

Memorandum

Date: May 3, 2019

To: Jessica Urbelis, Ph.D., Division of Food Contact Notifications (HFS-275)

Through: Sarah C. Winfield, Biologist, Environmental Team, Division of Biotechnology and GRAS Notice Review (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) 1962 for amines, hydrogenated tallow alkyl, acetates (CAS Reg. No. 61790-59-8).

Notifier: Akzo Nobel Industrial Chemicals B.V.

Attached is the Finding of No Significant Impact (FONSI) for FCN 1962, request for use of amines, hydrogenated tallow alkyl, acetates as a processing aid in the separation of potassium chloride from sodium chloride.

After this notification becomes effective, copies of this FONSI, revision sheet, and the notifier's environmental assessment (EA), dated March 29, 2019, may be made available to the public. We will post digital transcriptions of the FONSI, revision sheet 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

EA Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 1962), submitted by Akzo Nobel Industrial Chemicals B.V., to provide for safe use of amines, hydrogenated tallow alkyl, acetates, as a processing aid in the separation of potassium chloride from sodium chloride. The FCS may be present at a level not to exceed 10 ppm in sodium chloride. The sodium chloride containing the FCS is not for use in contact with infant formula and 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 FCN 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 submitter in an environmental assessment, dated March 29, 2019. 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 food-contact substance (FCS) aids in the separation of potassium chloride from sodium chloride in salt mining and processing operations in Europe. Trace amounts (max. 10 ppm) of the FCS remain in salt that is added to food and exported from Europe to the United States. The main potential for environmental impact is through excretion of the FCS from consumers to surface waters via publicly-owned treatment works (POTW) throughout the United States. Another pathway for environmental exposure is to landfills when food is discarded.

The expected exposure to the FCS is 47 µg/person/day. When adjusted for diet and body weight, this equates to 16 µg/kg (ppb). Although the FCS—a fatty acid—is expected to be efficiently metabolized by the human body similarly to other dietary fatty acids, a worst-case assumption is made that all of the FCS enters POTWs across the country. The FCS is not expected to survive primary and secondary wastewater treatment: secondary (biological) treatment accounts for 90% removal of organic material with any remainder being discharged to surface waters by the POTW in accordance with NPDES permits.

Discarded food is not expected to be released to the environment due to regulations governing permitted landfills and municipal solid waste (MSW) combustion facilities (40 CFR Parts 258 and 60, respectively).

A greenhouse gas analysis demonstrates that CO₂ equivalent emissions are expected to be well below the 25,000 metric ton reporting threshold in 40 CFR 98.2.

Use of the FCS is not expected to cause a significant impact on resources or energy. No mitigation measures are needed since no significant adverse impacts are expected from use of the FCS. The alternative to not allowing the FCN to become effective would be continued use of currently approved processing aids; such action would have no significant environmental impact.

As evaluated in the EA, the use of the FCS as described in FCN 1962 is not expected to significantly affect the human environment, and, therefore an environmental impact statement will not be prepared.

Prepared by _____ Date: digitally signed on 05-03-2019

Leah D. Proffitt

Biologist

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

Approved by _____ Date: digitally signed on 05-03-2019

Sarah C. Winfield

Biologist

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

U.S. Food and Drug Administration

Revision Sheet for the March 29, 2019 EA for FCN 1962

Dated: May 3, 2019

The U.S. Food and Drug Administration (FDA) in its review of the March 29, 2019 Environmental Assessment (EA) for Food Contact Substance Notification (FCN) 1962 concluded that the action will not constitute a significant impact. The revisions are 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. These revisions do not impact our Finding of No Significant Impact (FONSI).

These revisions are necessary to clarify the following:

- On page 003 of the EA, the dietary level is mistakenly recorded as 0.016 ppb. The correct amount, which is reflected directly prior, is 16 ppb.
- On page 010, the notifier lists a reference (“Illinois”) that is not cited/used in the body of the EA. This reference is disregarded.