An EA Revision Sheet has been prepared for this Environmental Assessment
See the FONSI for this Food Contact Notification

Environmental Assessment

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4. Description of Proposed Action

a. Requested Action

The action requested in this food contact notification (FCN) is to permit the use of the substance Benzene, diethenyl-, polymer with ethenylbenzene and ethenylethylbenzene, chloromethylated (CAS number 69011-14-9) (the food contact substance or FCS) as an ion-exchange resin used in the production of food. Specifically, the FCS will be used to remove organic substances from FDA's food types I ("Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0)"), II ("Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content"), and VI ("Beverages"), including streams containing up to 30% alcohol.[1] The FCS is not intended for use in contact with infant formula, human milk, or bottled water. The finished resin is intended for repeated use applications in the processing of food at stream temperatures not to exceed 40°C.

b. Need for Action

Use of the FCS offers several technical properties that make it useful for removing organic substances from food streams. It has a highly cross-linked polymer matrix and high surface area.[2] The spherical resin beads also have good physical strength.

c. Locations of Use/Disposal

The FCS is intended for use in food manufacturing and processing facilities throughout the United States. The typical lifetime of an adsorbent resin in commercial processes is five to seven

[1] FDA's food types are described at *Food Types and Conditions of Use for Food Contact Substances*, http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/ucm109358.htm

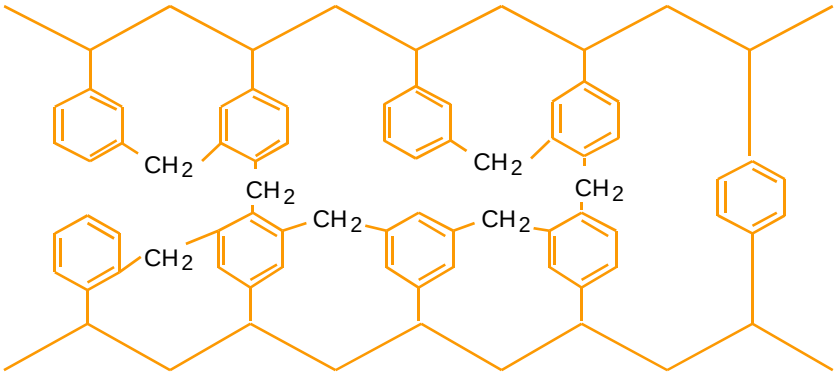
[2] DOWEX OPTIPORE L493 and V493 Polymeric Adsorbents Product Information Sheet, available via http://msdssearch.dow.com/PublishedLiteratureDOWCOM/dh_004f/0901b8038004fadd.pdf?filepath=liquidseps/pdfs/noreg/177-01731.pdf&fromPage=GetDoc

years and at the end of the service life the resin will be disposed of in a sanitary landfill or through incineration following local and federal requirements.

The main applications for the FCS are polyphenol recovery (and subsequent reuse) from aqueous and aqueous/acid liquid food streams, in debittering citrus juices by removing limonin and naringin, and in ethanol recovery in breweries by removing ethyl esters. The polyphenols absorbed by the resin are eluted using ethanol. The polyphenols are then used as a component in the manufacturing or processing of food. As such, no disposal of polyphenols is expected. The ethanol used to elute the polyphenols from the resin is recovered using processes such as flash heat recovery,[3] so no disposal of ethanol is expected. The limonin and naringin are eluted from the resin using sodium hydroxide. There is no known market for these recovered substances, and the mixture of sodium hydroxide and organic substances would enter the facility's liquid waste stream. The ethyl esters are eluted from the resin using hot water, after the resin has filtered the ethanol distilled from brewing byproducts. The water and ethanol are recovered and the water containing ethyl esters would enter the facility's liquid waste stream. It is expected that on-site waste water treatment facilities will discharge to publically owned treatment works (POTW) but we have also considered discharge to surface waters.

5. Identification of Substances that are Subject of the Proposed Action

The FCS is Benzene, diethenyl-, polymer with ethenylbenzene and ethenylethylbenzene, chloromethylated (CAS Reg. No. 69011-14-9), with a chemical formula of $(C_{10}H_{12}.C_{10}H_{10}.C_8H_8)x$- and the following structure:



[3] Katzen, R., Madson, P.W., and Moon Jr., G.D., *Ethanol Distillation: the fundamentals*, in The Alcohol Textbook (Jacques, K.A., Lyon T.P., and Kelsall, D.R. eds., 3rd Ed., 1999), http://my.chemeng.queensu.ca/courses/CHEE332/files/distillation.pdf

Supplied as 20-50 mesh spherical beads in 50-65% water.

6. Introduction of Substances into the Environment

a. Introduction of Substances into the Environment as a Result of Manufacture

Under 21 C .F.R. § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. The FCS is manufactured in plants which meet all applicable federal, state and local environmental regulations. Dow asserts that there are no extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS such as: 1) unique emission circumstances not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies where the emissions may harm the environment; 2) the proposed action threatening a violation of Federal, state or local environmental laws or requirements (40 C.F.R. § 1508.27(b)(10)); or 3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b. Introduction of Substances into the Environment as a Result of Use/Disposal

Substances Produced When the FCS is Used as Intended

The main applications for the FCS are polyphenol recovery (and subsequent reuse) from aqueous and aqueous/acid liquid food streams, in debittering citrus juices by removing limonin and naringin, and in ethanol recovery in breweries by removing ethyl esters from the ethanol.

Polyphenol Recovery

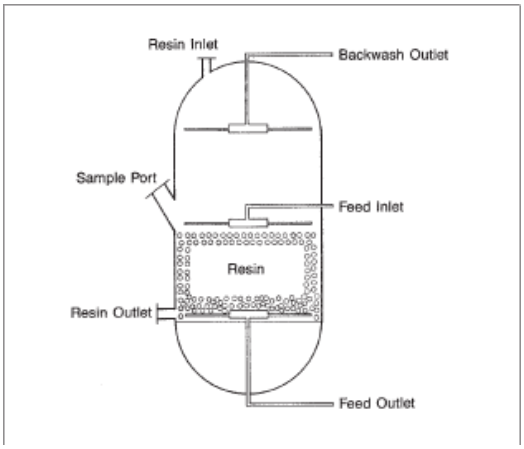
The FCS is used to recover polyphenols from aqueous food streams, such as cranberry, cherry, and grape juices.[4] The antioxidant properties of polyphenols has given rise to their recovery from what otherwise would be the food manufacturing waste stream and subsequent reuse in food manufacturing and processing.[5] The juice filtration process uses a fixed bed column,

[4] There is the potential for the resin to be used in the recovery of polyphenols from beer and wine using a similar process as described in this section.

[5] Manach, C. et al., *Polyphenols: Food Sources and Bioavailability*, The American Journal of Clinical Nutrition, 79, 727-747 (2004). Also see Footnote 11, Conde, 2013.

through which the liquid food stream passes down through the packed bed of the adsorbent resin material (figure 1).[6]

Figure 1



The polyphenols that are adsorbed by the resin are then recovered by elution using a solvent system.[7] For the juices of interest, ethanol is expected to be used. Based on Dow's experience and knowledge of the use of fixed bed columns, a typical bed volume of a polyphenol recovery process would be 1,000 liters, which would process seven bed volumes (7,000 L) of liquid food that we will conservatively assume contains approximately 0.5% polyphenol.[8] Based on Dow knowledge, approximately three bed volumes of ethanol (3,000 L) would be used in the elution process. Recovery through desorption varies depending on the resin, but similar resins have a recovery between 60-80%,[9] which results in a recovery of approximately 21 kg of polyphenol.[10] The recovered polyphenols will be returned to the food manufacturing/processing stream. The

[6] Ashurst, P.R. ed., *Dowex Ion Exchange Resins: Juice Enhancement by Ion Exchange and Adsorbent Technologies*, April 2002.
[7] Dai, J. and R. Mumper, *Plant Phenolics: Extraction, Analysis and Their Antioxidant and Anticancer Properties*, Molecules, 15: 7313-7352 (2010), available at http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.360.9960&rep=rep1&type=pdf.
[8] A review of the Phenol-Explorer database indicated that of the available information on juice products, grapefruit had the highest total polyphenol content at 351 mg/100 g, http://phenol-explorer.eu/contents/show/4/731/12, while another review of various fruit juices concluded that cranberry juice had the highest content, at 71.76 mg/100 ml (centrifuged), see Keskin-Šašić, I. et al, *Total Phenolic Content and Antioxidant Capacity of Fruit Juices*, Bulletin of the Chemists and Technologists of Bosnic and Herzegovina (2012), http://www.pmf.unsa.ba/hemija/glasnik/files/Issue%2039/39_6_Tahirovic.pdf. These values are equivalent to 3510 ppm (0.35%) and 717.6 ppm (0.07%), respectively. On this bases, 0.5% polyphenol content is a conservative assumption.
[9] Buran, T. et al., *Adsorption/desorption characteristics and separation of anthocyaninsand polyphenols from blueberries using macroporous adsorbent resins*, Journal of Food Engineering, 128: 167-173 (2014), https://www.researchgate.net/publication/259646593_AdsorptionDesorption_Characteristics_and_Separation_of_Anthocyanins_and_Polyphenols_from_Blueberries_using_Macroporous_Adsorbent_resins, see figure 1.
[10] 7000 L (kg) × 0.5% × 60% = 21 kg.

ethanol solvent is expected to be recovered through vacuum evaporation and reused in the elution process.[11] As such, no disposal of the recovered polyphenols or ethanol is expected and thus will be not discussed further in the EA. The environmental introduction of polyphenols remaining in the FCS upon disposal will be addressed separately.

Debittering Citrus Juices

Debittering has been used in commercial production of citrus juices for a considerable length of time in order to remove liminoids that occur naturally in fruit such as oranges and grapefruits, of which the primary substances of concern are limonin and naringin.[12] The FCS, like other adsorbent resins, will be used to remove liminoids from citrus juice streams. Based on Dow's knowledge and experience with adsorbent resins, a typical fixed bed column volume used for debittering process would be approximately 1,800 L and would process seventy bed volumes of citrus juice (126,000 L). The combined content of limonin and naringen is expected to be no more than 700 ppm.[13] The liminoid content is reduced by about 40% through adsorption,[14] resulting in approximately 280 ppm liminoid content remaining in the resin, or 35.3 kg (126,000 L × 0.00028). Based on Dow's experience and knowledge, approximately nine bed volumes of 2-5% sodium hydroxide (NaOH) solution would be used to regenerate the bed (16,200 L of solution, containing 810 L of NaOH), eluting the 35.3 kg liminoid in the solution (assuming 100% desorption). It is possible that the liminoids may be recovered from the column regeneration process,[15] as limonene is used in a variety of industry applications such as the manufacture of adhesives, degreasers, and flavors.[16] However, as a review of the literature indicates that limonene recovery is more common from citrus peel than through the debittering process, we have assumed that the limonoid-containing sodium hydroxide solution, with 2179 ppm limonoid content,[17] enters the citrus facility's wastewater treatment process. Water is used in juice processing plants for many uses, including washing the raw fruit, cleaning and sanitization of equipment, and cooling.[18] Wastewater is treated to decrease the biological

[11] Conde E., et al., *Recovery and Concentration of Antioxidants from Industrial Effluents and from Processing Streams of Underutilized Vegetal Biomass*, Food and Public Health, 3(2): 69-91 (2013), available at http://article.sapub.org/10.5923.fph.20130302.01.html, see figure 5; Patent No. US6544581 B1, *Process for extraction, purification and enrichment of polyphenolic substances from whole grapes, grape seeds and grape pomace*, Fig, 1c.

[12] Shaw, P., Baines, L, Milnes, B. and Agmon, G., *Commerical Debittering Processes to Upgrade Quality of Citrus Juice Products*, in Berhow M., et al., *Citrus Liminoids*, ACS Symposium Series, American Chemical Society (July 2000).

[13] Id. p. 125. Limonin content at ~25 ppm and naringin content at ~600 ppm, although as reported in this article, the actual naringin content is expected to be ~2.1 times less.

[14] Id.

[15] Id., p. 126.

[16] Goodrich, R.M. and R.J. Braddock, *Major By-Products of the Florida Citrus Processing Industry*, Doc. No. FSHN05-22, Food Science and Human Nutrition Department, Florida Cooperative Extension Service, Institute of Food and Agricultural Sciences, University of Florida (October 2004, revised February 2006).

[17] 35.3 kg (L) ÷ 16,200 L NaOH solution = 2179 ppm liminoid.

[18] See, generally, Reyes-de-Corcuera, J.I. et al, *Chapter 15 Processing of Fruit and Vegetable Beverages*, in Food Processing: Principles and Applications, Second Edition (2014).

oxygen demand to a level where it can be used for agricultural field irrigation or be discharged to a POTW.[19] Assuming, highly conservatively, that there are no other wastewater discharges from the processing facility to dilute the limonoid concentration, this results in an environmental introduction concentration (EIC) to land or surface water of 2179 ppm. We would expect this concentration to decrease to at least 304 ppm due to other wastewater effluent.[20] Before using this for irrigation, or discharging to surface water or a POTW, this wastewater would be treated to decrease the biological oxygen demand.[21] Although release to a POTW is possible, the analysis of environmental impact resulting from direct discharge to land or surface water will be protective of potential environmental impact after processing via a POTW because treatment at a POTW will involve further dilution and degradation. Although there is the potential for POTW biosolids to be land applied, due to the fate properties of limonene, this is not expected to result in terrestrial exposure (see Item 7 for additional discussion).

