March 22, 2018

Tina Rodrigues
Enviro Tech Chemical Services, Inc.
500 Winmoore Way
Modesto, CA 95358

RE: Food Contact Substance Notification (FCN) 001851
Final Letter

Dear Ms. Rodrigues:

This letter is in reference to the notification for the food contact substance and use described as follows:

Food Contact Substance (FCS)
An aqueous mixture of peroxyacetic acid (CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), 1-hydroxyethylidene-1,1-disphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and, optionally, sulfuric acid (CAS Reg. No. 7664-93-9)

Notifier
Enviro Tech Chemical Services, Inc.

Manufacturer/Supplier
Enviro Tech Chemical Services, Inc.

Intended Use
As an antimicrobial additive that may be used alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures prior to filling, except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging (see Limitations/Specifications).

Limitations/Specifications
The components of the FCS mixture will not exceed 4500 ppm peroxyacetic acid, 6600 ppm hydrogen peroxide, and 180 ppm HEDP. If the FCS mixture is applied at a rate exceeding 0.0175 milliliters treatment solution per ounce container capacity, the FCS mixture must be drained from the container and rinsed with sterile water and drained again. FDA's review of the use of the FCS to sterilize aseptic filling systems is limited to the extent that the FCS residues may transfer from the non-food contact surfaces of the aseptic filling system to food packaging materials. The FCS is not for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging. Such uses were not included as part of the intended use of the substance in the FCN.

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740
www.fda.gov

This is to inform you that as of April 1, 2018, FCN 001851 will become effective. It will be added to the list of effective notifications for FCNs, which can be accessed from the Internet in the Ingredients, Packaging & Labeling section under the Food topic of http://www.fda.gov.

The Agency has determined that allowing this notification to become effective will not have a significant impact on the quality of the human environment and therefore an environmental impact statement is not required. The Agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, will be publicly available after the effective date of the notification.

This effective notification is applicable only to aqueous mixtures of peroxyacetic acid, hydrogen peroxide, acetic acid, HEDP, and, optionally, sulfuric acid manufactured or prepared by Enviro Tech Chemical Services, Inc., and is limited to the use identified above. You should inform the Agency of any modification to the FCS, the limitations/specifications given in the notification, or of any alteration in the manufacturing process that would result in a change in the impurities or impurity level in the FCS. Such changes may require the submission of a new notification.

FDA's review of this notification was limited to Section 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The existence of an effective notification for a FCS does not relieve use of the subject substance from compliance with any other provision of the Act or with §174.5 (General provisions applicable to indirect food additives). For example, in accordance with section 402(a)(3) of the Act (21 U.S.C. 342), use of the FCS should not impart odor or taste to food rendering it unfit for human consumption.

Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our review of this notification, FDA did not consider whether section 301(ll) or any of its exemptions apply to the intended use of the FCS. Accordingly, allowing this FCN to become effective should not be construed as a statement that the intended use of the FCS would not violate section 301(ll).

If new data or information becomes available to FDA demonstrating that the intended use of the FCS is no longer safe, the Agency will inform you of its determination that the intended use of the FCS is unsafe. In addition, if you become aware of data that raise questions about the safety of the intended use of the FCS, you should notify the Agency immediately and be prepared to supply the necessary data to resolve any questions.

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Elizabeth J. Petro -S

Digitally signed by Elizabeth J. Petro -S
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Date: 2018.03.22 17:57:54 -04'00'

Elizabeth J. Petro, Ph.D.
Consumer Safety Officer
Division of Food Contact Notifications HFS-275
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition