

Memorandum

Date: October 10, 2023

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) 2316

Notifier: Clarentis Technologies, LLC

To: Katherine Wilkening, 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 Digitally signed by Mariellen Pfeil -S
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Attached is the FONSI for FCN 2316, which is for the use of hypochlorous acid (CAS Reg. No. 7790-92-3) as an antimicrobial agent in aqueous solution in the production and preparation of fish and seafood, fruits and vegetables, and shell eggs.

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 September 20, 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
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Antonetta Thompson-Wood

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2316 is submitted by Clarentis Technologies LLC for the use of hypochlorous acid (CAS Reg. No. 7790-92-3) as an antimicrobial agent in aqueous solution in the production and preparation of fish and seafood, fruits and vegetables, and shell eggs.

The FCS solutions will be stored for no more than six months before use. The concentration of available free chlorine in the diluted solution will not exceed 60 parts per million (ppm), and the FCS solution will be replaced if the concentration falls below 25 ppm available free chlorine. The diluted solution containing the FCS may be used in processing facilities and retail food establishments as follows:

1. in process water or ice for washing, rinsing, rehydrating, cooling, or spraying fruits and vegetables;
2. in ice for cooling whole or cut fish and seafood; and
3. in process water for washing or rinsing shell eggs.

When used to process fruits, vegetables, and fish and seafood products intended to be consumed raw, the treatment will be followed by either a 10-minute drain step or a potable water rinse to remove, to the extent possible, residues of the FCS. The FCS is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCN.

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 September 20, 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 as an antimicrobial agent in aqueous solution in the production and preparation of fish and seafood, fruits and vegetables, and shell eggs. The FCS reduces or eliminates pathogenic and non-pathogenic microorganisms that may be present in the food or process water, or ice used during production. Use of the FCS provides more options for efficacious antimicrobial interventions in processing facilities and retail food establishments.

After use, facilities will discharge directly to surface waters after on-site treatment in accordance with a permit issued under the National Pollutant Discharge Elimination System (NPDES); however, some applications may involve draining into publicly owned treatment works (POTW).

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. The FCS, its

reaction and breakdown products will be reduced to chloride at a concentration of 6ppm after a 10% reduction for dilution in surface waters. This concentration is much lower than the endpoint of the most sensitive species (735 ppm, *Cladocera* sp., EC50). The EIC of sodium hypochlorite will decay to less than 4×10^{-27} ppb active chlorine in approximately 9 hours. This EIC includes all breakdown products, including hypochlorite, chlorate, and chlorite. The lowest endpoint is 17 ppb (Chlorine-FAC, *Daphnia magna*, LC50). The EIC of 4×10^{-27} ppb is far below this endpoint.

Chloramines produced during the process will decay to 1×10^{-10} ppb, well below the lowest ecotoxicity endpoint of 0.016 ppm (*Daphnia magna*, LC50). The EEC of THM (8.6 µg/L) is well below the most sensitive endpoint for aquatic toxicity (freshwater fish at 185 µg/L). The EEC of trichloroacetic acid (3.14 µg/L) is 3-fold below the no effect concentration of 10 to the alga *Chlorella pyrenoidosa*. The tolerable daily intake for humans to monochloroacetic acid is 60-fold larger than the EEC of 3.6 µg/L. 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 2316 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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