

Memorandum

Date: May 28, 2024

From: Biologist, Environmental Team, Division of Science and Technology (HFS-255)

To: Sharon Koh-Fallet, Ph.D., Division of Food Contact Substances (HFS-275)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2353

Notifier: Chang Chun Petrochemical Co., Ltd.

Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
Date: 2024.06.04 16:58:14 -0400

Attached is the FONSI for FCN 2353, which is for the use of Ethylene-vinyl acetate-vinyl alcohol (EVOH) copolymers (CAS Reg. No. 26221-27-2). The FCS may be used (1) in base resins as a component of films, bottles, and molded articles, and (2) as a coating for paper and paperboard. This FONSI explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment dated March 27, 2024, may be made available to the public. We will post digital transcriptions of the FONSI and the environmental assessment on the agency's public website.

Please let us know if there is any change in the identity or use of the food contact substance.

Denis Wafula -S Digitally signed by Denis Wafula -S
Date: 2024.05.28 12:22:27 -0400

Denis Wafula, Ph.D.

Attachments: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2353, submitted by Chang Chun Petrochemical Co., Ltd. for the use of Ethylene-vinyl acetate-vinyl alcohol (EVOH) copolymers (CAS Reg. No. 26221-27-2). The FCS may be used (1) in base resins as a component of films, bottles, and molded articles, and (2) as a coating for paper and paperboard.

The FCS containing 17 to 40 percent ethylene units and 60 to 83 percent vinyl alcohol units by weight may be used:

1. in base resins as a component of films, bottles, and molded articles that may contact all foods, except those containing more than 8% alcohol, under Conditions of Use A through H as described in Tables 1 and 2.¹
2. in coatings for paper and paperboard at levels not to exceed 10 g/m² of the food-contact surface. The finished paper/paperboard is intended for use in contact with all foods, except those containing more than 8% alcohol, under Conditions of Use C through H and J (limited to microwave susceptor and microwave only container applications), as described in 1 and 2.

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.

The Office of Food Additive Safety has determined that allowing this notification to become effective will not significantly affect the quality of the human environment and, therefore, an environmental impact statement (EIS) will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA) dated March 27, 2024. The EA was prepared in accordance with 21 CFR 25.40. The EA is incorporated by reference in this Finding of No Significant Impact and is briefly summarized below.

Food-contact articles containing the FCS are expected to be disposed primarily through combustion, landfilling, or recycling at rates proportional to the national MSW disposal patterns for similar products. It is anticipated that due to EPA's regulations at 40 CFR Part 258, there will be no significant introduction of the FCS or its components into the environment resulting from land disposal of such articles. Incineration of food-contact articles containing the FCS will not significantly alter the emissions from properly operating MSW combustion facilities and will therefore not cause these facilities to threaten a violation of applicable emissions laws and regulations at 40 CFR Part 60 and/or relevant state and local laws. Recycling of food-contact articles containing the FCS is not expected to affect current recycling programs because substances similar to the FCS are commonly used in the manufacture of food-contact polymers and are thus encountered in the recycling stream. Based on market volume information provided in the confidential attachment to the EA, total annual emissions of greenhouse gases (GHG) resulting from disposal of items containing the FCS are expected to be below the 25,000 mT GHG reporting threshold described in 40 CFR 98.2. Therefore, no significant impacts are expected from incineration of the FCS at MSW combustion facilities.

Use of the FCS is not expected to result in a net increase in the use of energy and resources, because it is expected to substitute other similar or identical substances already in use. Manufacture of the FCS and its fabrication in food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of materials already in use.

No significant environmental impacts are expected from use and disposal of the FCS; therefore, mitigation measures have not been identified. The alternative of not allowing the FCN to become effective would be the continued use of the materials that the subject FCS would otherwise replace; such action would have no significant environmental impact.

¹ <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>

Consequently, we find that the use of the FCS as described in FCN 2353 will not significantly affect the quality of the human environment. Therefore, an EIS will not be prepared.

Prepared by **Denis Wafula -S** Digitally signed by Denis Wafula -S
Date: 2024.05.28 12:23:08 -0400'

Denis Wafula, Ph.D.
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by **Mariellen Pfeil -S** Digitally signed by Mariellen Pfeil -S
Date: 2024.06.04 16:58:57 -0400'

Mariellen Pfeil
Lead Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration