

Potassium Iodide

Handling/Processing

Identification of Petitioned Substance

Chemical Name: Potassium iodide	CAS Number: 7681-11-0
Other Names: Jodid Thyroblock Thyrojod	Other Codes: RTECS: TT2975000

Characterization of Petitioned Substance

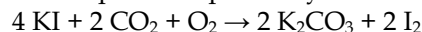
Composition of the Substance:

Potassium iodide is an inorganic compound with formula KI, a salt of stable iodine. It is ionic, K^+I^- . KI is comprised of 23.55% potassium and 76.45% iodine (Merck Index, 2006). This salt is the most commercially significant iodide compound. It is produced industrially by treating potassium hydroxide with iodine (Lyday, 2000).

Properties of the Substance:

Physical/Chemical Properties	
Molar mass	166.00 g/mol
Color	White or colorless
Appearance	Powder, granules, or crystals (hexahedral)
Odor	Odorless
Molecular weight	166.00 g/mol
Boiling point	1323 °C
Melting point	681 °C
Density/Specific gravity	3.12 g/cm ³
Solubility in Water	128 g/100 ml (0 °C) 140 g/100 ml (20 °C) 176 g/100 ml (60°C) 206 g/100 ml (100°C)
Solubility in Other Solvents	2 g/100 ml ethanol 1 g/8 ml methanol Soluble in acetone Slightly soluble in ether and ammonia 1 g/2 ml glycerol 1 g/about 2.5 ml glycol
pH	Aqueous solution in neutral or usually alkaline (pH 7-9)
Vapor pressure	9.9×10^{-18} mm Hg

KI crystallizes in the sodium chloride structure, hexahedral crystals. It is less hygroscopic than sodium iodide, making it easier to work with. Potassium iodide is stable in dry air but slightly hygroscopic in moist air. Aged and impure samples are yellow because of oxidation of the iodide to iodine (Lyday, 2000).



29 A small amount of iodate may be formed. Light and moisture accelerate the decomposition. Aqueous
 30 solution also becomes yellow in time due to oxidation, but a small amount of alkali prevents it (Merck
 31 Index, 2006).

32
 33 **Specific Uses of the Substance:**

34
 35 According to FDA, potassium iodide may be used as food additive and can serve the following functions:

- 36 • A nutrient in table salt as a source of iodine.
- 37 • A dietary supplement for human consumption and in animal feeds.
- 38 • A sanitizing agent for food processing equipment.

39
 40 When KI functions as a microbicide¹, it is used in emergency drinking water purification/ disinfection,
 41 fresh food sanitization, food-contact surface sanitization, hospital surface disinfection, and commercial and
 42 industrial water cooling tower systems (EPA RED, Case 3080, 2006). In addition, this substance can be
 43 used as an expectorant for treatment of chronic respiratory diseases, iodine source in treatment of thyroid
 44 disorders, manufacture of photographic emulsions (used with silver nitrate), ingredient in personal
 45 hygiene products, and laboratory reagent for analytical chemistry.

46
 47 Furthermore, as a thyroid blocking agent, potassium iodide protects the thyroid gland by blocking the
 48 thyroidal uptake of radioactive iodine. It may be used prior to and following administration of radioactive
 49 isotopes and in radiation emergencies involving the release of radioactive iodine.

50
 51 **Approved Legal Uses of the Substance:**

52
 53 **EPA** – KI (CAS No. 7681-11-0) is listed under 40 CFR §180.940 *Tolerance exemptions for active and inert*
 54 *ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions)*. When ready for use,
 55 the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of
 56 titratable iodine.

57
 58 **FDA** – Potassium iodide (CAS No. 7681-11-0) is a food additive listed in 21 CFR §172.375, §178.1010,
 59 §184.1634, and §582.80. Uses of KI are listed in Table 1.

60
 61 Table 1. FDA Regulations, 21 CFR
 62

Regulatory Citations		Technical Effects	Status	Use Limits
SUBCHAPTER B – FOOD FOR HUMAN CONSUMPTION	Part 172 – Food Additives Permitted for Direct Addition to Food for Human Consumption. Subpart D – Special Dietary and Nutritional Additives. §172.375 Potassium iodide	Dietary supplement	Added to a food as a source of the essential mineral iodine, provided the maximum intake of the food as may be consumed during a period of one day, or as directed for use in the case of a	When age or the conditions are specified: < 45 µg for infants; < 105 µg for children under 4 years old; < 225 µg for adults and children 4+

¹ It kills microbes such as bacteria, viruses, and fungi and used in disinfectant or antibacterial products.

	<p>Part 178 – Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers. Subpart B – Substances Utilized to Control the Growth of Microorganisms. §178.1010 Sanitizing solutions</p>	Sanitizing agent	<p>dietary supplement, will not result in daily ingestion of the additive so as to provide a total amount of iodine in excess of 225 µg for foods labeled without reference to age or physiological state.</p> <p>In addition to use on food processing equipment and utensils, this solution may be used on beverage containers, including milk containers and equipment and on food-contact surfaces in public eating places.</p>	<p>years old; <300 µg for pregnant or lactating women.</p> <p>Not more than 25 ppm of titratable iodine. This solution contain KI at a level not in excess of the minimum required to produce its intended functional effect.</p>
	<p>Part 184 – Direct Food Substances Affirmed As Generally Recognized As Safe. Subpart B – Listing of Specific Substances Affirmed as GRAS. §184.1634 Potassium iodide</p>	Nutrient	<p>GRAS; used in table salt as a source of dietary iodine.</p>	<p>Maximum level 0.01%.</p>
SUBCHAPTER E – ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS	<p>Part 582 – Substances Generally Recognized As Safe. Subpart A – General Provisions. §582.80 Trace minerals added to animal feeds</p>	Nutritional dietary supplement	<p>GRAS</p>	<p>At levels consistent with good feeding practice.</p>

63
 64 **USDA** – Potassium iodide is listed on NOP the National List of Allowed and Prohibited Substance: 7 CFR
 65 §205.605 (a) Nonsynthetics allowed and (b) Synthetics allowed (including nutrient vitamins and minerals,
 66 in accordance with 21CFR 104.20, Nutritional Quality Guidelines for Foods). In addition, KI may be
 67 allowed under §205.603 (d) (2), as feed additives (trace minerals, used for enrichment or fortification when
 68 FDA approved).
 69

Action of the Substance:

Potassium iodide is a salt of stable (non-radioactive) iodine. Its actions in different usage are as follows:

- Use as a nutrient, source of iodine — Iodine is an essential component of the thyroid hormones that are involved in the regulation of various enzymes and metabolic processes. In other words, iodine plays a major role in regulating the growth and development of the organism and its rate of metabolism.
- Act as a microbiocide by releasing iodine — Iodine, as a reactive oxidizing agent, has multiple effects on the cell surface (cell wall and membranes) and in the cytoplasm. [Note: The exact modes of action are unknown.] Iodine has a dramatic effect on microbial surfaces but also rapidly penetrates into microorganisms (McDonnell, 2007). Reactive iodine species have been shown to attack amino acids (particularly lysine, histidine, cysteine, and arginine) to cause protein disruption and loss of structure and function. Iodine reacts with and substitutes for various functional groups on these amino acids. Further, iodine reacts with nucleic acids, lipids, and fatty acids (including those in the cell membrane structures). These effects culminate in loss of cell function and death (McDonnell, 2007).
- Use as a thyroid blocking agent in radiation emergencies (radioactive iodine is released into the environment) — According to the FDA's guidance (2001) on this matter, potassium iodide is effective in reducing the risk of thyroid cancer in individuals or populations at risk for inhalation or ingestion of radioiodine when it is ingested in the proper dosage and taken at the appropriate time. KI floods the thyroid with non-radioactive iodine and prevents the uptake of the radioactive molecules, which are subsequently excreted in the urine over a period of a week or two. Thus, the body will eliminate the radioactive iodine and the thyroid will not absorb and store the radioactive iodine. Therefore, taking potassium iodide is a method of shutting down the thyroid absorption of iodine (a process call "blocking") until the body rids itself of any radioactive iodine.

Status**Domestic:**

EPA — Neither List 4A nor List 4B, updated August 2004, contains potassium iodide (EPA pesticide chemical code: 075701). According to the Reregistration Eligibility Decision (RED) for iodine, products containing iodine as the active ingredient were initially registered in the US by the USDA in 1948. This RED is inclusive of iodine and related compounds used as sanitizers and disinfectants. It includes iodine, potassium iodide, sodium iodide, and iodide embedded in organic polymers (EPA RED, Case 3080, 2006). In 40 CFR §180.940, residues of chemical substances (such as potassium iodide) are exempted from the requirement of a tolerance when used in accordance with good manufacturing practice as ingredients in an antimicrobial pesticide formulation, provided that the chemical substance is applied on a semi-permanent or permanent food-contact surface (other than being applied on food packaging) with adequate draining before contact with food. Under §180.940 (a), (b), and (c), when KI used as an ingredient in an antimicrobial pesticide formulation may be applied to (a) food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils; (b) dairy processing equipment, and food-processing equipment and utensils, and (c) food-processing equipment and utensils.

FDA — See the above, the Approved Legal Uses of the Substance section. In 1978, the Agency deemed potassium iodide a safe and effective means by which to block uptake of radioiodine by the thyroid gland in the event of radiation emergency under certain specified conditions of use.

USDA — Potassium iodide is listed on NOP the National List of Allowed and Prohibited Substance: 7 CFR §205.605 (a) Nonsynthetics allowed and (b) Synthetics allowed—for use only in agricultural products labeled "made with organic (specified ingredients of food group(s))," prohibited in agricultural products labeled "organic". In addition, KI may be allowed under §205.603 (d) (2), as feed additives (trace minerals, used for enrichment or fortification when FDA approved).

124
125 **OMRI** – Potassium iodide is listed on Organic Materials Review Institute (OMRI) Generic Materials List
126 as a nutrient (iodine) source in animal feeds and a sanitizer and topical disinfectant in livestock production.
127 Also, OMRI indicates that nonsynthetic KI is allowed as a processing nonagricultural ingredient and
128 processing aid; synthetic KI is allowed with restrictions as processing nonagricultural ingredient and
129 processing aid.

130
131 **International:**
132

133 **Codex** – In Codex Standard for Food Grade Salt, Section 3.4 (*Iodisation of Food Grade Salt*) under Subsection
134 3.4.1 (*Iodine compounds*), it states “For the fortification of food grade salt with iodine, use can be made of
135 sodium and potassium iodides or iodates.” In addition, “The maximum and minimum levels used for the
136 iodisation of food grade salt are to be calculated as iodine (expressed as mg/kg) and shall be established by
137 the national health authorities in the light of the local iodine deficiency situation.” is stated in Subsection
138 3.4.2 (*Maximum and minimum levels*) (CODEX STAN 150, Amend. 2001).

139
140 In *ADVISORY LIST OF MINERAL SALTS FOR USE IN FOODS FOR INFANTS AND CHILDREN*,
141 potassium iodide is listed as a source of iodine use in milk based, milk substitute, and meat-based
142 formulae. The Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and
143 Children were adopted by the Codex Alimentarius Commission at its 13th Session in 1979. Amendments to
144 the list of mineral salts and the special vitamin forms were adopted by the 19th Session in 1991 (CAC/GL
145 10, Amend. 1991).

146
147 **European Union** – Potassium iodide is listed under both Annex II (*Vitamin and mineral substances which*
148 *may be used in manufacture of food supplements*) of Directive 2002/46/EC and Annex II (*Vitamin formulations*
149 *and mineral substances which may be added to foods*) of Regulation (EC) No 1925/2006. These annexes have
150 been amended by Commission Regulation (EC) 1170/2009.

151
152 **Canada** – Section B.17.003 of the Canadian Food Drug Regulations requires that salt for general household
153 or table use contain 0.01% potassium iodide.

154
155 **Codex (organic)** – Not listed.

156
157 **Canada (organic)** – Natural potassium iodide and synthetic potassium iodide are listed under Subsections
158 6.4 (*Non-organic Ingredients Not Classified as Food Additives*) and 6.5 (*Substances Permitted in Products Whose*
159 *Contents Are 70% or More, and Less Than 95% organic Ingredients*), respectively, of Section 6 (*Permitted*
160 *Substances Lists for Processing*) of Organic Production System Permitted Substances Lists. Amended
161 October 2008 and December 2009 by Canadian General Standards Board.

162
163 **Evaluation Questions for Substances to be used in Organic Handling**

164
165 **Evaluation Question #1:** Discuss whether the petitioned substance is formulated or manufactured by a
166 chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).
167

168 A number of methods used for the preparation of potassium iodide are described as following –
169

170 (a) A hot aqueous solution of potassium hydroxide (KOH) is treated with iodine (I₂) in slight excess to
171 form a mixture of potassium iodide (KI) and potassium iodate (KIO₃):
172

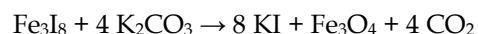


175 The solution is concentrated with heating. An excess of powdered charcoal is added and well
176 mixed. The mixture is evaporated to dryness and then ignited. The charcoal reduces the iodate to

177 iodide and all of the iodine is thus obtained as potassium iodide. The mass is soaked with water,
178 filtered, evaporated to a suitable concentration, and set aside to crystallize (Osol and others, 1975).
179

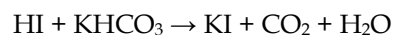
180 (b) One production involves absorption of I₂ in KOH to form KI and potassium iodate (KIO₃); the
181 chemical equation is the same as above, described in the (a) section. The KIO₃ precipitates out and
182 is further processed as a by-product. The iodide solution is evaporated to dryness and fused by
183 heating (about 600° C) to decompose residual iodates and any organic matters. The fused iodide is
184 re-dissolved in water and treated with small amounts of barium carbonate, potassium carbonate,
185 hydrogen sulfide, ferrous iodide, and carbon dioxide for pH adjustment and to precipitate trace
186 impurities. The solution is filtered into a second treating tank, with a pH adjustment, if necessary,
187 re-filtered and piped to a series of steam heated crystallizers. The slurry leaving the crystallizers is
188 centrifuged and the KI crystals are dried, screened, and packaged. The mother liquor from the
189 centrifuge is recycled to the initial treatment tank (EPA, ICM, 1975).
190

191 (c) Iron wire is reacted with iodine in the presence of water to form ferrosferic iodide (Fe₃I₈) first,
192 which does not involve the formation of iodate. A solution of potassium carbonate (K₂CO₃) is then
193 added until the solution is slightly alkaline :



196 After that, the solution was boiled for a few moments, and filtered; the filtrate is then concentrated
197 and set aside to crystallize (Osol and others, 1975).
198
199

200 (d) KI can be prepared by reacting hydriodic acid (HI) with potassium bicarbonate (KHCO₃); then, it is
201 purified by melting in dry hydrogen (Merck Index, 2006).
202



203 Iodine compounds can also be found in seawater, seaweed, marine organisms, and brines. Iodine is
204 present in brines as iodide, and its concentration varies from about 10 to 150 ppm (Krischwitz, 1999). The
205 predominant production process for iodine from brines is a blow-out process. This iodine recovery process
206 can be divided into brine clean-up, chlorine oxidation to convert iodide to iodine followed by air blowing
207 out and recovery, and iodine finishing (EPA, Iodine, 1991; Krischwitz, 1999).
208
209

210 **Evaluation Question #2: Describe the most prevalent processes used to manufacture or formulate the**
211 **petitioned substance. Further, describe any chemical change that may occur during manufacture or**
212 **formulation of the petitioned substance when this substance is extracted from naturally occurring plant,**
213 **animal, or mineral sources. (7 U.S.C. § 6502 (21))**
214
215

216 In accordance with the database of Hazardous Substance Data Bank (HSDB) in National Library of
217 Medicine, most US potassium iodide production involves absorption of iodine in potassium hydroxide, see
218 Evaluation Question (EQ) #1 (b).
219

220 Iodine compounds can also be found in seawater, seaweed, marine organisms, and brines. Seawater
221 contains 0.05 ppm iodine, or approximately 34 million tons (USGS², iodine, 2010). Seaweeds of the
222 *Laminaria* family are able to extract and accumulate up to 0.45% iodine on a dry basis. Although not as
223 economical as the production of iodine as a byproduct of gas, nitrate, and oil, the seaweed industry
224 represented a major source of iodine prior to 1959 and remains a large resource (USGS, iodine, 2010).
225

226 No information was identified to suggest that KI is extracted from brines, though iodine occurs frequently
227 as potassium iodide or sodium iodide in subsurface brines associated with oil and gas deposits (Lyday,
228 2000).

² U.S. Geological Survey.

229
230 **Evaluation Question #3: Provide a list of non-synthetic or natural source(s) of the petitioned substance**
231 **(7 CFR § 205.600 (b) (1)).**
232

233 No information reviewed specifically address non-synthetic potassium iodide.
234

235 **Evaluation Question #4: Specify whether the petitioned substance is categorized as generally**
236 **recognized as safe (GRAS) when used according to FDA's good manufacturing practices. (7 CFR §**
237 **205.600 (b)(5))**
238

239 Potassium iodide is listed in 21 CFR §184.1634 under *Listing of Specific Substance Affirmed as GRAS of*
240 *DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE*. This ingredient (KI,
241 CAS No. 7681-11-0) is used as a nutrient supplement as defined in 21 CFR §170.3 (o) (20)³; and it may be
242 added in table salt as a source of dietary iodine at a maximum level of 0.01%. This GRAS substance was
243 evaluated by the Select Committee on GRAS Substances (SCOGS) in 1975. The SCOGS concluded that
244 there was no evidence in the available information on potassium iodide, potassium iodate, or calcium
245 iodate that demonstrated, or suggested reasonable grounds to suspect a hazard to the public when they
246 were used at levels at that time or might reasonably be expected in the future.
247

248 In addition, KI added to animal feeds as nutritional dietary supplements is GRAS when added at levels
249 consistent with good feeding practice, see 21 CFR §582.80 Trace mineral added to animal feeds.
250

251 **Evaluation Question #5: Describe whether the primary function/purpose of the petitioned substance is**
252 **a preservative. If so, provide a detailed description of its mechanism as a preservative. (7 CFR § 205.600**
253 **(b)(4))**
254

255 According to 21 CFR §178.1010, potassium iodide solution is a sanitizer as an indirect food additive. In 40
256 CFR §180.940, residues of potassium iodide are exempted from the requirement of a tolerance when used
257 in accordance with good manufacturing practice as an active ingredient in an antimicrobial pesticide
258 formulation.
259

260 No information sources reviewed specifically address the primary function/purpose of potassium iodide
261 as a preservative.
262

263 **Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate**
264 **or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)**
265 **and how the substance recreates or improves any of these food/feed characteristics. (7 CFR § 205.600**
266 **(b)(4))**
267

268 According to the FDA's fortification policy in *NUTRITIONAL QUALITY GUIDELINES FOR FOODS*, see 21
269 CFR §104.20, iodine may appropriately be added to a food to restore such nutrient to a level representative
270 of the food prior to storage, handling, and processing. Moreover, all nutrients listed in 21 CFR §104.20 (d)
271 (3), including iodine, may appropriately be added to a food to correct a dietary insufficiency recognized by
272 the scientific community.
273

274 In 21 CFR §184.1634, potassium iodide may be an ingredient in table salt as a source of dietary iodine at a
275 maximum level of 0.01 percent. Furthermore, the Joint FAO/WHO Expert Committee on Food Additives,
276 in its 37th report concluded that "potassium iodate and potassium iodide should continue to be used for
277 fortification of salt for correction of iodine deficiency."
278

279 No information was identified to suggest that KI can be used primarily to recreate or improve flavors,
280 colors, or textures lost in processing.

³ Nutrient supplements: Substances which are necessary for the body's nutritional and metabolic processes.

281
282 **Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or**
283 **feed when the petitioned substance is used. (7 CFR § 205.600 (b)(3))**
284

285 Potassium iodide may be added to food as a nutrient/nutritional supplement for human consumption or
286 to animal feeds.

287
288 For human consumption, 21 CFR 172.375 stated “Potassium iodide may be safely added to a food as a
289 source of the essential mineral iodine, provided the maximum intake of the food as may be consumed
290 during a period of one day, or as directed for use in the case of a dietary supplement, will not result in
291 daily ingestion of the additive so as to provide a total amount of iodine in excess of 225 micrograms for
292 foods labeled without reference to age or physiological state; and when age or the conditions of pregnancy
293 or lactation are specified, in excess of 45 micrograms for infants, 105 micrograms for children under 4 years
294 of age, 225 micrograms for adults and children 4 or more years of age, and 300 micrograms for pregnant or
295 lactating women.” In addition, FDA has established requirements of nutrients in infant formulas. Mineral
296 iodine is one of the nutrients at levels of 5 to 75 micrograms/100 kilocalories of baby formula, see 21 CFR
297 §107.100 Nutrient specifications.

298
299 For animal feeds, 21 CFR §582.8 states that KI is one of the iodine compounds may be added to animal
300 feeds as a nutritional dietary supplement when added at a level consistent with good feeding practice.

301
302 **Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of**
303 **FDA tolerances that are present or have been reported in the petitioned substance. (7 CFR § 205.600**
304 **(b)(5))**
305

306 According to the specification of potassium iodide in Food Chemical Codex (2010-2011), it stipulates the
307 impurity acceptable criterion is not more than 4 mg/kg of lead.

308
309 No information was identified to suggest that the petitioned substance contains residues of heavy metals or
310 other contaminants in excess of FDA’s Action Levels for Poisonous or Deleterious Substances in Human
311 Food.

312
313 **Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the**
314 **petitioned substance may be harmful to the environment. (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. §**
315 **6517 (c) (2) (A) (i))**
316

317 EPA announced reregistration eligibility decision (RED) for iodine and iodophor complexes (List C, Case
318 3080) in 2006. Iodine and its related compounds presented in this document include: iodine, potassium
319 iodide, sodium iodide, hydriodic acid, and the iodine-releasing iodophor complexes. They all contain
320 iodine as the active ingredient and function by releasing molecular iodine (EPA-HQ-OPP-2006-0599-0006).
321 This report stated that iodine is an element ubiquitously present in water, air, and soils; and it is a part of
322 human diet. It is likely mobile in soils; iodine as iodide and iodate exist in water. It is less likely to
323 bioaccumulate in aquatic organisms. Iodine is not hydrolyzed in water as are other halogens preceding it
324 in the halogen family. It is photolytically unstable in the atmosphere as it can form iodine radicals. The
325 transfer of iodine from air, water, and land is due to the volatility of iodine. The wet deposition of iodine is
326 predominantly into soil. Iodine in water exists as iodide and iodate at a 55:45 ratio. Mobility of iodine in
327 soil depends on the soil porosity, saturation and the amount of organic matter and iron/aluminum oxides
328 in the soil. It is immobile to moderately immobile in most soils (EPA-HQ-OPP-2006-0599-0005). Office of
329 Pesticides Program’s Lower Risk Pesticide Chemical Group, in its Science Assessment for iodine chemicals
330 as active and inert, did not observe any real or potential environmental concerns for these pesticides
331 (Chemicals assessed were: Iodine, Potassium Iodide, Sodium Iodide, Hydriodic Acid, Potassium Iodate)
332 (EPA-HQ-OPP-2006-0599-0005).
333

334 For ecological effects, acute risks to non-target birds, aquatic invertebrates, and fish are highly unlikely,
335 based on the measured toxicity of iodine, iodide, and iodate, the physical properties of these chemicals, and
336 the environmental concentrations and fate of iodine and its principle environmental moieties iodide and
337 iodate (EPA-HQ-OPP-2006-0599-0006). Chronic risk to fish is likewise unlikely. Little or no environmental
338 exposure is expected from these uses, since industrial water treatment requires a NPDES⁴ permit in order
339 to discharge effluents, in accordance with the EAP RED for iodide and iodophor complexes.

