

## Memorandum

**Date:** March 13, 2022

**To:** Jessica Urbelis, Ph.D., Division of Food Contact Notifications, HFS-275

**Through:** Mariellen Pfeil, Lead Biologist, Office of Food Additive Safety, HFS-255

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S  
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**From:** Biologist, Environmental Team, Division of Biotechnology and GRAS Notice Review, HFS-255

**Subject:** Finding of No Significant Impact for food-contact notification (FCN) 2186 for hypochlorous acid (CAS Reg. No. 7790-92-3).

**Notifier:** Clarentis Technologies LLC

Attached is the Finding of No Significant Impact (FONSI) for FCN 2186 for use of hypochlorous acid (CAS Reg. No. 7790-92-3), in solutions used to rehydrate fresh and fresh-cut fruits and vegetables in food processing facilities, except for use in contact with infant formula and human milk.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated December 23, 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.

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Attachment: Finding of No Significant Impact

cc: HFS-255 Proffitt

File: FCN No. 2186

## FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 2186), submitted by Clarentis Technologies LLC, to provide for the safe use of hypochlorous acid (CAS Reg. No. 7790-92-3), in solutions used to rehydrate fresh and fresh-cut fruits and vegetables in food processing facilities, as described further below.

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 December 23, 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 concentrated FCS solution will be stored for no more than six months before use. In the diluted solution, the concentration of free available chlorine will not exceed 60 ppm, and the FCS solution will be replaced if the concentration falls below 25 ppm available free chlorine. Fresh and fresh-cut produce may be treated with the FCS solution by soaking for a minimum of 90 seconds or by spraying. After treatment, the produce will be allowed to drain for no less than 10 minutes before it is placed on display or consumed. 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 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. Wastewater 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.

Effective environmental concentrations (EECs) for the oxychlorine species (HOCl-, ClO<sub>2</sub>- and ClO<sub>3</sub>-) are calculated at  $4 \times 10^{-27}$  µg/L, which is 25 orders of magnitude lower than the most sensitive species (aquatic invertebrate 17 µg/L). For trihalomethane species the EEC is 8.64 ppb (µg/L), which is well below the most sensitive endpoint for aquatic toxicity of 185 µg/L for freshwater fish. Chloramines EEC is estimated to be  $1 \times 10^{-10}$  ppb. This EEC is over 11 orders of magnitude below the above lowest LC<sub>50</sub>, which is the water flea (*Daphnia magna*) with a static freshwater LC<sub>50</sub> of 0.016 mg/L. The EEC of 3.14 µg/L for trichloroacetic acid is three times lower than the 10 µg/L NOEC endpoint for the most sensitive species, *Chlorella pyrenoidosa*.

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.

Consequently, we find that use of the FCS as an antimicrobial agent to rehydrate fresh and fresh-cut fruits and vegetables in food processing facilities will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by

**Leah D. Proffitt -S**

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Food and Drug Administration

Approved by

**Mariellen Pfeil -S**

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