

Memorandum

Date: April 19, 2019

To: Sharon Koh-Fallet, Ph.D., Division of Food Contact Notifications (HFS-275)

Through: Leah Proffitt, Biologist, Environmental Review Team, Office of Food Additive Safety, HFS-255

From: Chemist, Senior Science Advisor Staff (HFS-006)

Subject: Finding of No Significant Impact for FCN 1985 – 2-(dimethyl amino) ethanol (CAS Reg. No. 108-01-0) as a pH control agent in polyolefin dispersions for use as coatings on paper and paperboard, except for use in contact with infant formula and human milk.

Notifier: The Dow Chemical Company

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Notification (FCN) 1985, request for use of the FCS as a pH control agent in polyolefin dispersions for use as coatings on paper and paperboard, except for use in contact with infant formula and human milk. The FCS may be used at a level not to exceed 1.9 g/m² in polyolefin dispersions for use as coatings on paper and paperboard in contact with all types of food under Conditions of Use C through G.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated April 1, 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.

Talia A. Lindheimer

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN 1985), submitted by Dow Chemical Company to provide for the safe use of 2-(dimethylamino)ethanol (CAS Reg. No. 108-01-0) as a pH control agent in polyolefin dispersions for use as coatings on paper and paperboard, except for use in contact with infant formula and human milk. The FCS may be used at a level not to exceed 1.9 g/m² in polyolefin dispersions for use as coatings on paper and paperboard in contact with all types of food under Conditions of Use C through G, as described in Tables 1 and 2.¹

The Office of Food Additive Safety has determined that allowing this food contact notification (FCN) to become effective will not significantly affect the quality of the human environment and, therefore, will not require the preparation of an environmental impact statement. This finding is based on information submitted by the notifier in an environmental assessment, dated April 1, 2019, as summarized below. The EA is incorporated by reference in this Finding of No Significant Impact, and is briefly summarized below. The EA was prepared in accordance with 21 CFR 25.40.

The FCS is incorporated into food-contact articles that will be used and disposed of as municipal solid waste (MSW). MSW is either disposed of via landfill, incineration, or recycled. When landfilled, consistent with the EA, we expect the regulations at 40 CFR 258 to prevent environmental introduction of the FCS. When incinerated, as the EA states and we agree, the FCS is composed of carbon, hydrogen, nitrogen and oxygen (elements typical of MSW), we expect no issue for MSW incineration facilities operating in compliance with 40 CFR 60.

We have also verified the analysis demonstrating that greenhouse gas emissions resulting from the incineration of articles manufactured with the FCS at MSW combustion units will be below the 25,000 metric tons carbon dioxide equivalent threshold for mandatory reporting (40 CFR 98.2) and therefore, will not represent a significant environmental impact.

The EA as well as confidential information provided to us supports that the FCS expected to volatilize and be released to the air during the curing process. The information describes the technicalities and conditions of the curing process with the FCS and supports there will be no significant impact to paper and paperboard recycling operations. Furthermore, if any residual FCS were to remain, it will travel with the pulp slurry and be treated with other chemicals from the recycling process.

Use of the FCS is not expected to cause a significant impact on resources and energy. No mitigation measures are needed since no adverse 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 microbial agents; such action would have no significant environmental impact.

¹ <https://www.fda.gov/food/ingredientpackaginglabeling/packagingfcs/foodtypesconditionsofuse/default.htm>

As evaluated in the EA, the proposed use of the FCS as a pH control agent as described in FCN 1985 is not expected to significantly affect the human environment; therefore, an environmental impact statement will not be prepared.

Prepared by _____ Date: digitally signed 04/19/2019

Talia A. Lindheimer
Chemist
Office of the Center Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____ Date: digitally signed 04/19/2019

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Biologist
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