

§ 176.320 Sodium nitrate-urea complex.

Sodium nitrate-urea complex may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) Sodium nitrate-urea complex is a clathrate of approximately two parts urea and one part sodium nitrate.

(b) Sodium nitrate-urea complex conforming to the limitations prescribed in paragraph (b)(1) of this section is used as provided in paragraph (b)(2) of this section.

(1) *Limitations.* (i) It is used as a plasticizer in glassine and greaseproof paper.

(ii) The amount used does not exceed that required to accomplish its intended technical effect or exceed 15 percent by weight of the finished paper.

(2) *Conditions of use.* The glassine and greaseproof papers are used for packaging dry food or as the food-contact surface for dry food.

§ 176.350 Tamarind seed kernel powder.

Tamarind seed kernel powder may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) Tamarind seed kernel powder is the ground kernel of tamarind seed (*Tamarindus indica* L.) after removal of the seed coat.

(b) It is used in the manufacture of paper and paperboard.

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

Subpart A [Reserved]

Subpart B—Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces

Sec.

- 177.1010 Acrylic and modified acrylic plastics, semirigid and rigid.
177.1020 Acrylonitrile/butadiene/styrene copolymer.
177.1030 Acrylonitrile/butadiene/styrene/methyl methacrylate copolymer.

- 177.1040 Acrylonitrile/styrene copolymer.
177.1050 Acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer.
177.1060 *n*-Alkylglutarimide/acrylic copolymers.
177.1200 Cellophane.
177.1210 Closures with sealing gaskets for food containers.
177.1211 Cross-linked polyacrylate copolymers.
177.1240 1,4-Cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate copolymer.
177.1310 Ethylene-acrylic acid copolymers.
177.1312 Ethylene-carbon monoxide copolymers.
177.1315 Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers.
177.1320 Ethylene-ethyl acrylate copolymers.
177.1330 Ionomeric resins.
177.1340 Ethylene-methyl acrylate copolymer resins.
177.1345 Ethylene/1,3-phenylene oxyethylene isophthalate/terephthalate copolymer.
177.1350 Ethylene-vinyl acetate copolymers.
177.1360 Ethylene-vinyl acetate-vinyl alcohol copolymers.
177.1380 Fluorocarbon resins.
177.1390 Laminate structures for use at temperatures of 250 °F and above.
177.1395 Laminate structures for use at temperatures between 120 °F and 250 °F.
177.1400 Hydroxyethyl cellulose film, water-insoluble.
177.1420 Isobutylene polymers.
177.1430 Isobutylene-butene copolymers.
177.1440 4,4'-Isopropylidenediphenol-epichlorohydrin resins minimum molecular weight 10,000.
177.1460 Melamine-formaldehyde resins in molded articles.
177.1480 Nitrile rubber modified acrylonitrile-methyl acrylate copolymers.
177.1500 Nylon resins.
177.1520 Olefin polymers.
177.1550 Perfluorocarbon resins.
177.1555 Polyarylate resins.
177.1556 Polyaryletherketone resins.
177.1560 Polyarylsulfone resins.
177.1570 Poly-1-butene resins and butene/ethylene copolymers.
177.1580 Polycarbonate resins.
177.1585 Polyester carbonate resins.
177.1590 Polyester elastomers.
177.1595 Polyetherimide resin.
177.1600 Polyethylene resins, carboxyl modified.
177.1610 Polyethylene, chlorinated.
177.1615 Polyethylene, fluorinated.
177.1620 Polyethylene, oxidized.
177.1630 Polyethylene phthalate polymers.
177.1632 Poly(phenyleneterephthalamide) resins.
177.1635 Poly(p-methylstyrene) and rubber-modified poly(p-methylstyrene).

§ 177.1010

- 177.1637 Poly(oxy-1,2-ethanedioxydicarbonyl-2,6-naphthalenediylcarbonyl) resins.
- 177.1640 Polystyrene and rubber-modified polystyrene.
- 177.1650 Polysulfide polymer-polyepoxy resins.
- 177.1655 Polysulfone resins.
- 177.1660 Poly(tetramethylene terephthalate).
- 177.1670 Polyvinyl alcohol film.
- 177.1680 Polyurethane resins.
- 177.1810 Styrene block polymers.
- 177.1820 Styrene-maleic anhydride copolymers.
- 177.1830 Styrene-methyl methacrylate copolymers.
- 177.1850 Textryls.
- 177.1900 Urea-formaldehyde resins in molded articles.
- 177.1950 Vinyl chloride-ethylene copolymers.
- 177.1960 Vinyl chloride-hexene-1 copolymers.
- 177.1970 Vinyl chloride-lauryl vinyl ether copolymers.
- 177.1980 Vinyl chloride-propylene copolymers.
- 177.1990 Vinylidene chloride/methyl acrylate copolymers.
- 177.2000 Vinylidene chloride/methyl acrylate/methyl methacrylate polymers.

Subpart C—Substances for Use Only as Components of Articles Intended for Repeated Use

- 177.2210 Ethylene polymer, chlorosulfonated.
- 177.2250 Filters, microporous polymeric.
- 177.2260 Filters, resin-bonded.
- 177.2280 4,4'-Isopropylidenediphenol-epichlorohydrin thermosetting epoxy resins.
- 177.2355 Mineral reinforced nylon resins.
- 177.2400 Perfluorocarbon cured elastomers.
- 177.2410 Phenolic resins in molded articles.
- 177.2415 Poly(aryletherketone) resins.
- 177.2420 Polyester resins, cross-linked.
- 177.2430 Polyether resins, chlorinated.
- 177.2440 Polyethersulfone resins.
- 177.2450 Polyamide-imide resins.
- 177.2460 Poly(2,6-dimethyl-1,4-phenylene) oxide resins.
- 177.2465 Polymethylmethacrylate/poly(trimethoxysilylpropyl) methacrylate copolymers.
- 177.2470 Polyoxymethylene copolymer.
- 177.2480 Polyoxymethylene homopolymer.
- 177.2490 Polyphenylene sulfide resins.
- 177.2500 Polyphenylene sulfone resins.
- 177.2510 Polyvinylidene fluoride resins.
- 177.2550 Reverse osmosis membranes.
- 177.2600 Rubber articles intended for repeated use.
- 177.2710 Styrene-divinylbenzene resins, cross-linked.

21 CFR Ch. I (4–1–25 Edition)

- 177.2800 Textiles and textile fibers.
- 177.2910 Ultra-filtration membranes.

AUTHORITY: 21 U.S.C. 321, 342, 348, 379e.

SOURCE: 42 FR 14572, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 177 appear at 61 FR 14482, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001; 66 FR 66742, Dec. 27, 2001; 68 FR 15355, Mar. 31, 2003; 70 FR 72074, Dec. 1, 2005; and 81 FR 49896, July 29, 2016.

Subpart A [Reserved]

Subpart B—Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces

§ 177.1010 Acrylic and modified acrylic plastics, semirigid and rigid.

Semirigid and rigid acrylic and modified acrylic plastics may be safely used as articles intended for use in contact with food, in accordance with the following prescribed conditions. The acrylic and modified acrylic polymers or plastics described in this section also may be safely used as components of articles intended for use in contact with food.

(a) The optional substances that may be used in the formulation of the semirigid and rigid acrylic and modified acrylic plastics, or in the formulation of acrylic and modified acrylic components of articles, include substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, substances permitted for use in such plastics by regulations in parts 170 through 189 of this chapter, and substances identified in this paragraph. At least 50 weight-percent of the polymer content of the acrylic and modified acrylic materials used as finished articles or as components of articles shall consist of polymer units derived from one or more of the acrylic or methacrylic monomers listed in paragraph (a)(1) of this section.

(1) Homopolymers and copolymers of the following monomers:

- n*-Butyl acrylate.
- n*-Butyl methacrylate.
- Ethyl acrylate.
- 2-Ethylhexyl acrylate.
- Ethyl methacrylate.

Methyl acrylate.
Methyl methacrylate.

(2) Copolymers produced by copolymerizing one or more of the monomers listed in paragraph (a)(1) of this section with one or more of the following monomers:

Acrylonitrile.
Methacrylonitrile.
 α -Methylstyrene.
Styrene.
Vinyl chloride.
Vinylidene chloride.

(3) Polymers identified in paragraphs (a)(1) and (2) of this section containing no more than 5 weight-percent of total polymer units derived by copolymerization with one or more of the monomers listed in paragraph (a)(3)(i) and (ii) of this section. Monomers listed in paragraph (a)(3)(ii) of this section are limited to use only in plastic articles intended for repeated use in contact with food.

(i) List of minor monomers:

Acrylamide.
Acrylic acid
1,3-Butylene glycol dimethacrylate.
1,4-Butylene glycol dimethacrylate.
Diethylene glycol dimethacrylate.
Dipropylene glycol dimethacrylate.
Divinylbenzene.
Ethylene glycol dimethacrylate.
Itaconic acid.
Methacrylic acid.
N-Methylolacrylamide.
N-Methylolmethacrylamide.
4-Methyl-1,4-pentanediol dimethacrylate.
Propylene glycol dimethacrylate.
Trivinylbenzene.

(ii) List of minor monomers limited to use only in plastic articles intended for repeated use in contact with food:

Allyl methacrylate [Chemical Abstracts Service Registry No. 96-05-9]
tert-Butyl acrylate.
tert-Butylaminoethyl methacrylate.
sec-Butyl methacrylate.
tert-Butyl methacrylate.
Cyclohexyl methacrylate.
Dimethylaminoethyl methacrylate.
2-Ethylhexyl methacrylate.
Hydroxyethyl methacrylate.
Hydroxyethyl vinyl sulfide.
Hydroxypropyl methacrylate.
Isobornyl methacrylate.
Isobutyl methacrylate.
Isopropyl acrylate.
Isopropyl methacrylate.
Methacrylamide.
Methacrylamidoethylene urea.

Methacryloxyacetamidoethylene urea.
Methacryloxyacetic acid.
n-Propyl methacrylate.
3,5,5-Trimethylcyclohexyl methacrylate.

(4) Polymers identified in paragraphs (a)(1), (2), and (3) of this section are mixed together and/or with the following polymers, provided that no chemical reactions, other than addition reactions, occur when they are mixed:

Butadiene-acrylonitrile copolymers.
Butadiene-acrylonitrile-styrene copolymers.
Butadiene-acrylonitrile-styrene-methyl methacrylic copolymers.
Butadiene-styrene copolymers.
Butyl rubber.
Natural rubber.
Polybutadiene.
Poly (3-chloro-1,3-butadiene).
Polyester identified in §175.300(b)(3)(vii) of this chapter.
Polyvinyl chloride.
Vinyl chloride copolymers complying with §177.1980.
Vinyl chloride-vinyl acetate copolymers.

(5) Antioxidants and stabilizers identified in §175.300(b)(3)(xxx) of this chapter and the following:

Di-*tert*-butyl-*p*-cresol.
2-Hydroxy-4-methoxybenzophenone.
2-Hydroxy-4-methoxy-2-carboxybenzophenone.
3-Hydroxyphenyl benzoate.
p-Methoxyphenol.
Methyl salicylate.
Octadecyl 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate (CAS Reg. No. 2082-79-3): For use only: (1) At levels not exceeding 0.2 percent by weight in semirigid and rigid acrylic and modified acrylic plastics, where the finished articles contact foods containing not more than 15 percent alcohol; and (2) at levels not exceeding 0.01 percent by weight in semirigid and rigid acrylic and modified acrylic plastics intended for repeated food-contact use where the finished article may be used for foods containing more than 15 percent alcohol.
Phenyl salicylate.

(6) Release agents: Fatty acids derived from animal and vegetable fats and oils, and fatty alcohols derived from such acids.

(7) Surface active agent: Sodium dodecylbenzenesulfonate.

(8) Miscellaneous materials:

Di(2-ethylhexyl) phthalate, for use only as a flow promoter at a level not to exceed 3 weight-percent based on the monomers.
Oxalic acid, for use only as a polymerization catalyst aid.

§ 177.1010

Tetraethylenepentamine, for use only as a catalyst activator at a level not to exceed 0.5 weight-percent based on the monomers. Toluene. Xylene.

(b) The semirigid and rigid acrylic and modified acrylic plastics, in the finished form in which they are to contact food, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature as determined from tables 1 and 2 of §176.170(c) of this chapter, shall yield extractives not to exceed the following, when tested by the methods prescribed in paragraph (c) of this section. The acrylic and modified acrylic polymers or plastics intended to be used as components of articles also shall yield extractives not to exceed the following limitations when prepared as strips as described in paragraph (c)(2) of this section:

(1) Total nonvolatile extractives not to exceed 0.3 milligram per square inch of surface tested.

(2) Potassium permanganate oxidizable distilled water and 8 and 50 percent alcohol extractives not to exceed an absorbance of 0.15.

(3) Ultraviolet-absorbing distilled water and 8 and 50 percent alcohol extractives not to exceed an absorbance of 0.30.

(4) Ultraviolet-absorbing *n*-heptane extractives not to exceed an absorbance of 0.10.

(c) *Analytical methods*—(1) *Selection of extractability conditions*. These are to be chosen as provided in §176.170(c) of this chapter.

(2) *Preparation of samples*. Sufficient samples to allow duplicates of all applicable tests shall be cut from the articles or formed from the plastic composition under tests, as strips about 2.5 inches by about 0.85-inch wide by about 0.125-inch thick. The total exposed surface should be 5 square inches ± 0.5 -square inch. The samples, after preparation, shall be washed with a clean brush under hot tapwater, rinsed under running hot tapwater (140 °F minimum), rinsed with distilled water, and air-dried in a dust-free area or in a desiccator.

(3) *Preparation of solvents*. The water used shall be double-distilled water, prepared in a still using a block tin

21 CFR Ch. I (4–1–25 Edition)

condenser. The 8 and 50 percent (by volume) alcohol solvents shall be prepared from ethyl alcohol meeting the specifications of the United States Pharmacopeia XX and diluted with double-distilled water that has been prepared in a still using a tin block condenser. The *n*-heptane shall be spectrophotometric grade. Adequate precautions must be taken to keep all solvents dust-free.

(4) *Blank values on solvents*. (i) Duplicate determinations of residual solids shall be run on samples of each solvent that have been exposed to the temperature-time conditions of the extraction test without the plastic sample. Sixty milliliters of exposed solvent is pipetted into a clean, weighed platinum dish, evaporated to 2–5 milliliters on a nonsparking, low-temperature hot plate and dried in 212 °F oven for 30 minutes. The residue for each solvent shall be determined by weight and the average residue weight used as the blank value in the total solids determination set out in paragraph (c)(6) of this section. The residue for an acceptable solvent sample shall not exceed 0.5 milligram per 60 milliliters.

(ii) For acceptability in the ultraviolet absorbers test, a sample of each solvent shall be scanned in an ultraviolet spectrophotometer in 5-centimeter silica spectrophotometric absorption cells. The absorbance of the distilled water when measured versus air in the reference cell shall not exceed 0.03 at any point in the wavelength region of 245 to 310 m μ . The absorbance of the 8 percent alcohol when measured versus distilled water in the reference cell shall not exceed 0.01 at any point in the wavelength region of 245 to 310 m μ . The absorbance of the 50 percent alcohol when measured versus distilled water in the reference cell shall not exceed 0.05 at any point in the wavelength region of 245 to 310 m μ . The absorbance of the heptane when measured versus distilled water in the reference cell shall not exceed 0.15 at 245, 0.09 at 260, 0.04 at 270, and 0.02 at any point in the wavelength region of 280 to 310 m μ .

(iii) Duplicate ultraviolet blank determinations shall be run on samples of each solvent that has been exposed to the temperature-time conditions of the extraction test without the plastic

sample. An aliquot of the exposed solvent shall be measured versus the unexposed solvent in the reference cell. The average difference in the absorbances at any wavelength in the region of 245 to 310 mμ shall be used as a blank correction for the ultraviolet absorbers measured at the same wavelength according to paragraph (c)(8)(ii) of this section.

(iv) The acceptability of the solvents for use in the permanganate test shall be determined by preparing duplicate permanganate test blanks according to paragraph (c)(7)(iv) of this section. For this test, the directions referring to the sample extract shall be disregarded. The blanks shall be scanned in 5-centimeter silica spectrophotometric cells in the spectrophotometer versus the appropriate solvent as reference. The absorbance in distilled water in the wavelength region of 544 to 552 mμ should be 1.16 but must not be less than 1.05 nor more than 1.25. The absorbance in the 8 and 50 percent alcohol must not be less than 0.85 nor more than 1.15.

(v) Duplicate permanganate test determinations shall be run on samples of distilled water and 8 and 50 percent alcohol solvents that have been exposed to the temperature-time conditions of the extraction test without the plastic sample. The procedure shall be as described in paragraph (c)(7)(iv) of this section, except that the appropriate exposed solvent shall be substituted where the directions call for sample extract. The average difference in the absorbances in the region of 544 to 552 mμ shall be used as a blank correction for the determination of permanganate oxidizable extractives according to paragraph (c)(7)(iv) of this section.

(5) *Extraction procedure.* For each extraction, place a plastic sample in a clean 25 millimeters × 200 millimeters hard-glass test tube and add solvent equal to 10 milliliters of solvent per square inch of plastic surface. This amount will be between 45 milliliters and 55 milliliters. The solvent must be preequilibrated to the temperature of the extraction test. Close the test tube with a ground-glass stopper and expose to the specified temperature for the specified time. Cool the tube and con-

tents to room temperature if necessary.

(6) *Determination of total nonvolatile extractives.* Remove the plastic strip from the solvent with a pair of clean forceps and wash the strip with 5 milliliters of the appropriate solvent, adding the washings to the contents of the test tube. Pour the contents of the test tube into a clean, weighed platinum dish. Wash the tube with 5 milliliters of the appropriate solvent and add the solvent to the platinum dish. Evaporate the solvent to 2-5 milliliters on a nonsparking, low-temperature hotplate. Complete the evaporation in a 212 °F oven for 30 minutes. Cool the dish in a desiccator for 30 minutes and weigh to the nearest 0.1 milligram. Calculate the total nonvolatile extractives as follows:

$$\frac{\text{Milligrams extractives}}{\text{per square inch}} = \frac{e - b}{s}$$

$$\frac{\text{Extractives in parts}}{\text{per million}} = \frac{eb}{s} \times 100$$

where:

e = Total increase in weight of the dish, in milligrams.

b = Blank value of the solvent in milligrams, as determined in paragraph (c)(4)(i) of this section.

s = Total surface of the plastic sample in square inches.

(7) *Determination of potassium permanganate oxidizable extractives.* (i) Pipette 25 milliliters of distilled water into a clean 125-milliliter Erlenmeyer flask that has been rinsed several times with aliquots of distilled water. This is the blank. Prepare a distilled water solution containing 1.0 part per million of *p*-methoxyphenol (melting point 54-56 °C, Eastman grade or equivalent). Pipette 25 milliliters of this *p*-methoxyphenol solution into a rinsed Erlenmeyer flask. Pipette exactly 3.0 milliliters of 154 parts per million aqueous potassium permanganate solution into the *p*-methoxyphenol and exactly 3.0 milliliters into the blank, in that order. Swirl both flasks to mix the contents and then transfer aliquots from each flask into matched 5-centimeter spectrophotometric absorption cells. The cells are placed in the spectrophotometer cell compartment with

§ 177.1010

21 CFR Ch. I (4–1–25 Edition)

the *p*-methoxyphenol solution in the reference beam. Spectrophotometric measurement is conducted as in paragraph (c)(7)(iv) of this section. The absorbance reading in the region 544–552 mμ should be 0.24 but must be not less than 0.12 nor more than 0.36. This test shall be run in duplicate. For the pur-

pose of ascertaining compliance with the limitations in paragraph (b)(2) of this section, the absorbance measurements obtained on the distilled water extracts according to paragraph (c)(7)(iv) of this section shall be multiplied by a correction factor, calculated as follows:

$$\frac{0.24}{\text{Average of duplicate } \rho\text{-methoxyphenol absorbance determinations according to this paragraph (c)(7)(i) of this section}} = \text{Correction factor for water extracts.}$$

(ii) The procedure in paragraph (c)(7)(i) of this section is repeated except that, in this instance, the solvent shall be 8 percent alcohol. The absorbance in the region 544–552 mμ should be 0.26 but must be not less than 0.13 nor more than 0.39. This test shall be run in duplicate. For the purpose of

ascertaining compliance with the limitations prescribed in paragraph (b)(2) of this section, the absorbance measurements obtained on the 8 percent alcohol extracts according to paragraph (c)(7)(iv) of this section shall be multiplied by a correction factor, calculated as follows:

$$\frac{0.26}{\text{Average of duplicate } \rho\text{-methoxyphenol absorbance determination according to this paragraph (c)(7)(ii) of this section}} = \text{Correction factor for aqueous 8 percent alcohol extracts.}$$

(iii) The procedure in paragraph (c)(7)(i) of this section is repeated except that, in this instance, the solvent shall be 50 percent alcohol. The absorbance in the region 544–552 mμ should be 0.25 but must be not less than 0.12 nor more than 0.38. This test shall be run in duplicate. For the purpose of

ascertaining compliance with the limitations prescribed in paragraph (b)(2) of this section, the absorbance measurements obtained on the 50 percent alcohol extracts according to paragraph (c)(7)(iv) of this section shall be multiplied by a correction factor, calculated as follows:

$$\frac{0.25}{\text{Average of duplicate } \rho\text{-methoxyphenol absorbance determinations according to paragraph (c)(7)(ii) of this section}} = \text{Correction factor for 50 percent aqueous alcohol extracts.}$$

(iv) *Water and 8 and 50 percent alcohol extracts.* Pipette 25 milliliters of the appropriate solvent into a clean, 125-milliliter Erlenmeyer flask that has been rinsed several times with aliquots of

the same solvent. This is the blank. Into another similarly rinsed flask, pipette 25 milliliters of the sample extract that has been exposed under the conditions specified in paragraph (c)(5)

of this section. Pipette exactly 3.0 milliliters of 154 parts per million aqueous potassium permanganate solution into the sample and exactly 3.0 milliliters into the blank, in that order. Before use, the potassium permanganate solution shall be checked as in paragraph (c)(7)(i) of this section. Both flasks are swirled to mix the contents, and then aliquots from each flask are transferred to matched 5-centimeter spectrophotometric absorption cells. Both cells are placed in the spectrophotometer cell compartment with the sample solution in the reference beam. The spectrophotometer is adjusted for 0 and 100 percent transmittance at 700 mμ. The spectrum is scanned on the absorbance scale from 700 mμ to 500 mμ in such a way that the region 544 mμ to 552 mμ is scanned within 5 minutes to 10 minutes of the time that permanganate was added to the solutions. The height of the absorbance peak shall be measured, corrected for the blank as determined in paragraph (c)(4)(v) of this section, and multiplied by the ap-

propriate correction factor determined according to paragraph (c)(7)(i), (ii), and (iii) of this section. This test shall be run in duplicate and the two results averaged.

(8) *Determination of ultraviolet-absorbing extractives.* (i) A distilled water solution containing 1.0 part per million of *p*-methoxyphenol (melting point 54 °C–56 °C. Eastman grade or equivalent) shall be scanned in the region 360 to 220 mμ in 5-centimeter silica spectrophotometric absorption cells versus a distilled water reference. The absorbance at the wavelength of maximum absorbance (should be about 285 mμ) is about 0.11 but must be not less than 0.08 nor more than 0.14. This test shall be run in duplicate. For the purpose of ascertaining compliance with the limitations prescribed in paragraph (b)(3) and (4) of this section, the absorbance obtained on the extracts according to paragraph (c)(8)(ii) of this section shall be multiplied by a correction factor, calculated as follows:

$$\frac{0.11}{\text{Average of duplicate } p\text{-methoxyphenol absorbance determinations according to this paragraph (c)(8)(i) of this section}} = \text{Correction factor for ultraviolet absorbers test.}$$

(ii) An aliquot of the extract that has been exposed under the conditions specified in paragraph (c)(5) of this section is scanned in the wavelength region 360 to 220 mμ versus the appropriate solvent reference in matched 5-centimeter silica spectrophotometric absorption cells. The height of any absorption peak shall be measured, corrected for the blank as determined in paragraph (c)(4)(iii) of this section, and multiplied by the correction factor determined according to paragraph (c)(8)(i) of this section.

(d) In accordance with current good manufacturing practice, finished semirigid and rigid acrylic and modified acrylic plastics, and articles containing these polymers, intended for repeated use in contact with food shall be thoroughly cleansed prior to their first use in contact with food.

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

(f) The acrylic and modified acrylic polymers identified in and complying with this section, when used as components of the food-contact surface of an article that is the subject of a regulation in this part and in parts 174, 175, 176, and 178 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

[42 FR 14572, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977, as amended at 43 FR 54927, Nov. 24, 1978; 45 FR 67320, Oct. 10, 1980; 46 FR 46796, Sept. 22, 1981; 49 FR 10108, Mar. 19, 1984; 49 FR 13139, Apr. 3, 1984; 50 FR 31045, July 24, 1985; 87 FR 31089, May 20, 2022]

§ 177.1020

21 CFR Ch. I (4–1–25 Edition)

§ 177.1020 Acrylonitrile/butadiene/styrene co-polymer.

Acrylonitrile/butadiene/styrene copolymer identified in this section may be safely used as an article or component of articles intended for use with all foods, except those containing alcohol, under conditions of use E, F, and G described in table 2 of § 176.170(c) of this chapter.

(a) *Identity.* For the purpose of this section, the acrylonitrile/butadiene/styrene copolymer consists of:

(1) Eighty-four to eighty-nine parts by weight of a matrix polymer containing 73 to 78 parts by weight of acrylonitrile and 22 to 27 parts by weight of styrene; and

(2) Eleven to sixteen parts by weight of a grafted rubber consisting of (i) 8 to 13 parts of butadiene/styrene elastomer containing 72 to 77 parts by weight of butadiene and 23 to 28 parts by weight of styrene and (ii) 3 to 8 parts by weight of a graft polymer having the same composition range as the matrix polymer.

(b) *Adjuvants.* The copolymer identified in paragraph (a) of this section may contain adjuvant substances required in its production. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted in this part, and the following:

Substance	Limitations
2-Mercapto- ethanol	The finished copolymer shall contain not more than 100 ppm 2-mercaptoethanol acrylonitrile adduct as determined by a method titled "Analysis of Cycopac Resin for Residual β -(2-Hydroxyethylmercapto) propionitrile," which is incorporated by reference. Copies are available from the Bureau of Foods (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html .

(c) *Specifications.* (1) Nitrogen content of the copolymer is in the range of 16 to 18.5 percent as determined by Micro-Kjeldahl analysis.

(2) Residual acrylonitrile monomer content of the finished copolymer articles is not more than 11 parts per million as determined by a gas chromatographic method titled "Determination of Residual Acrylonitrile and Styrene Monomers-Gas Chromatographic Internal Standard Method," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(d) *Extractive limitations.* (1) Total nonvolatile extractives not to exceed 0.0005 milligram per square inch surface area when the finished food contact article is exposed to distilled water, 3 percent acetic acid, or *n*-heptane for 8 days at 120 °F.

(2) The finished food-contact article shall yield not more than 0.0015 milligram per square inch of acrylonitrile monomer when exposed to distilled water and 3 percent acetic acid at 150 °F for 15 days when analyzed by a polarographic method titled "Extracted Acrylonitrile by Differential Pulse Polarography," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

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

(f) Acrylonitrile copolymers identified in this section are not authorized

Food and Drug Administration, HHS

§ 177.1030

to be used to fabricate beverage containers.

[42 FR 14572, Mar. 15, 1977, as amended at 42 FR 48543, Sept. 23, 1977; 47 FR 11841, Mar. 19, 1982; 54 FR 24897, June 12, 1989]

§ 177.1030 Acrylonitrile/butadiene/styrene/methyl methacrylate copolymer.

Acrylonitrile/butadiene/styrene/methyl methacrylate copolymer identified in this section may be safely used as an article or component of articles intended for use with food identified in table 1 of §176.170(c) of this chapter as Type I, II, III, IVA, IVB, V, VIB, (except bottles intended to hold carbonated beverages), VIIA, VIIB, VIII and IX, under conditions of use C, D, E, F, and G described in table 2 of §176.170(c) of this chapter with a high temperature limitation of 190 °F.

(a) *Identity.* For the purpose of this section, acrylonitrile/butadiene/styrene/methyl methacrylate copolymer consists of: (1) 73 to 79 parts by weight of a matrix polymer containing 64 to 69 parts by weight of acrylonitrile, 25 to 30 parts by weight of styrene and 4 to 6 parts by weight of methyl methacrylate; and (2) 21 to 27 parts by weight of a grafted rubber consisting of (i) 16 to 20 parts of butadiene/styrene/elastomer containing 72 to 77 parts by weight of butadiene and 23 to 28 parts by weight of styrene and (ii) 5 to 10 parts by weight of a graft polymer having the same composition range as the matrix polymer.

(b) *Adjuvants.* The copolymer identified in paragraph (a) of this section may contain adjuvant substances required in its production. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted under applicable regulations in this part, and the following:

Substances	Limitations
2-Mercaptoethanol ..	The finished copolymer shall contain not more than 800 ppm 2-mercaptoethanol acrylonitrile adduct as determined by a method titled "Analysis of Cycopac Resin for Residual β -(2-Hydroxyethylmercapto) propionitrile," which is incorporated by reference. Copies are available from the Bureau of Foods (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html .

(c) *Specifications.* (1) Nitrogen content of the copolymer is in the range of 13.0 to 16.0 percent as determined by Micro-Kjeldahl analysis.

(2) Residual acrylonitrile monomer content of the finished copolymer articles is not more than 11 parts per million as determined by a gas chromatographic method titled "Determination of Residual Acrylonitrile and Styrene Monomers-Gas Chromatographic Internal Standard Method," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(d) *Extractive limitations.* (1) Total nonvolatile extractives not to exceed 0.0005 milligram per square inch surface area of the food-contact article when exposed to distilled water, 3 percent acetic acid, 50 percent ethanol, and *n*-heptane for 10 days at 120 °F.

(2) The finished food-contact article shall yield not more than 0.0025 milligram per square inch of acrylonitrile monomer when exposed to distilled water, 3 percent acetic acid and *n*-heptane at 190 °F for 2 hours, cooled to 120 °F (80 to 90 minutes) and maintained at 120 °F for 10 days when analyzed by a polarographic method titled

§ 177.1040

21 CFR Ch. I (4–1–25 Edition)

“Extracted Acrylonitrile by Differential Pulse Polarography,” which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

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

(f) Acrylonitrile copolymers identified in this section are not authorized to be used to fabricate beverage containers.

[42 FR 14572, Mar. 15, 1977, as amended at 42 FR 48543, Sept. 23, 1977; 47 FR 11841, Mar. 19, 1982; 54 FR 24898, June 12, 1989]

§ 177.1040 Acrylonitrile/styrene copolymer.

Acrylonitrile/styrene copolymers identified in this section may be safely used as a component of packaging ma-

terials subject to the provisions of this section.

(a) *Identity.* For the purposes of this section acrylonitrile/styrene copolymers are basic copolymers meeting the specifications prescribed in paragraph (c) of this section.

(b) *Adjuvants.* (1) The copolymers identified in paragraph (c) of this section may contain adjuvant substances required in their production, with the exception that they shall not contain mercaptans or other substances which form reversible complexes with acrylonitrile monomer. Permissible adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted under applicable regulations in this part, and those authorized in paragraph (b)(2) of this section.

(2) The optional adjuvants for the acrylonitrile/styrene copolymer identified in paragraphs (c)(1) and (3) of this section are as follows:

Substances	Limitation
Condensation polymer of toluene sulfonamide and formaldehyde.	0.15 pct maximum.

(c) *Specifications.*

Acrylonitrile/styrene copolymers	Maximum residual acrylonitrile monomer content of finished article	Nitrogen content of copolymer	Maximum extractable fractions at specified temperatures and times	Conformance with certain specifications
1. Acrylonitrile/styrene copolymer consisting of the copolymer produced by polymerization of 66–72 parts by weight of acrylonitrile and 28–34 parts by weight of styrene; for use with food of Type VI-B identified in table 1 of §176.170(c) of this chapter under conditions of use C, D, E, F, G described in table 2 of §176.170(c) of this chapter.	80 ppm ¹	17.4 to 19 pct.	Total nonvolatile extractives not to exceed 0.01 mg/in ² surface area of the food contact article when exposed to distilled water and 3 pct acetic acid for 10 d at 66 °C (150 °F). The extracted copolymer shall not exceed 0.001 mg/in ² surface area of the food contact article when exposed to distilled water and 3 pct acetic acid for 10 d at 66 °C (150 °F) ¹ .	Minimum number average molecular weight is 30,000. ¹
2. Acrylonitrile/styrene copolymer consisting of the copolymer produced by polymerization of 45–65 parts by weight of acrylonitrile and 35–55 parts by weight of styrene; for use with food of Types, I, II, III, IV, V, VI (except bottles), VII, VIII, and IX identified in table 1 of §176.170(c) of this chapter under conditions B (not to exceed 93 °C (200 °F)), C, D, E, F, G described in table 2 of §176.170(c) of this chapter.	50 ppm ¹	12.2 to 17.2 pct.	Extracted copolymer not to exceed 2.0 ppm in aqueous extract or <i>n</i> -heptane extract obtained when 100 g sample of the basic copolymer in the form of particles of a size that will pass through a U.S. Standard Sieve No. 6 and that will be held on a U.S. Standard Sieve No. 10 is extracted with 250 ml of deionized water or reagent grade <i>n</i> -heptane at reflux temperature for 2 h. ¹	Minimum 10 pct solution viscosity at 25 °C (77 °F) is 10cP. ¹

Acrylonitrile/styrene copolymers	Maximum residual acrylonitrile monomer content of finished article	Nitrogen content of copolymer	Maximum extractable fractions at specified temperatures and times	Conformance with certain specifications
3. Acrylonitrile/styrene copolymer consisting of the copolymer produced by polymerization of 66–72 parts by weight of acrylonitrile and 28–34 parts by weight of styrene; for use with food of Types VI-A and VI-B identified in table 1 of § 176.170(c) of this chapter under conditions of use C, D, E, F, G described in table 2 of § 176.170(c) of this chapter.	0.10 ppm (calculated on the basis of the weight of the acrylonitrile copolymer resin in the finished articles). ²	17.4 to 19 pct.	Total nonvolatile extractives not to exceed 0.01 mg/in ² surface area of the food contact article when exposed to distilled water and 3 pct acetic acid for 10 d at 66 °C (150 °F). The extracted copolymer shall not exceed 0.001 mg/in ² surface area of the food contact article when exposed to distilled water and 3 pct acetic acid for 10 d at 66 °C (150 °F). ¹	Maximum carbon dioxide permeability at 23 °C (73 °F) for the finished article is 0.04 barrer. ³

¹ Use methods for determination of residual acrylonitrile monomer content, maximum extractable fraction, number average molecular weight, and solution viscosity, titled: "Determination of Residual Acrylonitrile and Styrene Monomers-Gas Chromatographic Internal Standard Method"; "Infrared Spectrophotometric Determination of Polymer Extracted from Barex 210 Resin Pellets"; "Procedure for the Determination of Molecular Weights of Acrylonitrile/Styrene Copolymers," and "Analytical Method for 10% Solution Viscosity of Tyril," which are incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), 5001 Campus Dr., College Park, MD 20740, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

² As determined by the method titled "Headspace Sampling and Gas-Solid Chromatographic Determination of Residual Acrylonitrile in Acrylonitrile Copolymer Solutions," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), 5001 Campus Dr., College Park, MD 20740, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

³ As determined on appropriately shaped test samples of the article or acrylonitrile copolymer layer in a multilayer construction by ASTM method D-1434-82, "Standard Method for Determining Gas Permeability Characteristics of Plastic Film and Sheet," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), 5001 Campus Dr., College Park, MD 20740, and the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(d) *Interim listing.* Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

(e) Acrylonitrile copolymer identified in this section may be used to fabricate beverage containers only if they comply with the specifications of item 3 in paragraph (c) of this section.

[42 FR 14572, Mar. 15, 1977, as amended at 42 FR 48543, Sept. 23, 1977; 47 FR 11841, Mar. 19, 1982; 49 FR 36643, Sept. 19, 1984; 52 FR 33803, Sept. 8, 1987]

§ 177.1050 Acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer.

Acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer identified in this section may be safely used as a component of bottles intended for use with foods identified in table I of § 176.170(c) of this chapter as Type VI-B under conditions for use E, F, or G described in table 2 of § 176.170(c) of this chapter.

(a) *Identity.* For the purpose of this section, acrylonitrile/styrene copoly-

mer modified with butadiene/styrene elastomer consists of a blend of:

(1) 82–88 parts by weight of a matrix copolymer produced by polymerization of 77–82 parts by weight of acrylonitrile and 18–23 parts of styrene; and

(2) 12–18 parts by weight of a grafted rubber consisting of (i) 8–12 parts of butadiene/styrene elastomer containing 77–82 parts by weight of butadiene and 18–23 parts by weight of styrene and (ii) 4–6 parts by weight of a graft copolymer consisting of 70–77 parts by weight of acrylonitrile and 23–30 parts by weight of styrene.

