

Memorandum

Date: September 21, 2018

To: Kenneth McAdams, Consumer Safety Officer, Division of Food Contact Notification (HFS-275)
Through: Mariellen Pfeil, Supervisory Biologist, Environmental Review Team, Office of Food Additive Safety; HFS-255

From: Physical Scientist, Division of Biotechnology and GRAS Notice Review (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 1920: Polyurethane resin produced by reacting hexamethylene diisocyanate homopolymer (CAS Reg. No 28182-81-2) with castor oil (CAS Reg. No. 8001-79-4) for use as a binder or adhesive in the manufacture of agglomerated cork stoppers that contact alcoholic beverages. The stoppers will function as closures for alcoholic beverage containers, i.e., Food Types VI-A and VI-C, under Conditions of Use D through G, as described in FDA Tables 1 and 2. The FCS is for use at levels not to exceed 32% by weight of finished agglomerated cork stoppers. The FCS is not for use in contact with infant formula and human milk

Notifier: Diam Bouchage SAS

Attached is the FONSI for FCN 1920

After this FCN becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated August 31, 2018, 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

Antonetta Thompson-Wood

Attachment: FONSI

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN) 1920, submitted by Diam Bouchage SAS for the use of Polyurethane resin produced by reacting hexamethylene diisocyanate homopolymer (CAS Reg. No. 28182-81-2) with castor oil (CAS Reg. No. 8001-79-4) as a binder or adhesive in the manufacture of agglomerated cork stoppers that contact alcoholic beverages. The stoppers will function as closures for alcoholic beverage containers, i.e., Food Types VI-A and VI-C, under Conditions of Use D through G, as described in FDA Tables 1 and 2. The FCS is for use at levels not to exceed 32% by weight of finished agglomerated cork stoppers. The FCS is not for use in contact with infant formula and human milk

The Office of Food Additive Safety has determined that allowing FCN 1920 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 August 31, 2018. The EA is incorporated by reference in this Finding of No Significant Impact (FONSI) and is briefly summarized below. The EA was prepared in accordance with 21 CFR 25.40

Impacts to the Environment as a Result of Use and Disposal

The FCS is intended for use as a component of agglomerated cork stoppers used as closures for bottles containing alcoholic beverages; therefore, food-contact articles containing the FCS will be widely distributed across the country. Post-consumer disposal of cork stoppers manufactured with the FCS will be to landfills or municipal solid waste (MSW) combustors complying with 40 CFR Parts 258 and 60, respectively. Cork stoppers manufactured with the FCS may be recycled¹; however, it is not a widespread practice. No significant effect on the concentrations of and exposures to any substances in air, water or soil are anticipated. Due to EPA's regulations governing landfills at 40 CFR Part 258, leaching into the environment by cork stoppers manufactured with the FCS is not anticipated. The FCS is comprised of carbon, hydrogen, oxygen, and nitrogen and will not significantly alter the emissions from properly operating MSW combustion facilities. Further, incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations at 40 CFR Part 60, regulations for mandatory emissions reporting at 40 CFR Part 98, and/or other relevant state and local laws. Based upon an analysis using market volume information there are no significant impacts with respect to greenhouse gas emissions resulting from incineration of cork stoppers manufactured with the FCS. Thus, the use of the FCS as proposed is not reasonably expected to result in significant environmental impacts

Use of Resources and Energy

The FCS will replace similar materials now on the market for use in food-contact articles. Use of the FCS will consume energy and resources in amounts comparable to the manufacture and use of other, similar food-contact substances. As such, replacement by the FCS is not expected to have any significant impact on the use of energy and resources. Urethane-based resins are currently authorized for use in agglomerated cork stoppers that are currently recycled. Thus, there will be no impact on current or future recycling programs

Mitigation Measures

No significant adverse environmental impacts are expected to result from the use and disposal of closures fabricated from the FCS. Therefore, mitigation measures are not required

Alternatives to the Proposed Action

No significant adverse environmental effects were identified in the EA that would necessitate alternative actions for the proposed use in this Food Contact Notification. If the proposed action is not approved, the result would be the continued use of the materials that the FCS would replace. Such action would have no significant environmental impacts

As evaluated in the EA, the proposed use of the FCS as described in FCN 1920 is not expected to significantly affect the human environment; therefore, an environmental impact statement will not be prepared

Prepared by _____ Date: Digitally signed 9-21-18

Antonetta Thompson-Wood

Physical Scientist

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

Approved by _____ Date: Digitally signed 9-21-18

Mariellen Pfeil

Supervisory Biologist, Environmental Review Team, Office of Food Additive Safety

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¹See Earth 911, How to Recycle Corks (2018), available at <https://earth911.com/recyclingguide/how-to-recycle-corks/>