U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: August 2, 2021

To: Sean Fischer, Ph.D., Division of Food Contact Notifications, HFS-275
Through: Mariellen Pfeil, Acting Environmental Supervisor, Office of Food Additive Safety, HFS-255

From: Biologist, Environmental Team, Division of Biotechnology and GRAS Notice Review, HFS-255

Subject: Finding of No Significant Impact for food-contact notification (FCN) 2161 for hypochlorous acid (CAS Reg. No. 7790-92-3).

Notifier: Ecolab

Attached is the Finding of No Significant Impact (FONSI) for FCN 2161 for use of hypochlorous acid (CAS Reg. No. 7790-92-3), as an antimicrobial agent in ice for cooling whole or cut fish and seafood in retail food establishments and food processing facilities. The concentration of available free chlorine will not exceed 60 ppm when diluted on site.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated July 21, 2021, 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.

Leah D. Proffitt

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 2161), submitted by Ecolab, to provide for the safe use of hypochlorous acid (CAS Reg. No. 7790-92-3), as an antimicrobial agent in ice for cooling whole or cut fish and seafood in retail food establishments and food processing facilities. The concentration of available free chlorine will not exceed 60 ppm when diluted on site.

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 will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment, dated July 21, 2021. The EA is incorporated by reference in this Finding of No Significant Impact and is briefly summarized below. The EA was prepared in accordance with 21 CFR 25.40.

The food-contact substance (FCS) is intended to inhibit the growth of undesirable or pathogenic microorganisms and will be used in food processing facilities throughout the United States, as well as in open water, on-board fish processing. Waste water from the proposed uses will be either discharged ultimately to a publicly-owned treatment works (POTW), or, if in possession of a National Pollutant Discharge Elimination System (NPDES) permit, directly to surface waters after onsite pre-treatment.

According to the E-FAST Probabilistic Dilution Model, the sum of chloro species (available free chlorine, chlorate, and chlorite), and the sum of tri-halo methanes that will be discharged into surface waters are well below the most sensitive aquatic toxicity endpoints:

Chloro species EEC[1]	0.00159 µg/L	LC_{50} chlorine 17 µg/L	(Δ = 5 orders of magnitude)
THM species EEC	0.0000132 µg/L	EC_{50} chloroform 0.185 mg/L	(Δ = 7000 orders of magnitude)

Use of the FCS as an antimicrobial agent in food processing is not expected to result in a net increase in the use of energy and resources, since the raw material used to produce the FCS are already in common use in other chemical and industrial processes.

No significant environmental impacts are expected from use and disposal of the FCS; therefore, mitigation measures have not been identified. The alternative of not allowing the FCN to become effective would be the continued use of the materials that the subject FCS would otherwise replace; such action would have no significant environmental impact.

[1] Effective environmental concentration

Consequently, we find that use of the FCS as an antimicrobial agent in ice for cooling whole or cut fish and seafood in retail food establishments and food processing facilities will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed 08-02-2021
Leah D. Proffitt
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 08-02-2021
Mariellen Pfeil
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