

1. **Date:** July 29, 2016
2. **Name of Applicant:** PeroxyChem, LLC
3. **Address:**

All communications on this matter are to be sent in care of Counsel for the Notifier:

Devon Wm. Hill
Keller and Heckman LLP
1001 G Street, N.W., Suite 500 West
Washington, D.C. 20001
Telephone: (202) 434-4279
Facsimile: (202) 434-4646
E-mail: hill@khlaw.com

4. **Description of the Proposed Action**

A. **Requested Action**

The action identified in this Notification is to provide for the use of an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) and optionally, sulfuric acid, as an antimicrobial agent for use in process water and ice used in the production and preparation of meat, including processed and preformed meat.

Mixtures containing these substances have previously been cleared by other Notifiers for the same uses. The concentration of components of the FCS mixture are not intended to exceed:

- (1) 1800 ppm peroxyacetic acid (PAA), 1215 ppm hydrogen peroxide (HP), and 121.5 ppm 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) in process water or ice used for washing, rinsing, or cooling whole or cut meat including carcasses, parts, trim, and organs; and,
- (2) 495 ppm PAA, 335 HP, and 33.5 HEDP in process water, brine, or ice used for washing, rinsing, storing, or cooling processed and preformed meat

B. **Need for Action**

The antimicrobial agent reduces or eliminates pathogenic and non-pathogenic microorganisms from the process water and ice used in the production and preparation of meat, including processed and preformed meat. The FCS will not have an ongoing antimicrobial effect on the

meat and/or processed and pre-formed meat. The FCS will serve a technical effect only in the process water and ice.

C. Locations of Use/Disposal

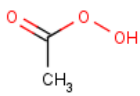
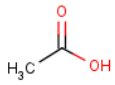
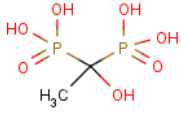
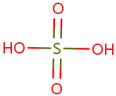
The antimicrobial agent is intended for use in meat processing plants throughout the United States. All waste process water containing the FCS at these plants is expected to enter the wastewater treatment unit at the plants. For the purposes of this Environmental Assessment, it is assumed that treated wastewater will be discharged directly to surface waters in accordance with the plants' National Pollutant Discharge Elimination System (NPDES) permit. This assumption can be considered a "worst-case" scenario since it does not take into account any further treatment that may occur at a Publically Owned Treatment Works (POTW). It is further assumed that very minor or negligible quantities of the FCS are lost via evaporation.

5. Identification of Chemical Substance that is the Subject of the Proposed Action

Chemical Identity

The subject of this notification is an aqueous mixture of peroxyacetic acid (CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and, optionally, sulfuric acid (CAS Reg. No. 7664-93-9). PAA formation is the result of a reaction between acetic acid and hydrogen peroxide.

The chemical structures are shown here:

<p>Peroxyacetic Acid CAS Reg. No. 79-21-0</p>  <p>MW: 76.0506</p>	<p>Hydrogen Peroxide CAS Reg. No. 7722-84-1</p> <p>HO — OH</p> <p>MW: 34.0138</p>
<p>Acetic Acid CAS Reg. No. 64-19-7</p>  <p>MW: 60.0516</p>	<p>HEDP CAS Reg. No. 2809-21-4</p>  <p>MW: 206.026</p>
<p>Sulfuric Acid CAS Reg. No. 7664-93-9</p>  <p>MW: 98.07</p>	<p>Water CAS Reg. No. 7732-18-5</p> <p>H₂O</p> <p>MW: 18.0148</p>

6. Introduction of Substances into the Environment

a. 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. Information available to the Notifier does not suggest that there are any extraordinary circumstances, in this case, indicating any adverse environmental impact as a result of the manufacture of the antimicrobial agent. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b. As a Result of Use and Disposal

Sulfuric acid is listed as an optional ingredient in the FCS formulation. It is also affirmed as GRAS for use directly in or on food under Title 21 C.F.R. § 184.1095. Sulfuric acid is used to catalyze the reaction between acetic acid and hydrogen peroxide, more rapidly producing a stable PAA solution, and to modify the pH of the FCS.

While the environmental effects of aerosols of sulfuric acid and sulfates on the atmosphere and rain are well known, small quantities of water or terrestrial discharges are not expected to have environmental effects.¹ Sulfate is a ubiquitous environmental anion and low concentrations are well tolerated in aquatic and terrestrial ecosystems. Sodium sulfate is a solid inorganic salt well soluble in water (161-190 g/l at 20 °C) with a melting point of 884 °C and density of 2.7 g/cm³. In water, sodium sulfate completely dissociates into sodium and sulfate ions. The ions cannot hydrolyze. In anaerobic environments, sulfate is biologically reduced to (hydrogen) sulfide by sulfate reducing bacteria, or incorporated into living organisms as a source of sulfur, and thereby included in the sulfur cycle. Sodium sulfate is not reactive in aqueous solution at room temperature. Sodium sulfate will completely dissolve, ionize and distribute across the entire planetary “aquasphere”. Some sulfates may eventually be deposited, but the majority of sulfates participate in the sulfur cycle in which natural and industrial sodium sulfate is not distinguishable. 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. Both sodium and sulfate ions are among the most common ions found in all living organisms. In mammals, sulfate is a normal metabolite of sulfur-containing amino-acids, it is normally incorporated in a variety of body compounds and it plays an important role in detoxification/ excretion processes due to sulfoconjugation. Sodium sulfate is a substance with a favorable ecological profile. Due to the low aquatic toxicity and the

¹ 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 <http://webnet.oecd.org/HPV/UI/handler.axd?id=248f397d-64b3-4e14-8be9-473974e8dfdb>.

natural recycling that occurs in the sulfur cycle, wide dispersive use of sodium sulfate does not present a major hazard to the environment.²

The FCS mixture is provided as a concentrate that is diluted on site. When diluted for use, the resulting concentration of PAA, hydrogen peroxide, and HEDP will be as follows:

Use	PAA	H ₂ O ₂	HEDP
Washing, rinsing, or cooling whole or cut meat	1800 ppm	1215 ppm	121.5 ppm
Washing, rinsing, storing, or cooling processed and pre-formed meat	495 ppm	335 ppm	33.5 ppm

Treatment of the process water at an on-site waste water treatment facility and/or at a Publically Owned Treatment Works (POTW) is expected to result in complete degradation of peroxyacetic acid, hydrogen peroxide, and acetic acid. Specifically, the peroxyacetic acid will breakdown into oxygen and acetic acid, while hydrogen peroxide will breakdown into oxygen and water.³ Acetic acid undergoes dissociation in water to acetate anion and the hydrated proton. The anion is subsequently rapidly biodegraded by ambient aerobic microorganisms to carbon dioxide and water.⁴ 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. The remainder of this section will therefore consider only the environmental introduction of HEDP.

Finally, we note that several other FCNs, including FCN 1490, already authorize the FCS for use in whole or cut meat including carcasses, parts, trim, and organs and pre-formed meat. While the HEDP levels authorized in previous FCNs covering the use of the FCS in meat processing facilities is less than requested here,⁵ the majority of the EIC value estimated here will be substitutional for the existing EIC for HEDP. Previous FCNs do cover the use of the FCS at the use levels requested here for alternative applications.

Assuming, in the worst-case, that all of the water used in any processing plant is treated with the FCS, the total HEDP expected introduction concentrations (EICs) would be as shown below. Approximately 80 - 90% of HEDP will adsorb to wastewater treatment sludge.⁶ Therefore, the sludge partition EICs of HEDP are calculated by multiplying the stated HEDP use level concentration by 80% (use level × 0.8). Multiplying the use level by 20% (use level × 0.2)

² Human and Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products, Sodium Sulfate, January 2006.

³ Environmental Protection Agency, Reregistration Eligibility Decision: Peroxy Compounds (December 1993), p. 18.

⁴ See U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Panel, American Chemistry Council, June 28, 2001.

⁵ However, there are existing FCNs that permit the use of greater levels of HEDP in poultry processing applications (see FCN 880).

⁶ Human and Environmental Risk Assessment (HERA) on ingredients of European Household Cleaning Products: Phosphonates (2004), available at <http://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf>.

provides the HEDP concentration remaining in wastewater. To estimate the expected environmental concentrations (EECs), we have incorporated a conservative 10-fold dilution factor for discharge to surface waters of the effluent from an onsite treatment facility or POTW,⁷ as indicated below.

Use	HEDP Use Level = EIC _{Total}	EIC _{Sludge} = EEC _{Sludge}	EIC _{Water}	EEC _{Water}
Meat Processing	121.5 ppm	97.2 ppm	24.3 ppm	2.4 ppm
Processed and Preformed meat	33.5 ppm	26.8 ppm	6.7 ppm	0.67 ppm

Because large-scale facilities do not typically process more than one type of food, we will use the use level of 121.5 ppm for HEDP as the worst-case EIC_{total} for all processing facilities using the FCS in the intended applications. Further, even if a POTW receives and mixes water from two different facilities employing the FCS, the maximum EEC will never be greater than the highest single use concentration, *i.e.*, 2.4 ppm HEDP. Therefore, the discussion of impacts from use of the FCS will focus on comparing the meat processing EECs to appropriate ecotoxicity endpoints that are provided under Item 8.

7. Fate of Emitted Substances in the Environment

As noted and referenced above, treatment of the process water at an on-site waste water treatment facility or at a POTW is expected to result in complete degradation of peroxyacetic acid, hydrogen peroxide, and acetic acid. The U.S. High Production Volume (HPV) Chemical Challenge Program determined that 99% of acetic acid degraded in 7 days under anaerobic conditions, and therefore acetic acid is not expected to concentrate in the waste water that is discharged to municipal treatment plants.⁸ Upon contact with organic materials, transition metals, and exposure to sunlight, peroxyacetic acid and hydrogen peroxide will rapidly degrade. According to ECETOC, the half-life for PAA in buffered solutions was 64 hours (pH = 7) for a 748 ppm solution and 48 hours (pH = 7) for a 95 ppm solution while the half-life for hydrogen peroxide varies based on the surface water.⁹

HERA reports that decomposition of HEDP occurs at a moderately slow pace using standard test methods, 33% in 28 days.¹⁰ The primary literature indicates however, that phosphonate utilizing bacteria are ubiquitous in the environment. HEDP removed via sludge would be expected, in the worst-case, to be slowly degraded to carbon dioxide, water and

⁷ Rapaport, Robert A., 1988 Prediction of consumer product chemical concentrations as a function of publically owned treatment works, treatment type, and riverine dilution. *Environmental Toxicology and Chemistry* 7(2), 107-115.

⁸ See U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Panel, American Chemistry Council, Appendix I. June 28, 2001.

⁹ ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals. JACC No. 40, "Peracetic Acid and its Equilibrium Solutions", January 2001 and JACC No. 22, "Hydrogen Peroxide", January 1993.

¹⁰ Human & Environmental Risk Assessment (HERA) on ingredients of European household cleaning Products: Phosphonates (2004).

phosphates. Phosphate anions are strongly bound to organic matter and soil particles, further, phosphate is a required macronutrient of plants.

In wastewater, sulfuric acid will completely dissociate into sulfate ions and hydrated protons, neither of which are a toxicological or environmental concern.^{11,12}

8. Environmental Effects of Released Substances

Terrestrial Toxicity

HEDP present in the sludge is not expected to have any adverse environmental impact based on the terrestrial toxicity endpoints available for plants, earthworms, and birds. Specifically, the NOEC for soil dwelling organisms was >1,000 mg/kg soil dry weight for earthworms in soil, while the 14-day LC₅₀ for birds was >248 mg/kg body weight.¹³ Using extremely conservative methodology, we have estimated an upper-bound concentration in sludge, not accounting for dilution upon mixing with soil of 97 ppm, which is well below these ecotoxicity endpoints. Therefore, no terrestrial environmental toxicity concerns exist at levels at which it is expected to be present in sludge. 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.¹⁴ When wastewater encounters the land, any increase in phosphates in soil will be only a minimal amount of the total phosphorus concentrations that already exist in the environment.¹⁵

Aquatic Toxicity

The available data on the aquatic toxicity of HEDP has been summarized in the public literature, and is shown in the following table.¹⁶

¹¹ Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Sodium Sulfate. Section 4 (Environment), January 2006, available at http://www.heraproject.com/files/39-f-06_sodium_sulfate_human_and_environmental_risk_assessment_v2.pdf

¹² 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>

¹³ Human and Environmental Risk Assessment (HERA) on ingredients of European Household Cleaning Products: Phosphonates (2004), Table 13, available at <http://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf>.

¹⁴ *Ibid.*

¹⁵ OECD, Current Approaches in the Statistical Analysis of Ecotoxicity Data: A guideline to Application, OECD Environmental health and Safety Publications, Series on Testing and Assessment, No. 54 Environmental Directorate, Paris, 2006.

¹⁶ Jaworska, J.; Van Genderen-Takken, H.; Han stveit, 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.

Environmental Toxicity Data for HEDP		
Species	Endpoint	mg/L
Short Term		
<i>Lepomis macrochirus</i>	96 hr LC ₅₀	868
<i>Oncorhynchus mykiss</i>	96 hr LC ₅₀	360
<i>Cyprinodon variegates</i>	96 hr LC ₅₀	2180
<i>Ictalurus punctatus</i>	96 hr LC ₅₀	695
<i>Leciscus idus melonatus</i>	48 hr LC ₅₀	207 – 350
<i>Daphnia magna</i>	24 – 48 hr EC ₅₀	165 – 500
<i>Palaemonetes pugio</i>	96 hr LC ₅₀	1770
<i>Crassostrea virginica</i>	96 hr EC ₅₀	89
<i>Selenastrum capricornutum</i> ^a	96 hr LC ₅₀	3
<i>Selenastrum capricornutum</i>	96 hr NOEC	1.3
Algae ^a	96 hr NOEC	0.74
<i>Chlorella vulgaris</i>	48 hr NOEC	≥100
<i>Pseudomonas putida</i>	30 minute NOEC	1000
Long Term		
<i>Oncorhynchus mykiss</i>	14 day NOEC	60 – 80
<i>Daphnia Magna</i>	28 day NOEC	10 - <12.5
Algae ^a	14 day NOEC	13

^a The source for this endpoint is the HERA_Phosphonates, 2004.

According to Jaworska *et.al* 2002, 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 EC₅₀/LC₅₀ 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. According to Jaworska, *et.al* 2002, the lowest relevant endpoint for food processing uses was determined to be the chronic NOEC of 10 ppm for *Daphnia magna*. Although FDA has previously noted that uncertainties intrinsic to its derivation make the usefulness of the NOEC/NOEL debatable, the agency has previously indicated that a NOEC for *Daphnia Magna* is an appropriate benchmark for environmental toxicology.¹⁷ The highly conservative upper-bound EEC of 2.4 ppm is greater than 4-fold lower than the 10 ppm chronic NOEC for *Daphnia magna*.

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-stabilized peroxyacetic acid antimicrobial agents already on the market.

¹⁷ See *e.g.* environmental reviews of FCN 1379 and 1419.

The manufacture of the antimicrobial agent will consume comparable amounts of energy and resources as similar products, and the raw materials used in the production of the mixture are commercially manufactured materials that are produced for use in a variety of chemical reactions and processes.

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. 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 effects are identified herein which would necessitate alternative actions to that proposed in this 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 processors is not expected to increase the use of peroxyacetic acid antimicrobial products.

12. List of Preparers

Devon Wm. Hill, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001. J.D. and Masters in Chemistry with 20 years of experience with FCN submissions and environmental assessments.

Peter N. Coneski, Ph.D., Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001. Ph.D. in Chemistry with 3 years of experience with FCN submissions and environmental assessments.

13. Certification

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



Devon Wm. Hill
Counsel for Notifier