Environmental Assessment

1. **Date:** August 7, 2019
2. **Name of Notifier:** DeLaval Inc.
3. **Address**

3000 Lakeside Drive, Suite 305S
Bannockburn, IL 60015

All communications regarding this Food Contact Notification environmental assessment should be sent in care of the authorized representative:

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4. **Description of Proposed Action**

   a. **Requested Action:** The action requested in this food contact notification (FCN) is the approval of the food contact substance "Premium Peroxide III," a mixture of peroxyacetic acid (PAA); hydrogen peroxide (HP); glacial acetic acid; 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP); sulfuric acid; and water. This product is intended for use as an antimicrobial agent in the following applications:

      i. Final sanitizing rinse for bottles. Dilute 1.1-6.9 ounces into 6 gallons of water followed by adequate draining. The maximum concentrations requested are approximately 508 ppm PAA, 2700 ppm HP, and 61 ppm HEDP. The FCS also contains acetic acid and sulfuric acid to stabilize the solution.

      ii. Sanitizing hard, non-porous, non-edible outside surfaces of airtight, sealed packages containing food products. Dilute 1.0 to 5.7 ounces per 5 gallons of water followed by adequate draining. The maximum concentrations requested are approximately 501 ppm PAA, 2668 ppm HP, and 60 ppm

HEDP. The FCS also contains acetic acid and sulfuric acid to stabilize the solution.

iii. Antimicrobial rinse of pre-cleaned or new containers. Use a 1.8% to 3.6% v/v solution by diluting 2.3 – 4.6 ounces per 1 gallon of water for a minimum of 15 seconds, drain adequately, and rinse interior container surfaces with potable water. The maximum concentrations requested are approximately 2030 ppm PAA, 10,802 ppm HP, 244 ppm HEDP. The FCS also contains acetic acid and sulfuric acid to stabilize the solution.

b. **Need for Action**: The antimicrobial agent reduces or eliminates pathogenic and non-pathogenic microorganisms that may be present on the bottle, package, or container surface which helps to reduce contamination and spoilage of the food that will be added to these containers, ultimately providing for safer foods for consumers. The action requested is needed to address current and future needs for processors and governmental agencies to address increased pressure to improve food safety and require more options for antimicrobial interventions. The use of peroxyacetic acid at higher concentrations for relatively short periods of time, and in smaller total volumes, enhances the capacity of the food industry to improve techniques (i.e., more flexibility in terms of time, concentrations, etc.) to better control food pathogens.

c. **Locations of Use and Disposal**: The antimicrobial agent is intended for use in bottling plants (for e.g., bottles for soft drinks, dressings and alcoholic beverages), food packaging facilities (for e.g. sealed bags like a Super Sack type bag with tomato paste inside), and container plants throughout the United States. As discussed below, the FCS is not expected to be released into the environment in significant quantities. The waste process water containing the FCS is expected to be disposed of through the plant's wastewater treatment facilities. Minor quantities would be lost through evaporation throughout wastewater treatment processes. All other waste water is collected and treated by the facility before being sent to a publicly owned treatment works (POTW).

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

The raw materials used in Premium Peroxide III are hydrogen peroxide, acetic acid, HEDP, sulfuric acid, and water (see Table 1 below). Peroxyacetic acid formation is the result of an equilibrium reaction between hydrogen peroxide and acetic acid. HEDP is the stabilizer. Sulfuric acid is added as a catalyst in the reaction process. The concentrated product is diluted at the processing plant for use to achieve the desired level of peroxyacetic acid.

Table 1. Chemical substances in Food Contact Substance

Component	CAS #	Mol. Wt.	Mol. Formula
Peroxyacetic Acid (PAA)	79-21-0	76.05	$C_2H_4O_3$
Hydrogen Peroxide	7722-84-1	34.01	H_2O_2
1-Hydroxyethylidene- 1,1-Diphosphonic Acid (HEDP)	2809-21-4	206.3	$C_2H_8O_7P_2$
Acetic Acid	64-19-7	60.05	$C_2H_4O_2$
Sulfuric Acid	7664-93-9	98.07	H_2SO_4
Water	7732-18-5	18.01	H_2O

a. Impurities

Premium Peroxide III is produced by reacting hydrogen peroxide with acetic acid in an aqueous solution containing sulfuric acid catalyst. The reaction yields peroxyacetic acid and water and does not lead to any impurities of toxicological significance associated with the active ingredient. No impurities are generated as a byproduct of degradation. The active PAA in this product does degrade over time, but the degradation products are, generally, acetic acid and water. Likewise, the hydrogen peroxide “equilibrium partner” will lose an oxygen molecule and degrade to water over time. No other impurities that could be present in *Premium Peroxide III* at a concentration ≥ 0.1% are associated with the active ingredient. No impurities of toxicological significance that could be present in *Premium Peroxide III* at a concentration ≥ 0.1% are associated with any starting material. The starting materials contain no ingredients other than sub-ppm levels (at most) of metals. There are no products of intended reactions or side reactions.

6. Introduction of Substances into the Environment

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

The FCS is manufactured in plants which meet all applicable federal, state and local environmental regulations. DeLaval Inc. 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 emissions that may harm the environment; 2) a proposed action that threatens a violation of Federal, State or local environmental laws or requirements (40 CFR 1508.27(b)(10)); and 3) production associated with a 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 in 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 spray application onto bottles, sealed packages, and containers, and the subsequent disposal of such spray drainage into the processing plant wastewater treatment facility. The total amount of product used at a typical facility can be estimated, although the actual amounts used will vary, depending on the equipment used and the amount of bottles, sealed packages, or containers processed.

	Maximum concentration (ppm)		
Component	**Bottle rinse sanitizer**	**Sealed packaging sanitizer**	**Container rinse**
Peroxyacetic Acid (PAA)	508	501	2030
Hydrogen Peroxide	2700	2668	10, 802
1-Hydroxyethylidene-1,1-Diphosphonic Acid (HEDP)	61	60	244
Acetic Acid	708	702	2833
Sulfuric Acid	37	37	150

Sulfuric acid dissociates readily in water to sulfate ions (SO_4^{2-}) and hydrated protons; at environmentally-relevant concentrations, sulfuric acid is practically totally dissociated[4]. 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[5]. 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[6].

Treatment of the process water at an on-site waste water treatment facility and/or at a Publicly Owned Treatment Works (POTW) is expected to result in complete degradation of PAA, hydrogen peroxide, and acetic acid. Specifically, the PAA will breakdown into oxygen and acetic acid, while hydrogen peroxide will breakdown into oxygen and water[7]. These 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 for a 95 ppm solution.[8] 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.[9] Acetic acid readily dissociates and the acetate anion is subsequently biodegraded**[10]** Acetic acid is not expected to concentrate in the wastewater discharged to the POTW. Therefore, these substances are not expected to be introduced into the environment to any significant extent as a result of the proposed uses of the FCS. As a result the remainder of this section will consider only the environmental introduction of HEDP.

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[4] OECD SIDS. 2001. SIDS Initial Assessment Report for 11th SIAM: Sulfuric acid. Available at http://www.inchem.org/documents/sids/sids/7664939.pdf

[5] HERA. 2006. Human & Environmental Risk Assessment (HERA) on ingredients of HouseholdCleaning Products: Sodium Sulfate. Edition 1.0, January 2006, available at: http://www.heraproject.com/files/39-f-06_sodium_sulfate_human_and_environmental_risk_assessment_v2.pdf

[6] HERA. 2006. See Footnote #2.

[7] U.S. EPA. 1993. Reregistration Eligibility Decision: Peroxy Compounds. p.18

[8] European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC). 2001. JACC No. 40. Peracetic Acid and its Equilibrium Solutions. JACC No. 40., January 2001

[9] ECETOC. 1993. JACC No. 22 Hydrogen Peroxide. January 1993.

[10] American Chemistry Council (ACC). 2003. Assessment plan for carboxylic food acids and salts category. Prepared by: The Weinberg Group, Inc. For the American Chemistry Council's Acetic Acid and Salts Panel April 16, 2003.

For the proposed uses, the maximum concentration at which HEDP may be introduced into the environment from the wastewater stream entering a POTW were calculated using the following assumptions:

- 100% of the amount used per day will ultimately be discharged to the wastewater from the manufacturing plant. Based on the fact that there is no potable water rinse following the bottle rinse and sealed package rinse uses, and the fact that this product is sprayed and not used as a dip/reservoir system, the concentration of HEDP that goes down the drain is expected to be only a fraction of what is being used. Therefore, this assumption adds significant conservatism into the Environmental Introduction Concentration (EIC) calculations for the end uses.
- The only wastewater produced by the plant is from the process of washing the bottles/packages and containers. This is a very conservative assumption since we know that the bottles that are involved in this process are used to package very specialized drinks and beverages and therefore are most likely a small proportion of the packaging occurring at any given bottling plant and the washing water is most likely a small proportion of the water discharged at the plant. In addition, the container rinse application *does* require a potable water rinse, and the rinse water is not accounted for in the wastewater calculation. This increases the conservatism in the present EIC estimate.
- HEDP does not degrade during rinsing or in any onsite wastewater treatment operation. Therefore, 100% of the HEDP from the FCS enters the waste stream.
- The HEDP discharge concentration is equal to the maximum use concentration of 244 ppm.

7. Fate of Emitted Substances in the Environment

HEDP is expected to significantly partition to sewage sludge. The Human and Environmental Risk Assessment Project (HERA) reports that the treatment steps at an onsite treatment facility or POTW will remove or decompose at least a portion of any HEDP that remains.[11] The HERA report cites 80% adsorption of HEDP to sewage treatment sludge. The potential environmental introduction of HEDP into water and sewage sludge was estimated applying the 20:80 partition factor derived in the HERA report.

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[11] Human & Environmental Risk Assessment (HERA). 2004. Risk Assessment of Ingredients of European Household Cleaning Products. Phosphonates. 06/09/2004

The EIC can therefore be calculated as:

- 244 ppm x 80% = 195.2 ppm $\text{EIC}_{\text{sludge}}$
- 244 ppm x 20% = 48.8 ppm $\text{EIC}_{\text{water}}$

A 10-fold dilution factor for discharge to surface waters from an onsite treatment facility (or POTW)[12] was implemented in the Estimated Environmental Concentration (EEC) calculation. The EEC for water is therefore 4.9 ppm. The EEC for sludge is 195.2 ppm and represents 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.

As previously mentioned, PAA and hydrogen peroxide are not expected to survive treatment at the primary wastewater treatment facilities at the bottling, container, or food packaging plant. Both 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 for a 95 ppm solution[13]. The half-life of hydrogen peroxide in natural river water ranged from 2.5 days when initial concentration was 10,000 ppm, and increased to 15.2 days when the concentration decreased to 250 ppm.[14] In biodegradation studies of acetic acid, 99% degraded in 7 days under anaerobic conditions[15]; it is not expected to concentrate in the wastewater discharged to the POTW. As discussed in Item 6.b., sulfuric acid readily dissociates in water.

As it was demonstrated that biodegradation of HEDP in waste water treatment plants can be neglected[16], the discussion below focuses on the removal of phosphonates through adsorption onto sludges.

8. Environmental Effects of Released Substances:

As noted above, wastewater from bottle/packaging/ container treatment operations as well as wastewater from other operations at the food processing plants will be directed to an on-site WWTP or a POTW, or both. It is expected that all peroxy compounds and acetic acid will completely decompose in the WWTP or POTW prior to water being discharged to the

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[12] Rapaport RA, 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. Found online at: http://onlinelibrary.wiley.com/doi/10.1002/etc.5620070204/full

[13] see footnote 5 (ECETOC 2001)

[14] see footnote 6 (ECETOC 1993)

[15] see footnote 7 (ACC 2003)

[16] see footnote 8 (HERA 2004)

environment. The concentration of sulfuric acid in the effluent due to use of the PAA mixture is below levels commonly found in the environment.

The aquatic toxicity of 1-Hydroxyethylidene-1,1-diphosphonic acid (HEDP) is summarized in the table below:

Exposure Duration	**Species**	**Endpoint**	**mg/L**	**Reference**
Short Term	*Lepomis macrochirus*	96-hr LC50	868	Jaworska et al. 2002[17]
	Oncorhynchus mykiss	96-hr LC50	360	
	Cyprinodon variegates	96-hr LC50	2180	
	Ictalurus punctatus	96-hr LC50	695	
	Leciscus idus melanatus	48-hr LC50	207 – 350	
	Daphnia magna	24 to 48-hr LC50	165 – 500	
	Planemonetes pugio	96-hr LC50	1770	
	Crassostrea virginica	96-hr LC50	89	
	Selenastrum capricornutum	96-hr LC50	3	HERA 2004[18]
	Selenastrum capricornutum	96-hr NOEC	1.3	
	Algae	96-hr NOEC	0.74	
	Chlorella vulgaris	48-hr NOEC	> 100	Jaworska et al. 2002[17]
	Pseudomonas putida	30-minute NOEC	1000	J
Long Term	*Oncorhychus mykiss*	14-day NOEC	60 – 180	Jaworska et al. 2002[17]
	Daphnia magna	28-day NOEC	10 – < 12.5	
	Algae	14-day NOEC	13	HERA 2004[18]

A risk assessment of phosphonates by the Human and Environmental Risk Assessment Project[19] included a discussion of aquatic toxicity resulting from chelation of nutrients, rather than direct toxicity to aquatic organisms. The lowest toxicity endpoints, those shown above for algae, *Selenastrum capricornutm, Daphnia magna,* and *Crassostrea virginica* are considered to result from chelation of nutrients, not from direct toxicity of HEDP. Chelation is not toxicologically relevant in the current evaluation because eutrophication, not nutrient depletion, has been

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[17] Jaworska, J, Van Genderen-Takken, H , Hanstve1t, A., van de Plassche, E , Feijtel, T. 2002. Environmental risk assessment of phosphonates, used in domestic laundry and cleaning agents in the Netherlands *Chemosphere 47*, 655-665.

[18] see footnote 8 (HERA 2004)

[19] see footnote 8 (HERA 2004)

demonstrated to be the controlling toxicological mode when evaluating wastewater discharges from food processing facilities.[20] The lowest relevant endpoint for this use was determined to be the chronic NOEC of 10 ppm for *Daphnia magna*[21]. Although uncertainties intrinsic to its derivation make the usefulness of the NOEC debatable[22], based on the available environmental toxicology data, reliance upon the NOEC for *Daphnia magna* is appropriate[23]. The EEC of 4.9 ppm is lower than the 10 ppm chronic NOEC for *Daphnia magna*.

The calculated environmental exposure to HEDP from effluent release from a WWTP to receiving waters is 4.9 mg/L (ppm). This was calculated by assuming that 80% of the HEDP was removed by sedimentation to sludge in the WWTP prior to discharge and that the HEDP concentration in water was further diluted 10-fold upon discharge to the receiving waters. This level of exposure is below the 10 ppm level of concern determined by Jaworksa et al. (2002).

If effluent from the WWTP were discharged directly to land rather than to receiving waters, the maximum short-term effluent concentration of 195.2 ppm would represent the concentration in soil. HEDP is not expected to have any adverse environmental impact based on the terrestrial toxicity endpoints available for plants, earthworms, and birds. The NOEC for soil dwelling organisms was >1000 mg/kg soil dry weight (dw) for earthworms (*Eisenia foetida*) and the 14-day median effect concentration (EC50) was >960 mg/kg dw for oats (Avena sativa). The 14-day median lethal dose (LD50) for birds (*Anas platyrhynchos* and *Colinus virginianus*) was >284 mg/kg body weight[24]. Application of the wastewater to land will result in phosphorus concentrations in soil that are a small fraction of total phosphorus concentrations currently found in the environment and used in fertilizers.

HEDP will be adsorbed to sludge during treatment in the WWTP. This sludge could be used as a soil amendment in land application resulting in an environmental release. As noted above, the maximum concentration of HEDP in sludge is 195.2 mg/kg. The HEDP concentration would be below any level of concern, either for toxicity to terrestrial organisms (NOEC 1000 mg/kg soil for *Eisenia foetida*) or as a significant source of phosphorus.

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[20] see footnote 14 (Jaworska et al. 2002)

[21] see FCN 801 Environmental Assessment

[22] 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, available at http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2006)18&doclanguage=en

[23] see footnote 14 (Jaworska et al. 2004)

[24] see footnote 8 (HERA 2004)

9. Use of Resources and Energy

The use of the PAA solution will not require additional energy resources for treatment and disposal of waste solution, as the peroxygen components and acetic and sulfuric acids readily degrade. 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 production processes. Energy used specifically for the production of the PAA solution 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 FCS-PAA-water solution. Thus, the use of the subject solution is not reasonably expected to result in any significant environmental impact requiring mitigation measures of any kind.

11. Alternatives to Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact Notification. The alternative of not approving the action proposed herein would simply result in the continued use of already-approved methods of ensuring the sterility of food packaging; such action would have no environmental impact.

12. List of Preparers

This assessment was prepared by Leslie E Patton, Ph.D. She is a toxicologist with over 10 years of experience in toxicology and risk assessment.

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13. Certification

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

Name: Leslie E. Patton, Ph.D.

Title: Senior Toxicologist

Signature: [redacted]

Dated August 15, 2019