FDA U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Memorandum

Date: January 24, 2025

From: Biologist, Environmental Review Team, Office of Pre-Market Additive Safety

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2401

Notifier: BYK-Chemie GmbH

To: Lillian Mawby, Ph.D., Consumer Safety Officer, Office of Pre-Market Additive Safety, Division of Food Chemical Safety

Through: Mariellen Pfeil, Lead Biologist, Environmental Review Team, Office of Pre-Market Additive Safety

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Date: 2025.01.24 11:52:09 -05'00'

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2401, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2401 is for the use of Silicate(2-), hexafluoro-, disodium, reaction products with lithium magnesium sodium silicate (Type 1, containing fluorine) (CAS Reg. No. 85085-18-3), Lithium magnesium sodium silicate (Type 2, without fluorine) (CAS Reg. No. 53320-86-8), as a barrier additive in the production of food-contact: (1) adhesives, and (2) polymeric dispersions used as coatings for plastic, metal, and paper and paperboard.

The finished adhesives and polymeric dispersions used as coatings for plastic, metal, and paper and paperboard containing the FCS may contact all food types, except alcoholic foods, under Conditions of Use (COU) E through G, as described in Tables 1 and 2.[1] The maximum use level for the FCS in adhesives and coatings will not exceed 50%. The maximum application rate for adhesives or coatings containing the FCS is 10 grams/m2 (or 6.46 mg/in2). 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.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated August 29, 2024 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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Date: 2025.01.24 11:12:33 -05'00'

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Attachment: Finding of No Significant Impact (FONSI)

[1] https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2401, submitted by BYK-Chemie GmbH for the use of Silicate(2-), hexafluoro-, disodium, reaction products with lithium magnesium sodium silicate (Type 1, containing fluorine), Lithium magnesium sodium silicate (Type 2, without fluorine), as a barrier additive in the production of food-contact: (1) adhesives, and (2) polymeric dispersions used as coatings for plastic, metal, and paper and paperboard, excluding 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 August 29, 2024. 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 expected to be entirely incorporated into and remain with the finished food-contact polymer and will be sold to manufacturers engaged in the production of the finished food contact articles. Any waste materials generated in this process, e.g. plant scraps, are expected to be disposed of as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures. Items manufactured with the FCS are expected to be utilized in patterns corresponding to the population density and then disposed of nationwide via the disposal patterns described in the U.S. Environmental Protection Agency's (EPA) report, *Advancing Sustainable Materials Management: 2018 Fact Sheet*.[2] It was calculated that 80.9% of the food-contact materials containing the FCS will be placed in a landfill, resulting in 19.1% of food-contact materials containing the FCS to be combusted annually.

The EA notes that post-consumer disposal of food-contact articles manufactured with the FCS via landfill or incineration at municipal waste combustors (MWCs) will comply with 40 CFR Parts 258 and 60, respectively.

The FCS does not readily volatilize, is inorganic, insoluble, and non-combustible; as such, it is unlikely to present any impact on the atmospheric environment. Virtually no leaching of potential migrants from the finished food-contact article into aquatic or terrestrial environments indicates that there is no anticipated significant impact on environmental concentrations of the FCS, including during combustion of the food-contact articles. Thus, no significant impact on the concentrations of and exposures to any substances in air, water, or soil are anticipated. Further, because of EPA's regulations governing emissions from MWCs, no significant impacts are expected from incineration of the FCS at MWCs.

As the FCS is inorganic, greenhouse gas (GHG) emissions were not required due to the lack of carbon, as well as its nature as non-combustible.[3]

Use of the FCS is not expected to result in a net increase in the use of energy and resources, because it is expected to replace, to a certain extent, other substances already in use. Manufacture of the FCS will consume energy and resources in amounts comparable to the manufacture and use of materials already in use.

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[2] Advancing Sustainable Materials Management: 2018 Tables and Figures updated on December 2020 (https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf).

[3] According to U.S. Environmental Protection Agency (EPA) data for 2018, approximately 50.0% of municipal solid waste (MSW) is currently deposited in land disposal sites, 11.8% is combusted, 23.6% is recycled, 8.5% is composted, and 6.1% is directed to other food management pathways. As the FCS is expected to be primarily disposed of through combustion or land-filling (i.e., not recycled, composted, or handled through other food management pathways), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that 19.1% of food-contact materials containing the FCS will be combusted annually.

No significant environmental impacts are expected from use and disposal of the FCS; therefore, mitigation measures have not been identified. The alternative of not allowing the FCN to become effective would be the continued use of the materials that the subject FCS would otherwise replace; such action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2401 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by Brittany Ott -S Digitally signed by Brittany Ott -S Date: 2025.01.24 11:12:57 -05'00'

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