

Memorandum

Date: May 9, 2023

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

To: Vivian Gilliam, Division of Food Contact Substances (HFS-275)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2288: Hexanedioic acid, polymer with hexahydro-2H-azepin-2-one and 1,6-hexanediamine (CAS Reg. No. 24993-04-2)

Notifier: UBE Corporation

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

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
Date: 2023.05.09 16:40:58 -04'00'

Attached is the FONSI for FCN 2288 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2288 is for the use of hexanedioic acid, polymer with hexahydro-2H-azepin-2-one and 1,6-hexanediamine (CAS Reg. No. 24993-04-2) as a component of multi-layer films intended to contact food, except 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.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment dated April 12, 2023, 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: 2023.05.09 15:39:25 -04'00'

Attachment: Finding of No Significant Impact (FONSI)

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2288, submitted by UBE Corporation for the use of hexanedioic acid, polymer with hexahydro-2H-azepin-2-one and 1,6-hexanediamine (CAS Reg. No. 24993-04-2) as a component of multi-layer films intended to contact with all types of food, except 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 will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA), dated April 12, 2023. The EA is incorporated by reference in this Finding of No Significant Impact and is briefly summarized below. The EA was prepared in accordance with 21 CFR 25.40.

The FCS is intended for use as a component of multi-layer films where it improves certain mechanical properties of the films. Finished food-contact materials containing the FCS will be widely distributed across the country, and therefore disposed of nationwide.

Food-contact articles containing the FCS are expected to be disposed primarily by landfilling or incineration at municipal solid waste (MSW) combustors. Food-contact articles containing the FCS are not expected to be significantly recycled. It is expected 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 food-contact articles containing the FCS. Incineration of food-contact articles containing the FCS will not significantly alter the emissions from properly operating MSW combustion facilities, and hence will not cause these facilities to threaten a violation of applicable emissions laws and regulations at 40 CFR Part 60. Based upon analysis of the 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.

Because the FCS is intended to be used as a substitute for other food-contact materials, its use as an alternative product is not anticipated to result in significant impacts on the use of energy and resources.

No potential adverse environmental effects are identified that would necessitate alternative actions to those proposed. The alternative of not approving the notified action would result in the continued use of the materials that the FCS would otherwise replace; such action would have no significant environmental impacts. Because no significant impacts are identified, mitigation measures are not required.

As evaluated in the EA, the use of the FCS as described in FCN 2288 will not significantly affect the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by **Denis Wafula -S** Digitally signed by Denis Wafula -S
Date: 2023.05.09 15:40:13 -04'00'

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: 2023.05.09 16:41:37 -04'00'

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