

Memorandum

Date: February 10, 2022

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

To: Laura Dye, Division of Food Contact Substances (HFS-275)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2209: Butanedioic acid, hydroxy-, polymer with butanedioic acid, 1,4-butanediol and 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (CAS Reg. No. 864132-20-7), optionally reacted with 1,6-diisocyanatohexane (CAS Reg. No. 822-06-0)

Notifier: Chang Chun Plastics Company, Limited

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

Mariellen Pfeil-S Digitally signed by Mariellen Pfeil -S
Date: 2022.02.11 12:25:31 -05'00'

Attached is the FONSI for FCN 2209 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2209 is for the use of Butanedioic acid, hydroxy-, polymer with butanedioic acid, 1,4-butanediol and 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (CAS Reg. No. 864132-20-7), optionally reacted with 1,6-diisocyanatohexane (CAS Reg. No. 822-06-0) in coatings, films, molded articles, and thermoformed articles. The FCS is for use in contact with all food types, except alcoholic foods, under Conditions of Use B through H as described in Tables 1 and 2.¹ 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.

After this FCN becomes effective, copies of this FONSI, and EA Revision Sheet and the notifier's environmental assessment dated November 19, 2021, 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
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Denis Wafula

Attachments: Finding of No Significant Impact

cc: HFS-255 Wafula

File: FCN No. 2209

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

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2209, submitted by Chang Chun Plastics Company, Limited for the use of Butanedioic acid, hydroxy-, polymer with butanedioic acid, 1,4-butanediol and 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (CAS Reg. No. 864132-20-7), optionally reacted with 1,6-diisocyanatohexane (CAS Reg. No. 822-06-0) in coatings, films, molded articles, and thermoformed articles. The FCS is for use in contact with all food types, except alcoholic foods, under Conditions of Use B through H as described in Tables 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 November 19, 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.

The FCS will be sold to manufacturers engaged in the production of food-contact articles; therefore, food-contact articles containing the FCS will be widely distributed across the country. Food-contact articles containing the FCS are not expected to be recycled. But rather, such articles will be disposed to sanitary landfills or by incineration at municipal solid waste (MSW) combustors. 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 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 and/or relevant state and local laws. Based upon an analysis using 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. Thus, the use of the FCS as proposed is not reasonably expected to result in significant environmental impacts.

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.

The use of the FCS, as described in FCN 2209, in coatings, films, molded articles, and thermoformed articles 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
Date: 2022.02.10 15:43:44 -05'00' Date: see electronic signature

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
Date: 2022.02.11 12:27:05 -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

U.S. Food and Drug Administration

Revision Sheet for the November 19, 2021 EA for FCN 2209

February 10, 2022

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of November 19, 2021 for food contact notification (FCN) 2209 concluded that the action will not constitute a significant impact. This revision is issued to inform the reader of the reason for the non-substantive changes made to the EA and also provide an explanation to an erroneously stated regulation.

Under Item 4. a) Requested Action

To be consistent with other sections of the FCN, the name of the FCS in the EA changes to *Butanedioic acid, hydroxy-, polymer with butanedioic acid, 1,4-butanediol and 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (CAS Reg. No. 864132-20-7), optionally reacted with 1,6-diisocyanatohexane (CAS Reg. No. 822-06-0).*

Under Item 6. Introduction of Substances into Environment

In discussing the landfill regulations (40 CFR Part 258) the notifier states that; 'Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collections systems, they are required to monitor ground water and take corrective action as appropriate.' **This part of the discussion should be ignored by the reader because it states a regulation that is only applicable to facilities that ceased accepting waste in 1993.**