

**Revised**

**Environmental Impact of Food Contact Substance (21 CFR Part 25)**

**FDA Form 3480 Part IV, Section B**

1. **Date:** November 17, 2016
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All communication regarding this food contact notification (FCN) environmental assessment (EA) should be sent to the attention of:

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**4. Description of Proposed Action**

**a) Requested Action:**

The action requested in this submission is the use of the food contact substance (FCS), an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>), water, and acetic acid (AA), stabilized with 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (hereinafter referred to as “antimicrobial agent”), and catalyzed with sulfuric acid, to be used at concentrations up to 350 ppm PAA, 117 ppm H<sub>2</sub>O<sub>2</sub>, and 4 ppm HEDP in process water used to wash raw and processed fruits and vegetables in food processing facilities.

The FCS is manufactured as an un-diluted concentrate (referred to herein as “FCS concentrate”) and is diluted with water at use sites. During use, the FCS is referred to as “diluted FCS solution” to differentiate it from the FCS concentrate. The diluted FCS solution is associated with the “in-use concentrations” of the component chemicals listed above in Item 4.a. Dilution is achieved by metering of concentrate into a metered

stream of water. In-use concentrations of the diluted FCS solution are monitored by manual titration of the reservoir that fruits and vegetables are submerged in.

**b) Need for Action:**

The FCS is intended for use as an antimicrobial agent in process water used to wash raw and processed fruits and vegetables in food processing facilities to provide safe products for human consumption throughout the United States.

**c) Locations of Use/Disposal:**

The FCS is intended for use in process water used to wash raw and processed fruits and vegetables in food processing facilities nationwide.

After use, the diluted FCS solution will be disposed of with processing plant wastewater. For processing plants that hold a National Pollutant Discharge Elimination System (NPDES) permit (i.e., direct dischargers), the FCS-containing wastewater will be treated on-site before directly discharged to surface waters.

For processing plants without such NPDES permits (i.e., indirect dischargers), the FCS-containing wastewater would travel through the sanitary sewer system into Publicly Owned Treatment Works (POTWs) for standard wastewater treatment processes before movement into aquatic environments.

**5. Identification of the Food Contact Substance**

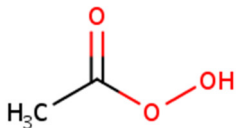
The diluted FCS solution is an aqueous mixture of PAA, H<sub>2</sub>O<sub>2</sub>, HEDP, AA, water, and sulfuric acid, produced by blending AA, H<sub>2</sub>O<sub>2</sub>, purified water, and HEDP, while using sulfuric acid as a catalyst for the reaction. PAA formation is the result of an equilibrium reaction between H<sub>2</sub>O<sub>2</sub> and AA (see Figure 1).




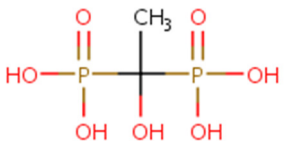
**Figure 1. PAA Formation**

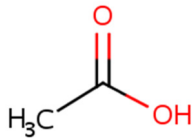
Identifying information for all chemicals present in the FCS is included below. Concentrations


of each identified chemical component in the FCS concentrate and diluted FCS solution are included in Confidential Attachment A.

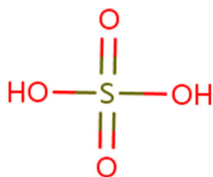
Name	Peroxyacetic Acid (PAA)	Source
CASRN	79-21-0	ChemIDplus
Formula	C <sub>2</sub> H <sub>4</sub> O <sub>3</sub>	
Structure		
Molecular weight	76.0506 g/mol	
Appearance	Colorless to pale yellow liquid	
Comment	Present in diluted FCS solution at a concentration up to 350 ppm.	

Name	Hydrogen Peroxide (H <sub>2</sub> O <sub>2</sub> )	Source
CASRN	7722-84-1	ChemIDplus
Formula	H <sub>2</sub> O <sub>2</sub>	
Structure		
Molecular weight	34.0138 g/mol	
Appearance	Colorless liquid	
Comment	Present in diluted FCS solution at a concentration up to 117 ppm.	

Name	1-Hydroxyethylidene-1,1-diphosphonic Acid (HEDP)	Source
CASRN	2809-21-4	ChemIDplus
Formula	C <sub>2</sub> H <sub>8</sub> O <sub>7</sub> P <sub>2</sub>	
Structure		
Molecular weight	206.0262 g/mol	
Appearance	Colorless to pale yellow liquid	
Comment	Present in diluted FCS solution at a concentration up to 4 ppm.	

Name	Acetic Acid (AA)	Source
CASRN	64-19-7	ChemIDplus
Formula	C <sub>2</sub> H <sub>4</sub> O <sub>2</sub>	
Structure		
Molecular weight	60.0516 g/mol	
Appearance	Clear, colorless liquid	
Comment	See Confidential Attachment A for concentration level.	

Name	Purified Water (H2O)	Source
CASRN	7732-18-5	ChemIDplus
Formula	H <sub>2</sub> O	
Structure		
Molecular weight	18.0148 g/mol	
Appearance	Colorless liquid	
Comment	Primary component in diluted FCS solution, which is diluted with water.	

Name	Sulfuric Acid	Source
CASRN	7664-93-9	ChemIDplus
Formula	H <sub>2</sub> SO <sub>4</sub>	
Structure		
Molecular weight	98.0778 g/mol	
Appearance	Colorless liquid	
Comment	Used as a catalyst but present in diluted FCS solution. See Confidential Attachment A for concentration level.	

## **6. Introduction of Substances into the Environment**

### **a) As a result of Manufacture**

Under 21 Code of Federal Regulations (CFR) § 25.40(a), an EA should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. The FCS concentrate is manufactured in plants that meet all applicable federal, state and local environmental regulations. CraftChem, Inc. asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS concentrate.

### **b) As a result of Use/Disposal**

Based on the described use pattern (i.e., diluted FCS solution in process water used to wash raw and processed fruits and vegetables in food processing facilities), and based on the chemical properties of the FCS component chemicals, the primary pathway of the FCS reaching the environment is through the disposal and treatment of plant processing wastewater. Thus, use of the diluted FCS solution will result in the introduction of the FCS into the environment following disposal of plant processing wastewater and subsequent treatment on-site or at local POTWs.

Following wastewater treatment, the only chemical component expected to reach the environment to any significant extent is HEDP (see discussion under Item 7). HEDP is expected to partition to sludge and effluent (80:20) during treatment and its potential introduction to aquatic and terrestrial environments from effluent discharges or land applications is examined herein.

#### **1) Maximum market volume for proposed use**

An estimated annual production volume of the FCS concentrate is included in Confidential Attachment A. However, the total amount of diluted FCS solution used at a typical food processing facility to wash raw and processed fruit and vegetables will vary depending on equipment used, amount and types of fruit and vegetables being washed, and microbial stress at a given site. Therefore, the expected introduction concentration (EIC) in surface water is estimated based on the maximum in-use concentrations described in Item 4.a.

#### **2) Percent of market volume that will enter the environment**

To estimate the introduction of FCS into aquatic and/or terrestrial environments, 100% of the component chemicals in the diluted FCS solution

are considered to be disposed of with waste processing waters. As a worst-case scenario, it is assumed that 100% of the diluted FCS solution enters an on-site water treatment system operated under an active NPDES permit. Therefore, the fate of each component chemical during wastewater treatment is considered when calculating the EIC.

### 3) The mode of chemical introduction into the environment

The diluted FCS solution may be used continuously or in batches/loads in accordance with demand at each processing facility.

### 4) Expected concentration of chemicals introduced into the environment

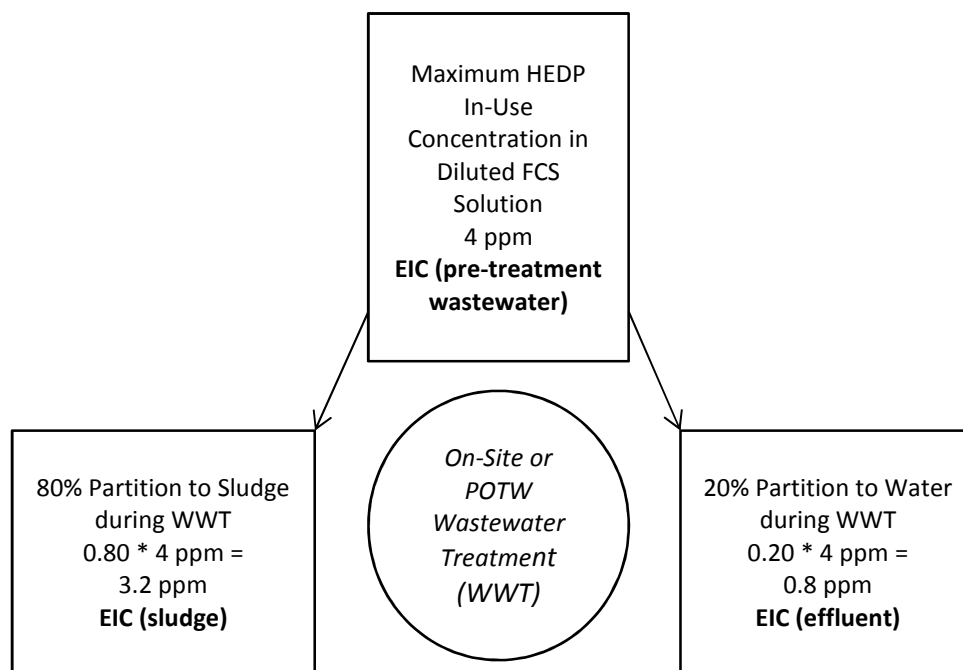
Based on the chemical properties of the FCS component chemicals, HEDP is the only component chemical anticipated to reach the environment to any significant extent following on-site or off-site wastewater treatment. We have provided a qualitative evaluation under Item 7 of this EA to support that, because PAA, H<sub>2</sub>O<sub>2</sub>, and AA will degrade rapidly in contact with organic matter, these substances are not expected to be introduced into the environment to any significant extent resulting from the proposed use of the diluted FCS solution (i.e., in process water used to wash raw and processed fruits and vegetables in food processing facilities). Furthermore, sulfuric acid will dissociate readily to sulfate in the presence of water. Therefore, quantitative evaluations of the expected introduction or environmental concentrations and ecotoxicity for these compounds are not necessary.

We elected to use the following framework (see Figure 2) to quantitatively estimate the Expected Introduction Concentration (EIC) of HEDP based on its maximum in-use concentration, 4 ppm, and its partitioning characteristics during wastewater treatment. Table 1 provides the in-use concentrations and EIC in pre-treatment wastewater of HEDP for the proposed uses, which includes use on raw and processed fruits and vegetables.

**Table 1. HEDP Maximum In-Use Concentrations and Expected Introduction Concentrations in Pre-Treatment Wastewater**

Use	HEDP EIC <sub>pre-treatment wastewater</sub>
Process water used to wash raw and processed fruits and vegetables	4 ppm

Wastewater containing the diluted FCS solution is expected to be disposed of through the processing plant wastewater treatment facility or through a local POTW. During on-site wastewater treatment or treatment at a POTW, HEDP is removed from water primarily through adsorption onto sludge; 80% of HEDP present expected to adsorb to sludge (HERA, 2004). Therefore, based on this unique partitioning behavior of HEDP (80:20), only 20% of the maximum in-use concentration is anticipated to remain in the aqueous phase (i.e., wastewater treatment effluent) for eventual release to surface water.



**Figure 2. Framework for Estimating EICs for HEDP**

**Expected Introduction Concentration (EIC):** Based on the framework shown in Figure 2 and the conservative assumptions outlined above, the estimated EICs for HEDP are 0.8 ppm in effluent and 3.2 ppm in wastewater treatment sludge (see Table 2).

**Table 2. HEDP Expected Introduction Concentrations in Effluent and Sludge**

Use	HEDP Maximum In-Use Concentration (ppm)	EIC <sub>effluent</sub> (ppm)	EIC <sub>sludge</sub> (ppm)
Process water used to wash raw and processed fruits and vegetables	4	0.8	3.2

Via Wastewater Effluent: The chemical species present in the diluted FCS solution are aqueous and, after use to wash raw and processed fruits and vegetables, chemicals surviving wastewater treatment will be introduced into the aquatic environment following treatment via the wastewater treatment and disposal stream. This pathway to surface water represents the primary route of introduction of the FCS into the environment.

As a worst-case scenario, it is assumed that 100% of the diluted FCS solution enters an on-site water treatment system operated under an active NPDES permit. Additionally, no pre-treatment/pre-release dilution with other process waters is assumed. Aside from assuming 100% of the diluted FCS solution used enters on-site water treatment and no pre-treatment dilution in other process waters, employing the maximum in-use concentration (i.e., 350 ppm PAA) adds another layer of conservatism, as this in-use concentration is only expected to be employed sporadically, as needed, due to economic considerations. Therefore, the estimation of the EIC in effluent represents a conservative estimate of environmental exposure.

Via Wastewater Sludge: Following wastewater treatment, sludge containing HEDP may subsequently be landfilled or land applied; however, releases of HEDP to the environment from such subsequent pathways are expected to be controlled through relevant EPA regulations and state and local guidelines. Under a scenario where HEDP-containing sludge ends up in a Municipal Solid Waste (MSW) landfill, the actual amount that would enter the environment would be minimal due to U.S. EPA regulations designed to restrict movement of waste into the environment, including location restrictions, composite liner requirements, leachate collection and removal systems, operating practices, and groundwater monitoring requirements (40 CFR Part 258). While landfills or surface impoundments are the most common destinations for wastewater treatment sludge, a portion may be land applied. Such applications are regulated under U.S. EPA 40 CFR 503 Standards, which establish pollutant limits, general requirements, operational standards for pathogen and vector attraction reduction, management practices, monitoring frequency, and recordkeeping and reporting requirements for land appliers and facilities generating sludge for use in land application (U.S. EPA, 1994). While, in general, MSW sludge may be incinerated, most sludge incinerators are located at POTW sites. As there are only a few facilities in the United States that co-fire MSW with biosolids, we do not expect sludge generated at food processing facilities when fruits and



vegetables are washed to be incinerated at MSW combustors (U.S. EPA, 1999).

**EIC - Untreated Wastewater Scenario:** Since fruit and vegetable facilities are not subject to Industrial Effluent Guidelines unless canning or other preservation steps are conducted<sup>1</sup>, under this scenario, it is conservatively assumed that all fruit and vegetable processors discharge directly to surface waters, in accordance to NPDES regulations. Therefore, as a worst-case scenario, it is assumed that wastewater containing the diluted FCS solution would not enter a waste water treatment system, undergo pre-treatment/pre-release dilution, or partitioning to sludge, and the estimated EIC for HEDP is 4 ppm in effluent (the same as HEDP maximum in-use concentration of 4 ppm).

## 7. Fate of Substances Released into the Environment

As introduced in Item 6.b., HEDP is the only component chemical of the diluted FCS solution expected to survive wastewater treatment and to be introduced into the environment in any measurable quantity. However, the environmental fate of other component chemicals is discussed qualitatively herein.

On-site treatment of processing wastewaters is expected to result in nearly 100% degradation of the PAA, H<sub>2</sub>O<sub>2</sub>, AA, and sulfuric acid components of the diluted FCS solution. This expectation is based on the half-lives and behavior of PAA, H<sub>2</sub>O<sub>2</sub>, AA, and sulfuric acid in sewage treatment plants and/or aquatic environments.

PAA and H<sub>2</sub>O<sub>2</sub> are short-lived due to the inherent instability of their peroxide (O-O) bonds, for which breaking such bonds to form water and O<sub>2</sub> is highly thermodynamically favored (U.S. EPA, 1993). In water, PAA rapidly degrades to AA and oxygen or hydrolyzes to AA and hydrogen peroxide. In buffered solutions, PAA's half-life ranged from <0.25 to 64 hours, depending on the concentration of PAA and solution pH, with decomposition occurring more rapidly when diluted solutions were used (ECETOC, 2001). H<sub>2</sub>O<sub>2</sub> degrades to water and oxygen due to a reaction with itself, transition metals, free radicals, organic compounds, heat, or light and degradation data demonstrates a half-life of only 2 minutes in sewage treatment plants (HERA, 2005). Likewise, AA readily dissociates in water to the hydrogen proton and acetate anion, which is readily biodegradable to carbon dioxide and water (The Weinberg Group, 2003; U.S. EPA, 1993). Sulfuric acid dissociates readily in water to sulfate ions (SO<sup>4-</sup>) and hydrated protons; at environmentally-relevant concentrations, sulfuric acid is practically totally dissociated (OECD SIDS, 2001). As part of the natural sulfur cycle, sulfate is either incorporated

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<sup>1</sup> <https://www.epa.gov/eg/industrial-effluent-guidelines>

