



December 31, 2007

Michael H. Auerbach, Ph.D.
Danisco A/S
565 Taxter Road - Suite 590
Elmsford, NY 10523

Re: Food Contact Substance Notification FCN 000750

Dear Mr. Auerbach:

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

Food Contact Substance

Octadecanoic acid, 1-(12-acetyloxy)-, 2,3-bis(acetyloxy) propyl ester; 1-(12-acetoxystearoyl)-2,3-diacetyl glycerol (CAS Reg. No. 736150-63-3).

Notifier

Danisco A/S

Manufacturer/Supplier

Danisco A/S

Intended Use

For use as:

1. a plasticizer at levels up to 34 percent by weight in polyvinylchloride bottle cap sealing rings for use in contact with all foods under conditions of use B through H, as described in Table 2;
2. a plasticizer at levels up to 3 percent by weight in polymers used to manufacture articles intended for repeated-use in contact with all foods under conditions of use E through H, as described in Table 2; and,
3. a colorant carrier or dispersant at levels up to 0.5 percent by weight in polymers used to manufacture articles intended for repeated-use in contact with all foods.

This is to inform you that as of October 18, 2007, FCN 000750 became 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 octadecanoic acid, 1-(12-acetyloxy)-, 2,3-bis(acetyloxy) propyl ester; 1-(12-acetoxystearoyl)-2,3-diacetyl glycerol manufactured by Danisco A/S 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,

Mark Hepp
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition