

VALLEY CHEMICAL SOLUTIONS

ENVIRONMENTAL ASSESSMENT

1. **Date:** 07/30/2019
2. **Name of Applicant/Petitioner:** VALLEY CHEMICAL SOLUTIONS
3. **Correspondence Address:** Jim Faller, Ph. D.
VALLEY CHEMICAL SOLUTIONS
4146 South Creek Road
Chattanooga, TN 37406
Telephone: 423-702-7674
E-mail: jim.faller@vincitgroup.com

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 peroxylic acid (PLA), hydrogen peroxide (H₂O₂), lactic acid, optionally stabilized with 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), optionally stabilized with dipicolinic acid (DPA), optionally catalyzed with sulfuric acid or phosphoric acid, to be used:

1. 1000 parts per million (ppm) peroxylic acid, 2480 ppm hydrogen peroxide, and 5.7 ppm HEDP, and 1.64 ppm DPA in process water or ice that contacts meat or poultry carcasses, parts, trim, and organs.
2. 268 ppm peroxylic acid, 665 ppm hydrogen peroxide, 1.53 ppm HEDP, and 0.44 ppm DPA 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, certain 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

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

VALLEY CHEMICAL SOLUTIONS

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: 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

VALLEY CHEMICAL SOLUTIONS

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.

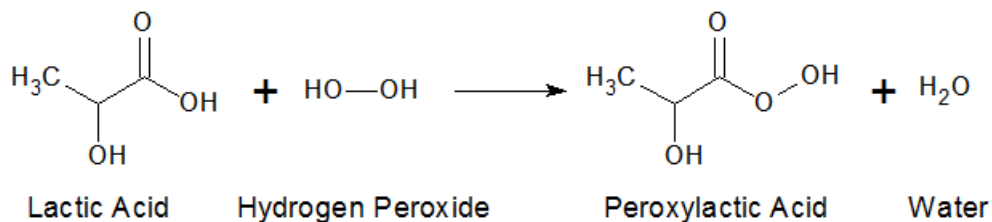
Processed and preformed poultry and meat facilities: This FCS may be applied to preformed and processed product both before and/or after stripping of casings to aid in controlling bacteria that may be present on the surface of formed and/or cased materials. The FCS may be applied to any process water 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:

Hydrogen peroxide	7722-84-1
Lactic acid	50-21-5
Peroxylic acid	75033-25-9
1-Hydroxyethylidene-1,1-diphosphonic Acid (optional)	2809-21-4
Dipicolinic Acid (optional)	499-83-2
Sulfuric acid (optional)	7664-93-9
Phosphoric acid (optional)	7664-38-2
Purified Water	7732-18-5

The FCS is an aqueous mixture of peroxylic acid (PLA), hydrogen peroxide, lactic acid, optional 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), optional dipicolinic acid (DPA), 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 and/or DPA.

VALLEY CHEMICAL SOLUTIONS



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 268 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 peroxylic 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

VALLEY CHEMICAL SOLUTIONS

into oxygen and water.² Lactic acid undergoes dissociation in water to lactate anion and the hydrated proton. The anion is subsequently rapidly biodegraded by ambient aerobic microorganisms to carbon dioxide and water³, while simultaneously PLA and H₂O₂ (when used as proposed in this application) to be completely degraded on protein surfaces within 60 minutes.⁴ 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 5). 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.⁵

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.⁶ 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 and DPA are the chemicals of environmental concern because of their 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 and DPA 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.⁷ 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

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

⁴ For additional information, see *Confidential Attachment 2*.

⁵ 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

⁶ 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>

⁷ 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>

VALLEY CHEMICAL SOLUTIONS

factor for discharge to surface waters⁸, as indicated below. No refinement was necessary for DPA since, as discussed below, this substance is anticipated to remain solely with water and not partition into sludge.

Use	HEDP Use Level = EIC _{total} (ppm)	EIC _{sludge} = EEC _{sludge} (ppm)	EIC _{water} (ppm)	EEC _{water} (ppm)
HEDP - Meat or poultry carcasses, parts, trim and organs	5.7	4.6	1.1	0.11
HEDP - Processed and pre-formed meat and poultry	1.5	1.2	0.3	0.03
DPA - Meat or poultry carcasses, parts, trim and organs	1.6	n/a	1.6	0.16
DPA - Processed and pre-formed meat and poultry	0.44	n/a	0.44	0.04

As large scale facilities typically do not process more than one type of food, we will use the use level of 5.7 ppm for HEDP and 1.64ppm DPA 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 5.7 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. When the water from the facility is discharged to surface waters, HEDP and DPA will be diluted a further 10-fold, resulting in an estimated environmental concentration (EEC) of 0.11ppm for HEDP and 0.16ppm DPA at maximum intended use concentrations of the FCS.

7. Fate of Emitted Components in the Environment:

Peroxylic 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.⁴ The half-life

⁸ 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: <https://setac.onlinelibrary.wiley.com/doi/abs/10.1002/etc.5620070204>

VALLEY CHEMICAL SOLUTIONS

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.⁹

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 above, may be applied to the EICs as derived above, resulting in maximum expected environmental concentrations (EEC) of approximately 0.11 ppm for HEDP in wastewater from poultry and meat processing.

Regarding **DPA**, it has been shown that a polysubstituted pyridine derivative readily biodegrades under both aerobic and anaerobic conditions.^{10,11,12} In presenting a review on the microbial metabolism of pyridines, including DPA, Kaiser, et al. describe aerobic metabolism of DPA to carbon dioxide, ammonium, and water, and anaerobic metabolism to dihydroxypyridine which is then rapidly photodegraded to organic acids (i.e., propionic acid, acetic acid), carbon dioxide, and ammonium.

As indicated above, the highest amount of DPA that may be released into the environment during use of the FCS would be a maximum of 0.16 ppm. The above-mentioned studies indicate there are mechanisms for the degradation of DPA at levels higher than would be discharged into the environment by intended uses of this FCS.

Studies concerning the environmental fate of DPA were not available from the published literature or proprietary sources. In the absence of environmental fate studies, a USEPA model (EPI Suite) was used to provide information on the environmental fate of DPA. The EPI Suite model uses the chemical structure of a substance to estimate chemical/physical properties and environmental fate characteristics.

The EPI Suite (v 1.11)¹⁶ results for DPA are shown in Appendix A and the key findings are summarized below.

- DPA is soluble in water, with the estimated water solubility ranging from 4,832 mg/L to 5,000 mg/L. The partition coefficient (Log Kow) is estimated to be 0.57.
- The biodegradation of DPA was evaluated using seven different Quantitative Structure Activity Relationship (QSAR) methods. The methods that are relevant to the expected environmental pathway of DPA (discharge to POTW's) are the MITI linear and nonlinear methods. Both of these methods, predict that DPA is readily biodegradable.

Based on EPI Suite estimates for DPA, it is reasonable to conclude that DPA will substantially remain with water and not be absorbed to sludge and that DPA will be readily biodegraded in

⁹ Hydrogen Peroxide. JACC No. 22. European Centre for Ecotoxicology and Toxicology of Chemicals, January, 1993

¹⁰ J.A. Amador and B.P. Tatlor, "Coupled metabolic and photolytic pathway for degradation of pyridinecarboxylic acids, especially dipicolinic acid" Applied and Environmental Microbiology 1990, 56(5), 1352-1356.

¹¹ B. Seyfried and B. Schnink, "Fermentive degradation of dipicolinic acid (Pyridine-2,6- dicarboxylic acid) by a defined coculture of strictly anaerobic bacteria," Biodegradation, 1990, 1(1), 1-7.

¹² J.P. Kaiser, Y. Feng, and J.M. Bollag, "Microbial metabolism of pyridine, quinolone, acridine, and their derivatives under aerobic and anaerobic conditions," Microbiological Reviews, 1996, 60(3), 483-498.

VALLEY CHEMICAL SOLUTIONS

POTW's. Since this Environmental Assessment assumes direct discharge of treated wastewater (containing the FCS) to surface waters, the expected biodegradation of DPA is not being considered.

8. Environmental Effects of Released Substances:

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

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		
<i>Lepomis macrochirus</i> ^a	96 hr LC50	868
<i>Oncorhynchus mykiss</i> ^a	96 hr LC50	360
<i>Cyprinodon variegatus</i> ^a	96 hr LC50	2180
<i>Ictalurus punctatus</i> ^a	96 hr LC50	695
<i>Leuciscus idus melanatus</i> ^a	48 hr LC50	207 – 350
<i>Daphnia magna</i> ^a	24 – 48 hr LC50	165 – 500
<i>Palaemonetes pugio</i> ^a	96 hr EC50	1770
<i>Crassostrea virginica</i> ^a	96 hr EC50	89
<i>Selenastrum capricornutum</i> ^b	96 hr EC50	3
<i>Selenastrum capricornutum</i> ^a	96 hr NOEC	1.3
Algae ^b	96 hr NOEC	0.74
<i>Chlorella vulgaris</i> ^a	48 hr NOEC	≥100
<i>Pseudomonas putida</i> ^a	30 minute NOEC	1000
Long Term		
<i>Oncorhynchus mykiss</i> ^a	14 day NOEC	60 -180
<i>Daphnia Magna</i> ^a	28 day NOEC	10 - <12.5
Algae ^b	14 day NOEC	13

^a 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.

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

VALLEY CHEMICAL SOLUTIONS

A recent risk assessment of phosphonates by the Human and Environmental Risk Assessment Project¹³ 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. Jaworska, et al., determined that the lowest relevant endpoint for this use pattern was 10 mg/L.¹⁴

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 (*Onchorhynchus 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.¹⁴

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 (LD50) for birds is >284 mg/kg body weight.¹³ 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.¹³ Therefore, we expect the amount of HEDP that is removed via sedimentation or filtration to slowly degrade into carbon dioxide, water, and phosphates.

Dipicolinic acid (DPA): There is little available ecotoxicology data for DPA. The Material Safety Data Sheet (MSDS) from one supplier states that the freshwater fish 96 hour LC50 is 322 mg/L for fathead minnow.¹⁵ The Ecological Structure Activity Relationships (ECOSAR) Class Program is a computerized predictive system maintained and developed by the U.S. EPA that estimates aquatic

¹³ 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>

¹⁴ 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.

¹⁵ CDH Fine Chemical – Safety Data Sheet for 2,6-Dipicolinic Acid: https://www.cdhfinechemical.com/images/product/msds/37_148505022_2,6-DIPICOLINICACID-CASNO-499-83-2-MSDS.pdf

VALLEY CHEMICAL SOLUTIONS

toxicity. The program estimates a chemical's acute (short-term) toxicity and chronic (long-term or delayed) toxicity to aquatic organisms, such as fish, aquatic invertebrates, and aquatic plants, by using computerized Structure Activity Relationships (SARs).¹⁶ This program is a sub-routine of the Estimation Program Interface (EPI) Suite – a structure-function predictive modeling suite also developed and maintained by the U.S. EPA.¹⁷ The ECOSAR results for DPA predict the following acute and chronic toxicity endpoints tabulated below. The complete ECOSAR report for this analysis is attached to this EA (See Appendix A).

ECOSAR Class	Organism	Endpoint	mg/L
Pyridine-alpha-acid	Fish	96 hr LC50	324
	Fish	ChV*	29
Neutral Organic SAR	Fish	96 hr LC50	2657
	Daphnid	48 hr LC50	1322
	Green Algae	96 hr EC50	570
	Fish	ChV*	222
	Daphnid	ChV*	89
	Green Algae	ChV*	111

*ChV (Chronic Toxicity) was estimated through application of acute-to-chronic ratios per methods outlined in the ECOSAR Methodology Document provided in the ECOSAR Help Menu.

These values are all much higher than the “worst-case” scenario of an EECaq of 0.16 ppm, which is over 100 times lower than the lowest chronic toxicity endpoint for the most sensitive species. Thus, the use of DPA at such a minimal level is not expected to result in any adverse environmental effects.

9. Use of Resources and Energy

The notified use of the FCS mixture will not require additional energy resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some degree replace similar HEDP/DPA stabilized peroxy antimicrobial agents already on the market. The 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.

11. Alternatives to the Proposed Action

¹⁶ Ecological Structure Activity Relationships (ECOSAR) Predictive Model

<https://www.epa.gov/tscs-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model>

¹⁷ EPI Suite predicts various physical-chemical properties and environmental fate endpoints and also include models for environmental transport. Running the tool will give the user an indication of the transport and persistence of a chemical. Information on EPI Suite is available at <https://www.epa.gov/tscs-screening-tools/epi-suite-estimation-program-interface>

VALLEY CHEMICAL SOLUTIONS

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/DPA-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/DPA-containing antimicrobial products currently on the market. Therefore, the alternative of not establishing this FCN would have no environmental impact.

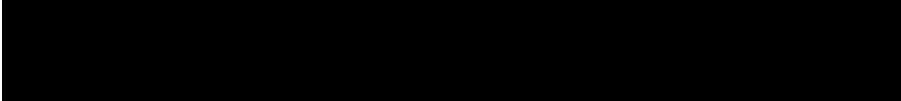
12. List of Preparers

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

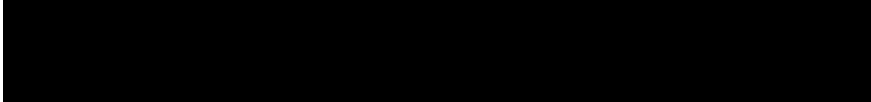
Rider Barnum, PhD Chemistry, 2+ years' experience conducting ecological risk assessments.

13. Certification

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



Jim Faller, PhD (Chemistry), PhD (Microbiology)
Technical Director
VALLEY CHEMICAL SOLUTIONS
Date: 07.30.2019



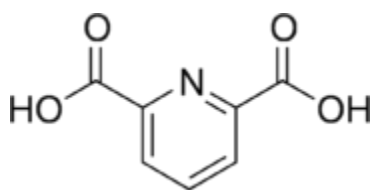
A. Rider Barnum, PhD (Chemistry)
Sr. R&D Chemist
VALLEY CHEMICAL SOLUTIONS
Date: 07.30.2019

VALLEY CHEMICAL SOLUTIONS

Appendix A

EPI Suite – ECOSAR Program Results for DPA, Date of Analysis: 04-24-2019

The Ecological Structure Activity Relationships (ECOSAR) Class Program is a computerized predictive system maintained and developed by the U.S. EPA that estimates aquatic toxicity. The program estimates a chemical's acute (short-term) toxicity and chronic (long-term or delayed) toxicity to aquatic organisms, such as fish, aquatic invertebrates, and aquatic plants, by using computerized Structure Activity Relationships (SARs). Information on ECOSAR can be found at: <https://www.epa.gov/tsca-screening-tools/epi-suite-estimation-program-interface>



Dypicolinic Acid

ECOSAR Version 1.11 Results Page

SMILES : O=C(O)c1ccncc1C(=O)O

CHEM : 2,6-Pyridinedicarboxylic acid

CAS Num: 000499-83-2

ChemID1:

MOL FOR: C7 H5 N1 O4

MOL WT : 167.12

Log Kow: 0.567 (EPI Suite Kowwin v1.68 Estimate)

Log Kow: 0.567 (User Entered)

Log Kow: (PhysProp DB exp value - for comparison only)

Melt Pt: 249.00 (deg C, User Entered for Wat Sol estimate)

Melt Pt: 249.00 (deg C, PhysProp DB exp value for Wat Sol est, 249 dec)

Wat Sol: 4832 (mg/L, EPI Suite WSKowwin v1.43 Estimate)

Wat Sol: 4829 (mg/L, User Entered)

Wat Sol: 5000 (mg/L, PhysProp DB exp value)

Values used to Generate ECOSAR Profile

Log Kow: 0.567 (User Entered)

Wat Sol: 4829 (mg/L, User Entered)

ECOSAR v1.11 Class-specific Estimations

Pyridine-alpha-Acid

Note: SARs use Entered MW (167.12) instead of SMILES MW (167.12)

Predicted

ECOSAR Class Organism Duration End Pt mg/L (ppm)

VALLEY CHEMICAL SOLUTIONS

Pyridine-alpha-Acid : Fish 96-hr LC50 323.758

Pyridine-alpha-Acid : Fish ChV 29.356 !

=====

Neutral Organic SAR : Fish 96-hr LC50 2658.311

(Baseline Toxicity) : Daphnid 48-hr LC50 1322.338

: Green Algae 96-hr EC50 569.969

: Fish ChV 222.293

: Daphnid ChV 89.232

: Green Algae ChV 111.169

Note: * = asterisk designates: Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported.

NOTE: ! = exclamation designates: The toxicity value was estimated through application of acute-to-chronic ratios per methods outlined in the ECOSAR Methodology Document provided in the ECOSAR Help Menu.

Class Specific LogKow Cut-Offs

If the log Kow of the chemical is greater than the endpoint specific cut-offs presented below, then no effects at saturation are expected for those endpoints.

Pyridine-alpha-Acid :

Maximum LogKow: 5.0 (LC50)

Maximum LogKow: 6.4 (EC50)

Maximum LogKow: 8.0 (ChV)

Baseline Toxicity SAR Limitations:

Maximum LogKow: 5.0 (Fish 96-hr LC50; Daphnid LC50)

Maximum LogKow: 6.4 (Green Algae EC50)

Maximum LogKow: 8.0 (ChV)