

BFGoodrich

AN 4457

The BFGoodrich Company
3925 Embassy Parkway
Akron, Ohio 44313-1799

August 8, 1990

Mr. Kevin Swatofh
Achilles, U.S.A.
P.O. Box 2287
Everett, Washington 98203

RE: FDA STATUS OF POLYVINYL CHLORIDE (PVC) RESIN

Dear Mr. Swatofh:

This is in response to our conversation regarding the prior sanctioned status of PVC.

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	

As promised, I am enclosing a copy of the 1986 FDA PVC proposal which acknowledges the prior sanctioned status of PVC. To date, the FDA has not finalized the proposed regulation mostly due to preparation of an environmental impact analysis. Consequently, PVC retains its prior sanction status as explained above.

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If you have any further questions, regarding the FDA status of PVC, please call me at 216/374-3422.

Sincerely

THE BFGOODRICH COMPANY



W. C. Bachtel
Toxicologist
Environmental Health and
Safety Management Systems

0808-1/jp

G. Schaaf - CL-OTM (w/o attachment)

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