

AN 7781
02/21/80

B. A. DILIDDO/
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R. K. HINDERER

5456

2/21/80

FDA POSITION ON ATSC

One of our licensees, BIP (UK), has requested a statement from BFG on how the FDA views (would view) [REDACTED] Please review and return this statement ASAP.

NOTE: Other individuals involved in the preliminary review were:
W. C. Bachtel, H. H. Marty, R. F. Koebel, R. W. Strassburg.

R. K. Hinderer
R. K. Hinderer

:kjs

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100-225702

ATSC - FDA STATUS

Polyvinyl chloride resin is prior sanctioned for use in general food contact applications. Prior sanctioned substances are those which are used in accordance with an approval granted prior to September 6, 1958 by the FDA or USDA. The prior sanctioned status of PVC was established by Dr. A.J. Lehman of the FDA in publications in the Quarterly Bulletin of the Association of Food and Drug officials of the United States, 1951 and 1956. The specifications which apply to PVC under the prior sanction are:

1. Maximum volatility - 3% (1 hour @ 105°C)
2. Inherent viscosity of not less than 0.35
ASTM Method D-1243-66, Method A

[REDACTED] 1
[REDACTED] In 1975, the
FDA proposed a regulation^{for} "Vinyl Chloride Polymer Resins". However, the regulation has never been promulgated. The proposed specifications for PVC were the same as those applying to the existing prior sanction. There are several use oriented regulations which list homo and copolymers of PVC. Examples of such regulations are 175.105 "Adhesives", 175.300 "Resinous and Polymeric Coatings" and 177.1200 "Cellophane". Other than the heat loss and viscosity specifications, the General Provisions Regulation 174.5 would apply to PVC resins.

Briefly these are:

1. The quantity of substance used shall be no more than necessary to accomplish the intended physical or technical effect.
2. Shall not be intended to accomplish any physical or technical effect in the food
3. Be of a purity suitable for its intended use.
4. Shall not impart taste or odor to food.

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3.

Consideration of these studies, [REDACTED]
including the short-term "in vitro" test results, [REDACTED]
[REDACTED]

Therefore, in my opinion, the use of acetone thiosemicarbozone
at the current use level or lower use levels in the polymerization
of polyvinyl chloride resins intended for use in the fabrication of
food contact articles [REDACTED]
[REDACTED]

WCB

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