
Memorandum

Date: April 13, 2020

To: Elizabeth Furukawa, Ph.D., Division of Food Contact Substances, HFS-275

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

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2032 for 1,4-benzenedicarboxylic acid, (or dimethyl ester) polymer with 1,4-butanediol, adipic or sebacic acid, hexamethylene diisocyanate and further reacted with no more than 1 percent by weight of the polyhydric alcohol described in the notification.

Notifier: BASF Corporation

Attached is the FONSI for FCN 2032 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2032 is for the use of 1,4-benzenedicarboxylic acid, (or dimethyl ester) polymer with 1,4-butanediol, adipic or sebacic acid, hexamethylene diisocyanate and further reacted with no more than 1 percent by weight of the polyhydric alcohol described in the notification. This food contact substance is intended for use in single-use polyester films, coatings, and molded articles, except for use in contact with infant formula and human milk.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated January 30, 2020, may be made available to the public. We will post digital transcriptions of the FONSI and the EA 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.

Leah D. Proffitt

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance (FCS) Notification (FCN) 2032: submitted by BASF Corp., for the safe use of 1,4-benzenedicarboxylic acid, (or dimethyl ester) polymer with 1,4-butanediol, adipic or sebacic acid, hexamethylene diisocyanate and further reacted with no more than 1 percent by weight of the polyhydric alcohol described in the notification. The FCS is intended for use in single-use polyester films, coatings, and molded articles. The FCS may be used in contact with all food types under Conditions of Use A through H, as described in Table 2. The FCS is not intended for use in contact with infant formula and human milk

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 January 30, 2020. 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.

Items manufactured with the FCS are expected to be land disposed or combusted proportionately with disposal patterns described in U.S. Environmental Protection Agency's (EPA) report "Advancing Sustainable Materials Management: Facts and Figures 2016 and 2017." Discarded items will go to landfills or municipal solid waste (MSW) combustion facilities complying with 40 CFR Parts 258 and 60, respectively. Since these items will not be recycled, they will not interfere with recycling patterns. The FCS will not significantly alter the emissions from properly operating MSW combustion facilities, and incineration of the FCS will 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.

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 replace, to a certain extent, other 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.

Consequently, we find that use of the FCS for use in single-use polyester films, coatings, and molded articles as described in FCN 2032, will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by _____
Leah D. Proffitt
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Date: digitally signed 04-13-2020/10-27-2021*
* to correct a typographical error (Notifier header)

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

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