
Memorandum

Date: January 14, 2021

To: Elizabeth Furukawa, Ph.D. Division of Food Contact Substances (HFS-275)

Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Division of Science and Technology (HFS-255)

From: Antonetta Thompson-Wood, Physical Scientist, Environmental Team, Division of Science and Technology (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2105: Alkyl (C₁₀₋₁₆) benzenesulfonic acid (DDBSA, CAS Reg. No. 68584-22-5) as an emulsifier in a coating used on wooden pallets used for hydrocooling produce.

Notifier: CHEP

Attached is the FONSI for FCN 2105, which is for the use of Alkyl (C₁₀₋₁₆) benzenesulfonic acid (CAS Reg. No. 68584-22-5) as an emulsifier in a coating used on wooden pallets used for hydrocooling produce. The FONSI explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

After this FCN becomes effective, copies of this FONSI, the notifier's environmental assessment (EA), dated January 5, 2021, and the EA Revision Sheet 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.

Antonetta Thompson-Wood

Attachments: FONSI; EA Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2105, submitted by CHEP for the use of Alkyl (C₁₀₋₁₆) benzenesulfonic acid (CAS Reg. No. 68584-22-5) as an emulsifier in a coating used on wooden pallets used for hydrocooling produce. Pallets containing the FCS may be used in contact with water used for hydrocooling produce.

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 January 5, 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 (FONSI) and is briefly summarized below.

The FCS is intended to promote the even spreading of a fungicide formulation applied in the treatment and assembly of wood pallets that are subsequently used in the hydrocooling of produce stored on the treated pallets. The fungicide protects the wood from fungal damage resulting from use in hydrocooling operations. The FCS will be utilized in patterns corresponding to crop production, processing and demand. Based upon a confidential life cycle analysis, approximately 90% of FCS-treated pallets will be chipped for mulch. The remainder will be land disposed or incinerated at disposal rates corresponding to The United States Environmental Protection Agency's (US EPA) Advancing Sustainable Materials Management: 2017 Fact Sheet.¹ FCS treated pallets may be disposed of in municipal solid waste (MSW) system throughout the United States by being landfilled or incinerated in municipal solid waste combustors (MWC) complying with 40 CFR Parts 258 and 60 respectively.

The FCS is water soluble. Therefore, the primary pathway by which the FCS is anticipated to be introduced to the environment is through treatment and disposal of hydrocooling process wastewater. Hydrocooling water is recycled through multiple hydrocooling cycles after which it is discharged to a municipal sewer. The water will then be transported to a publicly owned treatment works (POTW) where it will mix with other water sources and undergo water treatment. Direct discharge to surface waters is not anticipated.

The chemical ingredient containing the FCS also contains sulfuric acid. Sulfuric acid dissociates readily to sulfate in the presence of water and is not anticipated to be introduced to the environment to any extent; therefore, the EA focused on the environmental impacts of the FCS.

Using DDBSA migration data from a confidential laboratory hydrocooling process simulation and applying an assumption that 100% of pallets used for hydrocooling produce are treated with the FCS, the maximum concentration of the FCS entering wastewater systems is not anticipated to exceed 28.4 ppm. Following wastewater treatment, the estimated upper-bound aquatic introduction concentration (EIC) for the FCS in water flowing through a POTW system was calculated to be 14.2 ppb. A 10-fold dilution factor is applied to the amount of FCS that remains in water to account for dilution upon release to surface water. Therefore, the aquatic effective environmental concentration (EEC) is $14.2 \text{ ppb} \div 10 = 1.42 \text{ ppb}$. The lowest relevant endpoint for aquatic toxicity was determined to be the chronic No Observed Effect Concentration (NOEC) of 0.9 ppm for both *Pimephales promelas* and *Lemna minor*. The aquatic EEC is more than 1000-fold lower than the lowest effect value NOEC. Furthermore, the assessment conservatively assumes that FCS absorption to POTW sludge (estimated at 77 to 82 percent) does not occur. Therefore, adverse environmental effects to aquatic organisms are not expected.

As noted above, FCS absorption to wastewater treatment sludge is also anticipated. The calculated $\text{EIC}_{\text{sludge}}$ is also based upon the portion of treated pallets used in hydrocooling produce and does not consider biodegradation of the FCS. As such, the estimated $\text{EIC}_{\text{sludge}}$ and $\text{EEC}_{\text{sludge}}$ for the FCS are equivalent (0.72 ppm; 720 ppb). Sludge material containing the

¹ https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf
www.fda.gov

FCS may be landfilled, or land applied. The lowest relevant endpoint for terrestrial toxicity was determined to be the chronic NOEC of 10 mg/kg for *Phalaenopsis*. The terrestrial EEC is more than 10-fold lower than the lowest effect value NOEC and is conservative in that it does not consider soil degradation of the FCS (e.g., the soil-half life in sludge is 23.1 days). Therefore, adverse environmental effects to terrestrial organisms are not expected.

The EA also considered the impact of greenhouse gas (GHG) emissions. Based on information provided in a confidential attachment to the EA, the total estimated GHG emissions resulting from the combustion of food-contact articles manufactured with the FCS in this notification is below 25,000 metric tons CO₂-e, the US EPA threshold for mandatory reporting of GHG emissions (40 CFR 98.2). Therefore, no significant environmental impacts are anticipated.

No net increase in the use of energy and resources from the use and disposal of food-contact articles manufactured with the FCS is expected. Also, no mitigation measures are needed since no adverse environmental effects are expected from use and disposal of food-contact articles manufactured with the FCS. The alternative to not allowing the FCN to become effective would be continued use of materials that the FCS would otherwise replace and would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2105 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed 01-14-2021

Antonetta Thompson-Wood
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Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____ Date: digitally signed 01-14-2021

Mariellen Pfeil
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U.S. Food and Drug Administration Revision Sheet for the January 5, 2021 EA for FCN 2105

Revision Sheet Dated: January 14, 2021

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) dated January 5, 2021 for food contact notification (FCN) 2105 concluded that the action will not constitute a significant impact. This revision is 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. This revision does not impact our Finding of No Significant Impact (FONSI).

The revision is necessary to explain the following:

- The last paragraph on page 12 of the EA contains an apparent editorial error:

“[...] total estimated DDBSA [...] is 7658 kg/yr₁₃ [...]”

¹³ $1.9074 \times 10^7 \text{ kg/day} * 1.2 \text{ mg/kg} * 365 \text{ day/year} * 0.000001 \text{ kg/mg} = 8354 \text{ kg/year}$

This sentence should state:

“[...] total estimated DDBSA [...] is 8354 kg/yr₁₃ [...]”

- In Nov. 2020 the U.S. EPA issued an update to the Municipal Solid Waste report cited in the EA (see the below links).

https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf

https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf

We note that this update does not impact the conclusions presented in the EA, so no revision is required. However, the reader is advised to refer to these reports.