
Memorandum

Date: August 10, 2018

To: Jessica Urbelis, Ph.D., 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 1912 (Polypropylene, CAS Reg. No. 9003-07-0)

Notifier: Idemitsu Kosan Co., Ltd.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 1912, 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 1912 is polypropylene. The FCS is intended for use as an additive in single-use polyolefin food contact articles at a level not to exceed 50 weight percent. The finished article containing the FCS may contact all food types under Conditions of Use A 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 July 2, 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) 1912, submitted by Idemitsu Kosan Co., Ltd. for the use of polypropylene (CAS Reg. No. 9003-07-0) as an additive in single-use polyolefin food contact articles. The melting point of the FCS is between 65 – 80 °C, and the softening point is between 85 – 120 °C as determined by the ring and ball method. The FCS may be used at a level not to exceed 50 weight percent in polyolefin food contact articles complying with 21 CFR 177.1520. The finished article containing the FCS may contact all food types under Conditions of Use A through H, as described in Tables 1 and 2.¹ 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.

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 July 2, 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 an additive in single-use polyolefin food contact articles. 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 good manufacturing practices of polymers include proper labeling of end use articles to inform both users and recyclers. 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 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 1912.

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.

¹ <https://www.fda.gov/food/ingredientpackaginglabeling/packagingfcs/foodtypesconditionsofuse/default.htm>, accessed 6/21/18
www.fda.gov

As evaluated in the EA, the use of the FCS, as described in FCN 1912, as an additive in single-use polyolefin food contact articles, will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: Digitally signed 8/10/2018

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 8/10/2018

Mariellen Pfeil
Supervisory Biologist, Environmental Review Team
Office of Food Additive Safety
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U.S. Food and Drug Administration

Revision Sheet for the July 2, 2018 EA for FCN 1912

Dated: August 10, 2018

U.S. Food and Drug Administration (FDA) in its review of the July 2, 2018 Environmental Assessment (EA) for Food Contact Substance Notification (FCN) 1912 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 explain the following:

- On page 1, the EA states “According to the U.S. Environmental Protection Agency’s 2014 update regarding municipal solid waste in the United States, 52.6% of municipal solid waste generally was land disposed, 12.8% was combusted and 34.6% was recovered for recycling.” We note that 34.6% was recovered for recycling **and composting** (text bolded to highlight what was left out of the EA).
- On page 1, continuing onto page 2, the EA states:

“FCS is used by blending with other polymers to produce not only recycled food contact substances but also non-recycled food contact substances. Accordingly, even if used to recycleable food contact materials, it is difficult to classify into specific ‘recycleable’ Resin Identification Code.”

We understand these sentences to mean the FCS may be blended with other polymers to make recyclable or non-recyclable food contact articles. If the FCS is blended with polypropylene (PP), then the food contact article may be marked with Resin Identification Code 5 or 05 (PP), and enter the recycling stream. The FCS is not expected to change the properties of PP to an extent that would impact PP recycling. If the FCS is mixed with non-PP polymers the final blend of polymers that constitute the food contact article will be marked with Resin Identification 7 or 07 (OTHER category) and likely not accepted for recycling. Our understanding is informed by the EA, and by correspondence with the notifier.

The EA analysis then proceeds, assuming none of the FCS is recycled. 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.

- On page 3, the EA states “... the FCS will make up a very small portion of the total municipal solid waste currently combusted (indicated to be 33.1 million U.S. tons or 12.8% of million tons in 2014). We note that the EA should state “12.8 % of **258 million tons of municipal solid waste** in 2014.” The bolded text indicates the numbers and words left out of the EA.