ENVIRONMENTAL ASSESSMENT

1. **Date:** August 17, 2022

2. **Name of Submitter:** Safe Foods Corporation

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4. **Description of the Proposed Action**

A. Requested Approval

The approval requested in this notification is to provide for the use of the Food Contact Substance (FCS), which is an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide, acetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), and optionally, octanoic acid and peroxyoctanoic acid, as an antimicrobial agent to be used:

(1) At concentrations up to 1800 ppm PAA, 1050 ppm hydrogen peroxide, and 117 ppm HEDP for use in process water or ice used in washing, rinsing, or cooling whole or cut meat carcasses, parts, trim, and organs.

Mixtures of these substances have previously been approved for the same uses under 21 CFR 173.370[1], permitting the use of the substances at concentrations below the levels proposed above. Similar substances to the FCS have also been previously approved for the same uses with various FCNs (No. 1490, 1580, 1688, 1911, 1960, and 1986) permitting the use of the substances at concentrations at or above the levels proposed above.

B. Need for Action

The antimicrobial agent reduces or inhibits the growth of pathogenic and non-pathogenic microorganisms that may be present on and in food to provide safer foods for consumers.

Approval of the expanded use of the FCS will allow processors to address current needs of processors and government agencies to improve food safety by providing processors with additional tools to aid in reducing pathogenic and non-pathogenic microorganisms.

C. Locations of Use/Disposal

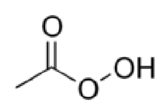
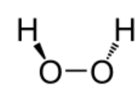
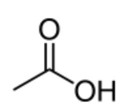
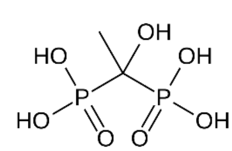
The antimicrobial agent is intended for use in meat processing plants throughout the United States. After use in processing plants, the waste process water containing the FCS is expected to be disposed of through the processing plant wastewater treatment facilities or through a local publicly owned treatment works (POTW).

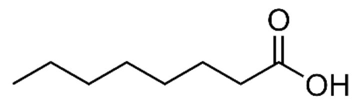
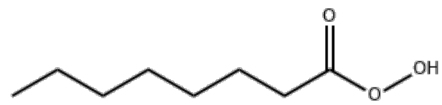
5. Identification of Substances that are the Subject of the Proposed Action

The Food Contact Substance is an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid, and optionally, octanoic acid and peroxyoctanoic acid. The formation of peroxyacetic acid (PAA) and peroxyoctanoic acid (POOA) is the result of a double equilibrium reaction between hydrogen peroxide and acetic and octanoic acids. The FCS is supplied in concentrated form and is diluted at the processing plant to achieve the desired level of PAA needed to address the microbial load.

The descriptions, chemical formulae, structures and molecular weights of the components are described in Table 1 below:

Table 1: Chemical Identity of Food Contact Substance Components

Component	CAS Number	Molecular Weight (g/mol)	Molecular Formula	Molecular Structure
Peroxyacetic acid	79-21-0	76.05	$C_2H_4O_3$	
Hydrogen peroxide	7722-84-1	34.015	H_2O_2	
Acetic acid	64-19-7	60.05	$C_2H_4O_2$	
1-hydroxyethylidene-1,1-diphosphonic acid	2809-21-4	206.028	$C_2H_8O_7P_2$	

Water	7732-18-5	18.015	H_2O	
Octanoic acid	124-07-2	144.214	$C_8H_{16}O_2$	
Peroxyoctanoic acid	33734-57-5	160.22	$C_8H_{16}O_3$	

6. Introduction of Substances into the Environment

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

As provided in 21 CFR 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. Notifier asserts that no extraordinary circumstances apply to the manufacture of the FCS including situations where: 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; 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 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

Peracids (peroxyacetic and peroxyoctanoic acids) decompose rapidly in the environment through several processes such as hydrolysis, spontaneous decomposition, metal-catalyzed decomposition, and oxidation of organic material. The reaction of the peracids, such as peroxyacetic acid (POAA) and peroxyoctanoic acid (POOA),with organic matter in the environment results in formation of octanoic acid, acetic acid and oxygen.[2] In its assessment of POOA and PAA, the EU uses a read-across approach with PAA for POOA degradation. This read-across approach is considered strong enough to support a rapid POOA degradation by abiotic chemical reactions that would result in a degradation rate difference in the order of minutes or hours between the two chemicals.[3] Both octanoic acid and acetic acid decompose rapidly by biotic degradation through β-oxidation pathway of fatty acids and are not expected to accumulate in the environment. The degradation products of these acids in soil and water are carbon dioxide and water.[4]

