PART IV – ENVIRONMENTAL INFORMATION

B - ENVIRONMENTAL ASSESSMENT

1. **Date:** February 5, 2020

2. **Applicant:** Biosan LLC

3. **Address:** 26 Freedom Way
Saratoga Springs, NY 12866

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4. **Description of Proposed Action**

a. Requested Action

The action identified in this food contact notification (FCN) is to provide for the use of the food contact substance (FCS) identified as an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide (HP), acetic acid (AA), 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP), dipicolinic acid (DPA), and, optionally, sulfuric acid, in the production and preparation of: whole or cut meat and poultry; processed and pre-formed poultry and meat; fruits and vegetables; fish and seafood; brines, sauces, and marinades; and, aseptic filling and packaging systems. This notification requests an increase in the use levels of the FCS components.

When used as intended, the components of the FCS mixture will not exceed:

1) An antimicrobial agent in in spray, wash, rinse, dip, chill, and scald process water, ice, or brine used in the production, processing, and preparation of whole or cut meat carcasses, parts, trim, and organs at a maximum use level of 2000 ppm PAA, 1474 ppm HP, 121.5 ppm HEDP, and 1.64 ppm DPA;

2) An antimicrobial agent in spray, wash, rinse, dip, chill, and scald process water, ice, or brine used in the production, processing, and preparation of whole or cut poultry carcasses, parts, trim, and organs at a maximum use level of 2000 ppm PAA, 1474 ppm HP, ppm 136 HEDP, and 4 ppm DPA;

3) An antimicrobial agent in process water, ice, or brine used for washing, rinsing, or cooling of processed and preformed meat at a maximum use level of 495 ppm PAA, 365 ppm HP, 33.5 ppm HEDP, and 0.44 ppm DPA;

4) An antimicrobial agent in process water, ice, or brine used for washing, rinsing, or cooling of processed and preformed poultry at a maximum use level of 495 ppm PAA, 365 ppm HP, 29 ppm HEDP, and 0.44 ppm DPA;

5) As an antimicrobial agent in process water or ice for washing, rinsing, chilling or processing fruits and vegetables in food processing facilities at a maximum use level of 500 ppm PAA, 1000 ppm HP, 34 ppm HEDP, and 0.68 ppm DPA;

6) An antimicrobial agent in process water and ice used to commercially prepare fish and seafood at a maximum use level of 230 ppm PAA, 280 ppm HP, 15 ppm HEDP, and 0.38 ppm DPA;

7) An antimicrobial agent in brines, sauces, and marinades applied either on the surface or injected into processed or unprocessed, cooked, or uncooked, whole or cut poultry parts and pieces at a maximum use level of 50 ppm PAA, 33 ppm HP, 8 ppm HEDP, and 0.1 ppm DPA;

8) An antimicrobial agent in surface sauces and in marinades applied on processed and preformed meat and poultry products at a maximum use level of 50 ppm PAA, 33 ppm HP, 8 ppm HEDP, and 0.1 ppm DPA; and,

9) as an antimicrobial additive that may be used alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures prior to filling, except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging, at a maximum use level of 4500 ppm PAA, 6600 ppm HP, 180 ppm HEDP, and 9 ppm DPA.

b. Need for Action

The FCS reduces and/or eliminates pathogenic and non-pathogenic microorganisms that may be present on the food during production.

The purpose of this FCN is to expand the uses currently approved for the FCS in order to address current and future needs of food processors and government agencies for improving food safety. Using the FCS provides more options for antimicrobial interventions. Using of PAA at higher concentrations for relatively short periods of time in smaller total volumes, allows the food industry to improve processing techniques and provide greater flexibility in terms of time, concentration, application method (e.g., spray vs. immersion) to improve the control of food pathogens.

c. Locations of Use/Disposal

The FCS is intended for use in meat and poultry, fruit and vegetable, and fish and seafood processing plants and filling and packaging facilities throughout the United States. It is expected that on-site waste water treatment facilities will discharge to publically owned treatment works (POTW). During the onsite treatment process, very minor quantities of the solution are lost to evaporation. 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.

1) Whole or Cut Meat and Poultry Processing

EPA requires meat and poultry processors to meet specific effluent pre-treatment standards.[1] Therefore, the waste process water containing the FCS is expected to be released to the processing plant's wastewater treatment facility before being discharged either to surface waters under National Pollution Discharge Elimination System (NPDES) permitting or to POTW.

In poultry processing facilities the diluted FCS is applied to poultry carcasses, organs, parts, or trim by an immersion dip or in a spray cabinet. Carcasses are carried on a conveyor through a spray cabinet and then submerged in the chiller baths. Parts and organs may also be chilled by submersion in baths containing the FCS. Chiller baths typically include a "main chiller" bath and a "finishing chiller" bath, which both contain the FCS. After the diluted FCS is sprayed onto the carcasses, or the carcasses are removed from an immersion dip, most of it drains off of the poultry. The waste solution runs into drains and enters the poultry processing plant water treatment facility. All water is collected and treated by the water treatment facility before being sent to a POTW. Very small quantities of this water would be lost to evaporation.

In meat processing facilities the diluted FCS is applied to meat carcasses or parts by spraying carcasses suspended on a moving conveyor line or rail system. The carcasses are carried into a spray cabinet where the dilute FCS solution is evenly applied onto the surface of the meat. The carcasses exit the spray cabinet and continue through the processing line. In some instances, meat parts are placed in a dip tank containing the diluted FCS in order to ensure full contact with the intervention treatment. After the diluted FCS is applied to the carcass, most of it drains off of the meat. This water ultimately runs into drains and enters the meat processing plant water treatment facility before being sent to a POTW. Very small quantities of water would be lost to evaporation.

2) Processed and Preformed Meat and Poultry

The FCS is used as a treatment for washing, rinsing, and cooling water applied to processed and pre-formed meat and poultry products. Most of the solution drains off the product.

3) Fruit and Vegetable Processing Facilities

Produce may be washed by submersion, spray, or both.[2] The FCS components that would enter environment will result from its use in the fruit and vegetable processing water and the subsequent disposal of such water draining into the processing plant wastewater treatment facility. There may also be direct discharge to surface waters from use of the PAA product in fruit and vegetable processing facilities.

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[1] US EPA Meat and Poultry Products Effluent Guidelines, 40 CFR Part 432 https://www.epa.gov/eg/meat-and-poultry-products-effluent-guidelines.
[2] U.S. Food and Drug Administration (February 2008) *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*, Section VIII.C.2.b, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-cut-fruits-and-vegetables

4) Fish and Seafood Processing Facilities

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 and enters the seafood processing plant water treatment facility. All of this water is collected and treated by the facility prior to it being sent to a POTW or discharged directly to surface water in accordance with the plants' NPDES permit. Direct discharge to surface water is considered the worst-case scenario as it does not take into account any further treatment that may occur at a POTW. Very small quantities would be 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 and is sent to a POTW.

On-Board Seafood Processing: The 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 components 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.

5) Brines, Sauces, Marinades for Meat and Poultry

In a typical marinade operation, a fresh marinade batch containing the FCS may be made prior to each 4 hour interval of an 8 hour shift, and then disposed after 4 hours of use. The marinade batches are commonly blended in 50-200 gallon tanks. Following each 4 hour interval, the remainder of the marinade batch, typically up to 30-40 percent, is treated at the meat or poultry processor's on-site pretreatment facilities before discharge to a POTW or surface waters, depending upon whether the facility has an individual NPDES permit. Therefore, meat and poultry processors discharge their waste water first to onsite treatment facilities and subsequently to POTWs or discharged directly to surface waters if the facility has an individual NPDES permit. Direct discharge to surface water is considered the worst-case scenario as it does not take into account any further treatment that may occur at a POTW.

The marinade may be treated with the FCS after the batch is initially made and again treated with the FCS after each hour of use in the marinade operation to maintain the target PAA concentration. For each 4 hour interval, the total amount of marinade that may be typically disposed of in an on-site pretreatment facility or wastewater discharge system is 80 gallons based on a 200 gallon marinade batch. For an 8 hour shift, the total amount of marinade containing the FCS that may be disposed of into an on-site pretreatment facility or wastewater discharge system is 160 gallons. For two 8 hour shifts, the total amount of marinade containing the FCS that may be disposed of into an on-site pretreatment facility or wastewater discharge system is 320 gallons. Within a meat or poultry processor's on-site wastewater discharge system, the FCS components would be diluted in a similar manner to other liquid products, then subsequently diluted further upon entry into the POTW and surface waters.

6) Aseptic Packaging

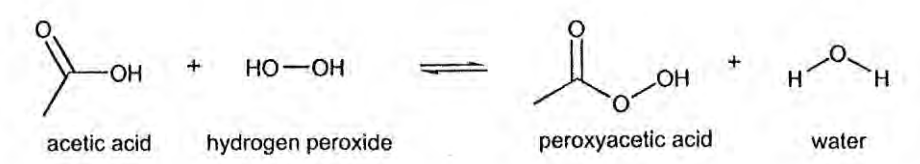
The FCS may be used alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures prior to filling, except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging. In a typical food processing facility, a fresh batch containing the FCS may be initially made prior to an eight (8) hour shift, and then completely disposed of after approximately 6 cycles of 8 hours each (48 hours total time) of use. Due to use of the FCS and loss of the FCS during treatment of the glass and plastic food packaging and their enclosures, it is often necessary to replenish the FCS containing reservoirs during the 6 cycles of use. The FCS used for replenishment is typically made at the beginning of an 8-hour shift during the 6 cycles of use. The reservoirs are then filled and re- filled as needed.

The batches containing the FCS are commonly blended in tanks filled to approximately 900 gallons. Typically, about 600 gallons of the FCS in a reservoir is intended for use in glass and plastic food packaging treatment operations and approximately 300 gallons of the FCS in a reservoir is used in enclosure treatment operations. During each 8-hour shift, the loss of the FCS solution due to its use, may be up to 50 percent or 450 gallons of the FCS. The FCS solution that is lost during use is diluted with other liquid waste products at the processing plant. The diluted FCS solution will be disposed of with processing plant wastewater according to NPDES regulations. For processing plants that hold a NPDES permit (i.e., direct dischargers), the FCS- containing wastewater will be treated on-site before direct discharge to surface waters. For processing plants without such NPDES permits (i.e., indirect dischargers), the FCS containing wastewater would travel through the sanitary sewer system into POTWs for standard wastewater treatment processes before movement into aquatic environments.

The FCS is initially made up at the target PAA concentration. For each 8-hour shift the total amount of FCS that may be typically disposed of in an on-site pretreatment facility or wastewater discharge system is 450 gallons based on a total of 900 gallons of FCS. For two 8 hour shifts consisting of a typical day, the total amount of the FCS that may be disposed is 900 gallons. The FCS solution will be disposed of with processing plant wastewater according to NPDES regulations. For processing plants that hold a NPDES permit (i.e., direct dischargers), the FCS-containing wastewater will be treated on-site before direct discharge to surface waters. For processing plants without such NPDES permits (i.e., indirect dischargers), the FCS containing wastewater would travel through the sanitary sewer system into POTWs for standard wastewater treatment processes before movement into aquatic environments.

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

The FCS is an aqueous mixture of HP, PAA, AA HEDP, and sulfuric acid (optionally). It is produced by blending AA, HP, HEDP and water. During the blending process, PAA is formed, *in situ*, as a result of an equilibrium reaction between HP and AA. Sulfuric acid is optionally added as a catalyst in the reaction process.



The aqueous mixture is provided to users as a concentrate which is then diluted, prior to use, on-site. The chemical structures for the components of the FCS and associated chemical identification information are provided below:

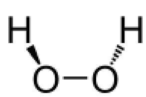
<u>Hydrogen Peroxide</u>

CASRN: 7722-84-1

Molecular Formula: H_2O_2

Molecular Weight: 34.01

Structure:



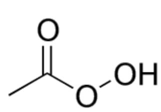
<u>Peroxyacetic Acid</u>

CASRN: 79-21-0

Molecular Formula: CH_3CO_3H

Molecular Weight: 76.05

Structure:



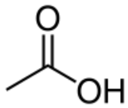
<u>Acetic Acid</u>

CASRN: 64-19-7

Molecular Formula: CH_3CO_2H

Molecular Weight: 60.05

Structure:



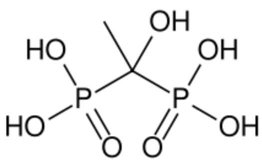
Hydroxyethylidene 1,1-diphosphonic acid

CASRN: 2809-21-4

Molecular Formula: $C_2H_8O_7P_2$

Molecular Weight: 206.02

Structure:



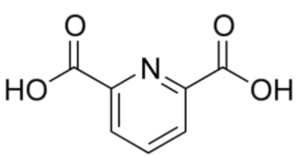
Dipicolinic acid

CASRN: 499-83-2

Molecular Formula: $C_7H_5NO_4$

Molecular Weight: 167.12

Structure:



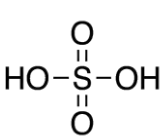
Sulfuric Acid

CASRN: 7664-93-9

Molecular Formula: H_2SO_4

Molecular Weight: 98.079

Structure:



6. Introduction of Substances into the Environment

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

Per 21 CFR Section 25.40(a), the environmental assessment for the FCS should focus on environmental issues only relating to the use and disposal from use of FDA-regulated articles. The FCS is manufactured in plants that meet all applicable federal, state and local environmental requirements. The Notifier confirms that there are no extraordinary circumstances pertaining to the manufacture of the FCS such as:

1) unique emissions that are not already addressed by general or specific emission requirements (including occupational) established by Federal, State or local environmental agencies and that may harm the environment; or,

2) an action in violation of Federal, State or local environmental laws or requirements (40 CFR Section 1508.27(b)(10)); or,

3) production associated with the proposed action that may adversely affect a species or the habitat of a species as determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under Federal law.

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

Any release of dilute solutions of the FCS into the environment will primarily occur via wastewater treatment systems. Release of the FCS components into the environment will result from its use as spray applications onto food and in processing water. The subsequent disposal of processing water and spray drainage will be to on-site treatment plants and/or POTWs. The total amount of FCS used at a facility will vary depending on the equipment used and the amount of food processed. The maximum use concentration of PAA, hydrogen peroxide, HEDP, and DPA for each application is as follows:

Summary of Intended Uses				
Use	**PAA (ppm)**	**H_2O_2 (ppm)**	**HEDP (ppm)**	**DPA (ppm)**
Process water or ice used for washing, rinsing, or cooling whole or cut meat, including carcasses, parts, trim, and organs	2000	1474	121.5	1.64
Spray, wash, rinse, dip, chiller water, low temperature (e.g., less than 40°F) immersion baths, or scald water for whole or cut poultry carcasses, parts, trim, and organs	2000	1474	136	4
Water, brine, or ice used for washing, rinsing, or cooling processed and pre-formed meat as defined in 21 CFR 170.3(n)(29)	495	365	33.5	0.44
Water, brine, or ice used for washing, rinsing, or cooling processed and	495	365	29	0.44

pre-formed poultry as defined in 21 CFR 170.3(n)(34)				
Water for washing or chilling fruits and vegetables in food processing facilities	500	1000	34	0.68
Water and ice used to commercially prepare fish and seafood	230	280	15	0.38
Brines, sauces, and marinades applied either on the surface or injected into processed or unprocessed, cooked, or uncooked, whole or cut poultry parts and pieces	50	33	8	0.1
Surface sauces and in marinades applied on processed and preformed meat and poultry products	50	33	8	0.1
Commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures prior to filling, except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging	4500	6600	180	9

Treatment of process water at an on-site wastewater treatment plant or POTW is expected to result in complete degradation of PAA, HP, and AA. PAA will break down into oxygen, water, and AA. HP will break down into oxygen and water.[3] All three 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.[4] The half-life of HP in natural river water ranged from 2.5 days when initial concentrations were 10,000 ppm, and increased to 15.2 days and 20.1 days when the concentration decreased to 250 ppm and 100 ppm, respectively.[5] In biodegradation studies of AA using activated sludge, 99% degraded in 7 days under anaerobic conditions.[6] AA is not expected to concentrate in the wastewater discharged to the wastewater treatment plant or POTW. In wastewater, sulfuric acid will completely dissociate into sulfate ions and hydrated protons,[7] neither of which are a toxicological or environmental concern at the proposed use levels. Therefore, peroxyacetic acid, hydrogen peroxide, acetic acid and sulfuric acid are not expected to be introduced into the environment to any significant extent as a result of the proposed use of the FCS. As a result, the remainder of this section will consider only the environmental introduction of HEDP and DPA.

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[3] Page 18 of U.S. Environmental Protection Agency, *Reregistration Eligibility Decision: Peroxy Compounds* (December 1993), https://archive.epa.gov/pesticides/reregistration/web/pdf/peroxy_compounds.pdf.

[4] Page 29, Table 11 of European Centre for Toxicology and Toxicology of Chemicals, *Joint Assessment of Commodity Chemicals No. 40 Peracetic Acid and its Equilibrium Solutions*, January 2001 http://www.ecetoc.org/publication/jacc-report-40-peracetic-acid-and-its-equilibrium-solutions/

[5] Page 23, Table 6 of European Centre for Toxicology and Toxicology of Chemicals, *Joint Assessment of Commodity Chemicals No. 22, Hydrogen Peroxide*, January, 1993 www.ecetoc.org/publication/jacc-report-22-hydrogen-peroxide/

[6] American Chemistry Council, Acetic Acid and Salts Panel, *U.S. High Production (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category*, June 28, 2001, Appendix 1, p. 1, https://iaspub.epa.gov/oppthpv/document_api.download?FILE=c13102tp.pdf.

[7] Sulfuric Acid. The organization for Economic Co-operation and Development (OECD) SIDS Voluntary Testing Program for International High Production Volume Chemicals. 2001, available at http://www.inchem.org/documents/sids/sids/7664939.pdf

1) Poultry Processing Facilities

When the FCS is used at the maximum level, HEDP and DPA would be present in water at a maximum level of 136 parts per million (ppm) and 4 ppm, respectively. Water is used in poultry processing for scalding (feather removal), bird washing before and after evisceration, chilling, cleaning and sanitizing of equipment and facilities, and for cooling of mechanical equipment such as compressors and pumps.[8] Many of these water uses will not utilize the FCS, resulting in significant dilution of HEDP and DPA into the total water effluent. Assuming, in the very worst-case, that all of the water used in a poultry processing plant is treated with the FCS, the level of HEDP and DPA in water entering the plant's wastewater treatment facility, the environmental introduction concentration (EIC), would be 136 ppm and 4 ppm, respectively.

2) Meat Processing

The FCS may be used in contact with all types of meat, including pork, venison, and mutton/lamb. Its use in the processing of beef constitutes the largest sector of the meat processing industry in terms of market share, while the processing of pork is the sector that is expected to generate the largest amount of effluent.[9]

Although the total water usage may differ between beef and pork processing plants, when the FCS is used in either application the maximum at-use concentration of HEDP and DPA in the wash water is limited to 121.5 ppm and 1.64 ppm, respectively. Water is used in meat processing facilities for purposes other than carcass and meat washing (i.e. for cleaning, boiler water, cooling waters, etc.). This additional water use will dilute the concentration of HEDP and DPA in the total water effluent to lower levels. Indeed, these other uses are reported to account for approximately 60% of the total water used in a hog slaughterhouse.[10] Nevertheless, assuming, in the very worst-case, that all of the water used in a meat processing plant is treated with the FCS, the maximum amount of HEDP and DPA entering a facility's wastewater treatment plant as a result of the requested use of the FCS (the EIC) in pork or beef processing facilities would be 121.5 ppm and 1.64 ppm respectively.

3) Processed and Preformed Meat and Poultry Facilities

Because there are many different types of RTE meat and poultry produced using a variety of methods, it is difficult to establish water usage levels. It is expected that water not containing the FCS will be used in plants for activities such as cleaning and sanitation, resulting in significant dilution of HEDP into the total water effluent. Because it is difficult to establish water usage levels, we assume, in the very worst-case, that all of the water used in a processed

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[8] Page 6-7 of U.S. Environmental Protection Agency, *Technical Development Document for the Final Effluent Limitations Guidelines and Standards for the Meat and Poultry Products Point Source Category (40 CFR 432)*, EPA-821R-04-011, September 8, 2004, https://www.epa.gov/sites/production/files/2015-11/documents/meat-poultry-products_tdd_2004_0.pdf.

[9] Page 6-6, Table 6-3 of U.S. Environmental Protection Agency, *Technical Development Document for the Final Effluent Limitations Guidelines and Standards for the Meat and Poultry Products Point Source Category (40 CFR 432)*, EPA-821R-04-011, September 8, 2004, available at https://www.epa.gov/sites/production/files/2015-11/documents/meat-poultry-products_tdd_2004_0.pdf

[10] Lawrence K. Wang, Yung-Tse Hung, Howard H. Lo, Constantine Yapijakis, *Waste Treatment in the Food Processing Industry*, 2006, Figure 3.2, p. 71 (summing values from the personal hygiene (~9%), cooling water (5%), knife sterilizing (5%), lairage washing (~3%), vehicle washing (~4%), and cleaning (~32%) categories, and assuming that all of the sprays and rinses are used during processing). https://www.semanticscholar.org/paper/Waste-treatment-in-the-food-processing-industry.-Wang-Hung/4e67ef8931da82b436c938d5f20cb405352398d8

and pre-formed meat and poultry plant is treated with the FCS, and the EIC of HEDP and DPA would be 33.5/29 ppm and 0.44 ppm, respectively.

4) Fruit and Vegetable Processing Facilities

Water is used for almost all aspects of fruit and vegetable processing operations, including washing, cooling, and conveying of produce.[11] When the FCS is used at the maximum level under the proposed action, HEDP and DPA would be present in water at a maximum level of 34 ppm and 0.68 ppm, respectively. Water is used in produce processing for a variety of applications that will not utilize the FCS, including blanching, filling, cleaning and sanitizing of plant equipment and facilities, and for processed product cooling,[12] resulting in significant dilution of HEDP and DPA into the total water effluent. Assuming, in the very worst-case, that all of the water used in a fruit and vegetable processing plant is treated with the FCS, the level of HEDP and DPA in water entering the plant's wastewater treatment facility, the EIC would be 34 ppm and 0.68 ppm, respectively.

5) Fish and Seafood Processing Facilities

Water is involved in nearly all aspects of fish and seafood processing operations. When the FCS is used at the maximum level under the proposed action, HEDP and DPA would be present in water at a maximum level of 15 ppm and 0.38 ppm, respectively. Water is used in produce processing for a variety of applications that will not utilize the FCS, including blanching, filling, cleaning and sanitizing of plant equipment and facilities, and for processed product cooling, resulting in significant dilution of HEDP and DPA into the total water effluent. Assuming, in the very worst-case, that all of the water used in a fish and seafood processing plant is treated with the FCS, the level of HEDP and DPA in water entering the plant's wastewater treatment facility, the EIC would be 15 ppm and 0.38 ppm, respectively.

6) Brines, Sauces, Marinades for Meat and Poultry

The FCS is proposed for use as an antimicrobial agent in: 1) brines, sauces, and marinades to be applied on the surface or injected into processed or unprocessed, cooked or uncooked whole or cut poultry and 2) in surface sauces and marinades applied on processed and preformed meat and poultry products. The marinade containing the FCS is commonly blended in 50-200 gallon tanks and used in 4 hour intervals. The FCS is re-applied on an hourly basis to maintain the desired PAA concentration. Following each 4 hour interval of an 8 hour shift, the remainder of the marinade batch is disposed of into the processor's on-site pretreatment facility before discharging to the local POTW and surface waters, depending upon whether the facility has an individual NPDES permit. Typically, the amount of marinade that may be discharged into the processing plant pre-treatment facility would be no more than 30-40 percent of the marinade batch or 60-80 gallons of marinade during each 4 hour interval based on a maximum batch size of 200 gallons. Assuming that an operation may operate for two 8 hour shifts, the maximum

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[11] U.S. Food and Drug Administration (February 2008) *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*, Section VIII.C.2.b, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-cut-fruits-and-vegetables

[12] Division of Pollution Prevention and Environmental Assistance and Division of Water Resources of the North Carolina Department of Environment and Natural Resources, and Land-of-Sky Regional Council, *Water Efficiency Manual for Commercial, Industrial, and Institutional Facilities*, August 1998, p. 87 https://www.monroenc.org/Portals/0/Departments/Water%20Resources/Documents/Water-efficency-for-industrial-commercial-and-institutional-customers.pdf .

total potential amount of marinade containing the FCS that may be disposed into the on-site pre-treatment facility is 320 gallons per day. Assuming, in the very worst-case, that all of the water used for brines, sauces, and marinades for meat and poultry is treated with the FCS, the level of HEDP and DPA in water entering the plant's wastewater treatment facility, the EIC would be 8 ppm and 0.1 ppm, respectively.

7) Aseptic Filling And Packaging Systems

The FCS is proposed to be used as an antimicrobial additive that may be used alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures prior to filling, except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging. The FCS is provided as a concentrate that is diluted on site. Based on the described use pattern above, the primary pathway for the FCS to reach the environment is by the use and disposal of the FCS. Following use or disposal of the FCS, the FCS enters the processor's on-site pretreatment facility before discharging to the local publicly-owned treatment works (POTW) and surface waters, depending upon whether the facility has an individual NPDES permit. Assuming, in the very worst-case, that all of the water used for aseptic packaging is treated with the FCS, the level of HEDP and DPA in water entering the plant's wastewater treatment facility, the EIC would be 180 ppm and 9 ppm, respectively.

As the aseptic filling and packaging systems use has the highest EIC for HEDP and DPA, these will be considered the worst-case scenario. We have estimated the potential environmental introductions of HEDP and DPA in water and sewage sludge based on the EIC of 180 ppm and 9 ppm, respectively.

7. Fate of Emitted Substances in the Environment

As previously mentioned, PAA, HP, and AA are not expected to survive treatment at the primary wastewater treatment facilities; therefore, Expected Environmental Concentrations (EECs) have not been calculated for these substances. The EEC for sulfuric acid has also not been calculated since, as noted above, no environmental impact is expected for this substance.

a. HEDP Fate in Terrestrial Environment

HEDP is expected to partition between water and sludge during wastewater treatment. Sludge resulting from wastewater treatment may end up landfilled or land applied. If applied to land, HEDP shows degradation in soil; as such, disposal on land should ensure mineralization and removal from the environment.[13] HEDP's half-life in soil is estimated to be 373 days, extrapolated from observed degradation of 20% after 120 days.[14] 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.[15]

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[13] Page 18 of HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates. 06/09/2004. https://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf

[14] Ibid.

[15] 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. https://www.ncbi.nlm.nih.gov/pubmed/12047077

The Human and Environmental Risk Assessment Project (HERA) report on phosphonates indicates that the treatment steps at an onsite wastewater treatment facility or POTW will remove at least a portion of any HEDP in the process water.[16] The HERA report cites 80% adsorption of HEDP to sewage treatment sludge.

