Environmental Assessment

1. **Date** April 30, 2020
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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), which is an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide (HP), acetic acid, 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP), and/or dipicolinic acid (DPA) and, optionally, sulfuric acid. The FCS is intended for use as an antimicrobial agent in the production and preparation of whole or cut or processed/pre-formed poultry and meat, fruits and vegetables, fish and seafood, brines, sauces, and marinades, shell eggs and hard-boiled, peeled eggs, and in aseptic filling systems.

Under its intended conditions of use, the components of the FCS mixture will not exceed:

(1) 2000 ppm peroxyacetic acid (PAA), 1474 ppm hydrogen peroxide (HP), 136 ppm 1-hydroxyethylidine- 1,1-diphosphonic acid (HEDP), and 6.7 ppm dipicolinic acid in process water, ice or brine applied as a wash, spray, dip, rinse, chiller water, low-temperature (less than 40°F) immersion bath, or scald water for whole or cut poultry, including carcasses, parts, trim, and organs.

(2) 495 ppm PAA, 1180 ppm HP, 29 ppm HEDP, and 0.44 ppm DPA in process water, ice or brine for washing, rinsing, or cooling processed and pre-formed poultry.

(3) 2000 ppm PAA, 1474 ppm HP, 121.5 ppm HEDP, and 6.7 ppm DPA in process water, ice or brine applied as a wash, spray, dip, rinse, chiller water, or scald water for whole or cut meat, including carcasses, parts, trim, and organs.

(4) 495 ppm PAA, 1180 ppm HP, 33.5 ppm HEDP, and 0.44 ppm DPA in process water, ice or brine for washing, rinsing, or cooling processed and pre-formed meat.

(5) 500 ppm PAA, 1000 ppm HP, 34 ppm HEDP, and 2 ppm DPA in process water and ice for washing, rinsing, chilling or processing fruits and vegetables in a food processing facility.

(6) 230 ppm PAA, 280 ppm HP, 15 ppm HEDP, and 0.8 ppm DPA in process water, ice or brine used during commercial preparation of fish and seafood in a food processing facility. (7)

2000 ppm PAA, 947 ppm HP, 120 ppm HEDP, and 6.7 ppm DPA in wash water for shell eggs in a food processing facility.

(8) 2000 ppm PAA, 1447 ppm HP, 85 ppm HEDP, and 6.7 ppm DPA in spray, wash, dip, rinse, mist or chiller water of hard-boiled, peeled eggs in a food processing facility.

(9) 50 ppm PAA, 33 ppm HP, 8 ppm HEDP, and 0.1 ppm DPA in brines, marinades and sauces applied to the surface or injected into processed or unprocessed, cooked or uncooked, whole or cut, meat and poultry.

(10) 50 ppm PAA, 33 ppm HP, 8 ppm HEDP, and 0.1 ppm DPA in surface sauces and marinades applied on processed and pre-formed meat and poultry products.

(11) 4500 ppm PAA, 6600 ppm HP, 600 ppm HEDP, and 9 ppm DPA in the commercial sterilization of aseptic filling systems and food packaging prior to filling.[1] If the FCS mixture is applied at a rate exceeding 0.0175 milliliters treatment solution per ounce container capacity, the FCS mixture must be drained from the container and rinsed with sterile water and drained again. Surfaces of polymeric food packaging will also be drained, rinsed and drained again following application of the FCS mixture.

b. Need for Action

The antimicrobial agent reduces or eliminates pathogenic and non-pathogenic microorganisms that may be present on food and food packaging during production.

The requested action to expand the currently approved uses of the FCS is needed to address current and future needs of food processors and governmental agencies to improve food safety. Use of the FCS provides more options for antimicrobial interventions. For example, the use of peroxyacetic acid at higher concentrations for relatively short periods of time, and in smaller total volumes, enhances the capacity of the food industry to improve processing techniques, such as providing more flexibility in terms of time, concentrations, and application method (spray vs. immersion) to better control food pathogens.

The use of HEDP and DPA improve stability of concentrated peroxyacetic acid formulations during storage until they are diluted with water.

c. Locations of Use/Disposal

The antimicrobial agent is intended for use in food processing facilities throughout the United States. The FCS may be applied to meat and poultry, fruits and vegetables, fish, seafood, shell eggs and hard-boiled peeled eggs. The FCS also may be used in brines, marinades and sauces, as well as in the commercial sterilization of aseptic filling systems. After use, the FCS will be disposed of with processing plant wastewater according to National Pollutant Discharge Elimination System (NPDES) regulations. For processing plants that hold a NPDES permit (i.e.,

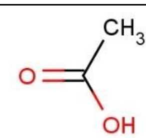
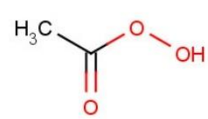
[1] Except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging.

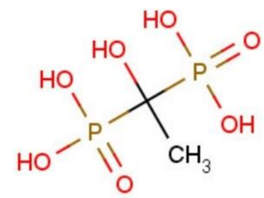
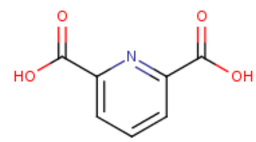
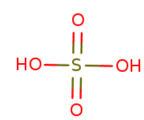
direct dischargers), the FCS-containing wastewater will be treated on-site before direct discharge to surface waters. For processing plants without such NPDES permits (i.e., indirect dischargers), the FCS-containing wastewater would travel through the sanitary sewer system into Publicly Owned Treatment Works (POTWs) for standard wastewater treatment processes before movement into aquatic environments. As a conservative approach, it can be assumed that wastewater will be treated onsite before discharge to surface water pursuant to a NPDES permit. It is expected that process water not containing the FCS will be used in plants for activities such as cleaning and sanitation, resulting in significant dilution of HEDP and DPA into the total water effluent. Wastewater from fishing vessels is expected to be disposed in the ocean. We have also estimated maximum potential concentrations in soil from application of sludge from wastewater treatment facilities to soil.

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

The raw materials used in this product are water, HP, acetic acid, HEDP and/or DPA, and, optionally, sulfuric acid. PAA formation is the result of an equilibrium reaction between HP and acetic acid. The FCS is supplied in concentrated form and is diluted at the processing plant for use to achieve the desired level of peroxyacetic acid that is needed to address the food safety and quality needs.

Table 1: Chemical Identity of Substances of the Proposed Action

Component	CAS No.	Molecular Weight	Structural Formula	Molecular Formula
Hydrogen peroxide	7722-84-1	34.01	HO-OH	H_2O_2
Acetic acid	64-19-7	60.05		$C_2H_4O_2$
Peroxyacetic acid	79-21-0	76.05		$C_2H_4O_3$

1-Hydroxyethylidene-1,1-diphosphonic acid	2809-21-14	206.3		$C_2H_8O_7P_2$
Dipicolinic acid	499-83-2	167.12		$C_7H6_6NO_4$
Sulfuric acid	7664-93-9	98.08		H_2SO_4
Water	7732-18-5	18.01	H-O-H	H_2O

6. Introduction of Substances into the Environment

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

Under 21 C.F.R § 25.40(a), an environmental assessment 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 which meet all applicable federal, state and local environmental regulations. The Notifier asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS, such as: 1) unique emission circumstances that are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and that may harm the environment; 2) the action threatening a violation of Federal, State or local environmental laws or requirements (40 C.F.R. § 1508.27(b)(10)); or 3) production associated with the proposed action that 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 or threatened, 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

Introduction of dilute solutions of the product into the environment will take place primarily via release from wastewater treatment systems. Introduction of the components of the product into the environment will result from use of the product as an antimicrobial agent in processing water and spray applications onto food. It is also 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. Following use, the disposal of such water and spray drainage will be into on-site treatment plants and/or POTWs. The total amount of product used at a typical facility will vary significantly, depending on the equipment used and the amount of food processed. The maximum at-use concentration of PAA, hydrogen peroxide, HEDP, and DPA for each application will be as follows:

Table 2: Summary of Intended Uses

Use	**PAA ppm**	**H_2O_2 ppm**	**HEDP ppm**	**DPA ppm**
Process water, ice or brine as applied as a wash, spray, dip, rinse, chiller water, low-temperature (less than 40°F) immersion bath, or scald water for whole or cut poultry, including carcasses, parts, trim, and organs.	2000	1474	136	6.7
Process water, ice or brine for washing, rinsing, or cooling processed and pre-formed poultry.	495	1180	29	0.44
Process water, ice or brine as applied as a wash, spray, dip, rinse, chiller water, or scald water for whole or cut meat, including carcasses, parts, trim, and organs.	2000	1474	121.5	6.7
Process water, ice or brine for washing, rinsing, or cooling processed and pre-formed meat.	495	1180	33.5	0.44
Process water and ice for washing, rinsing, chilling or processing fruits and vegetables in food processing facilities.	500	1000	34	2
Process water, ice or brine used during commercial preparation of fish and seafood in a food processing facility.	230	280	15	0.8
Wash water for shell eggs in a food processing facility.	2000	947	120	6.7

In spray, wash, dip, rinse, mist or chiller water of hard-boiled, peeled eggs in a food processing facility.	2000	1447	85	6.7
Brines, marinades and sauces applied to the surface or injected into processed or unprocessed, cooked or uncooked whole or cut meat and poultry.	50	33	8	0.1
In surface sauces and marinades applied on processed and pre-formed meat and poultry products.	50	33	8	0.1
Aseptic filling systems and food packaging 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	600	9

Treatment of the process water at an on-site wastewater treatment plant or POTW is expected to result in complete degradation of PAA, HP, and acetic acid. Specifically, the PAA will breakdown into oxygen, water and acetic acid, while HP will break down into oxygen and water.[2] 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.[3] 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.[4] In biodegradation studies of acetic acid using activated sludge, 99% degraded in 7 days under anaerobic conditions.[5] Acetic acid is not expected to concentrate in the wastewater discharged to the treatment facility/POTW.

Sulfuric acid is listed as an optional ingredient in the FCS formulation. Sulfuric acid is used to catalyze the reaction between acetic acid and hydrogen peroxide, more rapidly producing a stable PAA mixture, and to modify the pH of the FCS.

Sulfuric acid is not a toxicological or environmental concern at the proposed use levels. While the environmental effects of aerosols of sulfuric acid and sulfates on the atmosphere and

[2] U.S. Environmental Protection Agency, *Reregistration Eligibility Decision: Peroxy Compounds* (December 1993), p. 18, available at https://archive.epa.gov/pesticides/reregistration/web/pdf/peroxy_compounds.pdf.
[3] European Centre for Toxicology and Toxicology of Chemicals (ECETOC), *Joint Assessment of Commodity Chemicals (JACC) No. 40 Peracetic Acid and its Equilibrium Solutions*, January 2001, Table 11, p. 29, available at http://www.ecetoc.org/jacc-reports.
[4] ECETOC, *JACC No. 22, Hydrogen Peroxide*, January, 1993, Table 6, p. 23, "Degradation in the River Soane of Hydrogen Peroxide," available at http://www.ecetoc.org/jacc-reports.
[5] 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.

rain are well known, small quantities of water or terrestrial discharges are not expected to have significant environmental effects.[6]

Sodium sulfate is widely distributed in nature. It occurs as mineral salts (e.g., thenardite, mirabilite); it is present in almost all fresh and salt waters, and sulfate as such is normally present in almost all natural foodstuffs.

Due to the low aquatic toxicity and the natural recycling that occurs in the sulfur cycle, wide dispersive use of small amounts of sodium sulfate presents no significant hazard to the environment.[7]

Therefore, these substances 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, section 7 and section 8 will consider only the environmental introduction of HEDP and DPA.

Because it is difficult to establish water usage levels, we assume, in the very worst-case, that all of the water used in a plant is treated with the FCS, and we will use the maximum level of HEDP and DPA to calculate the environmental introduction concentration (EIC) of HEDP and DPA would be 600 ppm and 9 ppm, respectively.

7. *Fate of Emitted Substances in the Environment*

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.[8] The HERA report cites 80% adsorption of HEDP to sewage treatment sludge.

Information in the literature indicates that DPA, a polysubstituted pyridine derivative, readily biodegrades in both freshwater and marine water aerobic and anaerobic conditions,[9]

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[6] See Human and Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products, Sodium Sulfate, January 2006; *see also* The Organization for Economic Cooperation and Development (OECD) SIDS Voluntary Testing Programme for International High Production Volume Chemicals (OECD SIDS), Sulfuric Acid, 2001; available at https://hpvchemicals.oecd.org/UI/handler.axd?id=248f397d-64b3-4e14-8be9-473974e8dfdb

[7] HERA- Cover Note of Sodium sulfate, Human and Environmental Risk Assessment on ingredients of Household Cleaning Products Substance: Sodium sulfate (CAS# 7757-82-6), Page 5, Item 4. Available at: https://www.heraproject.com/files/39-F-06_Sodium_Sulfate_Human_and_Environmental_Risk_Assessment_V2.pdf

[8] HERA, Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products, *Phosphonates (CAS 6419-19-8; 2809-21-4; 15827-60-8),* Draft 06/09/2004, Table 12, p. 22 available at: http://www.heraproject.com/files/30-f-04-%20hera%20phosphonates%20full%20web%20wd.pdf .

[9] Amador, J.A. and Tatlor, B.P., *Coupled metabolic and photolytic pathway for degradation of pyridinecarboxylic acids, especially dipicolinic acid*, Applied and Environmental Microbiology, 56(5): 1352-1356 (1990); Seyfried B. and Schnink, B. *Fermentive degradation of dipicolinic acid (Pyridine-2,6- dicarboxylic acid) by a defined coculture of strictly anaerobic bacteria*, Biodegradation, 1(1), 1-7 (1990); 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, 60(3): 483-498 (1996).

and in both anaerobic and aerobic soil conditions.[10] 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 is then rapidly photodegraded to organic acids (i.e., propionic acid, acetic acid), carbon dioxide, and ammonium.[11] Further information indicates that DPA is soluble in water, with the estimated water solubility of 5,000 mg/L and an octanol-water partition coefficient estimated to be 0.57.[12] Based upon this information, it is reasonable to conclude that DPA will substantially remain with water and not be absorbed to sludge, and that DPA will be readily biodegraded during treatment at POTWs and on-site treatment facilities.

We have estimated the potential environmental introduction concentrations (EICs) of HEDP and DPA in water and sewage sludge based upon the information above. We have considered the aseptic filling and packaging system application as the worst-case scenario because it has the highest use level for both HEDP and DPA. To calculate the EICs for HEDP in water and sewer sludge we have applied the 20:80 partition factor from the HERA report (EIC_{sludge} = 600 x 80% = 480 ppm; EIC_{water} = 600 x 20% = 120 ppm). (See Table 3 below).

When the water from the facility or POTW is discharged to surface waters, HEDP and DPA will be diluted a further 10-fold, resulting in an effective environmental concentration (EEC) of 12.0 ppm and 0.9 ppm, respectively.[13]

Table 3: Worst-case EICs and EECs for HEDP and DPA Using Aseptic Packaging as the Worst Case for HEDP and DPA

Use	**EIC Total**	**EEC_{sludge}**	**EEC_{water}**
Aseptic packaging – HEDP	600 ppm	480 ppm[14]	12.0 ppm[15]
Aseptic packaging – DPA	9 ppm	-	0.9 ppm[16]

Finally, we 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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[10] Naik, M.N. et al, *Microbial Degradation and Phytotoxicity of Picloram and Other Substituted Pyridines*, Soil Biology and Biochemistry, 4: 313-323 (1972), see p. 320; Sims, G.K. and Sommers, L.E., *Biodegradation of Pyridine Derivatives in Soil Suspensions*, 5:503-509 (1986).

[11] Kaiser, p. 488.

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

[13] Rapaport, R.A., *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 (1988).

[14] Example Calculation 600 ppm*80% = 480 ppm

[15] Example Calculation 600 ppm*20%/10 = 12.0 ppm

[16] Example Calculation 9 ppm/10 = 0.9 ppm

8. Environmental Effects of Released Substances

a. Terrestrial Toxicity

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).[17] Our maximum estimated concentration in sludge (480 ppm) is well below 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 the NOEC. 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.[18]

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.

b. Aquatic Toxicity

Aquatic toxicity of HEDP has been summarized, and is showing in the following table:

Table 4: Summary of Environmental Toxicity Data for HEDP[19]

Species	**Endpoint**	**mg/L**
Short Term		
Lepomis macrochirus	96 hr LC_{50}	868
Oncorhynchus mykiss	96 hr LC_{50}	360
Cyprinodon variegatus	96 hr LC_{50}	2180
Ictalurus punctatus	96 hr LC_{50}	695
Leuciscus idus melonatus	48 hr LC_{50}	207 – 350
Daphnia magna	24 – 48 hr EC_{50}	165 – 500
Palaemonetes pugio	96 hr EC_{50}	1770
Crassostrea virginica	96 hr EC_{50}	89
Selenastrum capricornutum	96 hr EC_{50}	3

17 Jaworska, J., et al, *Environmental risk assessment of phosphonates, used in domestic industry and cleaning agents in the Netherlands*, Chemosphere 2002, 47(6), 655-665, May 2002.
18 *Id.*
19 Short term values for *Lepomis macrochirus*, *Oncorhynchus mykiss*, *Cyprinodon variegatus*, *Ictalurus punctatus*, *Leuciscus idus melonatus*, *Daphnia magna*, *Palaemonetes pugio*, *Crassostrea virginica*, *Chlorella vulgaris*, *Pseudomonas putida*, and long term values for *Oncorhynchus mykiss*, *Daphnia Magna* found in Jaworska, et al, p. 662 (2002). Short term values for *Selenastrum capricornutum*, and short and long term values for algae found in HERA (2004) (Tables 13 and 14, p. 29-31).

Selenastrum capricornutum	96 hr NOEC	1.3
Algae	96 hr NOEC	0.74
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
Algae	14 day NOEC	13

According to Jaworska et al,[20] the primary adverse effects of HEDP result from chelation of nutrients rather than direct toxicity of HEDP. 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. The lowest short-term EC_{50} values published for *Selenastrum capricornutum* (3 ppm), *Daphnia magna* (165 ppm), and *Crassostrea virginica* (89 ppm) are acute toxicity endpoints considered to result from this chelation effect. These values are not relevant when excess nutrients are present as expected in food processing wastewaters. The lowest relevant endpoint for food processing uses was determined to be the chronic NOEC of 10 ppm for *Daphnia magna*. Although uncertainties intrinsic to its derivation make the usefulness of the NOEC debatable,[21] based on the available environmental toxicology data, reliance upon the NOEC for *Daphnia magna* is appropriate.[22] 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 of 12.0 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.

There is little publicly available ecotoxicology data for DPA. A review of EPA's ECOTOX database provides one study indicating a freshwater fish 96-hour LC_{50} of 322 mg/L for fathead

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[20] Jaworska, et al (2002).

[21] Blok J. and Balk F., *Environmental regulation in the European Community*, in Fundamentals of Aquatic Toxicology: Effects, Environmental Fate, and Risk Assessment, (GM Rand, Ed.), Taylor & Francis, New York, 1995, chapter 27 ("NOEC determinations are likely more statistically variant (uncertain) than EC_{50} determinations"); also see Organisation for Economic Co-operation and Development (OECD), *Current Approaches in the Statistical Analysis of Ecotoxicity Data: A Guidance to Application*, OECD Environmental Health and Safety Publications, Series on Testing and Assessment, No. 54, Environment Directorate, Paris, 2006 (recommending that that NOECs be abandoned), available at http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2006)18&doclanguage=en.

[22] Jaworska, et al (2002).

minnow.[23] In the absence of literature data, we have evaluated DPA using the Ecological Structure Activity Relationships (ECOSAR) Class Program, which is a computerized predictive system maintained and developed by the U.S. EPA that estimates aquatic toxicity. The program estimates a chemical's acute (short-term) toxicity and chronic (long-term or delayed) toxicity to aquatic organisms, such as fish, aquatic invertebrates, and aquatic plants, by using computerized Structure Activity Relationships (SARs).[24] This program is a sub-routine of the Estimation Program Interface (EPI) Suite – a structure-function predictive modeling suite also developed and maintained by the U.S. EPA.[25] The ECOSAR results for DPA predict the following acute and chronic toxicity endpoints tabulated below.[26] The complete ECOSAR report for this analysis is attached to this EA.

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 much higher than the "worst-case" scenario of an EECaq of 0.9 ppm, which is over 30 times 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 notified use of the FCS mixture will not require additional energy resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some degree replace similar HEDP/DPA stabilized peroxy antimicrobial agents already on the market. The raw materials that are used in production of the mixture are commercially-manufactured

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[23] See enclosed ECOTOX report. The ECOTOX database can be accessed here: https://cfpub.epa.gov/ecotox/advanced_query.htm.

[24] Information on ECOSAR can be found at https://www.epa.gov/tsca-screening-tools/ecologicalstructure-activity-relationships-ecosar-predictive-model.

[25] EPISuite predicts various physical-chemical properties and environmental fate endpoints and also include models for environmental transport. Running the tool will give the user an indication of the transport and persistence of a chemical. Information on EPI Suite is available at https://www.epa.gov/tsca-screeningtools/epi-suitetm-estimation-program-interface.

[26] *See* EPI Suite – ECOSAR Program Results for CAS 499-83-2 included as an Attachment to this EA. Chronic toxicity was estimated through application of acute-to-chronic ratios per methods outlined in the ECOSAR Methodology Document provided in the ECOSAR Help Menu.

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, no mitigation measures are required.

11. Alternatives to the Proposed Action

No significant 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 significant environmental impact.

12. List of Preparers

Ms. Patricia Kinne, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036-1795. Ms. Kinne has over 8 years of experience with food contact compliance matters, including FCN submissions and chemical registration submissions.

Joan Sylvain Baughan, Partner, Steptoe & Johnson LLP, 1330 Connecticut Avenue N.W., Washington, D.C. 20036-1795. J.D. with 28 years of experience with Food Additive Petitions, FCN submissions, and environmental assessments.

13. Certification

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

Date: April 30, 2020

Respectfully submitted,

[redacted]

Joan Sylvain Baughan

14. References

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15. Attachments

ECOSAR modeling.

ECOTOX Report for Dipicolinic Acid.