U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: December 13, 2022

To: Sean Fischer, Ph.D., Division of Food Contact Substances (HFS-275)
Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Division of Science and Technology (HFS-255)

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S Date: 2022.12.14 13:35:33 -05'00'

From: Antonetta Thompson-Wood, Physical Scientist, Environmental Team, Division of Science and Technology (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2267: 2- Propenoic acid, polymer with 2,5-furandione, sodium salt (CAS Reg. No. 52255-49-9)

Notifier: Omya International AG and its Affiliates

Attached is the FONSI for FCN 2267, which is for the use of 2-Propenoic acid, polymer with 2,5-furandione, sodium salt (CAS Reg. No. 52255-49-9) (also referred to as MAPA) as a component of fillers or mineral coating for uncoated and clay-coated paper and paperboard. This FONSI explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

After this FCN becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated October 12, 2022, 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.

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Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2267, submitted by Omya International AG and its Affiliates for the use of 2-Propenoic acid, polymer with 2,5-furandione, sodium salt (CAS Reg. No. 52255-49-9) (also referred to as MAPA) as a component of fillers or mineral coatings for uncoated and clay-coated paper and paperboard. The FCS will be used at a maximum level of 0.07 percent by weight in the finished paper. The finished paper and paperboard containing the FCS may contact all food types under Conditions of Use A through H as described in FDA Tables 1 and 2. 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.

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 October 12, 2022. 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 in food-contact materials. Use of the FCS is needed to increase dispersion of the calcium carbonate filer added to food contact paper in order to increase brightness and opacity. Finished food-contact articles containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Disposal, recycling, and combustion rates of food contact articles manufactured with the FCS will correspond with The United States Environmental Protection Agency (US EPA) Advancing Sustainable Materials Management: 2018 Fact Sheet[1]. Post-consumer disposal of food-contact articles containing the FCS will be to landfills and municipal waste combustors (MWC) complying with 40 CFR Parts 258 and 60, respectively. No significant impact 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. Further, because of the regulations at 40 CFR Part 60, and others, no significant impacts are expected from incineration of the FCS at MWCs. Thus, the use of the FCS as proposed is not expected to result in significant environmental impacts.

The EA also considered the impact of greenhouse gas (GHG) emissions. Based on information provided in a confidential attachment to the EA, the total estimated GHG emissions resulting from the combustion of food-contact articles manufactured with the FCS in this notification is below 25,000 metric tons CO_2 equivalent, the US EPA threshold for mandatory reporting of GHG emissions (40 CFR 98.2). Therefore, no significant environmental impacts are anticipated.

The coating containing the FCS is applied during the dry-end of paper production where only evaporative losses would occur. Therefore, no loss of the FCS to processing water is anticipated. However, if it were, wastewater will be either discharged ultimately to a publicly owned treatment works (POTW), or, if in possession of a National Pollutant Discharge Elimination System (NPDES) permit, directly to surface waters after onsite treatment.

As a worst-case analysis, presuming addition of the FCS to the paper pulp/processing water mixture, the dosing amount of MAPA would be 168 ppm[2]. The FCS follows a 90:10 distribution to the pulp:process water. During wastewater treatment, the FCS again follows this distribution to wastewater treatment solids and is diluted a further ten-fold upon discharge to surface waters, resulting in an expected

[1] https://www.epa.gov/sites/production/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

[2] 0.07% is equal to 700 g MAPA/metric ton paper equal to 636 g MAPA/short ton paper ÷ 3,785 water/short ton paper/day = 168 ppm

aqueous environmental concentration (EEC) of 0.168 ppm. This concentration is below the toxicity endpoints for fish, invertebrates, and algae. Therefore, based on the low levels at which the product will be release into the environment and on available data regarding the toxicity of MAPA the potential release of the FCS in process whitewater is not expected to result in any significant environmental effects.

Manufacture of the FCS and its use finished food-contact articles will not result in a net increase in the use of energy and resources, will consume energy and resources in amounts comparable to the manufacture and use of similar paper and paperboard materials now on the market for use in food packaging applications. Therefore, no net increase in the use of energy and resources from the use and disposal of food-contact articles manufactured with the FCS is expected.

Due to its affinity for water, MAPA used in the filler application will remain with the whitewater in the processing plant. MAPA used in the coating application may be present in paper that is recycled. When the paper for recycling is re-pulped, the MAPA would be expected to dissolve into the pulp slurry and be treated as with other chemicals from the recycling process. As such, use of MAPA will have no effect on the recyclability of paper.

No mitigation measures are needed since no significant adverse environmental effects are expected from use and disposal of food-contact articles manufactured with the FCS, nor do we expect significant environmental impacts, which would necessitate alternative actions to those proposed in this FCN. The alternative to not allowing the FCN to become effective would be continued use of materials that the FCS would otherwise replace; therefore, this action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2267 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by

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