
Memorandum

Date: January 15, 2021

To: Laura Dye, Consumer Safety Officer, Division of Food Contact Substances, HFS-275

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

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

Subject: Finding of No Significant Impact for Food Contact Notification 2102 (1,2-Benzisothiazolin-3-one [CAS Reg. No. 2634-33-5])

Notifier: Lanxess Corporation

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2102 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2102 is for the use of 1,2-Benzisothiazolin-3-one as an antimicrobial preservative, alone or in combination with other biocides, in aqueous preparation formulations for:

- (1) adhesives and polymers that will be used to fabricate layers or adhesives for laminate structures, complying with 21 CFR 177.1390 and 177.1395 or an effective FCN for laminate structures, and
- (2) pressure-sensitive adhesives complying with 21 CFR 175.125 or an effective FCN for a pressure sensitive adhesive to be used on labels to be affixed directly to food.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment, dated November 10, 2020, may be made available to the public. We will post digital transcriptions of the FONSI and the environmental assessment 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.

Denis Wafula

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2102, submitted by Lanxess Corporation for the use of 1,2-Benzisothiazolin-3-one (CAS Reg. No. 2634-33-5) as an antimicrobial preservative, alone or in combination with other biocides, in aqueous preparation formulations for:

- (1) adhesives and polymers that will be used to fabricate layers or adhesives for laminate structures, complying with 21 CFR 177.1390 and 177.1395 or an effective FCN for laminate structures, and
- (2) pressure-sensitive adhesives complying with 21 CFR 175.125 or an effective FCN for a pressure sensitive adhesive to be used on labels to be affixed directly to food.

The FCS is used at a level not to exceed 300 ppm (0.03 weight-percent) in the aqueous formulations and at levels not to exceed 0.1 mg/in² in both the finished laminate structure and the finished adhesive. The FCS is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCN 2102.

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 November 10, 2020. 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 an antimicrobial preservative in aqueous preparation formulations for adhesives and polymers that will be used in fabricating laminate structures and pressure sensitive adhesives. Food-contact articles manufactured with the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country.

The food-contact articles manufactured using the FCS will be used and disposed as municipal solid waste (MSW) either by landfilling, incineration, or to a lesser extent, recycling. Because of EPA's regulations governing landfills (40 CFR Part 258), the FCS is not expected to be introduced to land or water when food-contact articles manufactured using the FCS are disposed via landfill. Similarly, when combusted, the EA explains that there is nothing to suggest the FCS would threaten a violation of 40 CFR Part 60, the regulations governing MSW combustion facilities. This analysis is based on the composition of the FCS and the insignificant contribution of the FCS to the total volume of all combusted MSW. In a confidential attachment to the EA, greenhouse gas (GHG) emissions resulting from combustion of articles manufactured with the FCS are shown to be below the 25,000 mT GHG reporting threshold described in 40 CFR 98.2. Therefore, no significant environmental impacts are expected from incineration of the FCS at MSW combustion facilities. In conclusion, we do not expect a significant impact to the environment from the use of the FCS as specified in FCN 2102.

As indicated in the EA, we do not expect a net increase in the use of energy and resources from the notified use of the FCS, nor do we expect adverse environmental effects, which would necessitate alternative actions to that proposed in this FCN. The alternative of not approving the action proposed herein would result in the continued use of substances the FCS would otherwise replace; such action would have no environmental impact. Furthermore, as the use and disposal of the FCS is not expected to result in significant adverse environmental impacts; mitigation measures are not identified.

As evaluated in the EA, the use of the FCS, as described in FCN 2102 is not expected to significantly affect the human environment, and, therefore an EIS will not be prepared.

Prepared by _____ Date: digitally signed 01-15-2021

Denis Wafula, Ph.D.
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____ Date: digitally signed 01-15-2021

Mariellen Pfeil
Lead Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration