Environmental Assessment

1. **Date**: July 15, 2025*

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:
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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 (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) as an antimicrobial additive to liquid, pasteurized whey used in the production of whey protein concentrate and whey protein isolate intended for use in food for the general population and in infant formula. The at-use concentration of the FCS components in the liquid, pasteurized whey will not exceed 16 ppm peroxyacetic acid, 76 ppm hydrogen peroxide, 21 ppm acetic acid, and 1 ppm sulfuric acid *at the point of addition*.

The active component of the FCS, peroxyacetic acid, will have no ongoing antimicrobial effect in or on the food products due to its rapid decomposition upon use.

B. Need for Action

This FCS is intended for use as an antimicrobial agent to inhibit the growth of undesirable or pathogenic microorganisms in liquid, pasteurized whey used to produce whey protein concentrate and whey protein isolate intended for use as food ingredients for the general population and in infant formula. The current FCN is needed to allow the Notifier to market the FCS for the intended use. Approval of this use will also allow whey protein concentrate and whey protein isolate processing plants more flexibility in managing microbial interventions in the production process.

* Subsequent to this date, this EA was edited using the Adobe text editor tool to make several corrections to harmonize the EA to the final FCN regulatory language.

C. Locations of Use/Disposal

The FCS is intended for use in liquid, pasteurized whey used to manufacture whey protein concentrate and whey protein isolate. The use of the FCS is limited to facilities that process whey protein concentrate and whey protein isolate. Any wastewater containing the FCS generated at whey processing facilities is expected to enter the wastewater treatment unit at the food plants. It is assumed that very minor quantities of the mixture 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 mixture 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). Peroxyacetic acid 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 due to 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

Water containing the FCS will be treated at an on-site wastewater treatment facility and/or at a POTW. None of the FCS constituents are expected to enter the environment to any significant extent. 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

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

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 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 peroxyacetic acid mixture, and to modify the pH of the FCS concentrate.

Sulfuric acid dissociates readily in water to sulfate ions (SO_4^{-2}) 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

Peroxyacetic acid, hydrogen peroxide, 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 prior to or during wastewater treatment (see Footnotes 2 & 3). Minute quantities of sulfate may be introduced into the environment due to 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]

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[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. No significant environmental introductions are expected, and, therefore, no significant environmental effects are anticipated.

9. Use of Resources and Energy

The notified use of the FCS mixture will require no additional energy resources for the treatment and disposal of wastes as the FCS is expected to compete with and replace similar antimicrobial agents such as other peroxyacetic acid-based antimicrobial agents 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.

10. Mitigation Measures

No significant adverse environmental impacts are expected to result from the use of the dilute FCS mixture. Therefore, no significant adverse impacts were identified that require mitigation measures.

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 significant environmental impact. The addition of the antimicrobial agent to the options available to whey processors is not expected to increase the use of peroxyacetic acid antimicrobial products.

12. List of Preparers

Catherine R. Nielsen, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, 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, N.W., Suite 500 West, Washington, DC 20001. Dr. Hepp has a Ph.D. in Chemistry with many years of experience both reviewing and preparing FCN submissions and environmental assessments.

Jade C. Williams, Ph.D., Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Dr. Williams has a Ph.D. in Chemistry with 1 year of experience performing evaluations relating to all aspects of preparing FCNs and 4 years of total experience in FDA-regulated industries.

13. Certification

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

Date: July 15, 2025

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Catherine R. Nielsen
Counsel for Notifier

14. List of References

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

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.