Brewery Ethanol Recovery

The FCS may be used to aid the recovery of aqueous ethanol in breweries, or other alcohol production facilities, by removing ethyl esters, such as ethyl acetate, ethyl isobutyrate, isobutyl acetate, ethyl isohexanoate, and ethyl isovalerate from the ethanol. The brewing process results in two effluent streams: wastewaters and byproducts.[22] The wastewater is typically treated prior to release while the byproducts (spent grains, kieselguhr sludge, surplus yeast, and beer waste), which contain an extremely high organic load, are otherwise disposed, with the spent grain sold as cattle food and the kieselguhr sludge sent to final disposal.[23] The ethanol present in the liquid fraction of the surplus yeast and beer waste (5−7% v/v) can be responsible for approximately 60% of the chemical oxygen demand of these effluents and can be easily removed by distillation.[24] Adsorbent resins may then be used for further purification,[25] although a review of the literature demonstrates that it does not appear to be a widespread practice.[26] Based on Dow's experience and knowledge, a typical resin bed in this application would be 500 L and would process one bed volume of aqueous ethanol (500 L) with a density of 0.789 g/cm^3 (kg/L)

[19] Id., pp. 348 and 360.
[20] In 1993, the California Food Industry reported that median water use by food processing facilities was 100 million gallons per year (Mannapperuma JD, Yates, ED, and Singh, RP, "Survey of Water Use in the California Food Processing Industry" 1993), dividing this number by 365 days and converting to liters results in about 1 million liters of water used per day. As this data is outdated,generic to food processing in general and as more facilities are implementing water conservation measures, we assume a minimum of 100,000 L used/discard per day – so 35.3 kg limonene/(16,2000 L NaOH solution + 100,000 additional wastewater) = 304 ppm
[21] Reyes-de-Corcuera, see footnote 18 pp 348 and 360
[22] Seluy, L. and M. Isla, *A Process To Treat High-Strength Brewery Wastewater via Ethanol Recovery and Vinasse Fermentation*, Industrial and Engineering Chemistry Research, 53: 17043-17050 (2014).
[23] *Id*.
[24] *Id*.
[25] Patent No. US 2879165 A, *Purification of aqueous ethyl alcohol for use in beverages* (1959).
[26] In a review of current wastewater treatment practices, use of adsorbent resins similar to the FCS is not discussed, see Simate, G., *The treatment of brewery wastewater for reuse: State of the art*, Desalination, 273: 235-247 (2011), https://www.researchgate.net/publication/221964511_The_treatment_of_brewery_wastewater_for_reuse_State_of_the_art#pfd.

(394.5 kg ethanol).[27] The ethanol would be recovered and returned to the manufacturing stream as a co-product. The bed would be regenerated with five bed volumes of hot water (2,500 L) and elute an aqueous solution of 16 ppm of esters.[28] The water solution would become part of the plant waste stream. The water used in the elution process is expected to rapidly cool when incorporated into the plant's general water waste stream, and is not expected to have any significant effect on the environment. Esters are produced by brewing yeasts during the anaerobic metabolism of sugars and will be a component of brewing wastes.[29] Treatment of brewery wastewater effluent is a significant issue for an industry that discharges 70% of its incoming water as effluent.[30] Esters will already be present in brewery wastewater; cleaning of brewing equipment such as the fermenters and storage tanks can result in wastewaters containing high levels of beer, active yeast, and proteins as suspended solids,[31] which will result in continued fermentation of wastewater,[32] and would produce esters. While we have not found research that specifically addresses the ester content of brewing wastewater, given that "end-of-pipe" levels of total suspended solids are reportedly 200-1,500 ppm, the 16 ppm of esters resulting from use of the resin will not represent a significant addition to this waste.[33] We would expect this concentration of esters to decrease to at least 0.4 ppm due to dilution with wastewater effluent.[34] Nevertheless, we have evaluated the safety of the environmental introduction of representative ethyl esters below.

The FCS

Disposal of the FCS at the end of its service life will be primarily by sanitary landfill or incineration and it is anticipated that disposal will occur nationwide. According to the US Environmental Protection Agency's (EPA) 2016 update regarding municipal solid waste (MSW) in the United States as of 2014, which is the most recent data available, 65.4% of MSW was not recycled or composted, of which 52.6% of MSW was disposed in landfills or elsewhere and 12.8% was combusted.[35] Thus, based on the above numbers, 80.4% of the material not recycled

[27] https://pubchem.ncbi.nlm.nih.gov/compound/ethanol . see section 4.2.9, density
[28] Information provided to The Dow Chemical Company in oral communication from a brewery.
[29] Peddie, H., *Ester Formation in Brewery Fermentations*, Journal of the Institute of Brewing, 96: 327-331 (Sept.-Oct. 1990), p. 327.
[30] Brewers Association, *Water and Wastewater: Treatment/Volume Reduction Manual*, https://www.brewersassociation.org/attachments/0001/1517/Sustainability_-_Water_Wastewater.pdf, p. 6.
[31] *Id*., p. 17, see table "Main Areas of Wastewater Generation."
[32] Mercer, J. *Wastewater basics for a growing craft brewery*, Craft Brewing Business (September 22, 2014), https://www.craftbrewingbusiness.com/equipment-systems/wastewater-basics-growing-craft-brewery/.
[33] Brewers Association, p. 17, table "Typical Ranges of Brewery Untreated "End-of-Pipe" Wastewater Effluent."
[34] 0.04 kg ester/(2,500 liters + 100,000 liters) = 0.4 ppb
[35] United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2014 Tables and Figures, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States*, December 2016, see Table 35, https://www.epa.gov/sites/production/files/2016-11/documents/2014_smm_tablesfigures_508.pdf.

is land disposed and 19.6% is combusted.[36] There are no special circumstances regarding the environment surrounding either the use or disposal of the FCS.

The subject resin consists of carbon and hydrogen, elements commonly found in municipal solid waste. The FCS is intended to replace chemically similar food-contact adsorbent resins currently permitted under FDA regulations and effective food contact notifications. There is no reason to believe that disposal patterns for the FCS will be different from current disposal patterns of other similar resins for similar uses. The resin may also contain substances that were not recovered through the elution process, such as polyphenols, ethyl esters, and liminoids. These substances consist of carbon, hydrogen, and oxygen.[37] As the resin will be used in only one application (i.e., a resin will not contain all of the materials identified above), we will use the worst case scenario discussed above of 35.3 kg liminoid content being disposed with the FCS.

On August 1, 2016, the Council on Environmental Quality (CEQ) issued final guidance[38] to agencies regarding addressing GHG emissions and climate change impacts in NEPA documents. This guidance is "intended to help Federal agencies ensure their analysis of potential GHG emissions and effects of climate change in an EA or EIS is commensurate with the extent of the effects of the proposed action."[39] The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in MSW combustion facilities. Such facilities are regulated by the EPA under 40 C.F.R. Part 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." Part 2 of this regulation (40 C.F.R. § 98.2), describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO2-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations under 40 C.F.R. § 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 C.F.R. § 1508.27(b)(10) states that when evaluating intensity of an impact, one should consider "whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment." GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the confidential attachment to the EA, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting

[36] 12.8% combusted ÷ (12.8% combusted + 52.6% land disposed) = 19.6% combusted. The remaining 80.4% will be land-disposed.
[37] See http://phenol-explorer.eu/compounds, https://chem.sis.nlm.nih.gov/chemidplus/rn/64-17-5, https://chem.sis.nlm.nih.gov/chemidplus/name/limonine, https://chem.sis.nlm.nih.gov/chemidplus/rn/10236-47-2.
[38] Council on Environmental Quality (CEQ), *Final Guidance for Federal Departments and Agencies on Consideration of Climate Change in National Environmental Policy Act Reviews,* August 1, 2016, available at: https://obamawhitehouse.archives.gov/sites/whitehouse.gov/files/documents/nepa_final_ghg_guidance.pdf
[39] Id., p. 3.

from combustion of the FCS in MSW combustion facilities contributing to GHG emissions. Furthermore, as the amount of FCS combusted compared to all MSW combusted is marginal (see confidential attachment to the EA) and because the FCS is comprised of elements typical of MSW, the FCS is not expected to threaten a violation of 40 CFR Part 60 that regulate MSW combustion facilities.

In light of EPA's regulations governing municipal solid waste landfills, only extremely small amounts, if any, of the FCS is expected to enter the environment as a result of the landfill disposal of the FCS. EPA's regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have groundwater monitoring systems. (40 C.F.R. Part 258.) Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

7. Fate of Emitted Substances in the Environment

a. Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS in food contact adsorbent resin applications. As described above, the emission of carbon dioxide due to the combustion the FCS and associated impurities is not expected to be significantly increased, and no other emissions are anticipated to threaten a violation of law or regulatory threshold. Thus, as no significant environmental impact is anticipated, the fate of the FCS in air is not discussed further.

b. Water

As discussed above, there are two potential sources of effluent that may become part of the aqueous wastestream: (1) liminoid-containing sodium hydroxide solution; and (2) ester-containing hot water solution. Sodium hydroxide dissociates completely in water to sodium cations (Na+) and hydroxide anions (OH-) and finally decomposes to water.[40] The addition of sodium hydroxide to water is expected to raise the pH, but is not expected to contaminate ground water or soil and does not accumulate in the food chain.[41] Use and disposal of waste sodium hydroxide solution must not cause a facility's wastewater to violate its National Pollutant Discharge Elimination System (NPDES) permit requires for pH[42] or discharge to a POTW with a pH <5.[43] Disposal of liquids with a pH $\leq$2 or $\geq$12.5 also is regulated as a corrosive hazardous waste under the Resource Conservation and Recovery Act (RCRA), and control and

[40] U.S. Environmental Protection Agency, *Sodium Hydroxide (Mineral Bases, Strong) Final Registration Review Decision, Registration Review Case 4065*, Docket No. EPA-HQ-OPP-2007-0922 (March 2009), p. 12.
[41] *Id*., p. 12-13.
[42] 40 C.F.R. § 401.17.
[43] 40 C.F.R. § 403.5(b)(2).

neutralization is required.[44] Based on the degradation profile and regulation of pH (the environmental effect of sodium hydroxide), no significant effect on the environment from the discharge of sodium hydroxide is expected.

Limonene is highly volatile and will readily volatilize from dry and moist soil, as well as water; therefore, limonene is likely to be found in the air. However, the tendency of limonene to adsorb to soil may slow down volatilization from soil; and in water, limonene may also be slowed from volatilizing if adsorbed to sediment or suspended organic matter. Once in the air, limonene is not expected to persist, and will likely degrade and dissipate in a matter of hours. Furthermore, limonene is expected to also degrade in soil/sediment/sludge under aerobic conditions.[45] In a test simulating aerobic sewage treatment, limonene disappeared almost completely (>93.8%) during 14 days of incubation, although it could not be determined to what extent the removal was due to biodegradation and sorption compared with volatilization.[46] Under anaerobic conditions, d-limonene appears to be persistent.[47] When wastewater is treated for biological oxygen demand, limonene is expected to partition extensively to the air, and once released to the air rapidly break down, with a half-life in air of less than 3 hrs.[48] Limonene that remains adsorbed to solids, is likely to be subject to aerobic degradation, and similarly break down. Based on the fate of limonene in wastewater treatment (i.e. volatization, degradation in air and sediment/sludge), we expect the aquatic EIC of 304 ppm to be at a minimum halved before release to surface water, resulting in an aquatic EIC of 150 ppm.

In considering the ethyl esters, ethyl acetate and isobutyl acetate have been evaluated by the OECD high production volume assessments, including evaluations of the environmental safety of these substances, summarized as follows. Both ethyl acetate[49] and isobutyl acetate[50] are readily biodegradable. Ethyl acetate is moderately volatile and calculated half-lives of volatilization was 5 hours and 5.6 days from model river or lake, respectively. For isobutyl acetate, the calculated half-lives of volatilization was 2.9 hours and 5.08 days from model river or lake, respectively. Neither ethyl acetate nor isobutyl acetate will be persistent in the environment.

c. Land

[44] 40 C.F.R. § 261.22.
[45] U.S. EPA, *d-Limonene: Ecological Risk Assessment for Registration Review*, Docket No. EPA-HQ-OPP-2010-0673 (December 5, 2014), p. 3.
[46] *Id*., p. 7.
[47] *Id*.
[48] U.S. EPA, *d-Limonene: Ecological Risk Assessment for Registration Review*, Docket No. EPA-HQ-OPP-2010-0673 (December 5, 2014), p. 14
[49] OECD SIDS Initial Assessment Profile, Ethyl acetate, March 2002, http://webnet.oecd.org/Hpv/UI/handler.axd?id=ce040b66-8367-47c0-aa41-599974654113
[50] OECD SIDS Initial Assessment Profile, Isobutyl acetate, November 2003, http://webnet.oecd.org/Hpv/UI/handler.axd?id=18cc5552-2630-4ed7-8c9a-80b0c9d88341.

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the FCS. The very stringent regulatory limitations on leachate from landfills preclude any substantial release to the environment of the FCS. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the FCS.

If limonene-containing wastewater is discharged to POTWs, there is the potential for land application of limonene-containing biosolids. Limonene binds strongly to soil, with an organic carbon partition coefficient of >1000 mL/g_{oc} and is expected to be relatively immobile in soil.[51] Degradation rates in aerobic sewage sludge have been reported to range from 41-98% degradation in 14 days, although these studies were not designed to determine the biodegradation rates of limonene, but suggested that limonene biodegradation was occurring as the biochemical oxygen demand ranged from 41 to 98% in 14 days.[52] Calculations based on published aerobic biodegradation studies estimated a first order biotransformation rate for limonene, resulting in a half-life of 38.5 days.[53]

Biosolids are the nutrient-rich organic materials resulting from the treatment of sewage sludge. When treated and processed, sewage sludge becomes biosolids which can be safely recycled and applied as fertilizer to sustainably improve and maintain productive soils and stimulate plant growth.[54] Biosolids are regulated by strict Federal standards, specifically EPA regulations in 40 C.F.R. Part 503. As EPA requires conditioning treatment of sludge before it can be land applied as biosolids, any sludge containing limonene would be conditioned prior to land application. Given the fast biodegradation rate and short half-life of limonene (as well as the propensity to partition to air and promptly degrade), we do not anticipate that there would be a significant impact to soil organisms or plants related to the presence of limonene in land-applied biosolids.

If limonene-containing water is reclaimed as irrigation water for citrus groves, as discussed above it is expected to bind to the soil and be relatively immobile. Some amount of the limonene will volatilize from the soil, although this volatilization may be slowed due to the strong tendency for adsorption. The limonene that does volatilize will likely degrade and dissipate in a matter of hours, as also discussed above. The amount of water needed for irrigation of citrus trees varies during the year, with mature citrus trees using approximately 17 gallons of water per day in the winter and up to 135 gallons/day in the summer.[55] Irrigation is not continuous, however, and mature trees will be watered approximately every two weeks.[56] Averaging the maximum

[51] *Id*., p. 3.
[52] *Id*.
[53] *Id*., p. 14.
[54] https://www.epa.gov/biosolids/basic-information-about-biosolids
[55] The University of Arizona Cooperative Extension, Publication AZ1151 Irrigating Citrus Trees (February 2000), https://extension.arizona.edu/sites/extension.arizona.edu/files/pubs/az1151.pdf
[56] Id., see Table 2.

irrigation amount over this 14-day period results in a daily application rate of 9.6 gallons. Assuming that all the water contains 150 ppm limonene, this results in an amount applied to the soil of 0.0053 kg/day.[57] With a citrus grove containing 140 trees in an acre,[58] this results in a maximum application rate of 0.74 kg/acre (1.6 lb/acre).

8. Environmental Effects of Released Substances

Limonene-containing wastewater may be discharged to surface water or used as irrigation water. On an acute exposure basis, d-limonene is classified as "slightly toxic" to freshwater fish and invertebrates based on a limited toxicity set with only one species of freshwater fish tested and no data for estuarine/marine (E/M) species (fish or invertebrates).[59] No chronic toxicity data are available for either freshwater or E/M species. The LC_{50} for rainbow trout is reported as 80 mg/L and the EC_{50} for *Daphnia magna* is 39 mg/L.[60] The lowest EC_{50} for aquatic plants is for blue-green algae at 9.353 mg/L.[61] The EIC calculated above is 150 ppm. As discussed above, in the aquatic and terrestrial environment limonene would be expected to primarily volatilize and partition to air, and also adsorb to sediment and suspended organic matter/soil. When the water from the facility treatment plant or POTW is discharged to surface waters, it will be diluted a further 10-fold, resulting in an estimated environmental concentration (EEC) of 15 ppm, and the estimated half-life of limonene in a river is on the order of hours, so this will be further reduced to 8 ppm.[62] This EEC is below the levels of concern for aquatic toxicity. Therefore, no significant adverse effect is expected as result of the discharge of wastewater containing liminoids.

When wastewater is used for irrigation or when sewage sludge is used as biosolids, there is the potential for release of limonene to soil. There are no data to assess the toxicity of limonene to birds on an acute or chronic oral basis, but on a sub-acute/dietary exposure basis, limonene is classified as "practically non-toxic" to birds based on a LC_{50} of >5,600 mg/kg diet and a lack of sublethal effects reported for the Bobwhite quail (*Colinus virginianus*).[63] Limonene is classified as "practically non-toxic" for mammals on an acute exposure basis, while on a chronic exposure basis, a No Observed Adverse Effect Level for the rat of 250 mg/kg/day was established in developmental toxicity study.[64] There are no toxicity studies available to assess the risk to terrestrial invertebrates, while for terrestrial plants, there were no effects reported in the available

[57] 9.6 gallons/day × 0.000150 = 0.0014 gallons, equivalent to 0.0053 kg/day.
[58] Florida Agriculture in the Classroom, Inc, Producing Citrus in Florida, http://faitc.org/wp-content/uploads/2013/08/Producing-Citrus-in-Florida2.pdf.
[59] U.S. EPA, *d-Limonene*, p. 26.
[60] *Id*., p. 17.
[61] *Id*.
[62] Rapaport, R.A., *Prediction of consumer product chemical concentrations as a function of publically owned treatment works treatment type and riverine dilution*, Environmental Toxicology and Chemistry 7(2), 107-115 (1988).
[63] U.S. EPA, *d-Limonene*, p. 17-18.
[64] *Id*.

seedling emergence study with a NOAEC of ≥265-345 lb/A but in the vegetative vigor toxicity study, there were effects reported at all treatment levels so the EC_{05} was used as a proxy for the NOAEC, with the lowest value seen in monocot-corn, at an EC_{05} of 0.19 lb/A.[65] The objective of the vegetative vigor test is to measure the effect of a test substance applied directly to the foliage of terrestrial plants during the vegetative growth period of their development; the irrigation water[66] and biosolids are applied directly to the soil, so the seedling emergence study is of most relevance for toxicity to terrestrial plants. The application rate of limonene from irrigation water of 1.6 lb/acre is well below the NOAEC seen in that study. In light of the biodegradation of limonene after treatment and the low concern for toxicity to terrestrial animals and plants, no significant adverse effect is anticipated from land application.

Ethyl ester-containing water may be discharged from breweries after treatment or discharged to POTWs. Common ethyl esters include ethyl acetate, ethyl hexanoate, and isobutyl acetate.[67] The aquatic EIC is calculated above as 0.4 ppm. Conservatively assuming no dilution, the EIC is calculated as 16 ppm. There is available ecotoxicity data on ethyl acetate and isobutyl acetate, and very little data on ethyl hexanoate, with isobutyl acetate appearing to be the more toxic. Volatilization of isobutyl acetate from water surfaces is expected based upon a Henry's Law constant of 4.54×10^{-4} atm-cu m/mole, and with a K_{oc} of 16, adsorption to suspended solids and sediment is not expected. The available aquatic ecotoxicity studies are reported:[68]

Group	**Species**	**Acute LC50 or EC50** (unless indicated)
Freshwater Fish	Carp	101-123 mg/L
Freshwater Invertebrates	Ciliate	727 mg/L (endpoint not reported)
	Daphnia Magna	250 mg/L
Saltwater Invertebrate	Brine Shrimp	1,200 mg/L
Freshwater Plants	Green Algae Order	600 mg/L
	Blue-Green Algae	205 mg/L (LOEC)
	Green Algae	80 mg/L (LOEC)
	Flagellate Euglenoid	411 mg/L (endpoint not reported)
	Cryptomonad	600 mg/L (endpoint not reported)

The most sensitive species is green algae, with a LOEC of 80 mg/L. No chronic data are reported, and as discharge of this product would be on an intermittent basis, acute data would be

[65] *Id*.
[66] Morgan, K.T., Zotarelli, L., and Dukes, M.D., Use of Irrigation Techniques for Citrus Trees in Florida, HortTechnology 20:1, 74-81, p. 74 (February 2010).
[67] Peddie, p. 327.
[68] https://cfpub.epa.gov/ecotox/advanced_query.htm, chemical entry for CAS Reg. No. 110-19-0, perform query for aquatic data. Print copy attached.

most relevant. The calculated EIC of 0.4 ppm (mg/L) is 200 times lower than the lowest endpoint, indicating that no significant adverse effect is expected due to disposal of ethyl esters.

No adverse effect on organisms in the environment is expected as a result of the land disposal of the FCS. In addition, use and disposal of the FCS is not expected to threaten a violation of applicable laws and regulations, such as the EPA's regulations in 40 C.F.R. Part 60 that pertain to municipal solid waste combustors or and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food contact substances, the production, use and disposal of the FCS involves the use of natural resources such as petroleum products and coal. However, the use of the FCS is not expected to result in a net increase in the use of energy and resources, since the FCS is intended to be used in place of similar polymers now on the market for processing food streams.

The replacement of these types of materials by the FCS is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS will consume energy and resources in amounts comparable to the manufacture of other similar resins. Moreover, the FCS will replace adsorbent resins that are not currently recovered for recycling but are disposed of by means of sanitary landfill and incineration.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the FCS. Therefore, the FCS is not expected to result in environmental issues that require mitigation measures.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this FCN. If the proposed action is not approved, the result would be the continued use of the currently marketed adsorbent resins that the subject FCS would replace. Such action would have no environmental impact. The addition of the FCS as an adsorbent resin to the options available to the food processing industry is not expected to increase the use of such resins.

12. List of Preparers

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13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date: March 13, 2017

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15. Attachments

Attachment 26: Confidential Attachment to the Environmental Assessment.