FDA U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: September 10, 2019

To: Kenneth McAdams, Consumer Safety Officer, Division of Food Contact Notification (HFS-275)
Through: Sarah C. Winfield, Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2002: 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).

Notifier: Flexpur – Polímeros de Poliuretano, S.A.

Attached is the FONSI for FCN 2002, which is for the use of polyurethane resin produced by reacting a mixture of 2,4-toluene diisocyanate and 2,6-toluene diisocyanate with polyoxyethylene-polyoxypropylene glyceryl ether and 1,4-butanediol 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.

After this FCN becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated August 2, 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: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2002, submitted by Flexpur – Polímeros de Poliuretano, S.A. for the 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) 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 (https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances, accessed 9/7/19). The Food Contact Substance (FCS) is for use at levels not to exceed 33% by weight of finished agglomerated stoppers.

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 August 2, 2019. 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.

The FCS is intended for use as a component of agglomerated cork stoppers used as closures for bottles containing alcoholic beverages (*i.e.*, Food Types VI-A ("Beverages: Containing up to 8 percent of alcohol") and VI-C ("Beverages: Containing more than 8% alcohol")) under FDA's Conditions of Use D ("Hot filled or pasteurized below 150°F") through G ("Frozen storage (no thermal treatment in the container)"). 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 waste combustors (MWC) complying with 40 CFR Parts 258 and 60, respectively. No significant impact 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. According to information in a confidential attachment to the EA, total annual emissions of greenhouse gases (GHG), including nitrous oxide (N2O), represented as CO2-equivalent (CO2-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. Thus, the use of the FCS as proposed is not reasonably expected to result in significant environmental impacts.

Use of the FCS is not expected to cause a significant impact on resources or energy. No mitigation measures are needed since no significant impacts are expected from use of the FCS. The alternative to not allowing the FCN to become effective would be continued use of currently approved binders or adhesives such action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2002 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 09-10-2019
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Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 09-10-2019
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