. BUSINESS CONFIDENTIAL PROJECT REPORT

STATUS OF UCC COATINGS RESINS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

AUTHORS: Z. E. Ster

SUPERVISOR: W. B. Ackart

DATE: April 17, 1980

PROJECT NO.: 321N01

FILE NO.: 6614

SUMMARY

The food additive status of various UCC coatings resins is discussed in this report and lists of specific products suitable for food contact uses are given. The dynamic nature of our products prevents such lists from being all-inclusive for more than a few days so that for completely up-to-date information, this office should be consulted directly.

Also, since products acceptable for food packaging are not automatically suitable for packaging drugs and cosmetics, the requirements for drug and cosmetic packaging are reviewed briefly. Those products additionally cleared with the USDA for use in meat and poultry processing are also discussed.

Research and Development Department
Chemicals and Plastics
Union Carbide Corporation
Bound Brook, New Jersey

DISCUSSION

I. Food Packaging Applications

The Federal Food, Drug, and Cosmetic Act administered by the FDA in the Department of Health, Education, and Welfare provides for the safe use of chemicals in foods. So-called incidental food additives are those which may result from inadvertent migration during the processing or packaging operations. Since these are specifically included in the 1958 Food Additives Amendment, plastic materials used in food contact applications must comply with the provisions of the law.

There are four general categories of materials suitable for food contact uses. These include substances which (1) do not migrate to the food, (2) are generally recognized as safe, (3) were sanctioned by FDA for food contact use prior to the enactment of the amendment, or (4) are permitted by regulation under the amendment.

The regulation most important for coatings materials is 21 CFR 175.300 for resinous and polymeric coatings, which lists hundreds of substances which may be used as components of coatings. The regulation also provides for extraction limitations on the finished food contact coating under intended end use conditions. An excerpt of 175.300 is given in the Appendix. This regulation was one of the earliest regulations issued by the FDA and resulted from a petition filed by the Can Manufacturers Association. It has been amended three times as a result of petitions filed by UCC covering our VERR and QEX-2033 (an experimental latex) resins. All listings are by chemical identity rather than trade names.

Regulations 176.170 for components of paper in contact with aqueous and fatty foods and Regulation 177.1210 for closures refer to 175.300 for lists of acceptable materials so that resins cleared for coatings are also suitable for paper and closures. Both regulations include extraction limits on the finished article under intended use conditions. Regulation 176.180 for components of paper in contact with dry foods includes substances listed in 176.170 plus many additional materials, but does not include extraction specifications since migration to dry foods is conceded to be nil.

Regulation 21 CFR 175.105 for adhesives lists in excess of 1000 substances suitable for use in food packaging adhesives and contains no extraction limitations but prohibits direct contact with food except for trace amounts at seams and edge exposures.

Our customers for these coating resins who fabricate items intended for use in contact with foods are entitled to a written statement from us certifying that our products are suitable for use in contact with foods. All such letters originate from this office and will be sent in response to a written or telephone request. A sample copy is also given in the Appendix.

II. The following sections contain excerpts from 175.300 which describe various classes of resins and the chemical identity of its approved members. Lists of UCC resins which are covered are also given.

(VI) Phenolic Resins

(vi) Phenolic resins as the basic polymer formed by reaction of phenols with formaldehyde:

(a) Phenolic resins formed by reaction of formaldehyde with:

Alkylated (methyl, ethyl, propyl, isopropyl, butyl) phenols.
p-tert-Amylphenol.
4,4'-*sec*-Butylidenediphenol.
p-tert-Butylphenol.
o-, *m*-, and *p*-Cresol.
p-Cyclohexylphenol.
4,4'-Isopropylidenediphenol.
p-Nonylphenol.
p-Octylphenol.
3-Pentadecyl phenol mixture obtained from cashew nut shell liquid.
Phenol.
Phenyl o-cresol.
p-Phenylphenol.
Xylenol.

(b) Adjunct for phenolic resins: Aluminum butylate.

Phenolic Resins

BK-5918	CK-0036
BKR-2620	CK-1282
BKS-2555	CK-1634
BKS-2600	CK-1636
BKS-2602	CK-2103
BKS-2750	CK-2400
BKUA-2370	CK-2432
BLS-2700	CKU-2266

(VIII) Epoxy Resins

(viii) Epoxy resins, catalysts, and adjuncts:

(a) Epoxy resins, as the basic polymer:

(Alkoxy C_{12}-C_{14})-2,3-epoxypropane, in which the alkyl groups are even numbered and consist of a maximum of 1 percent C_{12} carbon atoms and a minimum of 48 percent C_{13} carbon atoms and a minimum of 18 percent C_{14} carbon atoms, for use only in coatings that are intended for contact with dry bulk foods at room temperature.

4,4'-*sec*-Butylidenediphenol-epichlorohydrin

4,4'-*sec*-Butylidenediphenol-epichlorohydrin reacted with one or more of the drying oils or fatty acids listed in paragraph (b)(3)(i) of this section.

4,4'-*sec*-Betylidenediphenol-epichlorohydrin chemically treated with one or more of the following substances:

Allyl ether of mono-, di-, or trimethylol phenol.

4,4'-*sec*-Butylidenediphenol-formaldehyde.

4,4'-Isopropylidenediphenol-formaldehyde.

Melamine-formaldehyde.

Phenol-formaldehyde.

Urea-formaldehyde.

Epoxidized polybutadiene.

Glycidyl ethers formed by reacting phenol-novolak resins with epichlorohydrin.

4,4'-Isopropylidenediphenol-epichlorohydrin.

4,4'-Isopropylidenediphenol-epichlorohydrin reacted with one or more of the drying oils or fatty acids listed in paragraph (b)(3)(i) of this section.

4,4'-Isopropylidenediphenol-epichlorohydrin chemically treated with one or more of the following substances:

Allyl ether of mono-, di-, or trimethylol phenol.

4,4'-*sec*-Butylidenediphenol-formaldehyde.

4,4'-Isopropylidenediphenol-formaldehyde.

Melamine-formaldehyde.

Phenol-formaldehyde.

Urea-formaldehyde.

(b) Catalysts and cross-linking agents for epoxy resins:

Cyanoguanidine.

Dibutyl phthalate, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.

Diethylenetriamine.

Diphenylamine

Ethylenediamine.

Isophthalyl dihydrazide for use only in coatings subject to the provisions of paragraph (c) (3) or (4) of this section.

4,4'-Methylenedianiline, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.

N-Oleyl-1,3-propanediamine with not more than 10 percent by weight of diethylaminoethanol.

Polyamine produced when 1 mole of the chlorohydrin diether of polyethylene glycol 400 is made to react under dehydrohalogenating conditions with 2 moles of *N*-octadecyltrimethylenediamine for use only in coatings that are subject to the provisions of paragraph (c) (3) or (4) of this section and that contact food at temperatures not to exceed room temperature.

Salicylic acid, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.

Stannous 2-ethylhexanoate for use only as a catalyst at a level not to exceed 1 percent by weight of the resin used in coatings that are intended for contact with food under conditions of use D, E, F, and G described in table 2 of paragraph (d) of this section.

Styrene oxide, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.

Tetraethylenepentamine.

Tetraethylenepentamine reacted with equimolar quantities of fatty acids.

Tri(dimethylaminomethyl) phenol and its salts prepared from the fatty acid moieties of the salts listed in paragraph (b)(3)(xxii)(b) of this section, for use only in coatings subject to the provisions of paragraph (c) (3) or (4) of this section.

Triethylenetetramine.

Trimellitic anhydride for use only as a cross-linking agent at a level not to exceed 15 percent by weight of the resin intended for use only in contact with food under conditions of use D, E, F, and G described in table 2 of paragraph (d) of this section.

(c) Adjuncts for epoxy resins:

Aluminum butylate.

Benzoic acid, for use as a component in epoxy resins for coatings not exceeding a coating weight of 4 milligrams per square inch and that are intended for contact under conditions of use D, E, F or G described in table 2 of paragraph (d) of this section with alcoholic beverages containing less than 8 percent alcohol.

Polyamides from dimerized vegetable oils and the amine catalysts listed in paragraph (b)(3)(viii)(b) of this section, as the basic polymer.

Succinic anhydride, for use as a component in epoxy resins for coatings not exceeding a coating weight of 4 milligrams per square inch, and that are intended for contact under conditions of use D, E, F or G described in table 2 of paragraph (d) of this section with alcoholic beverages containing less than 8 percent alcohol.

