Environmental Assessment

1. Date	March 20, 2019
2. Name of Applicant	Ecolab Inc.
3. Address	Agent for Notifier: Mitchell Cheeseman, Ph.D. Steptoe & Johnson LLP 1330 Connecticut Avenue, NW Washington, DC 20036

4. Description of Proposed Action

a. Requested Action

The action identified in this food contact notification (FCN) is to provide for the use of the food contact substance (FCS) identified as an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, and 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP), used as an antimicrobial agent in process water used during the production and preparation of hard-boiled, peeled eggs. This notification requests a new intended use for a product currently on the market.

When used as intended, the components of the FCS mixture will not exceed: 2000 ppm peroxyacetic acid (PAA), 1447 ppm hydrogen peroxide (HP), 85 ppm 1-hydroxyethylidine- 1,1-diphosphonic acid (HEDP) in spray, wash, dip, rinse, mist, or chiller water.

b. Need for Action

The FCS is intended for use as an antimicrobial solution for use in the processing of hard-boiled peeled eggs. The antimicrobial agent reduces pathogenic and non-pathogenic microorganisms, for example *Listeria monocytogenes*, that may be present on the hard-boiled peeled eggs during production. The requested action to add a new use to the currently approved uses of the FCS is needed to address current and future needs of food processors and governmental agencies to improve food safety against harmful microorganisms.

c. Locations of Use/Disposal

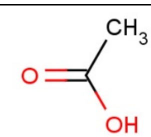
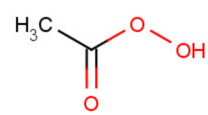
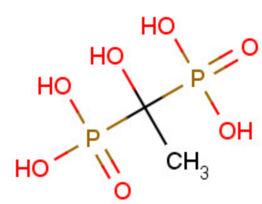
The antimicrobial agent is intended for use in hard-boiled peeled egg processing plants and packing facilities throughout the United States.

Water is used extensively in almost all aspects of processing hard-boiled peeled eggs. Different methods may be used to wash hard-boiled peeled eggs, including submersion, spray, or both. After use, the FCS 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. As a conservative approach, it can be assumed that waste water will be treated onsite before discharge to surface water pursuant to a NPDES permit. It is expected that process water not containing the FCS will be used in plants for activities such as cleaning and sanitation, resulting in significant dilution of HEDP into the total water effluent.

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

The raw materials used in this product are hydrogen peroxide, acetic acid, HEDP, and water. Peroxyacetic acid formation is the result of an equilibrium reaction between hydrogen peroxide and acetic acid. The FCS is supplied in concentrated form and is diluted at the processing plant for use to achieve the desired level of peroxyacetic acid that is needed to address the food safety and quality needs.

Table 1: Chemical Identity of Substances of the Proposed Action

Component	**CAS No.**	**Molecular Weight**	**Structural Formula**	**Molecular Formula**
Hydrogen peroxide	7722-84-1	34.01	HO-OH	H_2O_2
Acetic acid	64-19-7	60.05		$C_2H_4O_2$
Peroxyacetic acid	79-21-0	76.05		$C_2H_4O_3$
1-Hydroxyethylidene-1,1-diphosphonic acid (HEDP)	2809-21-14	206.3		$C_2H_8O_7P_2$
Water	7732-18-5	18.01	H-O-H	H_2O

6. Introduction of Substances into the Environment

a. Introduction of Substances into the Environment 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. The FCS is manufactured in plants which meet all applicable federal, state and local environmental regulations. Notifier asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS such as: 1) unique emission circumstances that are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and that may harm the environment; 2) the action threatening a violation of Federal, State or local environmental laws or requirements (40 C.F.R. § 1508.27(b)(10)); or 3) production associated with the proposed action that 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

Introduction of dilute solutions of the product into the environment will take place primarily via release from wastewater treatment systems. Introduction of the components of the product into the environment will result from use of the product as an antimicrobial agent in processing water applications for hard boiled peeled eggs, and the subsequent disposal of such water drainage into on-site treatment plants and/or POTW. The maximum at-use concentration of PAA, hydrogen peroxide, and HEDP for the application will be as follows:

Table 2: Summary of Intended Uses

Use	PAA	H_2O_2	HEDP
Spray, wash, dip, rinse, mist, or chiller water for peeled eggs	2000	1447	85

Treatment of the process water at an on-site wastewater treatment plant or POTW is expected to result in complete degradation of PAA and hydrogen peroxide, and acetic acid. Specifically, the PAA will breakdown into oxygen, water and acetic acid, while hydrogen peroxide will break down into oxygen and water.[1] All three 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

[1] U.S. Environmental Protection Agency, *Reregistration Eligibility Decision: Peroxy Compounds* (December 1993), p. 18, available at https://archive.epa.gov/pesticides/reregistration/web/pdf/peroxy_compounds.pdf.

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 and 20.1 days when the concentration decreased to 250 ppm and 100 ppm, respectively.[3] In biodegradation studies of acetic acid using activated sludge, 99% degraded in 7 days under anaerobic conditions.[4] Acetic acid is not expected to concentrate in the wastewater discharged to the treatment facility/POTW. 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. As a result the remainder of this section, section 7 and section 8 will consider only the environmental introduction of HEDP.

i. Hard-boiled Peeled Egg Processing Facilities

Introduction of the components of the product into the environment will result from use of the product as an antimicrobial agent in processing water for hard boiled peeled eggs and the subsequent disposal of such water into the processing plant wastewater treatment facility, as described above.

When the FCS is used at the maximum level under the proposed action, HEDP would be present in process water at a maximum level of 85 parts per million (ppm). Assuming in the very worst-case, that all the water used in an egg washing plant is treated with the FCS, the level of HEDP in water entering the plant’s wastewater treatment facility, the environmental introduction concentration (EIC), would not exceed 85 ppm.

7. Fate of Emitted Substances in the Environment

HEDP will mineralize to soil particles and organic matter and utilization of the phosphonate moiety by microorganisms as a phosphorus source.[5] Phosphate anions are strongly bound to organic matter and soil particles,[6] and phosphate is a required macronutrient of plants. However, given the maximum level estimated to be released, it would not be expected that phosphate released from HEDP would result in measurable increases in phosphate in soil or water receiving treated effluent. Decomposition of HEDP occurs at a moderately slow pace; a Dissolved Organic Carbon removal of 23-33% after 28 days was

[2] European Centre for Toxicology and Toxicology of Chemicals (ECETOC), *Joint Assessment of Commodity Chemicals (JACC) No. 40 Peracetic Acid and its Equilibrium Solutions*, January 2001, Table 11, p. 29, available at http://www.ecetoc.org/jacc-reports.
[3] ECETOC, *JACC No. 22, Hydrogen Peroxide*, January, 1993, Table 6, p. 23, “Degradation in the River Soane of Hydrogen Peroxide,” available at http://www.ecetoc.org/jacc-reports.
[4] American Chemistry Council, Acetic Acid and Salts Panel, *U.S. High Production (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category*, June 28, 2001, Appendix 1, p. 1, https://iaspub.epa.gov/oppthpv/document_api.download?FILE=c13102tp.pdf.
[5] Nowack, B., *Environmental chemistry of phosphonates*, Water Research 37(11): 253-2546, June 2003
[6] HERA, Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products, *Phosphonates (CAS 6419-19-8; 2809-21-4; 15827-60-8)*, Draft 06/09/2004, p. 11, available at http://www.heraproject.com/files/30-f-04-%20hera%20phosphonates%20full%20web%20wd.pdf.

observed in an inherent biodegradability test (Zahn-Wellens test).[7] Therefore, increases in phosphate in soils amended with wastewater sludge, or in water receiving treated effluent are not expected.

The Human and Environmental Risk Assessment Project (HERA) report on phosphonates indicates that the treatment steps at an onsite wastewater treatment facility or POTW will remove at least a portion of any HEDP in the process water.[8] The HERA report cites 80% adsorption of HEDP to sewage treatment sludge.

We have estimated the potential environmental introduction concentrations (EICs) of HEDP in water and sewage sludge based upon the information above. To calculate the EICs for HEDP in water and sewage sludge we have applied the 20:80 partition factor from the HERA report (EIC_{sludge} = 85 x 80% = 68 ppm; EIC_{water} = 85 x 20% = 17 ppm).

When the water from the facility or POTW is discharged to surface waters, HEDP will be diluted a further 10-fold, resulting in an estimated environmental concentration (EEC) of 1.7 ppm.[9] The worst-case EEC for sludge is 68 ppm. (See Table 3 below).

Table 3: Worst-case EIC/EECs for HEDP

Use	EIC total	EEC_{sludge}	EEC_{water}
HEDP	85 ppm	68 ppm[10]	1.7 ppm[11]

Finally, we note that the HEDP 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.

8. Environmental Effects of Released Substances

a. Terrestrial Toxicity

The HERA report discusses biodegradation of HEDP and estimates a half-life in soil of 373 days. Therefore HEDP is expected to degrade, albeit slowly, in soil. HEDP shows no toxicity to terrestrial organisms at levels up to 1000 mg/kg soil dry weight (No Observed Effect Concentration; NOEC).[12] Our maximum estimated concentration in sludge (68 ppm) is 14 -fold

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[7] HERA, Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products, *Phosphonates (CAS 6419-19-8; 2809-21-4; 15827-60-8)*, Draft 06/09/2004, Table 7, p. 16, available at http://www.heraproject.com/files/30-f-04-%20hera%20phosphonates%20full%20web%20wd.pdf.
[8] *Id.*, at Table 12, p. 22.
[9] Rapaport, R.A., *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 (1988).
[10] Example calculation 85 ppm x 80% = 68 ppm
[11] Example calculation 85 ppm x 20%/10 = 1.7 ppm
[12] Jaworska, J., et al, *Environmental risk assessment of phosphonates, used in domestic industry and cleaning agents in the Netherlands*, Chemosphere 2002, 47(6), 655-665, May 2002.

smaller than 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. Therefore, the FCS is not expected to have any terrestrial environmental toxicity concerns at levels at which it is expected to be present in sludge or soil. Moreover, the much smaller level of HEDP present in the surface water is not expected to have any adverse environmental impact with respect to sedimentation based on the terrestrial toxicity endpoints available for plants, earthworms, and birds.[13]

b. Aquatic Toxicity

Aquatic toxicity of HEDP has been summarized in the following table:

Table 4: Summary of Environmental Toxicity Data for HEDP[14]

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

According to Jaworska et al,[15] the primary adverse effects of HEDP result from chelation of nutrients rather than direct toxicity of HEDP. Chelation is not toxicologically relevant in the current evaluation because eutrophication, not nutrient depletion, has been demonstrated to

[13] *Id.*
[14] Short term values for *Lepomis macrochirus*, *Oncorhynchus mykiss*, *Cyprinodon variegatus*, *Ictalurus punctatus*, *Leuciscus idus melonatus*, *Daphnia magna*, *Palaemonetes pugio*, *Crassostrea virginica*, *Chlorella vulgaris*, *Pseudomonas putida*, and long term values for *Oncorhynchus mykiss*, *Daphnia Magna* found in Jaworska, et al, p. 662 (2002). Short term values for *Selenastrum capricornutum*, and short and long term values for algae found in HERA (2004) (Tables 13 and 14, p. 29-31).
[15] Jaworska, et al (2002).

be the controlling toxicological mode when evaluating wastewater discharges from food processing facilities. The lowest short-term LC_{50} values published for *Selenastrum capricornutum* (3 ppm), *Daphnia magna* (165 ppm), and *Crassostrea virginica* (89 ppm) are acute toxicity endpoints considered to result from this chelation effect. These values are not relevant when excess nutrients are present as expected in food processing wastewaters. The lowest relevant endpoint for food processing uses was determined to be the chronic NOEC of 10 ppm for *Daphnia magna*. Although uncertainties intrinsic to its derivation make the usefulness of the NOEC debatable,[16] based on the available environmental toxicology data, reliance upon the NOEC for *Daphnia magna* is appropriate.[17] The conservatively estimated EEC of 1.7 ppm is 5 -fold lower than the 10 ppm chronic NOEC for *Daphnia magna*.

9. Use of Resources and Energy

The use of the FCS will not require additional energy resources for treatment and disposal of waste solution, as the components readily degrade. The raw materials that are used in production of the mixture are commercially-manufactured materials that are produced for use in a variety of chemical reactions and production processes. Energy used specifically for the production of the mixture components is not significant.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the dilutions of antimicrobial product. Therefore mitigation measures of any kind are not required.

11. Alternatives to the Proposed Actionp

No potential significant adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact Notification..

12. List of Preparers

Ms. Deborah C. Attwood, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036

Ms. Attwood has eight years of experience preparing environmental submissions to FDA for the use of peroxyacetic acid antimicrobials.

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[16] Blok J. and Balk F., *Environmental regulation in the European Community*, in Fundamentals of Aquatic Toxicology: Effects, Environmental Fate, and Risk Assessment, (GM Rand, Ed.), Taylor & Francis, New York, 1995, chapter 27 ("NOEC determinations are likely more statistically variant (uncertain) than EC_{50} determinations"); also see Organisation for Economic Co-operation and Development (OECD), *Current Approaches in the Statistical Analysis of Ecotoxicity Data: A Guidance to Application*, OECD Environmental Health and Safety Publications, Series on Testing and Assessment, No. 54, Environment Directorate, Paris, 2006 (recommending that that NOECs be abandoned), available at http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2006)18&doclanguage=en.

[17] Jaworska, et al (2002).

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Dr. Cheeseman holds a Ph.D. in Chemistry from the University of Florida. Dr. Cheeseman served for 18 months as a NEPA reviewer in FDA's food additive program. He has participated in FDA's NEPA review of nearly 800 food additive and food contact substance authorizations and he supervised NEPA review for FDA's Center for Food Safety and Applied Nutrition for five and a half years from 2006 to 2011 including oversight of FDA's initial NEPA review for the regulations implementing the Food Safety Modernization Act.

13. Certification

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

Date: March 20, 2019

[redacted]

Mitchell Cheeseman, PhD

14. References

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

Blok J. and Balk F., *Environmental regulation in the European Community*, in Fundamentals of Aquatic Toxicology: Effects, Environmental Fate, and Risk Assessment, (GM Rand, Ed.), Taylor & Francis, New York, 1995.

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Rapaport, R.A., *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, 1988.

U.S. Environmental Protection Agency, *Reregistration Eligibility Decision: Peroxy Compounds* (December 1993).

15. Attachments