Environmental Assessment

1. **Date:** August 10, 2021
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 food contact substance (FCS) proposed in the Food Contact Notification is an aqueous mixture of peroxyacetic acid (CAS Reg No 79-21-0), hydrogen peroxide (CAS Reg No 7722-84-1), acetic acid (CAS Reg No 64-19-7), 2,6-pyridinedicarboxylic acid (variously identified in this document as Dipic, DPA, or dipicolinic acid) (CAS Reg No 499-83-2), and optionally sulfuric acid (CAS Reg No 7664-93-9).

i. The FCS is intended to be used as an antimicrobial agent to reduce or eliminate pathogenic or spoilage microorganisms during the tempering and before milling of grains of wheat, corn, and rice. Grains may be treated only once. The maximum concentration of the diluted FCS solution on grains is not to exceed 6,000 ppm as peroxyacetic acid, 8,800 ppm as hydrogen peroxide, and 16 ppm as 2,6-pyridinedicarboxylic acid (DPA). Application of the FCS in the preparing, packaging, or holding of food for commercial purposes, is consistent with the Federal Food, Drug & Cosmetic Act (FD&C Act) section 201(q)(1)(B)(i). The FCS is not for use in contact with ingredients used for making infant formula. Such use was not included as part of the intended use of the substance in the FCN.

Prior to use, the concentration solution of the FCS will be diluted with water to obtain the concentration of the application solution as listed in Section 4.a above. The use of the FCS and preparation of the diluted FCS solution prior to application on grains is a batch

application, i.e. diluted FCS solution is prepared daily and is applied directly to the grains during tempering (i.e. in process water as a bath application). The application of the diluted FCS solution is associated with the maximum concentrations of the FCS applied to grains as listed above in Item 4.a. A maximum amount of water moisture that is added during the tempering process is 3% (typical range 1-3%). This equates to 30-lbs (3.6-gallons) of water added per 1000-lbs grain which would limit the maximum dose of the concentrated FCS product to 16.23-fl oz per 30-lbs (3.6-gallons) water which would be the highest exposure potential.

b. Need for the Action: The FCS is intended for use as an antimicrobial agent to inhibit the growth of undesirable or pathogenic microorganisms on wheat, corn and rice grains, except for use in contact with ingredients used for making infant formula.

c. Locations of Use/Disposal:

Use: The FCS is intended for use as an antimicrobial agent to inhibit the growth of undesirable or pathogenic microorganisms on grains in grain processing facilities nationwide, where the processing of food will occur after treatment.

Disposal: After use, the diluted FCS solution will be disposed of with processing plant wastewater. For processing plants that hold a National Pollutant Discharge Elimination System (NPDES) permit (i.e., direct dischargers), the FCS-containing wastewater will be treated on-site before directly discharged to surface waters. For processing plants without such NPDES permits (i.e., indirect dischargers), the FCS-containing wastewater will undergo pretreatment on-site and travel through the sanitary sewer system into Publicly Owned Treatment Works (POTWs) for standard wastewater treatment processes before movement into aquatic environments.

5. Identification of Substance:

The antimicrobial component of the FCS is an equilibrium mixture of peroxyacetic acid, hydrogen peroxide and acetic acid. It is made by blending acetic acid, hydrogen peroxide, dipicolinic acid (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
Dipicolinic acid (2,6-pyridinedicarboxylic acid)	499-83-2
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:

Under 21 Code of Federal Regulations (CFR) § 25.40(a), an EA should focus on relevant environmental issues relating to the use and disposal from use, rather than the production of FDA-regulated articles. The FCS is manufactured in plants that meet all applicable federal, state, and local environmental regulations. Enviro Tech Chemical Services, Inc., asserts that the FCS is manufactured in EPA compliant (i.e., National Pollutant Discharge Elimination System, NPDES, permitted) facilities and that there are no extraordinary circumstances pertaining to the manufacture of the FCS.

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

The FCS is proposed for use as an antimicrobial agent for: (1) process water applied during the tempering and before milling of grains of wheat, corn, and rice. 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	Dipic
Process water applied during the tempering and before milling of grains of wheat, corn, and rice.	6,000	8,800	16

Based on the described use patterns 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 wastewater 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 dissociates readily in water to sulfate ions ($SO4^{2-}$) and hydrated protons. At environmentally relevant concentrations, sulfuric acid is practically totally dissociated[9]. As part of the natural sulfur cycle, sulfate is either incorporated into living organisms, reduced via anaerobic biodegradation to sulfides, deposited as sulfur, or re-oxidized to sulfur dioxide and sulfate[8]. Therefore, any terrestrial or aquatic discharges of sulfate associated with the use described in this FCN are not expected to have any significant environmental impact, as sulfate is ubiquitous anion that is naturally present in the ecosystem and virtually indistinguishable from industrial sources[8].

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 Dipic.

Information available in the literature indicates that dipicolinic acid is soluble in water, with an estimated solubility of 5,000 mg/L and an octanol-water partition coefficient estimated to be 0.57[10]. Based upon this information, it is reasonable to conclude that dipicolinic acid will remain substantially with water and not be absorbed to sludge, and that dipicolinic acid with be readily biodegraded during treatment at POTWs and on-site treatment facilities. The environmental introduction concentration (EIC) of the FCS is based on use and disposal of the FCS solution at the end of a work day into the food processor's on-site pre-treatment facility assuming no degradation of the FCS solution. The subsequent EECs including EEC_{sludge} and EEC_{water} are calculated below assuming no partition to sludge. With respect to the EEC_{water} calculation, a 10-fold dilution factor is recommended for use when estimating surface water concentrations[1]. Below are the worst-case EIC and EEC_{sludge} and EEC_{water} calculations for the FCS:

FCS EIC = 16 ppm FCS x 100% remaining = 16 ppm
EEC_{sludge} = 16 ppm FCS x 0% partition to sludge = 0 ppm
FCS EEC_{water} = (16 ppm FCS x 100% partition to water) / 10 fold dilution factor = 1.6 ppm FCS

7. Fate of the Substance in the Environment:

It is well documented and accepted in the scientific community that PAA, H_2O_2, Acetic acid, and Sulfuric acid are short lived in the environment, do not bioaccumulate, have innocuous degradation byproducts, and are of no toxicological or ecotoxicity concern[1, 2, 3].
Since these molecules are expected to completely degrading during wastewater treatment, their environmental fates will not be discussed further.

It has been shown that the Dipic, a poly-substituted pyridine derivative readily biodegrades under both aerobic and anaerobic conditions[11, 12, 13, 14]. In presenting a review on the microbial metabolism of pyridines, including dipic, Kaiser, et al. (p. 448), describe aerobic metabolism of Dipic 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[13].

When wastewater from food processing operations described above is released to a POTW and surface waters, the concentration of Dipic will be further diluted by the additional waters processed by the POTW and surface waters. The maximum Dipic EEC_{water} for process water applied during the tempering and before milling of grains of wheat, corn, and rice will be 1.6 ppm and the maximum Dipic EEC_{sludge} will be 0-ppm based on the above calculations using the 10 fold dilution factor for the EECwater and the 0:100 partition ratio to wastewater sludge and wastewater, respectively. As indicated above, the highest amount of Dipic that may be released into the environment would be a maximum of 1.6 ppm. Extrapolation of the data trend discussed in the study referenced above (which showed complete degradation of 20 ppm levels in 8 days) results in anticipated degradation in approximately one hour (20 ppm/192 hours = 0.1 ppm/hr). The degradation rate of the aforementioned showed 20-ppm DPA degraded within 8-days. Therefore, based on a maximum DPA concentration of 16-ppm, we suspect complete degradation of the DPA within 8-days regardless of environmental factors that may increase the degradation rate.

8. Environmental Effects of Released Substances:

This FCS is intended for microbiological control in (1) process water applied during the tempering and before milling of grains of wheat, corn, and rice. The concentrations of the proposed FCS in each application 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 H_2O_2, would degrade rapidly[1,2,3].

There is little available ecotoxicity data for the DPA. The Safety Data Sheet (SDS) from one supplier states that the freshwater fish 96 hour LC_{50} is 322 mg/L for the fathead minnow[5]. 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 Ecological Structure Activity Relationships (ECOSAR) Predictive Model[6]. 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[7]. 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.

ECOSAR Class	Organism	Endpoint	mg/L
Pyridine-alpha-acid	Fish	96 hr LC_{50}	324
	Fish	ChV	29
Neutral Organic SAR	Fish	96 hr LC_{50}	2657
	Daphnid	48 hr LC_{50}	1322
	Green Algae	96 hr EC_{50}	570
	Fish	ChV	222
	Daphnid	ChV	89
	Green Algae	ChV	111

These values are all much higher than the "worst-case" scenario of an EEC_{water} of 1.6 ppm, which is over 18-times lower than the lowest chronic toxicity endpoint for the most sensitive species. Thus, the use of Dipic at such a minimal level is not expected to result in any adverse environmental effects.

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 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 environmental impact.

12. List of Preparers:

a. Michael Harvey, BS. Cal. State University, Chico (Chemistry), 40 years of experience conducting ecological risk assessments and preparing regulatory submissions that have been submitted to the EPA and FDA
b. Brent Bankosky, BS., MBA, Pennsylvania State University, MS, Lehigh University, 15 years of experience preparing EPA and FDA regulatory submissions
c. Jonathan N. Howarth, Ph.D., Physical Chemistry, Univ. of Southampton, England; BS (Honors), Applied Chemistry, Leicester Polytechnic, England, 30 years of experience preparing EPA and FDA regulatory submissions
d. Joseph Donabed, B.Sc., Cal. State Stanislaus University, 10-years of experience preparing EPA and FDA regulatory submissions
e. Tina Rodrigues, BS, Cal. State Stanislaus University, 12 years of experience preparing EPA and FDA regulatory submissions
f.

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.

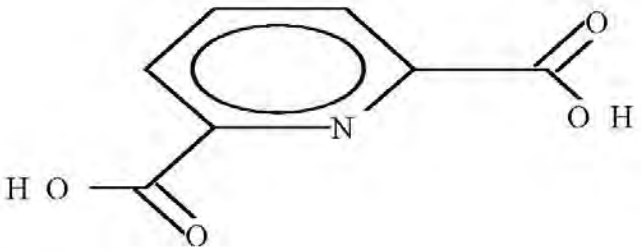
Date: August 10, 2021
Signature: Name and Title: Michael S. Harvey, President

14. BIBLIOGRAPHY and LITERATURE CITATIONS

(1) EPA: Reregistration eligibility Decision: Peroxy compounds; EPA Case 4072. Doc #738-F-93-026; Dec. 1993.
(2) ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals, JACC No. 40, "Peracetic Acid and its Equilibrium Solutions"; January 2001
(3) ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals, JACC No. 22, "Hydrogen Peroxide"; January 1993
(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) US EPA ECOTOX report for search parameter [CAS Reg. No.] 499-83-2. https://cfpub.epa.gov/ecotox/index.cfm
(6) Ecological Structure Activity Relationships (ECOSAR) Predictive Model run for [CAS Reg. No.] 499-83-2. Available at https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model. Report printout generated 7/16/2021 is provided as an attachment to this EA.

(7) HERA – Human & Environment Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates. 06/09/2004. www.heraproject.com – Phosphonates. It is available at https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca#fate
(8) HERA, (2006). Human & Environmental Risk Assessment (HERA) of Ingredients of Household Cleaning Products: Sodium Sulfate. Edition 1.0, January 2006. http://www.heraproject.com/files/39 f06_sodium_sulfate_human_and_environmental_risk_assessment_v2.pdf
(9) OECD SIDS. (2001). SIDS Initial Assessment Report for 11th SIAM: Sulfuric Acid. https://hpvchemicals.oecd.org/UI/handler.axd?id=248f397d-64b3-4e14-8be9-473974e8dfdb
(10) ChemID Plus Database entry for CAS Reg. No. 499-83-2. https://chem.nlm.nih.gov/chemidplus/name/dipicolinic%20acid
(11) Amador, J.A. and Taylor, B.P., Coupled metabolic and photolytic pathway for degradation of pyridinecarboxylic acids, especially dipicolinic acid, Applied and Environmental Microbiology, 56(5): 1352-1356 (1990)
(12) Seyfried B. and Schnick, B. Fermentive degradation of dipicolinic acid (Pyridine-2,6-dicarboxylic acid) by a defined coculture of strictly anaerobic bacteria, Biodegradation, 1(1), 1-7 (1990)
(13) Kaiser, J.P., Feng, Y., and Bollag, J.M. Microbial metabolism of pyridine, quinolone, acridine, and their derivatives under aerobic and anaerobic conditions, Microbiological Reviews, 60(3): 483-498 (1996)
(14) Naik, M.N. et al., Microbial Degradation and Phytotoxicity of Picloram and Other Substituted Pyridines, Soil Biology and Biochemistry, 4: 313-323 (1972), see p. 320; Sims, G.K. and Sommers, L.E., Biodegradation of Pyridine Derivatives in Soil Suspensions, 5:503-509 (1986)

ECOSAR Analysis Report on 2,6-Pyridinedicarboxylic Acid



ECOSAR Version 1.11 Results Page

SMILES : O=C(O)c(nc(cc1)C(=O)O)c1
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 (EPISuite Kowwin v1.68 Estimate)
Log Kow: (User Entered)
Log Kow: (PhysProp DB exp value - for comparison only)
Melt Pt: (User Entered for Wat Sol estimate)
Melt Pt: 249.00 (deg C, PhysProp DB exp value for Wat Sol est, 249 dec)
Wat Sol: 4829 (mg/L, EPISuite WSKowwin v1.43 Estimate)
Wat Sol: (User Entered)
Wat Sol: 5000 (mg/L, PhysProp DB exp value)

Values used to Generate ECOSAR Profile

Log Kow: 0.567 (EPISuite Kowwin v1.68 Estimate)
Wat Sol: 5000 (mg/L, PhysProp DB exp value)

ECOSAR v1.11 Class-specific Estimations

Pyridine-alpha-Acid

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
Pyridine-alpha-Acid	: Fish	96-hr	LC50	323.608
Pyridine-alpha-Acid	: Fish		ChV	29.342 !
Neutral Organic SAR	: Fish	96-hr	LC50	2656.694
(Baseline Toxicity)	: Daphnid	48-hr	LC50	1321.570
	: Green Algae	96-hr	EC50	569.703
	: Fish		ChV	222.165
	: Daphnid		ChV	89.187
	: Green Algae		ChV	111.124

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)