Memorandum

Date: December 21, 2018

To: Sharon Koh-Fallet, Ph.D., Division of Food Contact Notifications (HFS-275)

From: Mariellen Pfeil, Supervisory Biologist, Office of Food Additive Safety, HFS-255

Subject: Finding of No Significant Impact for food-contact notification (FCN) 1931 for 1,2,4,5,7,8-Hexoxonane,3,6,9-trimethyl-,3,6,9-tris(Et and Pr) derivs. [CAS Reg. No. 1613243-54-1].

Notifier: AkzoNobel Specialty Chemicals

Attached is the Finding of No Significant Impact (FONSI) for FCN 1931 for 1,2,4,5,7,8-Hexoxonane,3,6,9-trimethyl-,3,6,9-tris(Et and Pr) derivs. [CAS Reg. No. 1613243-54-1] as rheology modifier in the production of polypropylene polymers for single-use complying with 21 CFR 177.1520, except for use in contact with infant formula and human milk.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated August 9, 2018, 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.

Mariellen Pfeil

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 1931), submitted by AkzoNobel Specialty Chemicals, to provide for the safe use of 1,2,4,5,7,8-Hexoxonane,3,6,9-trimethyl-,3,6,9-tris(Et and Pr) derivs. [CAS Reg. No. 1613243-54-1] as rheology modifier in the production of polypropylene polymers for single-use complying with 21 CFR 177.1520, except for use in contact with infant formula and human milk. The FCS modifier is to be used at a level not to exceed 0.08 percent by weight of the polypropylene polymers. Single-use food contact articles manufactured with the polypropylene polymers modified with the food contact substance shall be used in contact with all types of food under FDA conditions of use A - H, unless restricted by applicable regulations for the polypropylene polymers.

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 9, 2018. The EA is incorporated by reference in this Finding of No Significant Impact and is briefly summarized below. The EA was prepared in accordance with 21 CFR 25.40.

The FCS completely decomposes during the controlled rheology-modification process for polypropylene (CRPP). The following decomposition products may be formed and released as volatiles: methyl acetate (MA), methyl isobutyl ketone (MIBK), methyl ethyl ketone (MEK), methyl propyl ketone (MPK), ethyl acetate (EtOAc), propyl acetate (PA), and additionally, the processing aid Spirdane. These carbon-containing substances have boiling points ranging from 50-100 degrees C to 240-260 degrees C and as such, are classified as volatile organic compounds or VOCs.[1] Additionally, MIBK is a U.S. Environmental Protection Agency (EPA) designated 'hazardous air pollutant' (HAP).[2]

Using FCS market volume and compositional data provided in the confidential attachment, the annual generation for each of the above identified decomposition products was calculated. These emissions were adjusted by a factor of 0.35 kg per metric ton of manufactured polypropylene, the EPA Air Pollutant Emission Factor (AP-42 emission factor)[3] for gaseous emissions resulting from manufacture of polypropylene. The analysis shows that even assuming as a worst-case analysis that all such emissions are generated by one CRPP manufacturing facility, these emissions are below the U.S. EPA Title V required major-source permitting thresholds for air pollutants, i.e., 10 tons/year single HAP or 25 tons/year for any combination of HAPs or 100 tons/year for any air pollutant (See 40 CFR 51.100(s) and https://www.epa.gov/indoor-air-quality-iaq/volatileorganic-compounds-impact-indoor-air-quality). Therefore, no significant environmental introductions resulting from the use of the FCS in the manufacture of CRPP are anticipated.

No environmental release is expected upon the use of the subject FCS in the fabrication of food-contact materials nor from the disposal (either by recycling, landfill or incineration) of such articles as the FCS is completely degraded during the rheology-modification process.

Therefore, no significant quantities of any substances will be released upon the use and disposal of finished materials manufactured with the FCS. As such a discussion of environmental fate and impact is not required.

The FCS product is formulated using the processing aid, Spirdane D60. As such the notifier provided an EA attachment delineating the environmental introduction, fate and impacts of this substance. The majority of this substance is retained within the finished polypropylene article. Items containing this processing aid are expected to be land disposed or combusted proportionately with disposal patterns for polypropylene packaging described in U.S. Environmental Protection Agency's (EPA) report "Advancing Sustainable Materials Management: Facts and Figures 2014." Discarded

[1] See 40 CFR 51.100(s) and https://www.epa.gov/indoor-air-quality-iaq/volatile-organic-compounds-impact-indoor-airquality
[2] https://www.epa.gov/haps; https://www.epa.gov/haps/initial-list-hazardous-air-pollutants-modifications
[3] https://www.epa.gov/air-emissions-factors-and-quantification/ap-42-compilation-air-emission-factors

items will go to landfills or municipal solid waste (MSW) combustion facilities complying with 40 CFR Parts 258 and 60, respectively. Analysis provided in this EA attachment indicate that the processing aid 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 processing aid will comprise a very small portion of MSW, compared to overall MSW generated; this comparison uses EPA's 2014 MSW statistics.

According to information in a confidential attachment to the EA, total annual emissions of greenhouse gases (GHG), 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 articles containing this processing aid at MSW combustion facilities. Additionally, losses of this processing aid that occur during the rheology modification process are included in the aforementioned confidential HAPs/VOC analysis. No significant environmental introductions resulting from the use of the processing aid in the manufacture of CRPP are anticipated.

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.

Consequently, we find that use of the FCS as a rheology modifier in the production of polypropylene used to manufacture food-contact articles as described in FCN 1931, will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed 12-21-2018
Mariellen Pfeil
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