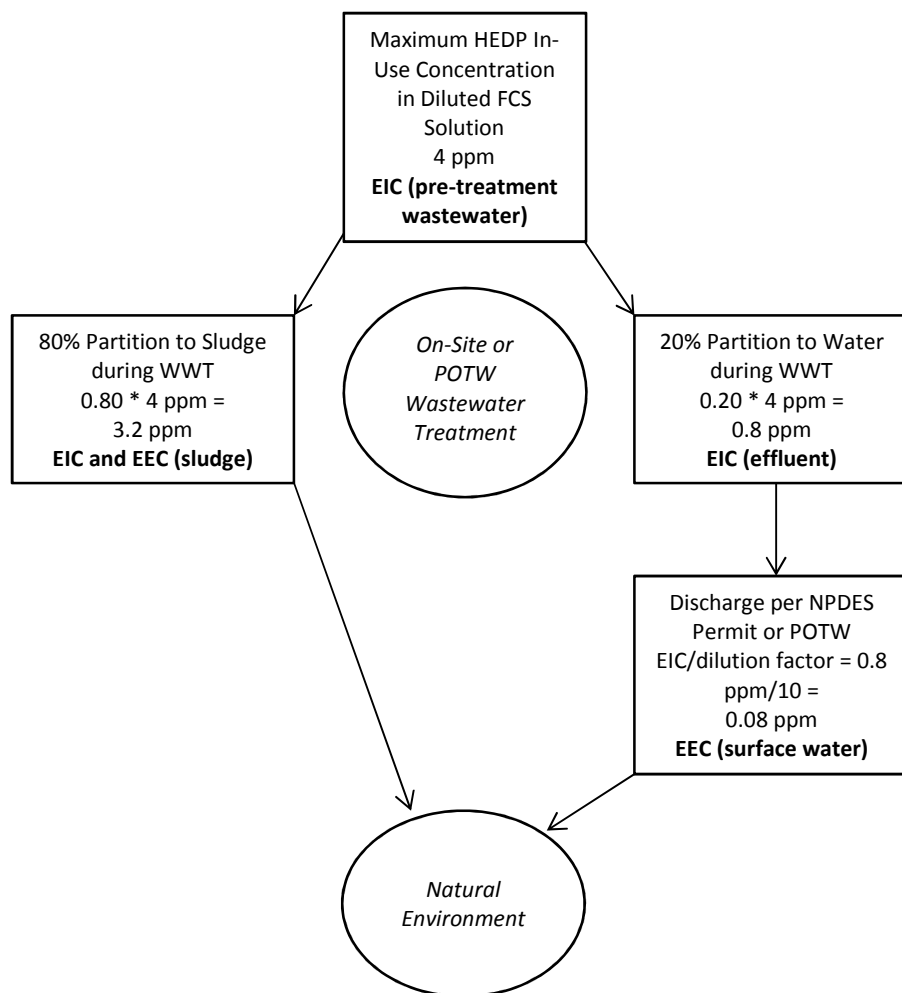
into living organisms, reduced via anaerobic biodegradation to sulfides, deposited as sulfur, or re-oxidized to sulfur dioxide and sulfate (HERA, 2006). None of these compounds (PAA, H<sub>2</sub>O<sub>2</sub>, AA, sulfuric acid) are expected to accumulate in living tissues.

For reasons described above, the only FCS component chemical that is likely to be present in measurable quantities in following wastewater treatment is HEDP. Table 3 presents environmental fate properties of HEDP and a discussion of the fate of HEDP in the environment follows.

**Table 3. Environmental Fate Properties of HEDP**

Property	Value	Source
Vapor Pressure	1 x 10 <sup>-10</sup> mmHg	HERA (2004)
Water Solubility @ 25°C	6.9 x 10 <sup>5</sup> mg/L	
Henry's Law Constant	5 x 10 <sup>-17</sup>	
Log K <sub>ow</sub>	-3.49	
pK <sub>a</sub> (Ca <sup>2+</sup> )	6.8	Jaworska et al. (2002)
pK <sub>a</sub> (Cu <sup>2+</sup> )	18.7	
K <sub>water-soil</sub>	20-190	
K <sub>water-active sludge</sub>	2600-12700	
K <sub>water-river sediment</sub>	920-1300	

During on-site wastewater treatment, HEDP is removed from water primarily through adsorption onto sludge; 80% of the HEDP present in wastewater is expected to adsorb to sludge, with some tests demonstrating >90% adsorption to sludge (HERA, 2004). Therefore, it is estimated that only 20% of the maximum in-use concentration is anticipated to remain in the aqueous phase for eventual release to surface water. For estimation of the Expected Environmental Concentration (EEC), i.e., the concentration organisms in the environment would be exposed to, FDA acknowledges a 10-fold dilution factor for discharge from POTWs to surface waters, which is applied to the aquatic EIC (Rapaport, 1988). See Figure 3 and Table 4 for the framework followed and resulting EEC estimates.



**Figure 3. Framework for Estimating EECs for HEDP**

**Expected Environmental Concentration (EEC) in Surface Water:** In order to evaluate the expected environmental concentration (EEC) of HEDP in surface water, a 10-fold dilution factor is applied to the aquatic EIC (EIC = 0.8 ppm). Therefore, the EEC of HEDP from the proposed use is estimated to be 0.08 ppm in surface waters directly receiving the treated effluent.

**Expected Environmental Concentration (EEC) in Wastewater Sludge:** The EEC of HEDP from the proposed use is estimated to be 3.2 ppm in sludge following on-site wastewater treatment. As no additional dilution factor or removal mechanism is applied following adsorption to sludge, the EIC is assumed to equal to the EEC in this scenario. Therefore, the EEC does not incorporate degradation.

Table 4 below displays the maximum in-use concentration; EICs in pre-treatment wastewater, effluent, and wastewater sludge; and the EEC in surface water for HEDP.

**Table 4. Maximum In-Use Concentration, Expected Introduction Concentrations, and Expected Environmental Concentrations for HEDP**

Use	HEDP Maximum In-Use Concentration (ppm)	EIC <sub>pre-treatment wastewater</sub> (ppm)	EIC <sub>effluent</sub> (ppm)	EIC <sub>sludge</sub> (ppm)	EEC <sub>water</sub> (ppm)	EEC <sub>sludge</sub> (ppm)
Process water used to wash raw and processed fruits and vegetables	4	4	0.8	3.2	0.08	3.2

**EEC – Untreated Wastewater Scenario:** As earlier noted, since fruit and vegetable facilities are not subject to Industrial Effluent Guidelines unless canning or other preservation steps are conducted, under this scenario, it is conservatively assumed that all fruit and vegetable processors discharge directly to surface waters, in accordance to NPDES regulations. Therefore, under the worst-case assumption that effluent is directly discharged to surface waters with no further treatment of effluent at a POTW and no partition to sludge, the EEC of HEDP in surface water would be the same as the EIC of 4 ppm. There would be no sludge disposal.

HEDP Fate in Aquatic Environment: Wastewaters from food processing facilities that contain the diluted FCS solution is expected to be disposed of through the processing plant wastewater treatment facility or through a local POTW. Once HEDP enters the aquatic environment, it is quite stable, though hydrolysis and degradation are enhanced in the presence of metal ions, aerobic conditions, and light (HERA, 2004). Photolysis can serve as an important route for the removal of phosphonates like HEDP from the environment, with photodegradation half-lives varying from hours to days depending on the presence of cofactors such as oxygen, peroxides, and complexing metals like iron, copper, or manganese (Jaworska et al., 2002). For example, in the presence of iron ions, 40-90% degradation occurs within 17 days (HERA, 2004).

In sediment/river water systems, the ultimate biodegradation of HEDP is estimated as 10% in 60 days, with a corresponding half-life of 395 days (HERA, 2004). In such systems, phosphonates like HEDP can become tightly adsorbed onto the sediment, indicating that the major part of biodegradation may occur in the sediment, where a half-life of 471 days was observed for HEDP (HERA, 2004). While hydrolysis half-lives are comparatively long (50-200 days) when compared with photodegradation, hydrolysis may serve as a significant route of removal in soil and sediment environments (Jaworska et al., 2002).

HEDP Fate in Terrestrial Environment: As shown earlier (see Figure 2), HEDP is expected to partition to water and sludge during wastewater treatment. Sludge resulting from wastewater treatment may end up landfilled or land applied. If land-applied, HEDP shows degradation in

soil; as such, disposal on land should ensure mineralization and removal from the environment (HERA, 2004). HEDP's half-life in soil is estimated to be 373 days, extrapolated from observed degradation of 20% after 120 days (HERA, 2004). Phosphonates are also sensitive to radical-mediated degradation, which may operate in the soil environment and serve as a method for the removal of phosphonate pollution (Jaworska et al., 2002).

