U.S. FOOD & DRUG ADMINISTRATION

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 2101 (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) 2101 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2101 is for the use of 1,2-Benzisothiazolin-3-one as a preservative in aqueous additive formulations such as latex emulsions, fillers, binders, mineral (pigment) slurries, and sizing solutions that comply with 21 CFR 176.170, 176.180 or an effective FCN for use in food-contact paper and paperboard, except for use in contact with infant formula and human milk.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment, dated November 10, 2020, and the EA revision sheet, 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

Attachments: Finding of No Significant Impact; EA Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2101, submitted by Lanxess Corporation for the use of 1,2-Benzisothiazolin-3-one (CAS Reg. No. 2634-33-5) as a preservative in aqueous additive formulations such as latex emulsions, fillers, binders, mineral (pigment) slurries, and sizing solutions that comply with 21 CFR 176.170, 176.180 or an effective FCN for use in food-contact paper and paperboard. The FCS is for use at a level not to exceed 300 ppm (0.03 weight-percent) in the aqueous formulation and at levels not to exceed 0.003 mg/in$_2$ in the finished paper and paperboard. 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 2101.

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 a preservative in aqueous additive formulations such as latex emulsions, fillers, binders, mineral (pigment) slurries, and sizing solutions that comply with 21 CFR 176.170, 176.180 or an effective FCN for use in food-contact paper and paperboard. 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 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 2101.

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 2101 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
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U.S. Food and Drug Administration
Revision Sheet for the November 10, 2020 EA for FCN 2101

January 15, 2021

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of November 10, 2020 for food contact notification (FCN) 2101 concluded that the action will not constitute a significant impact. This revision is issued to make minor corrections that should be acknowledged, while not making any substantive changes to the EA. These revisions do not impact our Finding of No Significant Impact (FONSI).

Under Item 4

1. The proposed action includes use in pigment (mineral) slurries and therefore should read as follows:

   'The proposed action is for the use of BIT as a preservative in aqueous additive formulations such as latex emulsions, fillers, binders, mineral (pigment) slurries, and sizing solutions that comply with 21 CFR 176.170, 176.180 or an effective FCN for use in food-contact paper and paperboard, except for use in contact with infant formula and human milk.'

2. The references cited in footnote 2 and footnote 3 are interchanged.