

AN 4709
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May 30, 1989

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SUBJECT: PVC/EVOH

Regulation 177.1360 permits the use of EVOH as articles or components of articles intended for use in contact with food. The phrase "as components of articles", would permit its use in the system you describe assuming the EVOH copolymer meets the specification as described in paragraphs (a)(1), (2) and/or (3). This is also assuming the wt. % of EVOH times the thickness of the end use article would not exceed 0.005, 0.003 and/or 0.007 inch as described in paragraphs (b), (c) and (d) respectively.

The EVOH copolymer in film form would have to meet the extractive limitations imposed for the particular type used. The end food contact article would be restricted to the food types and use conditions as described. I am enclosing copies of tables 1 and 2 from 21 CFR 176.170 for your information.

I hope this answers your questions, if not, please call.

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List of substances	Limitations
Vinyl chloride copolymers produced by copolymerizing vinyl chloride with one or more of the monomers acrylonitrile; fumaric acid and its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters; maleic acid and its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters; maleic anhydride; 5-norbornene-2, 3-dicarboxylic acid; mono-<i>n</i>-butyl ester; vinyl acetate and vinylidene chloride. The finished copolymers shall contain at least 50 weight percent of polymer units derived from vinyl chloride; shall contain no more than 5 weight percent of total polymer units derived from fumaric and/or maleic acid and/or their methyl, ethyl, propyl, butyl, amyl, heptyl, or octyl monoesters or from maleic anhydride or from mono-<i>n</i>-butyl ester of 5-norbornene-2, 3-dicarboxylic acid (however, in any case the finished copolymers shall contain no more than 4 weight percent of total polymer units derived from mono-<i>n</i>-butyl ester of 5-norbornene-2,3-dicarboxylic acid). Vinyl chloride-vinyl acetate hydroxyl-modified copolymers..... Vinyl chloride-vinyl acetate hydroxyl-modified copolymers reacted with trimellitic anhydride. Vinylidene chloride copolymers produced by copolymerizing vinylidene chloride with one or more of the monomers acrylamide acrylic acid; acrylonitrile, butyl acrylate, butyl methacrylate ethyl acrylate, ethyl methacrylate, fumaric acid, itaconic acid, methacrylic acid, methyl acrylate, methyl methacrylate, octadecyl methacrylate, propyl acrylate, propyl methacrylate, vinyl chloride and vinyl sulfonic acid. The finished copolymers shall contain at least 50 weight percent of polymer units derived from vinylidene chloride; and shall contain no more than 5 weight percent of total polymer units derived from acrylamide, acrylic acid, fumaric acid, itaconic acid, methacrylic acid, octadecyl methacrylate, and vinyl sulfonic acid.	

(c) The food-contact surface of the paper and paperboard in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of its intended use as determined from Tables 1 and 2 of this paragraph, shall yield net chloroform-soluble extractives (corrected for wax, petrolatum, mineral oil and zinc extractives as zinc oleate) not to exceed 0.5 milligram per square inch of food-contact surface as determined by the methods described in paragraph (d) of this section.

TABLE 1—TYPES OF RAW AND PROCESSED FOODS

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.

III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.

IV. Dairy products and modifications:

- A. Water-in-oil emulsions, high- or low-fat.
- B. Oil-in-water emulsions, high- or low-fat.

V. Low-moisture fats and oil.

VI. Beverages:

- A. Containing up to 8 percent of alcohol.
- B. Nonalcoholic.
- C. Containing more than 8 percent alcohol.

VII. Bakery products other than those included under Types VIII or IX of this table:

- A. Moist bakery products with surface containing free fat or oil.
- B. Moist bakery products with surface containing no free fat or oil.

VIII. Dry solids with the surface containing no free fat or oil (no-end test required).

IX. Dry solids with the surface containing free fat or oil.

TABLE 2—TEST PROCEDURES WITH TIME TEMPERATURE CONDITIONS FOR DETERMINING AMOUNT OF EXTRACTIVES FROM THE FOOD-CONTACT SURFACE OF UNCOATED OR COATED PAPER AND PAPERBOARD, USING SOLVENTS SIMULATING TYPES OF FOODS AND BEVERAGES

Condition of use	Types of food (see Table 1)	Food-simulating solvents			
		Water ¹	Heptane ^{1, 2}	8 percent alcohol ³	50 percent alcohol ³
A. High temperature heat-sterilized (e.g., over 212° F).	I, IV-B, VII-B III	250° F, 2 hr			
B. Boiling water sterilized	IV-A, VII-A	do	150° F, 2 hr		
	II, VII-B	212° F, 30 min.	120° F, 30 min.		
	III, VII-A	do	do		
C. Hot filled or pasteurized above 150° F.	II, IV-B, VII-B	Fill boiling, cool to 100° F.			
	III, IV-A, VII-A	do	120° F, 15 min.		
	V, IX		do		
D. Hot filled or pasteurized below 150° F.	II, IV-B, VI-B, VII-B	150° F, 2 hr	100° F, 30 min.		
	III, IV-A, VII-A	do			
	V, IX		do		
	VI-A			150° F, 2 hr	
	VI-C				150° F, 2 hr.
E. Room temperature filled and stored (no thermal treatment in the container).	I, II, IV-B, VI-B, VII-B	120° F, 24 hr	70° F, 30 min.		
	III, IV-A, VII-A	do			
	V, IX		do		
	VI-A			120° F, 24 hr	
	VI-C				120° F, 24 hr.
F. Refrigerated storage (no thermal treatment in the container).	III, IV-A, VII-A	70° F, 48 hr	70° F, 30 min.		
	I, II, IV-B, VI-B, VII-B	do			
	VI-A			70° F, 48 hr	
	VI-C				70° F, 48 hr.
G. Frozen storage (no thermal treatment in the container).	I, II, IV-B, VII-B	70° F, 24 hr	70° F, 30 min.		
	III, VII-A	do			
H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use.					
1. Aqueous or oil-in-water emulsion of high- or low-fat.	I, II, IV-B, VII-B	212° F, 30 min.			
2. Aqueous, high- or low-free oil or fat.	III, IV-A, VII-A, IX	do	120° F, 30 min.		

¹ Heptane extractability results must be divided by a factor of five in arriving at the extractability for a food product having water-in-oil emulsion or free oil or fat. Heptane food-simulating solvent is not required in the case of wax-polymer blend coatings for corrugated paperboard containers intended for use in bulk packaging of iced meat, iced fish, and iced poultry.

² Time and temperature.

(d) *Analytical methods*—(1) *Selection of extractability conditions.* First ascertain the type of food product (Table 1, paragraph (c) of this section) that is being packed commercially in the paper or paperboard and the normal conditions of thermal treatment used in packaging the type of food involved. Using Table 2, paragraph (c) of this section, select the food-simulating solvent or solvents and the time-temperature exaggera-

tions of the paper or paperboard use conditions. Having selected the appropriate food-simulating solvent or solvents and the time-temperature exaggeration over normal use, follow the applicable extraction procedure.

(2) *Reagents*—(i) *Water.* All water used in extraction procedures should be freshly demineralized (deionized) distilled water.

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