

Food and Drug Administration College Park, MD 20740

September 13, 2006

Michael S. Harvey Enviro Tech Chemical Services, Inc. 500 Winmoore Way Modesto, CA 95358

Re: Food Contact Substance Notification FCN 000641

Dear Mr. Harvey:

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

Food Contact Substance

A mixture of peroxyacetic acid, hydrogen peroxide, and 1-hydroxyethylidine-1,1-diphosphonic acid

Notifier

Enviro Tech Chemical Services, Inc.

Manufacturer/Supplier

Enviro Tech Chemical Services, Inc.

Intended Use

As an antimicrobial to control microorganisms in wash water used to manufacture lactose.

Limitations/Specifications

The components of the food-contact substance are limited to use in wash water at levels not exceeding: 30 parts per million peroxyacetic acid; 140 parts per million hydrogen peroxide; and, 3.2 parts per million hydroxyethylidine-1,1-diphosphonic acid.

This is to inform you that as of November 4, 2006, FCN 000641 will become effective. It will be added to the list of effective notifications for food contact substances available on the agency's internet site at http://vm.cfsan.fda.gov/~dms/opa-fcn.html.

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 a mixture of peroxyacetic acid, hydrogen peroxide, and 1-hydroxyethylidine-1,1-diphosphonic acid manufactured by Enviro Tech Chemical Services, Inc. and is limited to the use of the food-contact substance identified above.

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You should inform the agency of any modification in the FCS limitations/specifications given in the notification or of any alteration in the manufacturing process that would result in a change in the impurities in the FCS. Such changes may require submission of a new notification.

The existence of an effective notification for a food contact substance does not relieve use of the subject substance from compliance with any other provision of the Federal Food, Drug, and Cosmetic Act or with 21 CFR §174.5 General provisions applicable to indirect food additives. For example, in accordance with section 402(a)(3) of the Act, use of the food contact substance should not impart odor or taste to food rendering it unfit for human consumption.

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

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

Sincerely,

Mark Hepp

Division of Food Contact Notifications, HFS-275

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition