

## Memorandum

**Date:** July 24, 2023

**From:** Denis Wafula, Ph.D., Biologist, Environmental Team, Division of Science and Technology (HFS-255)

**To:** Jessica Urbelis, Ph.D., Division of Food Contact Substances (HFS-275)

**Subject:** Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2302

**Notifier:** Avient Corporation and its stewarded global affiliates

**Through:** Mariellen Pfeil, Lead Biologist, Environmental Team, Division of Science and Technology (HFS-255)

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S  
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Attached is the FONSI for FCN 2302, which is for the use of calcium hydride (CAS Reg. No. 7789-78-8) used in conjunction with platinum oxide (CAS Reg. No. 1314-15-4) or zeolite encapsulated platinum (CAS Reg. Nos. 63231-69-6 and 20634-12-2) as an oxygen scavenging system in closures. This FONSI explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

After this FCN becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated May 18, 2023, 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.

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Denis Wafula, Ph.D.

**Attachment:** Finding of No Significant Impact

## FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2302, submitted by Avient Corporation and its stewarded global affiliates for the use of calcium hydride (CAS Reg. No. 7789-78-8) used in conjunction with platinum oxide (CAS Reg. No. 1314-15-4) or zeolite encapsulated platinum (CAS Reg. Nos. 63231-69-6 and 20634-12-2) as an oxygen scavenging system in closures. Calcium hydride may be used in the non-food contact layer of a multi-layered inner liner for bottle closures at a level not to exceed 27 percent by weight. Platinum oxide or zeolite encapsulated platinum may be used in the food contact layer of a multi-layered inner liner for bottle closures at a level not to exceed 200 ppm platinum. Both the non-food contact layer containing calcium hydride and the food-contact barrier layer containing platinum may consist of any polymer regulated for use in contact with the food types and Conditions of Use listed below for the finished food contact article. The liner's food-contact surface area may not exceed 1.84 square inches. Finished closure liners may be used in contact with all foods under Conditions of Use C through G, as described in Table 2.<sup>1</sup> 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 May 18, 2023. The EA was prepared in accordance with 21 CFR 25.40. The EA is incorporated by reference in this Finding of No Significant Impact (FONSI) and is briefly summarized below.

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.

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 other oxygen scavenging systems 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.

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

As evaluated in the EA, the use of the FCS as described in FCN 2302 will not significantly affect the human environment. Therefore, an EIS will not be prepared.

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

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

**Mariellen Pfeil** -S Digitally signed by Mariellen Pfeil -S  
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Approved by

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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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