An EA Revision Sheet has been prepared for this Environmental Assessment – See the FONSI for this Food Contact Notification

VALLEY CHEMICAL SOLUTIONS

FCN 1856 ENVIRONMENTAL ASSESSMENT

1. **Date:** 12/21/2017
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 peroxyacetic acid (PAA), hydrogen peroxide (H_2O_2), acetic acid, stabilized with 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), catalyzed with optional sulfuric acid, to be used:

As an antimicrobial agent in:

(1) brines, sauces, and marinades to be applied on the surface or injected into processed or unprocessed cooked or uncooked whole or cut poultry, or parts and pieces thereof;
(2) brines, sauces, and marinades applied on the surface or injected into processed, preformed, or cooked poultry products as defined in 21 CFR 170.3 (n) (34);
(3) Brines, sauces, and marinades to be applied on the surface or injected into processed or unprocessed cooked or uncooked whole or cut meat, or parts and pieces thereof;
(4) Brines, sauces, and marinades applied on the surface or injected into processed, preformed, or cooked meat products as defined in 21 CFR 170.3 (n) (29).

Limitations/Specifications
The concentration will not exceed 50 ppm PAA, 19 ppm hydrogen peroxide, and 8 ppm HEDP.

b. Need for Action

This FCS is intended for use as an antimicrobial agent to inhibit the growth of undesirable or pathogenic microorganisms in brines, sauces and marinades that may be injected as flavoring agents into the poultry and products described above, ultimately providing safer products for consumption throughout the United States. This FCS is especially effective against human pathogens like Shiga toxin-producing *Escherichia coli* (STECs), Salmonella sp., Listeria sp., Campylobacter sp.

c. Locations of Use/Disposal

The FCS is intended for use in meat and poultry processing plants throughout the United States, including first and second processing in “fresh” or “kill” plants, and ready-to-eat (RTE or cooked product) plants. 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 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: Poultry and meat products may typically be injected with brines in fresh plants, and marinades or sauces in RTE plants. Brine injection solutions and flavored coatings are usually prepared in large holding tanks by mixing the component ingredients together and allowing them to stand until used. This FCS will be introduced into the brine injection solution or flavoring holding tank, or injected into brine or flavoring agent as it passes through a line feeding injection or coating equipment, to help prevent microbial growth on the treated poultry product. The FCS will, therefore, be mixed into the brines and flavoring agents before they are applied either by injection or coating of carcasses, parts, or preformed or cooked products.

Holding tanks are typically sized to provide enough volume of flavoring agent to get through a normal production shift. In the applicant's experience, a batch size of 500 gallons is common for many applications. As the volume of a holding tank is depleted during the production day, it may be recharged with both the ingredients of the brine, marinade or sauce, and also recharged as needed with an appropriate dilution of this FCS. Typically, at the end of the processing day, flavoring agent solutions will be flushed to drain so that the holding tanks can be properly cleaned and sanitized during the plant sanitation shift. Drains typically carry the discharged product to the processing plant water treatment facility where it is treated prior to discharge. Depending on the processing activities that are occurring at a particular plant, several holding tanks may be present. Again, in the applicant's experience, a large plant may utilize as many as nine or ten holding tanks.

Meat processing facilities: This FCS may be incorporated into marinades and sauces and applied to the surface of processed and preformed meat products as defined by 21 CFR 170.3 (n) (29) and (34). Coatings are usually prepared in large holding tanks by mixing the component ingredients together and allowing them to stand until used. This FCS will be introduced into the solution in the holding tank, or injected into a line feeding the solution to coating equipment, to help prevent microbial growth on the treated meat product. The FCS will, therefore, be mixed into the flavoring agents before they are applied as a coating to processed, preformed, or cooked meat products.

Holding tanks are typically sized to provide enough volume of flavoring agent to get through a normal production shift. In the applicant's experience, a batch size of 500 gallons is common for many applications. As the volume of a holding tank is depleted during the production day, it may be recharged with both the ingredients of the brine, marinade or sauce, and also recharged as needed with an appropriate dilution of this FCS. Typically, at the end of the processing day, flavoring agent solutions will be flushed to drain so that the holding tanks can be properly cleaned and sanitized during the plant sanitation shift. Drains typically carry the discharged product to the processing plant water treatment facility where it is treated prior to discharge.

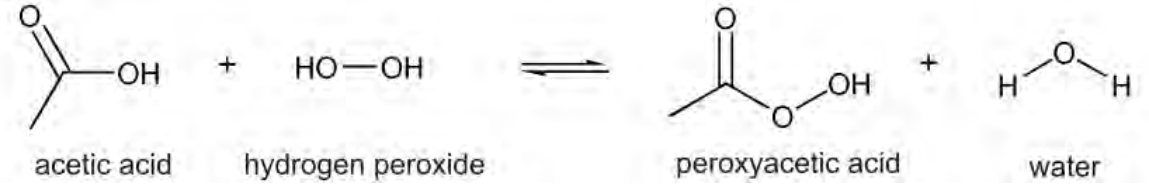
[1] See list of industries at https://www.epa.gov/eg/meat-and-poultry-products-effluent-guidelines

Depending on the processing activities that are occurring at a particular plant, several holding tanks may be present. Again, in the applicant's experience, a large plant may utilize as many as nine or ten holding tanks.

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

Chemical Substance	CAS Number
Hydrogen peroxide	7722-84-1
Acetic acid	64-19-7
Peroxyacetic acid	79-21-0
1-Hydroxyethylidene-1,1-diphosphonic Acid	2809-21-4
Sulfuric acid (optional)	7664-93-9
Purified Water	7732-18-5

The FCS is an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide, acetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), sulfuric acid (optional), and water . PAA results from an equilibrium reaction created by blending acetic acid, hydrogen peroxide together in purified water. The reaction is catalyzed and stabilized by the addition of sulfuric 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 containing this FCS will be discharged directly to surface waters in accordance with a plant's 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 brines, marinades, and sauces that may be injected into or coated onto poultry and meat carcasses or parts. Typically, waste from these processes is minimal. It is desirable from a cost-savings standpoint to make only as much brine, marinade, or sauce as can be used in a production day. However, rinsate from brine, marinade, and sauce holding tank cleaning will be flushed to the processing plant wastewater treatment facility. The total amount of flavoring product used at a typical facility can be estimated reasonably accurately based on equipment used and the number of carcasses or parts processed during a production day. The actual amount of FCS that may be flushed to drain on a typical production day is virtually indeterminable, being entirely dependent on how much of the flavoring agent(s) is flushed to drain. Under normal operating procedures, one would expect the volume of FCS in the waste stream due to brine, marinade or sauce operations to be very small, to the point of being negligible.

To consider a worst-case scenario, for purposes of this EA, all calculations used are based on the assumption that the entire contents of ten 500 gallon (5000 gallons) holding tanks of flavoring agent, treated at the maximum concentration of PAA, is released to the processing plant waste stream in a processing day. The 5000 gallons of solution would then contain 50 ppm PAA, 19 ppm H_2O_2, and 8 ppm HEDP.

Treatment of the process water at the on-site wastewater treatment plant is expected to result in nearly 100% degradation of the peroxyacetic acid, hydrogen peroxide, and acetic acid. Specifically, PAA will break down into oxygen, water, and acetic acid, and HP will break down into oxygen and water.[2] 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.[3] This expectation is based on the half-lives of peroxyacetic acid, hydrogen peroxide and acetic acid as described in section 7 of this Assessment. Based on this, a quantitative evaluation of the environmental impacts for these compounds is not necessary.

Sulfuric acid is a strong mineral acid that is used as a catalyst during peracetic acid formation, and to stabilize the pH of the final equilibrium solution. It is totally 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.[11] 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

[2] EPA Reregistration Eligibility Document: Peroxy compounds; December 1993; available at https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_G-67_1-Dec-93.pdf

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

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.[12]

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

Assuming, the worst-case scenario described above, that all of the 5000 gallons of FCS-treated brine, marinade and sauce solutions on site in a large processing plant is cataclysmically released and is the only discharge to the waste stream, 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.[4] 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. To calculate the expected environmental concentrations (EECs), we have incorporated a 10-fold dilution factor for discharge to surface waters[5], as indicated below.

Use	**HEDP Use Level = EIC_{total}**	**EIC_{sludge} = EEC_{sludge}**	**EIC_{water}**	**EEC_{water}**
Brines/ marinades/ sauces	8 ppm	6.40 ppm	1.28 ppm	0.13 ppm

7. Fate of Emitted Components in the Environment:

HEDP, when present in waste water from the food processing operations described above, is treated at an on-site wastewater treatment facility. Application of a standard 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 0.13 ppm for HEDP (when multiple additions of FCS are used) in wastewater from poultry and meat processing.

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

[5] 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

[6] 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

Peroxyacetic 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. 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.[7] 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.[8] In biodegradation studies of acetic acid, 99% degraded in 7 days under anaerobic conditions.[9]

Sulfuric acid: In wastewater, sulfuric acid will completely dissociate into sulfate ions and hydrated protons, neither of which are a toxicological or environmental concern at the proposed use levels.[10, 11]

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 peroxyacetic acid, hydrogen peroxide and acetic acid, and complete ionization of sulfuric acid. 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

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

[8] ECETOC. (2001). Peracetic Acid (CAS No. 79-21-0) and its Equilibrium Solutions. JACC No. 40. European Centre for Ecotoxicology and Toxicology of Chemicals. Brussels, January 2001. Available at: http://www.ecetoc.org/publication/jacc-report-40-peracetic-acid-and-itsequilibriumsolutions/

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

[10] The Organisation for Economic Co-operation and Development (OECD) SIDS Voluntary Testing Program for International High Production Volume Chemicals (OECD SIDS), Sulfuric Acid, 2001.

[11] Human and Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products, Sodium Sulfate, January 2006

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
Planemonetes pugio[1]	96 hr LC_{50}	1770
Crassostrea virginica[1]	96 hr LC_{50}	89
Selenastrum capricornutum[2]	96 hr LC_{50}	3
Selenastrum capricornutum[2]	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[12] 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 from food processing facilities. The lowest short-term 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. Jaworska, et al[13], determined that the lowest relevant endpoint for this use pattern was the chronic NOEC of 10 ppm for Daphnia magna. Although uncertainties intrinsic to its derivation make the usefulness of the NOEC debatable[14], based on the available environmental toxicology data, reliance upon the NOEC for Daphnia magna is appropriate for this use[15].

[12] 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

[13] 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.

[14] 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 EC50 determinations"); also see Organisation

Biodegradation study results were variable. Zahn-Wellens dissolved organic carbon removed 33% after 28 days; modified OECD screening theoretical carbon dioxide evolution was 2% after 70 days; modified SCAS dissolved organic carbon removed 90%; and closed container BOD_{30}/COD was 5%.

The maximum EEC for HEDP is provided in Section 6.b of this EA. The 0.13 ppm HEDP aquatic EEC is well below the NOEC of 10 ppm for Daphnia magna. Therefore, significant adverse impacts to aquatic species as a result of use and disposal of the FCS are not anticipated.

The 0.13 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).

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 was > 1000 mg/kg soil dry weight for earthworms and 1000 mg/kg for oats. The 14-day median lethal dose (LD_{50}) for birds was greater than 284 mg/kg body weight.[16] The 'worst-case' (e.g., the highest PAA use level) 6.40 ppm sludge HEDP EEC is several orders of magnitude lower than these ecotoxicities.

Therefore, none of these potential releases present 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.[17] In a low ortho-phosphate environment, breakdown of HEDP was found to be 94% in activated sludge "Maria Middelares" (ASMM) and the conditions were 28°C for 28 days.[18] Therefore, we expect the amount of HEDP that is removed via sedimentation or filtration to slowly degrade into carbon dioxide, water, and phosphates.[19]

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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.

[15] Jaworska, et al (2002).

[16] 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

[17] 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

[18] Schowanek D. and Verstraete W., Applied and Environmental Microbiology, Vol. 56, No. 4. Phosphonate

[19] Human & Environmental Risk Assessment (HERA) on ingredients of European household cleaning

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

As shown above, there are no significant adverse environmental effects associated with the use of the FCS. Thus, the use of the FCS as an antimicrobial and as described in this notification does not require any specific mitigation measures.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact Notification. The alternative of not approving the action proposed herein would simply result in the continued use of nearly identical products by the meat and poultry processing industries; such action would have no environmental impact. The addition of this product the options available to meat and poultry processors is not expected to increase the use of peroxyacetic acid antimicrobial products; rather provide a replacement product for those peroxyacetic acid products already in use.

12. List of Preparers

Jim Faller, PhD Chemistry, PhD Microbiology, 20+ 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]

Jim Faller, PhD (Chemistry), PhD (Microbiology)

Products: Phosphonates (2004) Available at: http://www.heraproject.com/files/30-f-04-%20hera%20phosphonates%20full%20web%20wd.pdf

Technical Director
VALLEY CHEMICAL SOLUTIONS

Date: 12.21.2017