Memorandum

Date: September 19, 2018

To: V. Komolprasert, Ph.D., Consumer Safety Officer, Division of Food Contact Notifications, HFS-275
Through: Mariellen Pfeil, Supervisory Biologist, Environmental Review Team, Office of Food Additive Safety (HFS-255)

From: Chemist, Division of Food Contact Notifications, HFS-275

Subject: Finding of No Significant Impact for Food Contact Notification 1917 for use of 2-amino-2-methyl-1-propanol (CASRN 124-68-5)

Notifier: ANGUS Chemical Company

Attached is the Finding of No Significant Impact (FONSI) for Food Contact substance Notification (FCN) 1917, which is for the use of 2-amino-2-methyl-1-propanol as a dispersant for mineral pigment suspensions used as a component of fillers or coatings for paper and paperboard in contact with all foods. The FCS is not intended for use in contact with infant formula and human milk.

After this notification becomes effective, copies of this FONSI, revision sheet and the notifier's environmental assessment, dated June 18, 2018, may be made available to the public. We will post digital transcriptions of the FONSI, revision sheet and the environmental assessment 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.

Daniel Chan

Attachments: Finding of No Significant Impact
Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 1917, submitted by ANGUS Chemical Company for the use of 2-amino-2-methyl-1-propanol as a dispersant for mineral pigment suspensions used as a component of fillers or coatings for paper and paperboard under conditions of use A-H and J in contact with all foods. The FCS is not intended for use in contact with infant formula and human milk.

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 June 18, 2018. 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.

Manufacture of the FCS is not expected to result in significant environmental impact. Manufacture of food-contact articles containing the FCS is also not expected to result in a significant impact to the environment. When the FCS is used in coatings on food-contact articles, the process is a dry-end application, and all of the FCS remains with the coating, and all of the coating remains on the food-contact article. Therefore, finished paper and paperboard containing the FCS will be recycled or disposed of via municipal solid waste (MSW) disposal into landfills or to MSW combustors. On the other hand, when the FCS is used as a filler, the process is a wet-end application, and because the FCS is highly soluble in water is expected to be lost with the white water associated with paper making. The FCS is not expected to significantly adsorb to sewage sludge as demonstrated by the low K_{ow} partition coefficient.

During the wet-end papermaking process, the FCS is expected to partition into and remain with the processing whitewater. Following an approximate 89% biodegradation during wastewater treatment and a 10-fold dilution into surface water the estimated environmental concentration (EEC) is 0.26 ppm. This value is greater than 3 orders of magnitude lower than the 179 ppm and 190 ppm acute toxicity EC50 endpoints for the most sensitive salt and fresh water species (saltwater shrimp (*Crangon crangon*) and bluegill (*Lepomis macrochrius*)), respectively.

As noted above, when the FCS is used in coatings for paper and paperboard, the anticipated routes of disposal after use are expected to be recycling, landfilling or combustion in MSW incinerators. The FCS is not expected to impact recyclability as clay, titanium dioxide or calcium carbonate coated paper is typical in the recycling stream, and the FCS will be less than 0.1% of the final food-contact article. When landfilled, the EA explains no environmental introduction is expected per 40 CFR 258, the regulations governing landfills. When combusted, the EA explains there is nothing to suggest the FCS would threaten a violation of 40 CFR 60, the regulations governing MSW combustion facilities (based on the composition of the FCS).

The EA also considered the impact of greenhouse gas (GHG) emissions. However, based on estimated market volume information provided in a confidential attachment to the EA, the total estimated GHG emissions resulting from the combustion of the FCS per FCN 1917, is below 25,000 metric tons CO_2-e, the U. S. EPA threshold for mandatory reporting of GHG emissions (40 CFR 98.2). Therefore, significant impacts to the environment are not 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.

The use of the FCS, as described in FCN 1917, as a dispersant for mineral pigment suspensions used as fillers and coatings for use in paper and paperboard food-contact materials will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: Digitally signed 9/18/2018
Daniel Chan
Chemist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: Digitally signed 9/19/2018
Mariellen Pfeil
Supervisory Biologist, Environmental Review Team
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U.S. Food and Drug Administration

Revision Sheet for the June 18, 2018 EA for FCN 1917

Dated: September 19, 2018

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of June 18, 2018 for food contact notification (FCN) 1917 concluded that the action will not constitute a significant impact. The 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:

- There are two sections numbered 5. The EA sections are revised to be numbered sequentially.

- On page 1 of the EA under item 4, the third line is revised from "suspensions *as used as* fillers…" to "suspensions *used as* fillers…"

- On pages 3 and 4 there is a series identity / subject value agreement error relating to the types of mills and the respective reported median water uses quoted from the Bryant, *et al.* reference. Therefore, we revise the following sentence:

  > "Although this reference does not specifically address the production of food contact paper, it does report information on the water use in various types of mills, including integrated pulp and paper mills, bleached kraft market pulp mills, and paper mills producing more and less than 100 tons paper/day."

  To the sentence below to correctly reflect the literature citation:

  > "Although this reference does not specifically address the production of food contact paper, it does report information on the water use in various types of mills, including integrated bleached and unbleached mills, paper mills producing more than 100 tons paper/day, and bleached market kraft pulp mills."

- On page 4 of the EA (1st paragraph), under item 6 b., the rate of water usage by 54% of paper mills is corrected from 4,000 gal/ton per day to 3,000 gal/ton per day to accurately reflect the information in the reference provided in Footnote 9 (Bryant, et al).

- On page 4 of the notifier's EA, they state that at a biodegradation rate of 89.3% the percentage of AMP remaining after degradation is 100%-95% = 5%. The EA is revised to the correct FCS biodegradation rate of 89.3%.

  The resulting EEC calculation is corrected from 0.12 to 0.26 mg/L on page 4 and on page 6 (1st and 3rd paragraphs) to reflect the revision of the biodegradation calculation ((0.24 mg FCS/kg water x (100%-89.3% biodegradation) ÷ 10-fold surface water dilution x (1 L water/1 kg water) = 0.26 mg/L)).

- On page 7, 3rd paragraph, the EA is corrected from "AMP would be *expected dissolve* into the pulp slurry" to read "AMP would be *expected to dissolve* into the pulp slurry"

- On page 9, the hyperlink to the US FDA Food Types and Conditions of Use tables is added (http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/ucm109358.htm)