U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: April 8, 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) 2205: Naphtha (petroleum), light steam-cracked aromatic, piperylene concentrate, polymerized (CAS Reg. No. 68478-07-9).

Notifier: ExxonMobil Chemical Company

To: Paulina Piotrowski, 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: 2022.04.08 15:35:18 -04'00'

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2205, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2205 is for the use of naphtha (petroleum), light-steam cracked aromatic, piperylene concentrate, polymerized, as a component of pressure-sensitive adhesives used as the food contact surface of labels and tapes as provided in 21 CFR 175.125. These labels and tapes will be used at room temperature or below, with a use level up to 60 percent by weight of the total adhesive formulation. The FCS is not for use in contact with infant formula and human milk, and such uses are 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 November 4, 2021 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: 2022.04.08 10:01:17 -04'00'

Brittany Ott

Attachments: Finding of No Significant Impact (FONSI)

cc: HFS-255 Ott
File: FCN No. 2205

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2205, submitted by ExxonMobil Chemical Company for the use of naphtha (petroleum), light-steam cracked aromatic, piperylene concentrate, polymerized as a component of pressure-sensitive adhesives used as the food contact surface of labels and tapes as provided in 21 CFR 175.125, except for use in contact with 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 November 4, 2021. 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 an aliphatic hydrocarbon resin in the manufacture of pressure sensitive adhesives used as the food contact surface of labels and tapes as provided in 21 CFR 175.125. These labels and tapes will be used at room temperature or below, with a use level up to 60 percent by weight of the total adhesive formulation. The FCS will 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).

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. Articles manufactured with the FCS are not expected to be recycled to a significant extent. EPA's regulations governing landfills at 40 CFR Part 258, preclude leaching into the environment from food-contact articles manufactured with the FCS. Additionally, a full assessment of green house gas (GHG) emissions is provided in a confidential attachment to the EA. Based on estimated market volume information provided in a confidential attachment to the EA, the total annual emissions of the greenhouse gases (GHG) resulting from combustion of items manufactured with the FCS are expected to be below the 25,000 mT GHG reporting threshold described in 40 CFR 98.2.[1]

Finally, as the FCS does not readily volatilize during use and will be entirely incorporated into the finished food contact article, no significant exposures to air, water, or land environments are anticipated. Thus, the use of the FCS as proposed is not expected to result in significant environmental impacts.

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.

[1] This statement is supported by data contained in a Confidential Attachment provided by the notifier in conjunction with the EA.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2205 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Brittany Ott -S Digitally signed by Brittany Ott -S
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Prepared by _____ 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

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