Attachment #16 Environmental Assessment

- 1. Date: November 29, 2017
- 2. Submitter: Enviro Tech Chemical Services, Inc.
- 3. Address: 500 Winmoore Way, Modesto, CA. 95358

4. Description of Proposed Action:

- a. Description of the Requested Action: The FCS proposed in the Food Contact Notification is composed of peroxyacetic acid (PAA), hydrogen peroxide (H₂O₂), acetic acid, 1-hydroxy ethylidene-1,1diphosphonic acid (HEDP) and optionally sulfuric acid. The intended use is as an antimicrobial additive that may be used alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures prior to filling, except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging. The maximum proposed use concentration of the FCS is 4500 ppm as PAA at $65^{\circ} \pm 1^{\circ}$ C. A 4500 ppm ceiling for PAA also equates to 6600 ppm as H₂O₂ and 180 ppm as HEDP.
- b. The Need for the Action: The FCS is intended to be used as an antimicrobial additive that may be used alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures prior to filling, except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging. The need for an antimicrobial to treat food contact surfaces of glass and plastic food packaging and their enclosures is to eliminate pathogenic and non-pathogenic microorganisms that may be present on the food packaging or on the enclosure surface. The action requested by this FCN addresses

current and future needs for processors and governmental agencies to respond to increased pressures to improve food safety.

c. Brief Discussion of the Use and Disposal of the FCS: The FCS may be used alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures prior to filling, except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging. In a typical food processing facility, a fresh batch containing the FCS may be initially made prior to an eight (8) hour shift, and then completely disposed of after approximately 6 cycles of 8 hours each (48 hours total time) of use. Due to use of the FCS and loss of the FCS during treatment of the glass and plastic food packaging and their enclosures, it is often necessary to replenish the FCS containing reservoirs during the 6 cycles of use. The FCS used for replenishment is typically made at the beginning of an 8-hour shift during the 6 cycles of use. The reservoirs are then filled and refilled as needed.

The batches containing the FCS are commonly blended in tanks filled to approximately 900 gallons. Typically, about 600 gallons of the FCS in a reservoir is intended for use in glass and plastic food packaging treatment operations and approximately 300 gallons of the FCS in a reservoir is used in enclosure treatment operations. During each 8-hour shift, the loss of the FCS solution due to its use, may be up to 50 percent or 450 gallons of the FCS. The FCS solution that is lost during use is diluted with other liquid waste products at the processing plant. The diluted FCS solution will be disposed of with processing plant wastewater according to National Pollutant Discharge Elimination System (NPDES) regulations. For processing plants that hold a NPDES permit (i.e., direct dischargers), the FCScontaining wastewater will be treated on-site before direct discharge to surface waters. For processing plants without such NPDES permits (i.e., indirect dischargers), the FCS containing wastewater would travel through the sanitary sewer system into Publicly Owned Treatment Works (POTWs) for standard wastewater treatment processes before movement into aquatic environments.

The FCS is initially made up at the target PAA concentration. For each 8-hour shift the total amount of FCS that may be typically disposed of in an on-site pretreatment facility or wastewater discharge system is 450 gallons based on a total of 900 gallons of FCS. For two 8 hour shifts consisting of a typical day, the total amount of the FCS that may be disposed is 900 gallons. The FCS solution will be disposed of with processing plant wastewater according to National Pollutant Discharge Elimination System (NPDES) regulations. For processing plants that hold a NPDES permit (i.e., direct dischargers), the FCS-containing wastewater will be treated on-site before direct discharge to surface waters. For processing plants without such NPDES permits (i.e., indirect dischargers), the FCS containing wastewater would travel through the sanitary sewer system into Publicly Owned Treatment Works (POTWs) for standard wastewater treatment processes before movement into aquatic environments. The potential use and disposal of the FCS is discussed below and describes worst case scenarios and associated potential risks along with the Environmental Introduction Concentration (EIC) and Expected Environmental Concentration (EEC) calculations.

5. Identification of Substance:

The FCS is a liquid equilibrium mixture of peroxyacetic acid, hydrogen peroxide and acetic acid. It is made by blending acetic acid, hydrogen peroxide, HEDP (as a chelating agent), optionally sulfuric acid (to speed the reaction process) and reverse osmosis purified water. Ingredients:

Chemical Name	CAS#
Peroxyacetic acid	79-21-0
Hydrogen peroxide	7722-84-1
Acetic acid	64-19-7
Sulfuric acid (optional)	7664-93-9
HEDP (1-hydroxyethylidine-1,1-diphosphonic acid)	2809-21-4
Water	7732-18-5

The basic reaction by the above combination is as follows: $CH_3CO_2H + H_2O_2 \rightarrow CH_3CO_3H + H_2O$ (molecular weight is 76.05 g/mole)

6. Introduction of Substance into the Environment:

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

The FCS is currently manufactured in EPA approved facilities at the addresses listed below and no unusual or factual threat to the environment exist.

Establishment Number	Establishment Name	Establishment Site Address
63838-CA-01	Enviro Tech Chemical Services, Inc.	500 Winmoore Way, Modesto CA
63838-AR-01	Enviro Tech Chemical Services – Plant 6	724 Phillips County Road 411, Helena, AR 72342

Attached are the Facility Registry Service (FRS) website pages that document the EPA Establishment Numbers at the addresses listed above. Below are the website links:

http://iaspub.epa.gov/enviro/fii_query_detail.disp_program_facility?p_regist

ry_id=110024498890 and

https://iaspub.epa.gov/enviro/fii_query_detail.disp_program_facility?p_regi stry_id=110063867383. No extraordinary environmental circumstances would apply to the continued on-going manufacture of the FCS.

b. Introduction of substances into the environment as a result of use/disposal:

The FCS is proposed to be used as an antimicrobial additive that may be used alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures prior to filling, except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging. The FCS is provided as a concentrate that is diluted on site. The maximum concentrations of the FCS by use are as follows:

Use	PAA	H202	HEDP
	(ppm)	(ppm)	(ppm)
As an antimicrobial additive that may be used	4500	6600	180
alone or in combination with other processes in			
the commercial sterilization of aseptic filling			
systems and glass and plastic food packaging and			
their enclosures prior to filling, except for use on			
food packaging used in contact with infant			
formula or human milk or on aseptic filling			
equipment used to fill such packaging.			

Based on the described use pattern above, the primary pathway for the FCS to reach the environment is by the use and disposal of the FCS. Following use or disposal of the FCS, the FCS enters the processor's on-site pretreatment facility before discharging to the local publicly-owned

treatment works (POTW) and surface waters, depending upon whether the facility has an individual NPDES permit.

Treatment of the process water at an on-site waste water treatment facility and then at a POTW and surface waters is expected to result in a complete degradation of PAA, hydrogen peroxide and acetic acid. The PAA will breakdown into oxygen and acetic acid while hydrogen peroxide will breakdown into oxygen and water⁽¹⁾. PAA, hydrogen peroxide and acetic acid all rapidly degrade 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⁽²⁾. 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⁽³⁾.

Biodegradation is the most significant removal mechanism for acetic acid. In biodegradation studies with acetic acid, 99% degraded in 7 days under anaerobic conditions⁽⁴⁾. Acetic acid is not expected to concentrate in the wastewater discharged to the POTW and surface waters. Therefore, these substances are not expected to be introduced into the environment to any significant extent as a result of the proposed use of the FCS.

Sulfuric acid is an optional ingredient in the FCS formulation and is used to catalyze the reaction between acetic acid and hydrogen peroxide to more rapidly produce a stable PAA solution. Sulfuric acid is GRAS for use in or on food as listed under Title 21 C.F.R. § 184.1095. Sodium sulfate is an inorganic salt with a melting point of approximately 884 °C., a relative density of 2.7 g/cm³ at 20°C and a water solubility of 161 g/l at 20°C ⁽¹⁰⁾. Sulfuric acid is a strong mineral acid that dissociates readily in water to sulfate ions and hydrated protons and is totally miscible with water ⁽¹¹⁾. With a pKa of 1.92 at 25C, the dissociation of sulfuric acid is 99% at pH 3.92 for example. At environmentally relevant concentrations, sulfuric acid

is practically totally dissociated. In water, sodium sulfate completely dissociates into sodium and sulfate ions. Total ionization of sulfuric acid implies that sulfuric acid, itself, will not adsorb on particulate matters or surfaces and will not accumulate in living tissues.

In anaerobic conditions, sulfate is biologically reduced to hydrogen sulfide by sulfate reducing bacteria or incorporated into living organisms and included in the sulfur cycle. Sodium sulfate is not reactive in aqueous solution at room temperature. Sodium sulfate will completely dissolve, ionise and distribute across the entire planetary "aquasphere" $^{(10)}$. Some sulfates may eventually be deposited, but the majority of sulfates participate in the sulfur cycle in which natural and industrial sodium sulfate is not distinguishable. Sodium sulfate is widely distributed in nature; it occurs as mineral salts (e.g. thenardite, mirabilite), it is present in almost all fresh and salt waters, and sulfate as such is normally present in almost all natural foodstuffs. Both sodium and sulfate ions are among the most common ions found in all living organisms. In mammals, sulfate is a normal metabolite of sulfur-containing amino-acids, it is normally incorporated in a variety of body compounds and it plays an important role in detoxification/ excretion processes due to sulfoconjugation. Sodium sulfate is a substance with a favorable ecological profile. Due to the low aquatic toxicity and the natural recycling that occurs in the sulfur cycle, wide dispersive use of sodium sulfate does not present a major hazard to the environment $^{(10)}$.

The substances discussed above (PAA, hydrogen peroxide, acetic acid and the optional ingredient sulfuric acid) are not expected to be introduced into the environment to any significant extent as a result of the proposed use of the FCS. The remainder of this section will therefore consider only the environmental introduction of HEDP.

The Environmental Introduction Concentration (EIC) may be calculated by multiplying the concentration of HEDP in the FCS by the estimated

percentage of degradation associated with use of the FCS. The worst-case concentration of HEDP will be used to calculate the EIC. The Human and Environmental Risk Assessment Project (HERA) report showed that HEDP adsorption to wastewater sludge is greater than 90%⁽⁷⁾. To be conservative, an estimate of 80% adsorption to wastewater sludge in sewage treatment plants will be used for the below Estimated Environmental Concentration (EEC) calculations.

The environmental introduction concentration (EIC) of HEDP is based on use and disposal of the FCS at the end of a work day into the food processor's on-site pre-treatment facility assuming no degradation of the FCS components. The subsequent EECs including EEC_{sludge} and EEC_{water} are calculated below using the 80:20 partition factor arrived at in the HERA report. With respect to the EEC_{water} calculation, a 10 fold dilution factor is recommended for use when estimating surface water concentrations⁽⁶⁾. Below are the worst-case EIC and EEC_{sludge} and EEC_{water} calculations for HEDP:

HEDP EIC = 180 ppm HEDP x 100% remaining = 180 ppm $EEC_{sludge} = 180$ ppm HEDP x 80% partition to sludge = 144 ppm HEDP $EEC_{water} = (180 \text{ ppm HEDP x } 20\% \text{ partition to water}) / 10 \text{ fold}$ dilution factor = 3.6 ppm

7. Fate of the Substance in the Environment:

It is well documented and accepted in the scientific community that PAA and H_2O_2 are short lived in the environment, do not bioaccumulate, have innocuous degradation byproducts, and are of no toxicological or ecotoxicity concern^(1, 2, 3). Peroxyacetic acid and hydrogen peroxide are not expected to survive treatment at the primary wastewater treatment facility due to their reactivity and pH sensitivity⁽¹⁾. Both compounds are rapidly degraded on contact with organic matter, transition metals, and upon exposure to sunlight^(2, 3). The half-life of PAA in buffered solution solutions was 63 hrs at pH 7 for a 748 ppm solution, and 48 hrs for a 95 ppm solution, also at pH 7⁽²⁾. 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⁽³⁾. In filtered lake water the half-life of H_2O_2 (initial concentration 3.4 ug/l) was 8.6 hrs-31 hrs. (page 21 reference #3).

Since PAA and H_2O_2 rapidly degrade, they will not be introduced into the natural environment in wastewater at toxic levels. Therefore toxicity and fate data should not be required for these compounds. Biodegradation is the most significant removal mechanism for acetic acid. In biodegradation studies with acetic acid, 99% degraded in 7 days under anaerobic conditions⁽⁴⁾.

When wastewater from food processing operations described above is released to a POTW and surface waters, the concentration of HEDP will be further diluted by the additional waters processed by the POTW and surface waters. The maximum HEDP EEC_{water} will be 3.6 ppm and the maximum HEDP EEC_{sludge} will be 144 ppm based on the above calculations using the 10-fold dilution factor for the EEC water and the 80:20 partition ratio to wastewater sludge and wastewater, respectively. The chelating agent, HEDP, is added to the FCS to sequester transition metal ions in solution. HEDP increases shelf life of the product significantly by preventing metal ions from breaking down PAA and H_2O_2 . HEDP is in a class of compounds known as a phosphonates. HEDP slowly biodegrades into phosphates at a rate of about 1% per day when chelated with transition metal ions⁽⁵⁾. Because of the nature of the carbon-phosphorus bond in HEDP, it adsorbs very strongly to mineral surfaces and rarely exists free in solution⁽⁵⁾. The HERA report shows that HEDP adsorption to sludge is greater than $90\%^{(7)}$. Our calculations used a conservative estimate of 80% adsorption to sludge in sewage treatment plants.

In wastewater, sulfuric acid will completely dissociate into sulfate ions and hydrated protons, neither of which are a toxicological or environmental concern ^(10, 11).

8. Environmental Effects of Released Substances:

The FCS is intended to be used as an antimicrobial additive that may be used alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures prior to filling, except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging. The concentrations of the proposed FCS are quite diluted, and once the FCS contacts the balance of the site's wastewater, and subsequently further downstream with the main body of discharge/waste water at the POTW and surface waters, the pH would be such that the peroxygens, PAA and H₂O₂, would degrade rapidly^(1,2,3).

a. Aquatic Environment

The FCS is intended to be used as an antimicrobial additive that may be used alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures prior to filling, except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging. Wastewater from such facilities contains liquid nutrient waste from the packaged food product and from disposal of ingredients. HEDP is a strong chelating agent and can result in adverse effects on environmental organisms by complexation of essential nutrients⁽⁷⁾. For strong chelating agents, it is suggested that two types of No Observed Effect Concentration's (NOEC's) be determined: an intrinsic NOEC (NOECi) measured with excess nutrients available and an NOEC measured to protect from the chelating effects in natural waters (NOECc)⁽⁹⁾. A realistic NOECc should be determined by testing in natural waters, by predicting metal speciation and algal trace element requirements, and/or using metal speciation modeling programs⁽⁹⁾. However, excess nutrients are expected to be present in industrial wastewater as eutrophication is a well-known phenomenon seen in industrial wastewaters from food processing facilities⁽⁸⁾.

Aquatic toxicity of HEDP is summarized and shown in the following table below.

Table 1: Environmental Toxicity Data for HEDP

Species	Endpoint	mg/L
Short Term		
Lepomis macrochirus ⁹	96 hr LC ₅₀	868
Oncorhynchus mykiss ⁹	96 hr LC ₅₀	360
Cyprindon variegates ⁹	96 hr LC ₅₀	2180
Ictalurus punctatus ⁹	96 hr LC ₅₀	695
Leciscus idus melanatus ⁹	96 hr LC ₅₀	207 - 350
Daphnia magna ⁹	24 – 48 hr LC 50	165 - 500
Planemonetes pugio ⁹	96 hr EC ₅₀	1770
Crassostrea virginica ⁹	96 hr EC ₅₀	89
Selenastrum capricornutum ⁷	96 hr LC ₅₀	3
Selenastrum capricornutum ⁷	96 hr NOEC	1.3
Algae ⁷	96 hr EC ₅₀	0.74
Chlorella vulgaris ⁹	48 hr NOEC	≥100
Pseudomonas putida ⁹	30 minute NOEC	1000
Long Term		
Oncorhychus mykiss ⁹	14 day NOEC	60 - 180
Daphnia magna ⁹	28 day NOEC	10 - <12.5
Algae ⁷	14 day NOEC	13

Jaworska *et. al.* showed that the acute toxicity endpoints for HEDP ranged from 0.74 - 2,180 mg/L while the chronic NOECs ranged from 10 mg/L for the 28 day NOEC for *Daphnia magna* to 60-80 mg/L for the 14 day NOEC for *Oncorhynchus mykiss*. Although a chronic NOEC of 0.1 mg/L was reported for reproductive effects in *Daphnia magna*, it is inconsistent with other toxicity data and Jaworska *et. al.* The relevant endpoint for a high orthophosphate environment is 10mg/L (28 day) NOEC for *Daphnia magna* as published by Jaworska et al. The values calculated herein of HEDP EEC_{water} = 3.6 ppm fall below these limits so no significant adverse impacts are expected.

b. Terrestrial Environment

HEDP accumulated in wastewater sludge is eventually discharged to land and is not expected to have any adverse environmental impact on the terrestrial toxicity endpoints for plants, earthworms or birds. The NOEC for soil-dwelling organisms was 1000 mg/kg soil dry weight for red worms in soil⁽⁷⁾. The 14 day median lethal dose (LD₅₀) for birds was greater than 284 mg/kg body weight⁽⁷⁾. As a comparison,

the HEDP $\text{EEC}_{\text{sludge}}$ is 144 ppm which is less than the LD_{50} for birds at 248ppm so no significant adverse impacts are expected.

9. Use of Resources and Energy:

The proposed FCS would not pose any significant additional burden on existing resources or energy in the manufacture, transport, use or disposal of the FCS above and beyond those already existing, and the proposed use will not create any significant additional burden on resources or energy. The FCS is made in a PAA manufacturing facility with existing fixed costs that would not be increased in a significant way by the manufacture of this FCS. The ingredients used in the manufacture of the FCS are purchased in bulk quantities for several products and this FCS would not pose a significant additional burden on those requirements. The transportation of the FCS is similar to other PAA products at the facility and would only increase the cost of transportation by the weight and incremental fuel required for transport. The disposal of the FCS would not significantly increase any wastewater usage or processing costs any more than a similar volume of a product.

10. Mitigation Measures:

The proposed FCS is not reasonably expected to result in any significant adverse environmental impacts that would require mitigation measures of any kind.

11. Alternatives to Proposed Action:

There are no potential adverse environmental effects that would necessitate alternative actions to that proposed in this FCN. The alternative of not approving the action proposed herein would simply result in the continued use of the materials that the FCS would otherwise replace, and such action would have no significant environmental impact.

12. List of Preparers:

a. Michael Harvey, President & CEO, Enviro Tech Chemical Services, Inc. Education: B.S. Cal. State University, Chico (Chemistry) Experience: 30 years of experience conducting ecological risk assessments and preparing regulatory submissions that have been submitted to the EPA and FDA

b. Brent Bankosky, Sr. Vice President, Business Operations, Enviro Tech Chemical Services, Inc.

Education: BS., MBA, Pennsylvania State University, MS, Lehigh University

Experience: 12 years of experience preparing EPA and FDA regulatory submissions

c. Jonathan N. Howarth, Sr. Vice President, Technology, Enviro Tech Chemical Services, Inc.

Education: Ph.D., Physical Chemistry, Univ. of Southampton, England; BS (Honors), Applied Chemistry, Leicester Polytechnic, England Experience: 25 years of experience preparing EPA and FDA regulatory submissions

- d. Joseph Donabed, R&D Manager, Enviro Tech Chemical Services, Inc. Education: BS, Cal. State Stanislaus University Experience: 3 years of experience preparing EPA and FDA regulatory submissions
- e. Tina Rodrigues, Director, Regulatory Affairs, Enviro Tech Chemical Services, Inc.

Education: BS, Cal. State Stanislaus University

Experience: 8 years of experience preparing EPA and FDA regulatory submissions

13. Certification:

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Enviro Tech Chemical Services, Inc.

Date: November 29, 2017

Signature: Name and Title: Michael S. Harvey, President & CEO



14. BIBLIOGRAPHY and LITERATURE CITATIONS

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

- (5) NOWACK, B. (2003) "Environmental chemistry of phosphonates"; Water Research, 1-14.
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- (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. <u>http://webnet.oecd.org/HPV/UI/handler.axd?id=248f397d-64b3-4e14-8be9-473974e8dfdb</u>

EPA FRS Facility Detail Report Exhibit



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