

## Memorandum

**Date:** February 21, 2017

**To:** Kenneth McAdams, Ph.D., Division of Food Contact Notifications (HFS-275)

**Through:** Leah Proffitt, Acting Environmental Supervisor, Office of Food Additive Safety, HFS-255

**From:** Biologist, Environmental Team, Division of Biotechnology and GRAS Notice Review (HFS-255)

**Subject:** Finding of No Significant Impact for food-contact notification (FCN) 1854

**Notifier:** Amorim & Irmãos, S.A. (Agent: Exponent, Inc.)

Attached is the Finding of No Significant Impact (FONSI) for FCN 1854 for use of polyurethane resin produced by reacting a mixture of 2,4-toluene diisocyanate (CAS Reg. No. 584-84-9) and 2,6-toluene diisocyanate (CAS Reg. No. 91-08-7) with polyoxyethylene-polyoxypropylene glyceryl ether (CAS Reg. No. 9082-00-2) and 1,4-butanediol (CAS Reg. No. 110-63-4) at levels not to exceed 18% by weight as a binder or adhesive in the manufacture of agglomerated cork stoppers that contact wine, sparkling wine, and microbrew beer under FDA Conditions of Use E through G.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated Jan. 5, 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.

Mariellen Pfeil

Attachment: Finding of No Significant Impact

## FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 1854), submitted by Amorim & Irmãos, S.A., to provide for the safe use of polyurethane resin produced by reacting a mixture of 2,4-toluene diisocyanate (CAS Reg. No. 584-84-9) and 2,6-toluene diisocyanate (CAS Reg. No. 91-08-7) with polyoxyethylene-polyoxypropylene glyceryl ether (CAS Reg. No. 9082-00-2) and 1,4-butanediol (CAS Reg. No. 110-63-4) at levels not to exceed 18% by weight as a binder or adhesive in the manufacture of agglomerated cork stoppers that contact wine, sparkling wine, and microbrew beer under FDA Conditions of Use E through G.

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, dated January 5, 2018. 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 improves compressibility, elasticity, and density in cork-granule stoppers compared with synthetic stoppers. Items containing the FCS are expected to be land disposed or combusted proportionately with disposal patterns

described in U.S. Environmental Protection Agency's (EPA) report "Advancing Sustainable Materials Management: Facts and Figures 2014." Recycling is not expected to be a significant disposal pathway. Discarded items will go to landfills or municipal solid waste (MSW) combustion facilities complying with 40 CFR Parts 258 and 60, respectively. The FCS will not significantly alter the emissions from properly operating MSW combustion facilities, and incineration of the FCS 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. Market volume information provided in a confidential attachment to the EA demonstrates that the FCS will comprise a very small portion of MSW, compared to overall MSW generated; this comparison uses EPA's 2014 MSW statistics.

According to information in a confidential attachment to the EA, total annual emissions of greenhouse gases (GHG) represented as CO<sub>2</sub>-equivalent (CO<sub>2</sub>-e) in metric tons (mT), are well 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.

Use of the FCS in the fabrication of agglomerated cork stoppers is not expected to result in a net increase in the use of energy and resources, because the FCS is intended to replace similar substances.

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 environmental impact. Consequently, we find that use of the FCS as a component of agglomerated cork stoppers used as closures for alcoholic beverage bottles, as described in FCN 1854, will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by \_\_\_\_\_ Date: digitally signed 02-21-2018

Mariellen Pfeil  
Biologist  
Office of Food Additive Safety  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration

Approved by \_\_\_\_\_ Date: digitally signed 02-21-2018

Leah D. Proffitt  
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