Ion Exchange Filtration
Handling/Processing

1	**Identification of Petitioned Substance**

2
3 **Chemical Names:**   Lewatit
4 N/A   Amberlite™
5   POROS™
6 **Other Names:**   Amberlyst™
7 Ion exchange resin
8 Ion exchange polymer   **CAS Numbers:**
9 Ion exchange beads   7440-44-0 (activated carbon)
10 Polystyrene   Variable with each ion exchange polymer
11 Anionic exchange resin
12 Cationic exchange resin   **Other Codes:**
13 Strongly acidic resin   EC No. 231-153-3 (activated carbon)
14 Weakly acidic resin   RTECS No. FF5250100 (activated carbon)
15 Strongly basic resin   Variable with each ion exchange polymer
16 Weakly basic resin
17 Zeolite
18 Activated carbon
19 Clay
20 Clay Minerals
21
22 **Trade Names:**
23 Dowex™

24	**Summary of Petitioned Use**

25
26 Ion exchange filtration is a process through which the composition of treated foodstuffs and water sources
27 used in food processing are purified by removing undesired substances. However, unlike a typical
28 filtration process, where substances are simply removed by some structural characteristic (e.g., size,
29 solubility), ion exchange filtration uses an exchange of substances. These exchanges are often based on
30 acid–base chemistry, where one acidic or basic group in the treated substance is exchanged for a different
31 acid or base from the filtration material. While acid and base functionalities are common in ion exchange
32 filtration materials, the process may also be governed by electrostatic attractions. For example, a cation
33 (positively charged ion) in the substance is exchanged for a cation from the filtration material. In all cases,
34 the filtration process results in the exchange of one chemical species from the substance with another from
35 the filtration material with a similar charge (+ with +, - with -) to maintain net neutrality.
36
37 Ion exchange filtration is a purification technique that is used in many handling and processing
38 applications across many industries, including food, water treatment, pharmaceuticals, and chemical and
39 biochemical production (Andrés et al. 1997, Skoog et al. 2007, Kammerer et al. 2011). This report was
40 requested by the National Organic Program (NOP) for background on the technique and will focus on the
41 uses of ion exchange filtration in the processing and handling of organic food products (USDA 2019a).
42

43	**Characterization of Petitioned Substance**

44
45 **Composition of the Substance:**
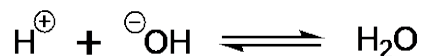46 *Synthetic ion exchange materials*
47

48 Ion exchange filtration most commonly employs a synthetic, polymer-based material through which the
49 purification takes place (Skoog et al. 2007). The filtration material can be employed through several forms,
50 including as porous beads, adsorbent resins, or membranes (Bazinet et al. 1999, Ma and Lada 2003, González et
51 al. 2006, Atungulu et al. 2007, Serpen et al. 2007, Skoog et al. 2007, Coca et al. 2008, Dardel and Arden 2008,
52 Kammerer et al. 2011).
53
54 Within the polymeric materials used in ion exchange filtration, there are several formats for the material and
55 processes through which it is used, each featuring a different composition. Acidic or cation exchange resins
56 employ acidic functional groups (groups that give an H^+) bonded to the polymer structure. These acidic groups
57 exchange a cation (e.g., H^+, Na^+, K^+, Mg^{2+}) from the filtration material for another cation in the treated substance.
58 The most common functional groups are sulfonic acids ($-SO_3H$) in strong acid exchange media and carboxylic
59 acids ($-COOH$) in weak acid exchange media (structures shown in Table 1) (Skoog et al. 2007, Kammerer et al.
60 2011).
61
62 Basic or anion exchange resins employ basic functional groups (groups that give an OH^-) bonded to the polymer
63 structure. The most common functional groups are quaternary ammonium species (positively charged nitrogen
64 bonded to four total alkyl groups [R] [$-NR_3^+$]) in strongly basic ion exchange filtration materials (Table 1)
65 (Kammerer et al. 2011). Common weakly basic functional groups include primary ammonium species (positively
66 charged nitrogen with three hydrogens [$-NH_3^+$]), iminium species (positively charged nitrogen including a
67 double bond [$=NR_2^+$, where R is an alkyl group or a hydrogen]), and nitrilium species (positively charged
68 nitrogen with a triple bond [$\equiv NR^+$, where R is an alkyl group or a hydrogen]) (Table 1) (Kammerer et al. 2011). In
69 all basic media (whether strong or weak), the positively charged nitrogen bound to the exchange material is
70 commonly associated with a hydroxide ion (OH^-), although there have also been reports of chloride (Cl^-), sulfate
71 ions (SO_4^{2-}), and carbonate ions (González et al. 2006, Kammerer et al. 2011, Chandrasekara and Pashley 2015).
72 The hydroxide, chloride, sulfate, or carbonate anions from the filtration material is exchanged with an anion
73 (negatively charged ion) from the treated substance.
74
75 When the filtration material anion is hydroxide, the resin is capable of reacting with acids in the treated material
76 to release water rather than hydroxide ions, as shown in Equation 1 below. In the case illustrated below in
77 Equation 1, the hydroxide is initially present in the basic polymeric structure (it is electrostatically bound to the
78 incorporated positively charged nitrogen). The presence of an initially present hydroxide as the basic anion
79 allows two mechanisms for ion exchange: 1) The hydroxide ion (OH^-) is exchanged for another negatively
80 charged ion (e.g., chloride [Cl^-], nitrate [NO_3^-], etc.), which provides the same mechanism for exchange as the
81 acidic, cationic resins described above. 2) The initially present hydroxide ion (OH^-) reacts with an acidic
82 substance in the treated food product; this is illustrated in Equation 1 below, where the acid has been simplified
83 to a hydrogen ion (H^+), which is the active portion of acidic substances. In this second case, the remaining portion
84 of the neutralized acidic substance will bear a negative charge and replace the hydroxide ion that was initially
85 present in the polymer resin.
86

$$H^{\oplus} + {}^{\ominus}OH \rightleftharpoons H_2O$$

87
88
89   **Equation 1.**
90
91 Mixed ion exchange materials incorporate both weak acid ($-COOH$) and weak base ($-NR_2H^+$, $=NR_2^+$, or
92 $\equiv NR^+$), enabling the exchange of both anions and cations simultaneously (Shimizu 1980, Chandrasekara
93 and Pashley 2015).
94
95 Once maximum loading has been reached, the filtration media must be regenerated or recharged
96 (discussed in greater detail in the Action of the Substance section below). Recharging solutions of

97 hydrochloric and sulfuric acids or ammonium bicarbonate regenerate the initial acidic functionality (-
98 SO_3H and -COOH) from the deprotonated versions (-SO_3^- and -COO^-), whose negative charge bind cationic
99 compounds from the treated substances (Dzyazko and Belyakov 2004, González et al. 2006, Chandrasekara
100 and Pashley 2015). The return to a neutral functionality by reaction with acids frees the cationic
101 compounds from the filtered substances, regenerating the filtering material for further use.
102
103 Recharging solutions for basic ion exchange filtration systems are predominantly sodium hydroxide, but
104 there are also regeneration processes that use solutions of potassium hydroxide, calcium hydroxide,
105 ammonium carbonate, ammonium bicarbonate, and sodium chloride (González et al 2006, Xing et al. 2007,
106 Kammerer et al. 2011, Chandrasekara and Pashley 2015). In the regeneration of basic ion exchange
107 materials, the anions used in the regeneration process (e.g., hydroxide [OH^-], chloride [Cl^-], carbonate
108 [CO_3^{2-}]) exhibit high binding affinities with the basic functional groups present in the ion exchange
109 material, displacing the anions removed during the purification event (Tzeng et al. 1988, González et al.
110 2015).
111
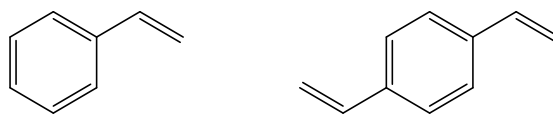112 *Non-synthetic ion exchange materials*
113
114 Natural ion exchange substrates include zeolites, clay, and activated carbon (USDA 2002a, Skoog et al. 2007,
115 Kammerer et al. 2011, Marakatti et al. 2014). Zeolites are crystalline structures of aluminosilicates that feature
116 cations of alkali or alkali earth metals (metals in group 1 and 2 of the periodic table) (e.g., potassium [K^+], sodium
117 [Na^+], calcium [Ca^{2+}]) that can be of either non-synthetic or synthetic origin (Kammerer et al. 2011, Marakatti et
118 al. 2014). Activated carbon is derived from natural plant and animal sources, including bones, coals, peat, wood,
119 and lignite (USDA 2002a, Skoog et al. 2007, Kammerer et al. 2011, Marakatti et al. 2014).
120
121 **Source or Origin of the Substance:**
122
123 *Synthetic ion exchange materials*
124
125 Ion exchange filtration uses an ion exchange polymeric material, which is a synthetic substance. The
126 polymer can be produced in several forms, most commonly as beads, resins, or membranes (Bazinet et al.
127 1999, Ma and Lada 2003, González et al. 2006, Atungulu et al. 2007, Serpen et al. 2007, Skoog et al. 2007,
128 Coca et al. 2008, Dardel and Arden 2008, Kammerer et al. 2011). Most of the polymeric substrates used in
129 ion exchange filtration are produced with the polymerization of styrene and divinyl benzene (Figure 1)
130 (Davankov and Tsyurupa 1990, Kammerer et al 2011, Alvarado and Chen 2014). Acidic or basic functional
131 groups (discussed above in Composition of the Substance) are incorporated within the polymeric
132 backbone. The function of the ion-exchange polymer dictates the identity and density of the functional
133 groups (Davankov and Tsyurupa 1990, Skoog et al. 2007, Kammerer et al. 2011).
134

styrene   divinyl benzene

135
136
137   **Figure 1.**
138
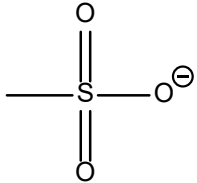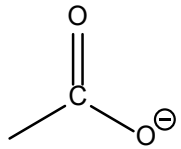139 *Non-synthetic ion exchange materials*
140

141 Non-synthetic exchange media include clay and zeolites (alkali or alkali earth compounds with
142 aluminosilicates). Clay is naturally present in soil horizons, marine sediments, geothermal fields, volcanic
143 deposits and weathered rock formation (USGS 1999). Zeolites are formed upon the reaction of volcanic
144 rocks with alkaline water sources and can be found in many mineral sources (Marakatti et al. 2014). Ion
145 exchange can also be carried out via activated carbon, which is derived from natural sources such as bones,
146 coals, peat, wood, and lignite (USDA 2002a, Kammerer et al. 2011). However, unlike clay and zeolites,
147 activated carbon must be manufactured rather than be used in its natural state.
148
149 **Properties of the Substance:**
150 Ion exchange filtration is used in a range of applications such as food processing, water purification and
151 treatment, and pharmaceuticals (Andrés et al. 1997, Skoog et al. 2007, Kammerer et al. 2011, Marakatti et al.
152 2014). Given the large range of these applications, the ion exchange media used in each application are
153 quite different and include both non-synthetic and synthetic substrates. The properties of non-synthetic
154 substrates (clay, zeolites) and synthetic substrates (activated carbon, acidic exchange polymers, basic
155 exchange polymers) are listed below in Table 1. Table 1 lists the most common functional groups that are
156 associated with various types of ion exchange materials, as well as the types of ions or compounds that are
157 typically exchanged during the ion exchange filtration process. Specifically, the exchanges with column
158 describes the ions/molecules that are most often removed from the substance or solution being purified.
159 These ions/molecules are removed from the treated substances and remain within the ion exchange
160 material until they are removed through a regeneration event.
161
162

Table 1: Properties of Ion Exchange Substrates

Ion Exchange Material	Functional Group(s)	Exchanges with
Activated Carbon	N/A	Gases, and compounds, depending on activation process
Clay	SiO_2, Al_2O_3, MgO	Cations
Zeolites	Aluminosilicates (AlO_4^+), (SiO_4)	Cations
Acid exchangers	Sulfonate $(-SO_3^-)$ Carboxylate $(-COO^-)$	Cations (M^{n+}) e.g., Na^+, K^+, Li^+, Ca^{2+}, Mg^{2+}, Ba^{2+}, Pb^{2+}, Cd^{2+}, Fe^{2+}, Fe^{3+}

Basic exchangers		Anions (R⁻)
	R ——N⊕——R R Ammonium (-NR$_4^+$)	e.g., citrate, carbonate, bicarbonate, phenolates,
	R ===N⊕ R Iminium (=NR$_2^+$)	Organic acids e.g., citric acid, lactic acid, ascorbic acid, acetic acid
	≡≡≡N⊕——R Nitrilium (≡NR⁺) (R = alkyl group or H)	

163   Sources: Guggenheim and Martin 1995, USDA 2002a, Skoog et al. 2007, Kammerer et al. 2011,
164   Sigma-Aldrich 2019.

165
166   **Specific Uses of the Substance**:

167
168   *Water Purification*

169
170   Ion exchange filtration is commonly used in water purification applications. The process is most commonly
171   employed to remove undesirable tastes and smells (e.g., sulfur and sulfide [S^{2-}] compounds, phosphate
172   [PO_4^{3-}] and other phosphorus-containing compounds) and ions that give unfavorable characteristics such
173   as hard-water (calcium [Ca^{2+}] and magnesium ions [Mg^{2+}]), or it removes poisonous heavy metal ions (e.g.,
174   lead [Pb^{2+}], cadmium [Cd^{2+}], chromium [Cr^{6+}], nickel [Ni^{2+}], cobalt [Co^{2+}]) (Tzeng et al. 1988, Dzyazko and
175   Belyakov 2004, Yeon et al. 2004, Chen and Wu 2005, Atungulu et al. 2007, Xing et al. 2007, Kammerer et al.
176   2011, WHO 2011, Alvarado and Chen 2014).

177
178   *Food Processing*

179
180   Beverage processing applications include ion exchange filtration as a means of removing undesirable
181   substances that reduce shelf-life and promote "off-tastes" (Shaw and Buslig 1986, Andrés et al. 1997, Ma
182   and Lada 2003, Mishra and Kar 2003, Coca et al. 2008, Kola et al. 2010). Fruit juice processing includes the
183   removal of tartaric acid and tartrate to avoid precipitation of tartaric crystals post-processing. The
184   incorporation of ion exchange filtration, specifically anionic exchange, results in removal of tartrate and
185   tartaric acid, which is replaced by chloride ions (Cl^-) from the ion exchange material (Andrés et al. 1997).
186   Fruit juice production employs ion exchange processes to remove bitter compounds and improve the taste
187   of the final product (Shaw and Buslig 1986, Kammerer et al. 2011). Ion exchange filtration is commonly
188   used in the production of orange, grapefruit, and other fruit juices to remove bitter phenolic compounds
189   such as limonin (Mishra and Kar 2003, Kola et al. 2010). Ion exchange is used in beverage production to
190   remove undesired colors and to clarify the final product (Vivekanand and Iyer 2006, Kammerer et al. 2011).

191   These results have been reported across several beverage types, including wine, beer, and fruit juices
192   (Kammerer et al. 2011).
193
194   Ion exchange filtration is also used as a clarification and decoloring step in sugar and syrup production.
195   Sugars undergo oxidative reactions such as the Maillard reaction that result in browning or other
196   discolorations (Serpen et al. 2007, Coca et al. 2008, Kammerer et al. 2011). Anionic exchange resins have
197   been reported to remove discolorations and the inorganic impurities that catalyze these undesirable
198   oxidative processes (Serpen et al. 2007, Coca et al. 2008, Kammerer et al. 2011).
199
200   Ion exchange filtration has also been applied to the removal of naturally occurring compounds within
201   some beverage formulations. These include applications for decaffeination of coffee and tea beverages
202   through anionic exchange resins (Dawson-Ekeland and Stringfield 1991, Kammerer et al. 2011). In addition,
203   ion exchange polymers have also been formulated for the removal of sugar molecules to produce low-
204   calorie beverages that are later sweetened with zero-calorie compounds (Blase and Thomas 2008,
205   Kammerer et al. 2011).
206
207   As in water purification applications, ion exchange filtration can be used to remove heavy metal
208   contaminants from treated food products. Ion exchange filtration has been used to successfully remove
209   zinc, magnesium, copper, iron, and cadmium from scallop broth (Atungulu et al. 2007).
210
211   Ion exchange filtration has been investigated for its ability to isolate usable products from by-products of
212   other manufacturing applications. These studies have explored whey and other protein isolations,
213   purification and desalination of scallop broth, tartaric acid isolation, and pectin and phenolic compounds
214   (Andrés et al. 1997, Bazinet et al. 1999, Schieber et al. 2003, Doultani et al. 2004, Atungulu et al. 2007,
215   Kammerer et al. 2011, EFSA 2018). When used in the processing of whey protein from milk and cheese
216   manufacturing processes, ion exchange replaces calcium ions (Ca^{2+}) from dairy products with sodium ions
217   (Na^+) from the ion exchange material to yield products that exhibit improved gelation properties (Johns
218   and Ennis 1981, Schmidt et el. 1984).
219
220   **Approved Legal Uses of the Substance:**
221   The United States Food and Drug Administration (FDA) states that "ion-exchange resins are used in the
222   purification of foods, including potable water, to remove undesirable ions or replace less desirable ions
223   with one or more of the following: bicarbonate, calcium, carbonate, chloride, hydrogen, hydroxyl,
224   magnesium, potassium, sodium, and sulfate," at 21 CFR 173.25(b). The FDA has approved the use of ion-
225   exchange membranes for the "processing of food," at §173.20. The FDA has approved the use of
226   perfluorinated ion exchange membranes for "use in the treatment of bulk quantities of liquid food," at
227   §173.21.
228
229   The FDA has approved ion exchange filtration materials for a wide range of uses in the processing and
230   treatment of food products and water sources. These applications include the use of ion exchange filtration
231   "to minimize the concentration of naturally occurring trace minerals," in the production of sugar beet
232   extract at 21 CFR 172.585. The FDA has listed "anionic ion-exchange resins permitted by §173.25 … to
233   reduce the acidity of the food," at §146.148. The FDA has approved the use of ion exchange resin to purify
234   dimethyl sulfoxide used in the production of petroleum wax at 21 CFR 172.886, and "polyhydric alcohol
235   esters of oxidatively refined (Gersthofen process) montan wax acids," at §178.3770.
236
237   The FDA has approved the use of ion exchange purification for drug and medical applications, such as in
238   the "sorbent cartridge" and for "sorbent regenerated dialysate system for hemodialysis," at 21 CFR
239   876.5600. When used as a purification method for the production of drugs for animals, the FDA requires "a

240 complete description of the extraction and purification processes including the names and compositions of
241 all solvents, precipitants, ion exchange resins, emulsifiers, and all other agents used," when filing an
242 application for a new animal drug, as stipulated at §514.1.
243
244 The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) allows the use of ion exchange purification
245 for "various application in the treatment of juice or wine," with the stipulation that "anion, cation, and
246 non-ionic resins, except those anionic resins in the mineral acid state, may be used in batch or continuous
247 column processes as total or partial treatment of wine," at 27 CFR 24.248. The ATF also allows the use of
248 ion exchange purification in concert with nanofiltration to "reduce the level of volatile acidity in wine," at
249 §24.248. The ATF requires a formula to be filed for the application of ion exchange purification that results
250 in the "removal of any volume of water from beer, filtration of beer to substantially change the color,
251 flavor, or character," at §25.55. The ATF allows the use of "distilled spirits used in recharging an ion
252 exchange column," at 27 CFR 17.152.
253
254 The EPA has approved ion exchange purification for water pretreatment at 40 CFR 421.106. The EPA has
255 also approved ion exchange as an additional treatment option to minimize lead and copper levels in water
256 systems at §141.83.
257
258 **Action of the Substance:**
259 In the literature, ion exchange filtration and adsorption filtration processes are sometimes used interchangeably,
260 although they are different processes (Kammerer et al. 2011). Adsorption filtration removes an element, ion, or
261 compound by nature of it "sticking" to the surface of the filtration material. Ion exchange filtration requires the
262 replacement of bound ions (ions initially present in the filtration material) by others with the same charge and
263 requires electroneutrality (Bazinet et al. 1999, Kammerer et al. 2011). This means that ion exchange filtration is
264 based on the principle that if an ion is removed from the treated substance by the filtration material, it is replaced
265 by an ion of the same charge that began in the filtration material (e.g., removal of positive ion from treated
266 substance is replaced by a different positive ion from the filtration material). The ion exchange process is a result
267 of electrostatic attractions between the ion of interest (ion to be removed from the treated substance) and the
268 charged functional groups incorporated into the filtration material (Kammerer et al. 2011, Alvarado and Chen
269 2014). The electrostatic ion binding within the treated substance is affected by (1) the type and density of function
270 groups incorporated into the polymer, (2) the concentration of the ions to be removed from the treated substance,
271 and (3) the binding affinity of the various ions (Skoog et al. 2007, Kammerer et al 2011, Alvarado and Chen 2014).
272
273 The binding affinity of ions represents the strength of their electrostatic attraction to the functional groups of the
274 filtration material. This is affected by the charge density of the ion, where smaller and more highly charged ions
275 (larger positive or negative charges) exhibit an increased attractive force to the filtration material (Skoog et al.
276 2007). When the binding affinity of the ions in the treated substance is greater than the binding affinity of the ions
277 initially present within the ion exchange material, those ions are easily displaced, resulting in their exchange for
278 the ions initially present within the treated substance (Skoog et al. 2007, Alvarado and Chen 2014).
279
280 Acidic exchange and cation exchange are used interchangeably in the literature. This is because exchange
281 materials that incorporates acidic functional groups results in a negatively charged surface upon deprotonation
282 (loss of H^+ from acidic functionalities) (Skoog et al. 2007, Kammerer et al. 2011). The negatively charged
283 functionalities (sulfonate [$-SO_3^-$], carboxylate [$-COO^-$]) are then able to "accept" a cation (positively charged ion
284 [M^{n+}]) in place of the lost H^+, as depicted below in Figure 2 (Skoog et al. 2007, Kammerer et al. 2011).
285
286 Basic exchange and anionic exchange are used interchangeably in the literature. Removing basic hydroxide
287 anions from the filtration material by neutralization by acidic groups found in the treated substance (shown in
288 general in Equation 1) results in a positively charged surface that can "accept" an anion (negatively charged ion)

289   (Kammerer et al. 2011). The process shown below in Figure 2 shows that both the acidic and basic ion exchange
290   substrates operate via a similar electrostatically driven process. Anionic exchanges for larger, less polar organic
291   molecules (e.g., organic anions, organic acids) allow for improved efficiency once the exchange process has begun
292   due to the increased hydrophobicity (less polar nature) of the media resulting in a greater partitioning from
293   aqueous solutions (Kammerer et al. 2011).
294
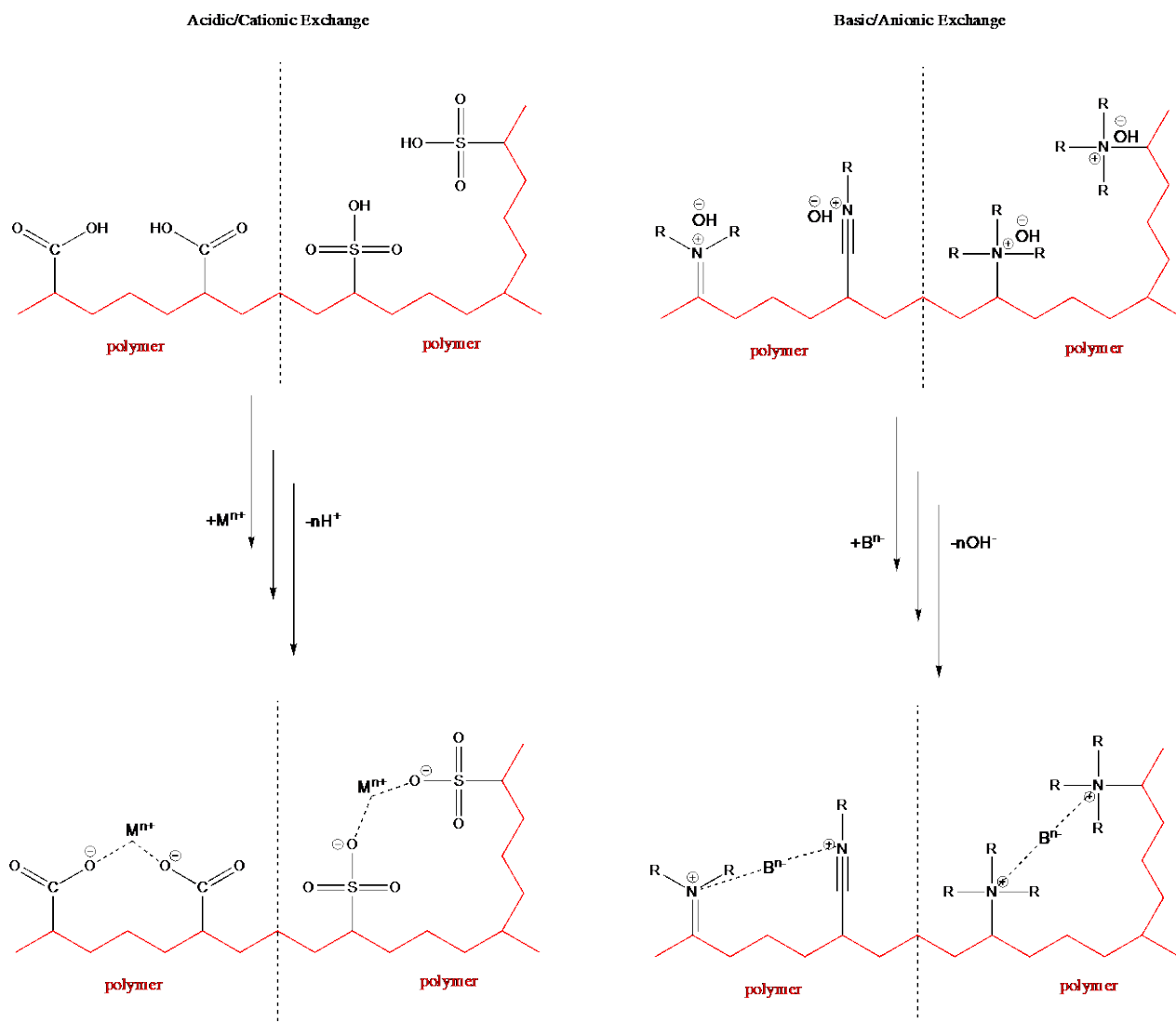
Figure 2.

299   A similar mechanism of action is followed when the substrate is naturally occurring clay or zeolites, although the
300   specifics of the substrate are different. In the natural cases, the presence of the alkali or alkaline earth metals
301   (elements in group 1 and group 2 of the periodic table, e.g., sodium, potassium, magnesium, calcium) in the
302   initial filtration material is important in the formation of the natural crystal structure (Atkins et al. 2008,
303   Kammerer et al. 2011). This is important since the packing of the initial crystal structure dictates the proximity of
304   functional groups (the acidic or basic components that facilitate the ion exchange process) in space and
305   determines the size of the channels through which the treated solution will pass (Kammerer et al. 2011).
306

307   *Regeneration of ion exchange filtration materials*
308
309   Ion exchange filtration requires the loss of ions initially present in the ion exchange material (transferred to
310   the treated substance) during the exchange process to maintain electroneutrality (Bazinet et al. 1999,
311   Kammerer et al. 2011). However, at some point the filtration material reaches its exchanged ion capacity
312   and is no longer able to "accept" any more ions from the substance being purified (Andrés et al. 1997,
313   Crittenden and Thomas 1998, Zagorodni 2007, Coca et al. 2008, Kammerer et al. 2011, Alvarado and Chen
314   2014, Chandrasekara and Pashley 2015). This point saturation for the ion exchange filtration is known as
315   breakthrough, since the ions/molecules to be removed from the treated substance begin to pass through
316   the ion exchange material (Xing et al. 2007, Kammerer et al. 2011, Chandrasekara and Pashley 2015).
317
318   Chemical regeneration
319
320   Once the breakthrough point has been reached the filtration media must be regenerated or recharged. This
321   process commonly occurs through the chemical treatment of the filtration media with a recharging
322   solution, which varies based on the type of ion exchange that is occurring (Kammerer et al. 2011). Common
323   commercial recharging solutions include water, hydrochloric acid (HCl), sulfuric acid (H_2SO_4), ammonium
324   bicarbonate (NH_4HCO_3), ammonium carbonate (($NH_4)_2CO_3$), sodium hydroxide (NaOH), potassium
325   hydroxide (KOH), calcium hydroxide ($Ca(OH)_2$), sodium chloride (NaCl), potassium chloride (KCl), and
326   ammonium chloride (NH_4Cl) (Crittenden and Thomas 1998, Dzyazko and Belyakov 2004, González et al.
327   2006, Xing et al. 2007, Zagorodni 2007, Coca et al. 2008, Kammerer et al. 2011, Chandrasekara and Pashley
328   2015).
329
330   Thermal regeneration
331
332   Thermal regeneration processes use changes in temperature to influence the binding affinity of ions once
333   breakthrough has been reached (Chandrasekara and Pashley 2015). As temperatures are increased the
334   electrostatic attractions between the ion exchange material functional groups and the ions collected from
335   the treated substance are weakened (Bolto et al. 1968, Chandrasekara and Pashley 2015). The changes in
336   binding affinity can be significant, with reports of an eight-fold reduction in ion-filtration material
337   interactions when temperatures are increased from 30 ℃ (slightly above room temperature) to 80 ℃
338   (Chanda et al. 2009). The reduced binding affinity of ions at higher temperatures allows for reduced
339   concentrations and amounts of chemical treatments required to complete the regeneration process, and
340   also the use of less reactive recharging solutions (e.g., sodium chloride vs. sodium hydroxide) (Chanda et
341   al. 2009, Chandrasekara and Pashley 2015).
342
343   The ability of thermal regeneration, and the relatively low reactivity profiles of the required recharging
344   solutions has brought reports of recyclable recharging chemicals. These include the use of ammonium
345   bicarbonate (NH_4HCO_3), which incorporates acidic (ammonium, [NH_4^+]) and basic (bicarbonate, [HCO_3^-])
346   ions that is able to recharge acidic and basic ion exchange materials (Ng et al. 2006, Chandrasekara and
347   Pashley 2015). The ammonium cation is able to displace the cations that have been collected from the
348   treated substance. The ammonium ion is also able to react with acidic ion exchange materials, where it acts
349   as an acid by donating H^+ to reform the neutral acidic functional groups, as shown in Equation 2 below.
350   The resulting product is ammonia (NH_3), which is a gas at room temperature, enabling its removal from
351   the ion exchange material during the regeneration process (Chandrasekara and Pashley 2015).
352
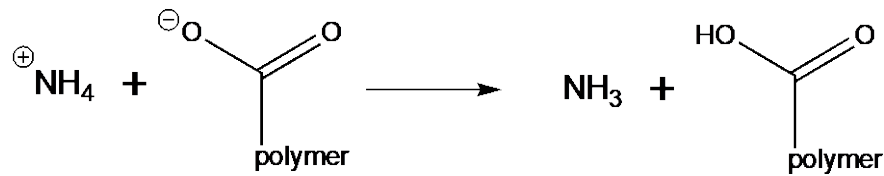
353
354
355   **Equation 2.**
356
357   The basic bicarbonate anion is able to displace the anions that have been collected from the treated
358   substance. Once the bicarbonate anion is electrostatically bound by the ion exchange material, it can
359   undergo a reaction to produce a hydroxide ion (OH⁻), regenerating the ion exchange material
360   (Chandrasekara and Pashley 2015). However, unlike the acidic ammonium, the bicarbonate ion reacts with
361   water from the solution rather than the functional groups on the ion exchange material, as shown below in
362   Equation 3. The hydroxide ion (OH⁻) produced remains with the positively charged functional groups
363   present within basic ion exchange materials, completing the regeneration process (Chandrasekara and
364   Pashley 2015).
365
366
367

$$HCO_3^- \;+\; H_2O \;\rightleftharpoons\; H_2CO_3 \;+\; {}^-OH$$

368
369
370   **Equation 3.**
371
372   The carbonic acid (H_2CO_3) that is produced from the interaction of bicarbonate and water is unstable at the
373   elevated temperatures and spontaneously decomposes to reform water and produce carbon dioxide, as
374   shown below in equation 4 (Silberberg 2003). Carbon dioxide (CO_2) is a gas at room temperature, which
375   enables its removal from the ion exchange material during the regeneration process (Chandrasekara and
376   Pashley 2015).
377

$$H_2CO_3 \;\longrightarrow\; CO_2 \;+\; H_2O$$

378
379
380   **Equation 4.**
381
382   The gases that result from the ammonium bicarbonate recharging solution (ammonia [NH_3, Equation 2], carbon
383   dioxide [CO_2, Equation 4]) can be captured and recombined to reform the active ammonium bicarbonate species,
384   as shown below in Equation 5 (Chandrasekara and Pashley 2015). The ability to capture the gaseous products of
385   the regeneration and reform the active ammonium bicarbonate compound enables a thermal regeneration
386   process with no net chemical use for regeneration.
387

$$NH_3 \;+\; CO_2 \;+\; H_2O \;\rightleftharpoons\; NH_4HCO_3$$
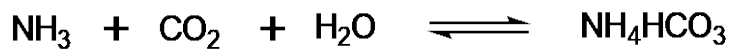
388
389
390   **Equation 5.**
391
392   Electrical regeneration
393
394   Electrically-based regeneration processes use the application of electrical energy to overcome ion binding
395   affinities, coupled with the electrolysis (break-down) of water to form the hydrogen (H⁺) and hydroxide (OH⁻)
396   ions required for the chemical regeneration of ion exchange materials (Dzyazko and Belyakov 2004, Yeon et al.

397 2004, Chen and Wu 2005, Xing et al. 2007, Alvarado and Chen 2014). When electric voltage is applied to the ion
398 exchange material, the ions within the material (those previously exchanged from the treated substance) begin to
399 migrate based on their charges in relation to the applied electric field (Alvarado and Chen 2014). Specifically,
400 positively charged ions move towards the cathode (negative charge from the applied voltage), while negatively
401 charged ions move towards the anode (positive charge from the applied field (Xing et al 2007, Alvarado and
402 Chen 2014). The migration due to the applied electric field results in the accumulation of ions near the anode and
403 cathode, and their removal from the ion exchange material.
404
405 The application of electric voltage also results in the electrolysis of water, which takes place as two distinct
406 reactions at the anode and cathode. At the cathode (applied negative charge), water is reduced (accepts electrons)
407 to form hydroxide ions that remain in the ion exchange material, and hydrogen, which is removed as a gas
408 (shown below in Equation 6) (Skoog et al. 2007, Alvarado and Chen 2014). Due to the negative charge on the
409 hydroxide ion it migrates towards the anode (applied positive charge). Over the course of the migration the
410 hydroxide ions displace the initially bound exchange anions to regenerate the basic ion exchange material (Xing
411 et al. 2007, Alvarado and Chen 2014).
412

413 $$2\,H_2O \;+\; 2\,e^{\ominus} \longrightarrow H_2 \;+\; 2\,{}^{\ominus}OH$$
414
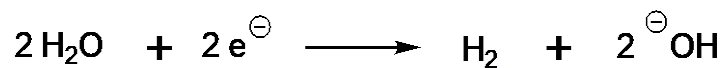
415   **Equation 6.**
416

417 In the electrolysis also includes the oxidation (loss of electrons) of water at the anode (applied positive charge), to
418 form the hydrogen ions that react with the ion exchange material, form oxygen, which is removed as a gas
419 (shown below in Equation 7) (Skoog et al. 2007, Alvarado and Chen 2014). Due to the positive charge on the
420 hydrogen ion, it migrates towards the cathode (applied negative charge). Over the course of the migration, the
421 hydrogen ions react with the negatively charged functional groups present within acidic ion exchange materials,
422 reforming a neutral material (similar to the reaction shown in Equation 2). The neutral ion exchange material
423 results in the loss of the electrostatic attractions that bound the cations (exchanged from the treated substance),
424 and dramatically enhances the migration of the cations towards the cathode (Alvarado and Chen 2014).
425

426 $$2\,H_2O \longrightarrow O_2 \;+\; 4\,H^{\oplus} \;+\; 4\,e^{\ominus}$$
427
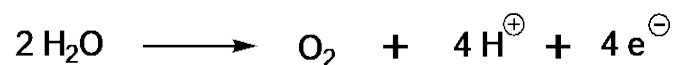
428   **Equation 7.**
429

430 *Common commercial ion exchange processes*
431

432 Regardless of the specific type of ion exchange material, most applications use either the bed or batch process to
433 carry out the filtration (Kammerer et al. 2011). Of the two, the bed process is the more commonly used in
434 commercial applications due to the simpler technology required (Zagorodni 2007, Kammerer et al. 2011). In the
435 bed process, the ion exchange material is loaded with sample until it (i.e., ion exchange beads, membrane, or
436 resin) reaches its maximum capacity, or breakthrough. Once the material reaches breakthrough, the filtration
437 system must be regenerated to restore its initial composition (i.e., replace H^+ in acidic exchange and OH^- or
438 anionic counter ion basic exchange for the ions removed from the treated substance) (Zagorodni 2007, Kammerer
439 et al. 2011). The bed process may also include the incorporation of an adsorbent substance to increase the
440 working time of the ion exchange media between regenerations (Zagorodni 2007, Kammerer et al. 2011). The
441 most common commercially incorporated adsorbent compounds are activated charcoal (or carbon), zeolites, and
442 silica gel. These substances also have ion exchange capabilities, which may work to remove similar compounds
443 as the polymeric exchange material or target a broader range of ionic compounds (Kammerer et al. 2011).

444
445   Another common means for ion exchange purification is the batch process. The batch process uses several
446   concurrent purification steps that are based on equilibrium exchange processes (Crittenden and Thomas 1998,
447   Zagorodni 2007, Kammerer et al. 2011). In a batch process, different ion exchange or other purification materials
448   are used to selectively remove specific ions/molecules. This enables a longer working time for each step within
449   the overall batch process, as each step removes a smaller concentration of a specific substance rather than many
450   substances being removed in the same step (such as what occurs in the bed process described above). The
451   increased number of steps results in a more complicated process but also one that is more efficient because the
452   various exchange materials can be removed and regenerated or replaced while the overall purification process
453   simultaneously continues in the other steps (Crittenden and Thomas 1998, Zagorodni 2007, Kammerer et al.
454   2011). The efficiency of batch processing has resulted in its common usage in beverage and water purification
455   applications (Kammerer et al. 2011).
456
457   **Combinations of the Substance:**
458   Due to the requirement of a regeneration process (discussed above in the Action of the Substance section)
459   over the course of ion exchange filtrations, the most common chemical combinations with the ion exchange
460   materials are the chemicals that are used during the regeneration event. Common commercial recharging
461   solutions include water, hydrochloric acid (HCl), sulfuric acid (H_2SO_4), ammonium bicarbonate
462   (NH_4HCO_3), ammonium carbonate (($NH_4)_2CO_3$), sodium hydroxide (NaOH), potassium hydroxide (KOH),
463   calcium hydroxide ($Ca(OH)_2$), sodium chloride (NaCl), potassium chloride (KCl), and ammonium chloride
464   (NH_4Cl) (Crittenden and Thomas 1998, Dzyazko and Belyakov 2004, González et al. 2006, Xing et al. 2007,
465   Zagorodni 2007, Coca et al. 2008, Kammerer et al. 2011, Chandrasekara and Pashley 2015). Of the
466   substances used in recharging solutions, hydrochloric acid, sulfuric acid, and ammonium chloride are not
467   permitted for use in organic food production. Sodium chloride is allowed in organic production, and
468   potassium chloride, sodium hydroxide, potassium hydroxide, and calcium hydroxide are all approved for
469   use in organic food processing at 7 CFR 205.605. Ammonium carbonate and ammonium bicarbonate are
470   also permitted for use in organic processing, although only as leavening ingredients, as stated at 7 CFR
471   205.605(b).
472
473   As described above in Action of the Substance, adsorbents are added in some applications to extend the life
474   of the exchange media between recharging (Zagorodni 2007, Kammerer et al. 2011). Activated carbon is
475   among the most common adsorbent substance and has been approved as a filtering aid for use in organic
476   processing as activated charcoal at 7 CFR 205.605(b). The USDA has also approved the use of diatomaceous
477   earth, cellulose, and perlite as filtering aids at 7 CFR 205.605.
478

479 | **Status** |
       | --- |

480
481   **Historic Use:**
482   Ion exchange purification processed have been historically used for many purposes, with reports of
483   charcoal (early activated carbon) being used by ancient Sumerians and Egyptians for purification of ores
484   used in metal-working and bronze production (Kammerer et al. 2011). There are also early reports of ion
485   exchange in water purification with Old Testament accounts of producing potable water from treatment
486   with wood containing rotted cellulose, and Aristotle's description of purifying water by treatment with
487   sand (natural zeolites) (Kammerer et al. 2011).
488
489   More modern accounts of ion exchange began in the 1850s. Thompson (1850) and Way (1850) reported ion
490   exchange in soils, and documented changes in organic and inorganic mineral content via natural ion
491   exchange media (clay, zeolites). The field of ion exchange purification began to quickly develop in the
492   1900s. Synthetic exchange media were developed upon further study of natural sources, and by the 1930s,

493   they were used prominently in water softening, deionization, and purification applications (Skoog et al.
494   2007).
495
496   Within the realm of organic food production, ion exchange filtration processes have had a somewhat
497   complicated and changing status. Ion exchange filtration materials are not discussed in the Organic Foods
498   Production Act of 1990. Furthermore, ion exchange materials are not currently present in the USDA NOP
499   regulations, found at 7 CFR 205, although activated charcoal, which has been reported as an ion exchange
500   material derived from natural sources does appear on the National List as a filtering aid as 7 CFR
501   205.605(b) (Kammerer et al. 2011).
502
503   In 2010, the USDA Agricultural Marketing Service (AMS) stated that "ion exchange technology is allowed,
504   as long as materials used are on the National List. For example: listed items sodium hydroxide, sodium
505   chloride, not listed: hydrochloric acid," referring to recharging solutions (USDA 2019a). On May 11, 2019
506   the NOP sent a memo to certifying agents stating the following:
507
508   [I]on-exchange filtration is allowed in organic processing. However, nonagricultural
509   substances used in the ion-exchange process must be on the National List of Allowed and
510   Prohibited Substances (National List). This includes, but is not limited to, resins,
511   membranes, and recharging materials,
512
513   This memo was considered effective as of May 1, 2020 (USDA 2019a). However, this memo sends a
514   contradictory message, since, as stated above, there are no ion exchange materials currently present on the
515   National List.
516
517   On August 27, 2019, the NOP sent a memo to the National Organic Standards Board (NOSB) in response to
518   questions by organic producers to clarify the regulations and notice of the previous May 11 memo. In the
519   August 27 memo, the NOP requested that the NOSB provide a recommendation on the use of ion exchange
520   filtration, clarify previous inconsistencies, and delay enforcement of the previous May 11 memo until NOP
521   was able to review the NOSB recommendation (USDA 2019a).
522
523   **Organic Foods Production Act, USDA Final Rule:**
524   Ion exchange filtration is not listed in the Organic Foods Production Act of 1990 (OFPA).
525
526   Ion exchange filtration is not specifically addressed in the United States Code of Federal Regulations under
527   the USDA organic regulations (7 CFR Part 205). The USDA organic regulations include several synthetic
528   substances that may be used as recharging solutions in ion exchange filtration, although they are not
529   specifically noted for that use at § 205.605(b). The USDA organic regulations do not include any synthetic
530   resins or membranes used for ion exchange filtration at § 205.605(b), although cellulose and activated
531   charcoal (activated carbon) are included as filtering aids at section 205.605(b). Several non-synthetic
532   substances that may be used in ion exchange filtration can be found in the USDA organic regulations at §
533   205.605, although they are not specifically noted for that use, such as bentonite, diatomaceous earth, and
534   perlite.
535
536   The USDA NOP has stated that ion exchange filtration is allowed for use in organic production to "clarify,
537   decolor, or otherwise filter liquids using a chemical exchange process" (USDA 2019a).
538

539   **International:**
540
541   **Canadian General Standards Board Permitted Substances List –**
542   Ion exchange filtration is not listed in the Canadian General Standards Board Permitted Substances List
543   (CAN/CGSB-32.311-2015).
544
545   **CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing**
546   **of Organically Produced Foods (GL 32-1999) –**
547   Ion exchange filtration is not listed in the CODEX (GL 32-1999).
548
549   **European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 –**
550   Ion exchange filtration is not listed in EC No. 834-151 2007 or EC No. 889/2008.
551
552   **Japan Agricultural Standard (JAS) for Organic Production –**
553   Ion exchange filtration is not listed in the JAS for Organic Production.
554
555   **International Federation of Organic Agriculture Movements (IFOAM) –**
556   Ion exchange filtration is not listed in IFOAM.
557

558 | **Evaluation Questions for Substances to be used in Organic Handling** |
       | --- |

559
560   **Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the**
561   **petitioned substance. Further, describe any chemical change that may occur during manufacture or**
562   **formulation of the petitioned substance when this substance is extracted from naturally occurring plant,**
563   **animal, or mineral sources (7 U.S.C. § 6502 (21)).**
564
565   The most prominent ion exchange materials are synthetic polymers that incorporate specific functional
566   groups based on their specific filtration application (discussed above in the Action of the Substance section)
567   (González et al. 2006, Atungulu et al. 2007, Kammerer et al. 2011). The most common commercial polymer
568   substrates are synthesized by the combination of styrene, which provides the bulk of the polymer
569   backbone, and divinyl benzene, which is used to promote cross-linking (connections between polymer
570   strands that provide 3D stricture), as shown in Equation 8 (Davankov and Tsyurupa 1990, Kammerer et al.
571   2011). The polymer structure is synthesized through a radical mechanism (movement of single, unpaired
572   electrons) (Kammerer et al. 2011, Wade 2017). The highly reactive nature of radicals (molecules with an
573   odd number of electrons) is stabilized due to the ability for the unpaired electron to inhabit many locations
574   throughout the molecular structure (radical delocalization) of the aromatic substrates and their
575   intermediates (Silberberg 2003, Skoog et al. 2007, Wade 2017). Benzolyl peroxide, shown as a catalyst in
576   Equation 8, is a common radical initiator (source of unpaired electrons), although other initiators can be
577   used in the polymer synthesis (Kammerer et al. 2011).
578

benzolyl peroxide

(radical initiator)

styrene   divinyl benzene

polymer structure

579
580 **Equation 8.**
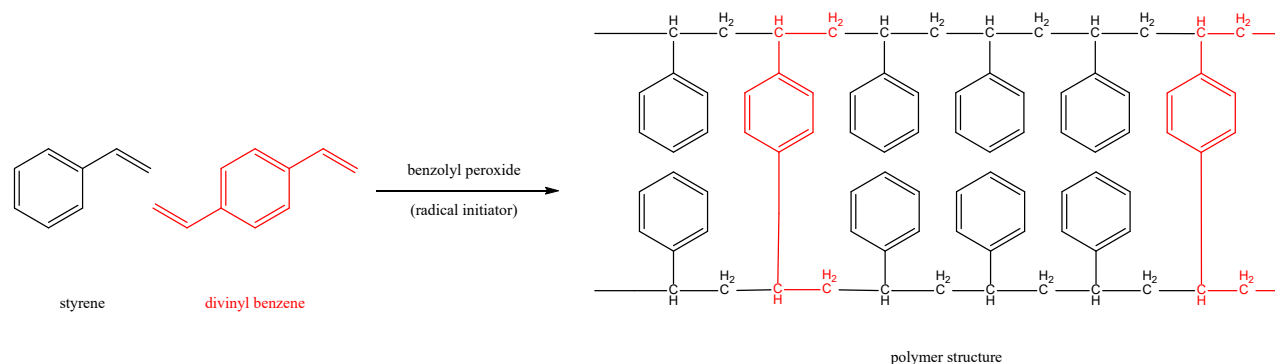
581
582 Once the backbone has been isolated (product in Equation 8), the functional groups can be introduced via
583 traditional organic chemistry aromatic substitution reactions. Acidic functional groups, such as the
584 sulfonate ($-SO_3^-$) can be accessed through electrophilic aromatic substitutions catalyzed by strong acids
585 (e.g., H_2SO_4), as shown below in Equation 9 (Kammerer et al. 2011, Wade 2017).

586
587 **Equation 9.**
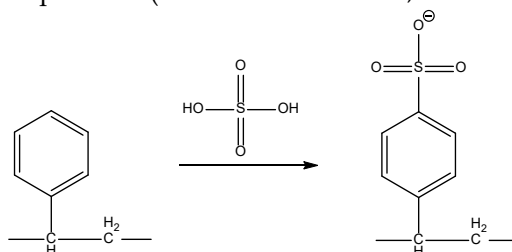
588
589 Basic functionality is installed on the polymer backbone through a two-step process. The first step is the
590 installation of an alkyl halide group (a functional group that contains a carbon-halogen bond) onto the
591 aromatic structure through a Friedel-Crafts alkylation reaction in the presence of a strong Lewis acid
592 catalyst (an ion/molecule that is able to accept electrons from another molecule, e.g., $AlCl_3$), as shown
593 below in Equation 10 (Silberberg 2003, Skoog et al. 2007, Kammerer et al. 2011, Wade 2017). The
594 ammonium (group that includes a positively charged nitrogen) or other basic functionality is then installed
595 in a second step on the middle polymer containing carbon-halogen bonds as a classic substitution reaction
596 (a reaction in which one atom or functional group is replaced by another) (Skoog et al. 2007, Wade 2017).
597 During the substitution reaction, the nitrogen species (NR_3 in the second step of Equation 10) acts as a
598 nucleophile (an ion/molecule with an excess of electron density) and displaces the halogen (e.g., chlorine)
599 as shown in Equation 10 below (Kammerer et al. 2011, Wade 2017).
600

CH_3OCH_2Cl

$AlCl_3$

NR_3
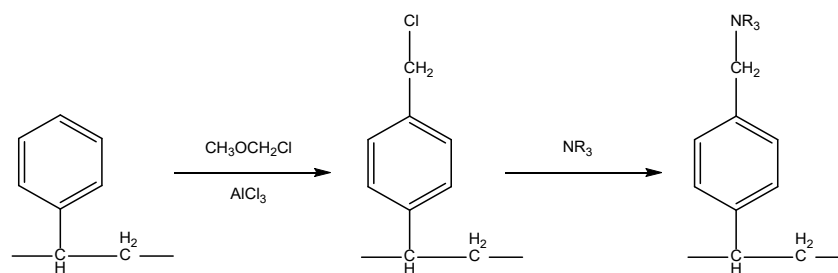
601
602 **Equation 10.**
603

604 **Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a**
605 **chemical process or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss**
606 **whether the petitioned substance is derived from an agricultural source.**
607
608 Ion exchange filtration uses an insoluble media on which the ion exchange process takes place. This
609 support can be a natural substance in the form of clay or zeolites derived from naturally existing minerals
610 (Skoog et al. 2007, Kammerer et al. 2011, Marakatti et al. 2014). Activated carbon can also be used, which is
611 derived from natural plant and animal sources such as bones, coal, peat, wood, and lignite (USDA 2002a,
612 Kammerer et al. 2011). However, most commercial ion exchange purification processes use a synthetic
613 polymer that bears additional functionality based on the application (Andrés et al. 1997, González et al.
614 2006, Atungulu et al. 2007, Kammerer et al. 2011). The polymer is synthetically produced (discussed in
615 further detail above in Evaluation Question #1 and in Source or Origin of the Substance) in the form of
616 beads, resins, or membranes and is neither naturally occurring, nor derived from agricultural sources.
617
618 **Evaluation Question #3: If the substance is a synthetic substance, provide a list of non-synthetic or**
619 **natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).**
620
621 As stated above in Evaluation Question #2, most commercial ion exchanges processes feature a solid
622 support in the form of a synthetic polymer (Tzeng et al. 1988, Andrés et al. 1997, González et al. 2006,
623 Atungulu et al. 2007, Skoog et al. 2007, Kammerer et al. 2011). There are no natural sources for these
624 polymers, as they are synthetically derived, largely from styrene and divinyl benzene monomers (shown in
625 Figure 1 and as the reactants in Equation 8) (Davankov and Tsyurupa 1990, Kammerer et al. 2011). Both
626 styrene and divinyl benzene are derived by the dehydrogenation (loss of hydrogen gas (H_2) that produces
627 a carbon-carbon double bond) of ethyl and diethylbenzene, which are isolated from coal tar and petroleum
628 sources (ATSDR 2007, Jia et al. 2019).
629
630 However, original reports of ion exchange used exchange materials that are natural or derived from
631 natural sources in the form of clay, zeolites, and activated carbon/charcoal (Skoog et al. 2007, Kammerer et
632 al. 2011, Marakatti et al. 2014). Of these three alternatives to polymeric ion exchange substrates, both clay
633 and zeolites are both nonsynthetic and naturally occurring, with their sources being described in greater
634 detail in the Source or Origin of the Substance section above (USGS 1999, Skoog et al. 2007, Kammerer et al.
635 2011, Marakatti et al. 2014).
636
637 **Evaluation Question #4: Specify whether the petitioned substance is categorized as generally**
638 **recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR §205.600**
639 **(b)(5)). If not categorized as GRAS, describe the regulatory status.**
640
641 The FDA has not granted GRAS status to any ion exchange material. The FDA has classified several ion
642 exchange specific resins as a food contact surfaces (FDA 2000a, FDA 2000b, FDA 2000c, FDA 2000d, FDA
643 2001a, FDA 2001b, FDA 2003a, FDA 2003b, FDA 2004, FDA 2005a, FDA 2005b). The FDA has stated "ion-
644 exchange resins are used in the purification of foods, including potable water, to remove undesirable ions
645 or replace less desirable ions with one or more of the following: bicarbonate, calcium, carbonate, chloride,
646 hydrogen, hydroxyl, magnesium, potassium, sodium, and sulfate," at 21 CFR 173.25(b). The FDA has also
647 approved the use of ion-exchange membranes for the "processing of food," at §173.20, which has also been
648 extended to the use of perfluorinated ion exchange membranes for "use in the treatment of bulk quantities
649 of liquid food," at §173.21.
650
651 **Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned**
652 **substance is a preservative. If so, provide a detailed description of its mechanism as a preservative**
653 **(7 CFR § 205.600 (b)(4)).**

654
655   The primary function of ion exchange filtration is to remove undesirable elements, ion, or compounds,
656   desalinate, and purify food products and water sources used in food processing, not to act as a
657   preservative. However, there have been reports that incorporation of ion exchange during processing
658   results in a longer shelf-life, thereby the removal of some compounds provides some preservative action.
659
660   These reports include vanillin, rosmarinic acid, and fruit juices (Ma and Lada 2003, Georgiev et al. 2006,
661   Hua et al. 2007). The longer shelf-life of products that undergo ion exchange processes is attributed to the
662   removal of compounds that produce off-flavors and/or colors, or their precursor compounds (Ma and
663   Lada 2003). Once these compounds are removed the stability of the product is enhanced, this is especially
664   important in commercial fruit juices, which are commonly stored and sold at room temperature (Andrés et
665   al. 1997, Ma and Lada 2003).
666
667   **Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or**
668   **improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)**
669   **and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600**
670   **(b)(4)).**
671
672   In some cases, ion exchange filtration is used to improve colors of products. This is common in the
673   treatment of beverages and sugars and syrups, where ion exchange filtration is commonly used for
674   clarifying and decolorizing the liquid product (Tzeng et al. 1988, Andrés et al 1997, Ma and Lada 2003,
675   Coca et al. 2008, Kammerer et al. 2011). Clarifying (removing haziness) and decoloring are accomplished in
676   the same manner as ion exchange filtration removes compounds that are associated with haziness or color.
677   The process may also remove selected ions that have relatively low solubility as a means of removing
678   precipitates (solids) that form over time (Andrés et al. 1997, Ma and Lada 2003, Kammerer et al. 2011).
679   These applications are used to improve colors/clarity by removing compounds naturally present the
680   treated substances. Ion exchange filtration is not used to affect changes in treated food products that are
681   brought about by other processing.
682
683   **Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or**
684   **feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).**
685
686   As described above in the Specific Uses of the Substance section, ion exchange filtration is used to remove
687   heavy metal contaminants from water sources and food products. There are reports of a range of heavy
688   metals removed from treated substances including iron, copper, cobalt, chromium, calcium magnesium,
689   lead, cadmium, nickel, and zinc (Dzyazko and Belyakov 2004, Yeon et al. 2004, Chen and Wu 2005,
690   Atungulu et al. 2007, Xing et al. 2007, Kammerer et al. 2011, WHO 2011, Alvarado and Chen 2014). Several
691   of these metals are highly toxic (e.g., cadmium, lead), and their removal from food products will improve
692   nutritional quality. However, other metals are important trace minerals that are essential for proper protein
693   function (e.g., iron, magnesium, zinc) (Timberlake 2016). The full removal of essential minerals would
694   result in the decreased nutritional of treated substances.
695
696   While mineral content may be affected by ion exchange filtration, most studies have shown that ion
697   exchange filtration selectively removes undesired compounds, while having no significant effect on the
698   levels of proteins and amino acids (Atungulu et al. 2007, Serpen et al. 2007, Coca et al. 2008). Therefore,
699   significant changes to larger molecules (e.g., amino acids, protein, carbohydrates) are unlikely to be
700   affected by ion exchange treatments.
701
702   Some ion exchange processes have been selectively developed to alter nutritional values of food products
703   by removing sugars to create low-calorie or diet products from sources that contain high sugar content

704 (e.g., fruit juices) (Blase and Thomas 2008, Kammerer et al. 2011). Similarly, ion exchange filtration has been
705 used to isolate proteins from by-products of other food processes, which has been used in the production
706 of whey, pectin, and tofu (Schmidt et el. 1984, Bazinet et al. 1999, Schieber et al. 2003, Doultani et al. 2004,
707 Kammerer et al. 2011, EFSA 2018).
708
709 **Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of**
710 **FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600**
711 **(b)(5)).**
712
713 At the time of publication of this report, the author found no published reports of ion exchange filtration
714 contributing to heavy metals or other contaminants. Ion exchange filtration is often used as a purification
715 method to remove heavy metals and contaminants from food and water sources (Andrés et al. 1997, Skoog
716 et al. 2007, Kammerer et al. 2011, Marakatti et al. 2014).
717
718 **Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the**
719 **petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i)**
720 **and 7 U.S.C. § 6517 (c) (2) (A) (i)).**
721
722 The FDA Environmental Review Team (ERT) has issued a finding of no significant impact in relation to
723 any environmental impact of polymeric ion exchange materials on the environment (FDA 2000e, FDA
724 2000f, FDA 2000g, FDA 2000h). Additionally, ion exchange filtration is often employed as a means of water
725 purification to help remove environmental pollutants in water systems (Tzeng et al. 1988, Dzyazko and
726 Belyakov 2004, Yeon et al. 2004, Chen and Wu 2005, Atungulu et al. 2007, Xing et al. 2007, Kammerer et al.
727 2011, WHO 2011, Alvarado and Chen 2014).
728
729 The most likely cause for harm to the environment and/or biodiversity is by improper handling of
730 recharging solutions. As discussed above in the regeneration of ion exchange filtration materials subsection
731 of the Action of the Substance section, there are several methods that are used for the regeneration of ion
732 exchange materials. The specific type of regeneration process is dependent on the specific ion exchange
733 material, its functional groups, and the substance that is being treated (Dzyazko and Belyakov 2004). The
734 composition of the filtration material, and the ions that need to be removed in the regeneration event, make
735 some materials incompatible with the relatively unreactive recharging solutions frequently used in
736 thermally and electrically driven regeneration processes (Dzyazko and Belyakov 2004, Alvarado and Chen
737 2014, Chandrasekara and Pashley 2015).
738
739 When the ion exchange material is regenerated through only chemical regeneration processes relatively
740 high concentrations (~1 M (molar)) of strong acids (hydrochloric and sulfuric acids) and strong bases
741 (sodium and potassium hydroxide) are commonly used (González et al. 2006, Xing et al. 2007, Alvarado et
742 al. 2014, Chandrasekara and Pashley 2015). The recharging solutions are often highly acidic or basic
743 (depending on the type of ion exchange media being recharged) and may also contain contaminants or
744 heavy metals that were collected by the ion exchange material (Andrés et al. 1997, González et al. 2006).
745 These concentrated and reactive solutions may not be properly handled, and there are reports that the
746 recharging solutions are often not properly neutralized (treated with either acid or base to bring them to a
747 neutral pH) (González et al. 2006).
748
749 Regardless of the regeneration process, each one will result in solutions containing the ions that were
750 removed from the ion exchange material during the regeneration process. Given the wide range of
751 applications and substances treated through ion exchange filtration it is impossible to discuss the resulting
752 solutions in general terms. However, the resulting regeneration solutions may contain heavy metals,