Phenoxy Resins

PKHA

PKHC

PKHH

PKHJ

(XV) Vinyl Resinous Substances

(xv) Vinyl resinous substance, as the basic polymers:

Polyvinyl acetate.
Polyvinyl alcohol
Polyvinyl butyral
Polyvinyl chloride.
Polyvinyl formal.
Polyvinylidene chloride.
Polyvinyl pyrrolidone.
Polyvinyl stearate.
Vinyl chloride-acetate-2,3-epoxypropyl methacrylate copolymers containing not more than 10 weight percent of total polymer units derived from 2,3-epoxypropyl methacrylate and not more than 0.1 weight percent of unreacted 2,3-epoxypropyl methacrylate monomer for use in coatings for containers.
Vinyl chloride-acetate, hydroxyl-modified copolymer.
Vinyl chloride-acetate, hydroxyl-modified copolymer, reacted with trimellitic anhydride.
Vinyl chloride copolymerized with acrylamide and ethylene in such a manner that the finished copolymers have a minimum weight average molecular weight of 30,000 and contain not more than 3.5 weight percent of total polymer units derived from acrylamide; the acrylamide portion may or may not be subsequently partially hydrolyzed
Vinyl chloride copolymerized with one or more of the following substances
Acrylonitrile.
Fumaric acid and/or its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters
Maleic acid and/or its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters.
5-Norbornene-2,3-dicarboxylic acid, mono-n-butyl ester; for use such that the finished vinyl chloride copolymers contain not more than 4 weight percent of total polymer units derived from this comonomer.
Vinyl acetate.
Vinylidene chloride.
Vinyl chloride-vinylidene chloride-2,3-epoxypropyl methacrylate copolymers containing not more than 10 weight percent of total polymer units derived from 2,3-epoxypropyl methacrylate and not more than 0.05 weight percent of unreacted 2,3-epoxypropyl methacrylate monomer based on polymer solids for use only in coatings for containers intended for contact with foods under conditions E, C, D, E, F, G, or H described in Table 2 of paragraph (d) of this section.

Vinyl Acetate Resins

AYAA
AYAB*
AYAC*
AYAF
AYAT

Vinyl Butyral Resins

XYHL
XYSG

Vinyl Chloride Acetate Resins

VAGD
VAGH
VERR-40
VMCA
VMCC
VMCH
VYDS
VYDS-66
VYHD
VYHH
VYLF
VYNS

UCC vinyl acetate resins AYAB and AYAC are also cited by chemical identity in Title 21 CFR 172.615 for chewing gum base. AYAB and AYAC meet the specifications for polyvinyl acetate given in the Food Chemicals Codex and may therefore be used as components of chewing gum.

Although vinyl resins have recently been suspect because of the chronic toxicity associated with vinyl chloride monomer, their use as coatings materials has never been questioned by the Food and Drug Administration. In their proposal of 1973 which has never been either implemented or withdrawn, the FDA confirmed the safe use of vinyl resins as coatings, gaskets and cap liners, flexible tubing, and plasticized films and indicated the continued validity of regulations permitting these uses (see Section I). Union Carbide has continually been in touch with the FDA regarding continued use of our vinyl resins in coating applications and is presently preparing a report for submission to the FDA describing an extensive study which documents the low level of residual monomer in these resins, demonstrates that monomer levels are drastically reduced in the solution coating process, and concludes that use of these resins in food contact coatings would not reasonably be expected to result in monomer becoming a component of foods.

III. Drug Packaging

Products that comply with appropriate food additive regulations are not automatically qualified for packaging drugs and pharmaceuticals. There are no blanket clearances for drug packaging materials comparable to the food additive regulations. Each drug package must be proven to be both safe and effective for the particular drug involved, usually through long-term storage and stability tests. These data are included as part of the New Drug Application which the drug manufacturer must file with the Food and Drug Administration before he can market his product.

IV. Cosmetic Packaging

Again, there are no blanket clearances for cosmetic packaging materials as there are for food packaging materials. Sec. 601 of the General Regulations states that a cosmetic shall be deemed to be adulterated if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health. Under this regulation any packaging material that complies with the food additive regulations is also suitable for packaging cosmetics. In addition, many products which are not suitable for food contact uses may be perfectly safe for cosmetics. In this case it is necessary to consider the toxicity of the questionable component, together with its tendency to extract into the cosmetic and, in consultation with the UCC Law and Medical Departments, determine whether the product is suitable for use in the particular application. Questions regarding specific products should be directed to us.

V. Meat and Poultry Packaging

The Wholesome Meat Act and the Wholesome Poultry Act provide for Federal Inspection of meat and poultry packaging plants by the Food Safety and Quality Service (FSQS) of the U.S. Department of Agriculture (formerly known as the MID, MIB, and APHIS). All raw materials used in such establishments must be "approved" individually by the FSQS. For packaging materials that comply with the FDA food additive requirements, USDA clearance is almost automatic and we receive a letter from them indicating that the specific product is chemically acceptable provided that it is functionally effective. We provide a copy of this letter to our customer which ultimately is filed at the packing plant for scrutiny of the USDA Inspector. These clearances are obtained at the customer's request and normally require four to six weeks. We have obtained letters of acceptability for the following active products:

Phenolic Resins

CK-0036
CK-1634
CK-2103
CK-2400
CK-2432

Phenoxy Resins

PKHC
PKHJ

Vinyl Acetate Resins

AYAA

Vinyl Chloride Acetate Resins

VAGD
VAGH
VMCC
VMCH
VYHD
VYHH
VYNS

It is intended that this report will be updated at periodic intervals or as required. If we can be of further help, please contact us.

Z. E. Ster

ZES:bs

9-A-16

APPENDIX

1. Regulation 175.300
2. Sample customer letter

panediol in each extracting solvent not to exceed 0.3 micrograms per square inch of food-contact surface. In testing the finished food-contact articles, a separate test sample is to be used for each required extracting solvent.

§ 175.270 Poly(vinyl fluoride) resins.

Poly(vinyl fluoride) resins identified in this section may be safely used as components of food-contact coatings for containers having a capacity of not less than 5 gallons, subject to the provisions of this section.

(a) For the purpose of this section, poly(vinyl fluoride) resins consist of basic resins produced by the polymerization of vinyl fluoride.

(b) The poly(vinyl fluoride) basic resins have an intrinsic viscosity of not less than 0.75 deciliter per gram as determined by ASTM Method D 1243-66, modified as follows:

(1) Solvent: *N,N*-Dimethylacetamide, technical grade.

(2) Solution: Powdered resin and solvent are heated at 120° C until the resin is dissolved.

(3) Temperature: Flow times of the solvent and solution are determined at 110° C.

(4) Viscometer: Cannon-Ubbelohde size 50 semimicro dilution viscometer (or equivalent).

(5) Calculation: The calculation method used is that described in appendix A1.2.2 (ASTM Method D 1243-66) with the reduced viscosity determined for three concentration levels, not greater than 0.5 gram per deciliter, and extrapolated to zero concentration for intrinsic viscosity. The following formula is used for determining reduced viscosity:

Reduced viscosity in terms of deciliters per gram = $t - to/to \times c$

Where:
t = Solution efflux time.
to = Solvent efflux time.
c = Concentration of solution in terms of grams per deciliter.

§ 175.300 Resinous and polymeric coatings.

Resinous and polymeric coatings may be safely used as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The coating is applied as a continuous film or enamel over a metal substrate, or the coating is intended for repeated food-contact use and is applied to any suitable substrate as a continuous film or enamel that serves as a functional barrier between the food and the substrate. The coating is characterized by one or more of the following descriptions:

(1) Coatings cured by oxidation.

(2) Coatings cured by polymerization, condensation, and/or cross-linking without oxidation.

(3) Coatings prepared from prepolymerized substances.

(b) The coatings are formulated from optional substances that may include:

(1) Substances generally recognized as safe in food.

(2) Substances the use of which is permitted by regulations in this part or which are permitted by prior sanction or approval and employed under the specific conditions, if any, of the prior sanction or approval.

(3) Any substance employed in the production of resinous and polymeric coatings that is the subject of a regulation in Subchapter B of this chapter and conforms with any specification in such regulation. Substances named in this paragraph (b)(3) and further identified as required:

(i) Drying oils, including the triglycerides or fatty acids derived therefrom:

Beechnut.
Candlenut.
Castor (including dehydrated).
Chinawood (tung).
Coconut.

Corn.
Cottonseed.
Fish (refined).
Hempseed.
Linseed.
Oiticica.
Perilla.
Poppyseed.
Pumpkinseed.
Safflower.
Sesame.
Soybean.
Sunflower.
Tall oil.
Walnut.

The oils may be raw, heat-bodied, or blown. They may be refined by filtration, degumming, acid or alkali washing, bleaching, distillation, partial dehydration, partial polymerization, or solvent extraction, or modified by combination with maleic anhydride.

(ii) Reconstituted oils from triglycerides or fatty acids derived from the oils listed in paragraph (b)(3)(i) of this section to form esters with:

Butylene glycol.
Ethylene glycol.
Pentaerythritol.
Polyethylene glycol.
Polypropylene glycol.
Propylene glycol.
Sorbitol.
Trimethylol ethane.
Trimethylol propane.

(iii) Synthetic drying oils, as the basic polymer:

Butadiene and methylstyrene copolymer.
Butadiene and styrene copolymer, blown or unblown.
Maleic anhydride adduct of butadiene styrene.
Polybutadiene

(iv) Natural fossil resins, as the basic resin:

Copal
Damar.
Elemi
Gilsonite.
Glycerol ester of damar, copal, elemi, and sandarac.
Sandarac
Shellac.
Utah coal resin

(v) Rosins and rosin derivatives, with or without modification by polymerization, isomerization, incidental decarboxylation, and/or hydrogenation, as follows:

(a) Rosins, refined to color grade of K or paler:

Gum rosin.
Tall oil rosin.
Wood rosin.

(b) Rosin esters formed by reacting rosin (paragraph (b)(3) (v)(a) of this section) with:

4,4'-*sec*-Butylidenediphenol-epichlorohydrin (epoxy).
Diethylene glycol.
Ethylene glycol.
Glycerol.
4,4'-Isopropylidenediphenol-epichlorohydrin (epoxy).
Methyl alcohol.
Pentaerythritol.

(c) Rosin esters (paragraph (b)(3) (v)(b) of this section) modified by reaction with:

Maleic anhydride
o-, *m*-, and *p*-substituted phenol formaldehydes listed in paragraph (b)(3)(vi) of this section.
Phenol-formaldehyde.

(d) Rosin salts:

Calcium resinate (limed rosin).
Zinc resinate

(vi) Phenolic resins as the basic polymer formed by reaction of phenols with formaldehyde:

(a) Phenolic resins formed by reaction of formaldehyde with:

Alkylated (methyl, ethyl, propyl, isopropyl, butyl) phenols
p-tert-Amylphenol.
4,4'-*sec* Butylidenediphenol
p-tert-Butylphenol.
o-, *m*-, and *p*-Cresol
p-Cyclohexylphenol
4,4'-Isopropylidenediphenol.
p Nonylphenol
p Octylphenol
3-Pentadecyl phenol mixture obtained from cashew nut shell liquid
Phenol
Phenyl *o*-cresol
p Phenylphenol
Xylenol.

(b) Adjunct for phenolic resins: Aluminum butylate.

(vii) Polyester resins (including alkyd-type), as the basic polymers, formed as esters of acids listed in paragraph (b)(3)(vii) (a) and (b) of this section by reaction with alcohols in paragraph (b)(3) (vii) (c) and (d) of this section.

(a) Polybasic acids:

Adipic.
Dimerized fatty acids derived from oils listed in paragraph (b)(3)(i) of this section.
Diphenolic acid.
Fumaric.
Isophthalic.
Maleic.
Orthophthalic.
Sebacic.
Terephthalic.
Terpene-maleic acid adduct.
Trimellitic.

(b) Monobasic acids:

Benzoic acid.
tert-Butyl benzoic acid.
Fatty acids derived from oils listed in paragraph (b)(3)(i) of this section.
Rosins listed in paragraph (b)(3)(v)(a) of this section, for use only as reactants in oil-based or fatty acid-based alkyd resins.

(c) Polyhydric alcohols:

Butylene glycol.
Diethylene glycol.
2,2-Dimethyl-1,3-propanediol for use only in forming polyester resins for coatings intended for use in contact with non-alcoholic foods.
Ethylene glycol.
Glycerol.
Mannitol.
α-Methyl glucoside.
Pentaerythritol.
Propylene glycol.
Sorbitol.
Triethylene glycol, for use as a component in polyester resins for coatings not exceeding a coating weight of 4 milligrams per square inch and that are intended for contact under conditions of use D, E, F or G described in table 2 of paragraph (d) of this section with alcoholic beverages containing less than 8 percent alcohol.
Trimethylol ethane.
Trimethylol propane.

(d) Monohydric alcohols:

Cetyl alcohol.
Decyl alcohol.
Lauryl alcohol.
Myristyl alcohol.
Octyl alcohol.
Stearyl alcohol.

(viii) Epoxy resins, catalysts, and adjuncts:

(a) Epoxy resins, as the basic polymer:

(Alkoxy C_{12}-C_{14})-2,3-epoxypropane, in which the alkyl groups are even numbered and consist of a maximum of 1 percent C_{12} carbon atoms and a minimum of 48 percent C_{14} carbon atoms and a minimum of 18 percent C_{16} carbon atoms, for use only in coatings that are intended for contact with dry bulk foods at room temperature.
4,4'-*sec*-Butylidenediphenol-epichlorohydrin.
4,4'-*sec*-Butylidenediphenol-epichlorohydrin reacted with one or more of the drying oils or fatty acids listed in paragraph (b)(3)(i) of this section.
4,4'-*sec*-Betylidenediphenol-epichlorohydrin chemically treated with one or more of the following substances:
Allyl ether of mono-, di-, trimethylol phenol.
4,4'-*sec*-Butylidenediphenol-formaldehyde.
4,4'-Isopropylidenediphenol-formaldehyde.
Melamine-formaldehyde.
Phenol-formaldehyde.
Urea-formaldehyde.
Epoxidized polybutadiene.
Glycidyl ethers formed by reacting phenol-novolak resins with epichlorohydrin.
4,4'-Isopropylidenediphenol-epichlorohydrin.
4,4'-Isopropylidenediphenol-epichlorohydrin reacted with one or more of the drying oils or fatty acids listed in paragraph (b)(3)(i) of this section.
4,4'-Isopropylidenediphenol-epichlorohydrin chemically treated with one or more of the following substances:
Allyl ether of mono-, di-, or trimethylol phenol.
4,4'-*sec*-Butylidenediphenol-formaldehyde.
4,4'-Isopropylidenediphenol-formaldehyde.
Melamine-formaldehyde.
Phenol-formaldehyde
Urea-formaldehyde.

(b) Catalysts and cross-linking agents for epoxy resins:

Cyanoguanidine.
Dibutyl phthalate, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.
Diethylenetriamine.
Diphenylamine.
Ethylenediamine.
Isophthalyl dihydrazide for use only in coatings subject to the provisions of paragraph (c) (3) or (4) of this section.
4,4'-Methylenedianiline, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.
N-Oleyl-1,3-propanediamine with not more than 10 percent by weight of diethylaminoethanol.
Polyamine produced when 1 mole of the chlorohydrin diether of polyethylene glycol 400 is made to react under dehydrohalogenating conditions with 2 moles of *N*-octadecyltrimethylenediamine for use only in coatings that are subject to the provisions of paragraph (c) (3) or (4) of this section and that contact food at temperatures not to exceed room temperature.
Salicylic acid, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.
Stannous 2-ethylhexanoate for use only as a catalyst at a level not to exceed 1 percent by weight of the resin used in coatings that are intended for contact with food under conditions of use D, E, F, and G described in table 2 of paragraph (d) of this section.
Styrene oxide, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.
Tetraethylenepentamine.
Tetraethylenepentamine reacted with equimolar quantities of fatty acids
Tri(dimethylaminomethyl) phenol and its salts prepared from the fatty acid moieties of the salts listed in paragraph (b)(3)(xxii)(b) of this section, for use only in coatings subject to the provisions of paragraph (c) (3) or (4) of this section
Triethylenetetramine
Trimellitic anhydride for use only as a cross-linking agent at a level not to exceed 15 percent by weight of the resin intended for use only in contact with food under conditions of use D, E, F, and G described in table 2 of paragraph (d) of this section.

(c) Adjuncts for epoxy resins:

Aluminum butylate
Benzoic acid, for use as a component in epoxy resins for coatings not exceeding a coating weight of 4 milligrams per square inch and that are intended for contact under conditions of use D, E, F or G described in table 2 of paragraph (d) of this section with alcoholic beverages containing less than 8 percent alcohol.
Polyamides from dimerized vegetable oils and the amine catalysts listed in paragraph (b)(3)(viii)(b) of this section, as the basic polymer.
Succinic anhydride, for use as a component in epoxy resins for coatings not exceeding a coating weight of 4 milligrams per square inch, and that are intended for contact under conditions of use D, E, F or G described in table 2 of paragraph (d) of this section with alcoholic beverages containing less than 8 percent alcohol.

(ix) Coumarone-indene resin, as the basic polymer.

(x) Petroleum hydrocarbon resin (cyclopentadiene type), as the basic polymer.

(xi) Terpene resins, as the basic polymer, from one or more of the following:

Dipentene.
α-Pinene.
β-Pinene.

(xii) Urea-formaldehyde, resins and their curing catalyst:

(a) Urea-formaldehyde resins, as the basic polymer:

Urea-formaldehyde.
Urea-formaldehyde chemically modified with methyl, ethyl, propyl, isopropyl, butyl, or isobutyl alcohol.
Urea-formaldehyde chemically modified with one or more of the amine catalysts listed in paragraph (b)(3)(viii)(b) of this section.

(b) Curing (cross-linking) catalyst for urea-formaldehyde resins:

Dodecyl benzenesulfonic acid (C.A. Registry No. 27176-87-0).

(xiii) Triazine-formaldehyde resins and their curing catalyst:

(a) Triazine-formaldehyde resins, as the basic polymer:

Benzoguanamine-formaldehyde.
Melamine-formaldehyde.
Melamine-formaldehyde chemically modified with one or more of the following amine catalysts:
Amine catalysts listed in paragraph (b)(3)(viii)(b) of this section.
Dimethylamine-2-methyl-1-propanol.
Methylpropanolamine.
Triethanolamine.
Melamine-formaldehyde chemically modified with methyl, ethyl, propyl, isopropyl, butyl, or isobutyl alcohol.

(b) Curing (cross-linking) catalyst for triazine-formaldehyde resins:

Dodecyl benzenesulfonic acid (C.A. Registry No. 27176-87-0).

(xiv) Modifiers (for oils and alkyds, including polyesters), as the basic polymer:

Butyl methacrylate.
Cyclopentadiene.
Methyl, ethyl, butyl, or octyl esters of acrylic acid.
Methyl methacrylate.
Styrene.
Vinyl toluene.

(xv) Vinyl resinous substance, as the basic polymers:

Polyvinyl acetate.
Polyvinyl alcohol.
Polyvinyl butyral.
Polyvinyl chloride.
Polyvinyl formal.
Polyvinylidene chloride.
Polyvinyl pyrrolidone.
Polyvinyl stearate.
Vinyl chloride-acetate-2,3-epoxypropyl methacrylate copolymers containing not more than 10 weight percent of total polymer units derived from 2,3-epoxypropyl methacrylate and not more than 0.1 weight percent of unreacted 2,3-epoxypropyl methacrylate monomer for use in coatings for containers.
Vinyl chloride-acetate, hydroxyl-modified copolymer.
Vinyl chloride-acetate, hydroxyl-modified copolymer, reacted with trimellitic anhydride.
Vinyl chloride copolymerized with acrylamide and ethylene in such a manner that the finished copolymers have a minimum weight average molecular weight of 30,000 and contain not more than 3.5 weight percent of total polymer units derived from acrylamide; the acrylamide portion may or may not be subsequently partially hydrolyzed
Vinyl chloride copolymerized with one or more of the following substances:
Acrylonitrile
Fumaric acid and/or its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters.
Maleic acid and/or its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters.
5-Norbornene-2,3-dicarboxylic acid, mono-*n*-butyl ester; for use such that the finished vinyl chloride copolymers contain not more than 4 weight percent of total polymer units derived from this comonomer.
Vinyl acetate.
Vinylidene chloride.
Vinyl chloride-vinylidene chloride-2,3-epoxypropyl methacrylate copolymers containing not more than 10 weight percent of total polymer units derived from 2,3-epoxypropyl methacrylate and not more than 0.05 weight percent of unreacted 2,3-epoxypropyl methacrylate monomer based on polymer solids for use only in coatings for containers intended for contact with foods under conditions B, C, D, E, F, G, or H described in Table 2 of paragraph (d) of this section.

(xvi) Cellulosics, as the basic polymer:

Carboxymethylcellulose.
Cellulose acetate.
Cellulose acetate-butyrate.
Cellulose acetate-propionate.
Ethylcellulose.
Ethyl hydroxyethylcellulose.
Hydroxyethylcellulose.
Hydroxypropyl methylcellulose.
Methylcellulose.
Nitrocellulose.

(xvii) Styrene polymers, as the basic polymer:

Polystyrene.
α-Methyl styrene polymer.
Styrene copolymerized with one or more of the following:
Acrylonitrile.
α-Methylstyrene.

(xviii) Polyethylene and its copolymers as the basic polymer:

Ethylene-ethyl acrylate copolymer.
Ethylene-isobutyl acrylate copolymers containing no more than 35 weight percent of total polymer units derived from isobutyl acrylate
Ethylene-vinyl acetate copolymer
Polyethylene.

(xix) Polypropylene as the basic polymer:

Polypropylene.
Maleic anhydride adduct of polypropylene The polypropylene used in the manufacture of the adduct complies with § 177.1520(c), item 1.1; and the adduct has a maximum combined maleic anhydride content of 0.8 percent and a minimum intrinsic viscosity of 0.9, determined at 135° C on a 0.1 percent solution of the modified polypropylene in decahydronaphthalene as determined by a method available on request from the Commissioner of Food and Drugs.

(xx) Acrylics and their copolymers, as the basic polymer:

Acrylamide with ethylacrylate and/or styrene and/or methacrylic acid, subsequently reacted with formaldehyde and butanol.
Acrylic acid and the following esters thereof:
Ethyl.
Methyl.
Butyl acrylate-styrene-methacrylic acid-hydroxyethyl methacrylate copolymers containing no more than 20 weight percent of total polymer units derived from methacrylic acid and containing no more than 7 weight percent of total polymer units derived from hydroxyethyl methacrylate; for use only in coatings that are applied by electrodeposition to metal substrates.
Butyl acrylate-styrene-methacrylic acid-hydroxypropyl methacrylate copolymers containing no more than 20 weight percent of total polymer units derived from methacrylic acid and containing no more than 7 weight percent of total polymer units derived from hydroxypropyl methacrylate; for use only in coatings that are applied by electrodeposition to metal substrates and that are intended for contact, under condition of use D, E, F, or G described in table 2 of paragraph (d) of this section, with food containing no more than 8 percent of alcohol.
Ethyl acrylate-styrene-methacrylic acid copolymers for use only as modifiers for epoxy resins listed in paragraph (b)(3)(viii)(a) of this section.
Ethyl acrylate-methyl methacrylate-styrene-methacrylic acid copolymers for use only as modifiers for epoxy resins listed in paragraph (b)(3)(viii)(a) of this section
2-Ethylhexyl acrylate-ethyl acrylate copolymers prepared by copolymerization of 2-ethylhexyl acrylate and ethyl acrylate in a 7/3 weight ratio and having a number average molecular weight range of 5,800 to 6,500 and a refractive index, n_D^{25} (40 percent in 2,2,4-trimethyl pentane) of 1.4130-1.4190, for use as a modifier for nylon resins complying with § 177.1500 of this chapter and for phenolic and epoxy resins listed in paragraph (b)(3) (vi) and (viii) of this section, respectively, at a level not to exceed 1.5 percent of the coating
2-Ethylhexyl acrylate-methyl methacrylate-acrylic acid copolymers for use only as modifiers for epoxy resins listed in paragraph (b)(3)(viii) of this section.
Methacrylic acid and the following esters thereof:
Butyl.
Ethyl.
Methyl.
Methacrylic acid or its ethyl and methyl esters copolymerized with one or more of the following:
Acrylic acid.
Ethyl acrylate.
Methyl acrylate.
n-Butyl acrylate-styrene-methacrylic acid-hydroxyethyl methacrylate copolymers containing no more than 2 weight percent of total polymer units derived from methacrylic acid and containing no more than 9.5 weight percent of total polymer units derived from hydroxethyl methacrylate; for use only in coatings in contact with dry food (food type VIII in table 1 of paragraph (d) of this section). 2-(Dimethylamino) ethanol (C.A.S. Registry No. 108-01-0) may be employed as an optional adjuvant substance limited to no more than 2 weight percent based on polymer solids in the coating emulsion.

(xxi) Elastomers, as the basic polymer:

Butadiene-acrylonitrile copolymer.
Butadiene-acrylonitrile-styrene copolymer.
Butadiene-styrene copolymer.
Butyl rubber.
Chlorinated rubber.
2-Chloro-1,3-butadiene (neoprene).
Natural rubber (natural latex or natural latex solids, smoked or unsmoked).
Polyisobutylene
Rubber hydrochloride.
Styrene-isobutylene copolymer.

(xxii) Driers made by reaction of a metal from paragraph (b)(3)(xxii)(a) of this section with acid, to form the salt listed in paragraph (b)(3)(xxii)(b) of this section:

(a) Metals:

Aluminum
Calcium.
Cerium
Cobalt.
Iron
Lithium
Magnesium
Manganese.
Zinc
Zirconium

(b) Salts:

Caprate.

Caprylate.
Isodecanoate.
Linoleate.
Naphthenate.
Neodecanoate.
Octoate (2-ethylhexoate).
Oleate.
Palmitate.
Resinate.
Ricinoleate.
Soyate.
Stearate.
Tallate.

(xxiii) Waxes:

Paraffin, Type I.
Paraffin, Type II.
Polyethylene.
Sperm oil.
Spermaceti.

(xxiv) Plasticizers:

Acetyl tributyl citrate.
Acetyl triethyl citrate.
Butyl phthalyl butyl glycolate.
Butyl stearate.
p-tert-Butyl phenyl salicylate.
Dibutyl sebacate.
Diethyl phthalate.
Diisobutyl adipate.
Diisooctyl phthalate.
Epoxidized soybean oil (iodine number maximum 14; oxirane oxygen content 6% minimum), as the basic polymer.
Ethyl phthalyl ethyl glycolate.
2-Ethylhexyl diphenyl phosphate.
di-2-Ethylhexyl phthalate.
Glycerol.
Glyceryl monooleate.
Glyceryl triacetate.
Monoisopropyl citrate.
Propylene glycol.
Sorbitol.
Mono-, di-, and tristearyl citrate
Triethyl citrate.
Triethylene glycol.
3(2-Xenoxyl)-1,2-epoxypropane.

(xxv) Release agents, as the basic polymer, when applicable:

N,N'-Distearoyl ethylenediamine.
Linoleic acid amide.
Oleic acid amide.
Palmitic acid amide.
Petrolatum
Polyethylene wax.
Polyoxyethylene glycol monooleate (mol. wt. of the polyoxyethylene glycol moiety greater than 300).
Polytetrafluoroethylene.
Silicones (not less than 300 centistokes viscosity): Dimethylpolysiloxanes and/or methylphenylpolysiloxanes. The methylphenylpolysiloxanes contain not more than 2.0 percent by weight of cyclosiloxanes having up to and including 4 siloxy units.
Silicones (not less than 100 centistokes viscosity): Dimethylpolysiloxanes and/or methylphenylpolysiloxanes limited to use only on metal substrates. The methylphenylpolysiloxanes contain not more than 2.0 percent by weight of cyclosiloxanes having up to and including 4 siloxy units.

(xxvi) Pigments and colorants:

Aluminum.
Aluminum hydrate.
Aluminum and potassium silicate (mica).
Aluminum mono-, di-, tristearate.
Aluminum silicate (China clay).
Barium sulfate.
Bentonite.
Bentonite, modified with dimethyl dioctadecyl ammonium ion.
Burnt umber.
Calcium carbonate.
Calcium silicate.
Calcium sulfate.
Carbon black (channel process).
Cobalt oxide-aluminum oxide.
Diatomaceous earth.
Iron oxides.
Magnesium oxide.
Magnesium silicate (talc).
Phthalocyanine blue (C.I. pigment blue 15, C.I. No. 74160).
Raw sienna.
Silica.
Tartrazine lake (certified FD&C Yellow No 5 only).
Titanium dioxide.
Titanium dioxide-barium sulfate.
Titanium dioxide-magnesium silicate.
Zinc carbonate.
Zinc oxide.

(xxvii) Surface lubricants:

Cottonseed oil and other edible oils.
Dibutyl sebacate.
Dioctyl sebacate.
Glyceryl monostearate.
Lanolin.
Mineral oil, white.
Palm oil.
Paraffin, Type I.
Paraffin, Type II.
Petrolatum.
Stearic acid.

(xxviii) Silicones and their curing catalysts:

(a) Silicones as the basic polymer:

Siloxane resins originating from methyl hydrogen polysiloxane, dimethyl polysiloxane, and methylphenyl polysiloxane.

(b) Curing (cross-linking) catalysts for silicones (the maximum amount of tin catalyst used shall be that required to effect optimum cure but shall not exceed 1 part of tin per 100 parts of siloxane resins solids):

Dibutyltin dilaurate.
Stannous oleate.
Tetrabutyl titanate.

(xxix) Surface active agents:

Poly [2-(diethylamino) ethyl metharylate] phosphate (minimum intrinsic viscosity in water at 25° C is not less than 9.0 deciliters per gram as determined by ASTM Method D 1243-60), for use only as a suspending agent in the manufacture of vinyl chloride copolymers and limited to use at levels not to exceed 0.1 percent by weight of the copolymers.
Sodium dioctyl sulfosuccinate.
Sodium dodecyl benzenesulfonate.
Sodium lauryl sulfate.

(xxx) Antioxidants:

Butylated hydroxyanisole.
Butylated hydroxytoluene.
Gum guaiac.
Dilauryl thiodipropionate.
Nordihydroguaiaretic acid.
Propyl gallate.
Distearyl thiodipropionate.
Thiodipropionic acid.
2,4,5-Trihydroxybutyrophenone.

(xxxi) Can end cements (sealing compounds used for sealing can ends only): In addition to the substances listed in paragraph (b) of this section and those listed in § 177.1210(b)(5) of this chapter, the following may be used:

Butadiene-styrene-fumaric acid copolymer.
4,4'-Butylidenebis (6-*tert*-butyl-*m*-cresol).
Dibenzamido phenyl disulfide.
Di-β-naphthyl phenylenediamine.
Dipentamethylene thiuram tetrasulfide.
Isobutylene-isoprene-divinylbenzene copolymers for use only at levels not to exceed 15 percent by weight of the dry cement composition.
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt, for use only at levels not to exceed 0.6 percent by weight of the cement solids in can end cements for containers having a capacity of not less than 5 gallons.
Sodium decylbenzene sulfonate.
Sodium nitrite for use only at levels not to exceed 0.3 percent by weight of the cement solids in can end cements for containers having a capacity of not less than 5 gallons.
Sodium pentachlorophenate for use as a preservative at 0.1 percent by weight in can-sealing compounds on containers having a capacity of 5 gallons or more.
Sodium phenylphenate.
Tetrakis[methylene(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate)] methane for use as an antioxidant at levels not to exceed 0.05 percent by weight of isobutylene-isoprene-divinylbenzene copolymers in the cement.
Tetrasodium EDTA (tetrasodium ethylenediaminetetraacetate).
Tri (mixed mono- and dinonylphenyl) phosphite.
Zinc dibutyldithiocarbamate.

(xxxii) Side seam cements: In addition to the substances listed in paragraph (b)(3) (i) to (xxx), inclusive, of this section, the following may be used.

p-tert-Butyl perbenzoate as a catalyst for epoxy resin.
epsilon-Caprolactam-(ethylene-ethyl acrylate) graft polymer.
Dicumyl peroxide for use only as polymerization catalyst.
Diisodecyl phthalate for use only as plasticizer in side seam cements for containers intended for use in contact with food only of the types identified in paragraph (d) of this section, table 1, under categories I, II, and VI.
Ethyl toluene sulfonamide.
Polyamides derived from the following acids and amines:
  Acids:
    Adipic.
    Azelaic.
    Sebacic.
    Vegetable oil acids (with or without dimerization).
  Amines:
    Diethylenetriamine.
    Diphenylamine.
    Ethylenediamine.
    Hexamethylenediamine
    Tetraethylenepentamine.
    Triethylenetetramine.
Sodium pentachlorophenate for use as a preservative at 0.1 percent by weight in can-sealing compounds on containers having a capacity of 5 gallons or more.
Toluene sulfonamide formaldehyde resin (basic polymer).
Triethylene glycol methacrylate for use only as polymerization cross-linking agent in side seam cements for containers intended for use in contact with food only of the types identified in paragraph (d) of this section, table 1, under categories I, II, and VI.
Urea

(xxxiii) Miscellaneous materials:

Ammonium citrate

Ammonium potassium phosphate.
Calcium acetate.
Calcium ethyl acetoacetate.
Calcium glycerophosphate.
Calcium, sodium, and potassium oleates.
Calcium, sodium, and potassium ricinoleates.
Calcium, sodium, and potassium stearates.
Castor oil, hydrogenated.
Cetyl alcohol.
Cyclohexanone-formaldehyde resin produced when 1 mole of cyclohexanone is made to react with 1.65 moles of formaldehyde such that the finished resin has an average molecular weight of 600–610 as determined by ASTM Method D2503. For use only in contact with nonalcoholic and nonfatty foods under conditions of use E, F, and G, described in table 2 of paragraph (d) of this section.
Decyl alcohol.
Disodium hydrogen phosphate.
Ethyl acetoacetate.
Lauryl alcohol.
Lecithin.
Magnesium, sodium, and potassium citrate.
Magnesium glycerophosphate.
Magnesium stearate.
Mono-, di-, and tricalcium phosphate.
Monodibutylamine pyrophosphate as sequestrant for iron.
Mono-, di-, and trimagnesium phosphate.
Myristyl alcohol.
Octyl alcohol.
Phosphoric acid.
Polybutene, hydrogenated; complying with the identity and limitations prescribed by § 178.3740 of this chapter.
Poly(ethylene oxide).
Sodium pyrophosphate.
Stannous chloride.
Stannous stearate.
Stannous sulfate.
Stearyl alcohol.
Tetrasodium pyrophosphate.
Tridecyl alcohol produced from tetrapropylene by the oxo process, for use only as a processing aid in polyvinyl chloride resins.
Vinyl acetate-dibutyl maleate copolymers produced when vinyl acetate and dibutyl maleate are copolymerized with or without one of the monomers: Acrylic acid or glycidyl methacrylate. For use only in coatings for metal foil used in contact with foods that are dry solids with the surface containing no free fat or oil. The finished copolymers shall contain at least 50 weight-percent of polymer units derived from vinyl acetate and shall contain no more than 5 weight-percent of total polymer units derived from acrylic acid or glycidyl methacrylate.

(xxxiv) Polyamide resins derived from dimerized vegetable oil acids (containing not more than 20 percent of monomer acids) and ethylenediamine, as the basic resin, for use only in coatings that contact food at temperatures not to exceed room temperature.

(xxxv) Polyamide resins having a maximum acid value of 5 and a maximum amine value of 8.5 derived from dimerized vegetable oil acids (containing not more than 10 percent of monomer acids), ethylenediamine, and 4,4-bis (4-hydroxyphenyl) pentanoic acid (in an amount not to exceed 10 percent by weight of said polyamide resins); as the basic resin, for use only in coatings that contact food at temperatures not to exceed room temperature provided that the concentration of the polyamide resins in the finished food-contact coating does not exceed 5 milligrams per square inch of food-contact surface.

(xxxvi) Methacrylonitrile grafted polybutadiene copolymers containing no more than 41 weight percent of total polymer units derived from methacrylonitrile; for use only in coatings that are intended for contact, under conditions of use D, E, F, or G described in Table 2 of paragraph (d) of this section, with food containing no more than 8 percent of alcohol.

(c) The coating 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 paragraph (d) of this section, shall yield chloroform-soluble extractives, corrected for zinc extractives as zinc oleate, not to exceed the following:

(1) From a coating intended for or employed as a component of a container not to exceed 1 gallon and intended for one-time use, not to exceed 0.5 milligram per square inch nor to exceed that amount as milligrams per square inch that would equal 0.005 percent of the water capacity of the container, in milligrams, divided by the area of the food-contact surface of the container in square inches. From a fabricated container conforming with the description in this paragraph (c)(1), the extractives shall not exceed 0.5 milligram per square inch of food-contact surface nor exceed 50 parts per million of the water capacity of the container as determined by the methods provided in paragraph (e) of this section.

(2) From a coating intended for or employed as a component of a container having a capacity in excess of 1 gallon and intended for one-time use, not to exceed 1.8 milligrams per square inch nor to exceed that amount as milligrams per square inch that would equal 0.005 percent of the water capacity of the container in milligrams, divided by the area of the food-contact surface of the container in square inches.

(3) From a coating intended for or employed as a component of a container for repeated use, not to exceed 18 milligrams per square inch nor to exceed that amount as milligrams per square inch that would equal 0.005 percent of the water capacity of the container in milligrams, divided by the area of the food-contact surface of the container in square inches.

(4) From coating intended for repeated use, and employed other than as a component of a container, not to exceed 18 milligrams per square inch of coated surface.

(d) Tables:

TABLE 1.—*Types of food*

I	Nonacid (pH above 5.0), aqueous products, may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content
II	Acidic (pH 5.0 or below), 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 emulsion, high or low fat
	B. Oil-in-water emulsion, high or low fat
V	Low moisture fats and oils
VI	Beverages
	A. Containing alcohol
	B. Nonalcoholic
VII	Bakery products
VIII	Dry solids (no end test required)

TABLE 2.—Test procedures for determining the amount of extractives from resinous or polymeric coatings, using solvents simulating types of foods and beverages

Condition of use	Types of food (see table 1)	Extractant: Water (time and temperature)	Extractant: Heptane [1] (time and temperature)	Extractant: 8 pct alcohol (time and temperature)
A High temperature heat-sterilized (e.g., over 212° F)	I, IV-B	250° F, 2 hr.		
	III IV-A, VII	do	150° F, 2 hr	
B Boiling water sterilized	II	212° F, 30 min		
	III VII	do	120° F, 30 min	
C Hot filled or pasteurized above 150° F	II, IV-B	Full boiling, cool to 100° F		
	III IV-A	do	120° F, 15 min	
	V		do	
D Hot filled or pasteurized below 150° F	II IV-B VI-B	150° F, 2 hr		
	III IV-A	do	100° F, 30 min	
	V		do	150° F, 2 hr
	VI-A			
E Room temperature filled and stored (no thermal treatment in the container)	I II IV-B, VI-B	120° F, 24 hr		
	III IV-A	do	70° F, 30 min	
	V VII		do	120° F, 24 hr
	VI-A			
F Refrigerated storage (no thermal treatment in the container)	I, II, III, IV-A, IV-B VI-B VII	70° F, 48 hr		
	VI-A			70° F, 48 hr
G Frozen storage (no thermal treatment in the container)	I II III IV-B VII	70° F, 24 hr		
H Frozen 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	212° F, 30 min		
2 Aqueous, high or low free oil or fat	III, IV-A, VII	do	120° F, 30 min	

[1] Heptane extractant not to be used on wax lined containers.
[2] Heptane extractivity results must be divided by a factor of five in arriving at the extractivity for a food product.

(e) *Analytical methods*—(1) *Selection of extractability conditions.* First ascertain the type of food product (Table 1, paragraph (d) of this section) that is being packed commercially in the test container and the normal conditions of thermal treatment used in packaging the type of food involved. Using Table 2 (paragraph (d) of this section), select the food-simulating solvent or solvents (demineralized distilled water, heptane, and/or 8 percent ethyl alcohol) and the time-temperature exaggerations of the container-use conditions. Aqueous products (types I, II, IV-B, and VI-B) require only a water-extractability test at the temperature and time conditions shown for the most severe "conditions of use." Aqueous products with free oil or fat, and water-oil emulsions (types III, IV-A, and VII) will require determinations of both water extractability and heptane extractability. Low-moisture fats and oils (type V with no free water) require only the heptane extractability. Alcoholic beverages (type VI-A) require only the 8 percent alcohol extractant. Having selected the appropriate extractant or extractants simulating various types of foods and beverages and the time-temperature exaggerations over normal use, follow the applicable extraction procedure. Adapt the procedure, when necessary, for containers having a capacity of over 1 gallon.

(2) *Selection of coated-container samples.* For consumer-sized containers up to 1 gallon, quadruplicate samples of representative containers (using for each replicate sample the number of containers nearest to an area of 180 square inches) should be selected from the lot to be examined.

(3) *Cleaning procedure preliminary to determining the amount of extractables from coated containers.* Quadruplicate samples of representative containers should be selected from the lot to be examined and must be carefully rinsed to remove extraneous material prior to the actual extraction procedure. Soda fountain pressure-type hot water rinsing equipment, consisting in its simplest form of a ⅛-inch-¼-inch internal diameter metal tube attached to a hot water line and bent so as to direct a stream of water upward, may be used. Be sure hot water has reached a temperature of 190° F-200° F before starting to rinse the container. Invert the container over the top of the fountain and direct a strong stream of hot water against the bottom and all sides for 1 minute, drain, and allow to dry.

(4) *Exposure conditions*—(i) *Water (250° F for 2 hours), simulating high-temperature heat sterilization.* Fill the container within ¼-inch of the top with a measured volume of demineralized distilled water. Cover the container with clean aluminum foil and place the container on a rack in a pressure cooker. Add a small amount of demineralized distilled water to the pressure cooker, but do not allow the water to touch the bottom of the container. Close the cooker securely and start to heat over a suitable burner. When a steady stream of steam emerges from the vent, close the vent and allow the pressure to rise to 15 pounds per square inch (250° F) and continue to maintain this pressure for 2 hours. Slowly release the pressure, open the pressure cooker when the pressure reads zero, and composite the water of each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(ii) *Water (212° F for 30 minutes), simulating boiling water sterilization.* Fill the container within ¼-inch of the top with a measured volume of boiling, demineralized distilled water. Cover the container with clean aluminum foil and place the container on a rack in a pressure cooker in which a small amount of demineralized distilled water is boiling. Do not close the pressure vent, but operate at atmospheric pressure so that there is a continuous escape of a small amount of steam. Continue to heat for 30 minutes, then

remove the test container and composite the contents of each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(iii) *Water (from boiling to 100° F), simulating hot fill or pasteurization above 150° F.* Fill the container within ¼-inch of the top with a measured volume of boiling, demineralized distilled water. Insert a thermometer in the water and allow the uncovered container to stand in a room at 70° F-85° F. When the temperature reads 100° F, composite the water from each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(iv) *Water (150° F for 2 hours), simulating hot fill or pasteurization below 150° F.* Preheat demineralized distilled water to 150° F in a clean Pyrex flask. Fill the container within ¼-inch of the top with a measured volume of the 150° F water and cover with clean aluminum foil. Place the test container in an oven maintained at 150° F. After 2 hours, remove the test container from the oven and immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(v) *Water (120° F for 24 hours), simulating room temperature filling and storage.* Preheat demineralized distilled water to 120° F in a clean Pyrex flask. Fill the container within ¼-inch of the top with a measured volume of the 120° F water and cover with clean aluminum foil. Place the test container in an incubator or oven maintained at 120° F. After 24 hours, remove the test container from the incubator and immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section

(vi) *Water (70° F for 48 hours), simulating refrigerated storage.* Bring demineralized distilled water to 70° F in a clean Pyrex flask. Fill the container within ¼-inch of the top with a measured volume of the 70° F water, and cover with clean aluminum foil. Place the test container in a suitable room maintained at 70° F. After 48 hours, immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(vii) *Water (70° F for 24 hours), simulating frozen storage.* Bring demineralized distilled water to 70° F in a clean Pyrex flask. Fill the container within ¼-inch of the top with a measured volume of the 70° F water and cover with clean aluminum foil. Place the container in a suitable room maintained at 70° F. After 24 hours, immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(viii) *Water (212° F for 30 minutes), simulating frozen foods reheated in the container.* Fill the container to within ¼-inch of the top with a measured volume of boiling, demineralized distilled water. Cover the container with clean aluminum foil and place the container on a rack in a pressure cooker in which a small amount of demineralized distilled water is boiling. Do not close the pressure vent, but operate at atmospheric pressure so that there is a continuous escape of a small amount of steam. Continue to heat for 30 minutes, then remove the test container and composite the contents of each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(ix) *Heptane (150° F for 2 hours) simulating high-temperature heat sterilization for fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208° F) carefully in a

clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 150° F. At the same time preheat a pressure cooker or equivalent to 150° F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 150° F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 150° F incubator. After 2 hours, remove the pressure cooker from the incubator, open the assembly, and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(x) *Heptane (120° F for 30 minutes), simulating boiling water sterilization of fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208° F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 120° F. At the same time, preheat a pressure cooker or equivalent to 120° F in an incubator. This pressure cooker is to serve only as a vented container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 120° F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 120° F incubator. After 30 minutes, remove the pressure cooker from the incubator, open the assembly, and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xi) *Heptane (120° F for 15 minutes), simulating hot fill or pasteurization above 150° F for fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208° F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 150° F. At the same time preheat a pressure cooker or equivalent to 150° F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 150° F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 150° F incubator. After 2 hours, remove the pressure cooker from the incubator, open the assembly, and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xii) *Heptane (100° F for 30 minutes) simulating hot fill or pasteurization below 150° F for fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208° F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 100° F. At the same time preheat a pressure cooker or equivalent to 100° F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 100° F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 100° F incubator. After 30 minutes, remove the pressure cooker from the incubator, open the assembly and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xiii) *Heptane (70° F for 30 minutes) simulating room temperature filling and storage of fatty foods only.* Fill the test container within ¼-inch of the top with a measured volume of the 70° F heptane and cover with clean aluminum foil. Place the test container in a suitable room maintained at 70° F. After 30 minutes, composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xiv) *Heptane (120° F for 30 minutes), simulating frozen fatty foods reheated in the container.* Preheat redistilled reagent-grade heptane (boiling point 208° F) carefully in a clean Pyrex flask on a water bath or hot plate in a well-ventilated hood to 120° F. At the same time, preheat a pressure cooker to 120° F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 120° F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 120° F incubator. After 30 minutes, remove the pressure cooker from the incubator, open the assembly and immediately composite the heptane from each replicate into a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xv) *Alcohol—8 percent (150° F for 2 hours), simulating alcoholic beverages hot filled or pasteurized below 150° F.* Preheat 8 percent (by volume) ethyl alcohol in demineralized distilled water to 150° F in a clean Pyrex flask. Fill the test container with within ¼-inch of the top with a measured volume of the 8 percent alcohol. Cover the container with clean aluminum foil and place in an oven maintained at 150° F. After 2 hours, remove the container from the oven and immediately composite the alcohol from each replicate in a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xvi) *Alcohol—8 percent (120° F for 24 hours), simulating alcoholic beverages room-temperature filled and stored.* Preheat 8 percent (by volume) ethyl alcohol in demineralized distilled water to 120° F in a clean Pyrex flask. Fill the test container within ¼-inch of the top with a measured volume of the 8 percent alcohol, cover the container with clean aluminum foil and place in an oven or incubator maintained at 120° F. After 24 hours, remove the container from the oven or incubator and immediately composite the alcohol from each replicate into a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xvii) *Alcohol—8 percent (70° F for 48 hours), simulating alcoholic beverages in refrigerated storage.* Bring 8 percent (by volume) ethyl alcohol in demineralized distilled water to 70° F in a clean Pyrex flask. Fill the test container within ¼-inch of the top with a measured volume of the 8 percent alcohol. Cover the container with clean aluminum foil. Place the test container in a suitable room maintained at 70° F. After 48 hours, immediately composite the alcohol from each replicate into a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

NOTE: The tests specified in paragraph (e)(4) (i) through (xvii) of this section are applicable to flexible packages consisting of coated metal contacting food, in which case the closure end is double-folded and clamped with metal spring clips by which the package can be suspended

(5) *Determination of amount of extractives*—(i) *Total residues.* Evaporate the food-simulating solvents from paragraph (e)(4) (i) to (xvii), inclusive, of this section to about 100 milliliters in the Pyrex flask and transfer to a clean, tared platinum dish, washing the flask three times with the solvent used in the extraction procedure, and evaporate to a few milliliters on a nonsparking low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at a temperature of 212° F. Cool the platinum dish in a desiccator for 30 minutes and weigh the residue to the nearest 0.1 milligram (e). Calculate the extractives in milligrams per square inch and

in parts per million for the particular size of container being tested and for the specific food-simulating solvent used.

(a) *Water and 8-percent alcohol.*

Milligrams extractives per square inch = e/s
Extractives residue = $Ex = (e)(a)(1000)/(c)(s)$

(b) *Heptane:*

Milligrams extractives per square inch = $e/(s)(F)$
Extractives residue = $Ex = (e)(a)(1000)/(c)(s)(F)$

Where:

Ex = Extractives residue in ppm for any container size.
e = Milligrams extractives per sample tested.
a = Total coated area, including closure in square inches.
c = Water capacity of container, in grams.
s = Surface of coated area tested, in square inches.
F = Five, the ratio of the amount of extractives removed from a coated container by heptane under exaggerated time-temperature test conditions compared to the amount extracted by a fat or oil from a container tested under exaggerated conditions of thermal sterilization and use.
e = Chloroform-soluble extractives residue.
ee' = Zinc corrected chloroform-soluble extractive residue.
e' or ee' is substituted for e in the above equations when necessary.

If when calculated by the equations in paragraph (e)(5)(i) (*a*) and (*b*) of this section, the concentration of extractives residue (Ex) exceeds 50 parts per million or the extractives in milligrams per square inch exceed the limitations prescribed in paragraph (c) of this section for the particular container size, proceed to paragraph (e)(5)(ii) of this section (method for determining the amount of chloroform-soluble extractives residue).

(ii) *Chloroform-soluble extractives residue.* Add 50 milliliters of chloroform (freshly distilled reagent grade or a grade having an established consistently low blank) to the dried and weighed residue, (*e*), in the platinum dish, obtained in paragraph (e)(5)(i) of this section. Warm carefully, and filter through Whatman No. 41 filter paper in a Pyrex funnel, collecting the filtrate in a clean, tared platinum dish. Repeat the chloroform extraction, washing the filter paper with this second portion of chloroform. Add this filtrate to the original filtrate and evaporate the total down to a few milliliters on a low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at 212° F. Cool the platinum dish in a desiccator for 30 minutes and weigh to the nearest 0.1 milligram to get the chloroform-soluble extractives residue (*e'*). This *e'* is substituted for *e* in the equations in paragraph (e)(5)(i) (*a*) and (*b*) of this section. If the concentration of extractives (Ex) still exceeds 50 parts per million or the extractives in milligrams per square inch exceed the limitations prescribed in paragraph (c) of this section for the particular container size, proceed as follows to correct for zinc extractives ("C" enamels only): Ash the residue in the platinum dish by heating gently over a Meeker-type burner to destroy organic matter and hold at red heat for about 1 minute. Cool in the air for 3 minutes, and place the platinum dish in the desiccator for 30 minutes and weigh to the nearest 0.1 milligram. Analyze this ash for zinc by standard Association of Official Agricultural Chemists methods or equivalent. Calculate the zinc in the ash as zinc oleate, and subtract from the weight of chloroform-soluble extractives residue (*e'*) to obtain the zinc-corrected chloroform-soluble extractives residue (*ee'*). This *ee'* is substituted for *e* in the formulas in paragraph (e)(5)(i) (*a*) and (*b*) of this section. To comply with the limitations in paragraph (c) of this section, the chloroform-soluble extractives residue (but after correction for the zinc extractives in case of "C" enamels) must not exceed 50 parts per million and must not exceed in milligrams per square inch the limitations for the particular article as prescribed in paragraph (c) of this section.

(f) *Equipment and reagent requirements*—(1) *Equipment.*

Rinsing equipment, soda fountain pressure-type hot water, consisting in simplest form of a ⅜-inch-¾-inch inside diameter metal tube attached to a hot water line delivering 190° F-200° F water and bent so as to direct a stream of water upward.

Pressure cooker, 21-quart capacity with pressure gage, safety release, and removable rack, 12.5 inches inside diameter × 11 inches inside height, 20 pounds per square inch safe operating pressure.

Oven, mechanical convection, range to include 120° F-212° F explosion-proof, inside dimensions (minimum), 19" × 19" × 19", constant temperature to ±2° F (water bath may be substituted).

Incubator, inside dimensions (minimum) 19" × 19" × 19" for use at 100° F±2° F explosion proof (water bath may be substituted).

Constant-temperature room or chamber 70° F±2° F minimum inside dimensions 19" × 19" × 19".

Hot plate, nonsparking (explosion proof), top 12" × 20", 2,500 watts, with temperature control.

Platinum dish, 100-milliliter capacity minimum.

All glass, Pyrex or equivalent.

(2) *Reagents.*

Water, all water used in extraction procedure should be freshly demineralized (deionized) distilled water.

Heptane, reagent grade, freshly redistilled before use, using only material boiling at 208° F.

Alcohol, 8 percent (by volume), prepared from undenatured 95 percent ethyl alcohol diluted with demineralized or distilled water.

Chloroform, reagent grade, freshly redistilled before use, or a grade having an established, consistently low blank.

Filter paper, Whatman No. 41 or equivalent.

(g) In accordance with good manufacturing practice, finished coatings intended for repeated food-contact use shall be thoroughly cleansed prior to their first use in contact with food.

(h) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

[42 FR 14534, Mar. 15, 1977, as amended at 42 FR 18610, Apr. 8, 1977; 42 FR 21771, Apr. 29, 1977; 43 FR 2873, Jan. 20, 1978; 43 FR 6216, Feb. 14, 1978; 43 FR 11697, Mar. 21, 1978]

§ 175.320 Resinous and polymeric coatings for polyolefin films.

Resinous and polymeric coatings may be safely used as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The coating is applied as a continuous film over one or both sides of a base film produced from one or more of the basic olefin polymers complying with § 177.1520 of this chapter. The base polyolefin film may contain optional adjuvant substances permitted for use in polyolefin film by applicable regulations in Parts 170 through 189 of this chapter.

(b) The coatings are formulated from optional substances which are:

(1) Substances generally recognized as safe for use in or on food.

(2) Substances the use of which is permitted under applicable regulations in Parts 170 through 189 of this chapter, by prior sanctions, or approvals.

(3) Substances identified in this paragraph (b)(3) and subject to such limitations as are provided:

List of substances	*Limitations*
(i) Resins and polymers.	
Acrylic acid polymer and its ethyl or methyl esters	
Acrylamide copolymerized with ethyl acrylate and/or styrene and/or methacrylic acid, and the copolymer subsequently reacted with formaldehyde and butanol	
Butadiene-acrylonitrile copolymer	
Butadiene-acrylonitrile-styrene terpolymer	
Butyl rubber	
N,N'-Diphenyl *p*-phenylenediamine	For use only as a polymerization inhibitor in 2 sulfoethyl methacrylate, sodium salt
2 Ethylhexyl acrylate copolymerized with one or more of the following:	
Acrylonitrile	
Itaconic acid	
Methacrylonitrile	
Methyl acrylate	
Methyl methacrylate	
4,4'-Isopropylidenediphenolepichlorohydrin average molecular weight 900	
Melamine-formaldehyde as the basic polymer or chemically modified with methyl alcohol	

bcc: T. W. Carmody-NY-22
M. E. Eisenhour-TC
W. F. Gorham-BB-200
R. A. Gregory-BB-203
J. T. Lucking-NY-46
G. M. Palm-BB-98
G. S. Peacock-BB-98
N. H. Reinking-BB-98
D. F. Smith-BB-200
W. I. Wertz-BB-98

UNION CARBIDE CORPORATION
CHEMICALS AND PLASTICS
RIVER ROAD, BOUND BROOK, N. J. 08805 • TELEX

Mr.

Dear Mr.

We have been asked to write you regarding the food additive status of BAKELITE brand resin.

resin is listed by chemical identity in Food Additive Regulation 175.300* for Resinous and Polymeric Coatings as food contact surfaces applied to metal substrates. Food Additive Regulation 176.170 for components of paper and paperboard and 177.1210 for closures refer to 175.300 for a list of acceptable materials. resin may be used under use conditions B, C, D, E, F, G, or H. An excerpt of 176.170 is attached which explains these use conditions.

The finished coating or closure must meet the extraction specifications given in the appropriate regulation.

Very truly yours,

W. B. Ackart, Ph.D.
Manager, FDA Liaison

WBA:sdb
29-A-20

Attachment

* formerly 121.2514

UCC 102525