

FINDING OF NO SIGNIFICANT IMPACT
FOR

Food Additive Petition 3B4367, submitted by Lonza, Inc., to amend the food additive regulations to provide for the safe use of a mixture of hydroxymethyl-5,5-dimethylhydantoin and 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin as a preservative in clay-type fillers for paper and paperboard in food-contact articles.

The Environmental Impact Staff (EIS), Center for Food Safety and Applied Nutrition, has determined that the approval of this petition will not significantly affect the quality of the human environment and therefore will not require the preparation of an environmental impact statement. This finding is based on information submitted by the petitioner in an environmental assessment prepared using the format described in 21 CFR 25.31a(a) and the following:

The additive is expected to degrade upon use to 5,5-dimethylhydantoin (DMH) and formaldehyde. The chemicals introduced into the environment through the use of the additive are expected to enter the environment mainly through disposal of the process water from papermaking facilities. EIS has estimated that the concentrations of DMH and formaldehyde entering the environment from disposal of process water from papermaking plants as a result of the proposed use of the additive are not likely to exceed 850 ppb and 35 ppb, respectively. These levels are below the toxic concentration criteria (29 mg/l for DMH and 360 ppb for formaldehyde), as described in 21 CFR 25.15(b)(6), based on a reported lowest observed adverse effect level of 29 mg/l for DMH in fathead minnows and on the LC50 for formaldehyde of 36 ppm in fathead minnows. DMH is expected to biodegrade in 1-2 days under acclimated conditions, and formaldehyde is expected to biodegrade in hours.

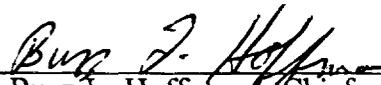
The incineration of food-contact materials containing the proposed additive is not expected to have adverse impacts on the environment. Although the proposed additive contains nitrogen and will produce the acid gases associated with its combustion, the additive is intended to replace other, similar additives containing nitrogen, sulfur, and halogens as described under format item 9 of the EA. Therefore, approval of the proposed additive is not expected to result in a net increase in the levels of acid-gas emissions from the combustion of food-contact paper and paperboard.

Prepared by:


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Date: November 30, 1995

Approved by:


Buzz L. Hoffmann, Chief
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Date: November 30, 1995

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