(b) *Adjuvants.* The modified copolymer identified in paragraph (a) of this section may contain adjuvant substances required in its production. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted under applicable regulations in this part, and the following:

Substances	Limitations
<i>n</i> -Dodecylmercaptan	The finished copolymer shall contain not more than 500 parts per million (ppm) dodecylmercaptan as dodecylmercapto-propionitrile as determined by the method titled, "Determination of β -Dodecylmercapto-propionitrile in NR-16 Polymer," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal-register/code-of-federal-regulations/ibr-locations.html .

(c) *Specifications.* (1) Nitrogen content of the modified copolymer is in the range of 17.7–19.8 percent.

(2) Intrinsic viscosity of the matrix copolymer in butyrolactone is not less than 0.5 deciliter/gram at 35 °C, as determined by the method titled "Molecular Weight of Matrix Copolymer by Solution Viscosity," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/code-of-federal-regulations/ibr-locations.html>.

(3) Residual acrylonitrile monomer content of the modified copolymer articles is not more than 11 ppm as determined by a gas chromatographic method titled "Determination of Residual Acrylonitrile and Styrene Monomers-Gas Chromatographic Internal Standard Method," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or

go to: <http://www.archives.gov/federal-register/code-of-federal-regulations/ibr-locations.html>.

(d) *Extractives limitations.* The following extractives limitations are determined by an infrared spectrophotometric method titled "Infrared Spectrophotometric Determination of Polymer Extracted from Borex® 210 Resin Pellets," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/code-of-federal-regulations/ibr-locations.html>. Copies are applicable to the modified copolymers in the form of particles of a size that will pass through a U.S. Standard Sieve No. 6 and that will be held on a U.S. Standard Sieve No. 10:

(1) The extracted copolymer shall not exceed 2.0 ppm in aqueous extract obtained when a 100-gram sample of copolymer is extracted with 250 milliliters of freshly distilled water at reflux temperature for 2 hours.

(2) The extracted copolymer shall not exceed 0.5 ppm in *n*-heptane when a 100-gram sample of the basic copolymer is extracted with 250 milliliters spectral grade *n*-heptane at reflux temperature for 2 hours.

(e) *Accelerated extraction end test.* The modified copolymer shall yield acrylonitrile monomer not in excess of 0.4 ppm when tested as follows:

(1) The modified copolymer shall be in the form of eight strips ½ inch by 4 inches by .03 inch.

(2) The modified copolymer strips shall be immersed in 225 milliliters of 3 percent acetic acid in a Pyrex glass pressure bottle.

(3) The pyrex glass pressure bottle is then sealed and heated to 150 °F in either a circulating air oven or a thermostat controlled bath for a period of 8 days.

(4) The Pyrex glass pressure bottle is then removed from the oven or bath and cooled to room temperature. A sample of the extracting solvent is

then withdrawn and analyzed for acrylonitrile monomer by a gas chromatographic method titled "Gas-Solid Chromatographic Procedure for Determining Acrylonitrile Monomer in Acrylonitrile-Containing Polymers and Food Simulating Solvents," which is incorporated by reference. Copies, are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

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

(g) Acrylonitrile copolymers identified in this section are not authorized to be used to fabricate beverage containers.

[42 FR 14572, Mar. 15, 1977, as amended at 42 FR 48544, Sept. 23, 1977; 47 FR 11841, Mar. 19, 1982; 47 FR 16775, Apr. 20, 1982; 54 FR 24898, June 12, 1989]

§ 177.1060 *n*-Alkylglutarimide/acrylic copolymers.

n-Alkylglutarimide/acrylic copolymers identified in this section may be safely used as articles or components of articles intended for use in contact with food subject to provisions of this section and part 174 of this chapter.

(a) *Identity*. For the purpose of this section, *n*-alkylglutarimide/acrylic copolymers are copolymers obtained by reaction of substances permitted by §177.1010(a)(1), (2), and (3) with the following substance: Monomethylamine (CAS Reg. No. 74-89-5), to form *n*-methylglutarimide/acrylic copolymers.

(b) *Adjuvants*. The copolymers identified in paragraph (a) of this section may contain adjuvant substances required in their production. The optional adjuvant substances required in the production of the basic polymer may include substances permitted for such use by applicable regulations, as set forth in part 174 of this chapter.

(c) *Specifications*. Maximum nitrogen content of the copolymer determined by micro-Kjeldahl analysis, shall not exceed 8 percent.

(d) *Limitations*. (1) The *n*-alkylglutarimide/acrylic copolymers in the finished form in which they shall contact food, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature described in tables 1 and 2 of §176.170(c) of this chapter, shall yield extractives not to exceed the limitations of §177.1010(b) of this chapter, when prepared as strips, as described in §177.1010(c)(2) of this chapter.

(2) The *n*-alkylglutarimide/acrylic copolymers shall not be used as polymer modifiers in vinyl chloride homo- or copolymers.

(e) *Conditions of use*. The *n*-alkylglutarimide/acrylic copolymers are used as articles or components of articles (other than articles composed of vinyl chloride homo- or copolymers) intended for use in contact with all foods except beverages containing more than 8 percent alcohol under conditions of use D, E, F, and G as described in table 2 of §176.170(c) of this chapter.

[54 FR 20382, May 11, 1989, as amended at 58 FR 17098, Apr. 1, 1993]

§ 177.1200 Cellophane.

Cellophane may be safely used for packaging food in accordance with the following prescribed conditions:

(a) Cellophane consists of a base sheet made from regenerated cellulose to which have been added certain optional substances of a grade of purity suitable for use in food packaging as constituents of the base sheet or as coatings applied to impart desired technological properties.

(b) Subject to any limitations prescribed in this part, the optional substances used in the base sheet and coating may include:

(1) Substances generally recognized as safe in food.

(2) Substances for which prior approval or sanctions permit their use in cellophane, under conditions specified in such sanctions and substances listed in §181.22 of this chapter.

(3) Substances that by any regulation promulgated under section 409 of the

§ 177.1200

21 CFR Ch. I (4–1–25 Edition)

act may be safely used as components of cellophane.

(4) Substances named in this section and further identified as required.

(c) *List of substances:*

List of substances	Limitations (residue and limits of addition expressed as percent by weight of finished packaging cellophane)
Acrylonitrile-butadiene copolymer resins	As the basic polymer.
Acrylonitrile-butadiene-styrene copolymer resins	Do.
Acrylonitrile-styrene copolymer resins	Do.
Acrylonitrile-vinyl chloride copolymer resins	Do.
<i>N</i> -Acyl sarcosines where the acyl group is lauroyl or stearyl ...	For use only as release agents in coatings at levels not to exceed a total of 0.3 percent by weight of the finished packaging cellophane.
Alkyl ketene dimers identified in § 176.120 of this chapter.	
Aluminum hydroxide.	
Aluminum silicate.	
Ammonium persulfate.	
Ammonium sulfate.	
Behenamide.	
Butadiene-styrene copolymer	As the basic polymer.
1,3-Butanediol.	
<i>n</i> -Butyl acetate	0.1 percent.
<i>n</i> -Butyl alcohol	Do.
Calcium ethyl acetoacetate.	
Calcium stearoyl-2-lactylate identified in § 172.844 of this chapter.	Not to exceed 0.5 percent weight of cellophane.
Carboxymethyl hydroxyethylcellulose polymer.	
Castor oil, hydrogenated.	
Castor oil, sulfonated, sodium salt.	
Cellulose acetate butyrate.	
Cellulose acetate propionate.	
Cetyl alcohol.	
Clay, natural.	
Coconut oil fatty acid (C ₁₂ -C ₁₈) diethanolamide, coconut oil fatty acid (C ₁₂ -C ₁₈) diethanolamine soap, and diethanolamine mixture having total alkali (calculated as potassium hydroxide) of 16–18% and having an acid number of 25–35.	For use only as an adjuvant employed during the processing of cellulose pulp used in the manufacture of cellophane base sheet.
Copal resin, heat processed	As basic resin.
Damar resin.	
Defoaming agents identified in § 176.200 of this chapter.	
Dialkyl ketones where the alkyl groups are lauryl or stearyl	Not to exceed a total of 0.35 percent.
Dicyclohexyl phthalate	Do.
Diethylene glycol ester of the adduct of terpene and maleic anhydride.	
Di(2-ethylhexyl) adipate.	
Di(2-ethylhexyl) phthalate	Alone or in combination with other phthalates where total phthalates do not exceed 5 percent.
Dimethyldialkyl (C ₈ -C ₁₈) ammonium chloride	0.005 percent for use only as a flocculant for slip agents.
Di- <i>n</i> -ocyltin bis (2-ethylhexyl maleate)	For use only as a stabilizer at a level not to exceed 0.55 percent by weight of the coating solids in vinylidene chloride copolymer waterproof coatings prepared from vinylidene chloride copolymers identified in this paragraph, provided that such vinylidene chloride copolymers contain not less than 90 percent by weight of polymer units derived from vinylidene chloride.
<i>N,N'</i> -Dioleoyethylenediamine, <i>N,N'</i> -dilinoleoylethylene-diamine and <i>N</i> -oleoyl- <i>N'</i> linoleoylethylene-diamine mixture produced when tall oil fatty acids are made to react with ethylenediamine such that the finished mixture has a melting point of 212°–228 °F., as determined by ASTM method D127–60 ("Standard Method of Test for Melting Point of Petrolatum and Microcrystalline Wax" (Revised 1960), which is incorporated by reference; copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/libr_locations.html), and an acid value of 10 maximum.	0.5 percent.
<i>N,N'</i> -Dioleoylethylenediamine (<i>N,N'</i> -ethylenebisoleamide).	
Disodium EDTA.	
Distearic acid ester of di(hydroxyethyl) diethylenetriamine monoacetate.	0.06 percent.
<i>N,N'</i> -Distearoylethylenediamine (<i>N,N'</i> -ethylenebis stearamide).	

Food and Drug Administration, HHS

§ 177.1200

List of substances	Limitations (residue and limits of addition expressed as percent by weight of finished packaging cellophane)
Epoxidized polybutadiene	For use only as a primer subcoat to anchor surface coatings to the base sheet.
Erucamide.	
Ethyl acetate.	
Ethylene-vinyl acetate copolymers complying with § 177.1350.	
2-Ethylhexyl alcohol	0.1 percent for use only as lubricant.
Fatty acids derived from animal and vegetable fats and oils, and the following salts of such acids, single or mixed: Aluminum, ammonium, calcium, magnesium, potassium, sodium.	
Ferrous ammonium sulfate.	
Fumaric acid.	
Glycerin-maleic anhydride	As the basic polymer.
Glycerol diacetate.	
Glycerol monoacetate.	
Hydroxyethyl cellulose, water-insoluble.	
Hydroxypropyl cellulose identified in § 172.870 of this chapter.	
Isopropyl acetate	Residue limit 0.1 percent
Isopropyl alcohol	Do.
Itaconic acid.	
Lanolin.	
Lauryl alcohol.	
Lauryl sulfate salts: ammonium, magnesium, potassium, sodium.	
Maleic acid	1 percent.
Maleic acid adduct of butadienestyrene copolymer.	
Melamine formaldehyde	As the basic polymer.
Melamine-formaldehyde modified with one or more of the following: Butyl alcohol, diaminopropane, diethylenetriamine, ethyl alcohol, guanidine, imino-bis-butylamine, imino-bis-ethylamine, imino-bis-propylamine, methyl alcohol, polyamines made by reacting ethylenediamine or trimethylenediamine with dichloroethane or dichloropropane, sulfanilic acid, tetraethylenepentamine, triethanolamine, triethylenetetramine.	As the basic polymer, and used as a resin to anchor coatings to substrate.
Methyl ethyl ketone	Residue limit 0.1 percent
Methyl hydrogen siloxane	0.1 percent as the basic polymer.
α -Methylstyrene-vinyltoluene copolymer resins (molar ratio 1 α -methylstyrene to 3 vinyltoluene).	
Mineral oil, white.	
Mono- and bis-(octadecyldiethylene oxide) phosphates (CAS Reg. No. 62362-49-6).	For use only as a release agent at a level not to exceed 0.6 percent by weight of coatings for cellophane.
Naphthalenesulfonic acid-formaldehyde condensate, sodium salt.	0.1 percent, for use only as an emulsifier.
Nitrocellulose, 10.9 percent–12.2 percent nitrogen.	
Nylon resins complying with § 177.1500.	
<i>n</i> -Octyl alcohol	For use only as a defoaming agent in the manufacture of cellophane base sheet.
Olefin copolymers complying with § 177.1520.	
Oleic acid reacted with <i>N</i> -alkyl trimethylenediamine (alkyl C ₁₆ to C ₁₈).	
Oleic acid, sulfonated, sodium salt.	
Oleyl palmitamide.	
<i>N,N</i> -Oleoyl-stearylethylenediamine (<i>N</i> -(2-stearoylaminoethyl)oleamide).	
Paraffin, synthetic, complying with § 175.250 of this chapter.	
Pentaerythritol tetrastearate	0.1 percent.
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 cellophane coatings that contact food at temperatures not to exceed room temperature.
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 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.
Polybutadiene resin (molecular weight range 2,000–10,200; bromine number range 210–320).	For use only as an adjuvant in vinylidene chloride copolymer coatings.
Polycarbonate resins complying with § 177.1580.	
Polyester resin formed by the reaction of the methyl ester of rosin, phthalic anhydride, maleic anhydride, and ethylene glycol, such that the polyester resin has an acid number of 4 to 11, a drop-softening point of 70 °C–92 °C, and a color of K or paler.	

§ 177.1200

21 CFR Ch. I (4–1–25 Edition)

List of substances	Limitations (residue and limits of addition expressed as percent by weight of finished packaging cellophane)
<p>Polyethylene.</p> <p>Polyethyleneaminostearamide ethyl sulfate produced when stearic acid is made to react with equal parts of diethylenetriamine and triethylenetetramine and the reaction product is quaternized with diethyl sulfate.</p> <p>Polyethylene glycol (400) monolaurate.</p> <p>Polyethylene glycol (600) monolaurate.</p> <p>Polyethylene glycol (400) monooleate.</p> <p>Polyethylene glycol (600) monooleate.</p> <p>Polyethylene glycol (400) monostearate.</p> <p>Polyethylene glycol (600) monostearate.</p> <p>Polyethylene, oxidized: complying with the identity prescribed in § 177.1620(a).</p> <p>Polyethylenimine</p>	<p>0.1 percent.</p>
<p>Polyisobutylene complying with § 177.1420.</p> <p>Polyoxypropylene-polyoxyethylene block polymers (molecular weight 1,900–9,000).</p>	<p>As the basic polymer, for use as a resin to anchor coatings to the substrate and for use as an impregnant in the food-contact surface of regenerated cellulose sheet in an amount not to exceed that required to improve heat-sealable bonding between coated and uncoated sides of cellophane.</p> <p>For use as an adjuvant employed during the processing of cellulose pulp used in the manufacture of cellophane base sheet.</p>
<p>Polypropylene complying with § 177.1520.</p> <p>Polystyrene</p> <p>Polyvinyl acetate</p> <p>Polyvinyl alcohol (minimum viscosity of 4 percent aqueous solution at 20 °C of 4 centipoises).</p> <p>Polyvinyl chloride</p> <p>Polyvinyl stearate</p> <p><i>n</i>-Propyl acetate</p> <p><i>n</i>-Propyl alcohol</p> <p>Rapeseed oil, blown.</p> <p>Rosins and rosin derivatives as provided in § 178.3870 of this chapter.</p> <p>Rubber, natural (natural latex solids).</p> <p>Silica.</p> <p>Silicic acid.</p> <p>Sodium <i>m</i>-bisulfite.</p> <p>Sodium dioctyl sulfosuccinate.</p> <p>Sodium dodecylbenzenesulfonate.</p> <p>Sodium lauroyl sarcosinate</p>	<p>As the basic polymer.</p> <p>Do.</p> <p>As the basic polymer.</p> <p>Do.</p> <p>Residue limit 0.1 percent.</p> <p>Do.</p>
<p>Sodium oleyl sulfate-sodium cetyl sulfate mixture</p>	<p>0.35 percent; for use only in vinylidene chloride copolymer coatings.</p> <p>For use only as an emulsifier for coatings; limit 0.005 percent where coating is applied to one side only and 0.01 percent where coating is applied to both sides.</p>
<p>Sodium silicate.</p> <p>Sodium stearyl-2-lactylate identified in § 172.846 of this chapter.</p> <p>Sodium sulfate.</p> <p>Sodium sulfite.</p> <p>Spermaceti wax.</p> <p>Stannous oleate.</p> <p>2-Stearamido-ethyl stearate.</p> <p>Stearyl alcohol.</p> <p>Styrene-maleic anhydride resins</p> <p>Terpene resins identified in § 172.615 of this chapter.</p> <p>Tetrahydrofuran</p> <p>Titanium dioxide.</p> <p>Toluene</p> <p>Toluene sulfonamide formaldehyde</p> <p>Triethylene glycol.</p> <p>Triethylene glycol diacetate, prepared from triethylene glycol containing not more than 0.1 percent of diethylene glycol.</p> <p>2,2,4-Trimethyl-1,3 pentanediol diisobutyrate</p>	<p>Not to exceed 0.5 percent weight of cellophane.</p>
<p>Urea (carbamide).</p> <p>Urea formaldehyde</p>	<p>As the basic polymer.</p>

List of substances	Limitations (residue and limits of addition expressed as percent by weight of finished packaging cellophane)
Urea formaldehyde modified with methanol, ethanol, butanol diethylenetriamine, triethylenetetramine, tetraethylenepentamine, guanidine, sodium sulfite, sulfanilic acid, imino-bis-ethylamine, imino-bis-propylamine, imino-bis-butylamine, diaminopropane, diaminobutane, aminomethylsulfonic acid, polyamines made by reacting ethylenediamine or trimethylenediamine with dichlorethane or dichloropropane.	As the basic polymer, and used as a resin to anchor coatings to the substrate.
Vinyl acetate-vinyl chloride copolymer resins	As the basic polymer.
Vinyl acetate-vinyl chloride-maleic acid copolymer resins	Do.
Vinylidene chloride copolymerized with one or more of the following: Acrylic acid, acrylonitrile, butyl acrylate, butyl methacrylate, ethyl acrylate, 2-ethylhexyl acrylate, 2-ethylhexyl methacrylate, ethyl methacrylate, itaconic acid, methacrylic acid, methyl acrylate, methyl methacrylate, propyl acrylate, propyl methacrylate, vinyl chloride.	Do.
Vinylidene chloride-methacrylate decyloctyl copolymer	Do.
Wax, petroleum, complying with § 178.3710 of this chapter.	

(d) Any optional component listed in this section covered by a specific food additive regulation must meet any specifications in that regulation.

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

[42 FR 14572, Mar. 15, 1977, as amended at 47 FR 11842, Mar. 19, 1982; 64 FR 57978, Oct. 28, 1999; 87 FR 31089, May 20, 2022]

§ 177.1210 Closures with sealing gaskets for food containers.

Closures with sealing gaskets may be safely used on containers intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) Closures for food containers are manufactured from substances generally recognized as safe for contact with food; substances that are subject to the provisions of prior sanctions; substances authorized by regulations in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter; and closure-sealing gaskets, as further prescribed in this section.

(b) Closure-sealing gaskets and over-all discs are formulated from sub-

stances identified in § 175.300(b) of this chapter, with the exception of paragraph (b)(3)(v), (xxxi), and (xxxii) of that section, and from other optional substances, including the following:

(1) Substances generally recognized as safe in food.

(2) Substances used in accordance with the provisions of a prior sanction or approval within the meaning of section 201(s) of the act.

(3) Substances that are the subject of regulations in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter and used in accordance with the conditions prescribed.

(4) Substances identified in paragraph (b)(5) of this section, used in amounts not to exceed those required to accomplish the intended physical or technical effect and in conformance with any limitation provided; and further provided that any substance employed in the production of closure-sealing gasket compositions that is the subject of a regulation in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with the identity or specifications prescribed.

(5) Substances that may be employed in the manufacture of closure-sealing gaskets include:

TABLE 1

List of substances	Limitations (expressed as percent by weight of closure-sealing gasket composition)
Arachidy-l-behenyl amide (C ₂₀ -C ₂₂ fatty acid amides)	5 percent.
Azodicarbonamide	1. 2 percent.
	2. 5 percent; for use only in the manufacture of polyethylene complying with item 2.1 in § 177.1520(c) of this chapter.

TABLE 1—Continued

List of substances	Limitations (expressed as percent by weight of closure-sealing gasket composition)
Balata rubber.	
Benzyl alcohol	1 percent.
Brominated isobutylene-isoprene copolymers, produced when isobutylene-isoprene copolymers complying with § 177.1420(a)(2) are modified by bromination with not more than 2.3 weight-percent of bromine and having a Mooney Viscosity (ML 1 + 8 (125 °C)) of 27 or higher. The viscosity is determined by the American Society for Testing and Materials (ASTM) method D 1646–81, “Standard Test Method for Rubber—Viscosity and Vulcanization Characteristics (Mooney Viscometer),” which is incorporated by reference in accordance with 5 U.S.C. 522(a) and 1 CFR part 51. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877-2504 and the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal-register/code_of_federal_regulations/ibr_locations.html .	
1,3-Butanediol.	
Calcium tin stearate	2 percent.
Calcium zinc stearate	Do.
Carbon, activated	1 percent.
Castor oil, hydrogenated	2 percent.
Chlorinated isobutylene-isoprene copolymers complying with § 177.1420.	
Coco amide (coconut oil fatty acids amides)	2 percent.
Cork (cleaned, granulated).	
Diebenzamide phenyl disulfide	1 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.
Di(C ₇ , C ₉ -alkyl) adipate	Complying with § 178.3740 of this chapter; except that, there is no limitation on polymer thickness.
Di-2-ethylhexyl adipate.	
Di-2-ethylhexyl sebacate	2 percent.
Di-2-ethylhexyl terephthalate (CAS Reg. No. 006422–86–2).	For use as a plasticizer at levels not exceeding 75 parts per hundred by weight of permitted vinyl chloride homo- and/or copolymer resins used in contact with food of Types I, II, IV-B, VI-A, VI-B, VI-C (up to 15 percent alcohol by volume), VII-B, and VIII described in § 176.170(c) of this chapter, table 1, and under conditions of use A through H described in § 176.170 (c) of this chapter, table 2.
Dihexyl ester of sodium sulfosuccinate	1 percent.
Diisodecyl phthalate	No limitation on amount used but for use only in closure-sealing gasket compositions used in contact with non-fatty foods containing no more than 8 percent of alcohol.
Di-β-naphthyl- <i>p</i> -phenylenediamine	1 percent.
Dipentamethylenethiurametetrasulfide	0.4 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.
Eicosane (technical grade) (water-white mixture of predominantly straight-chain paraffin hydrocarbons averaging 20 carbon atoms per molecule).	
Epoxidized linseed oil.	
Epoxidized linseed oil modified with trimellitic anhydride.	
Epoxidized safflower oil.	
Epoxidized safflower oil modified with trimellitic anhydride.	
Epoxidized soybean oil modified with trimellitic anhydride.	
Erucylamide	5 percent.
Ethylene-propylene copolymer.	
Ethylene-propylene modified copolymer elastomers produced when ethylene and propylene are copolymerized with 5-methylene-2-norbornene and/or 5-ethylidene-2-norbornene. The finished copolymer elastomers so produced shall contain not more than 5 weight-percent of total polymer units derived from 5-methylene-2-norbornene and/or 5-ethylidene-2-norbornene, and shall have a minimum viscosity average molecular weight of 120,000 as determined by the method described in § 177.1520(d)(5), and a minimum Mooney viscosity of 35 as determined by the method described in § 177.1520(d)(6).	

TABLE 1—Continued

List of substances	Limitations (expressed as percent by weight of closure-sealing gasket composition)
Ethylene-vinyl acetate copolymer.	
Glyceryl mono-12-hydroxystearate (hydrogenated glyceryl ricinoleate).	2 percent.
Gutta-percha.	
Hexamethylenetetramine	1 percent.
Hexylene glycol	0.5 percent.
Isobutylene-isoprene copolymers complying with § 177.1420.	
Maleic anhydride-polyethylene copolymer	5 percent.
Maleic anhydride-styrene copolymer	Do.
2,2'-Methylenebis[6-(1-methylcyclohexyl)-p-cresol]	1 percent.
Mixed octylated diphenylamine (CAS Reg. No. 68411-46-1) ...	0.1 percent in isobutylene-isoprene and chlorinated isobutylene-isoprene copolymers complying with § 177.1420, and brominated isobutylene-isoprene copolymers complying with this section.
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt.	0.2 percent.
Natural rubber (crepe, latex, mechanical dispersions).	
α -cis-9-Octadecenyl- ω -hydroxypoly (oxyethylene); the octadecenyl group is derived from oleyl alcohol and the poly (oxyethylene) content averages 20 moles.	0.5 percent.
Oleyl alcohol	1 percent.
4,4'-Oxybis (benzene sulfonyl hydrazide)	0.5 percent.
Paraformaldehyde	1 percent.
Polybutadiene.	
Poly-p-dinitroso benzene (activator for butyl rubber)	1 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.
Polyethylene glycol 400 esters of fatty acids derived from animal and vegetable fats and oils.	1 percent.
Polyisobutylene complying with § 177.1420.	
Polyoxypropylene-polyoxyethylene condensate, average mol. wt. 2750-3000.	0.05 percent.
Polyurethane resins manufactured from diphenylmethane diisocyanate, 1,4-butanediol, and adipic acid (CAS Reg. No. 26375-23-5)..	For use only: No limitation on amount used, but for use only in closure gasket compositions used in contact with food types VI-A and VI-C (up to 15 percent alcohol) under conditions of use D, E, F, and G, as described in § 176.170(c) of this chapter, tables 1 and 2, respectively.
Potassium benzoate	1 percent.
Potassium propionate	2 percent.
Potassium and sodium persulfate	1 percent.
Resorcinol	0.24 percent; for use only as a reactive adjuvant substance employed in the production of gelatin-bonded cord compositions for use in lining crown closures. The gelatin so used shall be technical grade or better.
Rosins and rosin derivatives as defined in § 175.300(b)(3)(v) of this chapter for use only in resinous and polymeric coatings on metal substrates; for all other uses as defined in § 178.3870 of this chapter.	
Sodium cetyl sulfate	1 percent.
Sodium decylbenzenesulfonate	Do.
Sodium decyl sulfate	Do.
Sodium formaldehyde sulfoxylate	0.05 percent.
Sodium lauryl sulfate	1 percent.
Sodium lignin sulfonate	0.2 percent.
Sodium myristyl sulfate (sodium tetradecyl sulfate)	0.6 percent.
Sodium nitrite	0.2 percent; for use only in annular ring gaskets applied in aqueous dispersions to closures for containers having a capacity of not less than 5 gallons.
Sodium o-phenylphenate	0.05 percent.
Sodium polyacrylate	5 percent.
Sodium and potassium pentachlorophenate	0.05 percent.
Sodium salt of trisopropyl naphthalenesulfonic acid	0.2 percent.
Sodium tridecylsulfate	0.6 percent.
Stearic acid amide	5 percent.
Sulfur	For use only as a vulcanizing agent in vulcanized natural or synthetic rubber gasket compositions at a level not to exceed 4 percent by weight of the elastomer content of the rubber gasket composition.
Tallow, sulfated	1 percent.
Tin-zinc stearate	2 percent.
Tri(mixed mono- and dinonylphenyl) phosphite	1 percent.

TABLE 1—Continued

List of substances	Limitations (expressed as percent by weight of closure-sealing gasket composition)
Vinyl chloride-vinyl stearate copolymer. Zinc dibutylthiocarbamate	0.8 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.

TABLE 2—MAXIMUM EXTRACTIVES TOLERANCES
[In parts per million]

Type of closure-sealing gasket composition	Chloroform fraction of water extractives	Chloroform fraction of heptane extractives	Chloroform fraction of alcohol extractives
1. Plasticized polymers, including unvulcanized or vulcanized or otherwise cured natural and synthetic rubber formed in place as overall discs or annular rings from a hot melt, solution, plastisol, organisol, mechanical dispersion, or latex	50	500	50
2. Preformed overall discs or annular rings of plasticized polymers, including unvulcanized natural or synthetic rubber	50	250	50
3. Preformed overall discs or annular rings of vulcanized plasticized polymers, including natural or synthetic rubber	50	50	50
4. Preformed overall discs or annular rings of polymeric or resinous-coated paper, paperboard, plastic, or metal foil substrates	50	250	50
5. Closures with sealing gaskets or sealing compositions as described in 1, 2, 3, and 4, and including paper, paperboard, and glassine used for dry foods only	(¹)	(¹)	(¹)

¹ Extractability tests not applicable.

(c) The closure assembly to include the sealing gasket or sealing compound, together with any polymeric or resinous coating, film, foil, natural cork, or glass that forms a part of the food-contact surface of the assembly,

when extracted on a suitable glass container with a solvent or solvents characterizing the type of foods, and under conditions of time and temperature characterizing the conditions of its use as determined from tables 3 and 4 shall yield net chloroform-soluble extractives (corrected for zinc as zinc oleate) not to exceed the tolerances specified in table 2, calculated on the basis of the water capacity of the container on which the closure is to be used. Employ the analytical method described in §175.300 of this chapter, adapting the procedural details to make the method applicable to closures; such as, for example, placing the closed glass container on its side to assure contact of the closure's food-contacting surface with the solvent.

TABLE 3—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 emulsions, high- or low-fat.
 - B. Oil-in-water emulsions, 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 4—TEST PROCEDURES WITH TIME-TEMPERATURE CONDITIONS FOR DETERMINING AMOUNT OF EXTRACTIVES FROM CLOSURE-SEALING GASKETS, USING SOLVENTS SIMULATING TYPES OF FOODS AND BEVERAGES

Conditions of use	Types of food (see Table 3)	Extractant		
		Water (time and temperature)	Heptane ¹ (time and temperature)	8% 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.	

TABLE 4—TEST PROCEDURES WITH TIME-TEMPERATURE CONDITIONS FOR DETERMINING AMOUNT OF EXTRACTIVES FROM CLOSURE-SEALING GASKETS, USING SOLVENTS SIMULATING TYPES OF FOODS AND BEVERAGES—Continued

Conditions of use	Types of food (see Table 3)	Extractant		
		Water (time and temperature)	Heptane ¹ (time and temperature)	8% alcohol (time and temperature)
B. Boiling water-sterilized	II	212 °F, 30 min	150 °F, 2 hr.
C. Hot filled or pasteurized above 150 °F.	III, VII	do	120 °F, 30 min.	
	II, IV-B	Fill boiling, cool to 100 °F.	.	
D. Hot filled or pasteurized below 150 °F.	III, IV-A	do	120 °F, 15 min.	
	V	do	do.	
	II, IV-B, VI-B	150 °F, 2 hr	
	III, IV-A	do	100 °F, 30 min.	
E. Room temperature filled and stored (no thermal treatment in the container).	V	do	do.	
	VI-A	do	do.	
	II, IV-B, VI-B	120 °F, 24 hr	
	III, IV-A	do	70 °F, 30 min.	
F. Refrigerated storage (no thermal treatment).	V	do	do.	120 °F, 24 hr.
	VI-A	do	do.	
	I, II, III, IV-A, IV-B, VI-B, VII.	70 °F, 48 hr	70 °F, 30 min.	
	VI-A	do	do.	
G. Frozen storage (no thermal treatment in the container).	I, II, III, IV-B, VII ...	70 °F, 24 hr	70 °F, 48 hr.

¹Heptane extractant not applicable to closure-sealing gaskets overcoated with wax.

[42 FR 14572, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977, as amended at 47 FR 22090, May 21, 1982; 49 FR 5748, Feb. 15, 1984; 55 FR 34555, Aug. 23, 1990; 61 FR 14480, Apr. 2, 1996; 65 FR 26745, May 9, 2000; 65 FR 52908, Aug. 31, 2000; 70 FR 67651, Nov. 8, 2005; 76 FR 59249, Sept. 26, 2011; 78 FR 14665, Mar. 7, 2013; 82 FR 20832, May 4, 2017]

§ 177.1211 Cross-linked polyacrylate copolymers.

Cross-linked polyacrylate copolymers identified in paragraph (a) of this section may be safely used as articles or components of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) *Identity.* For the purpose of this section, the cross-linked polyacrylate copolymers consist of:

(1) The grafted copolymer of cross-linked sodium polyacrylate identified as 2-propenoic acid, polymers with *N,N*-di-2-propenyl-2-propen-1-amine and hydrolyzed polyvinyl acetate, sodium salts, graft (CAS Reg. No. 166164-74-5); or

(2) 2-propenoic acid, polymer with 2-ethyl-2-(((1-oxo-2-propenyl)oxy)methyl)-1,3-propanediyl di-2-propenoate and sodium 2-propenoate (CAS Reg. No. 76774-25-9).

(b) *Adjuvants.* The copolymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such copolymers. The optional adjuvant substances may include substances permitted for such use by regulations in parts 170 through 179 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) *Extractives limitations.* The copolymers identified in paragraph (a) of this section, in the finished form in which they will contact food, must yield low molecular weight (less than 1,000 Daltons) extractives of no more than 0.15 percent by weight of the total polymer when extracted with 0.2 percent by weight of aqueous sodium chloride solution at 20 °C for 24 hours. The low molecular weight extractives shall be determined using size exclusion chromatography or an equivalent method.

§ 177.1240

When conducting the extraction test, the copolymer, with no other absorptive media, shall be confined either in a finished absorbent pad or in any suitable flexible porous article, (such as a "tea bag" or infuser), under an applied pressure of 0.15 pounds per square inch (for example, a 4 × 6 inch square pad is subjected to a 1.6 kilograms applied mass). The solvent used shall be at least 60 milliliters aqueous sodium chloride solution per gram of copolymer.

(d) *Conditions of use.* The copolymers identified in paragraph (a)(1) of this section are limited to use as a fluid absorbent in food-contact materials used in the packaging of frozen or refrigerated poultry. The copolymers identified in paragraph (a)(2) of this section are limited to use as a fluid absorbent in food-contact materials used in the packaging of frozen or refrigerated meat and poultry.

[64 FR 28098, May 25, 1999, as amended at 65 FR 16817, Mar. 30, 2000]

§ 177.1240 1,4-Cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate copolymer.

Copolymer of 1,4-cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate may be safely used as an article or component of articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

(a) The copolymer is a basic polyester produced by the catalytic condensation of dimethyl terephthalate and dimethyl isophthalate with 1,4-cyclohexanedimethanol, to which may have been added certain optional substances required in its production or added to impart desired physical and technical properties.

(b) The quantity of any optional substance employed in the production of the copolymer does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation further provided.

(c) Any substance employed in the production of the copolymer that is the subject of a regulation in parts 174, 175,

21 CFR Ch. I (4–1–25 Edition)

176, 177, 178 and §179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the production of the copolymer include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in the copolymer and used in accordance with such sanction or approval.

(3) Substances which by regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter may be safely used as components of resinous or polymeric coatings and film used as food-contact surfaces, subject to the provisions of such regulation.

(e) The copolymer conforms with the following specifications:

(1) The copolymer, when extracted with distilled water at reflux temperature for 2 hours, yields total extractives not to exceed 0.05 percent.

(2) The copolymer, when extracted with ethyl acetate at reflux temperature for 2 hours, yields total extractives not to exceed 0.7 percent.

(3) The copolymer, when extracted with *n*-hexane at reflux temperature for 2 hours, yields total extractives not to exceed 0.05 percent.

[42 FR 14572, Mar. 15, 1977; 49 FR 5748, Feb. 15, 1984, as amended at 55 FR 34555, Aug. 23, 1990]

§ 177.1310 Ethylene-acrylic acid copolymers.

The ethylene-acrylic acid copolymers identified in paragraph (a) of this section may be safely used as components of articles intended for use in contact with food subject to the provisions of this section.

(a) The ethylene-acrylic acid copolymers consist of basic copolymers produced by the copolymerization of ethylene and acrylic acid such that the finished basic copolymers contain no more than:

(1) 10 weight-percent of total polymer units derived from acrylic acid when used in accordance with paragraph (b) of this section; and

(2) 25 weight-percent of total polymer units derived from acrylic acid when used in accordance with paragraph (c) of this section.

(b) The finished food-contact articles made with no more than 10 percent

total polymer units derived from acrylic acid, when extracted with the solvent or solvents characterizing the type of food and under the conditions of its intended use as determined from tables 1 and 2 of §176.170(c) of this chapter, yield net acidified chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface when tested by the methods prescribed in §177.1330(e)(1), (3)(i) through (iv), (4), (5), and (6), except that

(1) The total residue method using 3 percent acetic acid, as prescribed in §177.1330(e)(6)(i)(a), does not apply, and

(2) The net acidified chloroform-soluble extractives from paper and paperboard complying with §176.170 of this chapter may be corrected for wax, petrolatum, and mineral oil as provided in §176.170(d)(5)(iii)(b) of this chapter.

If the finished food-contact article is itself the subject of a regulation in parts 174, 175, 176, 177, 178, and §179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation.

(c) The finished food-contact layer made with basic copolymers containing more than 10 weight-percent but no more than 25 weight-percent of total polymer units derived from acrylic acid and with a maximum thickness of 0.0025 inch (2.5 mils) may be used in contact with food types I, II, IVB, VIA, VIB, VIIB, and VIII identified in table 1 of §176.170(c) of the chapter under conditions of use B through H as described in table 2 of §176.170(c) of this chapter, and in contact with food types III, IVA, V, VIIA, and IX identified in table 1 of §176.170(c) of this chapter under conditions of use E through G as described in table 2 of §176.170(c) of this chapter.

(d) The provisions of this section are not applicable to ethylene-acrylic acid copolymers used in food-packaging adhesives complying with §175.105 of this chapter.

[42 FR 14572, Mar. 15, 1977, as amended at 51 FR 19060, May 27, 1986; 53 FR 44009, Nov. 1, 1988]

§ 177.1312 Ethylene-carbon monoxide copolymers.

The ethylene-carbon monoxide copolymers identified in paragraph (a) of

this section may be safely used as components of articles intended for use in contact with food subject to the provisions of this section.

(a) *Identity.* For the purposes of this section, ethylene-carbon monoxide copolymers (CAS Reg. No. 25052-62-4) consist of the basic polymers produced by the copolymerization of ethylene and carbon monoxide such that the copolymers contain not more than 30 weight-percent of polymer units derived from carbon monoxide.

(b) *Conditions of use.* (1) The polymers may be safely used as components of the food-contact or interior core layer of multilaminate food-contact articles.

(2) The polymers may be safely used as food-contact materials at temperatures not to exceed 121 °C (250 °F).

(c) *Specifications.* (1) Food-contact layers formed from the basic copolymer identified in paragraph (a) of this section shall be limited to a thickness of not more than 0.01 centimeter (0.004 inch).

(2) The copolymers identified in paragraph (a) of this section shall have a melt index not greater than 500 as determined by ASTM method D1238-82, condition E "Standard Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(3) The basic copolymer identified in paragraph (a) of this section, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use, as determined from

§ 177.1315

21 CFR Ch. I (4–1–25 Edition)

tables 1 and 2 of §176.170(c) of this chapter, yields net chloroform-soluble extractives in each extracting solvent not to exceed 0.5 milligram per square inch of food-contact surface when tested by methods described in §176.170(d) of this chapter.

(4) The provisions of this section are not applicable to ethylene-carbon monoxide copolymers complying with §175.105 of this chapter.

[57 FR 32422, July 22, 1992]

§ 177.1315 Ethylene-1, 4-cyclohexylene dimethylene terephthalate copolymers.

Ethylene-1, 4-cyclohexylene dimethylene terephthalate copolymer may be safely used as articles or components of articles intended for use in

contact with food subject to provisions of this section and of part 174 of this chapter.

(a) *Identity.* For the purposes of this section, ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers (1,4-benzene dicarboxylic acid, dimethyl ester, polymerized with 1,4-cyclohexanedimethanol and 1,2-ethanediol) (CAS Reg. No. 25640-14-6) or (1,4-benzenedicarboxylic acid, polymerized with 1,4-cyclohexanedimethanol and 1,2-ethanediol) (CAS Reg. No. 25038-91-9) are basic copolymers meeting the specifications prescribed in paragraph (b) of this section, to which may have been added certain optional substances required in their production or added to impart desired physical or technical properties.

(b) *Specifications:*

Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers	Inherent viscosity	Maximum extractable fractions of the copolymer in the finished form at specified temperatures and times (expressed in micrograms of the terephthaloyl moieties/square centimeter of food-contact surface)	Test for orientability	Conditions of use
1. <i>Non-oriented</i> ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer is the reaction product of dimethyl terephthalate or terephthalic acid with a mixture containing 99 to 66 mole percent of ethylene glycol and 1 to 34 mole percent of 1,4-cyclohexanedimethanol (70 percent <i>trans</i> isomer, 30 percent <i>cis</i> isomer).	Inherent viscosity of a 0.50 percent solution of the copolymer in phenol-tetrachloroethane (60:40 ratio wt/wt) solvent is not less than 0.669 as determined by using a Wagner viscometer (or equivalent) and calculated from the following equation: Inherent viscosity = (Natural logarithm of N_t)/(c) where: N_t = Ratio of flow time of the polymer solution to that of the solvent, and c = concentration of the test solution expressed in grams per 100 milliliters.	(1) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface when extracted with water added at 82.2 °C (180 °F) and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article.	No test required ...	In contact with foods, including foods containing not more than 25 percent (by volume) aqueous alcohol, excluding carbonated beverages and beer. Conditions of hot fill not to exceed 82.2 °C (180 °F), storage at temperatures not in excess of 48.9 °C (120 °F). No thermal treatment in the container.

Food and Drug Administration, HHS

§ 177.1315

Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers	Inherent viscosity	Maximum extractable fractions of the copolymer in the finished form at specified temperatures and times (expressed in micrograms of the terephthaloyl moieties/square centimeter of food-contact surface)	Test for orientability	Conditions of use
2. <i>Oriented</i> ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer is the reaction product of dimethyl terephthalate or terephthalic acid with a mixture containing 99 to 85 mole percent ethylene glycol and 1 to 15 mole percent of 1,4-cyclohexane-dimethanol (70 percent <i>trans</i> isomer, 30 percent <i>cis</i> isomer).do	(2) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface when extracted with 3 percent (by volume) aqueous acetic acid added at 82.2 °C (180 °F) and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article.do	Do.
do	(3) 0.08 microgram per square centimeter (0.5 microgram per square inch) of food-contact surface when extracted for 2 hours with <i>n</i> -heptane at 48.9 °C (120 °F). The heptane extractable results are to be divided by a factor of 5.do	Do.
do	(4) 0.16 microgram per square centimeter (1.0 microgram per square inch) of food-contact surface when extracted for 24 hours with 25 percent (by volume) aqueous ethanol at 48.9 °C (120 °F).do	Do.
do	(1) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of the oriented copolymer when extracted with water added at 87.8 °C (190 °F) and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article.	When extracted with heptane at 65.6 °C (150 °F) for 2 hours: terephthaloyl moieties do not exceed 0.09 microgram per square centimeter (0.60 microgram per square inch) of food-contact surface.	In contact with non-alcoholic foods including carbonated beverages. Conditions of hot fill not exceeding 87.8 °C (190 °F), storage at temperatures not in excess of 48.9 °C (120 °F). No thermal treatment in the container.
do	(2) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of oriented copolymer when extracted with 3 percent (by volume) aqueous acetic acid added at 87.8 °C (190 °F) and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article.do	Do.
do	(3) 0.08 microgram per square centimeter (0.5 microgram per square inch) of food-contact surface of oriented copolymer when extracted for 2 hours with <i>n</i> -heptane at 48.9 °C (120 °F). The heptane extractable results are to be divided by a factor of 5.do	Do.

Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers	Inherent viscosity	Maximum extractable fractions of the copolymer in the finished form at specified temperatures and times (expressed in micrograms of the terephthaloyl moieties/square centimeter of food-contact surface)	Test for orientability	Conditions of use
3. Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer is the reaction product of dimethyl terephthalate or terephthalic acid with a mixture containing 99 to 95 mole percent of ethylene glycol and 1 to 5 mole percent of 1,4-cyclohexanedimethanol (70 percent <i>trans</i> isomer, 30 percent <i>cis</i> isomer).do	(4) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of oriented copolymer when extracted with 20 percent (by volume) aqueous ethanol heated to 65.6 °C (150 °F) for 20 minutes and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article.do	In contact with foods and beverages containing up to 20 percent (by volume) alcohol. Conditions of thermal treatment in the container not exceeding 65.6 °C (150 °F) for 20 minutes. Storage at temperatures not in excess of 48.9 °C (120 °F).
do	(5) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of oriented copolymer when extracted with 50 percent (by volume) aqueous ethanol at 48.9 °C (120 °F) for 24 hours.do	In contact with foods and beverages containing up to 50 percent (by volume) alcohol. Conditions of fill and storage not exceeding 48.9 °C (120 °F). No thermal treatment in the container.
	No test required ...	For each corresponding condition of use, must meet specifications described in § 177.1630(f), (g), (h), or (j).	No test required ...	For each corresponding specification, may be used as a base sheet and base polymer in accordance with conditions of use described in § 177.1630(f), (g), (h), or (j).

(c) *Analytical method for determination of extractability.* The total extracted terephthaloyl moieties can be determined in the extracts, without evaporation of the solvent, by measuring the ultraviolet (UV) absorbance at 240 nanometers. The spectrophotometer (Varian 635-D, or equivalent) is zeroed with a sample of the solvent taken from the same lot used in the extraction tests. The concentration of the total terephthaloyl moieties in water, 3 percent acetic acid, and in 8 percent aqueous alcohol is calculated as bis(2-hydroxyethyl terephthalate) by reference to standards prepared in the appropriate solvent. Concentration of the terephthaloyl moieties in heptane is calculated as cyclic trimer (C₆H₄CO₂C₂H₄CO₂)₃, by reference to

standards prepared in 95:5 percent (v/v) heptane: tetrahydrofuran.

[45 FR 39252, June 10, 1980, as amended at 47 FR 24288, June 4, 1982; 49 FR 25629, June 22, 1984; 51 FR 22929, June 24, 1986; 60 FR 57926, Nov. 24, 1995]

§ 177.1320 Ethylene-ethyl acrylate copolymers.

Ethylene-ethyl acrylate copolymers may be safely used to produce packaging materials, containers, and equipment intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) Ethylene-ethyl acrylate copolymers consist of basic resins produced

by the catalytic copolymerization of ethylene and ethyl acrylate, to which may have been added certain optional substances to impart desired technological properties to the resin. Subject to any limitations prescribed in this section, the optional substances may include:

(1) Substances generally recognized as safe in food and food packaging.

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

(b) The ethyl acrylate content of the copolymer does not exceed 8 percent by weight unless it is blended with polyethylene or with one or more olefin copolymers complying with §177.1520 or with a mixture of polyethylene and one or more olefin copolymers, in such proportions that the ethyl acrylate content of the blend does not exceed 8 percent by weight, or unless it is used in a coating complying with §175.300 or §176.170 of this chapter, in such proportions that the ethyl acrylate content does not exceed 8 percent by weight of the finished coating.

(c) Ethylene-ethyl acrylate copolymers or the blend shall conform to the specifications prescribed in paragraph (c)(1) of this section and shall meet the ethyl acrylate content limits prescribed in paragraph (b) of this section, and the extractability limits prescribed in paragraph (c)(2) of this section, when tested by the methods prescribed for polyethylene in §177.1520.

(1) *Specifications*—(i) *Infrared identification*. Ethylene-ethyl acrylate copolymers can be identified by their characteristic infrared spectra.

(ii) *Quantitative determination of ethyl acrylate content*. The ethyl acrylate can be determined by the infrared spectra. Prepare a scan from 10.5 microns to 12.5 microns. Obtain a baseline absorbance at 11.6 microns and divide by the plaque thickness to obtain absorbance per mil. From a previously prepared calibration curve, obtain the amount of ethyl acrylate present.

(iii) *Specific gravity*. Ethylene-ethyl acrylate copolymers have a specific gravity of not less than 0.920 nor more than 0.935, as determined by ASTM method D1505-68 (Reapproved 1979), “Standard Test Method for Density of

Plastics by the Density-Gradient Technique,” which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(2) *Limitations*. Ethylene-ethyl acrylate copolymers or the blend may be used in contact with food except as a component of articles used for packaging or holding food during cooking provided they meet the following extractability limits:

(i) Maximum soluble fraction of 11.3 percent in xylene after refluxing and subsequent cooling to 25 °C.

(ii) Maximum extractable fraction of 5.5 percent when extracted with *n*-hexane at 50 °C.

(d) The provisions of paragraphs (b) and (c)(2) of this section are not applicable to ethylene-ethyl acrylate copolymers used in the formulation of adhesives complying with §175.105 of this chapter.

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10108, Mar. 19, 1984]

§ 177.1330 Ionomeric resins.

Ionomeric resins manufactured from either ethylene-methacrylic acid copolymers (and/or their ammonium, calcium, magnesium, potassium, sodium, and/or zinc partial salts), ethylene-methacrylic acid-vinyl acetate copolymers (and/or their ammonium, calcium, magnesium, potassium, sodium, and/or zinc partial salts), or methacrylic acid polymers with ethylene and isobutyl acrylate (and/or their potassium, sodium and/or zinc partial salts) may be safely used as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, the ethylene-methacrylic acid copolymers consist of basic copolymers produced by the copolymerization of ethylene and methacrylic acid such

that the copolymers contain no more than 20 weight percent of polymer units derived from methacrylic acid, and the ethylene-methacrylic acid-vinyl acetate copolymers consist of basic copolymers produced by the copolymerization of ethylene, methacrylic acid, and vinyl acetate such that the copolymers contain no more than 15 weight percent of polymer units derived from methacrylic acid.

(b) For the purpose of this section, the methacrylic acid copolymers with ethylene and isobutyl acrylate consist of basic copolymers produced by the copolymerization of methacrylic acid, ethylene, and isobutyl acrylate such that the copolymers contain no less than 70 weight percent of polymer units derived from ethylene, no more than 15 weight percent of polymer units derived from methacrylic acid, and no more than 20 weight percent of polymer units derived from isobutyl acrylate. From 20 percent to 70 percent of the carboxylic acid groups may optionally be neutralized to form sodium or zinc salts.

(c) The finished food-contact article described in paragraph (a) of this section, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 176.170(c) of this chapter, yields net acidified chloroform-soluble extractives in each extracting solvent not to exceed 0.5 milligram per square inch of food-contact surface when tested by the methods described in paragraph (e)(1) of this section, and if the finished food-contact article is itself the subject of a regulation in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation.

NOTE: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.

(d) The finished food-contact article described in paragraph (b) of this section, when extracted according to the methods listed in paragraph (e)(2) of this section and referenced in this paragraph (d), using the solvent or solvents characterizing the type of food as

determined from table I of paragraph (f) of this section, shall yield net acidified chloroform-soluble extractives as follows:

(1) *For fatty food use.* (i) For films of 2 mil (0.002 inches) thickness or less, extractives shall not exceed 0.70 milligram/square inch¹ (0.109 milligram/square centimeter) of food-contact surface (*n*-heptane extractions) when extracted by the abbreviated method cited in paragraph (e)(2)(i) of this section.

(ii) For films of greater than 2 mils (0.002 inch) thickness, extractives shall not exceed 0.40 milligram/square inch¹ (0.062 milligram/square centimeter) of food-contact surface (*n*-heptane extractions) when extracted by the abbreviated method cited in paragraph (e)(2)(i) of this section, or

(iii) Alternatively, for films of greater than 2 mils thickness, extractives shall not exceed 0.70 milligram/square inch¹ (0.109 milligram/square centimeter) of food-contact surface (*n*-heptane extractions) when extracted by the equilibrium method cited in paragraph (e)(2)(ii) of this section.

(2) *For aqueous foods.* (i) The net acidified chloroform-soluble extractives shall not exceed 0.02 milligram/square inch² (0.003 milligram/square centimeter) of food-contact surface (water, acetic acid, or ethanol/water extractions) when extracted by the abbreviated method cited in paragraph (e)(2)(i) of this section.

(ii) Alternatively, the net acidified chloroform-soluble extractives shall not exceed 0.05 milligram/square inch³ (0.078 mg/square centimeter) of food-contact surface (water, acetic acid, or ethanol/water extractions) when extracted by the equilibrium method cited in paragraph (e)(2)(ii) of this section. If when exposed to *n*-heptane, a particular film splits along die lines, thus permitting exposure of both sides of the film to the extracting solvent,

¹ Average of four separate values, no single value of which differs from the average of those values by more than ±10 percent.

² Average of four separate values, no single value of which differs from the average of those values by more than ±50 percent.

³ See footnote 2 to paragraph (d)(2)(i) of this section.

the results for that film sample are invalid and the test must be repeated for that sample until no splitting by the solvent occurs. If the finished food-contact article is itself the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation.

NOTE: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.

(e) *Analytical methods*—(1) *Selection of extractability conditions for ionomeric resins.* First ascertain the type of food (table 1 of §176.170(c) of this chapter) that is being packed or used in contact with the finished food-contact article described in paragraph (a) of this section, and also ascertain the normal conditions of thermal treatment used in packaging or contacting the type of food involved. Using table 2 of §176.170 (c) of this chapter, select the food-simulating solvent or solvents and the time-temperature test conditions that correspond to the intended use of the finished food-contact article. Having selected the appropriate food-simulating solvent or solvents and time-temperature exaggeration over normal use, follow the applicable extraction procedure.

(2) *Selection of extractability conditions for ionomeric resins.* Using table I of paragraph (f) of this section ascertain the type of food that is being packed or used in contact with the finished food-contact article described in paragraph (b) of this section, and also ascertain the food-simulating solvent or solvents that correspond to the intended use of the finished food-contact article.

(i) *Abbreviated test.* For intended use involving food contact at or below 120 °F (49 °C), the appropriate food-simulating solvent is to contact the food-contact film for the time and temperatures as follows:

Solvent	Time	Temperature
<i>n</i> -Heptane	12	120 °F (49 °C).
Water, 3% acetic acid, or 8%/50% ethanol.	148	120 °F (49 °C).

¹ Hours

(ii) *Equilibrium test.* For intended use involving food contact at or below 120 °F (49 °C), the appropriate food-simu-

lating solvent is to contact the food-contact film at a temperature of 120 °F until equilibrium is demonstrated.

Solvent	Minimum extraction times (hours)
<i>n</i> -Heptane	8, 10, 12
Water, 3% acetic acid, or 8%/50% ethanol	72, 96, 120

The results from a series of extraction times demonstrate equilibrium when the net chloroform-soluble extractives are unchanging within experimental error appropriate to the method as described in paragraphs (d)(1)(i) and (2)(i) of this section. Should equilibrium not be demonstrated over the above time series, extraction times must be extended until three successive unchanging values for extractives are obtained. In the case where intended uses involve temporary food contact above 120 °F, the food-simulating solvent is to be contacted with the food-contact article under conditions of time and temperature that duplicate the actual conditions in the intended use. Subsequently the extraction is to be continued for the time period and under the conditions specified in the above table.

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

(ii) *n-Heptane.* Reagent grade, freshly redistilled before use, using only material boiling at 208 °F (97.8 °C).

(iii) *Alcohol.* 8 or 50 percent (by volume), prepared from undenatured 95 percent ethyl alcohol diluted with demineralized (deionized), distilled water.

(iv) *Chloroform.* Reagent grade, freshly redistilled before use, or a grade having an established, consistently low blank.

(v) *Acetic acid.* 3 percent (by weight), prepared from glacial acetic acid diluted with demineralized (deionized), distilled water.

(4) *Selection of test method.* The finished food-contact articles shall be tested either by the extraction cell described in the *Journal of the Association of Official Agricultural Chemists*, Vol. 47, No. 1, p. 177–179 (February 1964), also

described in ASTM method F34–76 (Reapproved 1980), “Standard Test Method for Liquid Extraction of Flexible Barrier Materials,” which are incorporated by reference, or by adapting the in-container methods described in §175.300(e) of this chapter. Copies of the material incorporated by reference are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, and the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428–2959, respectively, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(5) *Selection of samples.* Quadruplicate samples should be tested, using for each replicate sample the number of finished articles with a food-contact surface nearest to 100 square inches.

(6) *Determination of amount of extractives—(i) Total residues.* At the end of the exposure period, remove the test container or test cell from the oven, if any, and combine the solvent for each replicate in a clean Pyrex (or equivalent) flask or beaker, being sure to rinse the test container or cell with a small quantity of clean solvent. Evaporate the food-simulating solvents to about 100 milliliters in the flask, and transfer to a clean, tared evaporating dish (platinum or Pyrex), washing the flask three times with small portions of 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 221 °F (105 °C). Cool the evaporating dish in a desiccator for 30 minutes and weigh the residues to the nearest 0.1 milligram, e . Calculate the extractives in milligrams per square inch of the container or material surface.

(a) *Water, 3 percent acetic acid, and 8 percent and 50 percent alcohol.* Milligrams extractives per square inch= e/s .

(b) *Heptane.* Milligrams extractives per square inch= $(e)/(s)(F)$

where:

e = Milligrams extractives per sample tested.
 s = Surface area tested, in square inches.

F = Five, the ratio of the amount of extractives removed by heptane under exaggerated time-temperature test conditions compared to the amount extracted by a fat or oil under exaggerated conditions of thermal sterilization and use.

e' = Acidified chloroform-soluble extractives residue. e' is substituted for e in the above equations when necessary (See paragraph (e)(6)(ii) of this section for method to obtain e').

If when calculated by the equations in paragraphs (e)(6)(i)(a) and (b) of this section, the extractives in milligrams per square inch exceed the limitations prescribed in paragraphs (c) or (d) of this section, proceed to paragraph (e)(6)(ii) of this section (method for determining the amount of acidified chloroform-soluble extractives residue).

(ii) *Acidified chloroform-soluble extractives residue.* Add 3 milliliters of 37 percent ACS reagent grade hydrochloric acid and 3 milliliters of distilled water to the evaporating dish containing the dried and weighed residue, e , obtained in paragraph (e)(6)(i) of this section. Mix well so every portion of the residue is wetted with the hydrochloric acid solution. Then add 50 milliliters of chloroform. Warm carefully, and filter through Whatman No. 41 filter paper (or equivalent) in a Pyrex (or equivalent) funnel, collecting the filtrate in a clean separatory funnel. Shake for 1 minute, then draw off the chloroform layer into a clean tared evaporating dish (platinum or Pyrex). Repeat the chloroform extraction, washing the dish, the filter paper, and the separatory funnel 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 221 °F. Cool the evaporating dish in a desiccator for 30 minutes and weigh to the nearest 0.1 milligram to get the acidified chloroform-soluble extractives residue, e' . This e' is substituted for e in the equations in paragraphs (e)(6)(i)(a) and (b) of this section.

(f) The types of food and appropriate solvents are as follows:

TABLE 1

Types of food	Appropriate solvent
1. 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.	Water, <i>n</i> -heptane.
2. 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.	<i>n</i> -heptane, water, 3% acetic acid.
3. 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.	Water, <i>n</i> -heptane, 3% acetic acid.
4. Dairy products and modifications: Water, <i>n</i> -heptane. i. Water-in-oil emulsions, high or low fat. ii. Oil-in-water emulsions, high or low fat.	
5. Low moisture fats and oils	<i>n</i> -heptane.
6. Beverages: i. Containing up to 8% alcohol ii. Nonalcoholic	8% ethanol/water. 3% acetic acid.
iii. Containing more than 8% alcohol.	50% ethanol/water.
7. Bakery products	Water, <i>n</i> -heptane.
8. Dry solids (without free fat or oil).	No extraction test required.
9. Dry solids (with free fat or oil) ..	<i>n</i> -heptane.

(g) The provisions of paragraphs (c) and (d) of this section are not applicable to the ionomeric resins that are used in food-packaging adhesives complying with § 175.105 of this chapter.

[45 FR 22916, Apr. 4, 1980, as amended at 49 FR 10108, Mar. 19, 1984; 49 FR 37747, Sept. 26, 1984; 53 FR 44009, Nov. 1, 1988; 54 FR 24898, June 12, 1989]

§ 177.1340 Ethylene-methyl acrylate copolymer resins.

Ethylene-methyl acrylate copolymer resins may be safely used as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, the ethylene-methyl acrylate copolymer resins consist of basic copolymers produced by the copolymerization of ethylene and methyl acrylate such that the copolymers contain no more than 25 weight percent of polymer units derived from methyl acrylate.

(b) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and

temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 176.170(c) of this chapter, yields net chloroform-soluble extractives (corrected for zinc extractives as zinc oleate) in each extracting solvent not to exceed 0.5 milligram per square inch of food-contact surface when tested by the methods described in § 176.170(d) of this chapter. If the finished food-contact article is itself the subject of a regulation in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation.

NOTE: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.

(c) The provisions of this section are not applicable to ethylene-methyl acrylate copolymer resins used in food-packaging adhesives complying with § 175.105 of this chapter.

§ 177.1345 Ethylene/1,3-phenylene oxyethylene isophthalate/terephthalate copolymer.

Ethylene/1,3-phenylene oxyethylene isophthalate/terephthalate copolymer (CAS Reg. No. 87365-98-8) identified in paragraph (a) of this section may be safely used, subject to the provisions of this section, as the non-food-contact layer of laminate structures subject to the provisions of § 177.1395, and in blends with polyethylene terephthalate polymers complying with § 177.1630.

(a) *Identity.* For the purpose of this section, ethylene/1,3-phenylene oxyethylene isophthalate/terephthalate copolymer consists of the basic copolymer produced by the catalytic polycondensation of isophthalic acid and terephthalic acid with ethylene glycol and 1,3-bis(2-hydroxyethoxy)benzene such that the finished resin contains between 42 and 48 mole-percent of isophthalic moieties, between 2 and 8 mole-percent of terephthalic moieties, and not more than 10 mole-percent of 1,3-bis(2-hydroxyethoxy)benzene moieties.

(b) *Specifications*—(1) *Density.* Ethylene/1,3-phenylene oxyethylene isophthalate/terephthalate copolymer identified in paragraph (a) of this section has a density of 1.33±0.02 grams per cubic centimeter measured by ASTM Method D 1505-85 (Reapproved 1990),

“Standard Test Method for Density of Plastics by the Density-Gradient Technique,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(2) *Softening point.* Ethylene/1,3-phenylene oxyethylene isophthalate/terephthalate copolymer identified in paragraph (a) of this section has a softening point of 63±5 °C as measured by ASTM Method D 1525-87, “Standard Test Method for VICAT Softening Temperature of Plastics,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this material is provided in paragraph (b)(1) of this section.

(c) *Optional adjuvant substances.* Ethylene/1,3-phenylene oxyethylene isophthalate/terephthalate copolymer, identified in paragraph (a) of this section, may contain optional adjuvant substances required in their production. The optional adjuvants may include substances used in accordance with §174.5 of this chapter.

(d) *Limitations.* Copolymer blends described above shall not exceed 30 percent by weight of ethylene/1,3-phenylene oxyethylene isophthalate/terephthalate copolymer. The finished blend may be used in contact with food only under conditions of use C through G, as described in table 2 of §176.170(c) of this chapter, except that with food identified as Type III, IV-A, V, VII-A, and IX in §176.170(c), table 1, the copolymer may be used under condition

of use C at temperatures not to exceed 160 °F (71 °C).

[57 FR 43399, Sept. 21, 1992, as amended at 59 FR 62318, Dec. 5, 1994; 61 FR 14481, Apr. 2, 1996; 62 FR 34628, June 27, 1997; 81 FR 5593, Feb. 3, 2016]

§ 177.1350 Ethylene-vinyl acetate copolymers.

Ethylene-vinyl acetate copolymers may be safely used as articles or components 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)(1) Ethylene-vinyl acetate copolymers consist of basic resins produced by the catalytic copolymerization of ethylene and vinyl acetate to which may have been added certain optional substances to impart desired technological or physical properties to the resin. Subject to any limitations prescribed in this section, the optional substances may include:

(i) Substances generally recognized as safe in food and food packaging.

(ii) Substances the use of which is permitted under applicable regulations in parts 170 through 189 of this chapter, prior sanction, or approvals.

(iii) Substances identified in §175.300(b)(3)(xxv), (xxvii), (xxx), and (xxxiii) of this chapter, and colorants used in accordance with §178.3297 of this chapter.

(iv) Erucamide as identified in §178.3860 of this chapter.

(v) Xanthan gum as identified in §172.695 for use as a thickening agent at a level not to exceed 1 percent by weight of coating solids in aqueous dispersions of ethylene-vinyl acetate copolymers, where such copolymers are used only as coatings or a component of coatings.

(vi) The copolymer of vinylidene fluoride and hexafluoropropene (CAS Reg. No. 9011-17-0), containing 65 to 71 percent fluorine and having a Mooney Viscosity of at least 28, for use as a processing aid at a level not to exceed 0.2 percent by weight of ethylene-vinyl acetate copolymers.

(2) Maleic anhydride-grafted ethylene-vinyl acetate copolymers (CAS

Reg. No. 28064-24-6) consist of basic resins produced by the catalytic copolymerization of ethylene and vinyl acetate, followed by reaction with maleic anhydride. Such polymers shall contain not more than 11 percent of polymer units derived from vinyl acetate by weight of total polymer prior to reaction with maleic anhydride, and not more than 2 percent of grafted maleic anhydride by weight of the finished polymer. Optional adjuvant substances that may be added to the copolymers include substances generally recognized as safe in food and food packaging, substances the use of which is permitted under applicable regulations in parts 170 through 189 of this chapter, and substances identified in §175.300(b)(3)(xxv), (xxvii), (xxxiii), and (xxx) of this chapter and colorants for polymers used in accordance with the provisions of §178.3297 of this chapter.

(b)(1) Ethylene-vinyl acetate copolymers, with or without the optional substances described in paragraph (a) of this section, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of their intended use as determined from tables 1 and 2 of §176.170(c) of this chapter, shall yield net chloroform-soluble extractives corrected for zinc as zinc oleate not to exceed 0.5 milligram per square inch of an appropriate sample.

(2) Maleic anhydride grafted ethylene-vinyl acetate copolymers shall have a melt flow index not to exceed 2.1 grams per 10 minutes as determined by ASTM method D 1238-82, "Standard Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer," which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or at the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the

National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Compliance of the melt flow index specification shall be determined using conditions and procedures corresponding to those described in the method as Condition E, Procedure A). The copolymers shall be used in blends with other polymers at levels not to exceed 17 percent by weight of total polymer, subject to the limitation that when contacting food of types III, IV-A, V, VI-C, VII-A, and IX, identified in §176.170(c) of this chapter, Table 1, the polymers shall be used only under conditions of use C, D, E, F, and G, described in §176.170(c) of this chapter, Table 2.

(c) The provisions of paragraph (b) of this section are not applicable to ethylene-vinyl acetate copolymers used in food-packaging adhesives complying with §175.105 of this chapter.

(d) Ethylene-vinyl acetate copolymers may be irradiated under the following conditions to produce molecular crosslinking of the polymers to impart desired properties such as increased strength and increased ability to shrink when exposed to heat:

(1) Electron beam source of ionizing radiation at a maximum energy of 3 million electron volts: Maximum absorbed dose not to exceed 150 kiloGray (15 megarads).

(2) The finished food-contact film shall meet the extractives limitations prescribed in paragraph (e)(2) of this section.

(3) The ethylene-vinyl acetate copolymer films may be further irradiated in accordance with the provisions of paragraph (e)(1) of this section: *Provided*, That the total accumulated radiation dose from both electron beam and gamma ray radiation does not exceed 150 kiloGray (15 megarads).

(e) Ethylene-vinyl acetate copolymer films intended for contact with food may be irradiated to control the growth of microorganisms under the following conditions:

(1) Gamma photons emitted from a cobalt-60 sealed source in the dose

§ 177.1360

21 CFR Ch. I (4–1–25 Edition)

range of 5–50 kiloGray (0.5–5.0 megarads).

(2) The irradiated ethylene-vinyl acetate copolymer films, when extracted with reagent grade *n*-heptane (freshly redistilled before use) according to methods described under § 176.170(d)(3) of this chapter, at 75 °F for 30 minutes shall yield total extractives not to exceed 4.5 percent by weight of the film.

[42 FR 14572, Mar. 15, 1977, as amended at 43 FR 29287, July 7, 1978; 54 FR 35874, Aug. 30, 1989; 55 FR 18595, May 3, 1990; 56 FR 42932, Aug. 30, 1991; 64 FR 47108, Aug. 30, 1999; 78 FR 14665, Mar. 7, 2013; 81 FR 5593, Feb. 3, 2016]

§ 177.1360 Ethylene-vinyl acetate-vinyl alcohol copolymers.

Ethylene-vinyl acetate-vinyl alcohol copolymers (CAS Reg. No. 26221–27–2) may be safely used as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) Ethylene-vinyl acetate-vinyl alcohol copolymers are produced by the partial or complete alcoholysis or hydrolysis of those ethylene-vinyl acetate copolymers complying with § 177.1350.

(1) Those copolymers containing a minimum of 55 percent ethylene and a maximum of 30 percent vinyl alcohol units by weight may be used in contact with foods as described in paragraph (b) of this section.

(2) Those copolymers containing a minimum of 55 percent ethylene and a maximum of 15 percent vinyl alcohol units by weight may be used in contact with foods as described in paragraph (c) of this section.

(3) Those copolymers containing 17 to 40 percent ethylene and 60 to 83 percent vinyl alcohol units by weight may be used in contact with foods as described in paragraph (d) of this section.

(b) The finished food-contact article shall not exceed 0.013 centimeter (0.005 inch) thickness and shall contact foods only of the types identified in table 1 of § 176.170(c) of this chapter in Categories I, II, IV-B, VI, VII-B, and VIII under conditions of use D through G described in table 2 of § 176.170(c) of this chapter. Film samples of 0.013 centimeter (0.005) inch thickness representing the finished article shall meet the following extractive limitation when tested by ASTM method

F34–76 (Reapproved 1980), “Standard Test Method for Liquid Extraction of Flexible Barrier Materials,” which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(1) The film when extracted with distilled water at 21 °C (70 °F) for 48 hours yields total extractives not to exceed 0.0047 milligram per square centimeter (0.03 milligram per square inch) of food-contact surface.

(2) The film when extracted with 50 percent ethyl alcohol at 21 °C (70 °F) for 48 hours yields total extractives not to exceed 0.0062 milligram per square centimeter (0.04 milligram per square inch) of food-contact surface.

(c) The finished food-contact article shall not exceed 0.0076 centimeter (0.003 inch) thickness and shall contact foods only of the types identified in table 1 of § 176.170(c) of this chapter in Categories III, IV-A, VII-A, and IX under conditions of use F and G described in table 2 of § 176.170(c) of this chapter. Film samples of 0.0076 centimeter (0.003 inch) thickness representing the finished articles shall meet the following extractive limitation when tested by ASTM method F34–76 (Reapproved 1980), “Standard Test Method for Liquid Extraction of Flexible Barrier Materials,” which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b) of this section. The film when extracted with *n*-heptane at 38 °C (100 °F) for 30 minutes yields total extractives not to exceed 0.0078 milligram per square centimeter (0.05 milligram per square inch) of food-contact surface, after correcting the total extractives by dividing by a factor of five.

(d) The finished food-contact article shall not exceed 0.018 centimeter (0.007 inch) thickness and may contact all foods, except those containing more than 8 percent alcohol, under conditions of use B through H described in

table 2 of §176.170(c) of this chapter. Film samples of 0.018 centimeter (0.007 inch) thickness representing the finished articles shall meet the following extractive limitation when tested by ASTM method F34-76 (Reapproved 1980), "Standard Test Methods for Liquid Extraction of Flexible Barrier Materials," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b) of this section. The film when extracted with distilled water at 100 °C (212 °F) for 30 minutes yields ethylene-vinyl acetate-vinyl alcohol oligomers not to exceed 0.093 milligram per square centimeter (0.6 milligram per square inch) of food contact surface as determined by a method entitled "Analytical Method of Determining the Amount of EVOH in the Extractives Residue of EVOH Film," dated March 23, 1987, as developed by the Kuraray Co., Ltd., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal-register/code_of_federal_regulations/ibr_locations.html.

(e) The provisions of this section are not applicable to ethylene-vinyl acetate-vinyl alcohol copolymers used in the food-packaging adhesives complying with §175.105 of this chapter.

[47 FR 41531, Sept. 21, 1982, as amended at 49 FR 10108, Mar. 19, 1984; 65 FR 17135, Mar. 31, 2000; 78 FR 14665, Mar. 7, 2013; 81 FR 5593, Feb. 3, 2016]

§ 177.1380 Fluorocarbon resins.

Fluorocarbon resins may be safely used as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, fluorocarbon resins consist of basic resins produced as follows:

(1) Chlorotrifluoroethylene resins produced by the homopolymerization of chlorotrifluoroethylene.

(2) Chlorotrifluoroethylene-1,1-difluoroethylene copolymer resins produced by copolymerization of chlorotrifluoroethylene and 1,1-difluoroethylene.

(3) Chlorotrifluoroethylene-1,1-difluoroethylene-tetrafluoroethylene co-polymer resins produced by copolymerization of chlorotrifluoroethylene, 1,1-difluoroethylene, and tetrafluoroethylene.

(4) Ethylene-chlorotrifluoroethylene copolymer resins produced by copolymerization of nominally 50 mole percent of ethylene and 50 mole percent of chlorotrifluoroethylene. The copolymer shall have a melting point of 239 to 243 °C and a melt index of less than or equal to 20 as determined by ASTM Method D 3275-89 "Standard Specification for E-CTFE-Fluoroplastic Molding, Extrusion, and Coating Materials," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19013, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal-register/code_of_federal_regulations/ibr_locations.html.

(b) Fluorocarbon resins that are identified in paragraph (a) of this section and that comply with extractive limitations prescribed in paragraph (c) of this section may be used as articles or components of articles intended for use in contact with food as follows:

(1) Fluorocarbon resins that are identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section and that comply only with the extractive limitations prescribed in paragraphs (c)(1) and (c)(2) of this section may be used when such use is limited to articles or components of articles that are intended for repeated use in contact with food or that are intended for one-time use in

contact with foods only of the types identified in §176.170(c) of this chapter, table 1, under Types I, II, VI, VII-B, and VIII.

(2) Fluorocarbon resins that are identified in paragraph (a)(4) of this section and that comply with the extractive limitations prescribed in paragraphs (c)(1) and (c)(2) of this section may be used only when such use is limited to articles or components of articles that are intended for repeated use in contact with food.

(3) In accordance with current good manufacturing practice, those food-contact articles intended for repeated use shall be thoroughly cleansed prior to their first use in contact with food.

(c) Extractives limitations are applicable to the basic resins in the form of pellets that have been ground or cut into small particles that will pass through a U.S. Standard Sieve No. 6 and that will be held on a U.S. Standard Sieve No. 10.

(1) A 100-gram sample of the resin pellets, when extracted with 100 milliliters of distilled water at reflux temperature for 8 hours, shall yield total extractives not to exceed 0.003 percent by weight of the resins.

(2) A 100-gram sample of the resin pellets, when extracted with 100 milliliters of 50 percent (by volume) ethyl alcohol in distilled water at reflux temperature for 8 hours, shall yield total extractives not to exceed 0.003 percent by weight of the resins.

(3) A 100-gram sample of the resin pellets, when extracted with 100 milliliters of *n*-heptane at reflux temperature for 8 hours, shall yield total extractives not to exceed 0.01 percent by weight of the resins.

[42 FR 14572, Mar. 15, 1977, as amended at 57 FR 185, Jan. 3, 1992]

§ 177.1390 Laminate structures for use at temperatures of 250 °F and above.

(a) The high-temperature laminates identified in this section may be safely used for food contact at temperatures not exceeding 135 °C (275 °F) unless otherwise specified. These articles are layered constructions that are optionally bonded with adhesives. The interior (food-contact) layer(s) may be separated from the exterior layer(s) by a

functional barrier, such as aluminum foil. Upon review of the physical properties of a particular construction, the Food and Drug Administration may consider other layers to serve as functional barriers. This regulation is not intended to limit these constructions as to shape, degree of flexibility, thickness, or number of layers. These layers may be laminated, extruded, co-extruded, or fused.

(b) When containers subject to this regulation undergo heat sterilization to produce shelf-stable foods, certain control measures (in addition to the food additive requirements in paragraphs (c) and (d) of this section) are necessary to ensure proper food sterilization and package integrity. Refer to parts 108, 110, 113, and 114 of this chapter for details.

(c) Subject to the provisions of this paragraph, food-contact articles produced from high-temperature laminates may be safely used to package all food types except those containing more than 8 percent ethyl alcohol.

(1) *Polymeric films/layers.* Films or layers not separated from food by a functional barrier must meet the following requirements:

(i) Films/layers may consist of the following:

(a) Polyolefin resins complying with item 2.2 or 3.2 of the table in §177.1520(c).

(b) Polymeric resin blends formulated from a base polymer complying with item 2.2 or 3.2 of the table in §177.1520(c) blended with no more than 10 percent by weight of a copolymer of ethylene and vinyl acetate complying with §177.1350.

(c) Polymeric resin blends formulated from a base polymer complying with item 2.2 or 3.2 of the table in §177.1520(c) blended with no more than 38 percent by weight of a homopolymer of isobutylene complying with §177.1420(a)(1).

(d) Polyethylene phthalate resins complying with §177.1630(e)(4)(i) and (ii).

(e) Nylon MXD-6 resins that comply with item 10.3 of the table in §177.1500(b) of this chapter when extracted with water and heptane under the conditions of time and temperature specified for condition of use A, as set

forth in Table 2 of §176.170(c) of this chapter.

(f) Nylon $\frac{6}{12}$ resins (CAS Reg. No. 25191-04-2) complying with item 13.3 of the table in §177.1500(b), for use as nonfood-contact layers of laminated films and in rigid multilaminate constructions with polypropylene outer layers. Laminate structures with authorized food-contact materials yield no more than 0.15 milligrams of *epsilon*-caprolactam and 0.04 milligrams of *omega*-laurolactam per square inch when extracted with 95 percent ethanol at 121 °C (250 °F) for 2 hours.

(g) Polymeric resins that comply with an applicable regulation in this chapter which permits food type and time/temperature conditions to which the container will be exposed, including sterilization processing.

(ii) Adjuvants used in these layers must comply with an applicable regulation that permits food type and time/temperature conditions to which the container will be exposed, including sterilization processing.

(2) *Adhesives*. The use of adhesives in these containers is optional. Adhesives may be formulated from the following substances, subject to the prescribed limitations:

(i) Any substance suitable for use in formulating adhesives that complies with an applicable regulation of this chapter which permits food type and time/temperature conditions to which the container will be exposed, including sterilization processing.

(ii) Substances complying with §175.105 of this chapter may be used in these constructions, provided they are separated from the interior (food-contact) layer(s) by a functional barrier as discussed under paragraph (a) of this section.

(iii) Maleic anhydride adduct of polypropylene complying with §175.300 of this chapter.

(iv) Polyester-urethane adhesive for use at temperatures not exceeding 121 °C (250 °F) and formulated from the following:

(a) Polyester-urethanediol resin prepared by the reaction of a mixture of polybasic acids and polyhydric alcohols listed in §175.300(b)(3)(vii) of this chapter, 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS

Reg. No. 4098-71-9) and optional trimethoxysilane coupling agents containing amino, epoxy, ether, and/or mercapto groups not to exceed 3 percent by weight of the cured adhesive.

(b) Urethane cross-linking agent comprising not more than 25 percent by weight of the cured adhesive and formulated from 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg. No. 4098-71-9) adduct of trimethylol propane (CAS Reg. No. 77-99-6) and/or 1,3-bis(isocyanatomethyl) benzene (CAS Reg. No. 25854-16-4) adduct of trimethylol propane.

(v) Polyester-epoxy-urethane adhesives formulated from the following:

(a) Polyester resin formed by the reaction of polybasic acids and polyhydric alcohols listed in §175.300(b)(3)(vii) of this chapter. Azelaic acid may also be used as a polybasic acid.

(b) Epoxy resin listed in §175.300(b)(3)(viii)(a) of this chapter and comprising no more than 30 percent by weight of the cured adhesive.

(c) Urethane cross-linking agent comprising no more than 14 percent weight of the cured adhesive and formulated from 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate cyanurate (CAS Reg. No. 53880-05-0).

(vi) Polyurethane-polyester resin-epoxy adhesives formulated from the following mixture:

(a)(1) Polyester-polyurethanediol resins prepared by the reaction of a mixture of polybasic acids and polyhydric alcohols listed in §175.300(b)(3)(vii) of this chapter and 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg. No. 4098-71-9).

(2) Polyester resin formed by the reaction of polybasic acids and polyhydric alcohols listed in §175.300(b)(3)(vii) of this chapter. Additionally, azelaic acid and 1,6-hexanediol may also be used as reactants in lieu of a polyhydric alcohol.

(3) Epoxy resin listed in §175.300(b)(3)(viii)(a) of this chapter and comprising not more than 5 percent by weight of the cured adhesive.

(4) Optional trimethoxy silane curing agents, containing amino, epoxy, ether, or mercapto groups not in excess of 3 percent of the cured adhesive.

(b) Urethane cross-linking agent, comprising not more than 20 percent by weight of the cured adhesive, and formulated from trimethylol propane (CAS Reg. No. 77–99–6) adducts of 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg. No. 4098–71–9) or 1,3-bis(isocyanatomethyl)benzene (CAS Reg. No. 25854–16–4).

(vii) Polyester-polyurethane resin-acid dianhydride adhesives for use at temperatures not to exceed 121 °C (250 °F), in contact only with food Types I, II, VIA, VIB, VIIB, and VIII as described in Table I of §176.170 of this chapter, and formulated from the following mixture:

(a)(1) Polyester-polyurethanediol resins prepared by the reaction of a mixture of polybasic acids and polyhydric alcohols listed in §175.300(b)(3)(vii) of this chapter and 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg. No. 4098–71–9). Additionally, dimethylol propionic acid and 1,6-hexanediol may be used alone or in combination as reactants in lieu of a polybasic acid and a polyhydric alcohol.

(2) Acid dianhydride formulated from 3a,4,5,7a-tetrahydro-7-methyl-5-(tetrahydro-2,5-dioxo-3-furanyl)-1,3-isobenzofurandione (CAS Reg. No. 73003–90–4), comprising not more than one percent of the cured adhesive.

(b) Urethane cross-linking agent, comprising not more than twelve percent by weight of the cured adhesive, and formulated from trimethylol propane (CAS Reg. No. 77–99–6) adducts of 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg. No. 4098–71–9) and/or 1,3-bis(isocyanatomethyl)benzene (CAS Reg. No. 363–48–31).

(3) *Test specifications.* These specifications apply only to materials on the food-contact side of a functional barrier, if present. All tests must be performed on containers made under production conditions. Laminated structures submitted to extraction procedures must maintain complete structural integrity (particularly with regard to delamination) throughout the test.

(i) *Nonvolatile extractives.* (a) For use at temperatures not to exceed 121 °C

(250 °F): The container interior (food-contact side) shall be extracted with deionized distilled water at 121 °C (250 °F) for 2 hours.

(1) The chloroform-soluble fraction of the total nonvolatile extractives for containers using adhesives listed in paragraphs (c)(2)(i), (c)(2)(ii), (c)(2)(iii), (c)(2)(iv), and (c)(2)(vii) of this section shall not exceed 0.0016 milligram per square centimeter (0.01 milligram per square inch) as determined by a method entitled “Determination of Non-Volatile Chloroform Soluble Residues in Retort Pouch Water Extracts,” which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, and may be examined at the Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(2) The chloroform-soluble fraction of the total nonvolatile extractives for containers using adhesives listed in paragraph (c)(2)(v) of this section shall not exceed 0.016 milligram per square centimeter (0.10 milligram per square inch) as determined by a method titled “Determination of Non-volatile Chloroform Soluble Residues in Retort Pouch Water Extracts,” which is incorporated by reference in paragraph (c)(3)(i)(a)(1) of this section.

(b) For use at temperatures not to exceed 135 °C (275 °F): The container interior (food-contact side) shall be extracted with deionized distilled water at 135 °C (275 °F) for 1 hour.

(1) The chloroform-soluble fraction of the total nonvolatile extractives for containers using no adhesive, or adhesives listed in paragraphs (c)(2)(i), (ii), and (iii) of this section shall not exceed 0.0020 milligram per square centimeter (0.013 milligram per square inch) as determined by a method titled “Determination of Non-volatile Chloroform Soluble Residues in Retort Pouch

Water Extracts,” which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(3)(i)(a)(I) of this section.

(2) The chloroform-soluble fraction of the total nonvolatile extractives for containers using adhesives listed in paragraph (c)(2)(v) of this section shall not exceed 0.016 milligram per square centimeter (0.10 milligram per square inch) as determined by a method titled “Determination of Non-volatile Chloroform Soluble Residues in Retort Pouch Water Extracts,” which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(3)(i)(a)(I) of this section.

(3) The chloroform-soluble fraction of the total nonvolatile extractives for containers using adhesives listed in paragraph (c)(2)(vi) of this section shall not exceed 0.008 milligram per square centimeter (0.05 milligram per square inch) as determined by a method entitled, “Determination of Non-volatile Chloroform Soluble Residues in Retort Pouch Water Extracts,” which is incorporated by reference in paragraph (c)(3)(i)(a)(I) of this section.

(ii) *Volatiles*. Volatile substances employed in the manufacture of high-temperature laminates must be removed to the greatest extent possible in keeping with good manufacturing practice prescribed in §174.5(a) of this chapter.

(d) Nylon 12/aluminum foil high-temperature laminates: Subject to the provisions of this paragraph, containers constructed of nylon 12 laminated to aluminum foil may be safely used at temperatures no greater than 250 °F (121 °C) in contact with all food types except those containing more than 8 percent alcohol.

(1) The container is constructed of aluminum foil to which nylon 12 film is fused. Prior to fusing the nylon 12, the aluminum foil may be optionally precoated with a coating complying with §175.300 of this chapter.

(2) Nylon 12 resin complying with §177.1500 and having an average thickness not to exceed 0.0016 inch (41 microns) may be used as the food-contact surface of the container.

(3) Container test specifications. On exposure to distilled water at 250 °F (121 °C) for 2 hours, extractives from the food-contact side of the nylon 12 multilayered construction shall not exceed 0.05 milligram per square inch (0.0078 milligram per square centimeter) as total nonvolatile extractives.

[45 FR 2843, Jan. 15, 1980, as amended at 47 FR 49639, Nov. 2, 1982; 48 FR 236, Jan. 4, 1983; 48 FR 15242, Apr. 8, 1983; 48 FR 17347, Apr. 22, 1983; 49 FR 7558, Mar. 1, 1984; 52 FR 33575, Sept. 4, 1987; 53 FR 39084, Oct. 5, 1988; 54 FR 24898, June 12, 1989; 61 FR 14481, Apr. 2, 1996; 63 FR 55943, Oct. 20, 1998; 64 FR 4785, Feb. 1, 1999; 64 FR 46272, Aug. 25, 1999; 69 FR 15668, Mar. 26, 2004; 81 FR 5593, Feb. 3, 2016]

§ 177.1395 Laminate structures for use at temperatures between 120 °F and 250 °F.

(a) The laminates identified in this section may be safely used at the specified temperatures. These articles are layered structures that are optionally bonded with adhesives. In these articles, the food-contact layer does not function as a barrier to migration of components from non-food-contact layers. The layers may be laminated, extruded, coextruded, or fused.

(b) Laminate structures may be manufactured from:

(1) Polymers and adjuvants complying with §177.1390 of this chapter.

(2) Any polymeric resin listed in these regulations so long as the use of the resin in the structure complies with the conditions of use (food type and time/temperature) specified in the regulation for that resin.

(3) Optional adjuvant substances used in accordance with §174.5 of this chapter.

(4) The following substances in non-food-contact layers only:

§ 177.1400

Substances	Limitations
Ethylene/1,3-phenylene oxy-ethylene isophthalate/terephthalate copolymer (CAS Reg. No. 87365-98-8) complying with § 177.1345.	For use only with polyethylene terephthalate as the food-contact layer, complying with § 177.1630 under conditions of use C through G described in table 2 of § 176.170(c) of this chapter. Laminate structures, when extracted with 8 percent ethanol at 150 °F for 2 hours shall not yield <i>m</i> -phenylene dioxy-O,O'-diethyl isophthalate or cyclic bis(ethylene isophthalate) in excess of 7.8 micrograms/square decimeter (0.5 microgram/square inch) of food-contact surface.
Nylon 6/12 resins complying with § 177.1500(b), item 13.2, of this chapter (CAS Reg. No. 25191-04-2).	For use with nonalcoholic foods at temperatures not to exceed 100 °C (212 °F). Laminate structures with authorized food-contact materials yield no more than 0.15 milligram of <i>epsilon</i> -caprolactam and 0.04 milligram of <i>omega</i> -lauro lactam per square inch when extracted with water at 100 °C (212 °F) for 5 hours.
Nylon 6/66 resins complying with § 177.1500(b), item 4.2 of this chapter (CAS Reg. 24993-04-2).	For use only with: 1. Nonalcoholic foods at temperatures not to exceed 82.2 °C (180 °F). Laminate structures with authorized food-contact materials yield no more than 0.15 milligram of <i>epsilon</i> -caprolactam per square inch when extracted with water at 82.2 °C (180 °F) for 5 hours. 2. Nonalcoholic foods at temperatures not to exceed 100 °C (212 °F). Laminate films with authorized food-contact materials yield no more than 0.15 milligram of <i>epsilon</i> -caprolactam per square inch when extracted with water at 100 °C (212 °F) for 5 hours.

21 CFR Ch. I (4-1-25 Edition)

Substances	Limitations
Nylon 6/69 resins complying with § 177.1500(b), item 14, of this chapter (CAS Reg. No. 51995-62-1).	For use with nonalcoholic foods under conditions of use B, C, D, E, F, G, and H described in table 2 of § 176.170 of this chapter. Laminate structures with authorized food-contact materials may contain nylon 6/69 resins provided that the nitrogen content of aqueous extracts of a representative laminate (obtained at 100 °C (212 °F) for 8 hours) does not exceed 15 micrograms per square centimeter (100 micrograms per square inch).

[52 FR 33575, Sept. 4, 1987, as amended at 53 FR 19772, May 31, 1988; 57 FR 43399, Sept. 21, 1992; 58 FR 32610, June 11, 1993; 62 FR 53957, Oct. 17, 1997]

§ 177.1400 Hydroxyethyl cellulose film, water-insoluble.

Water-insoluble hydroxyethyl cellulose film may be safely used for packaging food in accordance with the following prescribed conditions:

(a) Water-insoluble hydroxyethyl cellulose film consists of a base sheet manufactured by the ethoxylation of cellulose under controlled conditions, to which may be added certain optional substances of a grade of purity suitable for use in food packaging as constituents of the base sheet or as coatings applied to impart desired technological properties.

(b) Subject to any limitations prescribed in parts 170 through 189 of this chapter, the optional substances used in the base sheet and coating may include:

(1) Substances generally recognized as safe in food.

(2) Substances permitted to be used in water-insoluble hydroxyethyl cellulose film by prior sanction or approval and under conditions specified in such sanctions or approval, and substances listed in part 181, subpart B of this chapter.

(3) Substances that by any regulation promulgated under section 409 of the act may be safely used as components of water-insoluble hydroxyethyl cellulose film.

(4) Substances identified in and used in compliance with § 177.1200(c).

(c) Any substance employed in the production of the water-insoluble hydroxyethyl cellulose film described in this section that is the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter conforms with any specification in such regulation.

§ 177.1420 Isobutylene polymers.

Isobutylene polymers may be safely used as components 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) For the purpose of this section, isobutylene polymers are those produced as follows:

(1) Polyisobutylene produced by the homopolymerization of isobutylene such that the finished polymers have a molecular weight of 750,000 (Flory) or higher.

(2) Isobutylene-isoprene copolymers produced by the copolymerization of isobutylene with not more than 3 molar percent of isoprene such that the finished polymers have a molecular weight of 300,000 (Flory) or higher.

(3) Chlorinated isobutylene-isoprene copolymers produced when isobutylene-isoprene copolymers (molecular weight 300,000 (Flory) or higher) are modified by chlorination with not more than 1.3 weight-percent of chlorine.

(b) The polymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of the polymers. The optional adjuvant substances required in the production of the polymers may include substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, and aluminum chloride.

(c) The provisions of this section are not applicable to polyisobutylene used in food-packaging adhesives complying with §175.105 of this chapter.

§ 177.1430 Isobutylene-butene copolymers.

Isobutylene-butene copolymers identified in paragraph (a) of this section may be safely used as components of articles intended for use in contact with food, subject to the provisions of this section.

(a) For the purpose of this section, isobutylene-butene copolymers consist of basic copolymers produced by the copolymerization of isobutylene with mixtures of *n*-butenes such that the finished basic copolymers contain not less than 45 weight percent of polymer units derived from isobutylene and meet the specifications prescribed in paragraph (b) of this section when tested by the methods described in paragraph (c) of this section.

(b) *Specifications:*

Isobutylene-butene copolymers	Molecular weight (range)	Viscosity (range)	Maximum bromine value
1. Used as release agents in petroleum wax complying with § 178.3710 of this chapter.	300 to 5,000 ...	40 to 20,000 seconds Saybolt at 200 °F.	40
2. Used as plasticizers in polyethylene or polypropylene complying with § 177.1520, and in polystyrene complying with § 177.1640.	300 to 5,000 ...	40 to 20,000 seconds Saybolt at 200 °F.	40
3. Used as components of nonfood articles complying with §§ 175.300, 176.170, 176.210, 177.2260(d)(2), 177.2800, and 178.3570 (provided that addition to food does not exceed 10 parts per million), or § 176.180 of this chapter.	300 to 5,000 ...	40 to 20,000 seconds Saybolt at 200 °F.	40
4. Used as production aids in the manufacture of expanded (foamed) polystyrene articles complying with § 177.1640 of this chapter.	150 to 5,000 ...	Less than 20,000 seconds Saybolt at 200 °F.	90.
5. Used in release coatings on backings or linings for pressure-sensitive adhesive labels complying with § 175.125 of this chapter.	150 to 5,000 ...	Less than 20,000 seconds Saybolt at 200 °F.	90

(c) The analytical methods for determining whether isobutylene-butene copolymers conform to the specifications in paragraph (b) are as follows:

(1) *Molecular weight.* Molecular weight shall be determined by American Society for Testing and Materials (ASTM) method D2503-82, "Standard Test Method for Molecular Weight

§ 177.1440

(Relative Molecular Mass) of Hydrocarbons by Thermoelectric Measurement of Vapor Pressure,” which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(2) *Viscosity*. Viscosity shall be determined by ASTM method D445-74, “Test for Kinematic Viscosity of Transparent and Opaque Liquids,” which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

(3) *Maximum bromine value*. Maximum bromine value shall be determined by ASTM method D1492-78, “Standard Test Method for Bromine Index of Aromatic Hydrocarbons by Coulometric Titration,” which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

(d) The provisions of this section are not applicable to isobutylene-butene copolymers used as provided under § 175.105 of this chapter.

[52 FR 11641, Apr. 10, 1987, as amended at 63 FR 36175, July 2, 1998]

§ 177.1440 4,4'-Isopropylidenediphenol-epichlorohydrin resins minimum molecular weight 10,000.

4,4'-Isopropylidenediphenol-epichlorohydrin resins having a minimum molecular weight of 10,000 may be safely used as articles or components 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) 4,4'-Isopropylidenediphenol-epichlorohydrin resins consist of basic resins produced by the condensation of equimolar amounts of 4,4'-isopropylidenediphenol and epichlorohydrin terminated with phenol, to which may have been added cer-

21 CFR Ch. I (4-1-25 Edition)

tain optional adjuvant substances required in the production of the resins.

(b) The optional adjuvant substances required in the production of the resins may include substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, and the following:

List of substances	Limitations
Butyl alcohol	Not to exceed 300 p.p.m. as residual solvent in finished resin.
Ethyl alcohol.	
Toluene	Not to exceed 1,000 p.p.m. as residual solvent in finished resin.

(c) 4,4'-Isopropylidenediphenol-epichlorohydrin resins shall meet the following nonvolatile extractives limitations:

(1) Maximum extractable nonvolatile fraction of 2 parts per million when extracted with distilled water at 70 °C for 2 hours, using a volume-to-surface ratio of 2 milliliters per square inch.

(2) Maximum extractable nonvolatile fraction of 3 parts per million when extracted with *n*-heptane at 70 °C for 2 hours, using a volume-to-surface ratio of 2 milliliters per square inch.

(3) Maximum extractable nonvolatile fraction of 6 parts per million when extracted with 10 percent (by volume) ethyl alcohol in distilled water at 70 °C for 2 hours, using a volume-to-surface ratio of 2 milliliters per square inch.

(d) The provisions of this section are not applicable to 4,4'-isopropylidenediphenol-epichlorohydrin resins listed in other sections of subchapter B of this chapter.

§ 177.1460 Melamine-formaldehyde resins in molded articles.

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

(a) For the purpose of this section, melamine-formaldehyde resins are those produced when 1 mole of melamine is made to react with not more than 3 moles of formaldehyde in water solution.

(b) The resins may be mixed with refined woodpulp and the mixture may

Food and Drug Administration, HHS

§ 177.1480

contain other optional adjuvant substances which may include the following:

List of substances	Limitations
Colorants used in accordance with § 178.3297 of this chapter.	
Hexamethylenetetramine	For use only as polymerization reaction control agent.
Phthalic acid anhydride ..	Do.
Zinc stearate	For use as lubricant.

(c) The molded melamine-formaldehyde articles in the finished form in which they are to contact food, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature as determined from tables 1 and 2 of §175.300(d) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface.

[42 FR 14572, Mar. 15, 1977, as amended at 56 FR 42933, Aug. 30, 1991; 87 FR 31089, May 20, 2022]

§ 177.1480 Nitrile rubber modified acrylonitrile-methyl acrylate copolymers.

Nitrile rubber modified acrylonitrile-methyl acrylate copolymers identified in this section may be safely used as components of articles intended for food-contact use under conditions of use D, E, F, or G described in table 2 of §176.170(c) of this chapter, subject to the provisions of this section.

(a) For the purpose of this section, nitrile rubber modified acrylonitrile-methyl acrylate copolymers consist of basic copolymers produced by the graft copolymerization of 73-77 parts by weight of acrylonitrile and 23-27 parts by weight of methyl acrylate in the presence of 8-10 parts by weight of butadiene-acrylonitrile copolymers containing approximately 70 percent by weight of polymer units derived from butadiene.

(b) The nitrile rubber modified acrylonitrile-methyl acrylate basic copolymers meet the following specifications and extractives limitations:

(1) *Specifications.* (i) Nitrogen content is in the range 16.5-19 percent as determined by Kjeldahl analysis.

(ii) Intrinsic viscosity in acetonitrile at 25 °C is not less than 0.29 deciliter

per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(iii) Residual acrylonitrile monomer content is not more than 11 parts per million as determined by gas chromatography.

(iv) Acetonitrile-soluble fraction after refluxing the base polymer in acetonitrile for 1 hour is not greater than 95 percent by weight of the basic copolymers.

(2) *Extractives limitations.* The following extractive limitations are determined by an infrared spectrophotometric method titled, "Infrared Spectrophotometric Determination of Polymer Extracted from Borex® 210 Resin Pellets," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies are applicable to the basic copolymers in the form of particles of a size that will pass through a U.S. standard sieve No. 6 and that will be held on a U.S. standard sieve No. 10:

(i) Extracted copolymer not to exceed 2.0 parts per million in aqueous extract obtained when a 100-gram sample of the basic copolymers is extracted with 250 milliliters of demineralized (deionized) water at reflux temperature for 2 hours.

(ii) Extracted copolymer not to exceed 0.5 part per million in *n*-heptane

§ 177.1500

extract obtained when a 100-gram sample of the basic copolymers is extracted with 250 milliliters of reagent grade *n*-heptane at reflux temperature for 2 hours.

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

(d) Acrylonitrile copolymers identified in this section are not authorized to be used to fabricate beverage containers.

[42 FR 14572, Mar. 15, 1977, as amended at 42 FR 48544, Sept. 23, 1977; 47 FR 11843, Mar. 19, 1982; 47 FR 16775, Apr. 20, 1982; 49 FR 10109, Mar. 19, 1984; 54 FR 24898, June 12, 1989; 61 FR 14481, Apr. 2, 1996]

§ 177.1500 Nylon resins.

The nylon resins listed in paragraph (a) of this section may be safely used to produce articles intended for use in processing, handling, and packaging food, subject to the provisions of this section:

(a) The nylon resins are manufactured as described in this paragraph so as to meet the specifications prescribed in paragraph (b) of this section when tested by the methods described in paragraph (d) of this section.

(1) Nylon 66 resins are manufactured by the condensation of hexamethylenediamine and adipic acid.

(2) Nylon 610 resins are manufactured by the condensation of hexamethylenediamine and sebacic acid.

(3) Nylon 66/610 resins are manufactured by the condensation of equal-weight mixtures of nylon 66 salts and nylon 610 salts.

(4) Nylon 6/66 resins manufactured by the condensation and polymerization of Nylon 66 salts and *epsilon*-caprolactam.

(5) Nylon 11 resins are manufactured by the condensation of 11-aminoundecanoic acid.

(6) Nylon 6 resins are manufactured by the polymerization of *epsilon*-caprolactam.

(7) Nylon 66T resins are manufactured by the condensation of hexamethylenediamine, adipic acid, and terephthalic acid such that composition in terms of ingredients is 43.1 ± 0.2 weight percent hexamethylenediamine, 35.3 ± 1.2 weight percent

21 CFR Ch. I (4–1–25 Edition)

adipic acid, and 21.6 ± 1.2 weight percent terephthalic acid.

(8) Nylon 612 resins are manufactured by the condensation of hexamethylenediamine and dodecanedioic acid.

(9) Nylon 12 resins are manufactured by the condensation of *omega*-laurolactam.

(10)(i) Impact modified Nylon MXD-6 resins (CAS Reg. No. 59655-05-9) manufactured by the condensation of adipic acid, 1,3-benzenedimethanamine, and *alpha*-(3-aminopropyl)-*omega*-(3-aminopropoxy)polyoxyethylene under such conditions that the *alpha*-(3-aminopropyl)-*omega*-(3-aminopropoxy) polyoxyethylene monomer content does not exceed 7 percent by weight of the finished resin.

(ii) Nylon MXD-6 resins (CAS Reg. No. 25718-70-1) manufactured by the condensation of adipic acid and 1,3-benzenedimethanamine.

(11) Nylon 12T resins are manufactured by the condensation of *omega*-laurolactam (CAS Reg. No. 0947-04-6), isophthalic acid (CAS Reg. No. 0121-91-5), and bis(4-amino-3-methylcyclohexyl)methane (CAS Reg. No. 6864-37-5) such that the composition in terms of ingredients is 34.4 ± 1.5 weight percent *omega*-laurolactam, 26.8 ± 0.4 weight percent isophthalic acid, and 38.8 ± 0.5 weight percent bis(4-amino-3-methylcyclohexyl)-methane.

(12) Nylon 6I/6T resins (CAS Reg. No. 25750-23-6) are manufactured by the condensation of hexamethylenediamine, terephthalic acid, and isophthalic acid such that 65 to 80 percent of the polymer units are derived from hexamethylene isophthalamide.

(13)(i) Nylon 6/12 resins (CAS Reg. No. 25191-04-2) are manufactured by the copolymerization of a 1 to 1 ratio by weight of *epsilon*-caprolactam and *omega*-laurolactam.

(ii) Nylon 6/12 resins (CAS Reg. No. 25191-04-2) are manufactured by the copolymerization of a ratio of at least 80 weight percent of *epsilon*-caprolactam and no more than 20 weight percent of *omega*-laurolactam.

(14) Nylon 6/69 resins (CAS Reg. No. 51995-62-1) are manufactured by the condensation of 49.5 ± 0.5 weight percent *epsilon*-caprolactam, 19.4 ± 0.2

Food and Drug Administration, HHS

§ 177.1500

weight percent hexamethylenediamine and 31.2 + 0.3 weight percent azelaic acid.

(15) Nylon 46 resins (CAS Reg. No. 50327-77-0) are manufactured by the condensation of 1,4-butanediamine and adipic acid.

(16) Nylon resins PA 6-3-T (CAS Registry No. 26246-77-5) are manufactured

by the condensation of 50 mol percent 1,4-benzenedicarboxylic acid, dimethyl ester and 50 mol percent of an equimolar mixture of 2,2,4-trimethyl-1,6-hexanediamine and 2,4,4-trimethyl-1,6-hexanediamine.

(b) *Specifications:*

Nylon resins	Specific gravity	Melting point (degrees Fahrenheit)	Solubility in boiling 4.2N HCl	Viscosity No. (mL/g)	Maximum extractable fraction in selected solvents (expressed in percent by weight of resin)			
					Water	95 percent ethyl alcohol	Ethyl acetate	Benzene
1. Nylon 66 resins	1.14±.015	475-495	Dissolves in 1 h.	1.5	1.5	0.2	0.2
2. Nylon 610 resins	1.09±.015	405-425	Insoluble after 1 h.	1.0	2.0	1.0	1.0
3.1 Nylon 66/610 resins	1.10±.015	375-395	Dissolves in 1 h.	1.5	2.0	1.0	1.0
4.1 Nylon 6/66 resins, <i>epsilon</i> -caprolactam monomer content not to exceed 0.7 percent by weight.	1.13±.015	440-460do	2.0	2.0	1.5	1.5
4.2 Nylon 6/66 resins with combined caprolactam content greater than 60 percent and residual <i>epsilon</i> -caprolactam monomer content not to exceed 0.4 percent by weight. For use only as specified in § 177.1395 of this chapter (CAS Reg. No. 24993-04-2).	1.14±.015	380-425do	0.8	1.0	0.5	0.5
5.1 Nylon 11 resins for use in articles intended for 1-time use or repeated use in contact with food.	1.04±.015	355-375	Insoluble after 1 h.30	.35	.25	.3
5.2 Nylon 11 resins for use only:	1.04±.015	355-375do35	1.60	.35	.40
a. In articles intended for repeated use in contact with food.								
b. In side-seam cements for articles intended for 1-time use in contact with food and which are in compliance with § 175.300 of this chapter.								
6.1 Nylon 6 resins	1.15±.015	392-446	Dissolves in 1 h.	1.0	2.0	1.0	1.0
6.2 Nylon 6 resins for use only in food-contact films having an average thickness not to exceed 0.001 in.	1.15±.015	392-446do	1.5	2.0	1.0	1.0
7. Nylon 66T resins for use only in food-contact films having an average thickness not to exceed 0.001 in.	1.16±.015	482-518	Insoluble after 1 h.	1.0	1.0	.25	.25

Nylon resins	Specific gravity	Melting point (degrees Fahrenheit)	Solubility in boiling 4.2N HCl	Viscosity No. (mL/g)	Maximum extractable fraction in selected solvents (expressed in percent by weight of resin)			
					Water	95 percent ethyl alcohol	Ethyl acetate	Benzene
8. Nylon 612 resins for use only in articles intended for repeated use in contact with food at temperatures not to exceed 212 °F.	1.06±.015	406–420do50	1.50	.50	.50
9. Nylon 12 resins for use only:	1.01±.015	335–355do	1.0	2.0	1.50	1.50
a. In food-contact films having an average thickness not to exceed 0.0016 inch intended for use in contact with nonalcoholic food under the conditions of use A (sterilization not to exceed 30 minutes at a temperature not to exceed 250 °F), and B through H of table 2 of § 176.170(c) of this chapter, except as provided in § 177.1390(d)								
b. In coatings intended for repeated use in contact with all food types described in table 1 of § 176.170(c) of this chapter, except those containing more than 8 percent alcohol, under conditions of use B through H described in table 2 of § 176.170(c) of this chapter.								
10.1 Nylon MXD–6 and impact modified Nylon MXD–6 film having an average thickness not to exceed 40 microns (0.0016 inch) for use in processing, handling, and packaging of food of types V and IX listed in table 1 of § 176.170(c) of this chapter under conditions of use C, D, E, F, G, and H in table 2 of § 176.170(C) of this chapter.	1.21±0.02	437–491	Dissolves in 1h.	2.0	2.5	1.0	1.0

Nylon resins	Specific gravity	Melting point (degrees Fahrenheit)	Solubility in boiling 4.2N HCl	Viscosity No. (mL/g)	Maximum extractable fraction in selected solvents (expressed in percent by weight of resin)			
					Water	95 percent ethyl alcohol	Ethyl acetate	Benzene
10.2 Impact modified Nylon MXD-6 resins for use as polymer use as polymer modifiers in Nylon 6 resin films complying with paragraph (a)(6) of this section, at levels not to exceed 13 percent by weight of films whose average thickness will not exceed 15 microns (0.6 mils). The finished film is used for packaging, transporting, or holding food, excluding beverages containing more than 8 percent alcohol (by volume) at temperatures not to exceed 49 °C (120 °F) (conditions of use E, F, and G in table 2 of § 176.170(c) of this chapter).	1.21±0.02	437-491	do	2.0	2.5	1.0	1.0
10.3 Nylon MXD-6 resins for use only as nonfood-contact layers of: (1) Multilayer films and (2) rigid plastic containers composed of polypropylene food-contact and exterior layers, as defined in § 177.1520(c), item 1.1(a) and 1.1(b), of this chapter. The finished food-contact laminate, in the form in which it contacts food, when extracted with the food simulating solvent or solvents characterizing the conditions of the intended use as determined from Table 2 of § 176.170(c) of this chapter, shall yield not more than 0.5 micrograms of <i>m</i> -xylylenediamine-adipic acid cyclic monomer per square inch of food-contact surface, when the food simulating solvent is analyzed by any appropriate, properly validated method.	1.22±0.02	455-470	Dissolves in 1 h.		1.0	1.5	0.2	0.2
11. Nylon 12T resins for use in contact with all types of food except those containing more than 8 percent alcohol.	1.06±0.015	N/A	Insoluble after 1 hour.	0.1	0.5	0.5
12. Nylon 6I/6T resins for use in contact with all types of food except alcoholic beverages containing more than 8 percent alcohol.	1.207±0.1	N/A	Insoluble after 1 hour.	0.2	1.0	0.1	0.1

Nylon resins	Specific gravity	Melting point (degrees Fahrenheit)	Solubility in boiling 4.2N HCl	Viscosity No. (mL/g)	Maximum extractable fraction in selected solvents (expressed in percent by weight of resin)			
					Water	95 percent ethyl alcohol	Ethyl acetate	Benzene
13.1 Nylon 6/12 resins for use only in food-contact films having an average thickness not to exceed 51 microns (0.002 inch). The finished film is intended to contact all foods except those containing more than 8 percent ethanol under conditions of use B, C, D, E, F, G, and H listed in table 2 of § 176.170(c) of this chapter.	1.06±0.015	260–285	Dissolves in 1 hour.	Greater than 140	2.0	1.5	1.5
13.2 Nylon 6/12 resins with residual <i>epsilon</i> -caprolactam not to exceed 0.5 percent by weight and residual <i>omega</i> -laurolactam not to exceed 0.1 percent by weight. For use only as specified in § 177.1395 of this chapter.	1.10±0.15	380–400	Dissolves in 1 h.	Greater than 160	0.8	1.0	0.5	0.5
13.3 Nylon 6/12 resins with residual <i>epsilon</i> -caprolactam not to exceed 0.8 percent by weight and residual <i>omega</i> -laurolactam not to exceed 0.1 percent by weight. For use only as specified in § 177.1390 of this chapter.	1.13 ±0.15	400–420	Dissolves in 1 h.	1.0	1.5	0.5	0.5
14. Nylon 6/69 resins for use only as specified in 21 CFR 177.1395 of this chapter.	1.09±0.02	270–277	>140 using the method described in § 177.1500(c)(5)(ii) of this chapter.	3.0			
15. Nylon 46 resins for use only in food-contact membrane filters intended for repeated use. The finished membrane filter is intended to contact beverages containing no more than 13 percent alcohol, under conditions of use E, F, and G listed in table 2 of § 176.170(c) of this chapter.	1.18±0.015	551–592	Dissolves in 1 h.	0.3	0.2	0.2	0.3
16. Nylon resins PA 6–3–T for repeated-use (excluding bottles) in contact with food of type VIA and VIB described in table 1 of § 176.170(c) of this chapter under conditions of use D through H described in table 2 of § 176.170(c) of this chapter with a hot-fill temperature limitation of 40 °C.	1.12±0.03	NA	Insoluble after 1 h.	>110	0.007	0.64	0.003	0

(c) *Nylon modifier*—(1) *Identity*. Copolyester-graft-acrylate copolymer is the substance 1,4-benzenedicarboxylic acid, polymer with 1,4-butanediol, (*E*)-2-butenedioic acid, 1,2-ethanediol, ethyl 2-propenoate, hexanedioic acid and 2-propenoic acid, graft (CAS Reg. No. 175419-23-5), and is derived from grafting of 25 weight percent of acrylic polymer with 75 weight percent of copolyester. The copolyester is polymerized terephthalic acid (55 mol%), adipic acid (40 mol%), and fumaric acid (5 mol%) with ethylene glycol (40 mol%) and 1,4-butanediol (60 mol%). The acrylic polymer is made from acrylic acid (70 mol%) and ethyl acrylate (30 mol%).

(2) *Specifications*. The finished copolyester-graft-acrylate copolymer shall meet the following specifications:

(i) Weight average molecular weight 15,000–35,000,

(ii) pH 7.2 to 8.2, and

(iii) Glass transition temperature –15 to –25 °C.

(3) *Conditions of use*. (i) Copolyester-graft acrylate copolymer described in paragraph (c)(1) of this section is intended to improve the adhesive qualities of film. It is limited for use as a modifier of Nylon 6 and Nylon 6 modified with Nylon MXD-6 at a level not to exceed 0.17 weight percent of the additive in the finished film.

(ii) The finished film is used for packaging, transporting, or holding all types of foods under conditions of use B through H, described in table 2 of §176.170(c) of this chapter, except that in the case of Nylon 6 films modified with Nylon MXD-6 (complying with §177.1500, item 10.2), the use complies with the conditions of use specified in table 2.

(iii) *Extractives*. Food contact films described in paragraphs (c)(1) of this section, when extracted with solvent or solvents prescribed for the type of food and under conditions of time and temperature specified for the intended use, shall yield total extractives not to exceed 0.5 milligram per inch squared of food-contact surface when tested by the methods described in §176.170(d) of this chapter.

(iv) *Optional adjuvant substances*. The substances employed in the production

of Nylon modifiers listed in paragraph (c)(1) of this section may include:

(A) Substances generally recognized as safe for use in food and food packaging;

(B) Substances subject to prior sanction or approval for use in Nylon resins and used in accordance with such sanctions or approval; and

(C) Optional substances required in the production of the additive identified in this paragraph and other optional substances that may be required to accomplish the intended physical or technical effect.

(d) *Analytical methods*—(1) *Specific gravity*. Specific gravity shall be determined by weighing a 1-gram to 5-gram sample first in air and then in freshly boiled distilled water at 23 °C±2 °C.

(2) *Melting point*. The melting point shall be determined as follows: Use a hot-stage apparatus. The use of crossed nicol prisms with a microscope hot stage and reading of the thermometer when the birefringence disappears increases the accuracy. If the crossed nicol apparatus is not available, use the lowest temperature at which the sample becomes transparent or the sharp edges or corners of the sample become rounded as the melting point. In case of doubt as to the onset of melting, the sample is prodded with a sharp instrument. If it sticks to the heating block, it is considered to have melted. If the melting point is low, dry the sample in an oven at 85 °C for 24 hours in a nitrogen atmosphere then repeat the test.

(3) *Solubility in boiling 4.2N HCl*. The test shall be run on a sample approximately the size of a ¼-inch cube in at least 25 milliliters of 4.2 normal hydrochloric acid.

(4) *Maximum extractable fraction in selected solvents*. The procedure for determining the maximum extractable fraction of the nylon resins in selected solvents is as follows:

(i) Film should be cut with ordinary scissors into pieces of a convenient size such as ¼-inch squares, for the extraction tests described in this section. The granules of nylon molding powders are in the proper form for the extraction tests. Samples of fabricated articles such as pipe, fittings, and other similar articles must be cut to approximately

the size of the molding powder. This can be done conveniently by using a small-scale commercial plastics granulator and cutting the sample through a screen having ¼-inch mesh. Fine particles should be separated from the cut resin by screening through a 20-mesh screen. The material retained on the screen is suitable for the extraction tests.

(ii) The organic solvents must be of American Chemical Society analytical reagent grade; distilled water is used. Approximately 30 grams of the prepared sample is weighed to the nearest milligram. The weighed resin is transferred to a 500-milliliter round-bottom flask equipped with a reflux condenser. Approximately 300-milliliters of solvent is added to the flask and the contents refluxed gently for 8 hours with a heating mantle. The solvent is then filtered off immediately while still hot, using a Buchner funnel approximately 5 inches in diameter, a suction flask, and a hardened filter paper (Whatman No. 50 or equivalent). The paper is wet with the solvent and a slight suction applied just before starting the filtration. The resin is washed twice with approximately 100-milliliter portions of solvent and the combined filtrate and washings are reduced to approximately 25 milliliters by evaporation at reduced pressure (50 millimeters to 100 millimeters of mercury, absolute), heating as necessary. The contents of the flask are transferred to an evaporation dish (which has been held in a vacuum desiccator over anhydrous calcium sulfate until constant weight has been attained) and carefully evaporated to dryness. The weight of the solid residue is determined by difference after holding in a vacuum desiccator over anhydrous calcium sulfate until constant weight has been attained. The percent of solids extracted is calculated by dividing the weight of the solid residue by the weight of the sample and multiplying by 100.

(5) *Viscosity number (VN)*. (i) The viscosity number (VN) for Nylon 6/12 resin in a 96 percent sulfuric acid solution (5 milligrams resin per milliliter) shall be determined at 25 °C (77 °F) by method ISO 307-1984(E), "Plastics-Polyamides-Determination of Viscosity Number," which is incorporated by reference.

Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(ii) The viscosity number (VN) for Nylon 6/69 and Nylon PA-6-3-T resins in a 99 percent cresol solution (5 milligrams resin per milliliter) shall be determined at 25 °C (77 °F) by method ISO 307-1984(E), "Plastics-Polyamides-Determination of Viscosity Number," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (d)(5)(i) of this section.

[42 FR 14572, Mar. 15, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §177.1500, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 177.1520 Olefin polymers.

The olefin polymers listed in paragraph (a) of this section may be safely used as articles or components of articles intended for use in contact with food, subject to the provisions of this section.

(a) For the purpose of this section, olefin polymers are basic polymers manufactured as described in this paragraph, so as to meet the specifications prescribed in paragraph (c) of this section, when tested by the methods described in paragraph (d) of this section.

(1)(i) Polypropylene consists of basic polymers manufactured by the catalytic polymerization of propylene.

(ii) Propylene homopolymer consists of basic polymers manufactured by the catalytic polymerization of propylene with a metallocene catalyst.

(2)(i) Polyethylene consists of basic polymers manufactured by the catalytic polymerization of ethylene.

(ii) Fumaric acid-grafted polyethylene (CAS Reg. No. 26877-81-6) consists of basic polymers manufactured by the catalytic polymerization of

ethylene followed by reaction with fumaric acid in the absence of free radical initiators. Such polymers shall contain grafted fumaric acid at levels not to exceed 2 percent by weight of the finished polymer.

(3) Olefin basic copolymers consist of basic copolymers manufactured by the catalytic copolymerization of:

(i) Two or more of the 1-alkenes having 2 to 8 carbon atoms. Such olefin basic copolymers contain not less than 96 weight-percent of polymer units derived from ethylene and/or propylene, except that:

(a)(1) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and hexene-1 or ethylene and octene-1 shall contain not less than 90 weight-percent of polymer units derived from ethylene;

(2) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and hexene-1 shall contain not less than 80 but not more than 90 weight percent of polymer units derived from ethylene.

(3) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and pentene-1 shall contain not less than 90 weight-percent of polymer units derived from ethylene.

(4) Olefin basic copolymers manufactured by the catalytic polymerization of ethylene and octene-1 shall contain not less than 50 weight-percent of polymer units derived from ethylene.

(b) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and 4-methylpentene-1 shall contain not less than 89 weight-percent of polymer units derived from ethylene;

(c)(1) Olefin basic copolymers manufactured by the catalytic copolymerization of two or more of the monomers ethylene, propylene, butene-1, 2-methylpropene-1, and 2,4,4-trimethylpentene-1 shall contain not less than 85 weight-percent of polymer units derived from ethylene and/or propylene;

(2) Olefin basic copolymers manufactured by the catalytic copolymerization of propylene and butene-1 shall contain greater than 15 but not greater than 35 weight percent of polymer

units derived from butene-1 with the remainder being propylene.

(d) Olefin basic terpolymers manufactured by the catalytic copolymerization of ethylene, hexene-1, and either propylene or butene-1, shall contain not less than 85 weight percent polymer units derived from ethylene.

(e) Olefin basic copolymers manufactured by the catalytic polymerization of ethylene and octene-1, or ethylene, octene-1, and either hexene-1, butene-1, propylene, or 4-methylpentene-1 shall contain not less than 80 weight percent of polymer units derived from ethylene.

(ii) 4-Methylpentene-1 and 1-alkenes having from 6 to 18 carbon atoms. Such olefin basic copolymers shall contain not less than 95 molar percent of polymer units derived from 4-methylpentene-1, except that copolymers manufactured with 1-alkenes having from 12 to 18 carbon atoms shall contain not less than 97 molar percent of polymer units derived from 4-methylpentene-1; or

(iii) Ethylene and propylene that may contain as modifiers not more than 5 weight-percent of total polymer units derived by copolymerization with one or more of the following monomers:

5-Ethylidene-2-norbornene.

5-Methylene-2-norbornene.

(iv) Ethylene and propylene that may contain as a modifier not more than 4.5 weight percent of total polymer units derived by copolymerization with 1,4-hexadiene.

(v) Ethylene and butene-1 copolymers (CAS Reg. No. 25087-34-7) that shall contain not less than 80 weight percent of polymer units derived from ethylene.

(vi) Olefin basic copolymers (CAS Reg. No. 61615-63-2) manufactured by the catalytic copolymerization of ethylene and propylene with 1,4-hexadiene, followed by reaction with fumaric acid in the absence of free radical initiators. Such polymers shall contain not more than 4.5 percent of polymer units deriving from 1,4-hexadiene by weight of total polymer prior to reaction with fumaric acid and

§ 177.1520

21 CFR Ch. I (4–1–25 Edition)

not more than 2.2 percent of grafted fumaric acid by weight of the finished polymer.

(vii) Ethylene and 2-norbornene (CAS Reg. No. 26007–43–2) copolymers that shall contain not less than 30 and not more than 70 mole percent of polymer units derived from 2-norbornene.

(4) Poly(methylpentene) consists of basic polymers manufactured by the catalytic polymerization of 4-methylpentene-1.

(5) Polyethylene graft copolymers consist of polyethylene complying with item 2.2 of paragraph (c) of this section which subsequently has 3a,4,7,7a-tetrahydromethyl-4,7-methanoisobenzofuran-1,3-dione grafted onto it at a level not to exceed 1.7 percent by weight of the finished copolymer.

(6) Ethylene-maleic anhydride copolymers (CAS Reg. No. 9006–26–2) containing no more than 2 percent by weight of copolymer units derived from maleic anhydride.

(b) The basic olefin polymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic olefin polymers. The optional adjuvant substances required in the production of the basic olefin polymers or finished food-contact articles may include substances permitted for such use by applicable regulations in parts 170 through 189 of this chapter, substances generally recognized as safe in food and food packaging, substances used in accordance with a prior sanction or approval, and the following:

Substance	Limitations
Aromatic petroleum hydrocarbon resin, hydrogenated (CAS Reg. No. 88526–47–0), produced by the catalytic polymerization of aromatic-substituted olefins from distillates of cracked petroleum stocks with a boiling point no greater than 220 °C (428 °F), and the subsequent catalytic hydrogenation of the resulting aromatic petroleum hydrocarbon resin, having a minimum softening point of 110 °C (230 °F), as determined by ASTM Method E 28–67 (Reapproved 1982), "Standard Test Method for Softening Point by Ring-and-Ball Apparatus," and a minimum aniline point of 107 °C (225 °F), as determined by ASTM Method D 611–82, "Standard Test Methods for Aniline Point and Mixed Aniline Point of Petroleum Products and Hydrocarbon Solvents," both of which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html .	For use only as an adjuvant at levels not to exceed 25 percent by weight in blends with polypropylene complying with paragraph (c), item 1.1 of this section. The finished polymer may be used in contact with food Types I, II, IV-B, VI-A through VI-C, VII-B, and VIII identified in table 1 of § 176.170(c) of this chapter and under conditions of use B through H described in table 2 of § 176.170(c) of this chapter; and with food Types III, IV-A, V, VII-A, and IX identified in table 1 of § 176.170(c) of this chapter and under conditions of use D through G described in table 2 of § 176.170(c) of this chapter.
Colorants used in accordance with § 178.3297 of this chapter. 2,5-Dimethyl-2,5-di(<i>tert</i> -butylperoxy)hexane (CAS Reg. No. 78–63–7).	For use as an initiator in the production of propylene homopolymer complying with § 177.1520(c), item 1.1 and olefin copolymers complying with § 177.1520(c), items 3.1 and 3.2 and containing not less than 75 weight percent of polymer units derived from propylene, provided that the maximum concentration of <i>tert</i> -butyl alcohol in the polymer does not exceed 100 parts per million, as determined by a method titled "Determination of <i>tert</i> -Butyl Alcohol in Polypropylene," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html .

Food and Drug Administration, HHS

§ 177.1520

Substance	Limitations
Methyl methacrylate/butyl acrylate-grafted polypropylene copolymer containing methyl methacrylate/butyl acrylate-grafted polypropylene (CAS Reg. No. 121510-09-6), methyl methacrylate/butyl acrylate copolymer (CAS Reg. No. 25852-37-3), methyl methacrylate homopolymer (CAS Reg. No. 9011-14-7), and polypropylene (CAS Reg. No. 9003-07-0), resulting from the reaction of a mixture of methyl methacrylate and butyl acrylate with polypropylene. The finished product contains no more than 55 percent by weight of polymer units derived from methyl methacrylate and butyl acrylate as determined by a method entitled, "Determination of the Total Acrylic in PP-MMA/BA Polymers," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html .	For use only at levels not to exceed 6 percent by weight of olefin polymers complying with paragraph (c) of this section, items 1.1, 3.1a, 3.2a, and 3.2b, where the copolymers complying with items 3.1a, 3.2a, and 3.2b contain not less than 85 weight-percent of polymer units derived from propylene.
Petroleum hydrocarbon resins (cyclopentadiene-type), hydrogenated (CAS Reg. No. 68132-00-3) produced by the thermal polymerization of dicyclopentadiene and cyclo diene codimers (consisting of a mixture of cyclopentadiene, methyl cyclopentadiene, and C ₄ -C ₅ acyclic dienes), followed by hydrogenation and having a ring-and-ball softening point of 119 °C minimum as determined by ASTM Method E 28-67 (Reapproved 1982), "Standard Test Method for Softening Point by Ring-and-Ball Apparatus," and a minimum viscosity of 3,000 centipoise, measured at 160 °C, as determined by ASTM Method D 3236-88, "Standard Test Method for Apparent Viscosity of Hot Melt Adhesives and Coating Materials," both of which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or from the Center For Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html .	For use only as an adjuvant at levels not to exceed 30 percent by weight in blends with: (1) Polypropylene complying with paragraph (c), item 1.1 of this section, or (2) a copolymer of propylene and ethylene containing not less than 94 weight percent propylene and complying with paragraph (c), item 3.2 of this section. The average thickness of the food-contact film is not to exceed 0.1 millimeter (0.004 inch). The finished polymer may be used in contact with (1) Food types I, II, IV-B, VI-A, VI-B, VII-B, and VIII identified in table 1 of § 176.170(c) of this chapter and under conditions of use C through G described in table 2 of § 176.170(c) of this chapter; and (2) food types III, IV-A, V, VI-C, VII-A, and IX identified in table 1 of § 176.170(c) of this chapter and under conditions of use D through G described in table 2 of § 176.170(c) of this chapter.
Polymethylsilsesquioxane (CAS Reg. No. 68554-70-1)	For use only as a surface lubricant or anti-blocking agent in films.
Poly(vinylidene fluoride) homopolymer (CAS Reg. No. 24937-79-9), having a melt viscosity of 6 to 37 kilopoise at a shear rate of 100 ⁻¹ seconds at 232 °C as determined by ASTM Method D 3835-79 (Reapproved 1983), "Standard Test Method for Rheological Properties of Thermoplastics with a Capillary Rheometer" using a capillary of 15:1 L/D, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html .	For use only as a processing aid in the production of olefin polymers complying with paragraph (c) of this section at levels not to exceed 1.0 percent by weight of the polymer. The finished polymers may be used only under the conditions described in § 176.170(c) of this chapter, table 2, under conditions of use B through H.
Polyoxyethylene-grafted polydimethylsiloxane (CAS Reg. No. 68937-54-2).	For use as an extrusion aid in the production of extruded olefin polymers that comply with § 177.1520(c) at levels not to exceed 0.3 percent by weight of the polymer. The finished polymer is used in contact with foods under conditions of use B through H described in table 2 of § 176.170 of this chapter.

§ 177.1520

21 CFR Ch. I (4–1–25 Edition)

Substance	Limitations
Triisopropanolamine (CAS Reg. No. 122–20–3)	For use as a Zeigler-Natta-type catalyst deactivator and anti-oxidant in the production of olefin polymers complying with § 177.1520(c), items 2.1, 2.2, and 2.3, and having a minimum density of 0.94 grams per cubic centimeter, and copolymers complying with § 177.1520(c), items 3.1 and 3.2, for use in contact with all foods under the following conditions of use: (a) films with a maximum thickness of 0.102 millimeter (0.004 inch) may be used under conditions A through H defined in table 2 of § 176.170(c) of this chapter; and (b) articles with thickness greater than 0.102 millimeter (0.004 inch) may be used under conditions C through G defined in table 2 of § 176.170(c) of this chapter.
Trimethylpyridine and dimethylpyridine mixture having percent by weight composition as follows: 2,4,6-trimethylpyridine (CAS Reg. No. 108–75–8), not less than 60 percent; 2,3,6-trimethylpyridine (CAS Reg. No. 1462–84–6), not more than 27 percent; 3,5-dimethylpyridine (CAS Reg. No. 591–22–0), not more than 12 percent; and other dimethylpyridines, not more than 6 percent.	For use only as an adjuvant substance in the production of propylene homopolymers complying with items 1.1, 1.2, and 1.3, and propylene copolymers complying with items 3.1, and 3.2 of paragraph (c) of this section provided that the adjuvant is used at a level not to exceed 20 parts per million by weight of the olefin polymers.
Vinylidene fluoride-hexafluoropropene copolymer (CAS Reg. No. 9011–17–0) having a fluorine content of 65 to 71 percent and a Mooney viscosity of at least 28, as determined by a method entitled “Mooney Viscosity,” which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal-register/code_of_federal_regulations/ibr_locations.html .	For use only as an extrusion aid in the production of extruded olefin polymers at levels not to exceed 0.2 percent by weight of the polymer. The finished polymers may be used only under the conditions described in § 176.170(c) of this chapter, table 2, under conditions of use B through H.
Vinylidene fluoride-hexafluoropropene copolymer (CAS Reg. No. 9011–17–0), having a vinylidene fluoride content of not less than 87 percent but less than 100 percent by weight and a melt viscosity of 12 to 27 kilopoise at a shear rate of 100 ^{–1} seconds at 232 °C as determined by ASTM Method D 3835–79 (Reapproved 1983), “Standard Test Method for Rheological Properties of Thermoplastics with a Capillary Rheometer” using a capillary of 15:1 L/D, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal-register/code_of_federal_regulations/ibr_locations.html .	For use only as a processing aid in the production of olefin polymers complying with paragraph (c) of this section at levels not to exceed 1.0 percent by weight of the polymer. The finished polymers may be used only under the conditions described in § 176.170(c) of this chapter, table 2, under conditions of use B through H.

(c) *Specifications:*

Olefin polymers	Density	Melting Point (MP) or softening point (SP) (Degrees Centigrade)—	Maximum extractable fraction (expressed as percent by weight of the polymer) in <i>N</i> -hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures
1.1a. Polypropylene described in paragraph (a)(1)(i) of this section	0.880–0.913	MP: 160°–180 °C	6.4 pct at reflux temperature	9.8 pct at 25 °C
1.1b. Propylene homopolymer described in paragraph (a)(1)(ii) of this section	0.880–0.913–	MP: 150°–180 °C	6.4 pct at reflux temperature	9.8 pct at 25 °C
1.2. Polypropylene, noncrystalline; for use only to plasticize polyethylene described under items 2.1 and 2.2 of this table, provided that such plasticized polymers meet the maximum extractable fraction and maximum soluble fraction specifications prescribed for such basic polyethylene	0.80–0.88			

Olefin polymers	Density	Melting Point (MP) or softening point (SP) (<i>Degrees Centigrade</i>)—	Maximum extractable fraction (expressed as percent by weight of the polymer) in <i>N</i> -hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in <i>xy</i> -lene at specified temperatures
1.3. Polypropylene, noncrystalline, for use only: To plasticize polypropylene described by item 1.1 of this table, provided that such plasticized polymers meet the maximum extractable fraction and maximum soluble fraction specifications prescribed for such basic polypropylene, and further provided that such plasticized polypropylene contacts food only of the types identified in § 176.170(c) of this chapter, table 1, under Types I, II, IV-B, VI-B, VII-B, and VIII; and for use at levels not to exceed 50 pct by weight of any mixture employed as a food-contact coating provided such coatings contact food only of the types identified in § 176.170(c) of this chapter, table 1, under Types I, II, IV-B, VI-B, VII-B, and VIII	0.80–0.88	SP:115°–138 °C.		
2.1. Polyethylene for use in articles that contact food except for articles used for packing or holding food during cooking	0.85–1.00	5.5 pct at 50 °C	11.3 pct at 25 °C
2.2. Polyethylene for use in articles used for packing or holding food during cooking	0.85–1.00	2.6 pct at 50 °C	Do.
2.3. Polyethylene for use only as component of food-contact coatings at levels up to and including 50 percent by weight of any mixture employed as a food-contact coating	0.85–1.00	53 pct at 50 °C	75 pct at 25 °C
2.4. Olefin polymers described in paragraph (a)(2)(ii) of this section, having a melt flow index not to exceed 17 grams/per 10 minutes as determined by the method described in paragraph (d)(7) of this section, for use in blends with other polymers at levels not to exceed 20 percent by weight of total polymer, subject to the limitation that when contacting food of types III, IV-A, V, VI-C, VII-A, and IX identified in § 176.170(c) of this chapter, Table 1, the polymers shall be used only under conditions of use C, D, E, F, and G, described in § 176.170(c) of this chapter, Table 2.				
3.1a. Olefin copolymers described in paragraph (a)(3)(i) of this section for use in articles that contact food except for articles used for packing or holding food during cooking; except olefin copolymers described in paragraph (a)(3)(i)(a)(3) of this section and listed in item 3.1c of this table and olefin copolymers described in paragraph (a)(3)(i)(e) of this section and listed in item 3.1b of this table	0.85–1.00	5.5 pct at 50 °C	30 pct at 25 °C
3.1b. Olefin copolymers described in paragraph (a)(3)(i)(e) of this section for use in contact with food only under conditions of use D, E, F, G, and H described in § 176.170(c) of this chapter, table 2	0.9–1.00	Do	Do.
3.1c. Olefin copolymers described in paragraph (a)(3)(i)(a)(3) of this section for use in contact with food only under conditions of use B, C, D, E, F, G, and H described in § 176.170(c) of this chapter, table 2; except that such copolymers when used in contact with food of the types identified in § 176.170(c), table 1, under types III, IVA, V, VIIA, and IX, shall be used only under conditions of use D, E, F, and G described in § 176.170(c) of this chapter, table 2	Not less than 0.92			

Olefin polymers	Density	Melting Point (MP) or softening point (SP) (<i>Degrees Centigrade</i>)—	Maximum extractable fraction (expressed as percent by weight of the polymer) in <i>N</i> -hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in <i>xy</i> -lene at specified temperatures
<p>3.2a. Olefin copolymers described in paragraph (a)(3)(i) of this section for use in articles used for packing or holding food during cooking; except olefin copolymers described in paragraph (a)(3)(i)(c)(2) of this section and listed in item 3.2b of this table; except that olefin copolymers containing 89 to 95 percent ethylene with the remainder being 4-methyl-pentene-1 contacting food Types III, IVA, V, VIIA, and IX identified in § 176.170(c) of this chapter, table 1, shall not exceed 0.051 millimeter (mm) (0.002 inch (in)) in thickness when used under conditions of use A and shall not exceed 0.102 mm (0.004 in) in thickness when used under conditions of use B, C, D, E, and H described in § 176.170(c) of this chapter, table 2. Additionally, olefin copolymers described in (a)(3)(i)(a)(2) of this section may be used only under conditions of use B, C, D, E, F, G, and H described in § 176.170(c) of this chapter, table 2, in contact with all food types identified in § 176.170(c) of this chapter, table 1</p> <p>3.2b. Olefin copolymers described in paragraph (a)(3)(i)(c)(2) of this section have a melt flow index no greater than 10 grams per 10 minutes as determined by the method described in paragraph (d)(7) of this section, and the thickness of the finished polymer contacting food shall not exceed 0.025 mm (0.001 in). Additionally, optional adjuvants permitted for use in olefin copolymers complying with item 3.2a of this table may be used in the production of this copolymer</p> <p>3.2c. Olefin copolymers described in paragraph (a)(3)(i)(a)(4) of this section have a melt flow index no greater than 50 grams per 10 minutes as determined by the method described in paragraph (d)(7) of this section. Articles manufactured using these polymers may be used with all types of food under conditions of use C through H as described in table 2 of § 176.170(c) of this chapter</p> <p>3.3a. Olefin copolymers described in paragraph (a)(3)(ii) of this section and manufactured with 1-alkenes having from 6 to 10 carbon atoms</p> <p>3.3b. Olefin copolymers described in paragraph (a)(3)(ii) of this section, provided that such olefin polymers have a melt temperature of 220 °C to 250 °C (428 °F to 482 °F) as determined by the method described in paragraph (d)(8) of this section and minimum intrinsic viscosity of 1.0 as determined in paragraph (d)(9) of this section.</p>	<p>0.85–1.00</p> <p>Do.</p> <p>0.85–0.92</p>	<p>.....</p>	<p>2.6 pct at 50 °C</p>	<p>Do.</p>

Olefin polymers	Density	Melting Point (MP) or softening point (SP) (<i>Degrees Centigrade</i>)—	Maximum extractable fraction (expressed as percent by weight of the polymer) in <i>N</i> -hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in <i>xy</i> -lene at specified temperatures
3.4. Olefin copolymers, primarily non-crystalline, described in par. (a)(3)(iii) of this section provided that such olefin polymers have a minimum viscosity average molecular weight of 120,000 as determined by the method described in par. (d)(5) of this section and a minimum Mooney viscosity of 35 as determined by the method described in par. (d)(6) of this section, and further provided that such olefin copolymers contact food only of the types identified in § 176.170(c) of this chapter, table 1, under Types I, II, III, IV-B, VI, VII, VIII, and IX	0.85–0.90			
3.5. Olefin copolymers, primarily non-crystalline, described in paragraph (a)(3)(iv) of this section, provided that such olefin polymers have a minimum viscosity average molecular weight of 95,600 as determined by the method described in paragraph (d)(5) of this section, and further provided that such olefin polymers are used only in blends with olefin polymers described under items 1.1, 2.1, and 2.2 of this table at a maximum level of 25 pct by weight, and provided that such olefin copolymers contact food only of the types identified in § 176.170 (c) of this chapter, table 1, under Types I, II, IV-B, VI, VII-B, and VIII at temperatures not exceeding 190 °F	0.85–0.90			
3.6. Olefin copolymers described in paragraph (a)(3)(v) of this section for use in blends with olefin polymer resins have a melt flow index no greater than 5 grams/10 minutes as determined by the method described in paragraph (d)(7) of this section and the thickness of the finished blends shall not exceed 0.1 millimeter (0.004 inch). The ethylene/butene-1 copolymer may be used subject to the following conditions: (1) For use at a level not to exceed 20 weight percent in polypropylene as described under item 1.1 of this table. (2) For use at a level not to exceed 40 weight percent in polyethylene as described under items 2.1 and 2.2 of this table. (3) For use at a level not to exceed 40 weight percent in olefin copolymers as described under items 3.1 and 3.2 of this table	Not less than 0.88			

Olefin polymers	Density	Melting Point (MP) or softening point (SP) (<i>Degrees Centigrade</i>)—	Maximum extractable fraction (expressed as percent by weight of the polymer) in <i>N</i> -hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in <i>xy</i> -lene at specified temperatures
3.7. Ethylene/propylene copolymers, meeting the identity described in paragraph (a)(3)(i) of this section, containing not less than 80 mole-percent of polymer units derived from ethylene and having a minimum viscosity average molecular weight of 95,000 as determined by the method described in paragraph (d)(5) of this section, and a minimum Mooney viscosity of 13 as determined by the method described in paragraph (d)(6) of this section. Ethylene/propylene copolymers described in this item 3.7 are to be used only in blends with other olefin polymers complying with this section, at levels not to exceed 30 percent by weight of the total polymer blend, and in contact with food only of types identified in § 176.170(c) of this chapter, Table 1, under Types I, II, III, IV-B, VI, VII, VIII, and IX. Additionally, optional adjuvants permitted for use in olefin copolymers complying with item 3.4 of this table may be used in the production of this copolymer	Not less than 0.86			
3.8. Olefin polymers described in paragraph (a)(3)(vi) of this section, having a melt flow index not to exceed 9.2 grams per 10 minutes as determined by the method described in paragraph (d)(7) of this section, for use in blends with other polymers at levels not to exceed 8 percent by weight of total polymer, subject to the limitation that when contacting food of types III, IV-A, V, VI-C, VII-A, and IX, identified in § 176.170(c) of this chapter, Table 1, the polymers shall be used only under conditions of use C, D, E, F, and G, described in § 176.170(c) of this chapter, Table 2.				
3.9. Olefin copolymers described in paragraph (a)(3)(vii) of this section may only be used in contact with dry foods, Type VIII, as identified in § 176.170(c) of this chapter, Table 1	Not less than 1.0			
4. Poly(methylpentene)	0.82–0.85	MP: 235°–250 °C	6.6 pct at reflux temperature 0.45 pct at 15 °C	7.5 pct at 25 °C 1.8 pct at 25 °C
5. Polyethylene copolymer described in paragraph (a)(5) of this section and having a melt index not to exceed 2, for use, either alone or in blends with other olefin polymers, subject to the limitation that when contacting foods of types III, IV-A, V, VI-C, VII-A, VIII, and IX identified in § 176.170(c) of this chapter, table 1, the thickness of the film (in mils) containing the polyethylene graft copolymer times the concentration of the polyethylene graft copolymer shall not exceed a value of 2	Not less than 0.94		
6. Ethylene-maleic anhydride copolymers described in paragraph (a)(6) of this section for use as the adhesive component in multilaminate structures, or as the sealant layer in flexible packaging, in contact with food at temperatures not exceeding 49 °C (120 °F)	0.92 or greater	1.36 pct at 50 °C	2.28 pct at 25 °C

(d) The analytical methods for determining whether olefin polymers conform to the specifications prescribed in

this section are as follows, and are applicable to the basic polymer in film form not exceeding 4 mils in thickness.

The film to be tested shall be cut into approximately 1-inch squares by any convenient method that avoids contamination by dust, dirt, or grease (NOTE: Do not touch samples with bare fingers—use forceps to hold or transfer samples).

(1) *Density*. Density shall be determined by ASTM method D1505-68 (Reapproved 1979), "Standard Test Method for Density of Plastics by the Density-Gradient Technique," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(2) *Melting point or softening point*—(i) *Melting point*. The melting point shall be determined by ASTM method D2117-82, "Standard Test Method for Melting Point of Semicrystalline Polymers by the Hot Stage Microscopy Method," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (d)(1) of this section.

(ii) *Softening point*. The softening point shall be determined by ASTM method E28-67 (Reapproved 1982), "Standard Test Method for Softening Point by Ring-and-Ball Apparatus," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (d)(1) of this section.

(3) *Maximum extractable fraction in n-hexane*—(i) *Olefin copolymers described in paragraph (a)(3)(ii) of this section*,

polypropylene, and poly(methylpentene). A sample is refluxed in the solvent for 2 hours and filtered at the boiling point. The filtrate is evaporated and the total residue weighed as a measure of the solvent extractable fraction.

(a) *Apparatus*. (1) Erlenmeyer flasks, 250-milliliter, with ground joint.

(2) Condensers, Allihn, 400-millimeter jacket, with ground joint.

(3) Funnels, ribbed 75-millimeter diameter, stem cut to 40 millimeters.

(4) Funnels, Buchner type, with coarse-porosity fritted disc, 60-millimeter diameter.

(5) Bell jar for vacuum filtration into beaker.

(b) *Reagent*. *n*-Hexane, commercial grade, specific gravity 0.663–0.667 (20 °C/20 °C), boiling range 66 °C–69 °C, or equivalent.

(c) *Procedure*. Weigh 1 gram of sample accurately and place in a 250-milliliter Erlenmeyer flask containing two or three boiling stones. Add 100 milliliters of solvent, attach the flask to the condenser (use no grease), and reflux the mixture for 2 hours. Remove the flask from the heat, disconnect the condenser, and filter rapidly, while still hot, through a small wad of glass wool packed in a short-stem funnel into a tared 150-millimeter beaker. Rinse the flask and filter with two 10-milliliter portions of the hot solvent, and add the rinsings to the filtrate. Evaporate the filtrate on a steam bath with the aid of a stream of nitrogen. Dry the residue in a vacuum oven at 110 °C for 2 hours, cool in a desiccator, and weigh to the nearest 0.0001 gram. Determine the blank on 120 milliliters of solvent evaporated in a tared 150-milliliter beaker. Correct the sample residue for this blank if significant. Calculation:

$$\frac{\text{Grams of residue}}{\text{Grams of sample} \times 100} = \text{Percent extractable with } n\text{-hexane.}$$

(ii) *Olefin copolymers described in paragraph (a)(3)(i) of this section and polyethylene*. A preweighed sample is extracted at 50 °C for 2 hours and filtered. The filtrate is evaporated and the total

residue weighed as a measure of the solvent extractable fraction. Alternatively, the sample is reweighed after the extraction period to give a measure of the solvent extractable fraction. The

maximum *n*-hexane-extractable fraction may be determined by the methods set forth in paragraphs (d)(3)(ii)(a) through (d)(3)(ii)(i) of this section.

(a) *Extraction apparatus.* Two-liter, straight-walled, Pyrex (or equivalent) resin kettles, fitted with three-hole ground-glass covers are most convenient for this purpose. The cover is fitted with a thermometer, a gas-tight stirrer driven by an air motor or explosion-proof electric motor, and a reflux condenser. The kettle is fitted with an electric heating mantle of appropriate size and shape, which is controlled by a variable-voltage transformer.

(b) *Evaporating apparatus.* Rapid evaporation of large volumes of solvent requires special precautions to prevent contamination by dust. This is facilitated by a special “gas” cover consisting of an inverted flat Pyrex crystallizing dish of an appropriate size (190 millimeters × 100 millimeters) to fit a 1-liter beaker. Through the center of the dish are sealed an inlet tube for preheated, oxygen-free nitrogen, and an outlet tube located 1 inch off center. Nitrogen is fed from the supply source through a coil of ¼-inch stainless steel tubing immersed in the same steam bath used to supply heat for solvent evaporation. All connections are made with flexible tetrafluoroethylene tubing.

(c) *Reagents—(1) n-Hexane.* Spectrograde *n*-hexane.

(2) *Nitrogen.* High-purity dry nitrogen containing less than 10 parts per million of oxygen.

(d) *Procedure.* Transfer 2.5 grams (accurately weighed to nearest 0.001 gram) of the polymer to the resin kettle. Add 1 liter of solvent and clamp top in position. Start water flowing through jacket of the reflux condenser and apply air pressure to the stirring motor to produce vigorous agitation. Turn on heating jacket with transformer set at a predetermined voltage to bring the temperature of the contents to 50 °C within 20–25 minutes. As the thermometer reading approaches 45 °C–47 °C, reduce the voltage to the predetermined setting that will just maintain the temperature at 50 °C. Do not overshoot the prescribed temperature. Should this occur discard the test and start afresh. Exactly 2 hours after the sol-

vent temperature has reached 50 °C, disconnect the heater, remove the resin kettle from the heating jacket, and decant the solvent, while still warm, through a coarse filter paper placed on top of a fritted-glass funnel, collecting the filtrate in a tared, glass-stoppered Erlenmeyer flask of 1-liter capacity. Determine the weight of the filtrate recovered to the nearest gram. Recovery should be at least 90 percent of the original solvent. Losses due to evaporation during heating and filtering have been found not to exceed 10 percent. Transfer about half of the solvent filtrate to a 1-liter beaker placed on an opening in the steam bath and immediately cover with the special “gas” cover, the inlet tube of which has been attached with flexible tetrafluoroethylene tubing to a source of high-purity nitrogen in series with a stainless steel heating coil immersed directly in the body of the steam bath. Maintain a positive flow of warm nitrogen gas throughout the evaporation of the solvent, adding the remainder of the filtrate from the Erlenmeyer flask as the evaporation proceeds. When the volume of the solvent has been reduced to about 50 milliliters, transfer the concentrated liquid to a previously tared weighing dish of suitable size. Wash the beaker twice with 20–30 milliliter portions of warm solvent, adding the washings to the weighing dish while continuing to evaporate the remainder of the solvent under the gas cover with its flow of warm nitrogen directed toward the center of the dish. In the event that an insoluble residue that cannot be removed with warm solvent remains in the beaker, it may be necessary to heat with a small amount of a higher boiling solvent such as benzene or toluene, transferring these washings to the weighing dish before final evaporation to dryness. Transfer the weighing dish with its residue to a vacuum desiccator, and allow it to remain overnight (at least 12 hours), after which the net weight of the dry residue is determined to the nearest 0.0001 gram. Correct the result for any solvent blank equivalent to the non-volatile matter determined to be contained in the amount of solvents used in the test.

(e) *Extraction apparatus for alternate method.* Two-liter extraction vessel, such as a resin kettle or round bottom flask, fitted with an Allihn condenser (size C), a 45/50 male joint with a Teflon sleeve, and a Teflon coated stir bar. Water bath maintained at $49.5\text{ }^{\circ}\text{C} \pm 0.5\text{ }^{\circ}\text{C}$ containing a submersible magnetic stirrer motor with power supply. Other suitable means of maintaining temperature control, such as electric heating mantles, may be used provided that the temperature range can be strictly maintained.

(f) *Sample basket (Optional).* A perforated stainless steel cylindrical basket that is approximately 1.5 inches in diameter, 1.6 inches high, and has perforations of 0.125 inches in diameter for 33 holes/in², or 40 percent open area. The basket should pass freely through the 45/50 female joint of the extraction flask. A No. 6-32 stainless steel eye-bolt is attached to the lid for positioning the basket in the extraction vessel. The positioning rod, approximately 18 inches long and made from $\frac{1}{16}$ inch outside diameter 316 stainless steel welding rod or equivalent and hooked at both ends, is used to position the basket in the extraction apparatus.

(g) *Vacuum oven.* Capable of maintaining $80\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$ and a minimum of 635 millimeters of mercury pressure.

(h) *Reagents.* *n*-Hexane, reagent or spectrograde, aromatic free (less than 1 milligram per liter), minimum 85 percent *n*-hexane. This reagent may be re-used until it contains a maximum of 1.5 grams polyolefin extractables or has been used for 12 determinations.

(i) *Procedure.* Assemble the extraction vessel, condenser, and magnetic stir bar. Add *n*-hexane (1 liter) to the extraction vessel and clamp the assembly into a water bath set at $49.5\text{ }^{\circ}\text{C} \pm 0.5\text{ }^{\circ}\text{C}$. Start the water flowing through the jacket of the reflux condenser. Adjust the air flow through the stirring motor to give a smooth and uniform stir rate. Allow the *n*-hexane to preheat for 1 hour to bring the temperature to $49.5\text{ }^{\circ}\text{C} \pm 0.5\text{ }^{\circ}\text{C}$. Temperature is a critical factor in this analysis and it must not vary more than $1\text{ }^{\circ}\text{C}$. If the temperature exceeds these limits, the test must be discontinued and restarted. Blown, compression molded, or extrusion cast films can be tested. Ideally, the film

should be prepared by the same process as will be used with the production resin. Using gloves and metal tweezers to avoid sample contamination, cut about 2.7 grams of the prepared film (4 mils or less in thickness) into about 1-inch squares using clean sharp scissors. Proceed with Option 1 or 2.

Option 1. Using tweezers and noting the number of film pieces, transfer 2.5 grams (accurately weighed to 0.1 milligram) of polymer to the extraction vessel. Extract the film sample for 2 hours. Allow the vessel to cool and filter the contents through a fritted porcelain funnel. Wash the film pieces with fresh *n*-hexane, aspirate to dryness, and transfer, using tweezers, to a beaker. Recount the film pieces to verify that none were lost during the transfer. Place the beaker in the vacuum oven for 2 hours at $80\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$. After 2 hours, remove and place in a desiccator to cool to room temperature (about 1 hour). After cooling, reweigh the film pieces to the nearest 0.1 milligram. Calculate the percent hexane-extractables content from the weight loss of the original sample. Multiply the result by 0.935 and compare with extraction limits in paragraph (c) of this section. Repeat the above procedure for successive samples.

Option 2. Transfer 2.5 ± 0.05 grams of the prepared 1-inch film sections into a tared sample basket and accurately weigh to the nearest 0.1 milligram. Carefully raise the condenser until the hook on the positioning rod is above the neck of the 2-liter extraction vessel. The basket should be totally below the level of *n*-hexane solvent. Extract the sample resin film for 2 hours and then raise the basket above the solvent level to drain momentarily. Remove the basket and rinse the contents by immersing several times in fresh *n*-hexane. Allow the basket to dry between rinsings. Remove the excess solvent by briefly blowing the basket with a stream of nitrogen or dry air. Place the basket in the vacuum oven for 2 hours at $80\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$. After 2 hours, remove and place in a desiccator to cool to room temperature (about 1 hour). After cooling, reweigh the basket to the nearest 0.1 milligram. Calculate

the percent hexane extractables content from the weight loss of the original sample. Multiply the result by 0.935 and compare with extraction limits in paragraph (c) of this section. Repeat the above procedure for successive samples. The same solvent charge should remain clear and can be used for at least 12 determinations. Applications of solvent reuse should be confirmed for each resin type before use.

(4) *Maximum soluble fraction in xylene*—(i) *Olefin copolymers described in paragraph (a)(3)(ii) of this section, polypropylene, and poly(methylpen-tene)*. A sample is dissolved completely in xylene by heating and stirring in a bottle with little free space. The solution is allowed to cool without stirring, whereupon the insoluble portion precipitates and is filtered off; the total solids content of the filtrate is then determined as a measure of the soluble fraction.

(a) *Apparatus*. (1) Pyrex (or equivalent) reagent bottle, 125-milliliter, glass-stoppered.

(2) Heating mantle of size for 150-milliliter beaker (or suitable aluminum block to fit the 125-milliliter bottle described in paragraph (d)(4)(i)(a)(1) of this section).

(3) Magnetic stirrer for use under the heating mantle (combination magnetic stirrer and hotplate may be used if aluminum block is used in place of heating mantle).

(4) Variable-voltage transformer, 7.5 amperes.

(5) Tetrafluoroethylene-resin-coated stirring bar, 1-inch long.

(6) Constant temperature water bath maintained at 25 °C±0.5 °C.

(7) *Aluminum* dishes, 18 millimeters × 60 millimeters, disposable.

(8) Funnel, Buchner type, with coarse-porosity fritted disc, 30–60 millimeter diameter.

(b) *Reagent*. Xylene with antioxidant. Dissolve 0.020 gram of phenyl-β-naph-

thylamine in 1 liter of industrial grade xylene having specific gravity 0.856–0.867 (20 °C/20 °C) and boiling range 123 °C–160 °C.

(c) *Procedure*. Weigh 1 to 2 grams of sample to the nearest 0.001 gram and place in a 125-milliliter Pyrex reagent bottle containing a 1-inch long tetrafluoroethylene-resin-coated stirring bar. Add 100 milliliters of solvent, set the stopper in lightly, and place the bottle in the heating mantle or aluminum block maintained at a temperature of 120 °C, and stir with a magnetic stirrer until the sample is completely dissolved. Remove the bottle from the heat and allow it to cool 1 hour in the air, without stirring. Then place the bottle in a water bath maintained at 25 °C ±0.5 °C, and allow to stand 1 hour without stirring. Next, remove the bottle from the water bath, shake, and pour part of the contents into the coarse-porosity fritted-glass funnel. Apply suction, and draw 30–40 milliliters of filtrate through, adding more slurry to the funnel, and catching the filtrate in a large test tube. (If the slurry is hard to filter, add 10 grams of diatomaceous earth filter aid to the bottle and shake vigorously just prior to the filtration.) Pipet a suitable aliquot (preferably 20 milliliters) of the filtrate into a tared aluminum disposable dish. Place the dish on a steam bath covered with a fresh sheet of aluminum foil and invert a short-stemmed 4-inch funnel over the dish. Pass nitrogen (heated if desired) down through the funnel at a rate sufficient to just ripple the surface of the solvent. When the liquid has evaporated, place the dish in a vacuum oven at 140 °C and less than 50 millimeters mercury pressure for 2 hours. Cool in a desiccator and weigh. (Note: If the residue value seems high, redry in the vacuum oven for one-half hour to ensure complete removal of all xylene solvent.) Calculation:

$$\frac{\text{Grams of residue}}{\text{Grams of sample}} \times \frac{100 \text{ milliliters}}{\text{volume of aliquot in milliliters}} \times 100 = \text{Percent soluble in xylene}$$

(ii) *Olefin copolymers described in paragraph (a)(3)(i) of this section and polyethylene.* A sample is extracted in xylene at reflux temperature for 2 hours and filtered. The filtrate is evaporated and the total residue weighed as a measure of soluble fraction.

(a) *Apparatus—(1) Extraction apparatus.* Two-liter, straight-walled Pyrex (or equivalent) resin kettles, fitted with ground-glass covers, are most convenient for this purpose. The cover is equipped with a thermometer and an efficient reflux condenser. The kettle is fitted with an electric heating mantle of appropriate size and shape which is controlled by a variable-voltage transformer.

(2) *Constant temperature water bath.* It must be large enough to permit immersion of the extraction kettle and set to maintain $25^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$.

(3) *Evaporating apparatus.* Gas cover consisting of a flat Pyrex crystallizing dish (190 millimeters \times 100 millimeters) inverted to fit over a 1-liter beaker with 8-millimeter gas inlet tube sealed through center and an outlet tube 1 inch off center. The beaker with gas cover is inserted in an electric heating mantle equipped with a variable-voltage transformer. The outlet tube is attached to an efficient condenser mounted on a receiving flask for solvent recovery and having an outlet for connection to an aspirator pump. The heating mantle (with the beaker) is mounted on a magnetic stirring device. An infrared heat lamp is mounted vertically 3-4 inches above the gas cover to prevent condensation of the solvent inside the cover. Make all connections with flexible tetrafluoroethylene tubing.

(b) *Reagents—(1) Xylene.* American Chemical Society reagent grade that has been redistilled through a fractionating column to reduce the nonvolatile residue.

(2) *Nitrogen.* High-purity dry nitrogen containing less than 10^4 parts per million oxygen.

(c) *Procedure.* Transfer 5 grams ± 0.001 gram of sample to the resin kettle, add 1,000 milliliters (840 grams) of xylene, and clamp top in position after inserting a piece of glass rod to prevent bumping during reflux. Start water flowing through the jacket of the

reflux condenser and apply full voltage (115 volts) to the heating mantle. When the xylene starts to boil, reduce the voltage to a level just sufficient to maintain reflux. After refluxing for at least 2 hours, disconnect the power source to the mantle, remove the kettle, and allow to cool in air until the temperature of the contents drops to 50°C , after which the kettle may be rapidly cooled to 25°C – 30°C by immersing in a cold water bath. Transfer the kettle to a constant temperature bath set to maintain $25^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$, and allow to equilibrate for a least 1 hour (may be left overnight if convenient). Break up any precipitated polymers that may have formed, and decant the xylene solution successively through a fast filter paper and then through a fritted-glass filter into a tared 1-liter Erlenmeyer flask, collecting only the first 450 milliliters—500 milliliters of filtrate (any attempt to collect more of the xylene solution usually results in clogging the filter and risking losses). Reweigh the Erlenmeyer flask and calculate the weight of the filtrate obtained to the nearest 0.1 gram. Transfer the filtrate, quantitatively, from the Erlenmeyer flask to the 1-liter beaker, insert the beaker in its heating mantle, add a glass-coated magnetic stirring bar, and mount the gas cover in place, connecting the inlet tube to the nitrogen source and the outlet to the condenser of the receiving flask. Start a flow of nitrogen (2 to 3 liters per minute) into the gas cover and connect an aspirator to the receiver using a free-flow rate equivalent to 6-7 liters of air per minute. With the infrared lamp on, adjust the voltage to the heating mantle to give a distillation rate of 12-13 milliliters per minute when the magnetic stirrer is revolving just fast enough to promote good boiling. When the volume of solvent in the beaker has been reduced to 30-50 milliliters, transfer the concentrated extractive to a suitable weighing dish that has been previously tared (dry). Rinse the beaker twice with 10-20 milliliter portions of fresh xylene, adding the rinsings to the weighing dish. Evaporate the remainder of the xylene on an electric hotplate set at low heat under the gas cover with a stream of nitrogen directed toward the center of the dish.

Avoid any charring of the residue. Transfer the weighing dish to a vacuum desiccator at room temperature and allow to remain under reduced pressure for at least 12 hours (overnight), after which determine the net weight of the residue to the nearest 0.0001 gram. Correct the result for non-volatile solvent blank obtained by evaporating the equivalent amount of xylene under identical conditions. Calculate the weight of residue originally present in the total weight of solvent (840 grams), using the appropriate factor based on the weight of filtrate evaporated.

(5) *Viscosity average molecular weight olefin copolymers described in paragraphs (a)(3)(iii) and (iv) of this section.* The viscosity average molecular weight shall be determined from the kinematic viscosity (using ASTM method D445–74, “Test for Kinematic Viscosity of Transparent and Opaque Liquids” (Revised 1974), which is incorporated by reference; copies are available from American Society for Testing and Materials (ASTM), 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.) of solutions of the copolymers in solvents and at temperatures as follows:

(i) Olefin polymers described in paragraph (a)(3)(iii) of this section in decahydronaphthalene at 135 °C.

(ii) Olefin polymers described in paragraph (a)(3)(iv) of this section in tetrachloroethylene at 30 °C.

(6) *Mooney viscosity—olefin copolymers described in paragraph (a)(3)(iii) of this section.* Mooney viscosity is determined by ASTM method D1646–81, “Standard Test Method for Rubber—Viscosity and Vulcanization Characteristics (Mooney Viscometer),” which is incorporated by reference (the availability of this incorporation by reference is given in paragraph (d)(1) of this section), using the large rotor at a temperature of 100 °C, except that a temperature of 127 °C shall be used for those copolymers whose Mooney viscosity cannot be de-

termined at 100 °C. The apparatus containing the sample is warmed for 1 minute, run for 8 minutes, and viscosity measurements are then made.

(7) *Melt flow index.* The melt flow index of olefin polymers described below shall be determined by ASTM method D-1238–82, “Standard Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer,” which is incorporated by reference in accordance with 5 U.S.C. 552(a). The availability of this incorporation by reference is given in paragraph (d)(1) of this section. The olefin polymers and test conditions and procedures are as follows:

List of polymers	Conditions/procedures
Olefin copolymers described in paragraph (a)(3)(i)(c)(2) of this section.	Condition L, procedure A.
Olefin copolymers described in paragraph (a)(3)(v) of this section.	Condition E, procedure A.
Olefin polymers described in paragraph (a)(2)(ii) of this section.	Condition E, procedure A.
Olefin polymers described in paragraph (a)(3)(vi) of this section.	Condition E, procedure A.

(8) *Melting peak temperature.* The melt temperature of the olefin polymers described in paragraph (a)(3)(ii) of this section shall be determined by ASTM method D 3418–82, “Standard Test Method for Transition Temperatures of Polymers by Thermal Analysis,” which is incorporated by reference in accordance with 5 U.S.C. 552(a). The availability of this incorporation by reference is given in paragraph (d)(1) of this section.

(9) *Intrinsic viscosity.* The intrinsic viscosity of the olefin polymers described in paragraph (a)(3)(ii) of this section shall be determined by ASTM method D 1601–78, “Standard Test Method for Dilute Solution Viscosity of Ethylene Polymers,” which is incorporated by reference in accordance with 5 U.S.C. 552(a). The availability of this incorporation by reference is given in paragraph (d)(1) of this section.

(e) Olefin copolymers described in paragraph (a)(3)(i) of this section and polyethylene, alone or in combination, may be subjected to irradiation bombardment from a source not to exceed 2.3 million volts intensity to cause molecular crosslinking of the polymers to impart desired properties, such as increased strength and increased ability to shrink when exposed to heat.

(f) The olefin polymers identified in and complying with this section, when used as components of the food-contact surface of any article that is the subject of a regulation in parts 174, 175, 176, 177, 178, and §179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(g) The provisions of this section are not applicable to olefin polymers identified in §175.105(c)(5) of this chapter and used in food-packaging adhesives complying with §175.105 of this chapter.

[42 FR 14572, Mar. 15, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §177.1520, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 177.1550 Perfluorocarbon resins.

Perfluorocarbon resins identified in this section may be safely used as articles or components of articles intended to contact food, subject to the provisions of this section:

(a) *Identity.* For the purpose of this section, perfluorocarbon resins are those produced by: (1) The homopolymerization and/or copolymerization of hexafluoropropylene and tetrafluoroethylene, and (2) the copolymerization of perfluoropropylvinylether and tetrafluoroethylene (CAS Reg. No. 26655-00-5). The resins shall meet the extractives limitations in paragraph (d) of this section.

(b) *Optional components.* The perfluorocarbon resins identified in paragraph (a) of this section as well as articles or coating made from these resins may include the following optional components except that the resin identified in paragraph (a)(2) of this section may not be used with the optional component, lithium polysilicate, mentioned in paragraph (b)(4) of this section.

(1) Substances generally recognized as safe (GRAS) in food or food packaging subject to any limitations cited on their use.

(2) Substances used in accordance with a prior sanction or approval, subject to any limitations cited in the prior sanction or approval.

(3) Substances authorized under applicable regulations in this part and in parts 175 and 178 of this chapter and subject to any limitations prescribed therein.

(4) The following substances, subject to any limitations prescribed:

List of substances	Limitations
Lithium polysilicate containing not more than 20 weight percent silica, not more than 2.1 percent lithium oxide and having a maximum mole ratio of $\text{SiO}_2/\text{Li}_2\text{O}$ of 8.5 to 1.	For use only as a component of repeated-use coatings not exceeding 0.030 millimeter (0.0012 inch) in thickness where the coatings are thermally cured at minimum sintering temperatures of 371 °C (700 °F). Lithium extractives shall not exceed 1.55 milligrams per square decimeter (0.1 milligram per square inch) of coating surface when tested in accordance with paragraph (e)(2) of this section.
Naphthalene sulfonic acid formaldehyde condensate, sodium salt.	For use only: 1. As a component of repeated-use coatings, based on the perfluorocarbon resin identified in paragraph (a)(1) of this section, not to exceed 0.030 millimeter (0.0012 inch) in thickness, and at a level not to exceed 0.4 weight percent of the coating. 2. As a component of repeated-use coatings, based on the perfluorocarbon resin identified in paragraph (a)(2) of this section, not to exceed 0.10 millimeter (0.004 inch) in thickness, and at a level not to exceed 0.4 weight percent of the coating.

(c) *Optional processing.* Poly-tetrafluoroethylene resins may be irradiated by either a cobalt-60 sealed source, at a maximum dose of gamma radiation not to exceed 7.5 megarads, or an electron beam at energy levels not to exceed 2.5 million electron volts with a maximum dosage of 7.5 megarads, to produce lubricant powders having a particle diameter of not more than 20 microns for use only as components of articles intended for repeated use in contact with food.

(d) *Specifications—(1) Infrared identification.* Perfluorocarbon resins can be identified by their characteristic infrared spectra.

(2) *Melt-viscosity.* (i) The perfluorocarbon resins identified in paragraph (a)(1) of this section shall have a melt viscosity of not less than 10^4 poises at 380 °C (716 °F) as determined by ASTM method D1238-82, “Standard Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer,” which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. The melt viscosity of the perfluorocarbon resins identified in paragraph (a)(1) of this section shall not vary more than 50 percent within one-half hour at 380 °C (716 °F).

(ii) Perfluorocarbon resins identified in paragraph (a)(2) of this section shall have a melt viscosity of not less than 10^4 poises at 372 °C (702 °F) as determined by a more detailed method titled “Determination of Melt Viscosity, Molecular Weight Distribution Index and Viscosity Stability,” which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(3) *Thermal instability index.* The thermal instability index of the tetrafluoroethylene homopolymer shall not exceed 50 as determined by ASTM method D1457-56T, “Test for Thermal Instability index of Tetrafluoroethylene Homopolymer” (Revised 1956), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of

this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. The requirements of this paragraph do not apply to polytetrafluoroethylene resin lubricant powders described in paragraph (c) of this section.

(e) *Limitations.*¹ (1) Perfluorocarbon-molded articles having a surface area of 6.45 square decimeters (100 square inches) or more and at least 1.27 millimeters (0.05 inch) thick shall be extracted at reflux temperatures for 2 hours separately with distilled water, 50 percent ethanol, *n*-heptane, and ethyl acetate.

(2) Perfluorocarbon resins identified in paragraphs (a)(1) and (2) of this section and intended for use as coatings or components of coatings shall meet extractability limits prescribed in paragraph (e)(3) of this section when the resins in the form of coatings described in paragraphs (e)(2)(i) and (ii) of this section are extracted at reflux temperatures for 2 hours separately with distilled water, 8 percent ethanol, and *n*-heptane:

(i) Perfluorocarbon resin coatings based on resins identified in paragraph (a)(1) of this section shall be applied to both sides of a 0.025-millimeter (0.001 inch) thick aluminum foil to a thickness of 0.025 millimeter (0.001 inch) after thermal curing at 399 °C (750 °F) for 10 minutes. If a primer is used, the total thickness of the primer plus topcoat shall equal 0.025 millimeter (0.001 inch) after heat curing.

(ii) Perfluorocarbon resin coatings based on resins identified in paragraph (a)(2) of this section shall be applied to both sides of a 0.025-millimeter (0.001

¹A more detailed procedure of extraction conditions is entitled, “Preparation of Extracts,” which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

inch) thick aluminum foil to a thickness of 0.10 millimeter (0.004 inch) after thermal curing at 427 °C (800 °F) for 10 minutes. If a primer is used, the total thickness of the primer plus topcoat shall equal 0.10 millimeter (0.004 inch) after heat curing.

(3) The extracted surfaces shall meet the following extractability limits:

(i) Total extractives not to exceed 3.1 milligrams per square decimeter (0.2 milligram per square inch).

(ii) Fluoride extractives calculated as fluorine not to exceed 0.46 milligram per square decimeter (0.03 milligram per square inch).

(f) *Conditions of use.* Perfluorocarbon resins identified in paragraph (a)(2) of this section are limited to use as coatings or components of coatings for articles intended for repeated food-contact use.

[43 FR 44834, Sept. 29, 1978, as amended at 47 FR 11843, Mar. 19, 1982; 47 FR 14699, Apr. 6, 1982; 49 FR 10109, Mar. 19, 1984; 50 FR 1502, Jan. 11, 1985; 54 FR 24898, June 12, 1989; 61 FR 14481, Apr. 2, 1996]

§ 177.1555 Polyarylate resins.

Polyarylate resins (CAS Reg. No. 51706-10-6) may be safely used as articles or components of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) *Identity.* Polyarylate resins (1, 3-benzenedicarboxylic acid, diphenyl ester, polymer with diphenyl 1,4-benzenedicarboxylate and 4,4'-(1-methylethylidene) bis(phenol)) are formed by melt polycondensation of bisphenol-A with diphenylisophthalate and diphenylterephthalate.

(b) *Specifications.* (1) The finished copolymers shall contain from 70 to 80 weight percent of polymer units derived from diphenylisophthalate and 20 to 30 weight percent of polymer units derived from diphenylterephthalate.

(2) Polyarylate resins shall have a minimum weight average molecular weight of 20,000.

(3) Polyarylate resins may be identified by their characteristic infrared spectra.

(c) *Extractive limitations.* The finished polyarylate resins in sheet form at least 0.5 millimeter (0.020 inch) thick, when extracted with water at 121 °C

(250 °F) for 2 hours, shall yield total nonvolatile extractives not to exceed 2.33 micrograms per square centimeter (15 micrograms per square inch) of the exposed resin surface.

(d) *Limitations.* Polyarylate resin articles may be used in contact with all foods except beverages containing more than 8 volume percent ethanol under conditions of use A through H, described in table 2 of § 176.170(c) of this chapter.

[52 FR 35540, Sept. 22, 1987]

§ 177.1556 Polyaryletherketone resins.

The poly(oxy-1,4-phenylenecarbonyl-1,4-phenyleneoxy-1,4-phenylenecarbonyl-1,4-phenylene) resins (CAS Reg. No. 55088-54-5 and CAS Reg. No. 60015-05-6 and commonly referred to as polyaryletherketone resins) identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with food, subject to the provisions of this section.

(a) *Identity.* Polyaryletherketone resins consist of basic resins produced by reacting 4,4'-diphenoxy benzophenone and terephthaloyl dichloride in such a way that the finished resins have a minimum weight average molecular weight of 20,000 grams per mole, as determined by light scattering measurements in sulfuric acid at room temperature.

(b) *Optional adjuvant substances.* The basic polyaryletherketone resins identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic resins. These adjuvants may include substances used in accordance with § 174.5 of this chapter and the following:

(1) Benzoyl chloride, poly(tetrafluoroethylene).

(2) [Reserved]

(c) *Extractive limitations.* The finished food-contact article yields net total extractives in each extracting solvent not to exceed 0.052 milligram per square inch (corresponding to 0.008 milligram per square centimeter) of food-contact surface, when extracted at reflux temperature for 2 hours with the following solvents: Distilled water, 50 percent (by volume) ethyl alcohol in

§ 177.1560

distilled water, 3 percent acetic acid (by weight) in distilled water, and *n*-heptane.

(d) In testing the finished food-contact article made of polyaryletherketone resin, use a separate test sample for each required extracting solvent.

[61 FR 42381, Aug. 15, 1996]

§ 177.1560 Polyarylsulfone resins.

Polyarylsulfone resins (CAS Reg. No. 79293-56-4) may be safely used as articles or components of articles intended for use in contact with food, at temperatures up to and including normal baking temperatures, in accordance with the following prescribed conditions:

(a) *Identity.* Polyarylsulfone resins are copolymers containing not more than 25 percent of oxy-*p*-phenylene-oxy-*p*-phenylenesulfonyl-*p*-phenylene polymer units and not less than 75 percent of oxy-*p*-phenylenesulfonyl-*p*-phenylene-oxy-*p*-phenylenesulfonyl-*p*-phenylene polymer units. The copolymers have a minimum reduced viscosity of 0.40 deciliter per gram in 1-methyl-2-pyrrolidinone in accordance with ASTM method D2857-70 (Reapproved 1977), "Standard Test Method for Dilute Solution Viscosity of Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) *Optional adjuvant substances.* The basic polyarylsulfone resins identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic copolymers. These optional adjuvant substances may include substances permitted for such use by regulations in parts 170 through 179 of this chapter, substances generally recognized as safe in food, substances used in accordance with a prior sanction of approval, and substances named in this

21 CFR Ch. I (4-1-25 Edition)

paragraph and further identified as required:

Substances	Limitations
Sulfolane	Not to exceed 0.15 percent as residual solvent in the finished basic resin.

(c) *Extractive limitations.* The finished polyarylsulfone resin when extracted for 2 hours with the following solvents at the specified temperatures yields total extractives in each extracting solvent not to exceed 0.008 milligram per square centimeter of food-contact surface: distilled water at 121 °C (250 °F), 50 percent (by volume) ethyl alcohol in distilled water at 71.1 °C (160 °F), 3 percent acetic acid in distilled water at 100 °C (212 °F), and *n*-heptane at 65.6 °C (150 °F).

NOTE: In testing the finished polyarylsulfone resin use a separate test sample for each required extracting solvent.

[50 FR 31046, July 24, 1985]

§ 177.1570 Poly-1-butene resins and butene/ethylene copolymers.

The poly-1-butene resins and butene/ethylene copolymers identified in this section may be safely used as articles or components of articles intended for use in contact with food subject to the provisions of this section.

(a) *Identity.* Poly-1-butene resins are produced by the catalytic polymerization of 1-butene liquid monomer. Butene/ethylene copolymers are produced by the catalytic polymerization of 1-butene liquid monomer in the presence of small amounts of ethylene monomer so as to yield no higher than a 6-weight percent concentration of polymer units derived from ethylene in the copolymer.

(b) *Specifications and limitations.* Poly-1-butene resins and butene/ethylene copolymers shall conform to the specifications prescribed in paragraph (b)(1) of this section, and shall meet the extractability limits prescribed in paragraph (b)(2) of this section.

(1) *Specifications—(i) Infrared identification.* Poly-1-butene resins and butene/ethylene copolymers can be identified by their characteristic infrared spectra.

(ii) *Viscosity.* Poly-1-butene resins and the butene/ethylene copolymers have

an intrinsic viscosity 1.0 to 3.2 as determined by ASTM method D1601-78, "Standard Test Method for Dilute Solution Viscosity of Ethylene Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(iii) *Density.* Poly-1-butene resins have a density of 0.904 to 0.920 gms/cm³, and butene/ethylene copolymers have a density of 0.890 to 0.916 gms/cm³ as determined by ASTM method D1505-68 (Reapproved 1979), "Standard Test Method for Density of Plastics by the Density-Gradient Technique," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(ii) of this section.

(iv) *Melt index.* Poly-1-butene resins have a melt index of 0.1 to 24 and the butene/ethylene copolymers have a melt index of 0.1 to 20 as determined by ASTM method D1238-82, condition E, "Standard Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(ii) of this section.

(2) *Limitations.* Poly-1-butene resins and butene/ethylene copolymers for use in articles that contact food, and for articles used for packing or holding food during cooking shall yield no more than the following extractables:

(i) Poly-1-butene resins may be used as articles or components of articles intended for use in contact with food, provided that the maximum extractables do not exceed 2.5 percent by weight of the polymer when film or molded samples are tested for 2 hours at 50 °C (122 °F) in *n*-heptane.

(ii) Butene/ethylene copolymers containing no more than 6 percent by weight of polymer units derived from ethylene may be used as articles or components of articles intended for

contact with food under conditions of use B, C, D, E, F, G, or H described in table 2 of §176.170(c) of this chapter, subject to the provisions of this section and provided that the maximum extractables from test films 0.1 to 0.2 millimeter (0.004 to 0.008 inch) in thickness do not exceed 0.80 percent by weight of the polymer when extracted in a soxhlet extractor for 6 hours with refluxing 95 percent ethanol.

(iii) Poly-1-butene resins may be used as articles or components of articles intended for packaging or holding food during cooking, provided that the thickness of such polymers in the form in which they contact food shall not exceed 0.1 millimeter (0.004 inch) and yield maximum extractables of not more than 2.5 percent by weight of the polymer when films are extracted for 2 hours at 50 °C (122 °F) in *n*-heptane.

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10109, Mar. 19, 1984; 50 FR 31349, Aug. 2, 1985]

§ 177.1580 Polycarbonate resins.

Polycarbonate resins may be safely used as articles or components 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) Polycarbonate resins are polyesters produced by:

(1) The condensation of 4,4'-isopropylidenediphenol and carbonyl chloride to which may have been added certain optional adjuvant substances required in the production of the resins; or by

(2) The reaction of molten 4,4'-isopropylidenediphenol with molten diphenyl carbonate in the presence of the disodium salt of 4,4'-isopropylidenediphenol.

(3) The condensation of 4,4'-isopropylidenediphenol, carbonyl chloride, and 0.5 percent weight maximum of *a*2,*a*6-bis (6-hydroxy-*m*-tolyl) mesitol to which may have been added certain optional adjuvant substances required in the production of branched polycarbonate resins.

(b) The optional adjuvant substances required in the production of resins produced by the methods described in

§ 177.1585

paragraph (a)(1) and (3) of this section may include substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, and the following:

List of substances	Limitations
<i>p</i> -tert-Butylphenol Chloroform <i>p</i> -Cumylphenol (CAS Reg. No. 599-64-4).	For use only as a chain terminator at a level not to exceed 5 percent by weight of the resin.
Ethylene dichloride. Heptane. Methylene chloride. Monochlorobenzene	
Pentaerythritol tetrastearate (CAS Reg. No. 115-83-3).	Not to exceed 500 p.p.m. as residual solvent in finished resin.
Phenol (CAS Reg. No. 108-95-2). Pyridine. Toluene: (CAS Reg. No. 108-88-3).	For use only as a mold release agent, at a level not to exceed 0.5 percent by weight of the finished resin.
Triethylamine.	Not to exceed 800 parts per million as residual solvent in finished resin.

(c) Polycarbonate resins shall conform to the specification prescribed in paragraph (c)(1) of this section and shall meet the extractives limitations prescribed in paragraph (c)(2) of this section.

(1) *Specification*. Polycarbonate resins can be identified by their characteristic infrared spectrum.

(2) *Extractives limitations*. The polycarbonate resins to be tested shall be ground or cut into small particles that will pass through a U.S. standard sieve No. 6 and that will be held on a U.S. standard sieve No. 10.

(i) Polycarbonate resins, when extracted with distilled water at reflux temperature for 6 hours, shall yield total extractives not to exceed 0.15 percent by weight of the resins.

(ii) Polycarbonate resins, when extracted with 50 percent (by volume) ethyl alcohol in distilled water at reflux temperature for 6 hours, shall yield total extractives not to exceed 0.15 percent by weight of the resins.

(iii) Polycarbonate resins, when extracted with *n*-heptane at reflux temperature for 6 hours, shall yield total extractives not to exceed 0.15 percent by weight of the resins.

(d) Polycarbonate resins may be used in accordance with this section except

21 CFR Ch. I (4-1-25 Edition)

in infant feeding bottles (baby bottles) and spill-proof cups, including their closures and lids, designed to help train babies and toddlers to drink from cups (sippy cups).

[42 FR 14572, Mar. 15, 1977, as amended at 46 FR 23227, Apr. 24, 1981; 49 FR 4372, Feb. 6, 1984; 50 FR 14096, Apr. 10, 1985; 53 FR 29656, Aug. 8, 1988; 59 FR 43731, Aug. 25, 1994; 77 FR 41902, July 17, 2012]

§ 177.1585 Polyester carbonate resins.

Polyester carbonate resins may be safely used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, or holding food, in accordance with the following prescribed conditions:

(a) Polyester carbonate resins (CAS Reg. No. 71519-80-7) are produced by the condensation of 4,4'-isopropylidenediphenol, carbonyl chloride, terephthaloyl chloride, and isophthaloyl chloride such that the finished resins are composed of 45 to 85 molepercent ester, of which up to 55 mole-percent is the terephthaloyl isomer. The resins are manufactured using a phthaloyl chloride/carbonyl chloride mole ratio of 0.81 to 5.7/1 and isophthaloyl chloride/terephthaloyl chloride mole ratio of 0.81/1 or greater. The resins are also properly identified by CAS Reg. No. 114096-64-9 when produced with the use of greater than 2 but not greater than 5 weight percent *p*-cumylphenol (CAS Reg. No. 599-64-4), as an optional adjuvant substance in accordance with paragraph (b)(2) of this section.

