



September 19, 2006

Susan Phillips, M.S.
ENVIRON International Corporation
4350 N. Fairfax Drive, Suite 300
Arlington, VA 22203

Re: Food Contact Substance Notification FCN 000649

Dear Ms. Phillips:

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

Food Contact Substance

Polyethylene terphthalate, modified with a derivative of hexamethyldisilazane and tetraethyl orthosilicate

Notifier

PTP Plastic Technologies & Products B.V.

Manufacturer/Supplier

PTP Plastic Technologies & Products B.V.

Intended Use

For use as a basic resin in food-contact articles.

Limitations/Specifications

The modifier shall not exceed 5 percent by weight of the final polymer. Used in contact with all types of foods under conditions of use C through G as described at our website:
<http://www.cfsan.fda.gov/~rdb/opa-fcn3.html>.

This is to inform you that as of October 3, 2006, FCN 000649 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 polyethylene terphthalate, modified with a derivative of hexamethyldisilazane and tetraethyl orthosilicate manufactured by PTP Plastic

Technologies & Products B.V. and is limited to the use of the food contact substance identified above. 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,

Elizabeth R. Sánchez, Ph.D.
Division of Food Contact Notifications
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration