U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Memorandum

Date: March 17, 2025

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2419

Notifier: Dalian Bio-Chem Company Limited, Bester Trading Co., LTD

To: Jessica Urbelis, Ph.D., Consumer Safety Officer, Office of Pre-Market Additive Safety

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

MARIELLEN PFEIL -S Digitally signed by MARIELLEN PFEIL -S Date: 2025.03.17 14:37:47 -04'00'

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2419, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2419 is for the use of 2-Methyl-4-isothiazolin-3-one (CAS Reg. No. 2682-20-4), as:

1. An antimicrobial in uncured liquid rubber latex used to manufacture repeat-use rubber gloves;
2. A preservative in coatings that comply with 21 CFR 175.300 and 175.320;
3. A preservative in can-end and side-seam cements that comply with 21 CFR 175.300;
4. A preservative in aqueous formulations of adhesives that will be used under use conditions defined in 21 CFR 175.105;
5. A preservative in aqueous coating formulations to be used on paper under use conditions defined in 21 CFR 176.170;
6. A preservative in aqueous additive formulations (latex emulsions, fillers, binders, pigment slurries, and sizing solutions) used in paper and paperboard manufacturing to produce paper in compliance with 21 CFR 176.170 and 176.180;
7. A slimicide in the wet-end of paper manufacturing to produce paper in compliance with 21 CFR 176.170 and 176.180.

The FCS may be used in contact with all food types. The intended uses 2 through 6 may be used under Conditions of Use A through H, as described in Tables 1 and 2.[1] The maximum use level of the FCS:

1. In latex emulsions for the manufacture of repeat-use gloves is 250 ppm;

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

2. In aqueous emulsions for can coatings or polymeric coatings on polyolefin film is 100 ppm;
3. In aqueous emulsions for can-end or side-seam cement is 150 ppm;
4. In adhesives is 150 ppm;
5. In paper coating formulations is 150 ppm with the exception of latex emulsions in paper coatings, where the maximum level is 250 ppm;
6. In aqueous additive formulations for use in paper is 150 ppm;
7. In the wet-end process water of paper manufacture is 150 ppm of dry weight fiber

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 January 24, 2025 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.

Brittany Ott -S

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Attachment: Finding of No Significant Impact (FONSI)

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2419, submitted by Dalian Bio-Chem Company Limited and Bester Trading Co., LTD for the use of 2-Methyl-4-isothiazolin-3-one as an antimicrobial preservative in the manufacturing of food contact articles, 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 January 24, 2025. 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 will be sold to manufacturers engaged in the production of the finished food contact articles and is expected to be entirely incorporated into and remain with 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. Manufactured articles containing 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] The EA indicates that the fate of articles containing the FCS within municipal solid waste (MSW) is as follows: 80.9% will be disposed of through land-filling while 19.1% will be combusted annually, as the articles are not presumed to be recycled, composted, or handled through other food management pathways.

Post-consumer disposal of food-contact articles manufactured with the FCS will be via landfill or incineration at municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively. The expected annual carbon dioxide equivalent emissions, calculated according to the confidential annual market volume, are below the 25,000 metric ton EPA reporting threshold (40 CFR 98).

The FCS does not readily volatilize and will be cured within a food contact substance or article; as such, it is unlikely to present any significant impact on the atmospheric environment. Further, significant environmental release of any unique combustion products is not anticipated from the MWC incineration of the food-contact articles manufactured with the FCS. Although the FCS is highly water soluble and presents significant aquatic ecotoxicity concerns, it is noted that the FCS present in the consumer products is bound in the polymer matrix of the food-contact material. In the event of the FCS being added to the wet end of paper manufacture process, the FCS is not expected to be introduced into the environment downstream of wastewater treatment.[3]

Virtually no leaching of potential migrants nor any release of unique combustion products from the finished food-contact article into atmospheric, aquatic or terrestrial environments indicates that there is no anticipated significant impact on environmental concentrations of the FCS. Thus, no significant impact exposures to any

[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] EPA, 2014. Methylisothiazolinone / Chloromethylisothiazolinone Preliminary Work Plan. Registration Review: Initial Docket Case Number 3092. Federal Document ID EPA-HQ-OPP-2013-0605-0002. Based on the reported anaerobic and aerobic aquatic metabolism half-lives ranging from about 5 to 9 hours, rapid degradation of MIT is indicated. The straight chain degradates, including N-methylmalonamic acid (NMMA), are transient degradates that are rapidly biodegraded and were not reported to be formed at significant quantities in metabolism studies. In addition, these are not expected to enter surface water from wastewater treatment.

substances in air, water, or soil are anticipated. Therefore, no significant impacts are expected from disposal of the FCS.

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.

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 2419 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: 2025.03.17 14:26:55 -04'00'

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