The FCS is supplied in concentrated form and is diluted at the processing plant. When diluted for use, the target levels of PAA in the process water for use will vary according to microbial load and type of application. The maximum at-use concentration of PAA, hydrogen peroxide (H_2O_2), and HEDP for each application will be as follows:

Application	**PAA**	**H_2O_2**	**HEDP**
Whole or cut meat, including carcasses, parts, trim, and organs	1800 ppm	1050 ppm	117 ppm

Treatment of the process water at the on-site wastewater treatment plant or at the POTW is expected to result in complete degradation of peroxyacetic acid, octanoic acid, hydrogen peroxide and acetic acid, based on the half-life of these substances (described in detail in section 7 of this EA). Specifically, peroxyacetic acid will break down into oxygen and acetic acid, hydrogen peroxide will break down into oxygen and water, and octanoic acid will break down into carbon dioxide and water. Therefore, these substances are not expected to be introduced into the environment in any significant extent as a result of the proposed use of the FCS. Consequently, the remainder of this section will consider only the environmental introduction of HEDP.

Meat Processing Facilities

All primary meat processing operations process live animals through a series of steps which include assembly and holding animals for slaughter, stunning and bleeding, hide and hair removal (for hogs), evisceration, variety meat (organ) harvest, carcass washing, trimming, and cooling. Although the FCS is expected to be used on all types of meat, such as beef, pork, lamb/mutton, etc., its single biggest user is expected to be beef processors. Therefore, the use of the FCS for meat processing will focus on beef processing.

The FCS is used in diluted form in the process water sprayed directly on the exposed surface of the beef carcasses after hide removal, and is also applied to carcasses, parts, trim, and organs through spraying and/or immersion. The FCS is typically sprayed on the carcass as it moves through a cabinet while on a conveyor. Majority of the spray solution sprayed on the carcass drains from the carcass and eventually enters the wastewater treatment facility.

While large water usage is expected from meat carcass washing and clean-up during processing, additional water is used in meat processing facilities for cleaning, boiler water, cooling water, etc. The above additional uses of water within the meat processing plant significantly dilute the concentration of HEDP introduced into the environment. Therefore, even though the maximum at-use concentration of HEDP in meat processing water is limited to 117 ppm, the actual environmental introduction concentration (EIC) will be diluted below this level.

A 10-fold dilution factor accounts for the expected dilution in surface waters of effluent from an on-site wastewater treatment facility or POTW. This information is reported by Rapaport (1988).[5] The environmental introduction concentrations (EIC) and expected environmental concentration (EEC) of each use is presented in Item 7 of the EA.

7. Fate of Substances Released into the Environment

As previously mentioned, treatment of the process water at the on-site wastewater treatment plant or at the POTW is expected to result in complete degradation of peroxyacetic acid, hydrogen peroxide and acetic acid. Peroxyoctanoic acid reacts with organic matter in the environment resulting in formation of octanoic acid, acetic acid and oxygen.

PAA and hydrogen peroxide rapidly degrade upon contact with organic matter, transition metals, and upon exposure to sunlight. According to the European Center for Ecotoxicology and Toxicology of Chemicals (ECETOC), 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.[6] The half-life of hydrogen peroxide in natural rivers ranged from 2.5 days when initial concentration was 10,000 ppm, to 20.1 days when initial concentration decreased to 100 ppm.[7] Biodegradability studies of acetic acid showed 99% degradation in 7 days under anaerobic conditions.[8] Acetic acid is not expected to concentrate in the waste water discharged to POTW.

Octanoic acid decomposes rapidly by biotic degradation through β-oxidation pathway of fatty acids and is not expected to accumulate in the environment. Octanoic acid and octanoic acid salts are readily biodegradable (80.2-86.2% in 28 days)[9]. Half-lives of fatty acids salts with chain lengths of C8-C18 are reported to be <25 h for starting concentrations of 7.3 to 24.7 mg/L.[10] Yoshimura reports 100% degradation in 20 days, with half-life for C8 chain length fatty acids (such as Octanoic acid) of 15 hours when the starting concentration is 7.3 mg/L, and 25h when the starting concentration is 24.7 mg/L. The environmental fate of octanoic acid can be found in EPA's registration review of caprylic acid. In this review, the degradation products of fatty acids, such as octanoic acid, in soil and water are listed as carbon dioxide and water. Octanoic acid does not bioaccumulate due to several factors including its rapid decomposition, and the fact that it is a fatty acid that is found naturally in the environment and in naturally occurring biological molecules found in all living organisms. Octanoic acid is found naturally in the milk of various mammals, and in coconut and palm kennel oils.[11] Due to the rapid degradation of octanoic acid, the Agency did not require any environmental fate or ecological effects studies at the time of its review of caprylic acid.[12]

Given the above description of the degradation of peroxyacetic acid, hydrogen peroxide, octanoic acid, and acetic acid, these components of the FCS are not expected to be introduced into the environment to any significant extent as a result of the proposed use of the FCS. Therefore, the remainder of this EA will consider only the environmental introduction of HEDP.

The 2004 Human and Environmental Risk Assessment (HERA) reports that decomposition of HEDP contained in the discharged wastewater occurs at a moderately slow pace, 33% in 28 days.[13] HEDP that is removed via sedimentation or filtration slowly degrades into carbon dioxide, water and phosphates. Phosphate anions are strongly bound to organic matter and soil particles, and phosphate is a required macronutrient of plants. The HERA report estimates a half-life of HEDP in soil of 373 days. Therefore, any aquatic or soil biodegradation of HEDP is not expected to lower the estimated EEC for HEDP.

The 2004 HERA publication on phosphonate indicates that 80-90% can be expected to adsorb to wastewater sludge. Therefore, the sludge partition EICs of HEDP are calculated by multiplying the stated HEDP use level concentration by 80% (use level x 0.8). Multiplying the use level by 20% (use level x 0.2) provides the HEDP concentration remaining in wastewater. The expected environmental concentrations (EECs) were calculated using a conservative 10-fold dilution factor for discharge to surface waters of the effluent from an onsite treatment facility or POTW, as determined by Rapaport (Rapaport 1988). A summary of these calculations is shown below.

Application	HEDP	EEC_{sludge} and $EIC_{sludge}{}^{a}$	EIC_{water}	$EEC_{water}{}^{b}$
Whole or cut meat, including carcasses, parts, trim, and organs	117	93.6	23.4	2.3
$^{a}EIC_{sludge}$ = HEDP x 80% $^{b}EEC_{water}$ = (HEDP x 20%) ÷ 10 dilution factor)				

8. Environmental Effects of Released Substances

Terrestrial Toxicity
According to the 2004 HERA report, HEDP in sludge is not expected to have any adverse environmental impact based on toxicity endpoints for terrestrial organisms. Specifically, HEDP shows no toxicity to terrestrial organisms (plants, earthworms, worms in soil, etc.) at levels up to 1000 mg/kg soil dry weight (No Observed Effect Concentration; NOEC). Therefore, there is no toxicity expected from land application of sludge containing 93.6 ppm HEDP.

Aquatic Toxicity
The 2004 HERA study demonstrates that toxic effects of HEDP result from chelation of nutrients, rather than direct toxicity to aquatic organisms. Chelation is not toxicologically relevant in the evaluation of the toxic effects of HEDP because eutrophication, not nutrient

depletion, has been demonstrated as the controlling toxicological mode when evaluating wastewater discharges from food processing facilities.

Jaworska et al.,[14] and the HERA 2004 study on phosphonates have summarized the aquatic toxicity data for HEDP as shown in the table below:

Environmental Toxicity Data for HEDP		
Species	**Endpoint**	**mg/L**
Short Term		
Lepomis macrochirus[1]	96 hr LC_{50}	868
Oncorhynchus mykiss[1]	96 hr LC_{50}	360
Cyprinodon variegatus[1]	96 hr LC_{50}	2180
Ictalurus punctatus[1]	96 hr LC_{50}	695
Leciscus idus melanatus[1]	48 hr LC_{50}	207-350
Daphnia magna[1]	24-48 hr EC_{50}	165-500
Palaemonetes pugio[1]	96 hr EC_{50}	1770
Crassostrea virginica[1]	96 hr EC_{50}	89
Selenastrum capricornutum[2]	96 hr EC_{50}	3
Selenastrum capricornutum[1]	96 hr NOEC	1.3
Algae[2]	96 hr NOEC	0.74
Chlorella vulgaris[1]	48 hr NOEC	≥100
Pseudomonas putida[1]	30 minute NOEC	1000
Long Term		
Oncorhynchus mykiss[1]	14 day NOEC	60-180
Daphnia magna[1]	28 day NOEC	10- <12.5
Algae[2]	14 day NOEC	13

[1]Data cited in Jaworska *et al.*
[2]Data cited in HERA Phosphonates, 2004

Jaworska et al. and HERA, 2004 found acute toxicity endpoints for HEDP ranged from 0.74 to 2180 mg/L, while chronic toxicity NOECs were 60-180 mg/L for the 14-day NOEC for *Oncorhynchus mykiss*, and 10 - <12.5 mg/L for the 28-day NOEC for *Daphnia magna.* The highest short-term EC_{50} values reported by Jaworska et al. and HERA, 2004 for algae, *Selenastrum capricornutum* (3 ppm), *Daphnia magna* (165-500 ppm), and *Crassostrea virginica* (89 ppm), are considered to result from chelation effect, rather than intrinsic toxicity. Therefore, these values are not relevant in food processing wastewaters, where excess nutrients are present. The lowest relevant endpoint for food processing uses was determined by Jaworska et al. to be chronic NOEC of 10ppm for *Daphnia magna*.[15] In comparison, the HEDP maximum (worst-case) EEC value of 2.3 ppm in water for the proposed use of the FCS in meat is well below the endpoint of 10 ppm chronic NOEC for *Daphnia magna*.

9. Use of Resources and Energy

The notified use of the FCS will not require additional energy resources for the treatment and disposal of waste solution because the components readily degrade. The FCS is expected to compete with, and to some degree replace similar HEDP stabilized peroxy antimicrobial agents already on the market. Thus, the FCS will consume comparable amounts of energy and resources as similar products. The raw materials that are used to manufacture the FCS are commercially manufactured chemicals that are produced for use in a variety of chemical reactions and production processes. Therefore, the energy used for the production of the FCS 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 dilute FCS mixture. Thus, the use of the FCS as proposed does not require mitigating measures.

11. Alternatives to the Proposed Action

No adverse environmental impacts are identified herein that would necessitate alternative actions to that proposed in this Notification. The alternative of not approving the action proposed herein would result in continued use of currently marketed antimicrobial agents that the subject FCS would replace. Such action would have no significant environmental impact. The addition of the FCS to the options available to food processors is not expected to increase the use of peroxyacetic acid antimicrobial products.

12. List of Preparers

Beatrice Maingi, Senior Manager, Regulatory Affairs & Quality Assurance Officer, Safe Foods Corporation, 1501 E. 8th Street, North Little Rock, AR 72114. M.A and B.S. in Chemistry and MBA, 11 years of experience preparing regulatory submissions to international regulatory jurisdictions, 6 years preparing regulatory submissions to FSIS, and 4 years preparing regulatory submissions to FDA.

13. Certification

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

Date: August 17, 2022

Beatrice Maingi
Senior Manager, QA, Compliance & Regulatory
Safe Foods Corporation

14. References

[1] U.S. Food and Drug Administration, 2001. Federal Register Vol. 65, No. 228, 70660-70661. (21 CFR 173.370, available online at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=173.370)
[2] Evaluating Competent Authority: France, April 2020. Assessment Report Reaction mass of peracetic acid and peroxyoctanoic acid.
[3] Ibid
[4] Ibid
[5] 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. Available online at: http://onlinelibrary.wiley.com/doi/10.1002/etc.5620070204/full
[6] European Center for Ecotoxicology and Toxicology of Chemicals, JACC No. 40: Peracetic Acid and Its Equilibrium Solutions, January 2001.
[7] European Center for Ecotoxicology and Toxicology of Chemicals, JACC No. 22: Hydrogen Peroxide, January 1993.
[8] U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category. Acetic Acid and Salts Panel, American Chemical Council, June 28, 2001.
[9] Simon, M. Manometric respirometry test: Ready biodegradability of octanoic acid, zinc salt, basic (CAS 90480-58-3 by activated sludge. Study report: Fraunhofer Institute for Molecular Biology and Applied Ecology (IME), 2012. (cited in European Chemicals Agency (ECHA)'s registration dossier, available at https://echa.europa.eu/registration-dossier/-/registered-dossier/11214/5/3/2#).
[10] Yoshimura, K.; Katsutoshi, A.; Hayashi, K.; Kawase, J.; Tsuji, J., 1984. Biodegradation of Linear Alkylbenze sulfonates and soap in river water. *Jap. J. Limnol.* 45 (3), 204-212.
(Cited in HERA Risk Assessment: Human & Environmental Risk Assessment on ingredients of European household cleaning products: Fatty Acid Salts (Soap); September 2003).
[11] EPA: Caprylic (Octanoic) Acid Final Registration Review Decision Registration Review; EPA Case 5028. Doc #EPA-HQ-OPP-2008-0477; June 2009.
[12] EPA Memorandum: Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Caprylic Acid Registration Review Decision Document; EPA Case No. 5028, PC Code: 128919; May 2008.
[13] HERA-Human and Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates, www.heraproject.com-Phosphonates
[14]Jaworska, J.; Van-Genderen-Takken, H.; Hanstveit, A.; van de Plasche, E.; Feijtel, T. Environmental risk assessment of phosphonates used in domestic laundry and cleaning agents in the Netherlands. *Chemosphere* 2002, 47, 655-665.
[15] *Ibid*