

VALLEY CHEMICAL SOLUTIONS

ENVIRONMENTAL ASSESSMENT FDA FORM 3480 PART IV, SECTION B

1. **Date:** 06/22/2016
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 peroxyacetic acid (PAA), hydrogen peroxide (H₂O₂), acetic acid, stabilized with 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), catalyzed with optional sulfuric acid, to be used:

- i. at concentrations up to 2000 ppm PAA, 750 ppm Hydrogen peroxide and 10 ppm HEDP for use in all process water that contact poultry carcasses, parts, trim, and organs during production, including water applied by wash, rinse, dip, chill, scald, spray and mist;
- ii. at concentrations up to 495 ppm PAA, 186 ppm Hydrogen peroxide, and 2.5 ppm HEDP for use in brine and ice that may contact poultry carcasses, parts, trim, and organs, and in process water, brine, or ice for washing, rinsing, or cooling processed and preformed poultry products;
- iii. at concentrations up to 2000 ppm PAA, 750 ppm Hydrogen peroxide and 10 ppm HEDP for use in all process water that contact meat carcasses, parts, trim, and organs during production, including water applied by wash, rinse, dip, chill, spray, and mist. Meat products include beef, pork, venison, lamb, and other animal sources that are not traditionally regarded as meat;
- iv. at concentrations up to 495 ppm PAA, 186 ppm Hydrogen peroxide and 2.5 ppm HEDP for use in brine and ice that may contact meat carcasses, parts, trim, and organs, and in process water, brine, or ice for washing, rinsing, or cooling processed and preformed meat products.

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. This product is especially effective against human pathogens like Shiga toxin-producing *Escherichia coli* (STECs), *Salmonella* sp., *Listeria* sp., *Campylobacter* sp., and also inhibits and/or reduces poultry and meat surface microbial contamination, aiding in preserving the shelf life of poultry and meat products. In poultry and meat processing operations, pathogenic microorganisms are often better controlled

VALLEY CHEMICAL SOLUTIONS

by exposure to high concentrations of PAA 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.

This FCS is an improvement to previous of the petitioner's FCNs because it reduces the HEDP exposure level for all uses, improving both food and environmental safety.

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 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 application of the diluted FCS to poultry carcasses will usually take place prior to submersion chilling and again at various intervention sites as carcasses move through second processing and are cut into parts.

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 nozzles inside the 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. Personnel are excluded from the area when air concentrations exceed acceptable levels.

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, as well, common antimicrobial intervention sites, where diluted FCS is applied to the chiller water to help eliminate microbial contamination from the carcasses. The typically lower FCS concentrations applied for the extended period of time that carcasses remain in the chillers to help control time-responsive microorganisms on the carcasses.

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. Cut-up parts may also be exposed to dip tanks for antimicrobial control. 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

¹ See list of industries at <http://water.epa.gov/scitech/wastetech/guide/industry.cfm>

VALLEY CHEMICAL SOLUTIONS

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 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, mist cabinets, as well, drain to the floor. 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. The term “meat” in the context of this FCS is defined by 21 CFR170.3 (n) (17), which includes beef, veal, pork, lamb and mutton. 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, with restricted access during application and are well-ventilated before personnel enter the area.

After the diluted product is applied to the carcass, parts or organs, the majority of the product 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.

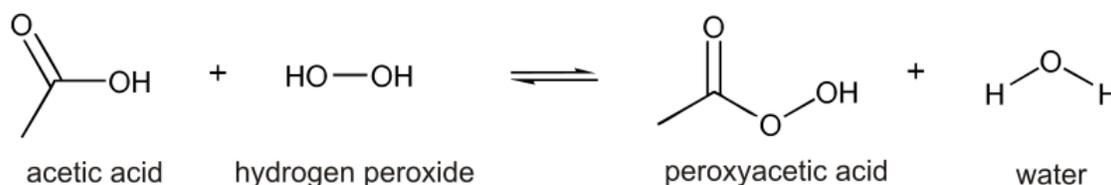
Processed and preformed poultry and meat facilities: This FCS may be applied to preformed and processed product both before and/or after stripping of casings to aid in controlling bacteria that may be present on the surface of formed and/or cased materials. The FCS may be applied to the product by dip, rinse, or spray applications. It may further be applied to any process water that comes in contact with these protein products as they 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:

VALLEY CHEMICAL SOLUTIONS

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	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, 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 (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; 2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (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, 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

VALLEY CHEMICAL SOLUTIONS

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 PAA specified for the applications listed in Section 4a above, *i.e.* at 2000 ppm PAA for poultry applications, 495 ppm PAA for preformed poultry applications, at 2000 ppm PAA for meat applications, and at 495 ppm PAA for preformed meat applications.

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 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.

Commonly, sulfuric acid dissociates in water to sulfate ion and the hydrated proton.⁴ At the maximum 2000 ppm concentration of PAA proposed for use in this FCN, sulfuric acid, optionally used to reduce the time required to establish equilibrium of the concentrated PAA solution, would be present at 39.2 ppm, based on information provided in the confidential attachment to this EA. The fate and environmental impact of sulfate are discussed in Items 7 and 8 of this Assessment.

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.⁵ 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

² EPA Reregistration Eligibility Document: Peroxy compounds; December 1993; available at http://www.epa.gov/pesticides/reregistration/REDS/old_reds/ peroxy_compounds.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

⁴ 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.

⁵ The Organisation for Economic Co-operation and Development (OECD) SIDS Voluntary Testing Program for International High Production Volume Chemicals, Sulfuric Acid, 2001.

VALLEY CHEMICAL SOLUTIONS

wastewater. To calculate the expected environmental concentrations (EECs), we have incorporated a conservative 10-fold dilution factor for discharge to surface waters⁶, as indicated below.

Use	HEDP Use Level = EIC _{total}	EIC _{sludge} = EEC _{sludge}	EIC _{water}	EEC _{water}
Poultry Processing /	10 ppm	8 ppm	2 ppm	0.20 ppm
Processed and Preformed Poultry	2.5 ppm	2 ppm	0.5 ppm	0.05 ppm
Meat Processing	10 ppm	8 ppm	2 ppm	0.20 ppm
Processed and Preformed Meat	2.5 ppm	2 ppm	0.5 ppm	0.05 ppm

As large scale facilities typically do not process more than one type of food, we will use the use level of 10 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., 0.20 ppm HEDP. Therefore, the discussion of impacts from use of the FCS will focus on comparing the poultry EECs to appropriate ecotoxicity endpoints that are provided under Item 8.

7. Fate of Emitted Components in the Environment:

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 it is not expected to concentrate in the wastewater discharged to

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>

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

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

VALLEY CHEMICAL SOLUTIONS

the POTW. Sulfuric acid degrades into sulfate (SO₄), which is not a toxicological or environmental concern at the proposed use levels.

Regarding **HEDP**, when waste water from the food processing operations described above is released to a POTW, the concentrations of the HEDP for the various different protein sources will be further diluted by the additional waters processed by the POTW. Application of a standard 10-fold dilution factor for surface water discharge, as described in Robert Rapaport's 1988 study cited below¹⁰, may be applied to the 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.

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.^{11, 12}

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 and sulfuric acid.

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
<i>Short Term</i>		
<i>Lepomis macrochirus</i> ¹	96 hr LC50	868
<i>Oncorhynchus mykiss</i> ¹	96 hr LC50	360
<i>Cyprinodon variegates</i> ¹	96 hr LC50	2180
<i>Ictalurus punctatus</i> ¹	96 hr LC50	695
<i>Leciscus idus melanatus</i> ¹	48 hr LC50	207 – 350
<i>Daphnia magna</i> ¹	24 – 48 hr LC50	165 – 500
<i>Planemonetes pugio</i> ¹	96 hr LC50	1770
<i>Crassostrea virginica</i> ¹	96 hr LC50	89

¹⁰ 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>

¹¹ The Organisation for Economic Co-operation and Development (OECD) SIDS Voluntary Testing Program for International High Production Volume Chemicals (OECD SIDS), Sulfuric Acid, 2001.

¹² Human and Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products, Sodium Sulfate, January 2006

VALLEY CHEMICAL SOLUTIONS

<i>Selenastrum capricornutum</i> ²	96 hr LC50	3
<i>Selenastrum capricornutum</i> ²	96 hr NOEC	1.3
Algae ²	96 hr NOEC	0.74
<i>Chlorella vulgaris</i> ¹	48 hr NOEC	≥100
<i>Pseudomonas putida</i> ¹	30 minute NOEC	1000
Long Term		
<i>Oncorhynchus mykiss</i> ¹	14 day NOEC	60 -80
<i>Daphnia Magna</i> 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 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

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 BOD₃₀/COD was 5%.

The maximum calculated EIC for HEDP for the various applications addressed in this FCN are provided in Section 6.b of this EA.

Even assuming the theoretical ‘worst-case’ scenario for poultry (e.g., the highest PAA use level), the resulting 0.05 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).

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.

VALLEY CHEMICAL SOLUTIONS

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 red worms and > 980 mg/kg for oats. The 14-day median lethal dose (LD50) for birds was greater than 284 mg/kg body weight.¹⁵ The ‘worst-case’ (e.g., the highest PAA use level) eight 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.¹⁶ In a low ortho-phosphate environment, breakdown of HEDP was found to be 94% in activated sludge “Maria Middelaers” (ASMM) and the conditions were 28°C for 28 days.¹⁷ Therefore, we expect the amount of HEDP that is removed via sedimentation or filtration to slowly degrade into carbon dioxide, water, and phosphates.¹⁸

Sulfuric acid: Sulfuric acid is used optionally in this FCS and, as noted in Sections 6 and 7 above, readily dissociates into sulfate in the environment. Both Sulfuric acid and Sodium sulfate are substances with favorable ecological profiles. Due to the low aquatic toxicity and the natural recycling that occurs in the sulfur cycle, wide dispersive use of sodium sulfate does not present a major hazard to the environment although locally, peak concentrations may be damaging to unadapted flora and fauna.¹⁹

In studies summarized on page 8 of the HERA cover notes of Sodium sulfate²⁰ it is stated that for algae, the most sensitive organisms to Sodium sulfate, the EC₅₀ 120h = 1,900 mg/l (ppm). “For invertebrates (*Daphnia magna*) the EC₅₀ 48h = 4,850 mg/l and fish appeared to be least sensitive with a LC₅₀ 96h = 7,960 mg/l for *Pimphales promelas*.”

¹⁵ 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>

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

¹⁸ 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>

¹⁹ The Organisation for Economic Co-operation and Development (OECD) SIDS Voluntary Testing Program for International High Production Volume Chemicals (OECD SIDS), Sulfuric Acid, 2001.

²⁰ Human and Environmental Risk Assessment(HERA) on ingredients of Household Cleaning Products. Substance: Sodium sulfate (CAS # 7757-82-6), Edition 1.0, January 2006.

VALLEY CHEMICAL SOLUTIONS

Futher, “overall, it can be concluded that sodium sulfate has no acute adverse effect on aquatic and sediment.”²¹

Also: “[n]o data were found for long term toxicity. The acute studies all show a toxicity of sodium sulfate higher than 100 mg/l, no bioaccumulation is expected, therefore it can be considered that no further chronic studies are required.”²²

The maximum concentration of optional Sulfuric acid that may be released from using this FCS at the highest concentration of PAA requested (2000 ppm), is 39.2 ppm, orders of magnitude below any concentration of concern expressed above.

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 negative environmental impact that would require mitigation measures. As discussed above, the use and disposal of the antimicrobial agent is not expected to result in significant adverse environmental impacts. Furthermore, the National Pollution Discharge Elimination System (NPDES) Program under the Clean Water Act (33 U.S.C. 125 1 et seq.) require the users of an antimicrobial agent such as hydrogen peroxide and peroxyacetic acid to have a current NPDES permit and to notify the permitting authority in writing prior to the discharge of an effluent to waters of the United States. Review of discharge of the FCS by the appropriate NPDES permitting program will help to mitigate any adverse effects resulting from use of the FCS.

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 beef, poultry and pork 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

²¹ Human and Environmental Risk Assessment(HERA) on ingredients of Household Cleaning Products. Substance: Sodium sulfate (CAS # 7757-82-6), Edition 1.0, January 2006.

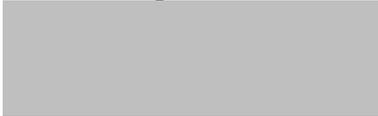
²² Human and Environmental Risk Assessment(HERA) on ingredients of Household Cleaning Products. Substance: Sodium sulfate (CAS # 7757-82-6), Edition 1.0, January 2006.

VALLEY CHEMICAL SOLUTIONS

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 to the best of his knowledge.



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

Date: 06.22.2016