October 1, 1993

To: Ed Fattler

Subject: Geon 3400 FDA Status

You will recall that Wally Bachtel reviewed the FDA status of Geon 3400 in 1990 (AN4449). In that letter Wally indicated that this product did not have any FDA clearance because the [redacted] (DAP) [redacted]

More recently, I reviewed this recipe under the principles of the "Basic Resins Doctrine" and good manufacturing practices standards. Based on this review I concluded that this product would meet the requirements for "prior sanctioned" status.

In order to resolve these conflicting opinions, I called Les Borodinsky at Keller & Heckman and asked him to address the following issues:

1. In light of the fact that DAP is used as a crosslinker, is Geon 3400 a PVC resin, a compound, or a copolymer from an FDA perspective? I noted that polymers/copolymers that incorporated crosslinkers are frequently described by their monomer constituents.

2. If this product is a basic PVC resin, what is the significance of the DAP migration data with respect to the FDA "prior sanctioned status of this material?

Les indicated that in order to answer these questions he used his expertise but also took a survey of opinions from the legal staff at K&H. Based on this review and the information that I provided, he concluded that Geon 3400 is a basic PVC resin. Secondly, he stated that evidence of low level DAP migration into food simulating solvents does not effect the apparent "prior sanctioned" status of this basic resin since the levels of DAP observed are toxicologically insignificant.

The basis for these conclusions appears to be the difference between substances used to manufacture resins and substances compounded with resins to achieve a technical effect in the compound. Clearances which have been established for resins are based on their monomer composition, not on the basis of process or raw materials. Essentially any raw material can be used to make an FDA acceptable resin as long as it functions to make the polymer, complies with GMP's, and does not pose any toxicity concerns. However, in order for a compound to have FDA clearance

all of the ingredients which can reasonably be expected to become a food additive must have FDA clearances which impart specific clearance(s) to the compound via the specific clearance(s) of the ingredients. Another difference is that resin raw materials are used to make the polymer where as compound ingredients are used to impart functional properties. While functional properties are imparted to the final product in both cases, resin raw materials function in creating a new chemical either by direct chemical interaction or by their own intrinsic chemical properties which facilitate or optimize the reaction. Compound ingredients on the other hand due not function to create a new chemical. While chemical reactions may occur in some cases, the particular properties that are imparted on the compound typically are the result of the physical property of the ingredient(s). Compound ingredients function as a simple mixture where the end properties are controlled by the ratio of the components.

Because some chemicals can function either as a resin raw material or as a compound ingredient, it is important to look closely at both the chemicals function and at the concentration that is used in the recipe. As you have described, DAP functions as a crosslinker in the production of Geon 3400. At approximately 0.6%, DAP reacts with the polymer resulting in a stable resin particle particularly important during processing. However, at some higher concentration DAP could play a dual role as a plasticizer, i.e. functioning as an ingredient which could change the FDA status of the final product.

For these reasons it is important to use DAP at the lowest levels that will enable you to product a stable polymer. Any proposed increases in DAP above the 0.6% level will need careful review and could effect its FDA status.

This letter will serve to summarize both general guidance and the verbal opinion of K&H. However, a formal opinion letter can be obtained from K&H for approximately $1000.

Bob Hinderer

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cc: Woody Ban
Les Borodinsky (Keller & Heckman)
Mark Hross
Ashok Shah