

**Environmental Impact of Food Contact Substance (21 CFR Part 25)  
FDA Form 3480 Part IV, Section B**

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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 to permit the use of the food contact substance (FCS) Neo-Temper<sup>®</sup> as an antimicrobial agent for use on grains during tempering and before milling. Neo-Temper<sup>®</sup>, an aqueous solution of peroxyacetic acid (PAA) (CAS Reg. No. 79-21-0), hydrogen peroxide (HP) (CAS. Reg. No. 7722-84-1), acetic acid (AA) (CAS Reg. No. 64-19-7), sulfuric acid (SA) (CAS Reg. No. 7664-93-9), and 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), that is prepared by mixing 40% Neo-Pure<sup>®</sup> and 60% Synergy<sup>®</sup> at the point of use.

Grains may be treated with the FCS **only once**, at a maximum use rate of 5 L of the FCS per 1 ton (1000 kg) of grain. Hence, the maximum concentrations of the components of the FCS **on** grains will not exceed 114 parts per million (ppm) peroxyacetic acid (PAA), 1,704 ppm Hydrogen Peroxide (HP), 193 ppm acetic acid (AA), 25 ppm sulfuric acid (SA), and 12.5 ppm 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP).

The use of the FCS and preparation of the diluted FCS solution prior to application on

grains is a batch application, i.e. diluted FCS solution is prepared daily and is applied directly to the grains during tempering (i.e. in process water as a bath application). The application of the diluted FCS solution is associated with the maximum concentrations of the FCS applied to grains as listed above in Item 4.a. A maximum amount of 5 L of the FCS is diluted in a minimum of 35L and a maximum of 65L of water for a total of 40-70L of solution, depending on the moisture content of the grain.

To calculate highest exposure potential, the diluted FCS solution with the highest potential concentration FCS is utilized for further calculations. In this scenario 5 L of the FCS is diluted in 35 L water to prepare a total volume of 40 L of diluted FCS solution and applied to one ton of grain. When the FCS is diluted with 35 L of water, based on the active components, the maximum concentrations of the components of the FCS in the solution will not exceed 2,500 ppm PAA, 37,750 ppm HP, 4,250 ppm AA, 550 ppm SA, and 275 ppm HEDP. Four to twenty-four hours after treatment, treated grains are dried.

**b) Need for Action:**

The FCS is intended for use as an antimicrobial agent to inhibit the growth of undesirable or pathogenic microorganisms on soft, hard and durum wheat, corn and rice grains.

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

Use: The FCS is intended for use as an antimicrobial agent to inhibit the growth of undesirable or pathogenic microorganisms on grains in grain processing facilities nationwide, where the processing of food will occur after treatment.

Disposal: 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 will undergo pretreatment on-site and 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 FCS is an aqueous solution of PAA, HP, AA, SA, HEDP and water produced by blending AA, HP, distilled water, and HEDP, while using SA as a catalyst for the reaction. PAA formation is the result of an equilibrium reaction between HP and AA (see Figure 1).

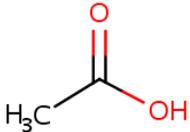
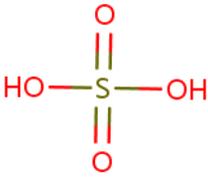


**Figure 1. PAA Formation.**

The chemical identity of the FCS is provided in Table 1. Concentration of each identified chemical component in the FCS and in the diluted in-use FCS solution are included in **Confidential Attachment A**.

**Table 1. Chemical Identity of the FCS.**

Name	CASRN	Formula	Structure	Molecular Weight (g/mol)
Peroxyacetic acid (PAA)	79-21-0	C <sub>2</sub> H <sub>4</sub> O <sub>3</sub>		76.0506
Hydrogen peroxide (HP)	7722-84-1	H <sub>2</sub> O <sub>2</sub>		34.0138
1-hydroxyethylidene-1,1 diphosphonic acid (HEDP)	2809-21-4	C <sub>2</sub> H <sub>8</sub> O <sub>7</sub> P <sub>2</sub>		206.0262

Acetic acid (AA)	64-19-7	C <sub>2</sub> H <sub>4</sub> O <sub>2</sub>		60.0516
Sulfuric acid (SA)	7664-93-9	H <sub>2</sub> SO <sub>4</sub>		98.0778

All chemical information presented in Table 1 above was obtained from ChemIDplus.

## 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 is manufactured in plants that meet all applicable federal, state and local environmental regulations. Agri-Neo, Inc. asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS.

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

Based on the specific use pattern of the FCS described above (i.e., diluted FCS solution utilized in process water for tempering grains, the primary pathway by which the FCS is anticipated to be introduced to the environment is through the treatment and disposal of plant processing wastewater. Thus, waste processing water generated at the facility and containing the diluted FCS material may be introduced to the environment via treatment and disposal of plant processing wastewater on-site, at local POTWs, or some combination thereof.

Following wastewater treatment, HEDP is the only chemical component of the FCS expected to reach the environment to any significant extent (see discussion under Item 7). Due to unique chemical properties, HEDP is anticipated to partition into sludge and effluent during on-site water treatment or treatment at a POTW. The majority of HEDP (80%) is assumed to adsorb into sludge during the treatment process. Remaining HEDP (20%) is anticipated to remain in aqueous solution (i.e., wastewater treatment effluent) (HERA, 2004). Potential HEDP introduction to aquatic and terrestrial environments from

effluent discharges or land application of sludge material is examined in this assessment.

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

An estimated annual sales volume of the FCS in the US is included in **Confidential Attachment A**. The total amount of FCS used at a typical grain processing facility to temper grains will depend on the total volume of grains being processed with the FCS at that site, as well as microbial stress level at that given site. Therefore, for the purposes of this assessment the expected environmental introduction concentration (EIC) in surface water is calculated based on a worst-case, intentionally conservative assumption that all of the diluted FCS solution utilized at a given site is discharged to surface waters.

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

To estimate the introduction of FCS into aquatic and/or terrestrial environments under a worst-case scenario in which 100% of the component chemicals in the FCS are disposed of with waste processing waters. Under this assumption, 100% of the FCS used at a given facility enters an on-site or off-site wastewater treatment system and may be released into aquatic and/or terrestrial environments. Therefore, the fate of each chemical component in the FCS during wastewater treatment is considered when calculating the EIC.

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

The diluted FCS solution will be batch-prepared prior to grain application in tempering. Assuming the worst-case exposure scenario, all of the diluted FCS solution will be discharged to surface waters.

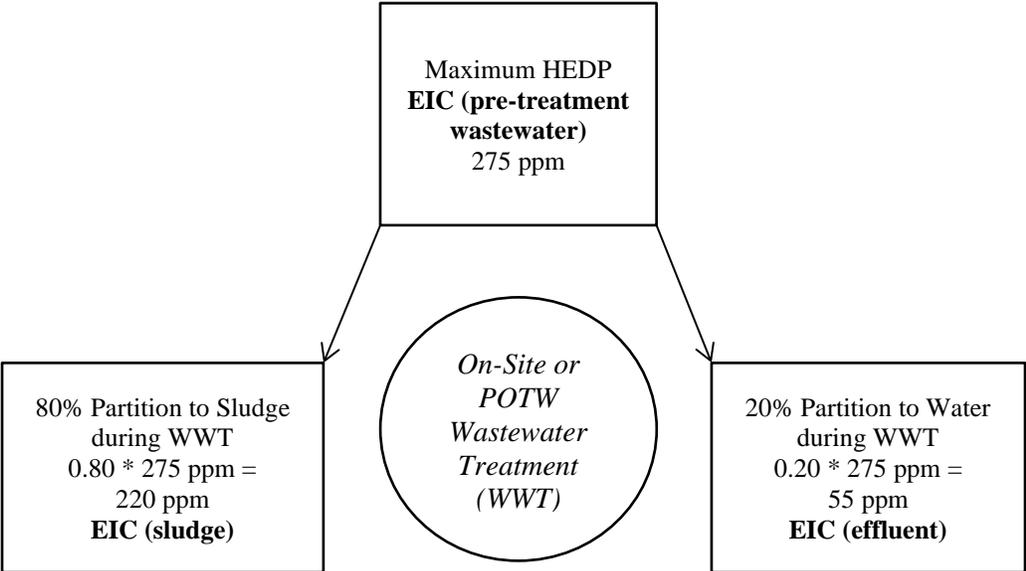
**4) Expected concentration of chemicals introduced into the environment**

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, HP, 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 FCS (i.e., in process water utilized to temper grains). 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.

HEDP is the only chemical component of the FCS anticipated to reach the environment to any significant extent following on-site or off-site wastewater treatment. Figure 2 below outlines the framework utilized in this assessment to quantitatively estimate the Expected Introduction Concentration (EIC) of HEDP.

Based on the label instruction, a maximum 5 L of the FCS is diluted in 35 L water, for a total volume of 40 L of the diluted FCS solution, is applied to 1 ton of grain in a tempering bath application. As outlined above, assumptions representing a worst-case scenario, in which 100% of the diluted FCS solution would be discharged into surface water, were utilized to calculate the Expected Introduction Concentration (EIC). Based on the above-outlined assumption, and the maximum HEDP concentration in the diluted FCS solution outlined in Confidential Attachment A, the upper-bound EIC for HEDP in pre-treated wastewater is 275 ppm.

Diluted FCS solution introduced to processing plant wastewater is expected to be disposed of through the 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. HEDP is anticipated to partition unequally, with 80% expected to adsorb to sludge (HERA, 2004). Therefore, based on the unique partitioning behavior of HEDP (80:20) and assuming a maximum of 80% of the introduced HEDP is adsorbed onto sludge, 220 ppm HEDP ( $275 \text{ ppm} \times 80\% = 220 \text{ ppm}$ ) is anticipated to be removed by adsorption onto wastewater treatment sludge. Only 20% of HEDP entering wastewater (i.e.,  $275 \text{ ppm} \times 20\% = 55 \text{ ppm}$ ) is anticipated to remain in aqueous wastewater treatment effluent, for eventual release to surface water (HERA, 2004).



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

**Expected Introduction Concentration:** Based on the above framework and the conservative assumptions outlined above, the estimated EICs for HEDP are 55 ppm in effluent, and 220 ppm in sludge (Table 2).

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

Use	HEDP Maximum		
	EIC <sub>pre-treatment wastewater</sub> (ppm)	EIC <sub>effluent</sub> (ppm)	EIC <sub>sludge</sub> (ppm)
Antimicrobial agent for use in process water utilized to temper grains	275	55	220

Some grains may have use rates lower than the maximum. As such, using the maximum use rate in the expected environmental concentrations is protective/covers the lower use rates.

Via Wastewater Effluent: The chemical species present in the FCS are in aqueous phase. After use in process water to temper grains, chemicals surviving wastewater treatment will be introduced into the aquatic environment (i.e., surface waters) via the wastewater disposal stream from the processing plant. This pathway to surface water represents the primary route of introduction of the FCS into the environment.

Via Wastewater Sludge: Within the U.S., residual sludge from the wastewater treatment process is most commonly disposed of by land application, relocation to a surface disposal site or by incineration. Following wastewater treatment, sludge containing HEDP may subsequently be landfilled or land applied.

However, 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 applicators and facilities generating sludge for use in land application (U.S. EPA, 1994).

