

Memorandum

Date: October 31, 2018
To: Sharon Koh-Fallet, 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) 1919 for 2,6-pyridinedicarboxylic acid (dipicolinic acid - DPA), CAS Reg. No. 499-83-2, to stabilize peroxyacid equilibrium mixtures during storage (i.e. before dilution with water and subsequent food-contact use).
Notifier: Enviro Tech Chemical Services, Inc.

Attached is the Finding of No Significant Impact (FONSI) for FCN 1919 for 2,6-pyridinedicarboxylic acid (dipicolinic acid - DPA), CAS Reg. No. 499-83-2, to stabilize peroxyacid equilibrium mixtures during storage (i.e. before dilution with water and subsequent food-contact use).

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated August 20, 2018, 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 -S
Digitally signed by Leah D. Proffitt -S
Date: 2018.10.31 14:05:26 -04'00'
Leah D. Proffitt

Attachment: Finding of No Significant Impact

cc: HFS-255 Proffitt
File: FCN No. 1919

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 1919), submitted by Enviro Tech Chemical Services, Inc., to provide for the safe use of 2,6-pyridinedicarboxylic acid (dipicolinic acid - DPA), CAS Reg. No. 499-83-2, to stabilize peroxyacid equilibrium mixtures during storage (i.e. before dilution with water and subsequent food-contact use) as described 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 August 20, 2018. 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 be used in peroxyacetic acid solutions authorized in effective Food Contact Notifications¹ with the following limitations in use-level for:

1. meat carcasses, parts, trim, and organs at a maximum use level of 1.64 ppm
2. poultry carcasses, parts, trim, and organs at a maximum use level of 4.00 ppm
3. processed and preformed meat and poultry at a maximum use level of 0.44 ppm
4. fruits and vegetables in food processing facilities at a maximum use level of 0.68 ppm
5. fish and seafood at a maximum use level of 0.38 ppm
6. brines, sauces, and marinades at a maximum use level of 0.10 ppm, and
7. the commercial sterilization of aseptic filling systems, glass and plastic food packaging and their enclosures prior to filling at a maximum use level of 9.0 ppm. If the peroxyacetic acid solution is applied at a rate exceeding 0.0175 milliliters treatment solution per ounce container capacity, the solution must be drained from the container and rinsed with sterile water and drained again.

The FCS will be used in food processing facilities throughout the United States. Waste water from the above-described 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. As a conservative measure, the highest DPA use concentration was assumed (see 7 above; 9 ppm) to calculate the environmental introduction concentration (EIC), and effective environmental concentration (EEC). DPA is water soluble and does not partition to sludge; therefore, it is assumed that the EIC is equal to the use concentration (9 ppm). The EEC is 0.9 ppm (i.e. $EIC \div 10$ -fold dilution factor upon release of effluent to surface waters).

There is little information available on DPA itself, so environmental toxicity was assessed using EPA's ECOSAR program, which estimates effects based on structure-activity relationships and predictions from similar chemical classes. The lowest toxicity endpoints, according to ECOSAR, are a chronic value of 29 mg/L for fish (proxy: pyridine-alpha-acid), and a chronic value of 89 mg/L (proxy: neutral organic SAR). The expected worst-case EEC of 0.9 ppm is 2 orders of magnitude below these concentrations.

¹ Those FCNs are: 699, 887, 908, 1132, 1419, 1654, 1738, 1806, 1851. They are incorporated by reference in the EA.


Use of the FCS in is not expected to result in a net increase in the use of energy and resources, because the raw materials used in the manufacture of the FCS are already in wide use in other industrial applications.

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 environmental impact.

Consequently, we find that use of the FCS to stabilize peroxyacid equilibrium mixtures during storage 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**  Digitally signed by Leah D. Proffitt -S
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Leah D. Proffitt
Biologist
Office of Food Additive Safety
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Food and Drug Administration

Approved by **Mariellen Pfeil -S**  Digitally signed by Mariellen Pfeil -S
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