FDA U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: February 4, 2019

To: Anita Chang, Ph.D., Division of Food Contact Notifications (HFS-275)
Through: Mariellen Pfeil, Supervisory Biologist, Office of Food Additive Safety, HFS-255

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

Subject: Finding of No Significant Impact for food-contact notification (FCN) 1945 for alcohols, C10-14-branched, C11-rich, reaction products with ethylene oxide, [(2- propenyloxy)methyl]oxirane and sulfamic acid (CASRN: 905843-50-7). The FCS is comprised primarily of poly(oxy-1,2-ethanediyl), α-sulfo-ω-[1-(hydroxymethyl)-2-(2-propen-1-yloxy)ethoxy]-, C11-rich, C10-14- branched alkyl ethers, ammonium salts (CASRN: 403983-53-9); aka Reasoap SR Series.

Notifier: ADEKA Corporation

Attached is the Finding of No Significant Impact (FONSI) for FCN 1945 for alcohols, C10-14-branched, C11-rich, reaction products with ethylene oxide, [(2- propenyloxy)methyl]oxirane and sulfamic acid a reactive emulsifier in emulsion polymerization processes of water-based polymers that are intended to be used in the manufacture of adhesives. The FCS is comprised primarily of poly(oxy-1,2-ethanediyl), α-sulfo-ω-[1-(hydroxymethyl)-2-(2-propen-1-yloxy)ethoxy]-, C11-rich, C10-14- branched alkyl ethers, ammonium salts.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated November 29, 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.

Leah D. Proffitt

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 1945), submitted by ADEKA Corporation, to provide for the safe use of alcohols, C10-14-branched, C11-rich, reaction products with ethylene oxide, [(2- propenyloxy)methyl]oxirane and sulfamic acid a reactive emulsifier in emulsion polymerization processes of water-based polymers that are intended to be used in the manufacture of adhesives. The FCS is comprised primarily of poly(oxy-1,2-ethanediyl), α-sulfo-ω-[1-(hydroxymethyl)-2-(2-propen-1-yloxy)ethoxy]-, C11-rich, C10-14- branched alkyl ethers, ammonium salts.

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 November 29, 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 may be used at levels up to 1% by weight of total monomers in adhesive polymers complying with 21 CFR 175.105 and 21 CFR 175.125. The FCS will be used as a reactive emulsifier in emulsion polymerization processes of water-based polymers. The FCN reacts like a monomer in the polymerization process and is bound covalently to the polymer.

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." Items manufactured with the FCS are not expected to be recycled, since adhesive polymers are not generally recycled. 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; this comparison uses EPA's 2015 MSW statistics.

According to information in a confidential attachment to the EA, third-year market volume projections constitute a very small fraction of total plastics packaging combusted for energy recovery, thus total annual emissions of greenhouse gases (GHG), 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 currently used.

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.

Consequently, we find that use of the FCS as as a polymeric component of food-contact articles as described in FCN 1945, will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by _____Date: see electronic signature
Leah D. Proffitt
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Food and Drug Administration

Approved by _____Date: see electronic signature
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