

October 30, 1991

To: Chuck Daniels
Keith Gardner
Joe Kelley
Bob Jeziorski
Pat McCauley
Ralph Purtell
Glen Schaaf
Carl Toensing

Subject: PVC RESINS FDA STATUS/GENERAL GUIDANCE

Because we frequently get questions on the FDA status of our PVC resins, I am providing general guidance in this area to assist all of us in the evaluation of our products and to insure proper communication of this information to our customers. This guidance is based on recent discussions with Dr. Les Borodinsky at Keller and Heckman.

When FDA first created the "Prior Sanctioned" category for PVC, they did not set any specifications for the resins. However, in 1963 a knowledgeable group of Industry representatives operating under the auspices of SPI set Good Manufacturing Specifications (GMP's) for PVC resins. This resulted in what are now the current GMP's consisting of a maximum volatility of 3.0% (1 hour at 105 degrees C) and an inherent viscosity of not less than 0.35 by ASTM D-1243-79.

If a PVC resin cannot meet these GMP's then it cannot be considered "Prior Sanctioned", and therefore, is not eligible for the broader clearances provided by this designation. Any PVC resin which does not meet these GMP's is acceptable only under the specific sections of the 21CFR where it is listed and where the subsequent specifications are described therein:

175.105	177.1200
175.300	177.2250
176.180	179.45
177.1010	

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If a PVC resin meets these GMP's, I must then review the recipe under the tenants of the "Basic Resins Doctrine" as the final step in determining whether the resin is indeed "Prior Sanctioned". In evaluating the "Prior Sanctioned" status of the resin the following must be considered:

- 1) What is the intended use of the ingredient? Is its prime function to accomplish the reaction enabling the manufacture of the product, or is it primarily intended to provide a physical property to the resin (i.e., plasticization, etc.).
- 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 1.0% is a grey area. Ingredients >1.0% 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.

Because of the importance of this subject, I am requesting your assistance in communicating this guidance throughout the GVD. I would also suggest that you review all of the resins where we claim "Prior Sanctioned" status in our literature in light of the above GMP's.

Please call me at Ext. 4534 if you have any questions.

Bob Hinderer/jp
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cc: Connie Dillon
Mark Hross
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