Our knowledge of disposal methods for food treatment facilities indicates that incineration is not a common disposal method for sludge generated at food treatment facilities. General MSW sludge is more commonly disposed of via incineration. Sewage

sludge incinerators are regulated under 40 CFR Part 60, and if/when HEDP is combusted, there is nothing to suggest the HEDP would threaten a violation of 40 CFR 60, the regulations governing sewage sludge incinerators, as carbon, hydrogen, phosphorus and oxygen are typical elements in MSW and in sludge.

## **7. Fate of Substances Released into the Environment**

As introduced in Item 6(b), on-site treatment of processing wastewaters is expected to result in nearly 100% degradation of the PAA, HP, AA, and SA components of the diluted FCS solution. The unique chemical properties of PAA, HP, and AA impart rapid degradation in contact with organic matter. Likewise, SA degrades readily in water. Thus, of the chemical components in the FCS, only HEDP is expected to survive wastewater treatment and to be introduced into the environment in any measurable quantity. The environmental fate of other component chemicals (PAA, HP, AA, SP) is discussed qualitatively below.

PAA and HP 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). HP 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<sub>4</sub><sup>2-</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 into living organisms, reduced via anaerobic biodegradation to sulfides, deposited as sulfur, or re-oxidized to sulfur dioxide and sulfate (HERA, 2006). Therefore, any terrestrial or aquatic discharges of sulfate associated with the use described in this FCN are not expected to have any significant environmental impact, as sulfate is a ubiquitous anion that is naturally present in the ecosystem and virtually indistinguishable from industrial sources (HERA, 2006).

Due to their rapid degradation, none of the above-outlined components (PAA, HP, AA, or SA) are expected to accumulate in living tissues.

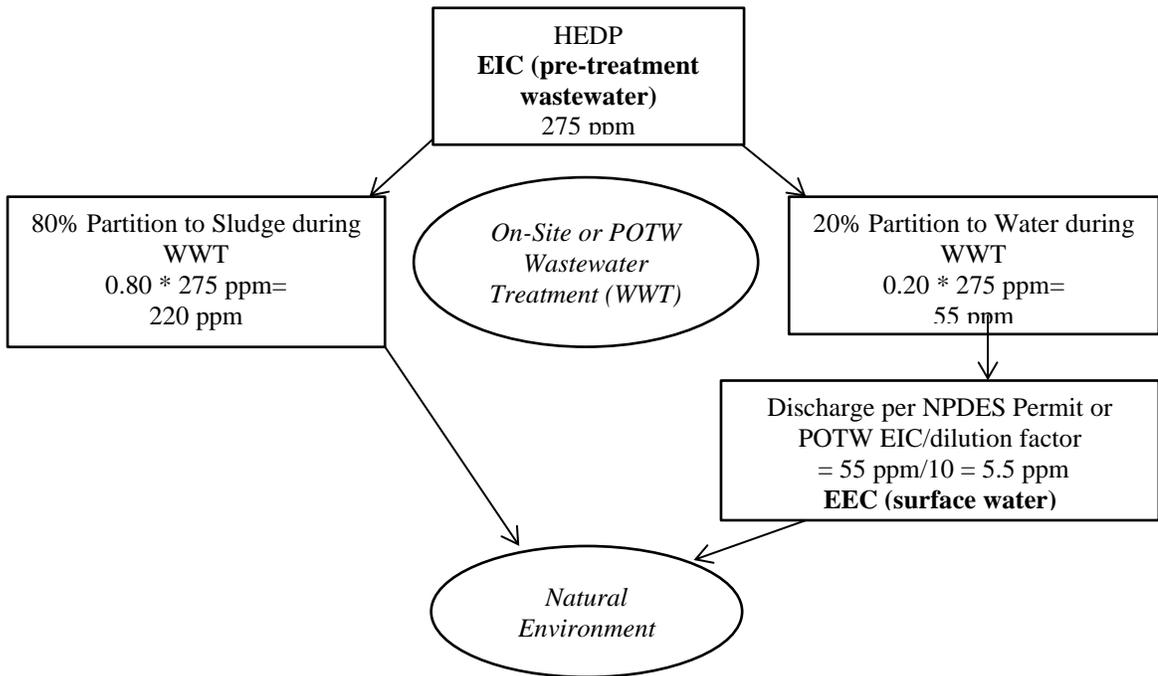
The only FCS component anticipated to survive wastewater treatment in any measurable

quantity is HEDP. Fate properties of HEDP are outlined in Table 3. A detailed discussion of the fate of HEDP in the environment is provided below.

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

Property	Value	Source
Vapor Pressure	$1 \times 10^{-10}$ mmHg	HERA (2004)
Water Solubility @ 25°C	$6.9 \times 10^5$ mg/L	
Henry's Law Constant	$5 \times 10^{-17}$	
Log $K_{ow}$	-3.49	
$pK_s$ ( $Ca^{2+}$ )	6.8	Jaworska et al. (2002)
$pK_s$ ( $Cu^{2+}$ )	18.7	
$K_{water-soil}$	20-190	
$K_{water-active\ sludge}$	2600-12700	
$K_{water-river\ sediment}$	920-1300	

During 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 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, a 10-fold dilution factor for discharge from POTWs to surface waters 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 = 5.5 ppm) (Rapaport, 1998). Therefore, the EEC of HEDP from the proposed use is estimated to be 5.5 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 220 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 (EIC = EEC = 220 ppm). Therefore, the EEC does not incorporate degradation.

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

**Table 4. Maximum Expected Introduction Concentrations, and Expected Environmental Concentrations for HEDP**

Use	Maximum 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)
Antimicrobial agent for use in process water utilized to temper grains	275	55	220	5.5	220

A detailed discussion of the potential fate of the HEDP that may be released into the environment is included as follows:

**a. Air**

No significant effect on the concentration of and exposure to HEDP in the atmosphere is anticipated due to the proposed use of the FCS.

**b. Water**

Wastewaters from food processing facilities that contain the FCS are 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 calculated 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).

### c. Land

As discussed in section 6(4) above, HEDP is expected to partition to water and sludge during wastewater treatment (see Figure 2). 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 (**Confidential Attachment A**). For example, USDA reported that, in 2015, over 7.7 million tons of phosphate fertilizers were consumed in the U.S. (USDA, 2019). Annual sales and use of the FCS itself is negligible when compared with this figure (**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, PAA, HP, AA, and SA are not anticipated to reach the environment to any significant extent following disposal and wastewater treatment, as discussed in item 7 above.

The FCS stabilizer, HEDP, is the only chemical component of the FCS anticipated to reach the environment to any significant extent following FCS disposal and wastewater treatment. Therefore, environmental effects are evaluated by comparing the most relevant 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.

**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	HERA (2004)
	<i>Chironomus</i> (Midge)	48-hr EC <sub>50</sub> = 8910 ppm	
	<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	HERA (2004), Jaworska et al. (2002)
	<i>Selenastrum capricornutum</i> (Green Algae) <sup>1</sup>	96-hr EC <sub>50</sub> = 3.0 ppm NOEC = 1.3 ppm	
	<i>Chlorella vulgaris</i> (Green Algae)	48-hr NOEC ≥ 100 ppm	
Long-Term	<i>Pseudomonas putida</i> (Bacterium)	30-min NOEC = 1000 ppm	Jaworska et al. (2002)
	<i>Oncorhynchus mykiss</i> (Rainbow Trout)	14-day NOEC = 60-180 ppm	
	<b><i>Daphnia magna</i> (Water Flea)</b>	<b>28-day NOEC = 10-&lt;12.5 ppm</b>	HERA (2004)
<i>Selenastrum capricornutum</i> (Green Algae) <sup>1</sup>	14-day NOEC = 13.2 ppm		
<b>Terrestrial Ecotoxicity Data</b>			
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 the NOEC in the range of 10 to <12.5 ppm, associated with long-term exposure to the freshwater invertebrate, *Daphnia magna*. When compared against the 28-day *Daphnia* NOEC range of 10 to < 12.5 ppm, the surface water EEC for HEDP (5.5 ppm) is below the NOEC range of the most relevant sensitive aquatic toxicity endpoint. Based on the comparison of the EECs against aquatic toxicity endpoints, in conjunction with the fact that the EECs were derived based on a conservative assumption that 100% of the FCS used at a facility enters an on-site or off-site wastewater treatment system, no significant adverse environmental effects to aquatic organisms are expected.

HEDP in effluent or sludge applied to land is not expected to have any significant 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 worst case theoretical EEC of HEDP in sludge is 220 ppm, which is well below the 14-day no effect level in earthworms. With respect to the terrestrial plant no effect level, we note that the worst case calculation used in this assessment assumes no degradation of HEDP before or after land applications, which is not likely. Additionally, this worst case calculation does not consider significant dilution of HEDP as it mixes with other soil, another conservative assumption. As such, soil HEDP levels are not expected to exceed 100 ppm.

## 9. Use of Resources and Energy

The production, transportation, use, and disposal of wastes from the FCS will involve the use of natural resources and energy. The actual amount of resources and energy used will depend on market penetration and demand for the product. However, due to the anticipated limited use of the FCS, the simple precursors used to produce the product and the quantities that will be used, these demands are expected to be minimal. The precursors used in the production of the FCS are commercially purchased commodity chemicals. No unusual natural resources or energy requirements are involved in the production of the precursors or in the production of the FCS. The FCS will need to be transported from manufacturing site(s) to use sites. This is anticipated to occur via typical means (e.g., railway, highway, etc.) with no extraordinary fuel demands. Use of the FCS will require water for use in preparing the diluted FCS solution (35 L water used to dilute 5 L FCS for a total volume of 40 L of the diluted FCS solution for maximum concentration; or 65 L water used to dilute 5 L FCS for a total volume of 70 L of the diluted FCS solution at minimal concentration); however, this is an insignificant demand on water resources (USGS, 2018; see **Confidential Attachment A** for calculation). Disposal of the FCS will occur via the processing plant wastewater treatment facility or through a local POTW. The former

option will entail some use of resources and energy to operate, while disposal through the latter option entails an insignificant increase, if any, on resource and energy use at the POTW. Impacts on land through land disposal of POTW wastewater sludge will be the same with or without the FCS. No impacts on minerals are involved with production, transportation, use or disposal of the FCS. In summary, the impacts of the FCS on natural resources and energy are insignificant.

#### **10. Mitigation Measures**

The intended use of the FCS is not expected to result in a significant impact to the environment 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 alternative of not establishing this FCN would result in the continued use of similar antimicrobial agents. The use of the FCS as specified in this FCN is expected to replace use of some products currently on the market. Therefore, the alternative of not establishing this FCN would have no environmental impact.

## 12. List of Preparers

**Nga Tran, Dr.PH, M.P.H.** Principal Scientist, Exponent, Inc., 1150 Connecticut Ave NW, Suite 1100, Washington, DC 20036. Telephone: 202-772-4915. Email: [NTran@exponent.com](mailto:NTran@exponent.com)

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*Dr. Tran has more than 20 years of experience in chemical safety and health risks assessment and has conducted research and review of chemical fate and toxicity data.*

*Ms. Wilken has a background in ecology and three years in federal chemical regulation, as well 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: 

Nga Tran  
Principal Scientist, Exponent, Inc.

