Memorandum

Date: March 10, 2020

To: V. Gilliam, M.S., 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

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

Subject: Finding of No Significant Impact for Food Contact Notification 2034 (copolymers of styrene (CAS Reg. No. 100-42-5), α-methylstyrene (CAS Reg. No. 98-83-9), butyl methacrylate (CAS Reg. No. 97-88-1), 2-ethylhexyl acrylate (CAS Reg. No. 103-11-7), methyl methacrylate (CAS Reg. No. 80-62-6), butyl acrylate (CAS Reg. No. 141-32-2), itaconic acid (CAS Reg. No. 97-65-4), methacrylic acid (CAS Reg. No. 79-41-4), hydroxypropyl acrylate (CAS Reg No. 999-61-1 and CAS Reg. No. 2918-23-2), sodium methallyl sulfonate (CAS Reg. No. 1561-92-8), and sodium styrene sulfonate (CAS Reg. No. 2695-37-6).

Notifier: Arakawa Chemical Industries, Ltd.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact substance Notification (FCN) 2034, which is for the use of copolymers of styrene (CAS Reg. No. 100-42-5), α-methylstyrene (CAS Reg. No. 98-83-9), butyl methacrylate (CAS Reg. No. 97-88-1), 2-ethylhexyl acrylate (CAS Reg. No. 103-11-7), methyl methacrylate (CAS Reg. No. 80-62-6), butyl acrylate (CAS Reg. No. 141-32-2), itaconic acid (CAS Reg. No. 97-65-4), methacrylic acid (CAS Reg. No. 79-41-4), hydroxypropyl acrylate (CAS Reg No. 999-61-1 and CAS Reg. No. 2918-23-2), sodium methallyl sulfonate (CAS Reg. No. 1561-92-8), and sodium styrene sulfonate (CAS Reg. No. 2695-37-6) for use as a dispersant for rosin sizing agents added prior to the sheet forming process in the manufacture of paper and paperboard, except for use in contact with infant formula and human milk.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment, dated January 31, 2020, 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.

Daniel Chan

Attachments: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2034, submitted by Arakawa Chemical Industries, Ltd., for the use of copolymers of styrene (CAS Reg. No. 100-42-5), α-methylstyrene (CAS Reg. No. 98-83-9), butyl methacrylate (CAS Reg. No. 97-88-1), 2-ethylhexyl acrylate (CAS Reg. No. 103-11-7), methyl methacrylate (CAS Reg. No. 80-62-6), butyl acrylate (CAS Reg. No. 141-32-2), itaconic acid (CAS Reg. No. 97-65-4), methacrylic acid (CAS Reg. No. 79-41-4), hydroxypropyl acrylate (CAS Reg No. 999-61-1 and CAS Reg. No. 2918-23-2), sodium methallyl sulfonate (CAS Reg. No. 1561-92-8), and sodium styrene sulfonate (CAS Reg. No. 2695-37-6) for use as a dispersant for rosin sizing agents added prior to the sheet forming process in the manufacture of paper and paperboard, except for use in contact with infant formula and human milk.

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 January 31, 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.

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 used as intended, a portion of the FCS will enter the facility wastewater processing system. The overall removal of high molecular weight polycarboxylates such as the FCS in conventional wastewater treatment is shown to range from 82-97%. After a 10-fold dilution into surface water, the estimated environmental concentration (EEC) is 0.2 ppm. This value is greater than 2 orders of magnitude lower than the 136 ppm acute toxicity EC50 endpoint for the most sensitive species (Hydra).

The paper and paperboard containing the FCS are anticipated to be disposed of through landfilling or combustion in municipal solid waste (MSW) incinerators. 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 2034, 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 2034, for use as a dispersant for rosin sizing agents added prior to the sheet forming process in the manufacture of paper and paperboard, will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 03-10-2020
Daniel Chan
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Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 03-10-2020
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