

OCT 18 1995

Mr. John B. Dubeck
Law Offices
Keller and Heckman
1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001

Dear Mr. Dubeck:

This responds to your submissions dated December 30, 1992, September 16, 1994, and June 21, August 24, and October 13, 1995, on behalf of Eastman Chemical Company, concerning the use of Eastman's multi-step methanolysis process to adequately remove post-consumer contaminants from poly(oxy-1,2-ethanediylloxycarbonyl-2,6-naphthalenediylcarbonyl) (PEN) resins and whether dimethylnaphthalene dicarboxylate (DMN) and ethylene glycol (EG) regenerated from recycled PEN will be of a purity suitable for use in the manufacture of PEN resins for food-contact applications. The submissions are contained in Eastman's food additive petition 8B4110 and indicate that Eastman's process is a multi-step methanolysis procedure in which DMN and EG are chemically recovered from PEN that has been depolymerized to its constituent monomers. The methanolysis method employed is classified by the Environmental Protection Agency as tertiary recycling.

We have reviewed the data that you have provided on Eastman's isolation and purification process to produce regenerated DMN and EG from depolymerized PEN resin materials. In particular, you have provided gas chromatographic data and inductively coupled plasma emission spectroscopy data demonstrating that marker contaminants deliberately added to pelletized PEN are removed during Eastman's multi-step process. Based upon review of these data, we believe that Eastman's multi-step methanolysis process is extremely efficient at reducing potential contaminants, and that DMN and EG produced by this process will be of suitable purity for use in the production of PEN resins intended for food-contact applications, in accordance with 21 CFR 174.5. Therefore, we do not object to the use of DMN and EG regenerated by this process as components in the manufacture of PEN resins for food-contact applications, provided that the resulting PEN is in compliance with 21 CFR 177.1637 and other applicable regulations.

We emphasize that the data you submitted and we reviewed, and the opinion set forth in this letter address only the use of regenerated DMN and EG from the Eastman process described in Eastman's December 30, 1992, petition submission for FAP 8B4110 and that the commercial process should be equivalent to that process. If the commercial process is not equivalent, new

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data may need to be evaluated. Thus, this opinion does not authorize or approve the use of PEN or other food-contact polymers to regenerate DMN and EG by other processes.

We further emphasize that we are issuing this letter addressing Eastman's process because, based on the data that you have submitted, we believe that the use of regenerated DMN and EG produced by this process from depolymerized post-consumer PEN to manufacture PEN food-contact articles is within the purview of existing regulations (21 CFR 174.5 and 177.1637).

Although we have concluded that your intended use of recycled PEN is acceptable, you should be aware that we are currently developing a formal policy on the use of post-consumer recycled plastics in contact with food. Thus, the decisions set forth in this letter may need to be modified due to future deliberations on this matter.

We trust this letter responds fully to your request on this matter. If you have any further questions related to this letter, please do not hesitate to contact the Indirect Additives Branch at 202-418-3080.

Sincerely yours,



Sandra L. Varner
Acting Chief
Indirect Additives Branch, HFS-216
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition