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Amendment of 1958 and which has been widely used since that time. Not all polyvinyl chloride formulations can be used in food packaging. Polyvinyl chloride having a maximum volatility of not over 3 percent when heated for 1 hour at 105° C., and having an inherent viscosity of not less than 0.35 when determined by American Society for Testing and Materials (ASTM) standard method D 1243-66, is prior-sanctioned for use as a component of a film for food wraps or as a can enamel.

An ingredient whose use in food or food packaging is subject to a prior-sanction or approval within the meaning of section 201(s)(4) of the Federal Food, Drug, and Cosmetic Act is exempt from classification as a food additive and may be used without pre-clearance by FDA.

The sanction for PVC rests on an article entitled "Food Packaging" by A. J. Lehman, Chief of the Division of Pharmacology, FDA, published in the "Association of Food and Drug Officials of the United States," volume 20, No. 4, October 1956. It is clear in the article that acceptance of the resins named therein was based on their lack of migration when tested for solubility in the listed solvent systems. The publication cited did not refer to polyvinyl chloride bottles and did not name an alcoholic medium as a test system.

In January 1973, the Food and Drug Administration began to receive reports of possible stability problems with PVC bottles used for distilled spirits. These bottles were part of an experimental program first authorized by the Treasury Department, Bureau of Alcohol, Tobacco, and Firearms in November 1968. Industrial users of these bottles had discovered an unpleasant taste in lightly flavored alcoholic beverages which had been kept in storage. Preliminary analytical results indicated that vinyl chloride monomer, a component of PVC, was extracted from the bottle to the liquor during storage. The level of vinyl chloride migrating varied, with some samples in a high range of 10-20 p/m. At that time the results had not been confirmed by mass spectrographic examination.

During April a new series of analytical results, including mass spectrographic examination, was presented to FDA by industry which confirmed the early reports of vinyl chloride monomer in various distilled spirits. These beverage samples had been stored in PVC bottles for up to 1 year. Information was also received which reported that wine packaged in PVC bottles was similarly affected.

FDA has now confirmed migration of the monomer in distilled spirits in its own laboratory. While analytical tests are continuing both at FDA and in industrial laboratories to resolve many unanswered technical questions relative to this problem, it seems certain at this time that vinyl chloride monomer migrates to alcohol from PVC bottles used to package distilled spirits and wine.

Vinyl chloride monomer as such is a poisonous and deleterious substance.

FDA knows of no studies which establish a safe level of consumption when this monomer is leached from containers into alcoholic foods. Accordingly, the Commissioner concludes that the use of polyvinyl chloride for packaging alcoholic foods may cause such foods to be adulterated.

There is no indication at this time that polyvinyl chloride resins in contact with nonalcoholic foods will result in migration of monomers, and such use need not be restricted.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 402, 409, 701(a), 52 Stat. 1042, 1046-1047 as amended, 1049, 1055; 21 U.S.C. 321(s), 342, 348, 371(a)) and under authority delegated to him (21 CFR 2.120), the Commissioner of Food and Drugs proposes to amend part 121 by adding a new section 121.2009 to read as follows:

§ 121.2009 Polyvinyl chloride resins.

(a) Polyvinyl chloride resins consist of basic resins produced by the polymerization of vinyl chloride.

(b) Polyvinyl chloride basic resins have a maximum volatility of not over 3 percent when heated for 1 hour at 105° C., and an inherent viscosity of not less than 0.35 when determined by ASTM method A 9, 1973.

(c) Polyvinyl chloride resins meeting the criteria of paragraphs (a) and (b) of this section may be used as a component of food packaging material, other than packaging material for use in contact with alcoholic foods.

Interested persons may, on or before July 16, 1973, file with the Hearing Clerk, Department of Health, Education, and Welfare, room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated May 15, 1973.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

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**Office of Education
[45 CFR Part 188]**

FINANCIAL ASSISTANCE FOR THE IMPROVEMENT OF EDUCATIONAL OPPORTUNITIES FOR ADULT INDIANS

Pursuant to the authority contained in section 314 of the Adult Education Act, as added by part C of title IV of the Education Amendments of 1972 (Public Law 92-318, 86 Stat. 342, 20 U.S.C. 1211a), the Commissioner of Education, with the approval of the Secretary of Health, Education, and Welfare,

Copies may be obtained from: American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pa. 19103.

**DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE**

Food and Drug Administration

[21 CFR Part 121]

**PRIOR-SANCTIONED POLYVINYL
CHLORIDE RESIN**

Notice of Proposed Rule Making

Polyvinyl chloride (PVC) is a polymeric resin which was used as a component of food packaging materials prior to the passage of the Food Additives