U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: April 6, 2023

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2265: Polyurethane resin produced by reacting 2,4-toluene diisocyanate (CAS Reg. No. 584-84-9) with polyoxyethylene-polyoxypropylene glycerol ether (CAS. Reg. No. 9082-00-2).

Notifier: FabriRes – Productos Quimicos S.A.

To: Kenneth McAdams, Ph.D., Consumer Safety Officer, Division of Food Contact Notification (HFS-275)

Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S Date: 2023.04.06 17:39:02 -04'00'

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2265, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2265 is for the use of polyurethane resin produced by reacting 2,4-toluene diisocyanate with polyoxyethylene-polyoxypropylene glycerol ether as a binder or adhesive in the manufacture of agglomerated cork stoppers that will function as closures for alcoholic beverage containers, i.e., Food Types VI-A and VI-C (up to 15% alcohol), under Conditions of Use E through G, as described in Table 2[1]. The FCS is for use at levels not to exceed 32% by weight of finished agglomerated stoppers. It is not intended for contact with infant formula and human milk; such uses were thus no included as part of the intended use of the substance in the FCN.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated March 23, 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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Attachment: Finding of No Significant Impact (FONSI)

[1] https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2265, submitted by FabriRes – Productos Quimicos S.A.for the use polyurethane resin produced by reacting 2,4-toluene diisocyanate with polyoxyethylene-polyoxypropylene glycerol ether intended for use in contact with alcoholic beverages (Food Types VI-A and VI-C – up to 15% alcohol), except in contact with infant formula and human milk, as specified below.

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 March 23, 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.

The FCS is intended for use of polyurethane resin produced by reacting 2,4-toluene diisocyanate with polyoxyethylene-polyoxypropylene glycerol ether as a binder or adhesive in the manufacture of agglomerated cork stoppers that will function as closures for alcoholic beverage containers, i.e., Food Types VI-A and VI-C (up to 15% alcohol), under Conditions of Use E through G, as described in Table 2[2]. The FCS is for use at levels not to exceed 32% by weight of finished agglomerated stoppers, and is also not intended for contact with infant formula and human milk. The FCS is expected to be entirely incorporated into and remain with the finished food-contact article.

Any waste materials generated in this process, e.g. plant scraps, are expected to be disposed of as part of the packaging manufacturer's overall non-hazardous solid waste in accordance with established procedures. Ultimate consumer disposal will be by conventional rubbish (sanitary landfill or incineration) and is not expected to be recovery through recycling.

Items manufactured with the FCS are expected to be utilized in patterns corresponding to the population and then disposed of via the disposal patterns described in the U.S. Environmental Protection Agency's (EPA) report, *Advancing Sustainable Materials Management: 2018 Fact Sheet*. Post-consumer disposal of food-contact articles containing the FCS will be by landfill disposal or incineration at municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively. The expected carbon dioxide equivalent emissions are below the 25,000 metric ton EPA reporting threshold (40 CFR 98).

Finally, the FCS is a polymer that does not readily volatize and virtually no leaching is expected; the FCS is therefore expected to remain with the finished food-contact article. Thus, no significant impact on the concentrations of and exposures to any substances in air, water, or soil are anticipated. Further, because of EPA's regulations governing emissions from MWCs, no significant impacts are expected from incineration of the FCS at MWCs. Thus, the use of the FCS as proposed is not expected to result in significant environmental impacts.

We do not expect a net increase in the use of energy and resources from the use of the FCS as notified here as this use will be substitutional to the same and similar materials already on the market.

[2] https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

Nor do we expect significant environmental impacts, which would necessitate mitigative actions. The alternative to not allowing the FCN to become effective would be continued use of materials that the FCS would otherwise replace; therefore, this action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2265 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by

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Approved by

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