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 previously described in Section 6.b.

b. HEDP Fate in Aquatic Environment

Wastewater from food processing facilities that contain the diluted FCS mixture 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 sunlight.[17] 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. For example, in the presence of iron, 40-90% degradation occurs within 17 days.[18]

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.[19] In such systems, phosphonates like HEDP can become tightly adsorbed onto the sediment, indicating that the major part of biodegradation may occur in the sediment, where a half-life of 471 days was observed for HEDP.[20] 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.[21]

c. Environmental Fate of DPA

It has been shown that DPA, a polysubstituted pyridine derivative readily biodegrades under both aerobic and anaerobic conditions.[22, 23, 24] In presenting a review on the microbial metabolism of pyridines, including DPA, Kaiser, et al. describe aerobic metabolism of DPA to carbon dioxide, ammonium, and water, and anaerobic metabolism to dihydroxypyridine which

[16] Page 22, Table 12 of HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates. 06/09/2004. https://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf

[17] Page 16 of HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates. 06/09/2004. https://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf

[18] Page 19 of HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates. 06/09/2004. https://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf

[19] Page 16 of HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates. 06/09/2004. https://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf

[20] Page 18 of HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates. 06/09/2004. https://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf

[21] 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. https://www.ncbi.nlm.nih.gov/pubmed/12047077

[22] Amador, J.A. and Tatlor, B.P. "Coupled metabolic and photolytic pathway for degradation of pyridinecarboxylic acids, especially dipicolinic acid" Applied and Environmental Microbiology 1990, 56(5), 1352-1356. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC184408/pdf/aem00086-0158.pdf

[23] Seyfried, B. and Schnink, B. "Fermentive degradation of dipicolinic acid (Pyridine-2,6- dicarboxylic acid) by a defined coculture of strictly anaerobic bacteria," Biodegradation, 1990, 1(1), 1-7. https://link.springer.com/article/10.1007/BF00117046

[24] Kaiser, J.P., Feng, Y., and Bollag, J.M., "Microbial metabolism of pyridine, quinolone, acridine, and their derivatives under aerobic and anaerobic conditions," Microbiological Reviews, 1996, 60(3), 483-498. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC239453/pdf/600483.pdf

is then rapidly photodegraded to organic acids (i.e., propionic acid, acetic acid), carbon dioxide, and ammonium.[25]

DPA is soluble in water, with an estimated water solubility of 5,000 mg/L and an estimated octanol-water partition coefficient of 0.57.[26] Therefore, DPA is expected to remain with water and not be absorbed to sludge and will be readily biodegraded during treatment at on-site wastewater treatment facilities and POTWs.

d. Environmental Concentrations of HEDP and DPA

We will consider the aseptic packaging use as the worst-case scenario because it has the highest use levels for both HEDP and DPA at 180 ppm and 9 ppm, respectively.

As previously discussed, HEDP is expected to partition between water and sludge so the EIC for HEDP needs to be refined. According to the HERA report, the treatment steps at an onsite treatment facility will remove or decompose at least a portion of any HEDP that remains. The HERA report cites 80% adsorption of HEDP to sewage treatment sludge. Therefore, the EIC for HEDP has been adjusted by applying the 20:80 (water: sludge) partition factor from the HERA report to estimate the concentrations in water and sewage sludge.

No refinement is necessary for DPA since, as discussed below, this substance is anticipated to remain solely with water and not partition into sludge.

The potential EICs of HEDP and DPA in water and sewage sludge have been estimated as follows:

EICs and EECs for HEDP and DPA Using Aseptic Packaging as the Worst Case Scenario

Use	EIC Total	EIC_{sludge}	EIC_{water}	EEC_{water}
HEDP for Aseptic Packaging	180 ppm	144 ppm[27]	36 ppm[28]	3.6
DPA for Aseptic Packaging	9 ppm	---	9 ppm	0.9

When water from the wastewater treatment facility or POTW is discharged to surface waters, HEDP and DPA will be further diluted by 10-fold, resulting in an estimated environmental concentration (EEC) of 3.6 ppm and 0.9 ppm, respectively.[29] We would like to note that the HEDP EIC for sludge is a maximum for terrestrial impacts, as any sludge used as a soil amendment will likely be significantly diluted by soil or sludge from other sources.

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[25] Ibid

[26] https://chem.nlm.nih.gov/chemidplus/rn/499-83-2.

[27] Calculation: 180 ppm x 80% = 144 ppm

[28] Calculation: 180 ppm x 20% = 36 ppm

[29] Rapaport, Robert A., 1988 Prediction of consumer product chemical concentrations as a function of publicly owned treatment works, treatment type, and riverine dilution. Environmental Toxicology and Chemistry 7(2), 107-115. http://onlinelibrary.wiley.com/doi/10.1002/etc.5620070204/abstract

8. Environmental Effects of Released Substances

a. Terrestrial Toxicity for HEDP

The HERA report discusses biodegradation of HEDP and estimates a half-life in soil of 373 days. Therefore HEDP is expected to degrade, albeit slowly, in soil. HEDP shows no toxicity to terrestrial organisms at levels up to 1000 mg/kg soil dry weight (No Observed Effect Concentration; NOEC).[30] The EIC_{sludge} of 144 ppm is only 14.4% the NOEC, and the maximum concentration in soil when used as a soil amendment should have an even larger margin of safety with respect to this NOEC level. Therefore, the FCS is not expected to have any terrestrial environmental toxicity concerns at levels at which it is expected to be present in sludge or soil. Moreover, the much smaller level of HEDP present in the surface water is not expected to have any adverse environmental impact with respect to sedimentation based on the terrestrial toxicity endpoints available for plants, earthworms, and birds.[31]

b. Aquatic Toxicity for HEDP

The aquatic toxicity for HEDP has been summarized in the public literature, and is shown in the following table:

