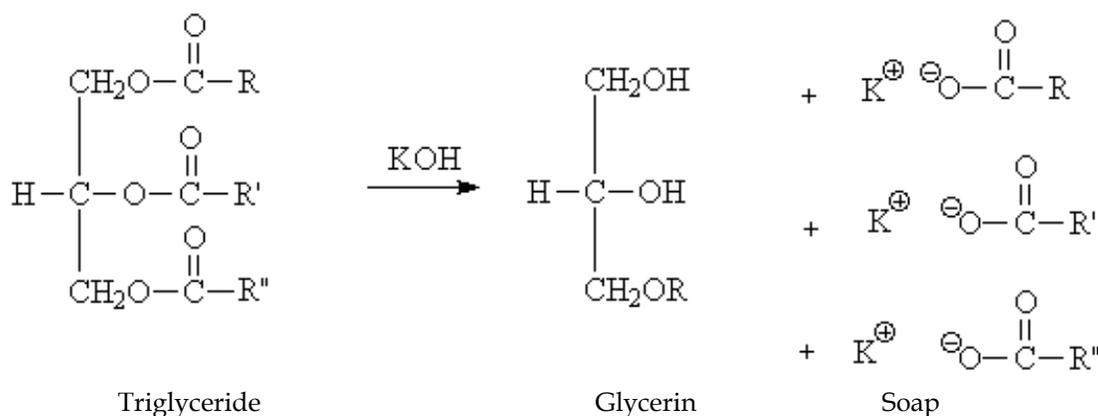


Figure 1: Saponification Process (Cornell BioChem Wiki 2015)

Combinations of the Substance:

Potassium hydroxide is used as an aqueous solution or it can be crystallized as caustic potash. In both cases, water is an ingredient. Carbonates, chlorine and heavy metals are possible contaminants. Commercially available food grade potassium hydroxide is subject to Food Chemicals Codex specifications that limit the contaminants and, if in liquid form, require that the percentage solution in water is specified (Food Chemicals Codex Committee 2011).

Various formulated products used for specific functions may contain potassium hydroxide. It can be used in combination with lauric acid, a fatty acid, in poultry scald water (Hinton and Ingram 2006). Potassium hydroxide is used to make various coloring agents, such as caramel, annatto and turmeric (Ash and Ash 1995; Burdock 1997). Processors will often combine a number of alkali buffering agents to control the speed of reaction (Lindsay 1996). Wetting agents are sometimes combined with lye used for peeling to increase the efficiency and recovery of solids (Woodroof 1986). Various fats and oils are used as sources of fatty acids, which in turn are reacted with potassium hydroxide to manufacture soap (Schumann and Siekmann 2012).

Status

Historic Use:

Historically, potassium hydroxide in the form of lye derived from wood ash has been used to make traditional foods such as brined fish, cured olives, pretzels, hominy grits and Chinese noodles. The first soaps are believed to be made from potassium hydroxide lye using wood ash (Schumann and Siekmann 2012).

Potassium hydroxide was reviewed for inclusion on the National List in 1995. The National Organic Standards Board (NOSB) originally recommended that potassium hydroxide be prohibited for use in lye peeling of fruits and vegetables. That recommendation included an annotation that stated that potassium hydroxide was “prohibited for the lye peeling of fruits and vegetables and where non-synthetic sodium carbonate is an acceptable substitute” (National Organic Standards Board 1995). The first NOP Final Rule carried the annotation “Potassium hydroxide – prohibited for use in lye peeling of fruits and vegetables” (USDA Agricultural Marketing Service 2000). Original concerns regarding lye peeling included the environmental effects of the effluent and other waste products, and the perception that mechanical or non-chemical alternatives were available for most fruits and vegetables.

Stone fruits – including peaches, nectarines and apricots – did not appear to have alternative methods available on a commercial scale to achieve peeling without the use of caustic substances. On March 1, 2001, a petitioner requested that the annotation for potassium hydroxide be changed to permit its use in the

142 peeling of peaches to produce individually quick frozen (IQF) products (Finn 2001). The NOSB voted in
143 favor of the petitioner's request in October 2001, recommending that the annotation be changed to add the
144 phrase "except when used for peeling peaches during the Individually Quick Frozen (IQF) production
145 process." The amendment was finalized by the NOP on November 3, 2003, becoming effective on the
146 following day (USDA Agricultural Marketing Service 2003).

147
148 A subsequent petition was received in 2011 to extend this use to include thermally canned peaches (Van
149 Gundy and Montecalvo 2011). On December 2, 2011, the NOSB voted to change the annotation again to
150 remove the phrase "during the Individually Quick Frozen (IQF) production process" (National Organic
151 Standards Board 2011). The NOP codified the annotation change through a final rule published on May 28,
152 2013, which became effective the following day (USDA Agricultural Marketing Service 2013). This is the
153 current status as of the date of this report.

154
155 The NOP recognized in 2005 that personal care products (e.g., soap) made from organically produced
156 agricultural products are covered under the NOP regulations (National Organic Program 2005). That
157 policy was subsequently retained as Policy Memo 11-2 as part of the NOP Handbook (National Organic
158 Program 2011). In 2008, the NOP offered further guidance in the form of a fact sheet on personal care
159 products which states, "If a cosmetic, body care product, or personal care product contains or is made up
160 of agricultural ingredients, and can meet the USDA/NOP organic production, handling, and labeling
161 standards, it may be eligible to be certified under the NOP regulations" (National Organic Program 2008).
162 The policy memo and fact sheet do not explicitly address saponification or the use of potassium hydroxide.
163 These documents do not specify how potassium hydroxide should be included in the calculation of the
164 percentage of organically produced ingredients of the final product.

165 166 167 **Organic Foods Production Act, USDA Final Rule:**

168 Potassium hydroxide is allowed in organic processing and handling as a synthetic nonagricultural
169 (nonorganic) substance listed at 7 CFR 205.605(b) for use as an ingredient in or on processed products
170 labeled as "organic" or "made with organic (specified ingredients or food group(s))" with the following
171 annotation: "prohibited for use in lye peeling of fruits and vegetables except when used for peeling
172 peaches."

173 174 175 **International**

176 Potassium hydroxide is allowed by most international organic standards for at least some uses.

177
178 **Canada - Canadian General Standards Board Permitted Substances List** – Allowed for pH adjustment
179 only. Prohibited for use in lye peeling of fruits and vegetables (CAN/CGSB 2011 Table 6.6).

180
181 **CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing**
182 **of Organically Produced Foods (GL 32-1999)** – Allowed for pH adjustment for sugar processing
183 (FAO/WHO Joint Standards Programme 1999, Table 4).

184
185 **European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008** – Caustic
186 potash is on Annex VII, "Products for cleaning and disinfection" (EU Commission 2008). However, it does
187 not appear in Annex VIII, "Certain products and substances for use in production of processed organic
188 food, yeast and yeast products."

189
190 **Japan Agricultural Standard (JAS) for Organic Production** – "Limited to be used for processing sugar as
191 pH adjustment agent" (Japan MAFF 2000).

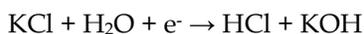
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193 **IFOAM - Organics International (IFOAM)** – Not found.
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Evaluation Questions for Substances to be used in Organic Handling

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

The FDA specifies that food grade potassium hydroxide is made by the electrolysis of potassium chloride (KCl) and water in the presence of a porous diaphragm [21 CFR 184.1631(a)]. Potassium chloride, also known as muriate of potash, is a naturally occurring mineral, with the main global source being Canada. Most U.S. production occurs in New Mexico and Utah (Jacinski 2015). Potassium chloride is put into aqueous solution and is electrolyzed by various processes. Diaphragm cells will produce a liquor that contains 10–15% by weight of KOH and about 10% KCl (Freilich and Petersen 2014). Most of the KCl crystallizes by evaporation and subsequent cooling during concentration. The concentrated KOH is about a 50% solution with about 0.6% KCl.

The reaction can be characterized as follows:



Potassium hydroxide is regarded by the chemical industry as a by-product of the process for producing hydrochloric acid (Bommaraju et al. 2000).

Mercury cells are used to produce most of the KOH in the United States for energy conservation and greater purity. This is different from the diaphragm process and is not considered to be food grade. A brine saturated with KCl is fed into the cell at a moderate temperature. Purification is important because the process will lead to a strong evolution of hydrogen in the cathodes (Schultz et al. 2006). After purification, in order to remove assorted metal impurities, the brine is fed into the cells, which operate on direct current (DC) systems. These cells have positive (anode) terminals composed of titanium, and negative (cathode) terminals composed of metallic mercury. The charged potassium in brine has a catalytic reaction with the layers of mercury and the amalgam flows into the denuder. Water is added and reacts with the elemental potassium in the amalgam to form potassium hydroxide and hydrogen. The mercury is stripped and recycled into the cells. The potassium is recovered as a 50% KOH solution. The remaining hydrogen is compressed to liquid hydrogen or is used to produce hydrochloric acid (Freilich and Petersen 2014).

The more traditional approach to manufacturing potassium hydroxide involves the use of wood or other plant ashes soaked in rain or soft water (Addison 2015). Ashes are collected in a wooden or plastic barrel with holes in the bottom. Boiling water without mineral impurities is added to the barrel, and then the contents are saturated with cold water. This saturated solution is then left to steep overnight during which time the cations in solution create lye that consists mostly of potassium hydroxide with some sodium hydroxide. After steeping, the barrel is drained and the lye is collected (Norman 2007). This is the lye traditionally used to make soap, but it does not meet the FDA's standard of identity for food grade.

A relatively new process, known as the membrane process, results in KOH with lower chloride impurities in the cell liquor and concentrations of KOH of about 40-50% after evaporation (Schultz et al. 2006). The process is similar to the diaphragm process, but relies on the use of a fluorinated cation exchange membrane to reduce the chloride content (Oda et al. 1977).

243 **Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a**
244 **chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss**
245 **whether the petitioned substance is derived from an agricultural source.**
246

247 Potassium hydroxide is classified as a synthetic, nonagricultural substance at 7 CFR 205.605(b). Food grade
248 potassium hydroxide is manufactured by electrolysis, which is a chemical process.
249

250 Potassium chloride and water are not agricultural substances. Potassium chloride is listed at 7 CFR
251 205.605(b) as a nonsynthetic, nonagricultural substance. It is also considered a salt.
252

253 While potassium hydroxide could be produced from the leaching of wood ashes as described in Evaluation
254 Question 1, such a source would not meet FDA's food grade specifications [21 CFR 184.1631].
255

256
257 **Evaluation Question #3: If the substance is a synthetic substance, provide a list of nonsynthetic or**
258 **natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).**
259

260 No nonsynthetic or natural sources are known to exist. Lye can be made from wood or other plant-derived
261 ashes (Addison 2015). However, such a source also involves chemical reactions, and results in lower
262 concentrations of KOH with greater impurities than the processes involving KCl.
263

264
265 **Evaluation Question #4: Specify whether the petitioned substance is categorized as generally**
266 **recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR §**
267 **205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.**
268

269 Potassium hydroxide is FDA GRAS [21 CFR 184.1631]. Table 2 lists the FDA approved food uses for
270 potassium hydroxide.
271

272
273 **Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned**
274 **substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7**
275 **CFR § 205.600 (b)(4)).**
276

277 The primary function of potassium hydroxide is as a pH adjuster, raising the pH of solutions that are too
278 acidic. Potassium hydroxide in poultry chill water increases the shelf life of broilers and other meat birds
279 by killing various spoilage organisms, particularly when used in combination with lauric acid (Hinton and
280 Ingram 2006). To a limited extent, potassium hydroxide will also act as a preservative in the curing of
281 certain foods, such as olives.
282

283
284 **Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate**
285 **or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)**
286 **and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600**
287 **(b)(4)).**
288

289 Nothing in a review of the scientific or technical literature indicated that potassium hydroxide is used for
290 any of these purposes.
291

292
293 **Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or**
294 **feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).**
295

296 Potassium is an essential mineral nutrient (Institute of Medicine 2004). Treatment of certain grains and
297 legumes with KOH can remove tannins that would interfere with nutrient uptake, for example with
298 sorghum (Chavan et al. 1979). KOH increases the solubility of protein in soybeans and is commonly used

299 as a solvent to determine protein quality and total soluble protein in assays (Parsons et al. 1991; Batal et al.
300 2000).

301
302 Potassium hydroxide can be used as a substitute for the traditional calcium hydroxide (lime water) used to
303 remove the pericarp of corn, a process known as 'nixtamalization' (Cortina and Madrazo 1964). Wood ashes
304 were used to make masa from corn in Meso-America (Wacher 2003). Nixtamalization increases the
305 nutritional quality of corn, sorghum and other grains by removing the pericarp or bran, and increasing the
306 digestible or available protein (Mertz 1970; Katz et al. 1974). Nixtamalization is believed to have prevented
307 widespread malnutrition in the pre-Columbian Americas, with the potassium in wood ash leaching
308 playing a regional secondary role to the more widespread practice of treating corn with lime water. Some
309 tribes would use wood ashes in combination with lime water (Katz et al. 1974).

310
311 Removal of fruit peels results in nutrient loss, and the less flesh that is removed, the better the nutrient
312 retention. Nutrient loss can also occur from leaching of water soluble constituents or degradation of heat
313 sensitive compounds. Ascorbic acid and thiamin were reduced by 12% as a result of lye peeling, although
314 carotenoids were not reduced. Fruit that is canned without peeling retains more nutrients than peeled
315 canned fruit (Salunkhe et al. 1991). Mechanical peeling, coring and slicing have the least effect on nutrients,
316 but these are not options for soft fruits.

317
318 By comparison with peeled canned fruit, frozen fruit does not have significant nutrient loss after peeling
319 (Salunkhe et al. 1991), indicating that the higher levels of lye used in peeling frozen fruit do not reduce
320 nutritional content. Oxygen sensitive nutrients such as vitamin C can decline during storage if the fruit is
321 not properly protected. Fruit maturity is a key factor in the overall quality and levels of nutrients found in
322 fruit. Fruit that is picked earlier for satisfactory texture in freezing may not have as high a content of
323 various nutrients, but other forms of processing such as canning and pureeing will result in a loss of
324 nutrients as well (Eskin 1991).

325
326
327 **Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of**
328 **FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600**
329 **(b)(5)).**

330
331 Food grade specifications for the content of potassium hydroxide, including heavy metals and
332 contaminants, are listed in Table 3.

333
334 Table 3: Food grade specification for potassium hydroxide (Food Chemicals Codex Committee 2011)

Identification	Dry caustic potash: 1 g dissolves in mL of water; Potassium hydroxide solution: 1.5 g of potassium hydroxide in 40 mL of recently boiled and cooled water
Assay	Not less than 85% and not more than 100.5% of total alkali, calculated as KOH
Carbonate (as K ₂ CO ₃)	Not more than 3.5%
Lead (as Pb)	Not more than 2 mg/kg
Mercury (as Hg)	Not more than 0.1 mg/kg
Insoluble Substances	Sample solution is complete, clear and colorless

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336
337 **Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the**
338 **petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i)**
339 **and 7 U.S.C. § 6517 (c) (2) (A) (i)).**

340
341 The amount of fresh water used in the lye peeling process and the release of effluent that increases
342 biological oxygen demand are two key environmental concerns about the lye peeling process (Stone 1974).
343 The release of potassium hydroxide in untreated or improperly treated wastewater will raise the pH and
344 potassium levels of the body of water receiving it.

345
346 Lye peeling of tomatoes by industry conventional methods, which would be prohibited under the current
347 NOP regulations, used 9,800 liters of water per metric ton of fruit (Luh and Kean 1988). Once used, the
348 water must be treated and discharged. The EPA has determined that potassium hydroxide is a category 1
349 water pollutant, and has established a reportable quantity of 1,000 pounds (454 kg) [40 CFR 302.4]. Dry
350 caustic peeling of clingstone peaches can reduce water use by 90% and biological demand of effluent by
351 60% (Stone 1974).

352
353 Soap manufacturing can also threaten environmental health in the immediate vicinity of the soap
354 manufacturing facility (Mustafa and Ahmed 2014). Nutrient loading of potassium may result in algal
355 blooms and eutrophication. Effluents from soap manufacturing include not only excessive lye, which can
356 increase foam, biological oxygen demand (BOD) and total dissolved solids (TDS), but also elevated levels
357 of manganese (Mn), copper (Cu), zinc (Zn), lead (Pb) and cadmium (Cd) (Odoi, Armah, and Luginaah
358 2011).

359
360 Mitigation of the adverse environmental impacts of lye peeling and research on alternatives have become
361 priorities for the food processing industry because of the adverse effects of caustic substances released into
362 the environment (Yaniga 2007; Rock et al. 2012).

363
364
365 **Evaluation Question #10: Describe and summarize any reported effects upon human health from use of**
366 **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**
367 **(m) (4)).**

368
369 The corrosive effects from ingestion of potassium hydroxide and other alkali compounds are well known
370 (LSRO 1973). Accidental ingestion may cause irreversible gastro-intestinal damage and death. While less
371 common than sodium hydroxide poisoning, potassium hydroxide can result in comparable injuries and
372 death. Incidents reported of strong alkali or lye poisoning often do not distinguish between sodium or
373 potassium hydroxide. The fatal dose of sodium hydroxide may be less than 10 g for an adult, with 5 g in
374 solution causing serious injury (Willimott and Gosden 1934).

375
376 Ingestion of lye inevitably leads to esophagus damage, with over 90% of the cases also involving stomach
377 damage. In a review of 31 cases of human poisonings involving lye, 13% were fatal (Zargar et al. 1992).
378 Prediction and prevention of irreversible organ damage and death after ingestion depend on a number of
379 factors. Death results from shock, perforation of the esophagus, aspiration from the esophagus into the
380 trachea, pneumonitis, inflammation of tissues in the chest, inability to retain water and digest food, or
381 infection (HSDB 2015). Age, body weight, physical condition, and cause of ingestion are all factors in the
382 extent of damage and the probability that ingestion will be fatal. Ingestion of caustic alkalis by children is
383 almost always accidental (Riffat and Cheng 2009), while ingestion by adults is more likely to be a deliberate
384 act of suicide, and therefore is often more serious and more likely to be fatal (Gumaste and Dave 1992;
385 Satar, Topal, and Kozaci 2004; Cheng et al. 2008).

386
387 Literature did not indicate that the use of potassium hydroxide in organic food processing would have
388 negative human health effects.

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390
391 **Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned**
392 **substance unnecessary (7 U.S.C. § 6518 (m) (6)).**

393
394 Sodium hydroxide is a substitute for many uses of potassium hydroxide. Sodium hydroxide is listed at 7
395 CFR 205.605(b) with the annotation: prohibited for use in lye peeling of fruits and vegetables. Although
396 sodium hydroxide is less expensive, potassium hydroxide is used in situations where sodium levels need
397 to be restricted (Saltmarsh 2000). Potassium carbonate may also be used for some applications where a
398 strong base is not necessary and natural sodium carbonate is not appropriate.

399

400 Mechanical, steam or hand peeling is an alternative to lye peeling. The NOSB considered a petition that
401 explained why mechanical and hand peeling were not practical with peaches prepared for individual quick
402 freezing (IQF) (Finn 2001). The petition to allow potassium hydroxide for use in processing thermally
403 canned peaches claimed that steam peeling resulted in lower quality (Van Gundy and Montecalvo 2011).
404 Electrical current in water with a salt solution using either sodium chloride (NaCl) or potassium chloride
405 (KCl) can reduce the amount of caustic used, but complete elimination of potassium hydroxide is not as
406 efficient (Sastry and Wongsangasri 2009). Other physical methods that are being explored include
407 infrared, ohmic heating, and physical ultrasonics (Rock et al. 2012; Li et al. 2014). While these are promising
408 alternatives that may address the various problems caused by lye peeling, they are not yet considered
409 commercially viable.

410
411

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

415

416 For the adjustment of pH, there are some naturally occurring alkali substances, such as sodium carbonate
417 and sodium bicarbonate, which may be alternatives to potassium hydroxide. Both sodium carbonate and
418 sodium bicarbonate are listed at 7 CFR 205.605(a). However, these are less soluble than potassium
419 hydroxide in water and are not always effective in raising the pH.

420

421

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

424

425 No agricultural product has the same functionality as potassium hydroxide.

426

427

428

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429

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