
Memorandum

Date: October 23, 2020

To: Vivian Gilliam, 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)

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2097: polymer of butyl acrylate and 4-hydroxybutyl acrylate, with a methylene diphenyl diisocyanate-based crosslinker.

Notifier: Avery Dennison Corporation

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2097, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2097 is for the use of a polymer of butyl acrylate and 4-hydroxybutyl acrylate, with a methylene diphenyl diisocyanate-based crosslinker.

After this notification becomes effective, copies of this FONSI, an environmental assessment (EA) Revision Sheet, and the notifier's environmental assessment (EA) dated August 28, 2020 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

Attachments: Finding of No Significant Impact (FONSI); EA Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2097, submitted by Avery Dennison Corporation for the use of a polymer of butyl acrylate and 4-hydroxybutyl acrylate, with a methylene diphenyl diisocyanate-based crosslinker as an adhesive 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 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 for use as an adhesive with all types of food, including use as an adhesive for reclosure labels of packaging, except for use in contact with infant formula and human milk. These uses were not included as part of the intended use of the substance in the FCN. A coat weight 23 g/m² of this FCS will be used under Conditions of Use A (“High temperature heat-sterilized (e.g. over 212°F)”) through H (“Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use”).

No significant environmental release is expected upon the use of the subject FCS. In these applications, the FCS (i.e., a polymer) is expected to remain with the finished food-contact article. Any waste materials generated in this process are expected to be disposed of as part of the food-contact article manufacturer’s overall nonhazardous solid waste in accordance with established procedures. Disposal by the ultimate consumer of the subject FCS will occur by conventional rubbish disposal and hence, primarily by sanitary landfill or incineration.

Only extremely small amounts, if any, of the FCS constituents are expected to enter the environment as a result of the landfill disposal of food-contact articles. Of the marginal amount of the FCS that would be landfilled, only very small amounts of the FCS are expected to be introduced to land. Similarly, because of the composition of the FCS and the low market volume of the FCS, it is not anticipated that combustion of the FCS would threaten a violation of EPA regulations governing MSW combustion facilities (e.g., 40 CFR 60). The FCS is a relatively high molecular weight polymer and is therefore inherently non-volatile. Additionally, the polymeric nature of the FCS is expected to result in virtually no leaching of the FCS components under normal environmental conditions when articles containing the FCS are disposed in sanitary landfills. As such, no adverse effect on organisms in the environment is expected as a result of the FCS disposal. Further, the low production volume of food-contact articles containing the FCS precludes any substantial release of its components to the environment.

There is no significant impact anticipated on the concentrations of and exposures to any substances in the atmosphere due to the proposed use of the FCS. The composition of the FCS is similar to other MSW incinerated at MSW combustion facilities, and the use of the FCS will not exceed the EPA GHGRP threshold of 25,000 metric tons (40 CFR 98.2). Additionally, no significant effects are predicted on the concentrations of exposures to any substances in fresh water, estuarine, or marine ecosystems due to the proposed use of the subject polymer.

As is the case with other food packaging materials, the production, use and disposal of the FCS involves the use of natural resources such as petroleum products, coal, etc. However, the use of the subject FCS is not expected to result in a net increase in the use of energy and resources, as the FCS will be used in place of other adhesives on the market. Manufacture of the FCS and its conversion to use in food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of other, similar FCSs. Finally, there will be no significant impact on current recycling programs, as the subject FCS is expected to be disposed of according to the same patterns when they are used in place of the current materials.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2097 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed 10-23-2020

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 _____ Date: digitally signed 10-23-2020

Mariellen Pfeil Lead Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

U.S. Food and Drug Administration Revision Sheet for the August 28, 2020 EA for FCN 2097

October 23, 2020

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of August 28, 2020 for food contact notification (FCN) 2097 concluded that the action will not constitute a significant impact. This revision is issued to make a minor correction that should be acknowledged, while not making any substantive changes to the EA. This revision does not impact our Finding of No Significant Impact (FONSI).

The revision is necessary to remove wording that directs the reader to a confidential attachment (CA). As this document will not be available to the public, the direction of the reader to the CA must be removed.

Therefore, in Item 6) (Introduction of Substances into the Environment), the sentence, *“Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the confidential attachment to the EA, are below 25,000 metric tons on an annual basis.”*

Is revised to, *“Based on the confidential market volume, the expected carbon dioxide equivalent emissions (Confidential Attachment) are below 25,000 metric tons on an annual basis.”*