

BFGoodrich

The BFGoodrich Company
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Akron, Ohio 44313-1799

AN-5465
deleted

July 23, 1991

William Ernst
Resintech
Costa Rica

SUBJECT: FDA STATUS OF RYT97453 TRANS 002

Dear Mr. Ernst:

In order to answer your questions regarding limitations/ extraction requirements for use of this compound for water bottles, I must first determine its FDA status. Although I can do most of this evaluation based on the information provided, I will need your help.

As you know, polyvinyl chloride is prior sanctioned for use in general food contact applications, both flexible and rigid. The prior sanction is based on an article by A. J. Lehman, from the FDA, published in the Journal of the Association of Food and Drug Officials, July, 1951. The current Good Manufacturing Practice (GMP) specifications for prior sanctioned PVC are a maximum volatility of 3.0% (1 hour at 105°C) and an inherent viscosity of not less than 0.35 by ASTM D-1243-79.

PVC is also listed as an acceptable ingredient of food contact articles under 21CFR:

175.105	177.1200
175.300	177.2250
176.180	179.45
177.1010	

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

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- 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.

You will need to provide this information to Skintech and ask them to review their recipe for Skintech SE-650A. They will need to provide you with a letter confirming the FDA status of their PVC resin.

Sincerely,

THE BFGOODRICH COMPANY

R. K. Hinderer/jp

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cc: Connie Dillon
Mark Hross

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