Land applications related to the proposed use will result in phosphorus concentrations in soil that are an insignificant fraction of total phosphorus concentrations introduced into the environment as fertilizers (see Confidential Attachment A). For example, USDA reported that, in 2011, over 8.5 million tons of phosphate fertilizers were consumed in the U.S. (USDA, 2013). Annual production and use of the FCS itself is negligible when compared with this figure (see Confidential Attachment A), and the annual land application of any HEDP-containing sludge or treated effluent that could be expected from the proposed use represents an even more insignificant portion of land-applied phosphorus.

If HEDP-containing sludge is disposed of in a landfill, HEDP would be expected to be controlled by the relevant EPA regulations and state or local guidelines, as described in Item 6.b.

## 8. Environmental Effect of Released Substances

Based on the chemical properties of the FCS component chemicals, HEDP is the only FCS component chemical anticipated to reach the environment to any significant extent following disposal and wastewater treatment, as discussed in Item 7. Therefore, environmental effects are evaluated by comparing the most sensitive aquatic and terrestrial toxicity endpoints against the EECs for HEDP alone. See Table 5 for a summary of HEDP's ecotoxicity endpoints, with the most-sensitive relevant endpoint bolded. However, because the sulfuric acid present in the diluted FCS solution is likely to reach the aquatic environment as sulfate, a discussion of sulfate toxicity is also included herein.

**Table 5. Summary of Environmental Toxicity Endpoints for HEDP**

Duration	Test Species	Endpoint	Source
<b>Aquatic Ecotoxicity Data</b>			
Short-Term	<i>Lepomis macrochirus</i> (Bluegill Sunfish)	96-hr LC <sub>50</sub> = 868 ppm	Jaworska et al. (2002)
	<i>Onchorhynchus mykiss</i> (Rainbow Trout)	96-hr LC <sub>50</sub> = 360 ppm	
	<i>Cyprinodon variegatus</i> (Sheepshead Minnow)	96-hr LC <sub>50</sub> = 2180 ppm	
	<i>Ictalurus punctatus</i> (Channel Catfish)	96-hr LC <sub>50</sub> = 695 ppm	
	<i>Leuciscus idus melonatus</i> (Ide)	48-hr LC <sub>50</sub> = 207-350 ppm	
	<i>Daphnia magna</i> (Water Flea)	24-48-hr EC <sub>50</sub> = 165-500 ppm	
	<i>Chironomus</i> (Midge)	48-hr EC <sub>50</sub> = 8910 ppm	HERA (2004)
	<i>Palaemonetes pugio</i> (Grass Shrimp)	96-hr EC <sub>50</sub> = 1770 ppm	Jaworska et al. (2002)
	<i>Crassostrea virginica</i> (Eastern Oyster)	96-hr EC <sub>50</sub> = 89 ppm	(2002)

Duration	Test Species	Endpoint	Source
	<i>Selenastrum capricornutum</i> (Green Algae) <sup>1</sup>	96-hr EC <sub>50</sub> = 3.0 ppm NOEC = 1.3 ppm	HERA (2004), Jaworska et al. (2002)
	<i>Chlorella vulgaris</i> (Green Algae)	48-hr NOEC ≥ 100 ppm	Jaworska et al. (2002)
	<i>Pseudomonas putida</i> (Bacterium)	30-min NOEC = 1000 ppm	
Long-Term	<i>Oncorhynchus mykiss</i> (Rainbow Trout)	14-day NOEC = 60-180 ppm	HERA (2004)
	<b><i>Daphnia magna</i> (Water Flea)</b>	<b>28-day NOEC = 10-&lt;12.5 ppm</b>	
	<i>Selenastrum capricornutum</i> (Green Algae) <sup>1</sup>	14-day NOEC = 13.2 ppm	
Terrestrial Ecotoxicity Data			
Short-Term	Terrestrial Plants	14-day EC <sub>50</sub> > 960 ppm No effects on seed germination up to 100 ppm	HERA (2004)
	<i>Eisenia foetida</i> (Earthworm)	14-day NOEC = 1000 ppm > 1000 ppm	
	Avian	Oral LD <sub>50</sub> >2500 ppm (diet) >284 ppm (bw)	

<sup>1</sup> For chelating agents, such as HEDP, algal growth inhibition results may be strongly impacted by chelation of trace nutrients. This effect is often interpreted incorrectly as a toxic effect, rather than what it is – a nutrient limitation. For such tests, results are likely to be of questionable value for classifying substances or for use in risk estimations (HERA, 2004).

The most sensitive relevant endpoint for HEDP is 10 ppm, associated with long-term exposure to the freshwater invertebrate, *Daphnia magna*. As footnoted, the lower endpoint associated with algal exposure is not toxicologically relevant, as it reflects the chelation of nutrients and nutrient limitation, rather than direct toxicity of HEDP. In HERA's 2004 risk assessment of phosphonates, authors described such results as being of questionable value for classifying a substance or for use in exposure and risk estimations. When compared against the 28-day *Daphnia* NOEC of 10 ppm, the worst-case surface water EEC for HEDP (4 ppm from the untreated wastewater scenario) is more than one order of magnitude lower than the most sensitive aquatic toxicity endpoint. Thus, adverse environmental effects to aquatic organisms are not indicated based on a comparison of the EECs against aquatic toxicity endpoints.

HEDP in effluent or sludge applied to land is not expected to have any adverse environmental impacts based on the available terrestrial toxicity endpoints for plants, invertebrates, and avian species, which range from a terrestrial plant no effect level of 100 ppm to a 14-day no effect level of 1000 ppm in earthworms. The highly-conservative EEC of HEDP in sludge is 3.2 ppm, which is more than one order of magnitude lower than the most sensitive terrestrial endpoint. This assumes no degradation of HEDP before or after such land applications, which is not likely.

Based on very conservative assumptions, the resulting EECs for HEDP are still far less than the most sensitive aquatic and terrestrial endpoints examined. Therefore, adverse environmental effects are not anticipated based on the proposed use.

As described in Item 7, sulfuric acid present in the diluted FCS solution is expected to rapidly dissociate in water to sulfate. Sulfate is a ubiquitous environmental anion and low concentrations are well-tolerated in aquatic environments. For example, sodium sulfate shows low acute toxicity, with LC<sub>50</sub>/EC<sub>50</sub> values for fish, algae, and Daphnia >1000 ppm and the most sensitive endpoint equal to 1900 ppm for algae (HERA, 2006). Due to sulfate's low aquatic toxicity and the natural recycling that occurs via the sulfur cycle, the release of sulfates to surface waters as a result of the proposed use is not anticipated to adversely impact the environment. Furthermore, the levels of sulfate that aquatic organisms would be exposed to as a result of the proposed use, and assuming no removal during wastewater treatment, would be low compared with background levels of sulfate found in river water (20-50 ppm) (HERA, 2006). See Confidential Attachment A for calculations supportive of this finding.

## **9. Use of Resources and Energy**

No net increase in the use of energy and resources is expected for the use of the antimicrobial agent as the components readily degrade. This FCS is expected to compete with, and to some degree replace, similar antimicrobial agents already on the market, include, i.e., the FCS identified in FCN No. 140, 699, 887, 908, 993, 1081, 1083, 1093, and 1594.

## **10. Mitigation Measures**

The intended use of the FCS is not reasonably expected to create any new environmental problem that would require mitigation measures. As discussed above, the use and disposal of the FCS is not expected to result in significant adverse environmental impacts; therefore, mitigation measures are not necessary.

## **11. Alternatives to the Proposed Action**

The addition of this product to the options available to food processors is not expected to increase the use of PAA antimicrobial agent products; rather, it will serve as a replacement product, competing with those already in use in the market place. No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials that the FCS would otherwise replace; such action would have no environmental impact.

## **12. List of Preparers**

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*Ms. Bi has a background in chemistry and more than eight years of experience in dietary assessments as well as the research and review of chemical residue and toxicity data.*

### 13. Certification

The undersigned official certifies that the information presented is true, accurate and complete to the best of her knowledge.

Signature: \_\_\_\_\_



Xiaoyu Bi  
Managing Scientist, Exponent, Inc.

Date: \_\_\_\_\_

November 17, 2016

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## **15. Attachments**

CONFIDENTIAL Attachment A: Sales Projections, Component Chemical Concentrations, and Associated Calculations (Separate Enclosure)