U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

February 28, 2025

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RE: Food Contact Substance Notification (FCN) 002420
Final Letter

Dear Ms. Clark:

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

Food Contact Substance (FCS)
Carbon Black (Thermal Carbon Black or Thermal Black) (CAS Reg. No. 1333-86-4)

L Thermax N990CG. Only

Notifier
Cancarb Limited

Manufacturer/Supplier
Cancarb Limited

Intended Use
To improve the physical properties, like tensile strength, of repeat-use rubber articles, such as gaskets, hoses, tubing, O-rings, and conveyor belts, used as components of food processing equipment, except for use in contact with infant formula and human milk (see Limitations/Specifications).

Limitations/Specifications
The FCS will be used at levels not to exceed 50% by weight in the finished articles in compliance with 21 CFR 177.2600. The FCS is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCN.

This is to inform you that as of March 15, 2025, FCN 002420 will become effective. It will be added to the Inventory of Effective Food Contact Substance (FCS) Notifications which is available on our website at: https://www.fda.gov/food/packaging-food-contact-substances-fcs/inventory-effective-food-contact-substance-fcs-notifications.

The Agency has determined under 21 CFR 25.32 item (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 carbon black (thermal carbon black or thermal black) (CAS Reg. No. 1333-86-4) manufactured or prepared by Cancarb Limited 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 (FD&C Act). The existence of an effective notification for an FCS does not relieve use of the subject substance from compliance with any other provision of the FD&C Act or with Title 21 of the Code of Federal Regulations (21 CFR) §174.5 – General provisions applicable to indirect food additives. For example, in accordance with section 402(a)(3) of the FD&C 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 FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, 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,

Adriana K. Alexander -S

Digitally signed by Adriana K. Alexander -S
Date: 2025.02.28 13:21:33 -05'00'

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