VALLEY CHEMICAL SOLUTIONS

ENVIRONMENTAL ASSESSMENT

1. **Date:** 02/15/2019
2. **Name of Applicant/Petitioner:** VALLEY CHEMICAL SOLUTIONS
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4. **Description of the Proposed Action:**

a. Requested Action

The action requested in this Notification is to establish an approval for the food-contact substance (FCS), which is an aqueous mixture of peroxylactic acid (PLA), hydrogen peroxide (H_2O_2), lactic acid, optionally stabilized with 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), optionally catalyzed with sulfuric acid or phosphoric acid, to be used:

1. 1000 parts per million (ppm) peroxylactic acid, 2384 ppm hydrogen peroxide, and 5.5 ppm HEDP in in process water or ice that contacts meat or poultry carcasses, parts, trim, and organs.
2. 495 ppm peroxylactic acid, 1180 ppm hydrogen peroxide, and 2.7 ppm HEDP in process water, ice, or brine that contacts processed and pre-formed meat and poultry.

b. Need for Action

This FCS is intended for use as an antimicrobial agent to inhibit the growth of undesirable or pathogenic microorganisms on poultry and meat products, ultimately providing safer products for consumption throughout the United States. In poultry and meat processing operations, pathogenic microorganisms are often better controlled by exposure to high concentrations of PLA at lower exposure times rather than lower concentrations at higher exposure times (dose-responsive rather than time-responsive). Dose-responsive organisms include *Campylobacter spp.*, whereas *Salmonella spp.* and other food pathogens are time-responsive. Extending the antimicrobial treatment concentration range allows processing plants more flexibility in utilizing and managing dose-responsive interventions.

c. Locations of Use/Disposal

The FCS is intended for use in meat and poultry 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.[1] 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

[1] See list of industries at https://www.epa.gov/eg/meat-and-poultry-products-effluent-guidelines

further treatment that may occur at a POTW. It is further assumed that very minor or negligible quantities of the FCS are lost via evaporation.

Poultry processing facilities: Spray and dip application of the diluted FCS to poultry carcasses will usually take place at various intervention sites as carcasses move through the kill side and second processing parts of the plant.

On the kill side of the plant a de-feathered, eviscerated carcass hung on a shackle is carried through various spray cabinets or dip tanks on a moving line. Spray or mist nozzles, usually contained within cabinet, apply the diluted FCS to the carcass. The carcass then exits the spray or mist cabinet as processing continues. Mist applications are usually restricted to enclosed areas or cabinets which are well-ventilated to prevent concentration of mist in the air.

After multiple processing steps, including evisceration and thorough cleansing of the inside and outside of the carcass, it is moved into a chiller bath to reduce the carcass temperature to no more than 40°F. The chill process generally takes up to 2 hours but, depending on the size and number of carcasses being chilled, may exceed this time frame. Carcasses may also pass through a series of pre-, main, and post- chillers during the chilling process. Chillers are common antimicrobial intervention sites, where diluted FCS is applied to the chiller water to help eliminate microbial contamination from the carcasses. Time-responsive food pathogens are generally controlled by the long residence time in chillers at lower FCS concentrations than those used in low contact time sprays and dips.

On the kill floor, dip applications into diluted FCS may also occur at a variety of potential intervention sites, including scalders, post-pick, and pre- or post-chiller tanks. Many of these dip applications may be at considerably higher concentrations of FCS than are present in the main chillers because the carcasses or parts are held in these much smaller tanks for a few seconds to a few minutes. Antimicrobial FCS applications in these sites are effective in controlling dose-responsive microorganisms on the carcasses.

Following chilling, carcasses may move into second processing, where they are cut up into parts and/or comminuted (deboned). Additional spray and dip applications of the FCS may occur at different sites during these processes to help control microorganisms that may be pathogenic or cause food spoilage. Organs may also be treated with applications of the FCS with either sprays or dips as they are processed before packaging for consumption.

The diluted FCS in dip tanks and chiller water will typically be disposed of by pouring down drains that lead to the poultry processing plant water treatment facility. Finishing chillers typically back-flow into the main chillers to help maintain FCS concentration at that antimicrobial intervention site. As with the main chillers, the water from finishing chillers is typically drained to the plant waste system every day. Spray and mist systems, too, drain to the floor or drainage system. All of this water is collected and treated by the facility prior to discharge. Virtually none of the FCS will be lost due to evaporation into the air.

Meat processing facilities: This FCS may be applied to the surface of freshly killed meat carcasses or parts at any point after the animal has been terminated. This FCS is applied by spraying the carcasses or sides on a moving conveyor line or rail system. The carcasses are suspended from a hook attached to the conveyor, which carries the carcass into a spray cabinet. Spray nozzles are distributed within the cabinet in a manner that ensures even application of the dilute FCS solution onto the surface of the carcass. The carcass exits the spray cabinet and continues on the processing line. In some instances, meat parts are sprayed on a conveyor line, or run through a dip tank containing a dilution of this FCS in order to ensure full contact with the intervention chemistry. Additionally, parts and organs may be sprayed with or dipped into solutions of the FCS at various intervention sites during processing for antimicrobial control. Mist applications typically occur in enclosed areas, like hot boxes, where sides of meat product are cooled to below 40˚F.

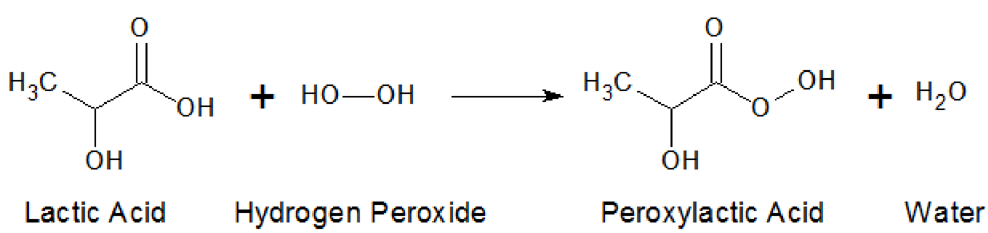
After the diluted product is applied to the carcasses, parts or organs, the majority of the FCS drains off of the meat and ultimately runs into drains and enters the meat processing plant water treatment facility prior to discharge. Very minor quantities are potentially lost to evaporation.

Processed and preformed poultry and meat facilities: This FCS may be applied to preformed and processed product both before and/or after stripping of casings to aid in controlling bacteria that may be present on the surface of formed and/or cased materials. The FCS may be applied to any process water that contacts the protein products by dip, rinse, spray or mist. It may further be applied to any process water that comes in contact with these protein products as the pass through cooking and chilling equipment. Treated process waters ultimately are flushed to drains and are treated in the processing plant water treatment facility prior to discharge. Very minor quantities are potentially lost to evaporation.

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

Chemical Substance	CAS Number
Hydrogen peroxide	7722-84-1
Lactic acid	50-21-5
Peroxylactic acid	75033-25-9
1-Hydroxyethylidene-1,1-diphosphonic Acid (optional)	2809-21-4
Sulfuric acid (optional)	7664-93-9
Phosphoric acid (optional)	7664-38-2
Purified Water	7732-18-5

The FCS is an aqueous mixture of peroxylactic acid (PLA), hydrogen peroxide, lactic acid, optional 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), optional sulfuric and/or phosphoric acid, and water . PLA results from an equilibrium reaction created by blending lactic acid, hydrogen peroxide together in purified water. The reaction is optionally catalyzed and optionally stabilized by the addition of sulfuric and/or phosphoric acid and HEDP.



6. Introduction of Substances into the Environment:

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

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

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.

Introduction of the components of the product into the environment will result from use of the product as an antimicrobial agent in processing and chill water and spray application onto carcasses, parts and organs, and the subsequent disposal of such water and spray drainage into the processing plant wastewater treatment facility. The total amount of product used at a typical facility can be estimated, although the actual amounts used will vary, depending on equipment used and the number of carcasses processed. The same concentrated FCS will be used to generate the desired treatment concentrations for poultry, meat, and preformed poultry and meat products.

All calculations used in this EA are based on the assumption that all process water used in poultry and meat processing plants is treated at the maximum concentration of PLA specified for the applications listed in Section 4a above, *i.e.* at 1000 ppm PLA for whole or cut meat and poultry applications and at 495 ppm PLA for processed and preformed meat and poultry applications.

Treatment of the process water at the on-site wastewater treatment plant is expected to result in nearly 100% degradation of the peroxylactic acid, hydrogen peroxide, and lactic acid. Specifically, PLA will break down into oxygen and lactic acid (the same process by which peracetic acid breaks down into acetic acid and oxygen) and hydrogen peroxide will break down into oxygen and water.[2a] Lactic acid undergoes dissociation in water to lactate anion and the hydrated proton. The anion is subsequently rapidly biodegraded by ambient aerobic

[2a] EPA Reregistration Eligibility Document: Peroxy compounds; December 1993; available at http://www.epa.gov/pesticides/reregistration/REDs/old_reds/peroxy_compounds.pdf

[2b] Bowmer et. al. "The ecotoxicity and the biodegradability of lactic acid, alkyl lactate esters, and lactate salts." 1998. *Chemosphere. 37(7), p 1317-33.*

[2c] *Data presented in Confidential Attachment 2 to application FCN 1946.*

microorganisms to carbon dioxide and water[2b], while simultaneously PLA and H2O2 (when used as proposed in this application) to be completely degraded on protein surfaces within 60 minutes.[2c] Based on this, a quantitative evaluation of the environmental impacts for these compounds is not necessary.

Sulfuric acid is a strong acid that is completely miscible with water and readily dissociates to sulfate ions and hydrated protons, neither of which is of any toxicological concern at the use levels proposed by this FCN (supported by footnote 3a). Small quantities of terrestrial or aquatic discharges are not expected to have any environmental effects, as sulfate is a ubiquitous anion already present in the ecosystem. Furthermore, sources of sulfate such as sulfuric acid and sodium sulfate are widely distributed in nature, and present in nearly all bodies of fresh and salt water. To this end, sulfate has a favorable ecological profile, participates in the sulfur cycle, and is a source of one of the most common ions found in all living organisms, where natural and industrial sources are virtually indistinguishable from one another. Finally, due to the low aquatic and terrestrial toxicity and natural recycling that occurs in the sulfur cycle of Earth's biosphere, there is no anticipated ecological impact on land, in water, or by air.[3a]

Similarly, phosphoric acid is a weak acid that is completely miscible with water and readily dissociates to phosphate ions and hydrated protons, neither of which is of any toxicological concern at the use levels proposed by this FCN.[3b] The small quantities of discharges are not expected to have any environmental effects as phosphate is a ubiquitous anion already present in the ecosystem. Phosphoric acid generated naturally in the human body, and resulting salts (such as sodium phosphate) are widely used for food and water treatment. Due to these points, there is no anticipated ecological impact.

HEDP is the chemical of environmental concern because of its persistence and behavior in the environment, as discussed under Item 7.

Assuming, in the worst-case, that all of the water used in a processing plant is treated with the FCS, the total HEDP expected introduction concentrations (EICs) would be as shown below. The HERA 2004 publication on phosphonates, indicates that 80% - 90% of HEDP can be expected to adsorb to wastewater treatment sludge.[3c] Therefore, the sludge partition EICs of HEDP are calculated by multiplying the stated HEDP use level concentration by 80% (use level x 0.8) to maximize the amount of HEDP that will remain in wastewater. Multiplying the use level by 20% (use level x 0.2), then, provides the HEDP concentration remaining in wastewater. To calculate the expected environmental concentrations (EECs), we have incorporated a 10-fold dilution factor for discharge to surface waters[4], as indicated below.

[3a] Human and Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products, Sodium Sulfate, January 2006. http://www.heraproject.com/files/39-f-06_sodium_sulfate_human_and_environmental_risk_assessment_v2.pdf

[3b] Human and Environmental Risk Assessment (HERA) on ingredients of European Household Cleaning Products, STPP http://www.heraproject.com/files/13-F-04-%20HERA%20STPP%20full%20web%20wd.pdf

[3c] Human & Environmental Risk Assessment (HERA) on ingredients of European household cleaning products: Phosphonates. http://www.heraproject.com/files/30-f-04-%20hera%20phosphonates%20full%20web%20wd.pdf

[4] 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. Found online at: http://onlinelibrary.wiley.com/doi/10/1002/etc.5620070204/abstract

Use	HEDP Use Level = EIC_{total} (ppm)	EIC_{sludge} = EEC_{sludge} (ppm)	EIC_{water} (ppm)	EEC_{water} (ppm)
Meat or poultry carcasses, parts, trim and organs	5.5	4.4	1.1	0.11
Processed and pre-formed meat and poultry	2.7	2.2	0.5	0.05

As large scale facilities typically do not process more than one type of food, we will use the use level of 5.5 ppm for HEDP as the worst-case EIC 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., the highest single use concentration of 5.5 ppm HEDP, would result in wastewater containing a maximum of 1.1 ppm HEDP, and this maximum of 1.1 ppm would not change even if wastewater from two facilities were combined). Therefore, the discussion of impacts from use of the FCS will focus on comparing the meat and poultry plant EECs to appropriate ecotoxicity endpoints that are provided under Item 8.

7. Fate of Emitted Components in the Environment:

Peroxylactic acid and **hydrogen peroxide** are not expected to survive treatment at the primary wastewater treatment facilities in poultry and meat processing plants. Both compounds are rapidly degraded on contact with organic matter, transition metals, and upon exposure to sunlight. Experiments on PLA show complete degradation of a 1200ppm solution exposed to organic matter is 16h, though on the poultry or beef surface, it is completely degraded within 1 hour.[2c] The half-life of hydrogen peroxide in natural river water ranged from 2.5 days when initial concentrations were 10,000 ppm, and increased to 15.2 days when the concentration decreased to 250 ppm.[5]

Regarding **HEDP**, when treated wastewater from the food processing operations described above is released to a receiving water body (in accordance with a NPDES permit) it is diluted by the receiving water body. Application of a 10-fold dilution factor for surface water discharge, as described in Robert Rapaport's 1988 study cited below[6], may be applied to the to EICs as derived above, resulting in maximum expected environmental concentrations (EEC) of approximately 0.2 ppm for HEDP in wastewater from poultry and meat processing.

8. Environmental Effects of Released Substances:

As described previously, treatment of process water at an on-site wastewater treatment facility and/or at a publically owned treatment works is expected to result in complete degradation of peroxylactic acid, hydrogen peroxide and lactic acid, and complete ionization of sulfuric or phosphoric acid.

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

[6] Rapaport, Rober 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. Found online at: http://onlinelibrary.wiley.com/doi/10/1002/etc.5620070204/abstract

Therefore, these substances are not expected to be introduced into the environment as a result of the proposed use of the FCS. The remainder of this section will therefore consider only the environmental effects of HEDP.

1 -Hydroxyethylidene-1,1-diphosphonic acid (HEDP): The available ecotoxicity data for HEDP have been reviewed. Jarworska et al (2002) and the HERA study on phosphonates have summarized the aquatic toxicity of HEDP, as indicated in the following table:

Environmental Toxicity Data for HEDP		
Species	**Endpoint**	**mg/L**
Short Term		
Lepomis macrochirus[1]	96 hr LC_{50}	868
Oncorhynchus mykiss[1]	96 hr LC_{50}	360
Cyprinodon variegates[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 LC_{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		
Oncorhychus mykiss[1]	14 day NOEC	60 -180
Daphnia Magna[1]	28 day NOEC	10 - <12.5
Algae[2]	14 day NOEC	13

[1] 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.

[2] HERA – Human & Environment Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates, 06/09/2004, www.heraproject.com -- Phosphonates

A recent risk assessment of phosphonates by the Human and Environmental Risk Assessment Project[7] included a discussion of aquatic toxicity resulting from chelation of nutrients, rather than direct toxicity to aquatic organisms. The lowest toxicity endpoints, those shown above for algae, *Selenastrum capricornutum*, *Daphnia magna*, and *Crassostrea virginica* are considered to result from chelation of nutrients, not from direct toxicity of HEDP. Chelation is not toxicologically relevant in the current evaluation because eutrophication, not nutrient depletion, has been demonstrated to be the controlling toxicological mode when evaluating wastewater discharges

[7] Human & 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

from food processing facilities. Jaworska, et al., determined that the lowest relevant endpoint for this use pattern was 10 mg/L.[8]

Even assuming the theoretical 'worst-case' scenario for poultry (e.g., the highest PLA use level), the resulting 0.11 ppm HEDP EEC from surface water discharge is well below the LC50 of Daphnia (Daphnia magna, 165 ppm), rainbow trout (Onchorhyncus mykiss, 360 ppm) and bluegill sunfish (Lepomis macrochirus, 868 ppm). The calculated HEDP EEC concentration from the intended use of the FCS is even below the lowest relevant endpoint value, determined by Jaworska et. al during an environmental risk assessment of phosphonates.[9]

HEDP in sludge from an on-site wastewater treatment plant may be applied to land as a soil amendment in agricultural settings and is not expected to have any adverse environmental impact based on the terrestrial toxicity endpoints available for plants, earthworms, and birds. The NOEC for soil dwelling organisms is >1000 mg/kg soil dry weight for earthworms and 1000 mg/kg for oats. The 14-day median lethal dose (LD_{50}) for birds is >284 mg/kg body weight.[9] The 'worst-case' (e.g., the highest PLA use level) 4.4 ppm sludge HEDP EEC is significantly lower than these ecotoxicities.

Therefore, none of these potential releases presents any toxicological concern at the low levels at which they could occur.

According to a report from the Human and Environmental Risk Assessment Project (HERA), very little degradation occurs under controlled conditions, but data on degradation in the environment show that phosphonate degrading bacteria exist in environments such as soil, sludge and riverwater.[10] Therefore, we expect the amount of HEDP that is removed via sedimentation or filtration to slowly degrade into carbon dioxide, water, and phosphates.

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 peroxy antimicrobial agents already on the market. 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

The intended use of the FCS is not reasonably expected to create any significant negative environmental impact that would require mitigation measures.

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[8] 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.

[9] Human & Environmental Risk Assessment (HERA) on ingredients of European household cleaning Products: Phosphonates (2004), pg. 30. Available at: http://www.heraproject.com/files/30-f-04-%20hera%20phosphonates%20full%20web%20wd.pdf

[10] Human & 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

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this FCN. The alternative of not establishing this FCN would merely result in the continued use of other HEDP-containing antimicrobial agents in the poultry and meat processing industries. The FCS is composed of widely used substances, and this FCN is not expected to impact their supply or demand. Furthermore, this FCN will compete with other HEDP-containing antimicrobial products currently on the market. Therefore, the alternative of not establishing this FCN would have no environmental impact.

12. List of Preparers

Jim Faller, PhD Chemistry, PhD Microbiology, 20+ years' experience conducting ecological risk assessments.

Rider Barnum, PhD Chemistry, 2+ years' experience conducting ecological risk assessments.

13. Certification

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

[redacted]

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Technical Director
VALLEY CHEMICAL SOLUTIONS
Date: 02.15.2019

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