

Food and Drug Administration College Park, MD 20740

January 24, 2011

David J. Ettinger Keller and Heckman LLP 1001 G Street, N.W., Suite 500 West Washington, DC 20001

Re: Food Contact Substance Notification (FCN) 001057

Dear Mr. Ettinger:

This letter acknowledges receipt of your notification, FCN 001057 received December 15, 2010, submitted on behalf of Ziko Ltd., for the food contact substance and use described as follows:

FCS:

2-Propenoic acid, 2-[1-[3,5-bis(1,1-dimethylpropyl)-2-hydroxyphenyl] ethyl]-4,6-bis(1,1-dimethylpropyl)phenyl ester (CAS Reg. No. 123968-25-2)

Notifier:

Ziko Ltd.

Manufacturer/Supplier:

Ziko Ltd.

Intended Use:

The FCS will be used as an stabilizer in polystyrene(PS) and rubber-modified polystyrene (RMPS) complying with 21 CFR 177.1640, styrene block copolymers(SB) complying with 21 CFR 177.1810, and PS, RMPS, or SB complying with an effective FCN.

Limitations/Specifications:

Maximum use level of 1% by weight of the polymer. The finished polymers are intended to contact all types of food under Conditions of Use A through H, as described in <u>Tables 1 and 2</u> unless otherwise restricted by the applicable limitations for styrene block polymers in 177.1810 or in an effective FCN. See Attachment 1.

If we do not object to your notification prior to April 14, 2011, the notification will become effective on that date. If your notification becomes effective, it will be added to the list of effective notifications available on the agency's internet site. This can be accessed from the Internet in the

Food Ingredients and Packaging section under the Food Topic of <u>www.fda.gov.</u> The above description will be used by FDA to describe your notification should it become effective.

Accordingly, please review the description for technical accuracy and provide us with any comments within 30 days from the date of this letter. If your comments result in changes to the identity or intended use of the substance, FDA will evaluate whether the changes affect the adequacy of information in your original FCN. If that adequacy is affected, the agency will request additional information to support the changes in identity or intended use. A new 120-day statutory time period will begin the date we receive the requested information.

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

Sincerely,

Kelly M. Randolph, D.V.M., M.P.H.
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

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Attachment 1 - Definitions of Food Types and Conditions of Use for Food Contact Substances

These tables were created for easy reference for notifications relating to a food contact substance.

Table 1--Types of Raw and Processed Foods

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
 - A. Water-in-oil emulsions, high- or low-fat.
 - B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:
 - A. Containing up to 8 percent of alcohol.
 - B. Nonalcoholic.
 - C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
 - A. Moist bakery products with surface containing free fat or oil.
 - B. Moist bakery products with surface containing no free fat or oil.
- VIII. Dry solids with the surface containing no free fat or oil (no end test required).
- IX. Dry solids with the surface containing free fat or oil.

Table 2--Condition of use

- A. High temperature heat-sterilized (e.g., over 212 deg.F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg.F.
- D. Hot filled or pasteurized below 150 deg.F.
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
- H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
 - 1. Aqueous or oil-in-water emulsion of high- or low-fat.
 - 2. Aqueous, high- or low-free oil or fat.

- I. Irradiation
- J. Cooking at temperatures exceeding 250 deg.F.