Xgenex LLC

ENVIRONMENTAL ASSESSMENT
FDA FORM 3480A PART IV, SECTION B NO. 1

1. **Date:**	3 August 2018
2. **Name of Applicant/Petitioner:**	Xgenex LLC
3. **Correspondence Address:**	James Byron, CEO Xgenex LLC 130 Corridor Road, Suite 469 Ponte Vedra Beach, FL 32004 Telephone: (484) 356-7283 Email:jimbyron828@gmail.com

4. **Description of the Proposed Action:**

a. Requested Action

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), an aqueous mixture of peroxyacetic acid (PAA, $C_2H_4O_3$), hydrogen peroxide (HP, H_2O_2), acetic acid (AA, $C_2H_4O_2$), stabilized with 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP, $C_2H_8O_7P_2$), and optionally sulfuric acid (SA, H_2SO_4) (hereinafter referred to as “antimicrobial agent”) to be used:

i. at concentrations up to 2000 ppm PAA, 950 ppm Hydrogen peroxide, 57 ppm HEDP for use in spray, wash, rinse, dip, chiller water, low-temperature (*e.g.*, less than 40°F) immersion baths, scald water or ice on poultry parts, organs, and carcasses.

ii. at concentrations up to 2000 ppm PAA, 950 ppm Hydrogen peroxide, 57 ppm HEDP for use in process water or ice used for washing, rinsing, or cooling whole or cut meat including carcasses, parts, trim, and organs.

iii. at concentrations up to 230 ppm PAA, 110 ppm Hydrogen peroxide, 7 ppm HEDP for use in process water or ice for washing, rinsing, storing or cooling of processed and pre-formed meat and poultry products.

iv. at concentrations up to 230 ppm PAA, 110 ppm Hydrogen peroxide, 7 ppm HEDP for use in process water or ice used to commercially prepare fish and seafood.

v. at concentrations up to 350 ppm PAA, 165 ppm Hydrogen peroxide, 10 ppm HEDP for use in process water or ice used to commercially prepare fruit & vegetables.

b. Need for Action

This antimicrobial agent is intended for use to inhibit the growth of undesirable or pathogenic microorganisms in fruits and vegetables, fish and seafood, meat, and poultry processing plants, to retard the spoilage of the contacted food, ultimately providing for safer produce, seafood, meat and poultry products for consumers throughout the United States, and may also be used aboard fishing vessels during the initial evisceration and cleaning of fresh caught seafood.

c. Locations of Use/Disposal

When used in processing plants, the waste process water containing the FCS is expected to be directed to drain systems, a processing plant wastewater treatment facility, or through a local publicly owned treatment works (POTW). When used aboard fishing vessels, the water containing the FCS is expected to be disposed back into the open waters in compliance with local fishing discharge regulations.

Meat processing facilities: This product will be applied to the surface of freshly killed meat including beef or swine carcasses following removal of the hide, head and hooves. This is accomplished by spraying the carcasses on a moving conveyor line or rail system. The carcasses are suspended from a hook attached to the conveyor, which carries the carcass into a spray cabinet. Spray nozzles are distributed within the cabinet in such a manner that ensures even application of the dilute FCS solution onto the surface of the meat carcass. The carcass exits the other side of the spray cabinet and continues on the processing line. Some meat products are cooled with ice and packaged.

After the diluted product is sprayed onto the carcass, the majority of the product drains off of the meat.

Poultry processing facilities: Spray application of the diluted product will usually take place prior to chilling by submersion. A de-feathered, eviscerated carcass hung on a shackle is carried into a spray cabinet by a moving line. Spray nozzles inside the cabinet apply the diluted product to the carcass. The carcass then exits the spray cabinet for further processing. As an alternative to a spray cabinet the moving line may carry the eviscerated carcass hung on a shackle through a submersion tank or tanks. Some poultry products are cooled with ice and packaged.

Application of the diluted product by submersion of multiple carcasses into a chiller or other tank application may also occur. Carcasses are usually moved through the chiller bath by a paddle or auger-type conveyor, then exit the chiller bath for further processing. Carcasses may also be moved through other dip tank applications by means of conveyor. Carcass parts or organs may also be chilled by submersion in water containing the FCS. Additional applications of the diluted FCS include submersion of multiple carcasses into an after-chiller processing bath (finishing chiller) containing diluted FCS, or spray of carcasses on conveyor belts in a post-chill spray cabinet.

After the diluted FCS is sprayed onto the poultry carcasses, the bulk of the solution drains from the carcasses. The waste solution ultimately runs into drains. Finishing chillers typically back-flow into the main chillers to help maintain FCS concentration at that antimicrobial intervention site. As with the main chillers, the water from finishing chillers is typically drained to the plant waste system every day. Very minor quantities are lost to evaporation into the air.

Land Based Seafood processing facilities: Seafood products are caught in open waters or grown in seafood farms. Caught seafood products are sorted and separated into parts. Parts of seafood products are then flash frozen and packaged. The diluted FCS is sprayed directly onto the raw or processed seafood products before flash-freezing. The bulk of the solution drains off of the seafood products. The waste solution ultimately runs into drains. Very minor quantities are lost to evaporation into the air.

The diluted FCS may also be frozen into ice and then packaged with the frozen seafood product. The dilute frozen product will eventually thaw and drain off the seafood products at downstream facilities in the supply chain (e.g. grocery stores). This waste solution ultimately runs into drains.

On-Board Seafood processing: Our proposed use in seafood and fish processing also includes use aboard fishing vessels during the initial evisceration and cleaning of freshly caught seafood. Some seafood products are cooled with ice. It is expected that wastewater will be discharged into the ocean where the peroxygen actives in the FCS would have a very short half-life. In this discharge case, the component dilution residuals into the ocean would be impossible to calculate, and the resultant concentration of the components in the ocean would be negligible. Direct discharge of wastewater is an accepted practice within the fishing industry.[1]

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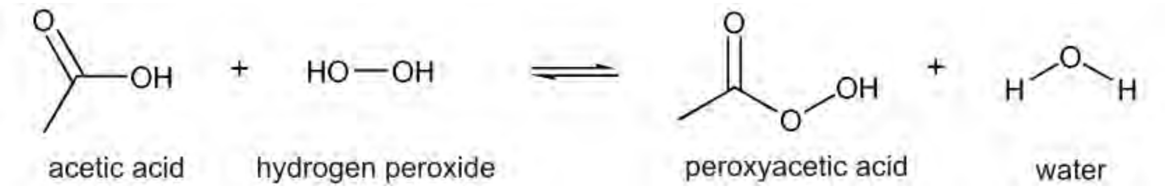
[1] U.S. EPA-800-R-11-005, November 2011, Fish Hold Effluent and Fish Hold Cleaning Wastewater Discharge

Fruit & Vegetable processing facilities: Fruit and vegetable products are grown, harvested and processed. Fruit and vegetable products are washed and then further processed and/or packaged into containers. Some fruit and vegetable products are cooled with ice and packaged. The diluted FCS is sprayed directly onto the raw or processed produce. The diluted FCS may also be used in tanks or conveyance systems that use water as a material to convey product while processing. The bulk of the dilute FCS solution drains off of the fruit and vegetable products. The waste solution ultimately runs into drains. Very minor quantities are lost to evaporation into the air.

The diluted FCS may also be frozen into ice and then packaged with the fruit and produce product. The dilute frozen FCS will eventually thaw and drain off the fruit and produce products at downstream facilities in the supply chain (e.g. grocery stores). This waste solution ultimately runs into drains.

5. Identification of the substances that are the subject of the proposed action:

The FCS is an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid, sulfuric acid, and water . It is produced by blending acetic acid, hydrogen peroxide, purified water, sulfuric acid, and HEDP. Peroxyacetic acid formation is the result of an equilibrium reaction between hydrogen peroxide and acetic acid.

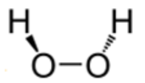


A concentrated product is supplied and is diluted at the processing plant for use on beef carcasses at PAA concentrations up to 2000 ppm; processed and preformed meat and poultry at PAA concentrations up to 230 ppm; poultry carcasses, poultry parts and organs at PAA concentrations up to 2000 ppm; fruit and vegetables at PAA concentrations up to 350 ppm; and seafood products at PAA concentrations up to 230 ppm.

Chemical Substance	**CAS Number**
Hydrogen peroxide	7722-84-1
Acetic acid	64-19-7
Peroxyacetic acid	79-21-0
1-Hydroxyethylidene-1,1-diphosphonic Acid	2809-21-4
Sulfuric acid	7664-93-9
Purified Water	7732-18-5

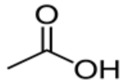
Chemical Name: **Hydrogen peroxide**

The formulas and molecular weight for hydrogen peroxide are:

Chemical Substance	**CAS No.**	**Molecular Weight**	**Molecular Formula**	**Structural Formula**
Hydrogen Peroxide	7722-84-1	34.0147 g/mol	H_2O_2	

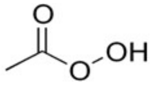
Chemical Name: **Acetic Acid**
Common or Trade Name: Acetic Acid

The formulas and molecular weight for acetic acid are as follows:

Chemical Substance	CAS No.	Molecular Weight	Molecular Formula	Structural Formula
Acetic Acid	64-19-7	60.05 g/mol	$C_2H_4O_2$	

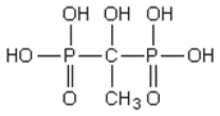
Chemical Name: **Peracetic / peroxyacetic acid**

The formulas and molecular weight for peroxyacetic acid are as follows:

Chemical Substance	CAS No.	Molecular Weight	Molecular Formula	Structural Formula
Peroxyacetic Acid	79-21-0	76.05 g/mol	$C_2H_4O_3$	

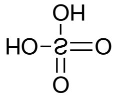
Chemical Name: **1-hydroxyethylidene-1,1-diphosphonic acid (HEDP)**

The formulas and molecular weight for 1-hydroxyethylidene-1,1-diphosphonic acid are as follows:

Chemical Substance	CAS No.	Molecular Weight	Molecular Formula	Structural Formula
1-Hydroxyethylidene-1,1-diphosphonic Acid	2809-21-4	206.03 g/mol	$C_2H_8O_7P_2$	

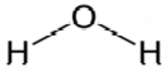
Chemical Name: **Sulfuric Acid**

The formulas and molecular weight for sulfuric acid are as follows:

Chemical Substance	CAS No.	Molecular Weight	Molecular Formula	Structural Formula
Sulfuric Acid	7664-93-9	98.08 g/mol	H_2SO_4	

Chemical Name: **Water**

The formulas and molecular weight for water are as follows:

Chemical Substance	CAS No.	Molecular Weight	Molecular Formula	Structural Formula
Water	7732-18-5	18.015 g/mol	H_2O	

6. Introduction of Substances into the Environment:

a. Introduction of substances into the environment as a result of manufacture:

The FCS is manufactured in plants that meet all applicable federal, state and local environmental regulations. Xgenex LLC asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS such as 1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; 2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 CFR 1508.27(b)(10)); and 3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered orthreatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

b. Introduction of substances into the environment as a result of use/disposal:

We have provided an evaluation under Item 7 of the EA to support that since peroxyacetic acid, hydrogen peroxide, and acetic acid will degrade rapidly in contact with organic matter [2, 3, 4] these substances are not expected to be introduced into the environment to any significant extent as a result of all proposed use of the FCS. Furthermore, sulfuric acid will dissociate readily in the presence of water.[5] Based on this, a quantitative evaluation of the environmental impacts for these compounds is not necessary.

HEDP is the chemical of environmental concern because of its persistence and behavior in the environment, as discussed under Item 7. Therefore, an evaluation of environmental impacts is necessary. As provided in Item 8 of the EA, we have determined it is appropriate to use an aquatic ecotoxicity endpoint of 10/mg/L and a terrestrial ecotoxicity endpoint of 1000mg/L to evaluate the environmental impacts of this action. As the use levels of HEDP are above the aquatic ecotoxicity endpoint, a quantitative assessment, calculating expected introduction concentrations (EICs) and expected environmental concentrations (EECs), is provided to evaluate environmental impacts.

Assuming, in the worst-case, that all of the water used in a processing plant is treated with the FCS, the HEDP expected introduction concentrations (EICs) would be shown below:

Use	HEDP EIC
Whole or cut meat carcasses, parts, trim, and organs	11.4 ppm
Whole or cut poultry, carcasses, parts, trim, and organs	11.4 ppm
Processed and pre-formed meat and poultry products	1.4 ppm
Fish and Seafood	1.4 ppm
Fruits and Vegetables	2 ppm

As large-scale facilities do not typically process more than one type of food, we will use the use level of 11.4 ppm for HEDP as the worst-case EIC for all land-based processing facilities using the FCS in the intended

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[2] Peracetic Acid and its Equilibrium Solutions. JACC No. 40. European Centre for Ecotoxicology and Toxicology of Chemicals, January, 2001.

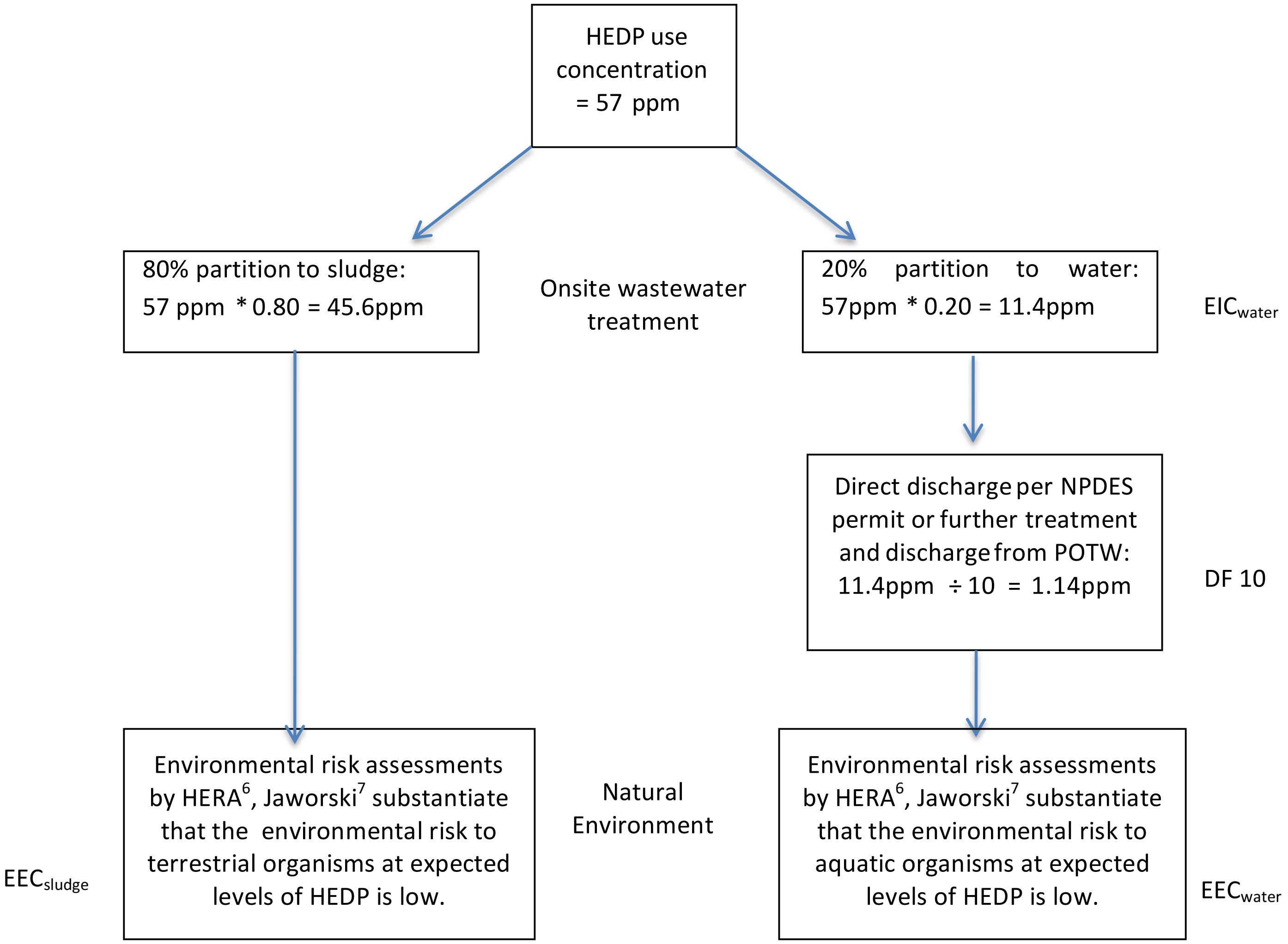
[3] Hydrogen Peroxide. JACC No. 22. European Centre for Ecotoxicology and Toxicology of Chemicals, January, 1993.

[4] Santos, GLNG Project Appendix G: Environmental Assessment Profiles, Acetic acid.

[5] Sulfuric Acid. The organization for Economic Co-operation and Development (OECD) SIDS Voluntary Testing Program for International High Production Volume Chemicals, 2001.

applications. Therefore, the discussion of impacts from use in land-based processing facilities will focus on comparing the Meat & Poultry EECs to appropriate ecotoxicity endpoints that are provided under Item 8. Onboard fish and seafood processing will also be discussed in Items 7 and 8.

For the worst-case MEAT & Poultry applications, based on the behavior of HEDP in the environment, the waste process water containing the FCS is expected to be disposed of through the processing plant wastewater treatment facilities or through a local publically owned treatment works (POTW). As facilities that are in possession of a National Pollutant Discharge Elimination System (NPDES) permit may discharge directly to receiving water, the correct order of events is as follows:



As outlined, the highest use concentration of HEDP (i.e., meat/poultry) is the expected introduction concentration (EIC). Based on the unique partitioning behavior of HEDP (80:20)[6] the expected environmental concentration (EEC) for sludge may be estimated by applying 80% to estimate the EIC. To estimate the EEC$_{water}$, a 20% factor is applied to estimate the EIC$_{water}$, and the product divided by 10.[8]

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[6] Human and Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products, Phosphonates, 2004.

[7] Jaworska, J; Van Genderen-Takken, H; Hanstveit, A; van de Plassche, E; Feijtel, T. Environmental risk assessment of phosphonates used in domestic laundry and cleaning agents in the Netherlands. Chemosphere 2002, 47, 655-665.

[8] Rappaport, Robert A., 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.

The EECs for sludge and water are provided in the following table:

Use	HEDP (max. use)	HEDP EIC_{water}[A]	HEDP EEC_{sludge}[A]	HEDP EEC_{water}
Whole or cut meat or poultry, carcasses, parts, trim, and organs	57 ppm	11.4 ppm	45.6 ppm	1.14 ppm

[A] EIC_{water} = use concentration x 20%
EIC_{sludge} = use concentration x 80%

<u>On-Board Seafood processing</u>: Our proposed use in seafood and fish processing also includes use aboard fishing vessels during the initial evisceration and cleaning of freshly caught seafood. It is expected that wastewater will be discharged into the ocean where the peroxygen activates in the FCS would have a very short half-life. In this discharge case, the component dilution residuals into the ocean would be impossible to calculate, and the resultant concentration of the components in the ocean would be negligible. Direct discharge of wastewater is an accepted practice within the fishing industry.[9]

7. Fate of Emitted Components in the Environment:

Peroxyacetic acid, hydrogen peroxide and sulfuric acid are not expected to survive treatment at the primary wastewater treatment facilities at either seafood, produce, poultry or beef processing plants. These compounds are rapidly degraded on contact with organic matter, transition metals, and upon exposure to sunlight. The half-life of PAA in buffered solutions was 63 hours at pH 7 for a 748 ppm solution, and 48 hours at pH 7 for a 95 ppm solution.[10] The half-life of hydrogen peroxide in natural river water ranged from 2.5 days when initial concentrations were 10,000 ppm, and increased to 15.2 days when the concentration decreased to 250 ppm.[11] In biodegradation studies of acetic acid, 99% degraded in 7 days under anaerobic conditions;[12] it is not expected to concentrate in the wastewater discharged to the POTW. Sulfuric acid dissociates readily in water to sulfate ions and hydrated protons. At environmentally relevant concentrations, sulfuric acid is practically totally dissociated, sulfate is at natural concentrations and any possible effects are due to acidification.[13] [14]

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[9] U.S. EPA-800-R-11-005, Op. Cit., footnote 1

[10] Peracetic Acid and its Equilibrium Solutions. JACC No. 40, Op. Cit., footnote2

[11] Hydrogen Peroxide. JACC No. 22, Op. Cit., footnote 3

[12] U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category. Acetic Acid and Salts Panel, American Chemistry Council, June 28, 2001

[13] Sulfuric Acid, Op. Cit., footnote 5

[14] Human and Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products, Sodium sulfate, 2006.

In a 2004 HERA (Human and Environmental Risk Assessment) publication, it was estimated that 80% of the HEDP discharged to a wastewater treatment plant would bind to the sludge.[15] The calculations under meat, poultry, fish, seafood and produce in Section 6b above for HEDP concentrations in discharged processing water assumes the 80% figure from this study is accurate, and it has been used in the calculations.

8. **Environmental Effects of Released Substances:** Waste antimicrobial solution (from application and drainage) may be directed to an on-site wastewater treatment facility. There, it is expected that decomposition of the components excluding HEDP will occur prior to water being discharged. A summary of ecotoxicity of the HEDP component in the formulation is provided.

Jarworska et al (2002)[16] have summarized the aquatic toxicity of HEDP, as indicated in the following table:

Environmental Toxicity Data for HEDP		
Species	**Endpoint**	**mg/L**
Short Term		
Lepomis macrochirus	96 hr LC50	868
Oncorhynchus mykiss	96 hr LC50	360
Cyprinodon variegates	96 hr LC50	2180
Ictalurus punctatus	96 hr LC50	695
Leciscus idus melanotus	48 hr LC50	207 – 350
Daphnia magna	24 – 48 hr EC50	165 – 500
Palanemonetes pugio	96 hr EC50	1770
Crassostrea virginica	96 hr EC50	89
Selenastrum capricornutum	96 hr NOEC	1.3
Chlorella vulgaris	48 hr NOEC	≥100
Pseudomonas putida	30 minute NOEC	1000
Long Term		
Oncorhynchus mykiss	14 day NOEC	60 -180
Daphnia Magna	28 day NOEC	10 - <12.5

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[15] HERA, Phosphonates, 2004, Op. Cit., footnote 6

[16] Jaworska, Op.Cit.,footnote 7

A document on phosphonates by the Human and Environmental Risk Assessment Project[17] included a discussion of aquatic toxicity resulting from chelation of nutrients, rather than direct toxicity to aquatic organisms. The lowest toxicity endpoints, for *Selenastrum capricornutum*, *Daphnia magna*, and *Crassostrea virginica* are considered to result from chelation of nutrients, not from direct toxicity of HEDP. Chelation is not toxicologically relevant in the current evaluation because eutrophication, not nutrient depletion, is the controlling toxicological mode.[18]

Biodegradation study results were variable. Zahn-Wellens dissolved organic carbon removed 33% after 28 days; modified OECD screening theoretical carbon dioxide evolution was 2% after 70 days; modified SCAS dissolved organic carbon removed 90%; and closed container BOD_{30}/COD was 5%.

The maximum calculated environmental exposure to HEDP for the worst-case scenerio use addressed in this FCN is 1.14 ppm. This level of exposure is orders of magnitude below the LC_{50} of Daphnia (*Daphnia magna*), rainbow trout (*Oncorhynchus mykiss*) and Bluegill sunfish (*Lepomis macrochirus*).

HEDP in effluent discharged to land is not expected to have any adverse environmental impact based on the terrestrial toxicity endpoints available for plants, earthworms, and birds. The NOEC for soil dwelling organisms was > 1000 mg/kg soil dry weight for red worms and >980 mg/kg for oats. The 14-day median lethal dose (LD_{50}) for birds was greater than 284 mg/kg body weight.[19]

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[17] HERA, Phosphonates, 2004, Op. Cit., footnote 6

[18] Jaworska, Op. Cit., footnote 7

[19] HERA, Phosphonates, 2004, Op. Cit., footnote 6

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. The Notifier's FCS is expected to compete with, and to some degree replace, similar antimicrobial agents already on the market. The partial replacement of other substances by the Notifier's antimicrobial agent is not expected to have any adverse impact on the use of energy and resources. The manufacture of the antimicrobial agent will consume comparable amounts of energy and resources as similar products, and the raw materials used in the production of the mixture are commercially manufactured materials that are produced for use in a variety of chemical reactions and processes. Energy used specifically for the production of the mixture components is not significant.

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 antimicrobial agent is not expected to result in significant adverse environmental impacts, therefore mitigation measures are not necessary.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact Notification. The alternative of not approving the action proposed herein would simply result in the continued use of nearly identical products by the beef, poultry, pork, fish, produce and seafood processing industry; such action would have no environmental impact. The addition of this product the options available to processors is not expected to increase the use of peroxyacetic acid antimicrobial products; rather provide a replacement product for those peroxyacetic acid products already in use.

12. **List of Preparers**

1. Mr. James A. Byron, Chief Executive Officer, Xgenex LLC
   Mr. Byron has 17 years experience with Nalco Chemical Company, now a division of Ecolab. His responsibilities included chemical application and regulatory compliance for water and wastewater chemical treatment in food and heavy industrial facilities in 17 states.
   Mr. Byron has over 10 years experience working in food production, food contact substances and chemical interventions associated with food safety.
   Mr. Byron holds a Bachelor of Arts, Business Administration, Boston College.

13. **Certification**

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

[redacted]

James A. Byron, CEO

Xgenex LLC
Date: August 3, 2018

CITATIONS

[1] U.S. EPA-800-R-11-005, November 2011, Fish Hold Effluent and Fish Hold Cleaning Wastewater Discharge.

[2] Peracetic Acid and its Equilibrium Solutions. JACC No. 40. European Centre for Ecotoxicology and Toxicology of Chemicals, January, 2001.

[3] Hydrogen Peroxide. JACC No. 22. European Centre for Ecotoxicology and Toxicology of Chemicals, January, 1993.

[4] Santos, GLNG Project Appendix G: Environmental Assessment Profiles, Acetic acid.

[5] Sulfuric Acid. The organization for Economic Co-operation and Development (OECD) SIDS Voluntary Testing Program for International High Production Volume Chemicals, 2001.

[6] Human and Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products, Phosphonates, 2004.

[7] Jaworska, J; Van Genderen-Takken, H; Hanstveit, A; van de Plassche, E; Feijtel, T. Environmentalrisk assessment of phosphonates usedindomestic laundry andcleaning agents intheNetherlands. Chemosphere 2002, 47, 655-665.

[8] Rappaport, Robert A., 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.

[12] U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category. Acetic Acid and Salts Panel, American Chemistry Council, June 28, 2001

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