



October 7, 2024

George C. Misko
Keller and Heckman LLP
1001 G Street NW, Suite 500 West
Washington, DC 20001

RE: Food Contact Substance Notification (FCN) 002380

Final Letter
Replaces FCN 1847

Dear Mr. Misko:

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

Food Contact Substance (FCS)

Carbon monoxide-ethylene-propylene terpolymer (CAS Reg. No. 88995-51-1)

Notifier

Hyosung Chemical Corporation

Manufacturer/Supplier

Hyosung Chemical Corporation

Intended Use

For use as articles or components of articles used in contact with food, except for use in contact with infant formula and human milk (see Limitations/Specifications).

Limitations/Specifications

The FCS may be used in contact with all food types under Conditions of Use A through H, and J (microwave-only containers) as described in Tables 1 and 2 (see Enclosure 1). 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 on September 28, 2024, FCN 002380 became 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 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 carbon monoxide-ethylene-propylene terpolymer (CAS Reg. No. 88995-51-1) manufactured or prepared by Hyosung Chemical Corporation 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(l) 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(l)(1)-(4) applies. In our review of this notification, FDA did not consider whether section 301(l) 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(l).

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
Division of Food Contact Substances
Office of Pre-Market Additive Safety
Office of Food Chemical Safety, Dietary Supplements, and
Innovation
Human Foods Program

Enclosure (1)

Enclosure 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.