Species	Endpoint	(mg/L) = ppm
	Short Term	
Lepomis macrochirus[A]	96h LC50	868
Oncorhynchus mykiss[A]	96h LC50	360
Cyprinodon variegatus[A]	96h LC50	2180
lctalurus punctatus[A]	96h LC50	695
Leuciscus idus melonatus[A]	48h LC50	207-350
Daphnia magna[A]	24 - 48h EC50	165-500
Palaemonetes pugio[A]	96 h EC50	1770
Crassostrea virginica[A]	96h EC50	89
Selenastrum capricornutum[B]	96h LC50	3
Selenastrum capricornutum[B]	96h NOEC	1.3
Algae[B]	96h NOEC	0.74
Chiarella vulgaris[A]	48h NOEC	>100
Pseudomonas putida[A]	30 minute NOEC	1000
	Long Term	
Oncorhynchus mykiss[A]	14 d NOEC	60-180
Daphnia magna[A]	28 d NOEC	10 - <12.5
Algae[B]	14 day NOEC	13

A Jaworska, J.; Van Genderen-Takken, H.; Hanstveit, A.; van de Plassche, E.; Feijtel, T. Environmental risk assessment of phosphonates, used in domestic industry and cleaning agents in the Netherlands. Chemosphere 2002, 47, 655-665
B HERA – Human & Environment Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates. 06/09/2004. www.heraproject.com – Phosphonates

[30] 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. https://www.ncbi.nlm.nih.gov/pubmed/12047077
[31] Ibid.

Jaworska *et al.* showed that acute toxicity endpoints for HEDP ranged from 0.74 to 2,180 mg/L, while chronic NOECs were 60 to 180 mg/L for the 14 day NOEC for *Oncorhynchus mykiss* and the 28 day NOEC for the *Daphnia magna* ranged from 10 mg/l to <12.5 mg/l. Although a chronic NOEC of 0.1 mg/L for reproductive effects in *Daphnia magna* was reported, it is inconsistent with other toxicity data, and Jaworska *et al.* suggest that it is due to the depletion of micronutrients by HEDP instead of the intrinsic toxicity of HEDP.[32]

Because HEDP is a strong chelating agent, which can result in negative environmental effects, such as the complexing of essential nutrients, both an intrinsic NOEC (NOECi) and a NOEC that accounts for chelating effects (NOECc) are determined. As noted, it is probable that there will be excess nutrients present in industrial wastewater because eutrophication occurs widely in industrial wastewater coming from food processing facilities.[33]

We note that the 96 hour NOEC, 24-48 hour EC50, and 96 hour EC50 values reported by Jarworska *et al*. for *Selenastrum capricornutum*, *Daphnia magna*, and *Crassostrea virginica,* respectively, were all likely due to chelation effects rather than intrinsic toxicity.[34] As such, these levels are not relevant in situations such as food processing plants, where excess nutrients are present. The HERA report on phosphonates includes a discussion of aquatic toxicity resulting from chelation of nutrients, rather than direct toxicity to aquatic organisms.[35] Chelation is not toxicologically relevant in the current evaluation because eutrophication, not nutrient depletion, has been demonstrated to be the controlling toxicological mode when evaluating wastewater discharges from food processing facilities. Jaworska *et al*. reports the lowest relevant endpoint for aquatic toxicity to be the 28 day NOEC for *Daphnia magna* (10 mg/L),[36] which is above the highest conservatively estimated EEC_{water} of 3.6 ppm for the aseptic packaging application. It is important to emphasize that these estimated EEC values are entirely substitutional for the EEC values resulting from previously effective FCNs for the same use. Consequently, there will be no new environmental introductions when this FCN becomes effective.

c. Ecotoxicology for DPA

As noted above, DPA is soluble in water and very little, if any, DPA is expected to partition to sludge. Accordingly, terrestrial releases of DPA from the intended uses of the FCS are anticipated to be negligible and no toxicity concerns are expected.

There is little publicly available ecotoxicology data for DPA. The Material Safety Data Sheet (MSDS) from one supplier states that the freshwater fish 96 hour LC50 is 322 mg/L for fathead minnow.[37] Due to the lack of available data in the literature, we have evaluated DPA using the

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32 Ibid.

33 US EPA Office of Water, Fact Sheet EPA-822-F-01-010; Ecoregional Nutrient Criteria, Dec 2001, https://nepis.epa.gov/Exe/ZyPDF.cgi/P1009KCN.PDF?Dockey=P1009KCN.PDF.

34 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. https://www.ncbi.nlm.nih.gov/pubmed/12047077

35 Page 25 of HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates. 06/09/2004. https://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf

36 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. https://www.ncbi.nlm.nih.gov/pubmed/12047077

37 See representative MSDS for DPA *available at* http://www.apolloscientific.co.uk/downloads/msds/OR5062_msds.pdf

Ecological Structure Activity Relationships (ECOSAR) Class Program, which is a computerized predictive system maintained and developed by US EPA that estimates aquatic toxicity. The program estimates a chemical's acute toxicity and chronic to aquatic organisms, such as fish, aquatic invertebrates, and aquatic plants, by using computerized Structure Activity Relationships (SARs).[38] This program is a sub-routine of the Estimation Program Interface (EPI) Suite, which is a structure-function predictive modeling suite also developed and maintained by the US EPA.[39] The ECOSAR results for DPA predict the following acute and chronic toxicity endpoints.[40] The complete ECOSAR report for DPA is attached.

ECOSAR Class	Organism	Endpoint	mg/L
Pyridine-alpha-acid	Fish	96 hr LC50	324
	Fish	Chronic value (ChV)	29
Neutral Organic SAR	Fish	96 hr LC50	2657
	Daphnid	48 hr LC50	1322
	Green Algae	96 hr EC50	570
	Fish	ChV	222
	Daphnid	ChV	89
	Green Algae	ChV	111

These values are all higher than the "worst-case" scenario of an EECaq of 0.9 ppm, which is lower than the lowest chronic toxicity endpoint for the most sensitive species. Thus, the use of DPA at such a minimal level is not expected to result in any adverse environmental effects.

9. Use of Resources and Energy

The use of the FCS will not require additional energy resources for treatment and disposal of waste solution, as the components readily degrade. The raw materials that are used in production of the mixture are commercially-manufactured materials that are produced for use in a variety of chemical reactions and production processes. Energy used specifically for the production of the mixture components is not significant.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the dilutions of antimicrobial product. Therefore, the mixture is not reasonably expected to result in any new environmental issues that require mitigation measures of any kind.

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. If the proposed action is not approved, the result would be the continued use of the currently marketed antimicrobial agents that the subject FCS would replace. Such action would have no environmental impact. The addition of the antimicrobial agent to the options available to food processers is not expected to increase the use of PAA antimicrobial products.

[38] Information for ECOSAR is available at https://www.epa.gov/tsca-screening-tools/ecologicalstructure-activity-relationships-ecosar-predictive-model.
[39] Information for EPI Suite is available at https://www.epa.gov/tsca-screeningtools/epi-suitetm-estimation-program-interface.
[40] See EPI Suite – ECOSAR Program Results for CAS 499-83-2; Attachment A.

12. List of Preparers

This Environmental Assessment was prepared on behalf of Biosan LLC, by Wendy A. McCombie of Lewis & Harrison, LLC. Ms. McCombie has a B.S. in Biology with over 25 years of experience providing consulting services for chemical regulations.

13. Certification

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

Name: Wendy A. McCombie, Lewis & Harrison LLC

Title: Agent for Biosan LLC

Signature: [redacted]

Date: February 5, 2020

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15. Attachments

Ecological Structure Activity Relationships (ECOSAR) for DPA

ATTACHMENT

Ecological Structure Activity Relationships (ECOSAR) for DPA

ECOSAR Version 1.11 Results Page

SMILES : O=C(O)c(nc(cc1)C(=O)O)c1
CHEM : 2,6-Pyridinedicarboxylic acid
CAS Num: 000499-83-2
ChemID1:
MOL FOR: C7 H5 N1 O4
MOL WT : 167.12
Log Kow: 0.567 (EPISuite Kowwin v1.68 Estimate)
Log Kow: 0.570 (User Entered)
Log Kow: (PhysProp DB exp value - for comparison only)
Melt Pt: (User Entered for Wat Sol estimate)
Melt Pt: 249.00 (deg C, PhysProp DB exp value for Wat Sol est, 249 dec)
Wat Sol: 4800 (mg/L, EPISuite WSKowwin v1.43 Estimate)
Wat Sol: (User Entered)
Wat Sol: 5000 (mg/L, PhysProp DB exp value)

Values used to Generate ECOSAR Profile

Log Kow: 0.570 (User Entered)
Wat Sol: 5000 (mg/L, PhysProp DB exp value)

Available Measured Data from ECOSAR Training Set

CAS No	Organism	Duration	End Pt	Measured mg/L (ppm)	Ecosar Class	Reference
000499-83-2	Fish	96-hr	LC50	322	Pyridine alpha-acid	DUL

ECOSAR v1.1 Class-specific Estimations

Pyridine-alpha-Acid

ECOSAR Class		Organism	Duration	End Pt	Predicted mg/L (ppm)
Pyridine-alpha-Acid	:	Fish	96-hr	LC50	322.219
Pyridine-alpha-Acid	:	Fish		ChV	29.208 !
Neutral Organic SAR	:	Fish	96-hr	LC50	2641.902
(Baseline Toxicity)	:	Daphnid	48-hr	LC50	1314.539
	:	Green Algae	96-hr	EC50	567.257
	:	Fish		ChV	220.993
	:	Daphnid		ChV	88.774
	:	Green Algae		ChV	110.708

Note: * = asterisk designates: Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported.

NOTE: ! = exclamation designates: The toxicity value was estimated through application of acute-to-chronic ratios per methods outlined in the ECOSAR Methodology Document provided in the ECOSAR Help Menu.

Class Specific LogKow Cut-Offs

If the log Kow of the chemical is greater than the endpoint specific cut-offs presented below, then no effects at saturation are expected for those endpoints.

```
Pyridine-alpha-Acid :
--------------------
Maximum LogKow: 5.0 (LC50)
Maximum LogKow: 6.4 (EC50)
Maximum LogKow: 8.0 (ChV)

Baseline Toxicity SAR Limitations:
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Maximum LogKow: 5.0 (Fish 96-hr LC50; Daphnid LC50)
Maximum LogKow: 6.4 (Green Algae EC50)
Maximum LogKow: 8.0 (ChV)
```