U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: May 3, 2022

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2217: Poly-1-butene homopolymer (CAS Reg. No.9003-28-5).

Notifier: LyondellBasell Industries

To: Vanee Komolprasert, Ph.D., Consumer Safety Officer, Division of Food Contact Notification (HFS-275)

Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S Date: 2022.05.03 16:42:06 -04'00'

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2217, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2217 is for the use of poly-1-butene homopolymer as the basic polymer in the production of articles intended to contact food, including infant formula and human milk. The FCS may be used in contact with all types of food under Conditions of Use A through H, as described in Tables 1 and 2[1]. The density of the FCS will range from 0.904 to 0.940 g/cm^3. The intrinsic velocity will not exceed 3.2 dl/g. Additives permitted for use in butene polymers complying with 21 CFR § 177.1570 or in olefin polymers complying with 21 CFR § 177.1520(c), items 3.1, and 3.2 may also be used in the FCS, subject to the prescribed limitations and specifications. The FCS may also be used in repeated-use articles (excluding baby bottle nipples) intended to contact infant formula and human milk.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated March 8, 2022 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 Digitally signed by Brittany Ott -S Date: 2022.05.03 16:04:59 -04'00'

Brittany Ott

Attachments: Finding of No Significant Impact (FONSI)

cc: HFS-255 Ott
File: FCN No. 2217

[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) 2217, submitted by LyondellBasell Industries for the use of poly-1-butene homopolymer as the basic polymer in the production of articles intended to contact food, including infant formula and human milk, as specified below.

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 March 8, 2022. 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 use as the basic polymer in the production of articles intended to contact food, including infant formula and human milk. The FCS may be used in contact with all types of food under Conditions of Use A through H, as described in Tables 1 and 2[2]. The density of the FCS will range from 0.904 to 0.940 g/cm^3. The intrinsic velocity will not exceed 3.2 dl/g. Additives permitted for use in butene polymers complying with 21 CFR § 177.1570 or in olefin polymers complying with 21 CFR § 177.1520(c), items 3.1, and 3.2 may also be used in the FCS, subject to the prescribed limitations and specifications. The FCS may also be used in repeated-use articles (excluding baby bottle nipples) intended to contact infant formula and human milk. The FCS is expected to be entirely incorporated into the finished food-contact article and will be sold to manufacturers engaged in the production of the finished food contact articles. Ultimate consumer disposal will be by conventional rubbish (sanitary landfill or incineration), and recycling of articles manufactured with the FCS is not anticipated.

Items manufactured with the FCS are expected to be utilized in patterns corresponding to the population and then disposed of via the disposal patterns described in the U.S. Environmental Protection Agency's (EPA) report, *Advancing Sustainable Materials Management: 2018 Fact Sheet*. Post-consumer disposal of food-contact articles containing the FCS will be by landfill disposal or incineration at municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively. The expected carbon dioxide equivalent emissions are below the 25,000 metric ton EPA reporting threshold.

Finally, migration and exposure estimates provided by the notifier show that there are no new or increased exposures to the oligomers, volatiles, and catalysts than those of similar materials cleared through Section 177.1570. As such, there are no anticipated impacts on the freshwater, atmospheric, or terrestrial environments.

We do not expect a net increase in the use of energy and resources from the use of the FCS as notified here as this use will be substitutional to the same and similar materials already on the market. Nor do we expect significant environmental impacts, which would necessitate mitigative actions. The alternative to not allowing the FCN to become effective would be continued use of materials that the FCS would otherwise replace; therefore, this action would have no significant environmental impact.

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

As evaluated in the EA, the proposed use of the FCS as described in FCN 2217 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: 2022.05.03 16:05:34 -04'00' Date: see electronic signature

Brittany Ott, Ph.D.
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S Date: 2022.05.03 16:44:08 -04'00' Date: see electronic signature

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