U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: January 31, 2018

To: Sharon Koh-Fallet, Ph.D., Division of Food Contact Notifications, HFS-275
Through: Leah Proffitt, 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) 1857 for an aqueous solution of hydrogen peroxide (CAS Reg. No. 7722-84-1), aluminum nitrate, nonahydrate (CAS Reg. No. 7784-27-2), and phosphoric acid (CAS Reg. No. 7664-38-2).

Notifier: PeroxyChem, LLC

Attached is the Finding of No Significant Impact (FONSI) for FCN 1857 for use of an aqueous solution of hydrogen peroxide, aluminum nitrate, nonahydrate and phosphoric acid intended for use as an antimicrobial additive that may be used alone or in combination with other processes for the commercial sterilization of aseptic filling systems and packaging prior to filling. The FCS will be used as a 35 percent by weight aqueous hydrogen peroxide solution, with a maximum of 0.006 percent by weight aluminum nitrate, nonahydrate at the time of application. The concentration of hydrogen peroxide in distilled water packaged under production conditions (assay to be performed immediately after packaging) must not exceed 0.5 parts per million (ppm). The FCS may be used on equipment and food packaging materials intended to contact infant formula products.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated December 20, 2017, 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.

Mariellen Pfeil

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 1857), submitted by PeroxyChem, LLC, to provide for the safe use of an aqueous solution of hydrogen peroxide (CAS Reg. No. 7722-84-1), aluminum nitrate, nonahydrate (CAS Reg. No. 7784-27-2), and phosphoric acid (CAS Reg. No. 7664-38-2) as an antimicrobial additive that may be used alone or in combination with other processes for the commercial sterilization of aseptic filling systems and packaging prior to filling. The FCS will be used as a 35 percent by weight aqueous hydrogen peroxide solution, with a maximum of 0.006 percent by weight aluminum nitrate, nonahydrate at the time of application. The concentration of hydrogen peroxide in distilled water packaged under production conditions (assay to be performed immediately after packaging) must not exceed 0.5 parts per million (ppm). The FCS may be used on equipment and food packaging materials intended to contact infant formula products.
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 20, 2017. 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 that may be present on the food-contact surfaces of containers and closures used to package food, and will be used in food processing facilities throughout the United States. 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.

Hydrogen peroxide decomposes rapidly to water and oxygen when exposed to transition metals (such as Fe or Mn) and organic material. It is not expected to enter the environment after treatment at the facility wastewater treatment plant.

Phosphoric acid introductions will be 70% of the aluminum nitrate introductions, or a time-averaged value of 0.0011 mg/L. Average phosphate concentrations in the environment have been reported to be 0.2 mg/L. Thus, the introduction of phosphoric acid into the environment due to the proposed use of the FCS will not change the background levels of this nutrient in the receiving streams in any measurable way.

Thus, the aluminum nitrate, nonahydrate stabilizer is the only component of the FCS that may be present at environmentally significant concentrations upon discharge of wastewater streams from processing facilities to the environment through aquatic or terrestrial routes. Because of the good solubility of the stabilizer, it is expected that it would not be adsorbed to sludge during treatment of wastewater. The maximum concentration of aluminum nitrate stabilizer released to the environment after onsite pre-treatment is estimated at 0.091 mg/L. This amount is orders of magnitude lower than the ecotoxicity endpoint for the most sensitive species (i.e., 13.6 mg/L 96 hr EC50 for *Bufo americanus* (toad)). The maximum nitrate ion release from the stabilizer is estimated at 0.045 mg/L. This amount is orders of magnitude lower than nitrate concentrations in natural ground water (reported at 2 to 18 mg/L). Therefore, no significant environmental impacts are anticipated.

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 for commercial sterilization of food packaging materials prior to filling and to aseptic filling systems will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed 01-31-2018
Mariellen Pfeil
Biologist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 01-31-2018
Leah D. Proffitt
Acting Environmental Supervisor
Office of Food Additive Safety
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