Memorandum

Date: August 12, 2020

From: Chemist, Division of Food Contact Notifications, HFS-275

To: K. Randolph, D.V.M., M.P.H., Consumer Safety Officer, Division of Food Contact Notifications, HFS-275
Through: Mariellen Pfeil, Supervisory Biologist, Environmental Review Team, Office of Food Additive Safety, HFS-255

Subject: Finding of No Significant Impact for Food Contact Notification 2079 (ethanol, 2-amino (CAS Reg. No. 141-43-5)).

Notifier: Omya International AG and its affiliates.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact substance Notification (FCN) 2079, which is for the use of 2-amino ethanol as a component of fillers at a maximum rate of 0.041 weight percent in finished paper and paperboard and as a component of coatings at a maximum rate of 0.01 weight percent in finished paper and paperboard. Finished food-contact articles containing the FCS may be used in single use applications, for contact with all food-types, including dry (powdered) infant formula, under Conditions of Use A through H.

After this notification becomes effective, copies of this FONSI, an environmental assessment (EA) revision sheet, and the notifier's environmental assessment, dated June 19, 2020, may be made available to the public. We will post digital transcriptions of the FONSI, EA revision sheet 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.

Daniel Chan

Attachments: Finding of No Significant Impact; EA Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2079, submitted by Steptoe and Johnson LLP., on behalf of Omya International AG and its affiliates, for the use of 2-amino ethanol as a component of fillers at a maximum rate of 0.041 weight percent in finished paper and paperboard and as a component of coatings at a maximum rate of 0.01 weight percent in finished paper and paperboard. Finished food-contact articles containing the FCS may be used in single use applications, for contact with all food-types, including dry (powdered) infant formula, under Conditions of Use A through H.

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 June 19, 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 dispersion and flotation agent for calcium carbonate that is in turn used as a filler and coating during the paper manufacturing process. The processing benefit provided by the FCS results in increased dispersion of the calcium carbonate filler added to food contact paper which in turn acts to increase brightness and opacity.

Manufacture of the FCS is not expected to result in significant environmental impact. Manufacture of food-contact articles containing the FCS is also not expected to result in a significant impact to the environment. When the FCS is used in coatings on food-contact articles, the process is a dry-end application, and all of the FCS remains with the coating, and all of the coating remains on the food-contact article. Finished paper and paperboard with a coating containing the FCS will be recycled or disposed of via municipal solid waste (MSW) disposal into landfills or to MSW combustors. On the other hand, when the FCS is used as a filler, the process is a wet-end application, and because the FCS is highly soluble in water it is expected to be lost with the white water associated with paper making. The FCS is not expected to significantly adsorb to sewage sludge as demonstrated by the low Kow partition coefficient. Following an approximate 95% biodegradation during wastewater treatment and a 10-fold dilution into surface water the estimated environmental concentration (EEC) is 0.5 ppm. This value is approximately three-fold lower than the 1.24 ppm NOEC (No Observed Effects Concentration) reproductive toxicity endpoint for the most sensitive species (Japanese killifish).

As noted above, when the FCS is used in coatings for paper and paperboard, the anticipated routes of disposal after use are expected to be recycling, landfilling or combustion in MSW incinerators. The FCS is not expected to impact recyclability as calcium carbonate coated paper is typical in the recycling stream, and the FCS will be less than 0.1% of the final food-contact article. When landfilled, the EA explains no environmental introduction is expected per 40 CFR 258, the regulations governing landfills. When combusted, the EA explains there is nothing to suggest the FCS would threaten a violation of 40 CFR 60, the regulations governing MSW combustion facilities (based on the composition of the FCS).

The EA also considered the impact of greenhouse gas (GHG) emissions. However, based on estimated market volume information provided in a confidential attachment to the EA, the total estimated GHG emissions resulting from the combustion of the FCS per FCN 2079, is below 25,000 metric tons CO2-e, the U. S. EPA threshold for mandatory reporting of GHG emissions (40 CFR 98.2). Therefore, significant impacts to the environment are not anticipated.

As indicated in the EA, we do not expect a net increase in the use of energy and resources from the 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 the materials which 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.

The use of the FCS, as described in FCN 2079, as a dispersion and flotation agent for calcium carbonate fillers and coatings for use in paper and paperboard food-contact materials, will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 08-12-2020
Daniel Chan
Chemist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 08-12-2020
Mariellen Pfeil
Supervisory Biologist
Environmental Review Team
Office of Food Additive Safety
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U.S. Food and Drug Administration
Revision Sheet for the June 19, 2020 EA for FCN 2079

The U.S. Food and Drug Administration (FDA) in its review of the June 19th, 2020 dated Environmental Assessment (EA) for food contact notification (FCN) 2079 concluded that the action will not constitute a significant impact. This revision is issued to make several minor changes and updates, 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 revisions are necessary to explain/clarify the following:

- In discussing the amount of paper and paperboard landfilled (EA section 4, page 2, 1st paragraph), the notifier mistakenly claims that 8,820 thousand tons were landfilled. This value is revised, according to the U.S. Environmental Protection Agency's 2017 update, to 5,460 thousand tons of paper and paperboard landfilled.[1]

- In EA section 6, part b (air (combustion)), page 6, 4th paragraph of the page, the notifier states that they calculate the potential environmental introduction of the FCS due to combustion of finished articles assuming that 5.3% of the market volume of the FCS will be combusted. However, in their confidential attachment, their calculations assume that 15.7% of the market volume of the FCS will be combusted. Therefore, the value is revised to 15.7%.

[1] Advancing Sustainable Materials Management: 2016 and 2017 Tables and Figures Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States, November 2019, Table 5A, *available at:* https://www.epa.gov/sites/production/files/2019-11/documents/2016_and_2017_facts_and_figures_data_tables_0.pdf .