FDA U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: May 28, 2019

To: Sharon Koh-Fallet, Ph.D., Consumer Safety Officer, Division of Food Contact Substances (HFS-275)
Through: Sarah C. Winfield, Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 1970: 2-Bromo-2-nitro-1,3-propanediol (CAS Reg. No. 52-51-7) for use as a preservative in wet-end paper additives. The FCS may be used at a maximum level of 500 ppm in wet-end paper additives. The total use level of the FCS in finished paper may not exceed 54 g of the FCS per metric ton of dry weight fiber. The FCS is not for use in contact with infant formula and human milk.

Notifier: The Dow Chemical Company

Attached is the FONSI for FCN 1970.

After this FCN becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated March 27, 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: FONSI

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN) 1970, submitted by The Dow Chemical Company for the use of 2-Bromo-2-nitro-1,3-propanediol (CAS Reg. No. 52-51-7) as a preservative in wet-end paper additives. The FCS may be used at a maximum level of 500 ppm in wet-end paper additives. The total use level of the FCS in finished paper may not exceed 54 g of the FCS per metric ton of dry weight fiber. The FCS is not for use in contact with infant formula and human milk.

The Office of Food Additive Safety has determined that allowing FCN 1970 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 27, 2019. The EA is incorporated by reference in this Finding of No Significant Impact (FONSI) and is briefly summarized below. The EA was prepared in accordance with 21 CFR 25.40.

Impacts to the Environment as a Result of Use and Disposal
The FCS is intended for use as a preservative in wet-end paper additives. Food-contact articles containing the FCS will be widely distributed across the country. It is expected that food-contact articles containing the FCS will either be recycled or disposed in landfills or municipal solid waste (MSW) incinerators complying with 40 CFR Parts 258 and 60, respectively. No significant effect 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. Based upon an analysis using market volume information there are no significant impacts with respect to greenhouse gas emissions resulting from food-contact articles manufactured with the FCS. Thus, the use of the FCS as proposed is not reasonably expected to result in significant environmental impacts.

Use of Resources and Energy
The FCS will replace other similar polymer preservatives such as 2-methyl-4-isothiazolin-3-one, 2-n-octyl-4-isothiazolin-3-one, and other anti-microbial preservatives currently allowed in Inventory of Effective Food Contact Notifications, and so no significant change in energy use is expected based on the approval of the requested use.

Mitigation Measures
No significant adverse environmental impacts are expected to result from the use and disposal of food-contact articles manufactured from the FCS. Therefore, mitigation measures are not required.

Alternatives to the Proposed Action
No significant adverse environmental effects were identified in the EA that would necessitate alternative actions for the proposed use in this Food Contact Notification. If the proposed action is not approved, the result would be the continued use of the articles that the FCS would replace. Such action would have no significant environmental impacts.

As evaluated in the EA, the proposed use of the FCS as described in FCN 1970 is not expected to significantly affect the human environment; therefore, an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed 05/28/2019
Antonetta Thompson-Wood
Physical Scientist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 05/28/2019
Sarah C. Winfield
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U.S. Food and Drug Administration
Revision Sheet for the March 27, 2019 EA for FCN 1970

Dated: May. 28, 2019

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of March 27, 2019 for food contact notification (FCN) 1970 concluded that the action will not constitute a significant impact. The revision is issued to make a minor change and update of an editorial nature that should be acknowledged, while not making any substantive changes to the EA. This revision does not impact our Finding of No Significant Impact (FONSI).

The revision is necessary to explain the following:

Under Item 6. b. 3) Recycling, the EA states:

Recycled paper or cardboard food packaging material would be re-processed in paper mills to make paper pulp and then final paper/cardboard products. The potential environmental impact of the wastewater from paper mills is beyond the scope of this environmental assessment because environmental regulations for paper mills wastewater will mitigate any potential impact of the FCS in the wastewater. Further, paper mills are obligated to comply with pertinent stringent environmental regulations in terms of wastewater treatment and emission control.

We understand this discussion to mean the following: when recycled paper or cardboard containing the FCS is recycled, the FCS could partition to wastewater from paper mills and/or be part of the recycled paper. However, since the FCS is registered for use at paper mills in the U.S. under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), we understand that the paper mill industry is familiar with (and using) the FCS.[1], [2]

Furthermore, we believe if the FCS did partition to wastewater or become a part of recycled paper – it would be a negligible amount (since the FCS is expected to degrade).

Lastly, the Environmental Protection Agency (EPA) promulgates wastewater effluent guidelines for the paper industry under 40 CFR 430, and we understand that any environmental introduction of the FCS (from food contact articles containing the FCS but partitioning to wastewater when recycled) are expected to be mitigated via these regulations and guidelines.[3]

We also note that we did not rely on EA footnotes 2 and 3 to support the conclusion that the FCS will not impact recycling. Instead, we rely on the rationale and references discussed above.

[1] Bioban BP-Plus Preservative, EPA Registration Number: 464-675. *Accessed 4/23/19 at* https://www3.epa.gov/pesticides/chem_search/ppls/000464-00675-20170328.pdf
[2] BIOBAN BP-10 Preservative, EPA Registration Number: 464-680. Accessed 4/23/19 at https://www3.epa.gov/pesticides/chem_search/ppls/000464-00680-20180424.pdf
[3] please see https://www.epa.gov/eg/pulp-paper-and-paperboard-effluent-guidelines, accessed 4/23/19