340
341 Potential occupational and residential exposures from use of iodine and iodine complexes do not present a
342 risk of concern and therefore, have not been quantitated based on data that show a low percentage dermal
343 absorption of iodine (1%) and an estimated worst-case inhalation exposure (0.008 ppm) that is well below
344 the ACGIH⁵ published TLV⁶ (0.1 ppm) for iodine vapor (EPA-HQ-OPP-2006-0599-0006). Based on a review
345 of the available toxicology data, EPA has concluded that iodine and iodophor complexes are of very low
346 toxicity by the oral, dermal, and inhalation routes of exposure.

347
348 **Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the**
349 **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))**

350
351 Potassium iodide, an iodine compound, is a source of iodine. It is a naturally-occurring chemical and
352 therefore, a background level of exposure to iodine cannot be avoided. Iodine (in the form of iodide) is a
353 necessary human nutrient that is required for proper functioning of the human endocrine system,
354 specifically synthesis of thyroid hormones – thyroxine (T4) and triiodothyronine (T3). These hormones
355 regulate many key biochemical reactions, especially protein synthesis and enzymatic activity. Major target
356 organs are the developing brain, muscle, heart, pituitary, and kidney (DRI⁷, 2001). It is well-documented
357 that pre-existing nutritional deficiency of iodine in the diet can perturb levels of thyroid hormones which
358 cause a spectrum of disorders that include in increasing order of severity, goiter and hypothyroidism,
359 mental retardation, and cretinism (DRI, 2001; Miller, 2006). With respect to excess iodine exposure, certain
360 disease states (thyroid gland adenoma, autoimmune thyroid disease) may make individuals with these
361 conditions at increased risk for thyroid dysfunction (EPA RED, Case 3080, 2006). The iodine in most food
362 sources is low and can be affected by content of soil, irrigation, and fertilizers. Most foods provide 3 to 75
363 µg per serving (DRI, 2001). Foods of marine origin have higher concentrations of iodine because marine
364 animals concentrate iodine from seawater. Processed foods may also contain higher levels of iodine due to
365 the addition of iodized salt or food additives, such as calcium iodate, potassium iodate, potassium iodide,
366 and cuprous iodide.

367
368 The National Academy of Sciences (NAS) has set the Recommended Dietary Allowances (RDAs) of iodine
369 for adult men and women at 150 µg/day; for children in the range of 90-150 µg/day (1-8 years: 90 µg/day,
370 9-13 years: 120 µg/day, 14-18 years: 150 µg/day); for pregnant and lactating women at 220 µg/day and 290
371 µg/day, respectively. For infants, the guidance for Adequate Intake (AI) is 110 µg/day of iodine for age 0
372 to 6 months and 130 µg/day of iodine for age 7 to 12 months. The Tolerable Upper Intake Level (UL), the
373 maximum level of daily intake that is likely to pose no risk of adverse effects, has been established at 1,100
374 µg/day for adult men and women based on serum thyrotropin concentration in response to varying
375 levels of ingested iodine. The ULs for children range from 200 to 600 µg/day of iodine (1-3 years: 200
376 µg/day, 4-8 years: 300 µg/day, 9-13 years: 600 µg/day). The ULs for adolescents and pregnant and
377 lactating women ages 14-18 years is 900 µg/day of iodine and for pregnant and lactating women ages 19-50
378 years is 1,100 µg/day of iodine. For infants (0-12 months), no UL was determined. However, to prevent
379 high intake of iodine, it is recommended that the only source of this essential nutrient for infants be from
380 food and formula (NAS, 2001).

381

⁴ National Pollutant Discharge Elimination System.

⁵ American Conference of Governmental Industrial Hygienists.

⁶ Occupational exposure limit set by ACGIH. An airborne concentration of a gas or particle to which most workers can be exposed on a daily basis for a working lifetime without adverse effect.

⁷ Dietary Reference Intakes.

