AN 4529
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June 21, 1991

Dave Polenda

SUBJECT: GEON 121X10/FDA 20CFR 177.2600

Recently you asked whether Geon 121X10 was acceptable under 177.2600 and sent me a copy of Wally Bachtel's letter dated 10/16/86. In order to resolve some of the issues we discussed, I called Leo Borodinsky at Keller & Heckman for guidance.

As you know, PVC is prior sanctioned and also is specifically listed under a number of sections (see RKH letter 5/13/91, attached). Clearance for PVC resin falls under the "Basic Resin Doctrine" which allows the use of those things needed to manufacture the resin as long as Good Manufacturing Practices (GMP's) are followed. In evaluating the clearance of the resin, one must consider the following:

1) What is the intended use of the ingredient? Is its prime function to accomplish the reaction, or is it primarily intended to provide a physical property to the resin (i.e., plasticization).

2) What is the toxicity of the ingredient? Is there an unusual or special hazard/concern?

3) How much is present in the recipe? As a rule of thumb, 0.5 to 1% is a gray area. Ingredient >1% must have specific clearances and are bound by the limitations of the relevant sections. Those ingredients used at <0.5% are acceptable unless they are unusually toxic.

Based on our discussions, the recipe that Wally reviewed (10/16/86) contained 0.25% di-(C_7 and C_9 Alkyl) adipate. Although some might argue that Wally's opinion is somewhat conservative, I believe that it was reasonable considering concerns about plasticizers.

With the above information in mind, your present goal of producing a Geon 121X10 type resin which meets 177.2600 can be achieved by either, 1) reducing the level of the di-(C_7 and C_9 Alkyl) adipate to <0.1% as long as its primary function is to facilitate the reaction, or, 2) changing to DOP (not to exceed 30% by weight).

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