(b) *Optional adjuvants*. The optional adjuvant substances required in the production of resins identified in paragraph (a) of this section may include:

(1) Substances used in accordance with § 174.5 of this chapter.

(2) Substances identified in § 177.1580(b).

(3) Substances regulated in § 178.2010(b) of this chapter for use in polycarbonate resins complying with § 177.1580:

Provided, That the substances are used in accordance with any limitation on concentration, conditions of use, and food types specified in § 178.2010(b) of this chapter.

(c) Polyestercarbonate resins shall conform to the specifications prescribed in paragraph (c)(1) of this section and shall meet the extractive limitations prescribed in paragraph (c)(2) of this section.

(1) *Specifications.* Polyestercarbonate resins identified in paragraph (a) of this section can be identified by their characteristic infrared spectrum. The resins shall comply with either or both of the following specifications:

(i) The solution intrinsic viscosity of the polyestercarbonate resins shall be a minimum of 0.44 deciliter per gram, as determined by a method entitled "Intrinsic Viscosity (IV) of Lexan® Polyestercarbonate Resin by a Single Point Method Using Dichloromethane as the Solvent," developed by the General Electric Co., September 20, 1985, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(ii) A minimum weight-average molecular weight of 27,000, as determined by gel permeation chromatography using polystyrene standards.

(2) *Extractives limitations.* The polyestercarbonate resins to be tested shall be ground or cut into small particles that will pass through a U.S. standard sieve No. 6 and that will be held on U.S. standard sieve No. 10.

(i) Polyestercarbonate resins, when extracted with distilled water at reflux temperature for 6 hours, shall yield total nonvolatile extractives not to exceed 0.005 percent by weight of the resins.

(ii) Polyestercarbonate resins, when extracted with 50 percent (by volume) ethyl alcohol in distilled water at

reflux temperature for 6 hours, shall yield total nonvolatile extractives not to exceed 0.005 percent by weight of the resins.

(iii) Polyestercarbonate resins, when extracted with *n*-heptane at reflux temperature for 6 hours, shall yield total nonvolatile extractives not to exceed 0.002 percent by weight of the resins.

(3) *Residual methylene chloride levels in polyestercarbonate resins.* Polyestercarbonate resin articles in the finished form shall not contain residual methylene chloride in excess of 5 parts per million as determined by a method titled "Analytical Method for Determination of Residual Methylene Chloride in Polyestercarbonate Resin," developed by the General Electric Co., July 23, 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

[57 FR 3940, Feb. 3, 1992, as amended at 64 FR 27178, May 19, 1999; 81 FR 5594, Feb. 3, 2015]

§ 177.1590 Polyester elastomers.

The polyester elastomers identified in paragraph (a) of this section may be safely used as the food-contact surface of articles intended for use in contact with bulk quantities of dry food of the type identified in §176.170(c) of this chapter, table 1, under Type VIII, in accordance with the following prescribed conditions:

(a) For the purpose of this section, polyester elastomers are those produced by the ester exchange reaction when one or more of the following phthalates—dimethyl terephthalate, and dimethyl isophthalate—is made to react with alpha-hydroxymethyl-hydroxypoly (oxytetramethylene) and/or 1,4-butanediol such that the finished elastomer has a number average molecular weight between 20,000 and 30,000.

(b) Optional adjuvant substances employed in the production of the polyester elastomers or added thereto to impart desired technical or physical properties may include the following substances:

List of substances	Limitations
4,4' - Bis (<i>alpha</i> , <i>alpha</i> -dimethyl-benzyl) diphenylamine.	For use only as an anti-oxidant.
Tetrabutyl titanate	For use only as a catalyst.

(c) An appropriate sample of the finished polyester elastomer in the form in which it contacts food when subjected to ASTM method D968-81, "Standard Test Methods for Abrasion Resistance of Organic Coatings by the Falling Abrasive Tester," which is incorporated by reference (Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html), using No. 50 emery abrasive in lieu of Ottawa sand, shall exhibit an abrasion coefficient of not less than 100 liters per mil of thickness.

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10109, Mar. 19, 1984; 87 FR 31089, May 20, 2022]

§ 177.1595 Polyetherimide resin.

The polyetherimide resin identified in this section may be safely used as an article or component of an article intended for use in contact with food, subject to the provisions of this section.

(a) *Identity.* For the purpose of this section, the polyetherimide resin is 1,3-isobenzofurandione, 5,5'[(1-methylethylidene)bis(4,1-phenyleneoxy)] bis-polymer with 1,3-benzenediamine (CAS Reg. No. 61128-46-9), and is derived from the condensation reaction of *m*-phenylenediamine and bisphenol A-dianhydride.

(b) *Optional adjuvants.* The basic polymer identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of basic resins or finished food-

contact articles. The optional adjuvant substances required in the production of the basic polymer may include substances permitted for such use by applicable regulations as set forth in part 174 of this chapter.

(c) *Specifications and extractives limitations—(1) Specifications.* Polyetherimide resin identified in paragraph (a) of this section shall have an intrinsic viscosity in chloroform at 25 °C (77 °F) of not less than 0.35 deciliter per gram as determined by a method titled "Intrinsic Viscosity of ULTEM Polyetherimide Using Chloroform as the Solvent," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(2) *Extractive limitations.* Extractive limitations are applicable to the basic polyetherimide resin in the form of molded discs of thickness 0.16 centimeter (0.063 inch). The resin discs when extracted with distilled water at 121 °C (250 °F) for 2 hours yield total nonvolatile extractives of not more than 12.3 micrograms per square centimeter.

[50 FR 31351, Aug. 2, 1985; 50 FR 35535, Sept. 3, 1985]

§ 177.1600 Polyethylene carboxyl modified. resins,

Carboxyl-modified polyethylene resins may be safely used as the food-contact surface of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) For the purpose of this section, carboxyl-modified polyethylene resins consist of basic polymers produced when ethylene-methyl acrylate basic copolymers, containing no more than 25 weight percent of polymer units derived from methyl acrylate, are made to react in an aqueous medium with one or more of the following substances:

Ammonium hydroxide.
Calcium carbonate.
Potassium hydroxide.
Sodium hydroxide.

(b) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of §176.170(c) of this chapter, yields total extractives in each extracting solvent not to exceed 0.5 milligram per square inch of food-contact surface as determined by the methods described in §176.170(d) of this chapter; and if the finished food-contact article is itself the subject of a regulation in parts 174, 175, 176, 177, 178, and §179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation. In testing the finished food-contact articles, a separate test sample is to be used for each required extracting solvent.

(c) The provisions of paragraph (b) of this section are not applicable to carboxyl-modified polyethylene resins used in food-packaging adhesives complying with §175.105 of this chapter.

§ 177.1610 Polyethylene, chlorinated.

Chlorinated polyethylene identified in this section may be safely used as articles or components of articles that contact food, except for articles used for packing or holding food during cooking, subject to the provisions of this section.

(a) For the purpose of this section, chlorinated polyethylene consists of basic polymers produced by the direct chlorination of polyethylene conforming to the density, maximum *n*-hexane extractable fraction, and maximum xylene soluble fraction specifications prescribed under item 2.1 of the table in §177.1520(c). Such chlorinated polyethylene contains a maximum of 60 percent by weight of total chlorine, as determined by ASTM method D1303-55 (Reapproved 1979), "Standard Test Method for Total Chlorine in Vinyl Chloride Polymers and Copolymers," which is incorporated by reference (Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West

Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html), and has a 7.0 percent maximum extractable fraction in *n*-hexane at 50 °C, as determined by the method described in §177.1520(d)(3)(ii).

(b) Chlorinated polyethylene may be used in contact with all types of food, except that when used in contact with fatty food of Types III, IV-A, V, VII-A, and IX described in table 1 of §176.170(c) of this chapter, chlorinated polyethylene is limited to use only as a modifier admixed at levels not exceeding 15 weight percent in plastic articles prepared from polyvinyl chloride and/or from vinyl chloride copolymers complying with §177.1980.

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10109, Mar. 19, 1984; 59 FR 14550, Mar. 29, 1994]

§ 177.1615 Polyethylene, fluorinated.

Fluorinated polyethylene, identified in paragraph (a) of this section, may be safely used as food-contact articles in accordance with the following prescribed conditions:

(a) Fluorinated polyethylene food-contact articles are produced by modifying the surface of polyethylene articles through action of fluorine gas in combination with gaseous nitrogen as an inert diluent. Such modification affects only the surface of the polymer, leaving the interior unchanged. Fluorinated polyethylene articles are manufactured from basic resins containing not less than 85 weight-percent of polymer units derived from ethylene and identified in §177.1520 (a)(2) and (3)(i).

(b) Fluorinated polyethylene articles conform to the specifications and use limitations of §177.1520(c), items 2.1 and 3.1.

(c) The finished food-contact article, 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

§ 177.1620

tables 1 and 2 of §176.170(c) of this chapter, yields fluoride ion not to exceed 5 parts per million calculated on the basis of the volume of food held by the food-contact article.

[48 FR 39057, Aug. 29, 1983]

§ 177.1620 Polyethylene, oxidized.

Oxidized polyethylene identified in paragraph (a) of this section may be safely used as a component of food-contact articles, in accordance with the following prescribed conditions:

(a) Oxidized polyethylene is the basic resin produced by the mild air oxidation of polyethylene conforming to the density, maximum *n*-hexane extractable fraction, and maximum xylene soluble fraction specifications prescribed under item 2.3 of the table in §177.1520(c). Such oxidized polyethylene has a minimum number average molecular weight of 1,200, as determined by high temperature vapor pressure osmometry, contains a maximum of 5 percent by weight of total oxygen, and has an acid value of 9 to 19.

(b) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of §176.170(c) of this chapter, yields net acidified chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface when tested by the methods described in §177.1330(c), except that net acidified chloroform-soluble extractives from paper and paperboard complying with §176.170 of this chapter may be corrected for wax, petrolatum, and mineral oil as provided in §176.170(d)(5)(iii)(b) of this chapter. If the finished food-contact article is itself the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by such regulations. (NOTE: In testing the finished food-contact article, use a separate test sample for each extracting solvent.)

(c) The provisions of this section are not applicable to oxidized polyethylene used as provided in §§175.105 and 176.210 of this chapter, and §177.2800. The provisions of paragraph (b) of this section

21 CFR Ch. I (4–1–25 Edition)

are not applicable to oxidized polyethylene used as provided in §§175.125 and 176.170(a)(5) of this chapter and §177.1200.

§ 177.1630 Polyethylene phthalate polymers.

Polyethylene phthalate polymers identified in this section may be safely used as, or components of plastics (films, articles, or fabric) intended for use in contact with food in accordance with the following prescribed conditions:

(a) Polyethylene phthalate films consist of a base sheet of ethylene terephthalate polymer, ethylene terephthalate-isophthalate copolymer, or ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in §177.1315(b)(3), to which have been added optional substances, either as constituents of the base sheet or as constituents of coatings applied to the base sheet.

(b) Polyethylene phthalate articles consist of a base polymer of ethylene terephthalate polymer, or ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in §177.1315(b)(3), to which have been added optional substances, either as constituents of the base polymer or as constituents of coatings applied to the base polymer.

(c)(1) Polyethylene phthalate spunbonded nonwoven fabric consist of continuous filaments of ethylene terephthalate polymer and ethylene terephthalate-isophthalate copolymer to which may have been added optional adjuvant substances required in their preparation and finishing.

(2) The ethylene terephthalate-isophthalate copolymer component of the fabric shall not exceed 25 percent by weight. The filaments may be blended with other fibers regulated for the specific use and the spunbonded fabric may be further bonded by application of heat and/or pressure.

(3) The fabric shall be used only in accordance with paragraph (i) of this section.

(d) The quantity of any optional substance employed in the production of polyethylene phthalate plastics does not exceed the amount reasonably required to accomplish the intended

physical or technical effect or any limitations further provided. Any substance employed in the production of polyethylene phthalate plastics that is the subject of a regulation in parts 174, 175, 176, 177, 178 and 179 of this chapter conforms with any specification in such regulation.

(e) Substances employed in the production of polyethylene phthalate plastics include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in polyethylene phthalate plastics and used in accordance with such sanction or approval.

(3) Substances which by regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter may be safely used as components of resinous or polymeric food-contact surfaces subject to the provisions of such regulation.

(4) Substances identified in this paragraph (e)(4) subject to the limitations prescribed:

LIST OF SUBSTANCES AND LIMITATIONS

(i) Base sheet:

Ethylene terephthalate copolymers: Prepared by the condensation of dimethyl terephthalate or terephthalic acid with ethylene glycol, modified with one or more of the following: Azelaic acid, dimethyl azelate, dimethyl sebacate, sebacic acid.

Ethylene terephthalate copolymers: Prepared by the condensation of dimethyl terephthalate or terephthalic acid with ethylene glycol, modified with one or more of the following: Azelaic acid, dimethyl azelate, dimethyl sebacate, sebacic acid, pyromellitic dianhydride. The level of pyromellitic dianhydride shall not exceed 0.5 percent by weight of the finished copolymer which may be used under conditions of use E through H as described in table 2 of §176.170(c) of this chapter.

Ethylene terephthalate-isophthalate copolymers: Prepared by the condensation of dimethyl terephthalate or terephthalic acid and dimethyl isophthalate or isophthalic acid with ethylene glycol. The finished copolymers contain either:

- (a) 77 to 83 weight percent or
- (b) At least 97 weight percent of polymer units derived from ethylene terephthalate.

(ii) Base sheet and base polymer:

Ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in §177.1315(b)(3).

Ethylene terephthalate polymer: Prepared by the condensation of dimethyl terephthalate and ethylene glycol.

Ethylene terephthalate polymer: Prepared by the condensation of terephthalic acid and ethylene glycol.

(iii) Coatings:

Acrylic copolymers (CAS Reg. No. 30394-86-6): Prepared by reaction of ethyl acrylate (CAS Reg. No. 140-88-5), methyl methacrylate (CAS Reg. No. 80-62-6), and methacrylamide (CAS Reg. No. 79-39-0) blended with melamine-formaldehyde resin (CAS Reg. No. 68002-20-0). For use in coatings for polyethylene phthalate films complying with paragraph (a) of this section.—

Ethylene azelate-terephthalate copolymer: The copolymer, dissolved in 1,1,2-trichloroethane and/or methylene chloride, may be used as a heat-activated sealant on polyethylene terephthalate film intended for sealing polyethylene terephthalate pouches that are used as containers of either nonalcoholic beverages or alcoholic beverages containing not more than 15 percent ethyl alcohol. The copolymer has a terephthalate/azelate molecular ratio of 1.25/1.00 and a relative viscosity of not less than 1.5 as determined by a method title "General Procedure of Determining the Relative Viscosity of Resin Polymers," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection, at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/code-of-federal-regulations/ibr-locations.html>. Total residual copolymer solvent (1,1,2-trichloroethane and/or methylene chloride) shall not exceed 0.13 milligram per square inch of film, and food contact of the film shall be limited to not more than 1 square inch per 250 grams of beverage.

2-Ethylhexyl acrylate copolymerized with one or more of the following:

Acrylonitrile.
Methacrylonitrile.
Methyl acrylate.
Methyl methacrylate.
Itaconic acid.

Vinylidene chloride copolymerized with one or more of the following:

Methacrylic acid and its methyl, ethyl, propyl, butyl, or octyl esters.
Acrylic acid and its methyl, ethyl, propyl, butyl, or octyl esters.

Acrylonitrile.
Methacrylonitrile.
Vinyl chloride.
Itaconic acid.

Styrene-maleic anhydride resin, partial 2-butoxyethyl ester, ammonium salt (CAS Reg. No. 68890-80-2). For use only as a coating for polyethylene phthalate films complying with paragraph (a) of this section, at levels not to exceed 0.025 gram per square meter (0.016 milligram per square inch) of the film, in contact with food of types VIII and IX in table 1 of §176.170(c) of this chapter, under use conditions E, F, and G in table 2 of §176.170(c) of this chapter.

(iv) Emulsifiers:

Sodium dodecylbenzenesulfonate: As an adjuvant in the application of coatings to the base sheet or base polymer.

Sodium lauryl sulfate: As an adjuvant in the application of coatings to the base sheet or base polymer.

2-Sulfoethyl methacrylate, sodium salt (CAS Reg. No. 1804-87-1). For use only in copolymer coatings on polyethylene phthalate film under conditions of use E, F, and G described in table 2 of §175.300(d) of this chapter, and limited to use at a level not to exceed 2.0 percent by weight of the dry copolymer coating.

(v) Modifier:

1,4-Benzenedicarboxylic acid, dimethyl ester, polymer with 1,4-butanediol and α -hydro- ω -hydroxypoly(oxy-1,4-butanediyl) (CAS Reg. No. 9078-71-1) meeting the following specifications:

Melting point: 200° to 215 °C as determined by ASTM method D2117-82, “Standard Test Method for Melting Point of Semicrystalline Polymers by the Hot Stage Microscopy Method,” which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Density: 1.15 to 1.20 as determined by ASTM method D1505-68 (Reapproved 1979), “Standard Test Method for Density of Plastics by the Density-Gradient Technique,” which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

code_of_federal_regulations/ibr_locations.html.

The modifier is used at a level not to exceed 5 percent by weight of polyethylene terephthalate film. The average thickness of the finished film shall not exceed 0.016 millimeter (0.0006 inch).

Hexanedioic acid polymer with 1,3-benzenedimethanamine (CAS Reg. No. 25718-70-1) meeting the specifications in §177.1500(b), item 10, when tested by the methods given in §177.1500(c). The modifier is used in polyethylene terephthalate at a level not to exceed 30 percent by weight of the polyethylene terephthalate.

Chloroform-soluble extractives shall not exceed 0.08 milligram/centimeter² (0.5 milligram/inch²) of food-contact surface of the modified polyethylene terephthalate article when exposed to the following solvents at temperatures and times indicated:

- (a) Distilled water at 49 °C (120 °F) for 24 hours;
- (b) *n*-Heptane at 49 °C (120 °F) for 24 hours;
- (c) 8 percent ethyl alcohol at 49 °C (120 °F) for 24 hours.

For use in contact with all types of foods except (a) those containing more than 8 percent alcohol, or (b) those at temperatures over 49 °C (120 °F).

(f) Polyethylene phthalate plastics conforming with the specifications prescribed in paragraph (f)(1) of this section are used as provided in paragraph (f)(2) of this section:

(1) *Specifications.* (i) The food contact surface, when exposed to distilled water at 250 °F for 2 hours, yields chloroform-soluble extractives not to exceed 0.5 mg/in² of food contact surface exposed to the solvent; and

(ii) The food contact surface, when exposed to *n*-heptane at 150 °F for 2 hours, yields chloroform-soluble extractives not to exceed 0.5 mg/in² of food contact surface exposed to the solvent.

(2) *Conditions of use.* The plastics are used for packaging, transporting, or holding food, excluding alcoholic beverages, at temperatures not to exceed 250 °F.

(g) Polyethylene phthalate plastics conforming with the specifications prescribed in paragraph (g)(1) of this section are used as provided in paragraph (g)(2) of this section.

(1) *Specifications.* (i) The food contact surface meets the specifications in paragraph (f)(1) of this section; and

(ii) The food contact surface when exposed to 50 percent ethyl alcohol at 120 °F for 24 hours, yields chloroform-soluble extractives not to exceed 0.5 mg/in² of food contact surface exposed to the solvent.

(2) *Conditions of use.* The plastics are used for packaging, transporting, or holding alcoholic beverages that do not exceed 50 percent alcohol by volume.

(h) Uncoated polyethylene phthalate plastics consisting of a base sheet or base polymer prepared as prescribed from substances identified in paragraphs (e)(4)(i) and (ii) of this section and conforming with the specifications prescribed in paragraph (h)(1) of this section are used as provided in paragraph (h)(2) of this section:

(1) *Specifications.* (i) The food contact surface, when exposed to distilled water at 250 °F for 2 hours yields chloroform-soluble extractives not to exceed 0.02 milligram/inch² of food contact surface exposed to the solvent; and

(ii) The food contact surface, when exposed to *n*-heptane at 150 °F for 2 hours, yields chloroform-soluble extractives not to exceed 0.02 milligram/inch² of food contact surface exposed to the solvent.

(2) *Conditions of use.* The plastics are used to contain foods during oven baking or oven cooking at temperatures above 250 °F.

(i) Polyethylene phthalate fabric, identified in paragraph (c) of this section and conforming with the specifications prescribed in paragraph (i)(1) of this section, is used only as provided in paragraph (i)(2) of this section.

(1) *Specifications.* Chloroform-soluble extractives shall not exceed 0.2 milligram/inch² of food-contact surface when exposed to the following solvents at temperatures and times indicated:

(i) Distilled water at 212 °F for 2 hours.

(ii) *n*-Heptane at 150 °F for 2 hours.

(iii) 50 percent ethyl alcohol at 120 °F for 24 hours.

(2) *Conditions of use.* The plastics are intended for:

(i) Dry food contact.

(ii) Bulk food (excluding alcoholic beverages) repeated use applications, including filtration, at temperatures not exceeding 212 °F.

(iii) Filtration of bulk alcoholic beverages, not exceeding 50 percent alcohol by volume, at temperatures not exceeding 120 °F.

(j) Polyethylene phthalate plastics, composed of ethylene terephthalate-isophthalate containing a minimum of 98 weight percent of polymer units derived from ethylene terephthalate, or ethylene-1,4-cyclohexylene

dimethylene terephthalate copolyesters described in §177.1315(b)(3), conforming with the specifications prescribed in paragraph (j)(1) of this section, are used as provided in paragraph (j)(2) of this section.

(1) *Specifications.* (i) The food contact surface meets the specifications in paragraph (f)(1) of this section and

(ii)(a) *Containers with greater than 500 mL capacity.* The food-contact surface when exposed to 95 percent ethanol at 120 °F for 24 hours should not yield chloroform-soluble extractives in excess of 0.005 mg/in².

(b) *Containers with less than or equal to 500 mL capacity.* The food contact surface when exposed to 95 percent ethanol at 120 °F for 24 hours should not yield chloroform-soluble extractives in excess of 0.05 mg/in².

(2) *Conditions of use.* The plastics are used for packaging, transporting, or holding alcoholic foods that do not exceed 95 percent alcohol by volume.

[42 FR 14572, Mar. 15, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §177.1630, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 177.1632

Poly(phenyleneterephthalamide) resins.

Poly(phenyleneterephthalamide) resins identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated contact with food.

(a) *Identity.* For the purpose of this section, the poly(phenylene-terephthalamide) resins (CAS Reg. No. 26125-61-1) are produced by the polymerization of terephthaloyl chloride with *p*-phenylenediamine. The poly(phenyleneterephthalamide) resin fibers and yarns may contain optional

adjuvant substances required in their preparation and finishing.

(b) *Optional adjuvant substances.* The poly(phenyleneterephthalamide) resins identified in paragraph (a) of this section may contain the following optional adjuvant substances, subject to any limitation on their use:

(1) Optional adjuvant substances authorized for this use in accordance with § 174.5 of this chapter.

(2) Optional finish components, total weight not to exceed 1 percent by weight of the base polymer, as follows:

List of substances	Limitations
Diundecylphthalate (CAS Reg. No. 3648–20–2). Mono- and dipotassium salts of lauryl phosphate (CAS Reg. No. 39322–78–6). o-Phenylphenol (CAS Reg. No. 90–43–7).	For use as a fungicide for finish coating materials. Not to exceed 0.01 percent by weight of the base polymer.
Poly(oxyethylene/oxypropylene)monobutylether (CAS Reg. No. 9038–95–3). Poly(oxyethylene)mono(nonylphenyl)ether (CAS Reg. No. 9016–45–9). Polyvinyl methylether (CAS Reg. No. 9003–09–2). Poly(oxyethylene) sorbitol monolaurate tetraoleate (CAS Reg. No. 71243–28–2). Poly(oxyethylene) sorbitol hexaoleate (CAS Reg. No. 57171–56–9).	
4,4'-Butylidenebis (6-tert-butyl-m-cresol) (CAS Reg. No. 85–60–9).	For use only as an oxidation inhibitor for finish coating materials. Not to exceed 0.01 percent by weight of the base polymer.

(c) *Specifications.* (1)

Poly(phenyleneterephthalamide) resins in the form of continuous filament yarns or fibers that have been scoured in accordance with paragraph (d)(1) of this section, when refluxed in a 50 percent ethanol/water mixture for 24 hours, yields total extractables not exceeding 0.5 percent by weight of the sample.

(2) Poly(phenyleneterephthalamide) resins in the form of pulp, when refluxed in a 50 percent ethanol/water mixture for 24 hours, yields total extractables not exceeding 0.65 percent by weight of the sample.

(d) *Conditions of use.* (1) Poly(phenyleneterephthalamide) resins in the form of continuous filament yarns and fibers may be used as components of articles intended for repeated use in contact with food at temperatures not to exceed 260 °C (500 °F). All items are scoured prior to use by agitation in a water bath containing 0.5 gram/liter of tetrasodium pyrophosphate and 0.5 percent detergent. The items are agitated at 80 °C (180 °F) for 20 minutes, and then subjected to a cold water rinse.

(2) Poly(phenyleneterephthalamide) resins in the form of pulp may be used as gaskets and packing for food processing equipment at temperatures not to exceed 260 °C (500 °F).

[57 FR 3125, Jan. 28, 1992, as amended at 69 FR 24512, May 4, 2004]

§ 177.1635 Poly(*p*-methylstyrene) and rubber-modified poly(*p*-methylstyrene).

Poly(*p*-methylstyrene) and rubber-modified poly(*p*-methylstyrene) identified in this section may be safely used as components of articles intended for use in contact with food, subject to the provisions of this section:

(a) *Identity.* For the purposes of this section, poly(*p*-methylstyrene) and rubber-modified poly(*p*-methylstyrene) are basic polymers, manufactured as described in this paragraph, meeting the specifications prescribed in paragraph (c) of this section.

(1) Poly(*p*-methylstyrene) (CAS Reg. No. 24936–41–2) polymer produced by the polymerization of *p*-methylstyrene.

(2) Rubber-modified poly(*p*-methylstyrene) (CAS Reg. No. 33520–88–6) polymer produced by combining styrene-butadiene copolymer and/or polybutadiene with poly(*p*-methylstyrene), either during or after polymerization of the poly(*p*-methylstyrene), such that the finished polymers contain not less than 75 weight percent of total polymer units derived from *p*-methylstyrene) monomer.

(b) *Optional adjuvants.* The basic polymers identified in paragraph (a) of

this section may contain optional adjuvant substances required in the production of such basic polymers. Such optional adjuvant substances may include substances permitted for such use by applicable regulations in this chapter, substances generally recognized as safe in food, substances generally recognized as safe in indirect additives, and substances used in accordance with prior sanction or approval.

(c) *Specifications.* (1) Poly(*p*-methylstyrene) basic polymers identified in paragraph (a)(1) of this section shall contain not more than 1 weight percent of total residual *p*-methylstyrene monomer, as determined by a gas chromatographic method titled, "Gas Chromatographic Determination of PMS and PET in PPMS Basic Polymers," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/code-of-federal-regulations/ibr-locations.html>.

(2) Rubber-modified poly(*p*-methylstyrene) basic polymers identified in paragraph (a)(2) of this section shall contain not more than 0.5 weight percent of total residual *p*-methylstyrene monomer, as determined by the method identified in paragraph (c)(1) of this section.

(d) *Other specifications and limitations.* The poly(*p*-methylstyrene) and rubber-modified poly(*p*-methylstyrene) identified in and complying with this section, when used as components of the food-contact surface of any article that is the subject of a regulation in parts 175, 176, 177, 178 and § 179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(e) *Conditions of use.* Poly(*p*-methylstyrene) basic polymers and rubber-modified poly(*p*-methylstyrene) basic polymers identified in paragraphs (a)(1) and (a)(2), respectively, of this

section shall be used in contact with food only under conditions of use B through H set forth in table 2 of § 176.170(c) of this chapter.

[48 FR 31384, July 8, 1983, as amended at 54 FR 24898, June 12, 1989; 55 FR 52989, Dec. 26, 1990]

§ 177.1637 Poly(oxy-1,2-ethanediylloxycarbonyl-2,6-naphthalenediylcarbonyl) resins.

Poly(oxy-1,2-ethanediylloxycarbonyl-2,6-naphthalenediylcarbonyl) resins identified in paragraph (a) of this section may be safely used as articles or components of articles intended for use in contact with food in accordance with the following conditions:

(a) *Identity.* For the purpose of this section, poly(oxy-1,2-ethanediylloxycarbonyl-2,6-naphthalenediylcarbonyl) resins (CAS Reg. No. 24968-11-4) are polymers formed by catalytic transesterification of 2,6-dimethylnaphthalene dicarboxylate with ethylene glycol followed by catalytic polycondensation.

(b) *Specifications—(1) Density.* The density of poly(oxy-1,2-ethanediylloxycarbonyl-2,6-naphthalenediylcarbonyl) resins shall be between 1.33 and 1.40 grams per cubic centimeter.

(2) *Inherent viscosity.* The finished food-contact article shall have a minimum inherent viscosity of 0.55 deciliter per gram in a solution of 0.1 gram of polymer in 100 milliliters of a 25/40/35 (weight/weight/weight) solution of *p*-chlorophenol/tetrachloroethane/phenol. The viscosity is determined by Eastman Chemical Co.'s method ECD-A-AC-G-V-1-5, "Determination of Dilute Solution Viscosity of Polyesters," dated May 31, 1988, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this

material at NARA, call 202–741–6030, or go to: <http://www.archives.gov/federal-register/code-of-federal-regulations/ibr-locations.html>.

(c) *Extraction limitations.* A 0.5 millimeter (0.02 inch) thick sheet of resin when extracted with water at 121 °C (250 °F) for 2 hours shall yield total nonvolatile extractives not exceeding 2.0 micrograms per square inch of exposed resin surface.

(d) *Conditions of use.* The finished food contact article shall be:

(1) Used in contact only with food of Types I, II, IVB, VIA, VIB, VIIB, and VIII identified in table 1 of §176.170(c) of this chapter, under conditions of use A through H described in table 2 of §176.170(c) of this chapter; and with food of Types III, IVA, V, VIC, VIIA, and IX identified in table 1 of §176.170(c) of this chapter, under conditions of use C through H described in table 2 of §176.170(c) of this chapter; and

(2) Identified in a manner that will differentiate the article from articles made of other polymeric resins to facilitate collection and sorting.

[61 FR 14965, Apr. 4, 1996, as amended at 78 FR 14666, Mar. 7, 2013; 81 FR 5594, Feb. 3, 2016]

§ 177.1640 Polystyrene and rubber-modified polystyrene.

Polystyrene and rubber-modified polystyrene identified in this section may be safely used as components of articles intended for use in contact with food, subject to the provisions of this section.

(a) *Identity.* For the purposes of this section, polystyrene and rubber-modified polystyrene are basic polymers manufactured as described in this paragraph so as to meet the specifications prescribed in paragraph (c) of this section when tested by the method described in paragraph (d) of this section.

(1) Polystyrene consists of basic polymers produced by the polymerization of styrene.

(2) Rubber-modified polystyrene consists of basic polymers produced by combining styrene-butadiene copolymers and/or polybutadiene with polystyrene, either during or after polymerization of the polystyrene, such that the finished basic polymers contain not less than 75 weight percent of total

polymer units derived from styrene monomer.

(b) *Optional adjuvants.* The basic polymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic polymers. Such optional adjuvant substances may include substances permitted for such use by regulations in parts 170 through 189 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) *Specifications.* (1) Polystyrene basic polymers identified in paragraph (a)(1) of this section shall contain not more than 1 weight percent of total residual styrene monomer, as determined by the method described in paragraph (d) of this section, except that when used in contact with fatty foods of Types III, IV-A, V, VII-A, and IX described in table 1 of §176.170(c) of this chapter, such polystyrene basic polymers shall contain not more than 0.5 weight percent of total residual styrene monomer.

(2) Rubber-modified polystyrene basic polymers identified in paragraph (a)(2) of this section shall contain not more than 0.5 weight percent of total residual styrene monomer, as determined by the method described in paragraph (d) of this section.

(d) *Analytical method for determination of total residual styrene monomer content—*(1) *Scope.* This method is suitable for the determination of residual styrene monomer in all types of styrene polymers.

(2) *Principle.* The sample is dissolved in methylene chloride. An aliquot of the solution is injected into a gas chromatograph. The amount of styrene monomer present is determined from the area of the resulting peak.

(3) *Apparatus—*(i) *Gas chromatograph.* Beckman GC-2A gas chromatograph with hydrogen flame detector or apparatus of equivalent sensitivity.

(ii) *Chromatograph column.* One-quarter inch outside diameter stainless steel tubing (0.028 inch wall thickness), 4 feet in length, packed with 20 percent polyethylene glycol (20,000 molecular weight) on alkaline treated 60–80 mesh firebrick.

(iii) *Recorder.* Millivolt range of 0–1, chart speed of 30 inches per hour.

(4) *Reagents.* Compressed air, purified; helium gas; hydrogen gas; methylene chloride, redistilled; and styrene monomer, redistilled.

(5) *Operating conditions for the gas chromatograph.* (i) The column is operated at a temperature of 100 °C with a helium flow rate of 82 milliliters per minute.

(ii) The hydrogen burner is operated with 15 pounds per square inch of air pressure and 7 pounds per square inch of hydrogen pressure.

(iii) The attenuation of the hydrogen flame detector is set at 2×10^2 .

(6) *Standardization.* (i) Prepare a standard solution by weighing accurately 15 to 20 milligrams of styrene monomer into a 2-ounce bottle containing 25.0 milliliters of methylene chloride. Cap the bottle tightly and shake to thoroughly mix the solution.

(ii) By means of a microliter syringe, inject 1 microliter of the standard solution into the gas chromatograph. Measure the area of the styrene monomer peak which emerges after approximately 12 minutes.

(7) *Procedure.* (i) Transfer 1 gram of sample (accurately weighed to the nearest 0.001 gram to a 2-ounce bottle and add several glass beads. Pipette 25.0 milliliters of methylene chloride into the bottle. Cap the bottle tightly and place on a mechanical shaker. Shake until the polymer is completely dissolved. If any insoluble residue remains, allow the bottle to stand (or centrifuge at a low speed) until a clear supernatant layer appears.

(ii) By means of a microliter syringe, inject 3 microliters of the clear supernatant liquid into the gas chromatograph.

(iii) Measure the area of the resulting styrene monomer peak. Compare the sample peak area with the area produced by the standard styrene monomer solution. Calculation:

Percent residual styrene monomer = $\frac{\text{Milligrams monomer in standard} \times \text{peak area of sample}}{\text{Peak area of monomer standard} \times \text{sample weight in grams}} \times 30$

(e) *Other specifications and limitations.* The polystyrene and rubber-modified polystyrene identified in and complying with this section, when used as

components of the food-contact surface of any article that is the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(f) *Nonapplicability.* The provisions of this section are not applicable to polystyrene and rubber-modified polystyrene used in food-packaging adhesives complying with §175.105 of this chapter.

§ 177.1650 Polysulfide polymer-polyepoxy resins.

Polysulfide polymer-polyepoxy resins may be safely used as the food-contact surface of articles intended for packaging, transporting, holding, or otherwise contacting dry food, in accordance with the following prescribed conditions:

(a) Polysulfide polymer-polyepoxy resins are the reaction products of liquid polysulfide polymers and polyfunctional epoxide resins, cured with the aid of tri(dimethylaminomethyl) phenol, to which have been added certain optional substances to impart desired technological properties to the resins. Subject to any limitations prescribed in this section, the optional substances may include:

(1) Substances generally recognized as safe in food and food packaging.

(2) Substances the use of which is permitted under applicable regulations in this part, prior sanctions, or approvals.

(3) Substances named in this subparagraph and further identified as required:

List of substances	Limitations
Bis(2-chloroethyl) formal.	Cross-linking agent.
Bis(dichloropropyl) formal	
Butyl alcohol	Solvent.
Carbon black (channel process).	Cross-linking agent.
Chlorinated paraffins	
Epoxidized linseed oil.	
Epoxidized soybean oil.	
Epoxy resins (as listed in § 175.300(b)(3)(viii)(a) of this chapter) ..	
Ethylene glycol monobutyl ether	Solvent.
Magnesium chloride.	Solvent.
Methyl isobutyl ketone	
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt.	

List of substances	Limitations
Sodium dibutyl naphthalene sulfonate. Sodium hydrosulfide. Sodium polysulfide. $\beta,\beta',\gamma,\gamma'$ -Tetrachloro normal propyl ether. Titanium dioxide.	Wetting agent.
Toluene Trichloroethane 1,2,3-Trichloropropane Urea-formaldehyde resins.	Cross-linking agent.
Xylene	Solvent.

(b) The resins are used as the food-contact surface for dry food.

