



Memorandum

Date: April 14, 2026

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2511

Notifier: Cotek Specialties (Taicang) Co., Ltd.

To: Lillian Mawby, Ph.D., Regulatory Review Scientist, Office of Pre-Market Additive Safety, Division of Food Contact Substances

Through: Antonetta Thompson-Wood, M.S., Office of Pre-Market Additive Safety, Environmental Review Team

ANTONETTATHOMPSON-WOOD -S

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Date: 2026.04.14 10:17:33 -04'00'

Attached is the FONSI for FCN 2511, which is for the use of 2-methyl-4-isothiazolin-3-one (CAS Reg. No. 2682-20-4) as an antimicrobial in uncured liquid rubber latex used to manufacture repeat-use rubber gloves. 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 notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated February 4, 2026, 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.

Denis Wafula -S

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Date: 2026.04.14 09:22:07 -04'00'

Denis Wafula, Ph.D.

Attachments: Finding No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2511, submitted by Cotech Specialties (Taicang) Co., Ltd., for the use of 2-methyl-4-isothiazolin-3-one (CAS Reg. No. 2682-20-4) as an antimicrobial in uncured liquid rubber latex used to manufacture repeat-use rubber gloves intended for use in contact with all food types. The maximum level of the FCS in latex emulsions is 250 ppm. The FCS is not for use in contact with infant formula or 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 February 4, 2026. The EA is incorporated by reference in this Finding of No Significant Impact and is briefly summarized below. The EA was prepared in accordance with 21 CFR 25.40.

The FCS functions as an antimicrobial preservative within the uncured rubber latex solution, preventing bacterial degradation during the manufacturing process. The FCS is expected to be entirely incorporated into and remain with the glove and will be supplied to glove manufacturers or manufacturers who produce latex compounds used in glove manufacturing. The food-contact articles are expected to be discarded as municipal solid waste (MSW) and disposed of via landfill, MSW combustion facilities, or commercial/industrial solid waste incinerators. Due to EPA's landfill regulations (40 CFR Part 258), leaching into the environment by food-contact articles manufactured with the FCS is not anticipated. When combusted, the FCS is not expected to cause MSW combustion facilities to threaten violations of 40 CFR Part 60. Thus, no significant impact on the concentrations of and exposures to any substances in air, water, or soil are anticipated. Therefore, the use of the FCS as proposed is not expected to result in significant environmental impacts.

Based on the foregoing analysis, the use of the FCS as specified in FCN 2511 is not expected to significantly affect the quality of the human environment. As indicated in the EA, the notified use of the FCS is not expected to result in a net increase in energy or resource consumption, nor are adverse environmental effects anticipated that would necessitate consideration of alternative actions. 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 result in no environmental benefit or detriment. Furthermore, because the use and disposal of the FCS are not expected to result in significant adverse environmental impacts, no mitigation measures are necessary.

As evaluated in the EA, the use of the FCS, as described in FCN 2511, is not expected to significantly affect the human environment, and therefore an EIS will not be prepared.

Prepared by

Denis Wafula -S

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Denis Wafula, Ph.D.
Biologist, Environmental Review Team
Office of Pre-Market Additive Safety
Office of Food Chemical Safety, Dietary Supplements, and Innovation
Human Foods Program
Food and Drug Administration

Approved by

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