Date:                     May 22, 2020                    

## 14. References

ChemIDplus. Acetic acid. National Library of Medicine. Accessed March 17, 2020. Available at: <https://chem.nlm.nih.gov/chemidplus/rn/64-19-7>

ChemIDplus. Hydrogen peroxide. National Library of Medicine. Accessed March 17, 2020. Available at: <https://chem.nlm.nih.gov/chemidplus/rn/7722-84-1>

ChemIDplus. Peracetic acid. National Library of Medicine. Accessed March 17, 2020. Available at: <https://chem.nlm.nih.gov/chemidplus/rn/79-21-0>

ChemIDplus. Sulfuric acid. National Library of Medicine. Accessed March 8, 2016. Available at: <https://chem.nlm.nih.gov/chemidplus/rn/7664-93-9>

ECETOC. (2001). Peracetic Acid (CAS No. 79-21-0) and its Equilibrium Solutions. JACC No.

40. European Centre for Ecotoxicology and Toxicology of Chemicals. Brussels, January 2001. Available at: <http://www.ecetoc.org/publication/jacc-report-40-peracetic-acid-and-its-equilibrium-solutions/>
- HERA. (2006). Human & Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products: Sodium Sulfate. Edition 1.0, January 2006, available at: [http://www.heraproject.com/files/39-f-06\\_sodium\\_sulfate\\_human\\_and\\_environmental\\_risk\\_assessment\\_v2.pdf](http://www.heraproject.com/files/39-f-06_sodium_sulfate_human_and_environmental_risk_assessment_v2.pdf)
- HERA. (2005). Human & Environmental Risk Assessment (HERA) on ingredients of household cleaning products: hydrogen peroxide. Edition 1.0, April 2005, available at: [http://www.heraproject.com/files/36-f-05-shor\\_h2o2\\_version1.pdf](http://www.heraproject.com/files/36-f-05-shor_h2o2_version1.pdf)
- HERA. (2004). Human & Environmental Risk Assessment (HERA) on ingredients of European household cleaning products: phosphonates. Available at: <https://www.heraproject.com/files/30-f-04-%20hera%20phosphonates%20full%20web%20wd.pdf>
- Jaworska J, Van Genderen-Takken H, Hanstveit A, van de Plassche E, Feijtel T. (2002). Environmental risk assessment of phosphonates, used in domestic laundry and cleaning agents in the Netherlands. *Chemosphere* 47, 655-665. Abstract available online at: <https://www.sciencedirect.com/science/article/pii/S0045653501003289>
- OECD SIDS. (2001). SIDS Initial Assessment Report for 11<sup>th</sup> SIAM: Sulfuric acid. Available at <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.738.3013&rep=rep1&type=pdf>
- Rapaport RA. (1988). 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. Abstract available online at: <https://setac.onlinelibrary.wiley.com/doi/abs/10.1002/etc.5620070204>
- USDA. (2019). Fertilizer Use and Price: Table 5 – U.S. consumption of selected phosphate and potash fertilizers, 1960-2015. Accessed March 17, 2020. Available at: <http://www.ers.usda.gov/data-products/fertilizer-use-and-price.aspx>
- U.S. EPA. (1994). Land Application of Sewage Sludge: A Guide for Land Appliers on the Requirements of the Federal Standards for the Use or Disposal of Sewage Sludge, 40 CFR Part 503. U.S. Environmental Protection Agency, Office of Enforcement and Compliance Assurance, EPA/831-B-93-002b, December, 1994. Available at: <https://www.epa.gov/sites/production/files/2018-11/documents/land-application-sewage-sludge.pdf>

U.S. EPA. (1993). Memorandum: Hydrogen Peroxide RED. Available at:  
<https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/000595/000595-004.pdf>

U.S. Geological Survey (USGS). (2018). Estimated Use of Water in the United States in 2015. Accessed March 17, 2020. Available at: <https://water.usgs.gov/watuse/wuto.html>.

The Weinberg Group, Inc. (2003). Assessment Plan for Carboxylic Food Acids and Salts Category. American Chemistry Council's Acetic Acid and Salts Panel. April 16, 2003. Available at: [https://ofmpub.epa.gov/opptpv/document\\_api/download?FILE=6-6-2003-c13102rt.pdf](https://ofmpub.epa.gov/opptpv/document_api/download?FILE=6-6-2003-c13102rt.pdf)

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