

Memorandum

Date: April 17, 2019

To: Ken McAdams, Consumer Safety Officer, Division of Food Contact Notification (HFS-275)

Through: Leah Proffitt, 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) 1975: 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) for use as a binder or adhesive in the manufacture of agglomerated cork stoppers.

Notifier: Amorim & Irmãos, S.A.

Attached is the FONSI for FCN 1975.

After this FCN becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated April 1, 2019, 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) 1975, submitted by Amorim & Irmãos, S.A. 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 18% by weight of finished agglomerated stoppers. The finished stoppers are for use in contact with wine, sparkling wine, and beer under Conditions of Use E through G, as described in FDA Table 2.

The Office of Food Additive Safety has determined that allowing FCN 1975 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 April 1, 2019. 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 binder or adhesive in the manufacture of agglomerated cork stoppers. Food-contact articles containing the FCS will be widely distributed across the country. Post-consumer disposal of food-contact articles containing the FCS will be to landfills or municipal solid waste (MSW) combustors complying with 40 CFR Parts 258 and 60, respectively. 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 food-contact articles manufactured with the FCS is not anticipated. Based upon an analysis using market volume information there are no significant impacts with respect to greenhouse gas emissions resulting from food-contact articles 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 and/or compete similar articles, such as 100% synthetic bottle closures. The manufacture of the FCS for the requested use is negligible and is therefore not anticipated to impact the energy and other resources required for the manufacture of such materials. Food-contact materials manufactured from the FCS are not expected to be collected for recycling.

Mitigation Measures

No significant adverse environmental impacts are expected to result from the use and disposal of food-contact articles manufactured 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 articles 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 1975 is not expected to significantly affect the human environment; therefore, an environmental impact statement will not be prepared.

Prepared by _____ Date: digitally signed on 04-19-2019

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 on 04-19-2019

Leah Proffitt

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