
Memorandum

Date: May 6, 2021

To: Anita Chang, PhD., Division of Food Contact Substances (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) 2120 for paraffin waxes and hydrocarbon waxes, oxidized (CAS Reg. No. 68153-22-0).

Notifier: Sasol Ltd.

Attached is the FONSI for FCN 2120 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2120 is for the use of paraffin waxes and hydrocarbon waxes, oxidized (CAS Reg. No. 68153-22-0), as described below.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated March 9, 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.

Leah D. Proffitt

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance (FCS) Notification (FCN) 2120: submitted by Sasol, Ltd., for the safe use of paraffin waxes and hydrocarbon waxes, oxidized (CAS Reg. No. 68153-22-0). The FCS will be used as a component of:

1. Resinous and polymeric coatings complying with 21 CFR 175.300;
2. Resinous and polymeric coatings on polyolefin films complying with 21 CFR 175.320;
3. Coatings for paper and paperboard complying with 21 CFR 176.170 and 21 CFR 176.180;
4. Defoaming agents used in the manufacture of paper and paperboard complying with 21 CFR 176.210;
5. Cellophane complying with 21 CFR 177.1200;

Except for use in contact with infant formula and human milk (see Limitations/Specifications).

Limitations/Specifications

1. The FCS is intended for use without limitation as a component of defoaming agents used in the manufacture of paper and paperboard intended to contact all types of food under Conditions of Use A through H.
2. When used as a component of resinous and polymeric coatings complying with 21 CFR 175.300, resinous and polymeric coatings on polyolefin films complying with 21 CFR 175.320, coatings for paper and paperboard complying with 21 CFR 176.170 and 21 CFR 176.180, and cellophane complying with 21 CFR 177.1200, the FCS will be used at levels not to exceed 2% by weight of finished food-contact articles or coatings intended to contact all types of food under Conditions of Use A through H.

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 9, 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 and is briefly summarized below.

Items manufactured with the FCS are expected to be land disposed or combusted proportionately with disposal patterns described in U.S. Environmental Protection Agency's (EPA) report "Advancing Sustainable Materials Management: 2018 Tables and Figures." Discarded items will go to landfills or municipal solid waste (MSW) combustion facilities complying with 40 CFR Parts 258 and 60, respectively. Since these items will not be recycled, they will not interfere with recycling patterns. The FCS will not significantly alter the emissions from properly operating MSW combustion facilities, and incineration of the FCS will not cause these facilities to threaten a violation of applicable emissions laws and regulations at 40 CFR Part 60 and/or relevant state and local laws.

In addition, effluent containing the FCS from the fabrication of food-contact pulp- and paperboard is expected to be discharged to surface waters after pre-treatment in accordance with the point source category requirements promulgated at 40 CFR Part 230 for the pulp, paper, and paperboard industry sector. Any resulting sludge may be either landfilled or applied as an agricultural amendment. The effective environmental concentrations (EEC) for sludge and water are estimated to be 20 mg/L and 2 mg/L, respectively. Although no aquatic toxicity results exist for the FCS itself, tests on comparable paraffin waxes have shown no acute or chronic aquatic toxicity. Similarly, data available in summary reports for related wax materials report no effects at saturation for 1-tetradecene for aquatic plants (72/96-h EC50). As for the terrestrial compartment, due to the high molecular weight of the FCS, no leaching is expected.

Total annual emissions of greenhouse gases (GHG) resulting from disposal of items containing the FCS, are expected to be 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.

Use of the FCS is not expected to result in a net increase in the use of energy and resources, because it is expected to replace, to a certain extent, other substances already in use. Manufacture of the FCS and its fabrication in food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of materials already in use.

No significant environmental impacts are expected from use and disposal of the FCS; therefore, mitigation measures have not been identified. The alternative of not allowing the FCN to become effective would be the continued use of the materials that the subject FCS would otherwise replace; such action would have no significant environmental impact.

Consequently, we find that use of the FCS as specified above, will not cause significant adverse impacts on the human environment. Therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed 05-06-2021

Leah D. Proffitt

Biologist, Environmental Team

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

Approved by _____ Date: digitally signed 05-06-2021

Mariellen Pfeil

Lead Biologist, Environmental Team

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration