

Memorandum

Date: September 26, 2018

To: Vivian Gilliam, Consumer Safety Officer, Division of Food Contact Notifications, HFS-275

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

From: Biologist, Environmental Review Team, Division of Biotechnology and GRAS Notice Review, HFS-255

Subject: Finding of No Significant Impact for Food Contact Notification 1918 (Hydrocarbons, C6-C20, polymers, hydrogenated, CAS reg. No. 69430-35-9)

Notifier: Eastman Chemical Company

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 1918, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

The Food Contact Substance (FCS) that is the subject of FCN 1918 is hydrocarbons, C6-C20, polymers, hydrogenated. The FCS is intended for use as a component of:

1. Pressure sensitive adhesive formulations
2. Resinous and polymeric coatings for polyolefin films
3. Can-end cement formulations
4. Coatings for paper and paperboard
5. Adhesives for seals of food-contact, glass containers

The FCS will be used at levels not to exceed 60 percent by weight of total polymer/formulation weight in contact with all types of food under Conditions of Use B through H. The FCS is not for use in contact with infant formula and/or human milk. Such uses were not included as part of the intended use of the substance in the FCN.

After this notification becomes effective, copies of this FONSI, revision sheet and the notifier's environmental assessment, dated August 31, 2018, may be made available to the public. We will post digital transcriptions of the FONSI, revision sheet 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.

Sarah C. Winfield

Attachments: Finding of No Significant Impact
Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 1918, submitted by Eastman Chemical Company for the use of hydrocarbons, C6-C20, polymers, hydrogenated (CAS Reg. No. 69430-35-9), when used:

1. As a component of pressure sensitive adhesive formulations complying with 21 CFR 175.125;
2. As a component of resinous and polymeric coatings for polyolefin films complying with 21 CFR 175.320;
3. As a component of can-end cement formulations complying with 21 CFR 175.300(b)(3)(xxxi);
4. As a component of coatings for paper and paperboard complying with 21 CFR 176.170 and 21 CFR 176.180;
and
5. As a component of adhesives for seals of food-contact, glass containers complying with 21 CFR 177.1210.

The FCS is intended to be used at levels not to exceed 60 percent by weight of total polymer/formulation weight in contact with all types of food under Conditions of Use B through H, as described in Table 2.¹ 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.

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 31, 2018. 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 a component of:

1. Pressure sensitive adhesive formulations,
2. Resinous and polymeric coatings for polyolefin films,
3. Can-end cement formulations,
4. Coatings for paper and paperboard, and
5. Adhesives for seals of food-contact, glass containers.

Once the FCS-containing food contact articles are made, they will be used and then disposed (recycled, landfilled or combusted). We do not expect an impact to recycling, as the FCS is like existing FCSs and will be used in the same manner. The food contact articles made with the FCS that are not recycled will be disposed of in a landfill or combusted. Based on confidential market volume information provided in a confidential attachment to the EA, the FCS will make up a very small portion of the total municipal solid waste (MSW) landfilled and combusted (even when assuming none of the FCS is recycled, which overestimates the amount landfilled and combusted). Because of the Environmental Protection Agency's (EPA's) regulations governing landfills (40 CFR Part 258) and the marginal amount of the FCS that would be landfilled, the FCS is not expected to be introduced to land or water when disposed via landfill. Similarly, when combusted, there is nothing to suggest the FCS would threaten a violation of 40 CFR 60, the regulations governing MSW combustion facilities (based on the composition of the FCS and the marginal amount of FCS compared to all combusted MSW). The EA also considered the impact of greenhouse gas (GHG) emissions in the confidential attachment. The EA confidential attachment estimates the total annual emissions of GHGs, represented as carbon dioxide-equivalents (CO₂-e) in metric tons (mT). The GHG estimate is well below the 25,000 mT GHG reporting threshold described in 40 CFR 98.2. Therefore, no significant impacts are expected from incineration of the FCS at MSW combustion facilities. In sum, we do not expect a significant impact to the environment from the use of the FCS as specified in FCN 1918.

¹ <https://www.fda.gov/food/ingredientspackaginglabeling/packagingfcs/foodtypesconditionsofuse/default.htm>, accessed 9/25/18
www.fda.gov

As indicated in the EA, we do not expect a net increase in the use of energy and resources from the 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 1918, as a component of:

1. Pressure sensitive adhesive formulations,
2. Resinous and polymeric coatings for polyolefin films,
3. Can-end cement formulations,
4. Coatings for paper and paperboard, and
5. Adhesives for seals of food-contact, glass containers,

will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: Digitally signed 9/26/2018

Sarah C. Winfield

Biologist

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

Approved by _____ Date: Digitally signed 9/26/2018

Mariellen Pfeil

Supervisory Biologist, Environmental Review 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 31, 2018 EA for FCN 1918****Dated: September 26, 2018**

U.S. Food and Drug Administration (FDA) in its review of the August 31, 2018 Environmental Assessment (EA) for Food Contact Substance Notification (FCN) 1918 concluded that the action will not constitute a significant impact. The revision is issued to make a minor change and update of an editorial nature 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 clarify the following:

- On page 2, the EA states:

In some of the above applications, specifically, can-end cement formulations, coatings for paper and paperboard, and seals for glass containers, the articles in which the FCS will be used may be collected for recycling.

As discussed in the FONSI, some applications of the FCS (*i.e.*, can-end cement formulations, coatings for paper and paperboard, and seals for glass containers) may be recycled. We do not anticipate an impact to recycling as the FCS is very similar to existing FCSs used for the same applications.

- On page 2, the EA continues:

In the other of the above applications, namely, pressure sensitive adhesives and coated polyolefin films, the articles in which the FCS will be used are not expected to be collected for recycling to a significant extent, except potentially as a part of a mixed plastics recycling stream. Thus, it is estimated that approximately 80.4% of the materials will be deposited in land disposal sites and 19.6% will be combusted.

Again, as discussed in the FONSI, assuming none of the FCS is recycled overestimates the amount of FCS landfilled and combusted. Since we have identified no impact to recycling, and this approach overestimates the amount of the FCS landfilled and combusted, we consider this approach protective.