

Memorandum

Date: July 13, 2023

To: Jessica Urbelis, Ph.D., Division of Food Contact Substances (HFS-275)

Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Division of Science and Technology (HFS-255)

Mariellen Pfeil -S
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Date: 2023.07.13 18:51:22 -04'00'

From: Antonetta Thompson-Wood, Physical Scientist, Environmental Team, Division of Science and Technology (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2297

Notifier: Ecolab, Inc.


Attached is the FONSI for FCN 2297, which is for the use of hypochlorous acid (CAS Reg. No. 7790-92-3) as an antimicrobial agent in ice for cooling whole or cut meat and poultry, whole or cut fish and seafood, and fruits and vegetables in retail food establishments and food processing facilities.

This FONSI explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

After this FCN becomes effective, copies of this FONSI, and the notifier's assessment (EA), dated June 23, 2023, may be made available to the public. We will post digital transcriptions of the FONSI, and the EA on the agency's public website.

Please let us know if there is any change in the identity or use of the food-contact substance.

Antonetta Thompson-wood -S


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Attachment: FONSI

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2297 is submitted by Ecolab, Inc. for the use of hypochlorous acid (CAS Reg. No. 7790-92-3) as an antimicrobial agent in ice for cooling whole or cut meat and poultry, whole or cut fish and seafood, and fruits and vegetables in retail food establishments and food processing facilities. The concentration of available free chlorine will not exceed 60ppm when diluted on site. The concentrated FCS solution will be stored for no more than six months before use.

The Office of Food Additive Safety has determined that allowing this notification to become effective will not significantly affect the quality of the human environment and, therefore, an environmental impact statement (EIS) will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA), dated June 23, 2023. The EA was prepared in accordance with 21 CFR 25.40. The EA is incorporated by reference in this Finding of No Significant Impact (FONSI) and is briefly summarized below.

The FCS is intended for use as an antimicrobial agent in ice for cooling whole or cut meat and poultry, whole or cut fish and seafood, and fruits and vegetables. The ice containing the FCS will be used to reduce or prevent the growth of spoilage organisms. The FCS provides more options for efficacious antimicrobial interventions to direct-to-consumer stores, such as grocery stores.

After use, the dilute hypochlorous acid solution, residual amounts of degraded oxychloro species (chlorite and chlorite), and trihalomethanes (THM) by-products will be drained from the sink via down-the-drain transport from grocery store use sites through the sanitary sewer system into Publicly Owned Treatment Works (POTWs) for standard wastewater treatment and subsequent release to surface waters and POTWs prior to movement into aquatic environments.


Oxychloro species are strong oxidizers that react readily with oxidizable compounds in the wastewater treatment process before discharge to surface waters. Oxychloro species have low bioaccumulation potential, high mobility, low volatility, and do not readily biodegrade under aerobic conditions. Chlorate does not bind to soil or sediment particulates, is mobile, and partitions predominantly into the water. Redox reactions reduce the concentration of chlorate in surface water. THMs transition out of the aquatic environment within hours to days, low bioaccumulation, and adsorb to suspended solids or sediment in aquatic environments. As such, the primary environmental exposure is through the aquatic compartment

Based on the primary route of environmental exposure, effects on terrestrial organisms are not expected from use and disposal of the FCS in this notification. Therefore, environmental effects are evaluated by comparing the most sensitive aquatic toxicity endpoints against the estimated environmental concentration. Modeled results indicate that the surface water concentration estimated environmental concentration (EEC) of the sum of chloro species is 0.0159 µg/L and THMs is 0.0000132µg/L. These values are below the lower than the most sensitive aquatic toxicity endpoints for chlorotoxicity (17 µg/L LC50 for the freshwater invertebrate) and THM (0.185 mg/L EC50 for freshwater fish)); therefore, discharge to surface waters of effluent containing the FCS is not expected to have any toxic effects and adverse environmental effects are not anticipated.


Manufacture of the FCS and its use as an antimicrobial will not require additional energy resources, as the FCS is expected to compete with and/or replace similar products on the market. No mitigation measures are needed since no significant adverse environmental effects are expected from use and disposal the FCS, nor do we expect significant environmental impacts, which would necessitate alternative actions to those proposed in this FCN. The alternative to not allowing the FCN to become

effective would be continued use of materials that the FCS would otherwise replace; therefore, this action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2297 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by **Antonetta
Thompson-wood -S**  Digitally signed by Antonetta Thompson-wood -S
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Physical Scientist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

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