753   organic acids, and concentrated salt solutions. Proper treatment of these potentially reactive and
754   environmentally harmful mixtures is essential for protection of the environment and biodiversity.
755
756   Many synthetic polymers are derived from petroleum deposits and their by-products (Lligadas et al. 2013,
757   Zhu et al. 2016). Common ion exchange resins fall into this petroleum category (described above in
758   Evaluation Question #3), with components primarily derived from alkyl benzenes found in coal tar and
759   petroleum (ATSDR 2007, Lligadas et al. 2013, Zhu et al. 2016, Jia et al. 2019). Given the sources of these
760   substances, the production of some ion exchange resins is connected to the environmental impacts and
761   risks associated with the isolation of petroleum feedstocks as well as the synthetic isolation and production
762   of these chemical commodities. However, there are many types and sources of polymers and ion exchange
763   resins, not all of which are isolated from petroleum. There are many alternative polymers that are
764   produced from renewable biomass, such as terpenes (from trees), vegetable oils, and starches and
765   carbohydrates (from corn, etc.) (Lligadas et al. 2013, Zhu et al. 2016). The use of these renewably sourced
766   polymers within ion exchange filtration processes has not been well reported at the time of this publication.
767
768   **Evaluation Question #10: Describe and summarize any reported effects upon human health from use of**
769   **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**
770   **(m) (4)).**
771
772   There have been few reports on the effect of ion exchange filtration on human health. Most of the reports
773   investigate the effects of ion exchange in water purification applications (WHO 2011). These reports look at
774   the water softening process, in which calcium (Ca^{2+}) and magnesium ions (Mg^{2+}) that are responsible for
775   hard water scale and soap scum are replaced with sodium ions (Na^+) (WHO 2011). The focus of these
776   reports are the contributions of hard water to dietary intake of essential calcium and magnesium, of which
777   the WHO has stated that hard water may contribute to daily essential mineral intake, especially for people
778   that have limited intake through their diet (WHO 2011). In connection to the calcium and magnesium
779   content of hard water, there have been some reports that hard water is linked with improved
780   cardiovascular health (Pocock et al. 1981, Rubenowitz et al. 1999). However, the WHO has stated that more
781   research needs to be conducted to establish whether the findings are indeed correlated to the mineral
782   content of hard water sources (WHO 2011).
783
784   Studies have shown that ion exchange resins degrade over time with some regeneration methods that
785   employ a combination of chemical and thermal methods being the most problematic (Zagorodni et al. 2002,
786   Arm et al. 2005, Chambree et al. 2005, Singare at el. 2011). The deterioration of resin material results in the
787   loss of resin activity in terms of efficiency or capacity (Arm et al. 2005, Chambree et al. 2005, Singare at el.
788   2011). In one method of degradation, the polymeric structure remains intact although the number of ion
789   exchange sites is reduced. This reduction is due to strong adsorption of compounds from purified food
790   products or additional crosslinking (bonding) between existing functional groups on the polymer or with
791   adsorbed materials (Zagorodni et al. 2002). Additionally, the ion exchange material may lose functional
792   groups that were initially present (Zagorodni et al. 2002, Arm et al. 2005, Chambree et al. 2005, Singare at
793   el. 2011). The loss of functional groups is thought to occur primarily during the regeneration process
794   (Zagorodni et al. 2002, Arm et al. 2005, Chambree et al. 2005, Singare at el. 2011). These studies on the
795   degradation of ion exchange resins do not comment on potential health effects from the resin material
796   leaching into treated food products. At the time of this report, no published studies on human health
797   effects of ion exchange degradation were found.
798
799   **Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned**
800   **substance unnecessary (7 U.S.C. § 6518 (m) (6)).**
801

802   There are several practices that may be used in place of ion exchange filtration to achieve specific aspects
803   required in food processing. In terms of clarifying and decoloring food products, alternatives include
804   chemical treatments (precipitation), centrifugation, and temperature treatments (USDA 2016a).
805   Centrifugation would result in the separation of suspended solid particles, accumulating them through
806   density differences and enable purification through mechanical filtration (Garrett and Grisham 2013).
807
808   Chemical treatments have been historically used to remove specific components of food products due to
809   their reactivity. These include the neutralization of acids and bases and the precipitation (forming of a
810   solid) by adding another soluble ionic compound (Andrés et al. 1997, Timberlake 2016, USDA 2016a). In
811   the case of acid neutralization, sodium hydroxide, potassium hydroxide, calcium hydroxide, calcium
812   carbonate, sodium carbonate, sodium bicarbonate, and potassium carbonate are basic substances that
813   appear on the National List at 7 CFR 205.605 (USDA 1995a, USDA 1995b, ODHS 1998, NHMRC 2011,
814   USDA 2016b, USDA 2018). For base neutralization ascorbic, citric, lactic, and tartaric acids are traditional
815   pH regulators in food products and appear on the National List at 7 CFR 205.605 (USDA 2011, USDA
816   2015a, USDA 2015b, USDA 2019b). The neutralization of acidic and basic compounds in the treated
817   substance may result in significant changes to the solubility of the neutralized compound, enabling it to be
818   removed via traditional filtration techniques (Timberlake 2016, Wade 2017).
819
820   However, chemical changes may also result in unintended reactions within the complex mixtures present
821   in most food products, which may result in unintended changes to flavors and colors. Specifically,
822   carbonate anions (CO_3^{2-}) and tartaric acid have relatively low solubility, and chemical treatments with them
823   may result in enhanced haziness of the treated substance (carbonates and organic acids are a target ion for
824   removal by ion exchange filtration).
825
826   Another alternative to ion exchange filtration is to use temperature fluctuations to take advantage of
827   changes in the solubility profiles of compounds. As temperatures are decreased, compounds exhibit
828   reduced solubility, which may allow for the removal of selected compounds (e.g., organic acids) through
829   mechanical filtration (Silberberg 2003, Timberlake 2016).
830
831   Given the wide range of applications and substances treated through ion exchange filtration it is
832   impossible to discuss the resulting solutions in general terms. In some cases, the alternative treatments
833   discussed above may promote the neutralization, precipitation, and/or removal of compounds within the
834   treated substance. However, in other cases these chemical agents or temperature changes may be
835   incompatible with the treated substance or may result in undesired reactions that impact the taste, color,
836   texture, or nutritional qualities of the substance.
837
838   **Evaluation Question #12: Describe all natural (non-synthetic) substances or products which may be**
839   **used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed**
840   **substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).**
841
842   While commercial ion exchange filtration is most affected using synthetic polymers bearing specific
843   functional groups, there are also natural materials that can be used to facilitate ion exchange. Clay and
844   zeolites can be found in natural sources with mineral content that facilitates ion exchange (USDA 2002a,
845   Skoog et al. 2007, Kammerer et al. 2011, Marakatti et al. 2014). The relative effectiveness of these natural
846   sources of ion exchange materials compared to their synthetically derived polymeric counterparts is
847   dependent on the specific application, amount, and substance that is being treated. There are no modern
848   reports that compare these materials with the synthetic ion exchange materials. However, given nearly all
849   commercial ion exchange processes use synthetic materials, it can be assumed that the polymeric materials
850   are more effective, more efficient, or more cost-effective (Bazinet et al. 1999, Ma and Lada 2003, González et

851 al. 2006, Atungulu et al. 2007, Serpen et al. 2007, Skoog et al. 2007, Coca et al. 2008, Dardel and Arden 2008,
852 Kammerer et al. 2011).
853
854 The USDA has approved the use of several synthetic filtering aids. Activated charcoal can by sourced from
855 natural materials and offers an additional substrate capable of ion exchange filtration and has been
856 approved for organic use at 7 CFR 205.605(b) (USDA 2002a). The USDA has approved cellulose as a
857 synthetic filtering aid at 7 CFR 205.605(b). Cellulose enables purification by filtration but works through
858 absorption of elements, ions, and molecules, rather than via ion exchange (USDA 2016a). The ability of
859 cellulose to absorb liquids makes it an efficient filtering aid (USDA 2016a). Cellulose is a component of
860 many plants, and therefore, it has many sources. However, the plant material must undergo significant
861 processing to remove lignin and other plant materials and to ensure the purity of the final product (USDA
862 2016a).
863
864 The USDA has approved the use of non-synthetic filtering aids. Diatomaceous earth as a filtering aid at 7
865 CFR 205.605(a). Diatomaceous earth is powdered or crumbled sedimentary rock that is known for its high
866 porosity (USDA 1995c). The porous nature of the substance allows for its utility in filtration processes. The
867 USDA has approved perlite as a filtering aid at 7 CFR 205.605(a). Perlite is a dense volcanic rock containing
868 aluminosilicates, which can be crushed into a powder for use as a filtering aid, and alternative to
869 diatomaceous earth (USDA 1996).
870
871 Once again, the wide range of applications and substances treated through ion exchange filtration make it
872 impossible to discuss non-synthetic alternatives in general terms. In some cases, the non-synthetic
873 alternative treatments discussed above may an effective alternative to synthetic ion exchange filtration
874 processes. However, in other cases these filtration techniques and materials, may be unable to remove
875 specific compounds, or may remove undesired compounds from the treated substance.
876
877 **Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for**
878 **the petitioned substance (7 CFR § 205.600 (b) (1)).**
879
880 There are no organic agricultural products that serve as an adequate alternative to ion exchange filtration
881 for the purification, clarification, decoloring, and desalination applications that are used throughout food
882 processing.
883

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896

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