

Memorandum

Date: December 5, 2022

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

To: Kenneth Mcadams, Division of Food Contact Substances (HFS-275)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2259: Oxirane, 2-methyl-, polymer with oxirane, ether with 1,2,3-propanetriol (3:1), polymer with 1,3-diisocyanato-2-methylbenzene and 2,4-diisocyanato-1-methylbenzene (CAS Reg. No. 68227-13-4)

Notifier: Diam Bouchage SAS

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

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
Date: 2022.12.08 11:07:41 -05'00'

Attached is the FONSI for FCN 2259 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2259 is for the use of oxirane, 2-methyl-, polymer with oxirane, ether with 1,2,3-propanetriol (3:1), polymer with 1,3-diisocyanato-2-methylbenzene and 2,4-diisocyanato-1-methylbenzene (CAS Reg. No. 68227-13-4) as a binder or adhesive in the manufacture of agglomerated cork stoppers. The FCS shall be used at levels not to exceed 32% by weight of finished agglomerated stoppers. The finished stoppers are for use in contact with wine, sparkling wine, and beer under Conditions of Use D through G, as described in Table 2.¹

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment dated August 22, 2022, 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: 2022.12.05 16:22:41 -05'00'

Denis Wafula

Attachment: Finding of No Significant Impact (FONSI)

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) 2259, submitted by Diam Bouchage SAS for the use of oxirane, 2-methyl-, polymer with oxirane, ether with 1,2,3-propanetriol (3:1), polymer with 1,3-diisocyanato-2-methylbenzene and 2,4-diisocyanato-1-methylbenzene (CAS Reg. No. 68227-13-4) as a binder or adhesive in the manufacture of agglomerated cork stoppers. The FCS shall be used at levels not to exceed 32% by weight of finished agglomerated stoppers. The finished stoppers are for use in contact with wine, sparkling wine, and beer under Conditions of Use D through G, as described in Table 2.

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 August 22, 2022. 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 to bind the components of agglomerated cork stoppers which are produced by natural cork granules and other components that require a binder or adhesive to bind the components together while maintaining desired viscoelastic properties of the stopper. Finished materials 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 and/or relevant state and local laws. 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.

The FCS is manufactured from raw materials that are already produced for various uses. Specifically, the FCS is intended to be used as a substitute for chemically identical or similar polyurethane resins that are already on the market for use in identical applications. Therefore, the use of the FCS 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 there are no significant impacts were identified, mitigation measures are not required.

As evaluated in the EA, the use of the FCS as described in FCN 2259 will not significantly affect the human environment. Therefore, an environmental impact statement will not be prepared.

Denis Wafula - S Digitally signed by Denis Wafula -S
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Prepared by _____

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

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Approved by _____

Mariellen Pfeil
Lead Biologist, Environmental Team
Office of Food Additive Safety
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