

Food and Drug Administration College Park, MD 20740-3835

November 25, 2015

Bradley Lampe NSF International 789 N. Dixboro Rd.. Ann Arbor, MI 48104

RE: Food Contact Substance Notification (FCN) 001590

Final Letter

Dear Dr. Lampe:

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

### **Food Contact Substance (FCS)**

Chromium Nitride (CAS Reg. No. 24094-93-7).

#### **Notifier**

Euclid Refinishing Inc. DBA Surftech Inc.

## Manufacturer/Supplier

Euclid Refinishing Inc. DBA Surftech Inc.

### **Intended Use**

The FCS will be used as a component of surface coating on repeat-use food processing and food packaging equipment to prevent abrasive wear to the components of the equipment, except for use in contact with infant formula (see Limitations/Specifications).

## **Limitations/ Specifications**

The FCS will be applied at a maximum thickness of  $10~\mu m$  and the finished food-contact equipment will be used in contact with all food types, and under Conditions of use A through H, as described in Table 2 (see Attachment 1). The FCS is not for use in contact with infant formula. Such use was not included as part of the intended use of the substance in the FCN.

This is to inform you that as of November 25, 2015, FCN 001590 will become effective. It will be added to the list of effective notifications for FCNs which is available on our website: http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/Notifications/default.htm. The Agency has determined under 21 CFR 25.32(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor environmental impact statement is required.

This effective notification is applicable only to Chromium Nitride (CAS Reg. No. 24094-93-7). manufactured by Euclid Refinishing Inc. DBA Surftech 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 (FFDCA). 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 FFDCA prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FFDCA, 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,

Kenneth McAdams Consumer Safety Officer Division of Food Contact Notifications HFS-275 Office of Food Additive Safety Center for Food Safety and Applied Nutrition

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