Environmental Assessment

1. **Date**: August 16, 2019

2. **Name of Applicant/Notifier**: Hydrite Chemical Co.

3. **Address**:

All communications on this matter are to be sent in care of Counsel for the Notifier:

Catherine R. Nielsen, Partner
Keller and Heckman LLP
1001 G Street, N.W., Suite 500 West
Washington, D.C. 20001
Telephone: (202) 434-4140
Facsimile: (202) 434-4646
E-mail: nielsen@khlaw.com

4. **Description of the Proposed Action**:

A. Requested Action

The action identified in this FCN is to provide for the use of the food-contact substance (FCS), an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide (HP), acetic acid (AA), and, optionally, sulfuric acid, as an antimicrobial agent for use as a spray on seeds for sprouting and edible seeds and nuts. The FCS solution is prepared by dilution from a concentrate with water and is applied directly to the seeds using a sprayer or fogging apparatus. The FCS at-use dilution is prepared at the time of use by a 1-to-10.3 dilution of the concentrate with water and is applied directly to the seeds at a metered rate using a sprayer or fogging apparatus. The seeds or nuts may be treated with the FCS solution only once, at a maximum use rate of 40 L of diluted solution per 1 ton (1000 kg) of seeds or nuts. The treated seeds/nuts are dried 24 hours after treatment. The maximum concentrations of the components of the FCS on the treated seeds or nuts will not exceed 229 parts per million (ppm) peroxyacetic acid, 1067 ppm hydrogen peroxide, 310 ppm acetic acid, and 37 ppm sulfuric acid.

The active component of the FCS will have no ongoing antimicrobial effect in or on the food products to which it is applied due to its rapid decomposition upon use.

The FCS identified herein will compete for a share of certain markets already occupied by the already cleared product when this notification becomes effective. Consequently, the environmental introductions at the sites of use and/or disposal will be largely substitutional for existing uses.

B. Need for Action

This FCS is intended for use as an antimicrobial agent to inhibit the growth of undesirable or pathogenic micro-organisms on edible seeds and nuts, and on seeds for sprouting.

Approval of this use will allow processing plants more flexibility in using and managing microbial interventions across the entire production process.

C. Locations of Use/Disposal

The antimicrobial agent is intended for use in food processing plants throughout the United States. The waste process water containing the FCS generated at facilities is expected to enter the wastewater treatment unit at the plants. It is assumed that very minor quantities of the solution are lost to evaporation throughout the process. It is assumed for the purposes of this Environmental Assessment that treated wastewater will be discharged directly to surface waters in accordance with the plants' National Pollutant Discharge Elimination System (NPDES) permit. This assumption can be considered a worst-case scenario since it does not account for any further treatment that may occur at a Publicly Owned Treatment Works (POTW).

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

Chemical Identity

The subject of this notification is an aqueous solution 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), and optionally sulfuric acid (CAS Reg. No. 7664-93-9). PAA formation is the result of an equilibrium reaction between acetic acid and hydrogen peroxide.

$$CH_3CO_2H + H_2O_2 \rightleftarrows CH_3CO_3H + H_2O$$

6. Introduction of Substances into the Environment:

A. As a Result of Manufacture

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 (21 C.F.R § 25.40(a)). Information available to the Notifier suggests no 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

Process water containing the FCS will be treated at an on-site wastewater treatment facility and/or at a Publicly Owned Treatment Works (POTW). Treatment of the process water at an on-site wastewater treatment facility and/or at a POTW is expected to result in complete degradation of peroxyacetic acid, hydrogen peroxide, and acetic acid.[1] Specifically the peroxyacetic acid will break down into oxygen and acetic acid, while hydrogen peroxide will break down into oxygen and water. Acetic acid is rapidly metabolized by ambient aerobic

[1] Environmental Protection Agency, Reregistration Eligibility Decision: Peroxy Compounds (December 1993), p. 18.

microorganisms to carbon dioxide and water.[2] Therefore, these substances are not expected to be introduced into the environment to any significant extent when the FCS is used as intended.

Sulfuric acid is listed as an optional ingredient in the FCS formulation. Sulfuric acid is used to catalyze the reaction between acetic acid and hydrogen peroxide, more rapidly producing a stable PAA solution, and to modify the pH of the FCS.

Sulfuric acid dissociates readily in water to sulfate ions (SO_4) and hydrated protons. Sulfuric acid is practically totally dissociated at environmentally-relevant concentrations.[3] Sulfate ions are either incorporated into living organisms, reduced via anaerobic biodegradation to sulfides, deposited as sulfur, or re-oxidized to sulfur dioxide and sulfate due to participation in the natural sulfur cycle.[4] Therefore, any terrestrial or aquatic discharges of sulfate associated with the use described in this FCN are expected to have no significant environmental impact, as sulfate is a ubiquitous anion that is naturally present in the ecosystem and virtually indistinguishable from industrial sources.[5]

7. Fate of Emitted Substances in the Environment:

PAA, HP, and acetic acid are not expected to be introduced into the environment when the FCS is used and disposed of as intended. These substances are completely decomposed during wastewater treatment (see Footnotes 2 & 3). Minute quantities of sulfate may be introduced into the environment as a result of the use and disposal of the FCS. These minute levels of sulfate will participate in the natural sulfur cycle where sulfate is either incorporated into living organisms, reduced via anaerobic biodegradation to sulfides, deposited as sulfur, or re-oxidized to sulfur dioxide and sulfate.[6]

---

[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] *See* The Organization for Economic Cooperation and Development (OECD) SIDS Voluntary Testing Programme for International High Production Volume Chemicals (OECD SIDS), Sulfuric Acid, 2001 at https://hpvchemicals.oecd.org/UI/handler.axd?id=248f397d-64b3-4e14-8be9-473974e8dfdb.

[4] *See* Human and Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products, Sodium Sulfate, January 2006.

[5] *Id.*

[6] *See* Human and Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products, Sodium Sulfate, January 2006.

8. Environmental Effects of Released Substances:

The FCS components are not expected to be introduced into the environment when the FCS is used and disposed of as intended. Because there will be no significant environmental introductions, no significant environmental effects are anticipated.

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 antimicrobial agents such as other PAA-based antimicrobials and chlorine-based antimicrobials that are 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. Further, the use of resources at facilities that apply the diluted FCS mixture is expected to be the same as for HEDP stabilized peroxyacetic acid antimicrobials already on the market (based on identical volumes and application methods).

10. Mitigation Measures:

No significant adverse environmental impacts are expected to result from the use and disposal of the dilute FCS mixture. Therefore, mitigation measures are not necessary for this FCN.

11. Alternatives to the Proposed Action:

No potential adverse effects are identified herein that 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 significant environmental impact.

12. List of Preparers:

Catherine R. Nielsen, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001. Ms. Nielsen has a J.D., with many years of experience drafting food additive petitions and FCN submissions and environmental assessments.

Mark Hepp, Ph.D., Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001. Dr. Hepp has a Ph.D. in Chemistry with many years of experience with FCN submissions and environmental assessments.

13. Certification:

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

Date: August 16, 2019

[redacted]

Counsel for Notifier

14. List of References:

1. Environmental Protection Agency, Reregistration Eligibility Decision: Peroxy Compounds (December 1993).
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. Human and Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products, Sodium Sulfate (January 2006).
4. The Organization for Economic Cooperation and Development (OECD) SIDS Voluntary Testing Programme for International High Production Volume Chemicals (OECD SIDS), Sulfuric Acid, 2001; *available at* https://hpvchemicals.oecd.org/UI/handler.axd?id=248f397d-64b3-4e14-8be9-473974e8dfdb.