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

FDA Form 3480 Part IV, Section B

1. **Date:** **November 22, 2017**

2. **Name of Submitter:** Agri-Neo, Inc.

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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) Neo-Pure®, an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide (HP), acetic acid (AA), sulfuric acid (H_2SO_4), and 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) as an antimicrobial agent for use as a spray on seeds for sprouting (alfalfa, clover, broccoli, flax, and chia), as well as select edible seeds (chia, flax, and hemp), and nuts (almond, cashew, and walnut). The seeds or nuts may be treated with the FCS **only once**, at a maximum use rate of 4 L of Neo-Pure® per 1 ton (1000 kg) of seeds or nuts; hence, the maximum concentrations of the components of the FCS **on** seeds or nuts will not exceed 229 parts per million (ppm) peroxyacetic acid, 1043 ppm hydrogen peroxide, 388 ppm acetic acid, 48 ppm sulfuric acid, and 25 ppm HEDP.

The use of the FCS and preparation of the diluted FCS solution prior to application on seeds/nuts is a batch application, i.e. diluted FCS solution is prepared daily and is applied directly to the seeds at a metered rate using a sprayer or fogger apparatus. The application of the diluted FCS solution is associated with the maximum concentrations of the component chemicals of the FCS sprayed on seeds or nuts listed above in Item 4.a. A maximum amount of 4 L of Neo-Pure® is diluted in water or water-ethanol (80:20) mixture to prepare a total volume of 40 L of diluted FCS solution and applied to 1 ton of seeds/nuts. 24 hour after treatment, the treated seeds/nuts 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 select edible seeds (hemp, flax, and chia), nuts (almond, cashew, and walnut), and sprouting seeds (alfalfa, clover, broccoli, flax, and chia).

c) Locations of Use/Disposal:

The FCS is intended for use as an antimicrobial agent to inhibit the growth of undesirable or pathogenic microorganisms on select edible seeds (hemp, flax, and chia), nuts (almond, cashew, and walnut), and sprouting seeds (alfalfa, clover, broccoli, flax, and chia), in food processing facilities nationwide, where the processing of food will occur after treatment.

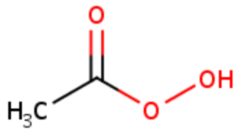
After use, the diluted FCS solution will be disposed of with processing plant wastewater. For processing plants that hold a National Pollutant Discharge Elimination System (NPDES) permit (i.e., direct dischargers), the FCS-containing wastewater will be treated on-site before directly discharged to surface 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 mixture of PAA, HP, HEDP, AA, sulfuric acid, and water produced by blending AA, HP, distilled water, and HEDP, while using sulfuric acid as a catalyst for the reaction. PAA formation is the result of an equilibrium reaction between HP and AA (see Figure 1).

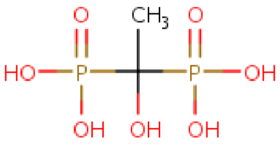
Figure 1. PAA Formation

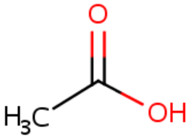
Identifying information for all chemicals present in the FCS and diluted FCS solution is included below. Concentrations of each identified chemical component in the FCS and diluted FCS solution are included in Confidential Attachment A.

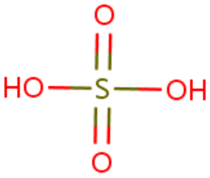
Name	Peroxyacetic Acid (PAA)	Source
CASRN	79-21-0	ChemID*plus*
Formula	$C_2H_4O_3$	
Structure		
Molecular weight	76.0506 g/mol	

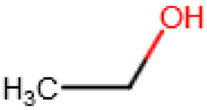
Name	Hydrogen Peroxide (HP)	Source
CASRN	7722-84-1	ChemID*plus*
Formula	H_2O_2	
Structure	HO—OH	
Molecular weight	34.0138 g/mol	

Name	1-Hydroxyethylidene-1,1-diphosphonic Acid (HEDP)	Source
CASRN	2809-21-4	ChemID*plus*
Formula	$C_2H_8O_7P_2$	

Structure		
Molecular weight	206.0262 g/mol	

Name	**Acetic Acid (AA)**	**Source**
CASRN	64-19-7	ChemID*plus*
Formula	$C_2H_4O_2$	
Structure		
Molecular weight	60.0516 g/mol	

Name	**Sulfuric Acid**	**Source**
CASRN	7664-93-9	ChemID*plus*
Formula	H_2SO_4	
Structure		
Molecular weight	98.0778 g/mol	

Name	**Ethanol**	**Source**
CASRN	64-17-5	ChemID*plus*
Formula	C_2H_6O	
Structure		
Molecular weight	46.0684 g/mol	

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 described use pattern (i.e., diluted FCS solution sprayed on select edible seeds (hemp, flax, and chia), nuts (almond, cashew, and walnut) and sprouting seeds (alfalfa, clover, broccoli, flax, and chia) in food processing facilities), the primary pathway of the FCS reaching the environment is through the disposal and treatment of plant processing wastewater. Thus, use of the FCS 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 sales volume of the FCS in the US is included in Confidential Attachment A. The total amount of FCS used at a typical food processing facility to spray select edible seeds (hemp, flax, and chia), nuts (almond, cashew, and walnut), and sprouting seeds (alfalfa, clover, broccoli, flax, and chia) will vary depending on the amount of edible seeds (hemp, flax, and chia), nuts (almond, cashew, and walnut), and sprouting seeds (alfalfa, clover, broccoli, flax, and chia) being sprayed, and microbial stress at a given site. Therefore, the expected introduction concentration (EIC) in surface water is based on the worst case assumption that all of the diluted FCS solution 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, 100% of the component chemicals in the FCS are considered to be disposed of with waste processing waters. As a worst-case scenario, it is assumed that 100% of the FCS used at a facility enters an on-site or off-site wastewater treatment system. 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 will be prepared prior to application to seeds/nuts (i.e., in batches). Assuming the worst case, 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., as a spray on select edible seeds (hemp, flax, and chia), nuts (almond, cashew, and walnut) and sprouting seeds (alfalfa, clover, broccoli, flax, and chia) in food processing facilities). Furthermore, sulfuric acid will dissociate readily to sulfate in the presence of water and ethanol, an optional diluent in the diluted FCS solution, readily biodegrades in water. Therefore, quantitative evaluations of the expected introduction or environmental concentrations and ecotoxicity for these compounds are not necessary.

We elected to use the framework as described in Figure 2 to quantitatively estimate the Expected Introduction Concentration (EIC) of HEDP.

> Based on the label instruction, a maximum 4 L of Neo-Pure® diluted in water (or water-ethanol 80:20 mixture) for a total volume of 40 L of the diluted FCS solution is used to apply to 1 ton of seeds/nuts. Therefore, the maximum concentration of HEDP in the diluted FCS solution is 540 ppm (i.e. (0.54% HEDP x 4 L NeoPure)/(40 L) = 540 ppm). It is assumed that 100% of the diluted FCS solution would be discharged into surface water. Thus, the maximum concentration (540 ppm HEDP) in the diluted

FCS solution is used to estimate the upper-bound worst-case EIC.

Based on the above worst case-assumption, the EIC for HEDP in pre-treated wastewater is 540 ppm. Wastewater containing the FCS 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 is expected to adsorb to sludge (HERA, 2004). Therefore, based on this unique partitioning behavior of HEDP (80:20), only 20% of the maximum concentration is anticipated to remain in the aqueous phase (i.e., wastewater treatment effluent) for eventual release to surface water.

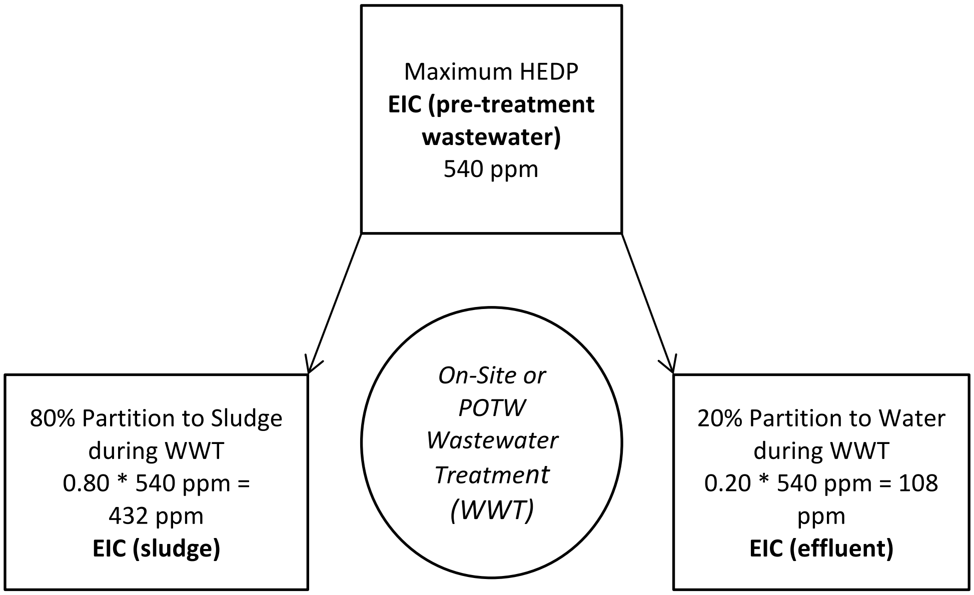


Figure 2. Framework for Estimating EICs for HEDP

Expected Introduction Concentration (EIC): Based on the above framework and the conservative assumptions outlined above, the estimated EICs for HEDP are 108 ppm in effluent and 432 ppm in wastewater treatment sludge (see Table 1).

Table 1. HEDP Expected Introduction Concentrations in Effluent and Sludge

Use	**HEDP Maximum $EIC_{\text{pre-treatment wastewater}}$ (ppm)**	**EIC_{effluent} (ppm)**	**EIC_{sludge} (ppm)**
Spray on select edible seeds (hemp, flax, and chia), nuts (almond, cashew, and walnut), and sprouting seeds (alfalfa, clover, broccoli, flax, and chia).	540	108	432

Via Wastewater Effluent: The chemical species present in the FCS are aqueous and, after use to spray select edible seeds (hemp, flax, and chia), nuts (almond, cashew, and walnut) and sprouting seeds (alfalfa, clover, broccoli, flax, and chia) 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.

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, based on our knowledge of the food processing facilities that process select edible seeds, nuts and sprouting seeds, we do not expect waste and/or sludge exposed to wastewater from these facilities to be incinerated. 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., HEDP is the only component chemical of the FCS 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, HP, AA, sulfuric acid, and potential ethanol components of the diluted FCS solution.

This expectation is based on the half-lives and behavior of PAA, HP, AA, sulfuric acid, and ethanol in sewage treatment plants and/or aquatic environments.

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_2 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_2^{4-}) 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).

For ethanol, fugacity-based modelling indicates that ethanol released into the environment will become distributed mainly into air and water with the rest to the soil, however, the most likely medium for ethanol release is the atmosphere from use of ethanol containing products (i.e., consumer products) (OECD SIDS, 2004). As a volatile organic compound (VOC) in the atmosphere, ethanol is expected to degrade rapidly in the presence of atmospheric pollutants (photochemical sensitizers such as nitrogen oxides and sulfur oxides present in industrial regions) and is a potential contributor to tropospheric ozone formation under certain conditions, however, its photochemical ozone creation potential is considered to be moderate to low (OECD, SIDS 2004). In EPA's Report of the Environment on volatile organic emissions, the national total estimated VOC emissions from anthropogenic sources in 2011 was 12.3 million tons (U.S. EPA, 2014). Under the conservative assumption that all nuts/seeds would be treated with the diluted FCS solution (FCS diluted with a mixture of water-ethanol (80:20) and the annual sales volume of the FCS, emission of ethanol as the result of the proposed use of the FCS contributes negligibly to the national VOC emission (See confidential Attachment A for calculation). In water, ethanol readily biodegrades in both aerobic and anaerobic conditions and ethanol released to soil is expected to move quickly through the soil based on its soil adsorption co-efficient of 1 (OECD SIDS, 2004).

None of these compounds (PAA, HP, AA, sulfuric acid, ethanol) 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 following wastewater treatment is HEDP. Table 2 presents environmental fate properties of HEDP and a discussion of the fate of HEDP in the environment follows.

Table 2. Environmental Fate Properties of HEDP

Property	Value	Source
Vapor Pressure	1×10^{-10} mmHg	HERA (2004)
Water Solubility @ 25°C	6.9×10^{5} mg/L	
Henry's Law Constant	5×10^{-17}	
Log K_{ow}	-3.49	
pK_a (Ca^{2+})	6.8	Jaworska et al. (2002)
pK_a (Cu^{2+})	18.7	
$K_{water\text{-}soil}$	20-190	
$K_{water\text{-}active\ sludge}$	2600-12700	
$K_{water\text{-}river\ sediment}$	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 3 for the framework followed and resulting EEC estimates.

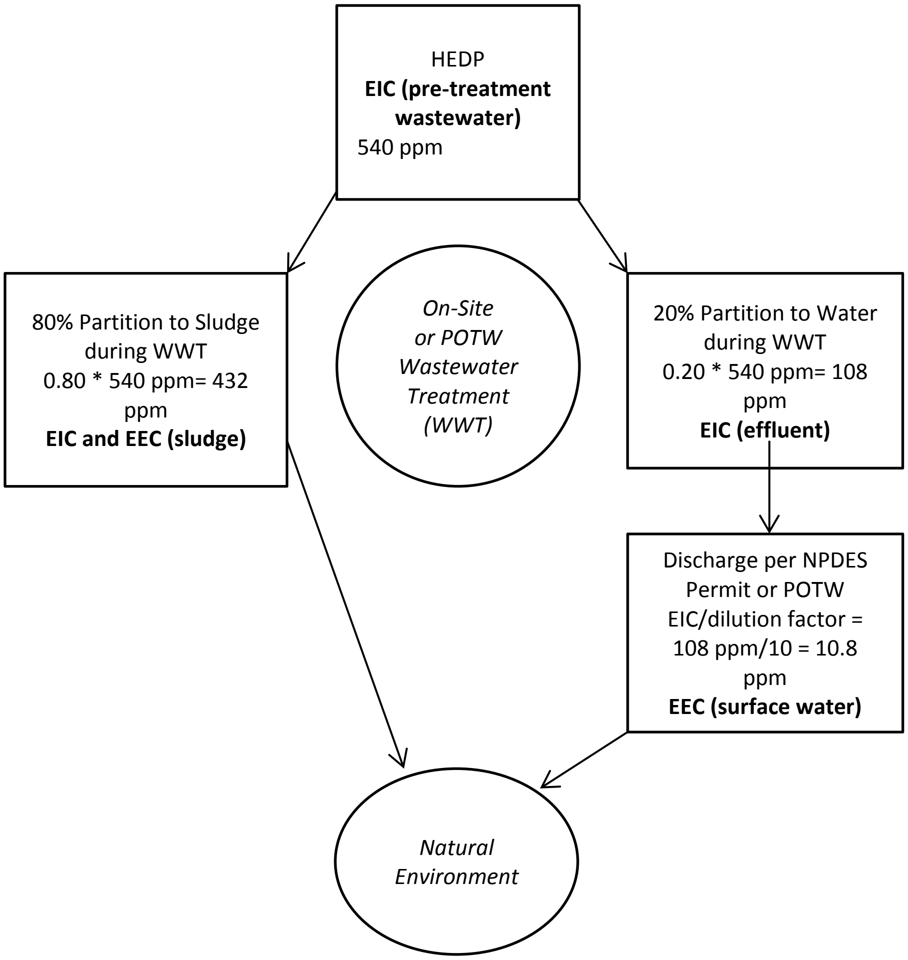


Figure 3. Framework for Estimating EECs for HEDP

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 = 108 ppm). Therefore, the EEC of HEDP from the proposed use is estimated to be 10.8 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 432 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 3 below displays the EICs in pre-treatment wastewater, effluent, and wastewater sludge; and the EEC in surface water for HEDP.

Table 3. Maximum Expected Introduction Concentrations, and Expected Environmental Concentrations for HEDP

Use	Maximum $EIC_{pre-treatment\ wastewater}$ (ppm)	$EIC_{effluent}$ (ppm)	EIC_{sludge} (ppm)	EEC_{water} (ppm)	EEC_{sludge} (ppm)
Spray on select edible seeds (hemp, flax, and chia) and nuts (almond, cashew, and walnut)	540	108	432	10.8	432

<u>HEDP Fate in Aquatic Environment</u>: Wastewaters from food processing facilities that contain the FCS 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 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).

<u>HEDP Fate in Terrestrial Environment</u>: 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 sales 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 4 for a summary of HEDP's ecotoxicity endpoints, with the most-sensitive relevant endpoint bolded. However, because the sulfuric acid present in the FCS is likely to reach the aquatic environment as sulfate, a discussion of sulfate toxicity is also included herein.

Table 4. Summary of Environmental Toxicity Endpoints for HEDP

Duration	Test Species	Endpoint	Source
Aquatic Ecotoxicity Data			
Short-Term	*Lepomis macrochirus* (Bluegill Sunfish)	96-hr LC_{50} = 868 ppm	Jaworska et al. (2002)
	Onchorhynchus mykiss (Rainbow Trout)	96-hr LC_{50} = 360 ppm	
	Cyprinodon variegatus (Sheepshead Minnow)	96-hr LC_{50} = 2180 ppm	
	Ictalurus punctatus (Channel Catfish)	96-hr LC_{50} = 695 ppm	
	Leuciscus idus melonatus (Ide)	48-hr LC_{50} = 207-350 ppm	
	Daphnia magna (Water Flea)	24-48-hr EC_{50} = 165-500 ppm	
	Chironomus (Midge)	48-hr EC_{50} = 8910 ppm	HERA (2004)
	Palaemonetes pugio (Grass Shrimp)	96-hr EC_{50} = 1770 ppm	Jaworska et al. (2002)
	Crassostrea virginica (Eastern Oyster)	96-hr EC_{50} = 89 ppm	
	Selenastrum capricornutum (Green Algae)[1]	96-hr EC_{50} = 3.0 ppm NOEC = 1.3 ppm	HERA (2004), Jaworska et al. (2002)
	Chlorella vulgaris (Green Algae)	48-hr NOEC ≥ 100 ppm	Jaworska et al. (2002)
	Pseudomonas putida (Bacterium)	30-min NOEC = 1000 ppm	
Long-Term	*Oncorhynchus mykiss* (Rainbow Trout)	14-day NOEC = 60-180 ppm	
	***Daphnia magna* (Water Flea)**	**28-day NOEC = 10-<12.5 ppm**	
	Selenastrum capricornutum (Green Algae)[1]	14-day NOEC = 13.2 ppm	HERA (2004)
Terrestrial Ecotoxicity Data			

Duration	Test Species	Endpoint	Source
Short-Term	Terrestrial Plants	14-day EC50 > 960 ppm No effects on seed germination up to 100 ppm	HERA (2004)
	Eisenia foetida (Earthworm)	14-day NOEC = 1000 ppm > 1000 ppm	
	Avian	Oral LD50 >2500 ppm (diet) >284 ppm (bw)	

[1] 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 (10.8 ppm) is within the NOEC range of the most 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, adverse environmental effects to aquatic organisms are not expected 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 worst case theoretical EEC of HEDP in sludge is 432 ppm, which is within the range of no effects among most sensitive terrestrial endpoint. Further, this worst case calculation assumes no degradation of HEDP before or after such land applications, which is not likely. Additionally, this worst case calculation assumes no dilution of HEDP as it mixes with other soil, another conservative assumption.

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. They are not derived from non-renewable resources. 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 entail water for use in preparing the diluted FCS solution (36 L water used to dilute 4 L FCS for a total volume of 40 L of the diluted FCS solution); however, this is an insignificant demand on water resources (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

11. Alternatives to the Proposed Action

The alternative of not establishing this FCN would merely 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

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13. Certification

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

Signature: [redacted]

Nga Tran
Principal Scientist, Exponent, Inc.

Date: November 22, 2017

14. References

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15. Attachments