ENVIRONMENTAL ASSESSMENT

1. Date: December 15, 2020

2. Name of Applicant: Diversey, Inc.

3. Address: 1300 Altura Road, Suite 125
Fort Mill, SC 29708

4. Description of the Proposed Action

A. Requested Action

The action identified in this Notification is to provide for the use of the food-contact substance (FCS), identified as an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide (HP), acetic acid (AA) and l-hydroxyethylidine-1, 1-diphosphonic acid (HEDP), as an antimicrobial at levels of 350 ppm PAA, 630 ppm HP, and 16 ppm HEDP in process water or ice used for washing, rinsing, chilling, or processing fruit and vegetables. The FCS is intended for use in food retail facilities (e.g., grocery stores, restaurants, fast food establishments, etc.).

Mixtures containing these substances have previously been approved for the same uses, with several FCNs (No. 1554, 1594, 1622, 1638, 1693, 1715, 1727, 1738, 1823, 1950, 1960, 1986, 2033, and 2036).

B. Need for Action

The higher proposed maximum FCS concentrations of 350 ppm PAA, 630 ppm HP, and 16 ppm HEDP reduces or inhibits the growth of pathogenic and non-pathogenic microorganisms that may be present on and in food to provide safer foods for consumers. The antimicrobial effect of peroxyacetic acid reduces or eliminates populations of pathogenic and nonpathogenic microorganisms from the process water used in the cleaning of fruits and vegetables in food retail facilities. The FCS will serve as a technical effect only in the process water.

This FCS is intended for use as an antimicrobial agent used for washing fruits and vegetables at retail facilities. The FCS identified herein therefore will compete for a share of the market already occupied by these other products rather than introduce a new product or create a new market when this notification becomes effective.

Approval of the expanded use of the FCS will allow retailers to address current needs of consumers and government agencies to improve food safety.

C. Locations of Use/Disposal

The FCS is intended for use in fruit and vegetable retail locations throughout the United States.

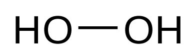
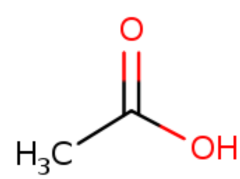
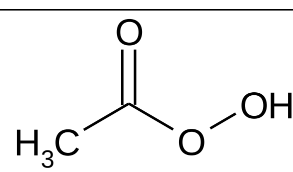
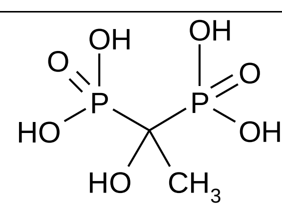
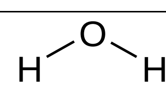
All waste water containing the FCS at retail facilities is expected to enter the municipal sewer system and be further processed at publicly owned waste water treatment facilities (POTWs) before discharge to surface waters. For those facilities (i.e., direct discharges) with NPDES (National Pollutant Discharge Elimination System) permitting, waste water may be treated on-site prior to direct discharge to surface waters.

5. Identification of Chemical Substance that is the Subject of the Proposed Action

Chemical Identity

The subject of this notification is a liquid solution containing peroxyacetic acid (CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and water (CAS Reg. No. 7732-18-5). A detailed confidential manufacturing process is cited in Attachment 5 of the Form 3480 of this Notification.

The chemical structures are shown here:

Complete Name	**CAS #**	**Molecular Weight**	**Molecular Formula**	**Structural Formula**	**Source**
Hydrogen Peroxide	7722-84-1	34.01 g/mol	H_2O_2		ChemID*plus*
Acetic Acid	64-19-7	60.05 g/mol	$C_2H_4O_2$		ChemID*plus*
Peracetic Acid	79-21-0	76.05 g/mol	$C_2H_4O_3$		ChemID*plus*
Hydroxyethylidene Diphosphonic Acid (HEDP)	2809-21-4	206.03 g/mol	$C_2H_8O_7P_2$		ChemID*plus*
Water	7732-18-5	18.01g/mol	H_2O		ChemID*plus*

6. Introduction of Substances into the Environment

A. As a Result of Manufacture

Under 21 C.F.R § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Information available to the Notifier does not suggest that there are any extraordinary circumstances, in this case, indicating any adverse environmental impact as a result of the manufacture of the antimicrobial agent. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

B. As a Result of Use and Disposal

The FCS mixture is provided as a concentrate that is diluted on site. When diluted for use, the resulting concentration of PAA, hydrogen peroxide, and HEDP will be as follows:

Use	PAA	H_2O_2	HEDP
Fruit and Vegetables	350 ppm	630 ppm	16 ppm

Treatment of the process water at a Publicly Owned Treatment Works (POTW) is expected to result in complete degradation of peroxyacetic acid and hydrogen peroxide. Specifically, the peroxyacetic acid will breakdown into oxygen and acetic acid, while hydrogen peroxide will breakdown into oxygen and water.[1] Acetic acid is rapidly metabolized by ambient aerobic microorganisms to carbon dioxide and water[2]. 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. 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[3]. The half-life of hydrogen peroxide in natural river water ranged from 2.5 days when initial concentrations were 10,000 ppm, and increased to15.2 days and 20.1 days when the concentration decreased to 250 ppm and100 ppm, respectively[3]. The remainder of this section will therefore consider only the environmental introduction of HEDP.

Finally, we note that several other FCNs already authorize the FCS for use in process water for fruit and vegetables. However, HEDP levels authorized in previous FCNs covering the use of the FCS in fruit and vegetable processing facilities are greater than or equal to the levels requested here. Therefore, these substances are not expected to be

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1 Environmental Protection Agency, Draft Risk Assessment: Peroxy Compounds (March 11, 2020), p. 17. https://beta.regulations.gov/document/EPA-HQ-OPP-2017-0354-0006

2 U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category; American Chemistry Council, June 28, 2001.

3 ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals. JACC No. 40, “Peracetic Acid and its Equilibrium Solutions”, January 2001 and JACC No. 22, “Hydrogen Peroxide”, January 1993.

introduced into the environment to any greater extent as a result of the proposed use of the FCS.

Fruit and Vegetable Retail Facilities

The maximum at-use concentration of HEDP in the process water of fruit and vegetable retail facilities using the FCS is limited to 16 ppm. However, water is used in fruit and vegetable retail facilities for purposes other than washing. This additional water use will dilute and thereby reduce the environmental introduction concentration (EIC) to levels below 16 ppm.

Assuming, in the very worst-case, that all of the water used in a fruit and vegetable retail facility is treated with the FCS, the EIC for HEDP would be its at-use concentration, 16 ppm.

We note that there already exist authorizations for the FCS for the same use proposed herein and at levels that limit the maximum level of HEDP to 16 ppm in process water. The use of this FCS is expected to replace other FCS containing similar components already on the market, therefore, the EIC values estimated here will substitute for existing EICs for HEDP ions. No new or additional environmental introductions of HEDP ion are expected when this FCN becomes effective.

With respect to environmental impact, it is the contents of the process water that pass into the wastewater treatment system and are ultimately released to the environment.

As indicated by the Human & Environmental Risk Assessment Project (HERA)[4], the treatment of wastewater at a POTW will result in the absorption of approximately 80% of HEDP into sewage treatment sludge. By applying this 80% factor, we are able to estimate the potential environmental introduction of HEDP to water and sewage sludge, respectively. To calculate the expected environmental concentrations (EECs), we have incorporated a conservative 10-fold dilution factor for discharge to surface waters of the effluent from an onsite treatment facility or POTW,[5] as indicated below.

HEDP EEC_{sludge} = 16 ppm x 0.8 = 12.8 ppm HEDP

HEDP $EEC_{aqueous}$ = 16 ppm x 0.2/10 = 0.32 ppm HEDP

Therefore, the discussion of impacts from use of the FCS will focus on comparing the fruit and vegetable EECs to appropriate ecotoxicity endpoints that are provided under Item 8.

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4 Human & Environmental Risk Assessment (HERA) on ingredients of European Household Cleaning Products: Phosphonates (2004), Tables 13-14, available at http://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf.

5 Rapaport, Robert A., 1988 Prediction of consumer product chemical concentrations as a function of publicly owned treatment works, treatment type, and riverine dilution. Environmental Toxicology and Chemistry 7(2), 107-115.

Furthermore, it should be noted that there already exist authorizations for the FCS for the same use proposed here, which permit higher concentrations of HEDP in process water.

7. Fate of Emitted Substances in the Environment

As noted and referenced above, treatment of the process water at a retail facility is expected to result in complete degradation of peroxyacetic acid and hydrogen peroxide. The U.S. High Production Volume (HPV) Chemical Challenge Program determined that 99% of acetic acid degraded in 7 days under anaerobic conditions, and therefore, the FCS is not expected to concentrate in the waste water that is discharged to municipal treatment plants.[6] Upon contact with organic materials, transition metals, and exposure to sunlight, peroxyacetic acid and hydrogen peroxide will rapidly degrade. According to the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC), the half-life for PAA in buffered solutions ranged from <0.25 to 64 hours ($pH = 7$) for a 748 ppm solution and 48 hours ($pH = 7$) for a 95 ppm solution while the half-life for hydrogen peroxide varies based on the surface water.[7]

The EEC for HEDP in surface water has been calculated by applying a 10-fold dilution factor to the estimated EIC[5]. This dilution factor accounts for the expected dilution in surface waters of effluent from an onsite treatment facility as supported by data reported by Rapaport[5]. Finally, we note that the EEC for sludge is a maximum for terrestrial impacts as any sludge used as a soil amendment will likely be significantly diluted by soil or sludge from other sources.

No terrestrial or aquatic biodegradation is assumed for HEDP. According to the published literature, decomposition of HEDP occurs at a moderately slow pace in water; 33% in 28 days[4]. Regarding soil biodegradation, the HERA report estimates an extrapolated half-life in soil of 373 days. Therefore, any aquatic or soil biodegradation of HEDP is not expected to significantly lower the estimated EECs for HEDP provided above.

8. Environmental Effects of Released Substances

Terrestrial Toxicity

HEDP present in the surface water is not expected to have any adverse environmental impact based on the terrestrial toxicity endpoints available for plants, earthworms, and birds. Specifically, the No Observed Effect Concentration (NOEC) for soil dwelling

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6 See U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Panel, American Chemistry Council, Appendix I. June 28, 2001.

7 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.

organisms was >1,000 mg/kg soil dry weight for earthworms in soil, while the 14-day LC_{50} for birds was >284 mg/kg body weight.[4]

Additionally, as noted above, the maximum concentration of HEDP in sludge is 12.8 ppm. A report by Jaworska et al[7] indicates that HEDP shows no toxicity to terrestrial organisms at levels of up to 1,000 mg/kg in soil NOEC. Therefore, the maximum concentration in sludge is less than 1% of the NOEC and the maximum concentration in soil, when used as a soil amendment, should have an even larger margin of safety with respect to the NOEC level. As such, the FCS is not expected to present any terrestrial environmental toxicity concerns.

Aquatic Toxicity

Aquatic toxicity of HEDP has been summarized, and is shown in the following table:

Environmental Toxicity Data for HEDP		
Species	**Endpoint**	**mg/L**
Short Term		
Lepomis macrochirus[4,7]	96 hr LC_{50}	868
Oncorhynchus mykiss[4,7]	96 hr LC_{50}	368
Cyprinodon variegatus[4,7]	96 hr LC_{50}	2180
Ictalurus punctatus[4,7]	96 hr LC_{50}	695
Leuciscus idus melonatus[4,7]	48 hr LC_{50}	207 – 350
Daphnia magna[4,7]	24 – 48 hr EC_{50}	165 – 500
Palaemonetes pugio[4,7]	96 hr EC_{50}	1770
Crassostrea virginica[4,7]	96 hr EC_{50}	89
Selenastrum capricornutum[4]	96 hr EC_{50}	3
Selenastrum capricornutum[4,7]	96 hr NOEC	1.3
Algae[4]	90 hr NOEC	0.74
Chlorella vulgaris[4,7]	48 hr NOEC	≥100
Pseudomonas putida[4,7]	30 minute NOEC	1000
Long Term		
Oncorhynchus mykiss[7]	14 day NOEC	60 – 180
Daphnia magna[7]	28 day NOEC	10 - <12.5
Algae[4]	14 day NOEC	13

Jaworska et al. and HERA 2004 showed that acute toxicity endpoints for HEDP ranged from 0.74 – 2,180 mg/L, while chronic NOECs were 60 – 180 mg/L for the 14 day NOEC for *Oncorhynchus mykiss* and the 28 day NOEC for the *Daphnia magna* was 10-<12.5 mg/L. Although a chronic NOEC of 0.1 mg/L for reproductive effects in *Daphnia magna* was reported, it is inconsistent with other toxicity data and Jaworska et al. suggest that it is due to the depletion of micronutrients by HEDP instead of the intrinsic toxicity of HEDP.[7]

Because HEDP is a strong chelating agent, which can result in negative environmental effects such as, the complexing of essential nutrients, both an intrinsic NOEC (NOECi) and a NOEC, which accounts for chelating effects (NOECc) are determined.

We note that the 96 hour NOEC, 24-48 hour EC_{50}, and 96 hour EC_{50} values reported by Jaworska et al. for *Selenastrum capricornutum*, *Daphnia magna*, and *Crassostrea virginica*, respectively, were all likely due to chelation effects rather than intrinsic toxicity.[7] As such, these levels are not relevant in such situations as for retail facilities, where excess nutrients may be present. The HERA report on phosphonates included a discussion of aquatic toxicity resulting from chelation of nutrients, rather than direct toxicity to aquatic organisms. 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 process water discharges from food retail facilities[4]. Jaworska *et al*. reports the lowest relevant endpoint for this use pattern to be 10 mg/L[7]. The worst-case EEC_{aq} for HEDP is below this value and is, thus, not expected to result in any adverse environmental effects.

9. Use of Resources and Energy

The notified use of the FCS mixture will not require additional energy resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some degree replace similar HEDP 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

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the dilute FCS mixture. Therefore, the mixture is not reasonably expected to result in any new environmental issues that require mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse effects are identified herein, which would necessitate alternative actions to that proposed in this Notification. If the proposed action is not approved, the result would be the continued use of the currently marketed antimicrobial agents that the subject FCS would replace. Such action would have no environmental impact. The addition of the antimicrobial agent to the options available to food retailers is not expected to increase the use of peroxyacetic acid antimicrobial products.

12. List of Preparers

Not applicable. Environmental Assessment prepared by onsite technical staff.

13. Certification

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

[redacted]

Eric Brown
Senior Registration Specialist

14. List of References

1. Environmental Protection Agency, Draft Risk Assessment: Peroxy Compounds (March 11, 2020), p. 17. https://beta.regulations.gov/document/EPA-HQ-OPP-2017-0354-0006.

2. U.S. High Production Volume (HPV) Chemical Challenge Program: *Assessment Plan for Acetic Acid and Salts Category*; American Chemistry Council, June 28, 2001.

3. ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals. JACC No. 40, "Peracetic Acid and its Equilibrium Solutions", January 2001 and JACC No. 22, "Hydrogen Peroxide", January 1993.

4. Human & Environmental Risk Assessment (HERA) on ingredients of European Household Cleaning Products: Phosphonates (2004), Tables 13-14, available at http://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf.

5. Rapaport, Robert A., 1988 Prediction of consumer product chemical concentrations as a function of publicly owned treatment works, treatment type, and riverine dilution. *Environmental Toxicology and Chemistry* 7(2), 107-115.

6. *See* U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Panel, American Chemistry Council, Appendix I. June 28, 2001.

7. 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.