U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: September 30, 2020

To: Jacqueline Heilman, Ph.D., Consumer Safety Officer, Division of Food Contact Substances (HFS-275)
Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

From: Biologist, Environmental Team, Division of Science and Technology (HFS-255)

Subject: Finding of No Significant Impact for Food Contact Notification 2081 (2-methyl-4-isothiazolin-3-one, CAS Reg. No. 2682-20-4)

Notifier: LANXESS Corporation

Attached is the Finding of No Significant Impact (FONSI) for FCN 2081, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2081 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 intended for use in contact with all types of food. The FCS is not for use in contact with infant formula and human milk.

After this notification becomes effective, copies of this FONSI, revision sheet and the notifier's environmental assessment, dated August 28, 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.

Denis Wafula

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2081, submitted by LANXESS Corporation, for 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 types of food. 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 August 28, 2020 and a confidential attachment to the EA dated August 28, 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.

The FCS is intended for as an antimicrobial in uncured liquid rubber latex used to manufacture repeat-use rubber gloves intended for use in contact with all types of food. 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. 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. Furthermore, manufacture of food-contact articles per FCN 2081 will happen outside of the United States, under the jurisdiction of a foreign nation (and not in the global commons); therefore, an assessment of the environmental impact related to the manufacture of food-contact articles per FCN 2081 is outside the scope of the EA. The finished food-contact articles containing the FCS will be used and disposed of in the United States; therefore, the EA considers the potential environmental impact from use and disposal of the finished food-contact articles.

The food-contact articles manufactured per FCN 2081 are not expected to be significantly recycled but will rather be discarded as municipal solid waste (MSW) which will either reach a landfill or an MSW combustion facility. Because of EPA's regulations governing landfills (40 CFR Part 258) and the small amount of the FCS that would be landfilled (as disclosed in a confidential attachment to the EA), the FCS is not expected to be introduced to land or water when disposed via landfill. Similarly, when combusted, the EA explains that there is nothing to suggest the FCS would threaten a violation of 40 CFR Part 60, the regulations governing MSW combustion facilities. This analysis is based on the composition of the FCS and the Insignificant contribution of the FCS to the total volume of all combusted MSW. The EA also considered the impact of greenhouse gas (GHG) emissions resulting from combustion of articles manufactured with the FCS and provided an analysis in the confidential attachment to the EA. Total annual emissions of GHGs represented as carbon dioxide-equivalents (CO_2-e) in metric tons (mT), are well below the 25,000 mT GHG reporting threshold described in 40 CFR 98.2. Therefore, no significant environmental impacts are expected from incineration of the FCS at MSW combustion facilities. In conclusion, we do not expect a significant impact to the environment from the use of the FCS as specified in FCN 2081.

As indicated in the EA, we do not expect a net increase in the use of energy and resources from the notified 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.

As evaluated in the EA, the use of the FCS, as described in FCN 2081 is not expected to significantly affect the human environment, and, therefore an EIS will not be prepared.

Prepared by _____Date: digitally signed 09-30-2020
Denis Wafula, Ph.D.
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 09-30-2020
Mariellen Pfeil
Lead Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration