FDA U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: August 21, 2019

To: Kenneth McAdams, Division of Food Contact Substances (HFS-275)
Through: Sarah C. Winfield, Biologist, Environmental Team, Office of Food Additive Safety, HFS-255

From: Chemist, Senior Science Advisor Staff, Office of the Center Director (HFS-006)

Subject: Finding of No Significant Impact for Food Contact Substance Notification (FCN) 2001 for a mixture of 1-decene, polymer with sulfur dioxide (CAS Reg. No. 33990-98-6); 1,3-propanediamine, N1-(9Z)-9-octadecen-1-yl-, polymer with 2-(chloromethyl)oxirane (CAS Reg. No. 1010121-89-7); and dodecylbenzenesulfonic acid (CAS Reg. No. 27176-87-0).

Notifier: Innospec Ltd.

Attached is the Finding of No Significant Impact (FONSI) for FCN 2001 for use of a mixture of 1-decene, polymer with sulfur dioxide (CAS Reg. No. 33990-98-6); 1,3-propanediamine, N1-(9Z)-9-octadecen-1-yl-, polymer with 2-(chloromethyl)oxirane (CAS Reg. No. 1010121-89-7); and dodecylbenzenesulfonic acid (CAS Reg. No. 27176-87-0), as an antistatic agent in the production of polyethylene and polypropylene polymers and copolymers used in food-contact applications. The FCS is intended for (1) use at levels not to exceed 20 parts per million (ppm) when intended to be used in contact with all food types under all conditions of use, except for use in contact with infant formula and human milk and (2) use at levels not to exceed 4 parts per million (ppm) in high-density polyethylene and polypropylene polymers and copolymers intended for use in contact with infant formula and human milk under Conditions of Use A through H, as described in Table 2.

After this notification becomes effective, copies of this FONSI and the notifier's Environmental Assessment (EA), dated August 13, 2019, 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.

Talia A. Lindheimer

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance (FCS) Notification (FCN) 2001, submitted by Innospec Ltd. for the use of a mixture of 1-decene, polymer with sulfur dioxide (CAS Reg. No. 33990-98-6); 1,3- propanediamine, N1-(9Z)-9-octadecen-1-yl-, polymer with 2-(chloromethyl)oxirane (CAS Reg. No. 1010121-89-7); and dodecylbenzenesulfonic acid (CAS Reg. No. 27176-87-0), as an antistatic agent in the production of polyethylene and polypropylene polymers and copolymers used in food-contact applications. More specifically, the FCS is intended: (1) For use at levels not to exceed 20 parts per million (ppm) in polyethylene and polypropylene polymers and copolymers intended to be used in contact with all food types under all conditions of use, except for use in contact with infant formula and human milk. (2) For use at levels not to exceed 4 parts per million (ppm) in high-density polyethylene and polypropylene polymers and copolymers intended for use in contact with infant formula and human milk under Conditions of Use A through H, as described in Table 2.[1]

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 will not be prepared. This finding is based on information submitted by the notifier in an Environmental Assessment (EA), dated August 13, 2019. 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.

The FCS improves the yield from the polymerization process and results in increased throughput rates. Items containing 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: Facts and Figures 2015." Since the FCS is intended to be used with polyolefins, recycling is also expected to occur in proportion to national figures reflected in the EPA report. Discarded items will go to landfills or municipal solid waste (MSW) combustion facilities complying with 40 CFR Parts 258 and 60, respectively. 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. Market volume information provided in a confidential attachment to the EA demonstrates that the FCS will comprise a very small portion of MSW, compared to overall MSW generated.

According to information in a confidential attachment to the EA, total annual emissions of greenhouse gases (GHG), including nitrous oxide (N2O), represented as CO2-equivalent (CO2-e) in metric tons (mT), are 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.

Use of the FCS in as an antistatic agent in the production of polyethylene and polypropylene polymers and copolymers is not expected to result in a net increase in the use of energy and resources, because the raw materials used in the manufacture of the FCS are already in wide use in other industrial applications.
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 environmental impact.

[1] https://www.fda.gov/food/ingredientspackaginglabeling/packagingfcs/foodtypesconditionsofuse/default.htm, accessed 8/19/19

Consequently, we find that use of the FCS as described in FCN 2001, will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed on 08-21-2019
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Office of the Center Director
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Approved by _____Date: digitally signed on 08-21-2019
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