U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: December 29, 2021

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2181 for 1,3-benzenedicarboxylic acid, polymer with 1,3-benzenedimethanamine and hexanedioic acid (CAS Reg. No. 28628-75-3).

Notifier: Mitsubishi Gas Chemical Co., Inc.

To: Anita Chang, Ph.D., Division of Food Contact Substances (HFS-275)

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

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S Date: 2021.12.30 15:25:10 -05'00'

Attached is the FONSI for FCN 2181 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2181 is for the use of 1,3-benzenedicarboxylic acid, polymer with 1,3-benzenedimethanamine and hexanedioic acid (CAS Reg. No. 28628-75-3) as a as a non-food-contact layer in multilayer food contact applications where the FCS is separated from food by a food-contact polymer layer which is authorized of the intended use, 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 October 22, 2021, 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 -S
Digitally signed by Leah D. Proffitt -S
Date: 2021.12.29 10:31:34 -05'00'
Leah D. Proffitt

Attachment: Finding of No Significant Impact

cc: HFS-255 Proffitt
File: FCN No. 2181

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance (FCS) Notification (FCN) 2181: submitted by Mitsubishi Gas Chemical Co., Inc., for the safe use of 1,3-benzenedicarboxylic acid, polymer with 1,3-benzenedimethanamine and hexanedioic acid (CAS Reg. No. 28628-75-3) as a non-food-contact layer in multilayer food contact applications where the FCS is separated from food by a food-contact polymer layer which is authorized of the intended use, except 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 October 22, 2021. 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: 2018 Tables and Figures." 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 as a non-food-contact layer in multilayer food contact applications where the FCS is separated from food by a food-contact polymer layer which is authorized of the intended use, will not cause significant adverse impacts on the human environment. Therefore, an EIS will not be prepared.

Prepared by Leah D. Proffitt -S Digitally signed by Leah D. Proffitt -S Date: 2021.12.29 10:32:31 -05'00' Date: see electronic signature

Leah D. Proffitt
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: 2021.12.30 15:24:33 -05'00' Date: see electronic signature

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