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

Environmental Assessment

1. **Date** May 2, 2018
2. **Name of Submitter** Evonik Corporation
3. **Address** 299 Jefferson Rd.
Parsippany, NJ

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 solution composed of peroxyacetic acid (PAA), hydrogen peroxide (H2O2), acetic acid, 1-hydroxy ethylidene-1,1-diphosphonic acid (HEDP) and optionally sulfuric acid. The FCS will be used in food processing facilities as an antimicrobial agent in: process water or ice used for washing or chilling fruits and vegetables in food processing facilities at concentrations up to 80 ppm PAA, 433 ppm H2O2 and 9.8 ppm HEDP.

b. The Need for the Action

The FCS is intended to be used as an antimicrobial agent to reduce or eliminate pathogenic microorganisms on fruits and vegetables.

c. Brief Discussion of the Use and Disposal of the FCS

The FCS is intended for use in process water or ice used for washing or chilling fruits and vegetables in food processing plants throughout the United States. After use, 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 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 further below.

5. **Identification of Substances that are Subject of the Proposed Action**

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, and Water 7732-18-5.

The basic reaction by the above combination is as follows:
CH3CO2H + H2O2 → CH3CO3H + H2O (molecular weight of PAA is 76.05 g/mole)

6. Introduction of Substances into the Environment

a. Introduction of Substances into the Environment as a Result of Manufacture

The FCS is currently manufactured in EPA approved facilities. 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 for use as an antimicrobial agent for: process water or ice used for washing or chilling fruits and vegetables at food processing plants throughout the United States. The FCS is provided as a concentrate that is diluted on site. 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), depending upon whether the facility has an individual NPDES permit. Treatment of the process water at an on-site waste water treatment facility or 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(3) . 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(4) . 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 (5) ppm . Biodegradation is the most significant removal mechanism for acetic acid. In biodegradation studies with acetic acid, 99% degraded in 7 days under anaerobic conditions(6) . Acetic acid is not expected to concentrate in the wastewater discharged to the POTW and surface waters. Therefore, these substances are not included in this Environmental Assessment for the current Food Contact Notification.

Sulfuric acid dissociates readily in water to sulfate ions (SO4) 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 a 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 HEDP.

The maximum concentration of HEDP that may be expected in a worst case scenario at use concentration: HEDP used for washing or chilling fruits and vegetables at food processing facilities

The Human and Environmental Risk Assessment Project (HERA) report showed that HEDP adsorption to wastewater sludge is 60- 90% (1) . The HERA report used an estimate of 80% adsorption to wastewater sludge to model exposure; we follow that approach here to calculate Estimated Environmental Concentrations (EECs). The EIC of HEDP is based on use or disposal of the FCS into the fruit and vegetable processor's on-site pre-treatment facility. The subsequent EECs including EECs sludge and EECwater are calculated below using the 80:20 partition factor arrived at in the HERA report. With respect to the EECwater calculation, a 10 fold dilution factor is used to account for the mixing and dilution that occurs when the treated wastewater enters the receiving water body when estimating surface water concentrations(2) . Below are the worst-case EIC and EECsludge and EECwater calculations for HEDP under each proposed application of the FCS:

HEDP EIC = 9.8 ppm HEDP x 100% remaining = 9.8ppm

HEDP EECsludge = 9.8 ppm HEDP x 80% partition to sludge = 7.84 ppm

HEDP EECwater = (9.8 ppm HEDP x 20% partition to water) / 10 fold dilution factor = 0.196 ppm

7. Fate of Emitted Substances in the Environment

As discussed in section 6, it is well documented and accepted in the scientific community that PAA and H2O2 are short lived in the environment, do not bioaccumulate, have innocuous degradation byproducts, and are of no toxicological or ecotoxicity concern (3,4,5) . Peroxyacetic acid and hydrogen peroxide are not expected to survive treatment at the primary wastewater treatment facility due to their reactivity and pH sensitivity (3). Both compounds are rapidly degraded on contact with organic matter, transition metals, and upon exposure to sunlight (4,5) . 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 (4). 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 (5). In filtered lake water the half-life of H2O2 (initial concentration 3.4 ug/l) was 8.6 hrs-31 hrs. (page 21 reference #5). Since PAA and H2O2 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 (6). 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 EECwater for process water or ice used for washing or chilling fruits and vegetables in food processing facilities will be 0.196 ppm and the maximum HEDP EECsludge will be 7.84 ppm based on the above calculations using the 10 fold dilution factor for the EECwater 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 H2O2. 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 (7). Because of the nature of the carbon-phosphorus bond in HEDP, it adsorbs very strongly to mineral surfaces and rarely exists free in solution (2). The HERA report shows that HEDP adsorption to sludge is 60- 90% (1).

8. Environmental Effects of Released Substances

This FCS is intended for microbiological control in process water or ice used for washing or chilling fruits and vegetables in food processing facilities.

a. Aquatic Environment HEDP is a strong chelating agent and can result in adverse effects on environmental organisms by complexation of essential nutrients (1). 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)(10) . 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(10) . However, excess nutrients are expected to be present in food processing wastewater as eutrophication is a well-known phenomenon seen in industrial wastewaters from food processing facilities(11)

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

Environmental Toxicity Data for HEDP[a]

Species	Endpoint	mg/L
Lepomis macrochirus[1]	96 hr LC_{50}	868
Oncorhynchus mykiss[1]	96 hr LC_{50}	360
Cyprinodon variegates[1]	96 hr LC50	2180
Ictalurus punctatus[1]	96 hr LC_{50}	695
Leuciscus idus melanatus[1]	48 hr LC_{50}	207-350
Daphnia magna[1]	24-48 hr EC_{50}	165-500
Palaemonetes pugio[1]	96 hr EC_{50}	1770
Crassostrea virginica[1]	96 hr EC_{50}	89
Selenastrum capricornutum[2]	96 hr EC_{50}	3
Selenastrum capricornutum[1]	96 hr NOEC	1.3
Algae[2]	96 hr EC_{50}	0.74
Chlorella vulgaris[1]	48 hr NOEC	≥100
Pseudomonas putida[1]	30 minute NOEC	1000
Oncorhynchus mykiss[1]	14 day NOEC	60-180
Daphnia magna[1]	28 day NOEC	10- <12.5
Algae[2]	14 day NOEC	13

[a]: *All data from* [(1)] *Jaworska, J.; Van Genderen-Takken, H.; Hanstveit, A.; van de Plassche, E.; Feijtel, T.; Chemosphere 2002, 47: 655-665* (10) *and* [(2)] *Draft Human and Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates; Human and Environmental Risk Assessment Initiative: June 9, 2004* (1).

Jaworska et. al. (10) and the Hera report on phosphonates (1) showed that the acute toxicity endpoints for HEDP ranged from 0.74 – 2,180 mg/L while the chronic NOECs ranged from 60-180 mg/L for the 14 day NOEC for *Oncorhynchus mykiss* and the 28 day NOEC for *Daphnia magna* was < 12.5 mg/L. 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 as discussed in Jaworska et. al is likely due to nutrient limitation, which will not be the case in food processing wastewater, and therefore this endpoint is not relevant to this FCN. The relevant endpoint for a food processing wastewater environment is 10mg/L (28 day) NOEC for *Daphnia magna* as published by Jaworska et al. The values calculated herein of HEDP EECwater = 0.196 ppm for for process water or ice used for washing or chilling fruits and vegetables in food processing facilities also fall far 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 (1). The 14 day median lethal dose (LD50) for birds was greater than 284 mg/kg body weight (1). As a comparison, the HEDP EECsludge is 7.84 ppm for process water for washing or chilling fruits and vegetables in food processing facilities which is also far less than the LD50 for birds at 284ppm 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 adverse environmental impacts that would require mitigation measures of any kind.

11. Alternatives to the 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

Tiana M. Rosamilia, MPH, 18 years experience as a toxicologist, experience in conducting product risk assessments.

13. Certification

The undersigned certifies that the information presented is true, accurate, and complete to the best of his knowledge.

[redacted]

Tiana M. Rosamilia 5/29/2018

14. Bibliography and Literature Citations

(1) HERA – Human & Environment Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates. 06/09/2004. www.heraproject.com – Phosphonates.

(2) 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

(3) EPA: Reregistration eligibility Decision: Peroxy compounds; EPA Case 4072. Doc #738-F-93-026; Dec. 1993.

(4) ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals, JACC No. 40, "Peracetic Acid and its Equilibrium Solutions"; January 2001
(5) ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals, JACC No. 22, "Hydrogen Peroxide"; January 1993
(6) 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
(7) Nowack, B. (2003) "Environmental chemistry of phosphonates"; Water Research, 1 14.
(8) 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
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(10) Jaworska, J.; Van Genderen-Takken, H.; Hanstveit, A.; van de Plassche, E.; Feijtel, T. Environmental risk assessment of phosphonates, used in domestic industry and cleaning agents in the Netherlands. Chemosphere 2002, 47, 655-665. Chemosphere. 2002, 47 655-665.
(11) US EPA. Fact Sheet: Ecoregional Nutrient Criteria EPA-822-F-02-008, http://nepis.epa.gov/Exe/ZPURL?DockeyP1009KCR.txt