382 In the FDA assessment entitled "Potassium Iodide and Potassium and Calcium Iodates: Proposed
383 Affirmation of GRAS Status as Direct Human Food Ingredients with Specific Limitations" (42 FR 29925,
384 June 10, 1977), the opinion of the Select Committee was that ingested potassium iodide and other iodides
385 are readily absorbed and utilized to the extent required for nutritional needs, the excess being excreted
386 primarily in the urine. There was no evidence in the studies on experimental animals and man available to
387 the Committee that indicated acute or chronic toxic effects, including mutagenic, teratogenic, and
388 carcinogenic effects, resulting from the consumption of potassium iodide by euthyroid⁸ individuals in
389 amounts that are several orders of magnitude greater than those now being consumed in the daily diet
390 (EPA, FR Doc 04-19620).

391
392 The report of EPA RED for iodine and iodophor complexes (List C, Case 3080, 2006) stated that the Agency
393 has no risk concerns for iodine and iodophor complexes with respect to human exposure through dietary,
394 drinking water, residential and occupational routes. The toxicology database is adequate to characterize
395 the hazard of iodine, and no data gaps have been identified. There are no indications of special sensitivity
396 of infants or children resulting from exposure to iodine. Therefore, the Food Quality Protection Act
397 (FQPA) Safety Factor has been removed (i.e., reduced to 1x) for iodine. Considering the reversible nature
398 of subclinical hypothyroidism observed in humans exposed to iodine, the Agency has not identified
399 toxicological endpoints of concern for iodine. Therefore, a quantitative human health risk assessment was
400 not conducted for this RED document.

401
402 **Evaluation Question #11: Provide a list of organic agricultural products that could be substituted for**
403 **the petitioned substance. (7 CFR § 205.600 (b)(1))**
404

405 Currently, KI is on NOP the National List of Allowed and Prohibited Substance under the section 205.603
406 (d) (2) and 205.605 (a) and (b). The following are excerpts from the National List:

407
408 **§ 205.603 Synthetic substances allowed for use in organic livestock production.**

409 (d) As feed additives.

410
411 (2) Trace minerals, used for enrichment or fortification when FDA approved.

412
413 **§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or**
414 **on processed products labeled as "organic" or "made with organic (specified**
415 **ingredients or food group(s))."**
416

417
418 The following nonagricultural substances may be used as ingredients in or on
419 processed products labeled as "organic" or "made with organic (specified
420 ingredients or food group(s))" only in accordance with any restrictions specified in
421 this section.

422
423 (a) Nonsynthetics allowed:

424 Potassium iodide.

425
426 (b) Synthetics allowed:

427 Potassium iodide—for use only in agricultural products labeled "made with
428 organic (specified ingredients or food group(s))," prohibited in agricultural
429 products labeled "organic".
430
431
432

⁸ The state of having normal thyroid gland function.

433 Nutrient vitamins and minerals, in accordance with 21CFR 104.20, Nutritional
434 Quality Guidelines For Foods.

435
436 However, there are no information sources reviewed specifically address that an organic agricultural
437 product could be substituted for potassium iodide.

438
439 **ADDITIONAL QUESTIONS** – Identified by the National Organic Standards Board (NOSB) Handling
440 Committee:

441
442 ➤ **What Are The Different Manufacturing Processes For Potassium Iodide?**

443
444 See EQ #1.

445
446 ➤ **Is Nonsynthetic Potassium Iodide Available?**

447
448 See EQ #3.

449
450 ➤ **Is There Justification For The Current Allowance Of *Synthetic* Potassium Iodide In “Made With
451 Organic” Products Only?**

452
453 Synthetic potassium iodide is currently allowed in “made with organic” products under 205.605(b). Any
454 changes to the National List must first be recommended by the National Organic Standards Board.

455
456
457 ➤ **Do All Food Uses Of Potassium Iodide (KI) Fit Under The Listing For Nutrient Vitamins And
458 Minerals [§205.605(b)], Since Iodine Is Listed In 21 CFR 104.20, Nutritional Quality Guidelines For
459 Foods?**

460
461 Potassium iodide used as a sanitizer would NOT be covered under the listing for nutrient vitamins and
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463
464
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