(c) An appropriate sample of the finished resin in the form in which it contacts food, when subjected to ASTM method D968–81, “Standard Test Methods for Abrasion Resistance of Organic Coatings by the Falling Abrasive Tester,” which is incorporated by reference (Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html), using No. 50 Emery abrasive in lieu of Ottawa sand, shall exhibit an abrasion coefficient of not less than 20 liters per mil of film thickness.

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10110, Mar. 19, 1984]

§ 177.1655 Polysulfone resins.

Polysulfone resins identified in paragraph (a) of this section may be safely used as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, polysulfone resins are:

(1) Poly(oxy-*p*-phenylenesulfonyl-*p*-phenyleneoxy-*p*-phenyleneisopropylidene-*p*-phenylene) resins (CAS Reg. No. 25154–01–2) consisting of basic resins produced when the disodium salt of 4,4'-isopropylidenediphenol is made to react with 4,4'-dichlorodiphenyl sulfone in such a way that the finished resins have a minimum number average mo-

lecular weight of 15,000, as determined by osmotic pressure in monochlorobenzene; or

(2) 1,1'-Sulfonylbis[4-chlorobenzene] polymer with 4,4'-(1-methylethylidene)bis[phenol] (minimum 92 percent) and 4,4'-sulfonylbis[phenol] (maximum 8 percent) (CAS Reg. No. 88285–91–0) produced when a mixture of 4,4'-isopropylidenediphenol (minimum 92 percent) and 4,4'-sulfonylbis[phenol] (maximum 8 percent) is made to react with 4,4'-dichlorodiphenyl sulfone in such a way that the finished resin has a minimum number average molecular weight of 26,000, as determined by osmotic pressure in dimethylformamide.

(b) The basic polysulfone resins identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic resins. The optional adjuvant substances required in the production of the basic polysulfone resins may include substances described in § 174.5(d) of this chapter and the following:

List of substances	Limitations
Dimethyl sulfoxide	Not to exceed 50 parts per million as residual solvent in finished basic resin in paragraph (a)(1) of this section.
Monochlorobenzene ..	Not to exceed 500 parts per million as residual solvent in finished basic resin in paragraph (a)(1) of this section.
<i>N</i> -methyl-2-pyrrolidone.	Not to exceed 0.01 percent (100 parts per million) as residual solvent in finished basic resin in paragraph (a)(2) of this section.

(c) Polysulfone resins, when extracted at reflux temperatures for 6 hours with the solvents—distilled water, 50 percent (by volume) ethyl alcohol in distilled water, 3 percent acetic acid in distilled water, and *n*-heptane, yield total extractives in each extracting solvent not to exceed 0.0078 milligram per square centimeter (0.05 milligram per square inch) of resin surface. Note: In testing the finished polysulfone resins, use a separate resin test sample for each required extracting solvent.

(d) Polysulfone resins intended for repeated use in contact with food may be used under conditions of use A through

H in table 2 of §176.170(c) of this chapter. The resins intended for single-service food-contact use may be used only under condition of use H described in table 2 of §176.170(c) of this chapter.

[51 FR 882, Jan. 9, 1986; 51 FR 4165, Feb. 3, 1986; 61 FR 29475, June 11, 1996]

§ 177.1660 Poly (tetramethylene terephthalate).

Poly(tetramethylene terephthalate) (poly (oxytetramethyleneoxyterephthaloyl)) [Chemical Abstracts Service Registry No. 24968-12-5] identified in this section may be safely used as articles or components of articles intended to contact food, in accordance with the following prescribed conditions:

(a) *Identity.* For the purpose of this section, poly (tetramethylene terephthalate) is the reaction product of dimethyl terephthalate with 1,4-butanediol to which may have been added certain optional substances to impart desired technological properties to the polymer.

(b) *Optional adjuvant substances.* Poly(tetramethylene terephthalate) identified in paragraph (a) of this section may contain optional adjuvant substances. The quantity of any optional adjuvant substance employed in the production of the polymer does not exceed the amount reasonably required to accomplish the intended technical or physical effect. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, and substances permitted under applicable regulations in this part.

(c) *Specifications.* (1) Inherent viscosity of a 0.50 percent solution of the polymer in phenol/tetrachloroethane (60/40 weight ratio) solvent is not less than 0.6 as determined using a Wagner viscometer (or equivalent) and calculated from the following equation:

$$\text{Inherent viscosity} = \frac{(\text{natural logarithm of } N_r)}{(c)}$$

where:

N_r = Ratio of flow time of the polymer solution to that of the solvent and c = polymer concentration of the test solution in grams per 100 milliliters.

(2) Poly(tetramethylene terephthalate) in the finished form in which it is to contact food shall yield total extractives as follows:

(i) Not to exceed 0.08 milligram per square inch of food contact surface when extracted for 2 hours at 250 °F with distilled water.

(ii) Not to exceed 0.02 milligram per square inch of food contact surface when extracted for 2 hours at 150 °F with *n*-heptane.

(iii) Not to exceed 0.04 milligram per square inch of food contact surface when extracted for 2 hours at 212 °F with 3 percent aqueous acetic acid.

(iv) Not to exceed 0.02 milligram per square inch of food contact surface when extracted for 2 hours at 65.6 °C (150 °F) with 50 percent ethanol.

[42 FR 14572, Mar. 15, 1977, as amended at 50 FR 20748, May 20, 1985; 52 FR 20069, May 29, 1987]

§ 177.1670 Polyvinyl alcohol film.

Polyvinyl alcohol film may be safely used in contact with food of the types identified in §176.170(c) of this chapter, table 1, under Types V, VIII, and IX, in accordance with the following prescribed conditions:

(a) The polyvinyl alcohol film is produced from polyvinyl alcohol having a minimum viscosity of 4 centipoises when a 4-percent aqueous solution is tested at 20 °C.

(b) The finished food-contact film for use in contact with Food Types V or IX, when extracted with the solvent characterizing the type of food and under the conditions of time and temperature characterizing its intended use as determined from tables 1 and 2 of §176.170(c) of this chapter, yields total extractives not to exceed 0.078 milligram per square centimeter (0.5 milligram per square inch) of food-contact surface when tested by ASTM method F34-76 (Reapproved 1980), "Standard Test Method for Liquid Extraction of Flexible Barrier Materials," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this

§ 177.1680

material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/code-of-federal-regulations/ibr-locations.html>.

(c) The finished food-contact film shall not be used as a component of food containers intended for use in contact with water.

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10110, Mar. 19, 1984]

§ 177.1680 Polyurethane resins.

The polyurethane resins identified in paragraph (a) of this section may be safely used as the food-contact surface of articles intended for use in contact with bulk quantities of dry food of the type identified in §176.170(c) of this chapter, table 1, under Type VIII, in accordance with the following prescribed conditions:

(a) For the purpose of this section, polyurethane resins are those produced when one or more of the isocyanates listed in paragraph (a)(1) of this section is made to react with one or more of the substances listed in paragraph (a)(2) of this section:

(1) Isocyanates:

Bis(isocyanatomethyl) benzene (CAS Reg. No. 25854-16-4).
Bis(isocyanatomethyl) cyclohexane (CAS Reg. No. 38661-72-2).
4,4'-Diisocyanato-3,3'-dimethylbiphenyl (bitolylene diisocyanate).
Diphenylmethane diisocyanate.
Hexamethylene diisocyanate.
3-Isocyanatomethyl - 3,5,5 - trimethylcyclohexyl isocyanate.
4,4-Methylenebis(cyclohexyl isocyanate).
Toluene diisocyanate.

(2) List of substances:

Adipic acid.
1,4-Butanediol.
1,3-Butylene glycol.
1,4-Cyclohexane dimethanol (CAS Reg. No. 105-08-8).

21 CFR Ch. I (4-1-25 Edition)

2,2-Dimethyl-1,3-propanediol.
Ethylene glycol.
1,6-Hexanediol (CAS Reg. No. 629-11-8). α -Hydro- ω -hydroxypoly(oxy-1,4-butanediyl) (CAS Reg. No. 25190-06-1).
 α -Hydro- ω -hydroxypoly (oxytetramethylene).
 α,α' -(Isopropylidenedi-*p*-phenylene)bis[ω -hydroxypoly (oxypropylene)(3-4 moles)], average molecular weight 675.
Maleic anhydride.
Methyl oxirane polymer with oxirane (CAS Reg. No. 9003-11-6).
Methyl oxirane polymer with oxirane, ether with 1,2,3-propanetriol (CAS Reg. No. 9082-00-2).
 α,α',α'' -Neopentetetrayltetrakis [ω -hydroxypoly (oxypropylene) (1-2 moles)], average molecular weight 400.
Pentaerythritol-linseed oil alcoholysis product.
Phthalic anhydride.
Polybutylene glycol.
Polyethyleneadipate modified with ethanolamine with the molar ratio of the amine to the adipic acid less than 0.1 to 1.
Poly(oxycarbonylpentamethylene).
Polyoxypropylene ethers of 4,4'-isopropylidenediphenol (containing an average of 2-4 moles of propylene oxide).
Polypropylene glycol.
 α,α',α'' -1,2,3-Propanetriyltris [ω -hydroxypoly (oxypropylene) (15-18 moles)], average molecular weight 3,000.
Propylene glycol.
 α,α',α'' -[Propylidynetris (methylene)] tris [ω -hydroxypoly (oxypropylene) (minimum 1.5 moles)], minimum molecular weight 400.
 α -[p(1,1,3,3-Tetramethylbutyl) - phenyl]- ω -hydroxypoly(oxyethylene) (5 moles), average molecular weight 425.
Trimethylol propane.

(b) Optional adjuvant substances employed in the production of the polyurethane resins or added thereto to impart desired technical or physical properties may include the following substances:

List of substances	Limitations
1-[(2-Aminoethyl)amino]2-propanol	As a curing agent.
1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	As a preservative.
Colorants used in accordance with § 178.3297 of this chapter..	
Dibutyltin diacetate	As a catalyst.
Dibutyltin dichloride	Do.
Dibutyltin dilaurate	Do.
<i>N,N</i> -Dimethyldodecylamine	Do.
<i>N</i> -Dodecylmorpholine	Do.
α,α' -[Isopropylidenebis(<i>p</i> -phenyleneoxy(2-hydroxytrimethylene)]bis[ω -hydroxypoly(oxyethylene) (136-170 moles)], average molecular weight 15,000.	As a stabilizer.
4,4'-Methylenedianiline	As a curing agent.
1,1',1''-Nitrilotri-2-propanol	Do.

List of substances	Limitations
2,2'-(<i>p</i> -Phenylenedioxy) diethanol	Do.
Polyvinyl isobutyl ether.	
Polyvinyl methyl ether.	
Soyaalkyd resin	Conforming in composition with § 175.300 of this chapter and containing litharge not to exceed that residual from its use as the reaction catalyst and creosol not to exceed that required as an antioxidant.
Tetrakis [methylene-(2,5-di- <i>tert</i> -butyl-4-hydroxyhydrocinnamate)]methane (CAS Reg. No. 6683-19-8).	Stabilizer.
<i>N,N,N,N</i> -Tetrakis (2-hydroxypropyl)ethylenediamine	As a curing agent.
Triethanolamine	Do.
Trimethyleneglycol di (<i>p</i> -aminobenzoate) (CAS Reg. No. 57609-64-0).	As a curing agent.

(c) An appropriate sample of the finished resin in the form in which it contacts food, when subjected to ASTM method D968-81, "Standard Test Methods for Abrasion Resistance of Organic Coatings by the Falling Abrasive Tester," which is incorporated by reference (Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html), using No. 50 Emery abrasive in lieu of Ottawa sand, shall exhibit an abrasion coefficient of not less than 20 liters per mil of film thickness.

[42 FR 14572, Mar. 15, 1977, as amended at 46 FR 57033, Nov. 20, 1981; 49 FR 10110, Mar. 19, 1984; 50 FR 51847, Dec. 20, 1985; 56 FR 15278, Apr. 16, 1991; 56 FR 42933, Aug. 30, 1991]

§ 177.1810 Styrene block polymers.

The styrene block polymers identified in paragraph (a) of this section may be safely used as articles or as components of articles intended for use in contact with food, subject to provisions of this section.

(a) For the purpose of this section, styrene block polymers are basic polymers manufactured as described in this paragraph, so that the finished polymers meet the specifications prescribed in paragraph (b) of this section, when tested by the methods described in paragraph (c) of this section.

(1) Styrene block polymers with 1,3-butadiene are those produced by the catalytic solution polymerization of styrene and 1,3-butadiene.

(2) Styrene block polymers with 2-methyl-1,3-butadiene are those produced by the catalytic solution polymerization of styrene and 2-methyl-1,3-butadiene.

(3) Styrene block polymers with 1,3-butadiene, hydrogenated are those produced by the catalytic solution polymerization of styrene and 1,3-butadiene, and subsequently hydrogenated.

(b) Specifications:

Styrene block polymers	Molecular weight (minimum)	Solubility	Glass transition points	Maximum extractable fraction in distilled water at specified temperatures, times, and thicknesses	Maximum extractable fraction in 50 percent ethanol at specified temperatures, times, and thicknesses
1. (i) Styrene block polymers with 1,3-butadiene; for use as articles or as components of articles that contact food of Types I, II, IV-B, VI, VII-B, and VIII identified in table 1 in § 176.170(c) of this chapter under conditions of use D, E, F, and G described in table 2 in § 176.170(c) of this chapter.	29,000	Completely soluble in toluene.	−98 °C (−144 °F) to −71 °C (−96 °F) and 86 °C (187 °F) to 122 °C (252 °F).	0.0039 mg/cm ² (0.025 mg/in ²) of surface at reflux temperature for 30 min on a 0.19 cm (0.075 in) thick sample.	0.002 mg/cm ² (0.01 mg/in ²) of surface at 66 °C (150 °F) for 2 hr on a 0.19 cm (0.075 in) thick sample.

Styrene block polymers	Molecular weight (minimum)	Solubility	Glass transition points	Maximum extractable fraction in distilled water at specified temperatures, times, and thicknesses	Maximum extractable fraction in 50 percent ethanol at specified temperatures, times, and thicknesses
(ii) Styrene block polymers with 1,3-butadiene; for use as components of pressure-sensitive adhesives that contact food of Types I, II, IV-B, VI, VII-B, and VIII identified in table 1 in § 176.170(c) of this chapter under conditions of use C, D, E, F and G described in table 2 in § 176.170(c) of this chapter, provided the pressure-sensitive adhesives be applied only to closure tapes for sealing containers having a capacity of not less than 160 cc (5.5 fluid ounces) and that the area of the adhesive exposed to food shall not exceed 4.03 cm ² (0.625 in ²). The pressure-sensitive adhesive may contain terpene resins as identified in § 175.125(b)(2) of this chapter.	29,000dododo	Do.
2. Styrene block polymers with 2-methyl-1,3-butadiene; for use as articles or as components of articles that contact food of Types I, II, IV-B, VI, VII-B, and VIII identified in table 1 in § 176.170(c) of this chapter.	29,000do	– 65 °C (– 85 °F) to – 47 °C (– 53 °F) and 86 °C (187 °F) to 122 °C (252 °F).	0.002 mg/cm ² (0.01 mg/in ²) of surface at reflux temperature for 2 hr on a 0.071 cm (0.028 in) thick sample. (Optionally, maximum net residue soluble in chloroform shall not exceed 0.00020 mg/cm ² (0.0013 mg/in ²) of surface.)	0.002 mg/cm ² (0.01 mg/in ²) of surface at 66 °C (150 °F) for 2 hr on a 0.071 cm (0.028 in) thick sample. (Optionally, maximum net residue soluble in chloroform shall not exceed 0.00040 mg/cm ² (0.0025 mg/in ²) of surface.)
3. (i) Styrene block polymers with 1,3-butadiene, hydrogenated (CAS Reg. No. 66070–58–4): for use as articles or as components of articles that contact food of Types I, II, IV-B, VI, VII-B, and VIII identified in table 1 in § 176.170(c) of this chapter.	16,000do	– 50 °C (– 58 °F) to – 30 °C (– 22 °F) and 92 °C (198 °F) to 98 °C (208 °F).	0.002 mg/cm ² (0.01 mg/in ²) of surface at reflux temperature for 2 hr on a 0.071 cm (0.028 in) thick sample.	0.002 mg/cm ² (0.01 mg/in ²) of surface at 66 °C (150 °F) for 2 hr on a 0.071 cm (0.028 in) thick sample.
(ii) Styrene block polymers with 1,3-butadiene, hydrogenated (CAS Reg. No. 66070–58–4): for use at levels not to exceed 42.4 percent by weight as a component of closures with sealing gaskets that would contact food of Types III, IV-A, V, VII-A, VIII, and IX identified in table 1 in § 176.170(c) of this chapter, and in condition of use D as described under table 2 in § 176.170(c) of this chapter.	16,000dododo	Do.

(c) The analytical methods for determining whether styrene block polymers conform to the specifications prescribed in this section are as follows and are applicable to the finished polymer.

(1) *Molecular weight.* Molecular weight shall be determined by intrinsic viscosity (or other suitable method).

(2) *Glass transition points.* The glass transition points shall be determined by either of the following methods:

(i) ASTM method D2236–70 (“Standard Method of Test for Dynamic Mechanical Properties of Plastics by Means of Torsional Pendulum,” which is incorporated by reference; copies are available from American Society for Testing and Materials (ASTM), 100

Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.) modified by using a forced resonant vibration instead of a fixed vibration and by using frequencies of 25 to 40 cycles per second instead of 0.1 to 10 cycles per second.

(ii) Direct reading viscoelastometric method titled "Direct Reading Viscoelastometric Method for Determining Glass Transition Points of Styrene Block Polymers" (which is incorporated by reference; copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.), by which the glass transition points are determined in the tensile mode of deformation at a frequency of 35 hertz using a Rheovibron Model DDV-II (or equivalent) Direct Reading Viscoelastometer. Take maxima in the out-of-phase component of the complex modulus as the glass transition points. For block polymers of low styrene content or for simple block polymers, the polymer may be treated with 0.3 part per hundred dicumyl peroxide and cured for 30 minutes at 153 °C to accentuate the upper transition point.

(3) *Maximum extractable fractions in distilled water and 50 percent ethanol and the maximum net residue solubles in chloroform.* The maximum extractable fractions in distilled water and 50 percent ethanol, and the maximum net residue solubles in chloroform, shall be determined in accordance with §176.170(d)(3) of this chapter using a sandwich form of the finished copolymer of the specified thickness and for the time and temperature specified in paragraph (b) of this section.

(d) The provisions of this section are not applicable to butadiene-styrene copolymers listed in other sections of this subpart.

(e) The provisions of this section are not applicable to styrene block polymers with 1,3-butadiene listed in §175.105 of this chapter.

[42 FR 14572, Mar. 15, 1977, as amended at 42 FR 43621, Aug. 30, 1977; 47 FR 11844, Mar. 19, 1982; 51 FR 16828, May 7, 1986; 54 FR 24898, June 12, 1989; 58 FR 65546, Dec. 15, 1993]

§ 177.1820 Styrene-maleic anhydride copolymers.

Styrene-maleic anhydride copolymers identified in paragraph (a) of this section may be safely used as articles or components of articles intended for use in contact with food, subject to provisions of this section.

(a) For the purpose of this section, styrene-maleic anhydride copolymers are those produced by the polymerization of styrene and maleic anhydride so that the finished polymers meet the specifications prescribed in paragraph (b) of this section, when tested by the methods described in paragraph (c) of this section.

(b) *Specifications:*

Styrene-maleic copolymers	Molecular weight (minimum number average)	Residual styrene monomer	Residual maleic anhydride monomer	Maximum extractable fraction in distilled water at specified temperatures, times, and particle size	Maximum extractable fraction in <i>n</i> -heptane at specified temperatures, times, and particle size
1. Styrene-maleic anhydride copolymers containing not more than 15 pct maleic anhydride units by weight; for use as articles or as components of articles that contact food of Types I, II, III, IV-A, IV-B, V, VI-B (except carbonated beverages), VII-A, VII-B, VIII, and IX identified in table 1 in § 176.170(c) of this chapter under conditions of use B, C, D, E, F, G, and H described in table 2 in § 176.170(c) of this chapter.	70,000	0.3 weight percent.	0.1 weight percent.	0.006 weight percent at reflux temperature for 1 hr utilizing particles of a size that will pass through a U.S. standard sieve No. 10 and will be held on a U.S. standard sieve No. 20.	0.02 weight percent at 73 °F for 2 hr utilizing particles of a size that will pass through a U.S. standard sieve No. 10 and will be held on a U.S. standard sieve No. 20.
2. Styrene-maleic anhydride copolymer modified with butadiene, (CAS Reg. No. 27288–99–9) containing not more than 15 percent maleic anhydride units by weight and not more than 20 percent styrene-butadiene and/or butadiene rubber units by weight; for use (except carbonated beverage bottles) as articles or as components of articles that contact food of Types I, II, III, IV-A, IV-B, V, VI, VII-A, VII-B, VIII, and IX identified in table 1 in § 176.170(c) of this chapter under conditions of use B, C, D, E, F, G, and H described in table 2 in § 176.170(c) of this chapter.	0.3	0.1	0.015 weight percent at reflux temperature for 1 hour utilizing particles of a size that will pass through a U.S. standard sieve No. 10 and will be held on a U.S. standard sieve No. 20.	1.0 weight percent at 23 °C (73 °F) for 2 hours utilizing particles of a size that will pass through a U.S. standard sieve No. 10 and will be held on a U.S. standard sieve No. 20.

(c) The analytical methods for determining conformance with specifications for styrene-maleic anhydride copolymers prescribed in this section are as follows:

(1) *Molecular weight.* Molecular weight shall be determined by membrane osmometry.

(2) *Residual styrene monomer content.* Residual styrene monomer content shall be determined by the method described in § 177.1640(d).

(3) *Residual maleic anhydride monomer content.* Residual maleic anhydride monomer content shall be determined by a gas chromatographic method titled “Determination of Residual Maleic Anhydride in Polymers by Gas Chromatography,” which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/

code_of_federal_regulations/ibr_locations.html.

(d) The provisions of this section are not applicable to styrene-maleic anhydride copolymers listed in other sections of this subpart.

[42 FR 14572, Mar. 15, 1977, as amended at 47 FR 11844, Mar. 19, 1982; 47 FR 14698, Apr. 6, 1982; 54 FR 24898, June 12, 1989]

§ 177.1830 Styrene-methyl methacrylate copolymers.

Styrene-methyl methacrylate copolymers identified in this section may be safely used as components of plastic articles intended for use in contact with food, subject to the provisions of this section.

(a) For the purpose of this section, styrene-methyl methacrylate copolymers consist of basic copolymers produced by the copolymerization of styrene and methyl methacrylate such that the finished basic copolymers contain more than 50 weight percent of polymer units derived from styrene.

(b) The finished plastic food-contact article, when extracted with the solvent or solvents characterizing the

type of food and under the conditions of time and temperature characterizing the conditions of intended use as determined from tables 1 and 2 of §176.170(c) of this chapter, yields extractives not to exceed the following when tested by the methods prescribed in §177.1010(c);

(1) Total nonvolatile extractives not to exceed 0.3 milligram per square inch of surface tested.

(2) Potassium permanganate oxidizable distilled water and 8 and 50 percent alcohol extractives not to exceed an absorbance of 0.15.

(3) Ultraviolet-absorbing distilled water and 8 and 50 percent alcohol extractives not to exceed an absorbance of 0.30.

(4) Ultraviolet-absorbing *n*-heptane extractives not to exceed an absorbance of 0.40.

§ 177.1850 Textryls.

Textryls identified in this section may be safely used as articles or components of articles, intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food, subject to the provisions of this section.

(a) Textryls are nonwoven sheets prepared from natural or synthetic fibers, bonded with fibryl (Fibryl consists of a polymeric resin in fibrous form commingled with fiber to facilitate sheet formation and subsequently heat cured to fuse the fibryl and effect bonding).

(b) Textryls are prepared from the fibers, fibryls, and adjuvants identified in paragraph (c) of this section, and subject to limitations prescribed in that paragraph, provided that any substance that is the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter conforms with any specifications in such regulation for that substance as a component of polymeric resins used as food contact surfaces.

(c) The fibers, fibryls, and adjuvants permitted are as follows:

Substances	Limitations
(1) Fibers prepared from polyethylene terephthalate resins.	Conforming with § 177.1630.
(2) Fibryls prepared from vinyl chloride-vinyl acetate copolymer.	As the basic polymer.

Substances	Limitations
(3) Adjuvant substance, dimethylformamide.	As a solvent in the preparation of fibryl.

(d) Textryls meeting the conditions of test prescribed in paragraph (d)(1) of this section are used as prescribed in paragraph (d)(2) of this section.

(1) *Conditions of test.* Textryls, when extracted with distilled water at reflux temperature for 1 hour, yield total extractives not to exceed 1 percent.

(2) *Uses.* Textryls are used for packaging or holding food at ordinary temperatures and in the brewing of hot beverages.

§ 177.1900 Urea-formaldehyde resins in molded articles.

Urea-formaldehyde resins may be safely used as the food-contact surface of molded articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, urea-formaldehyde resins are those produced when 1 mole of urea is made to react with not more than 2 moles of formaldehyde in water solution.

(b) The resins may be mixed with refined wood pulp and the mixture may contain other optional adjuvant substances which may include the following:

List of substances	Limitations
Hexamethylenetetramine	For use only as polymerization-control agent.
Tetrachlorophthalic acid anhydride.	Do.
Zinc stearate	For use as lubricant.

(c) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of §175.300(d) of this chapter, yields total extractives in each extracting solvent not to exceed 0.5 milligram per square inch of food-contact surface as determined by the methods described in §175.300(e) of this chapter.

NOTE: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.

§ 177.1950 Vinyl chloride-ethylene copolymers.

The vinyl chloride-ethylene copolymers identified in paragraph (a) of this section may be safely used as components of articles intended for contact with food, under conditions of use D, E, F, or G described in table 2 of § 176.170 (c) of this chapter, subject to the provisions of this section.

(a) For the purpose of this section, vinyl chloride-ethylene copolymers consist of basic copolymers produced by the copolymerization of vinyl chloride and ethylene such that the finished basic copolymers meet the specifications and extractives limitations prescribed in paragraph (c) of this section, when tested by the methods described in paragraph (d) of this section.

(b) The basic vinyl chloride-ethylene copolymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic copolymers. The optional adjuvant substances required in the production of the basic vinyl chloride-ethylene copolymers may include substances permitted for such use by regulations in parts 170 through 189 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) The vinyl chloride-ethylene basic copolymers meet the following specifications and extractives limitations:

(1) *Specifications.* (i) Total chlorine content is in the range of 53 to 56 percent as determined by any suitable analytical procedure of generally accepted applicability.

(ii) Intrinsic viscosity in cyclohexanone at 30 °C is not less than 0.50 deciliter per gram as determined by ASTM method D1243–79, “Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers,” which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/code-of-federal-regulations/ibr-locations.html>.

eral register/code of federal regulations/ibr locations.html.

(2) *Extractives limitations.* The following extractives limitations are determined by the methods described in paragraph (d) of this section:

(i) Total extractives do not exceed 0.10 weight-percent when extracted with *n*-heptane at 150 °F for 2 hours.

(ii) Total extractives do not exceed 0.03 weight-percent when extracted with water at 150 °F for 2 hours.

(iii) Total extractives obtained by extracting with water at 150 °F for 2 hours contain no more than 0.5 milligram of vinyl chloride-ethylene copolymer per 100 grams of sample tested as determined from the organic chlorine content. The organic chlorine content is determined as described in paragraph (d)(3) of this section.

(d) Analytical methods: The analytical methods for determining whether vinyl chloride-ethylene basic copolymers conform to the extractives limitations prescribed in paragraph (c) of this section are as follows and are applicable to the basic copolymers in powder form having a particle size such that 100 percent will pass through a U.S. Standard Sieve No. 40 and 80 percent will pass through a U.S. Standard Sieve No. 80:

(1) *Reagents*—(i) *Water.* All water used in these procedures shall be demineralized (deionized), freshly distilled water.

(ii) *n-Heptane.* Reagent grade, freshly distilled *n*-heptane shall be used.

(2) *Determination of total amount of extractives.* All determinations shall be done in duplicate using duplicate blanks. Approximately 400 grams of sample (accurately weighed) shall be placed in a 2-liter Erlenmeyer flask. Add 1,200 milliliters of solvent and cover the flask with aluminum foil. The covered flask and contents are suspended in a thermostated bath and are kept, with continual shaking at 150 °F for 2 hours. The solution is then filtered through a No. 42 Whatman filter paper, and the filtrate is collected in a graduated cylinder. The total amount of filtrate (without washing) is measured and called *A* milliliters. The filtrate is transferred to a Pyrex (or equivalent) beaker and evaporated on a steam bath under a stream of nitrogen

to a small volume (approximately 50–60 milliliters). The concentrated filtrate is then quantitatively transferred to a tared 100-milliliter Pyrex beaker using small, fresh portions of solvent and a rubber policeman to effect the transfer. The concentrated filtrate is evaporated almost to dryness on a hotplate under nitrogen, and is then transferred to a drying oven at 230 °F in the case of the

aqueous extract or to a vacuum oven at 150 °F in the case of the heptane extract. In the case of the aqueous extract, the evaporation to constant weight is completed in 15 minutes at 230 °F; and in the case of heptane extract, it is overnight under vacuum at 150 °F. The residue is weighed and corrected for the solvent blank. Calculation:

$$\frac{\text{Grams of corrected residue}}{\text{Grams of sample}} \times \frac{1,200 \text{ milliliters}}{\text{Volume of filtrate A in milliliters}} \times 100 = \text{Total extractives expressed as percent by weight of sample.}$$

(3) *Vinyl chloride-ethylene copolymer content of aqueous extract*—(i) *Principle.* The vinyl chloride-ethylene copolymer content of the aqueous extract can be determined by determining the organic chlorine content and calculating the amount of copolymer equivalent to the organic chlorine content.

(ii) *Total organic chlorine content.* A weighed sample of approximately 400 grams is extracted with 1,200 milliliters of water at 150 °F for 2 hours, filtered, and the volume of filtrate is measured (*A* milliliters) as described in paragraph (d)(2) of this section.

(a) A slurry of Amberlite IRA-400, or equivalent, is made with distilled water in a 150-milliliter beaker. The slurry is added to a chromatographic column until it is filled to about half its length. This should give a volume of resin of 15–25 milliliters. The liquid must not be allowed to drain below the top of the packed column.

(b) The column is regenerated to the basic (OH) form by slowly passing through it (10–15 milliliters per minute) 10 grams of sodium hydroxide dissolved in 200 milliliters of water. The column is washed with distilled water until the effluent is neutral to phenolphthalein. One drop of methyl red indicator is added to the *A* milliliters of filtered aqueous extract and, if on the basic side (yellow), nitric acid is added drop by drop until the solution turns pink.

(c) The extract is deionized by passing it through the exchange column at a rate of 10–15 milliliters per minute. The column is washed with 200 milliliters of distilled water. The deionized

extract and washings are collected in a 1,500-milliliter beaker. The solution is evaporated carefully on a steam plate to a volume of approximately 50 milliliters and then transferred quantitatively, a little at a time, to a clean 22-milliliter Parr cup, also on the steam plate. The solution is evaporated to dryness. Next 0.25 gram of sucrose and 0.5 gram of benzoic acid are added to the cup. One scoop (approximately 15 grams) of sodium peroxide is then added to the cup. The bomb is assembled and ignition is conducted in the usual fashion.

(d) After the bomb has cooled, it is rinsed thoroughly with distilled water and disassembled. The top of the bomb is rinsed into a 250-milliliter beaker with distilled water. The beaker is placed on the steam plate. The bomb cup is placed in the beaker and carefully tipped over to allow the water to leach out the combustion mixture. After the bubbling has stopped, the cup is removed from the beaker and rinsed thoroughly. The solution is cooled to room temperature and cautiously neutralized with concentrated nitric acid by slowly pouring the acid down a stirring rod until the bubbling ceases. The solution is cooled and an equal volume of acetone is added.

(e) The solution is titrated with 0.005 *N* silver nitrate using standard potentiometric titration techniques with a silver electrode as indicator and a potassium nitrate modified calomel electrode as a reference electrode. An expanded scale recording titrimeter.

§ 177.1960

Metrohm Potentiograph 2336 or equivalent, should be used; a complete blank must be run in duplicate.

21 CFR Ch. I (4–1–25 Edition)

(iii) *Calculations.*

$$\text{Milligrams of aqueous extracted copolymer per 100-gram sample} = \frac{T \times F \times 64.3}{\text{Weight of sample in grams}} \times 100$$

where:

T = Milliliters of silver nitrate (sample minus blank) \times normality of silver nitrate.

F = 1,200 / A (as defined above)

(e) The vinyl chloride-ethylene copolymers identified in and complying with this section, when used as components of the food-contact surface of any article that is the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(f) The provisions of this section are not applicable to vinyl chloride-ethylene copolymers used as provided in §§175.105 and 176.180 of this chapter.

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10110, Mar. 19, 1984]

§ 177.1960 Vinyl chloride-hexene-1 copolymers.

The vinyl chloride-hexene-1 copolymers identified in paragraph (a) of this section or as components of articles intended for use in contact with food, under conditions of use D, E, F, or G described in table 2 of §176.170(c) of this chapter, subject to the provisions of this section.

(a) *Identity.* For the purposes of this section vinyl chloride-hexene-1 copolymers consist of basic copolymers produced by the copolymerization of vinyl chloride and hexene-1 such that the finished copolymers contain not more than 3 mole-percent of polymer units derived from hexene-1 and meet the specifications and extractives limitations prescribed in paragraph (b) of this section. The copolymers may optionally contain hydroxypropyl methylcellulose and trichloroethylene used as a suspending agent and chain transfer

agent, respectively, in their production.

(b) *Specifications and limitations.* The vinyl chloride-hexene-1 basic copolymers meet the following specifications and extractives limitations:

(1) *Specifications.* (i) Total chlorine content is 53 to 56 percent as determined by any suitable analytical procedure of generally accepted applicability.

(ii) Inherent viscosity in cyclohexanone at 30 °C is not less than 0.59 deciliters per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal-register/code_of_federal_regulations/ibr_locations.html.

(2) *Extractives limitations.* The following extractives limitations are determined by the methods prescribed in §177.1970(d).

(i) Total extractives do not exceed 0.01 weight percent when extracted with water at 150 °F for 2 hours.

(ii) Total extractives do not exceed 0.30 weight percent when extracted with *n*-heptane at 150 °F for 2 hours.

(c) *Other specifications and limitations.* The vinyl chloride-hexene-1 copolymers identified in and complying with this section, when used as components of the food-contact surface of any article that is subject to a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter, shall comply with any

specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10110, Mar. 19, 1984]

§ 177.1970 Vinyl chloride-lauryl vinyl ether copolymers.

The vinyl chloride-lauryl vinyl ether copolymers identified in paragraph (a) of this section may be used as an article or as a component of an article intended for use in contact with food subject to the provisions of this section.

(a) *Identity.* For the purposes of this section vinyl chloride-lauryl vinyl ether copolymers consist of basic copolymers produced by the copolymerization of vinyl chloride and lauryl vinyl ether such that the finished copolymers contain not more than 3 weight-percent of polymer units derived from lauryl vinyl ether and meet the specifications and extractives limitations prescribed in paragraph (c) of this section.

(b) *Optional adjuvant substances.* The basic vinyl chloride-lauryl vinyl ether copolymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic copolymers. These optional adjuvant substances may include substances permitted for such use by regulations in parts 170 through 189 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) *Specifications and limitations.* The vinyl chloride-lauryl vinyl ether basic copolymers meet the following specifications and extractives limitations:

(1) *Specifications.* (i) Total chlorine content is 53 to 56 percent as determined by any suitable analytical procedure of generally accepted applicability.

(ii) Inherent viscosity in cyclohexanone at 30 °C is not less than 0.60 deciliter per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West

Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(2) *Extractives limitations.* The following extractives limitations are determined by the method described in paragraph (d) of this section:

(i) Total extractives do not exceed 0.03 weight-percent when extracted with water at 150 °F for 2 hours.

(ii) Total extractives do not exceed 0.60 weight-percent when extracted with *n*-heptane at 150 °F for 2 hours.

(d) *Analytical methods.* The analytical methods for determining total extractives are applicable to the basic copolymers in powder form having a particle size such that 100 percent will pass through a U.S. Standard Sieve No. 40 and such that not more than 10 percent will pass through a U.S. Standard Sieve No. 200.

(1) *Reagents*—(i) *Water.* All water used in these procedures shall be demineralized (deionized), freshly distilled water.

(ii) *n-Heptane.* Reagent grade, freshly distilled *n*-heptane shall be used.

(2) *Determination of total amount of extractives.* Place an accurately weighed sample of suitable size in a clean borosilicate flask, and for each gram of sample add 3 milliliters of solvent previously heated to 150 °F. Maintain the temperature of the contents of the flask at 150 °F for 2 hours using a hot plate while also maintaining gentle mechanical agitation. Filter the contents of the flask rapidly through No. 42 Whatman filter paper with the aid of suction. Transfer the filtrate to flat glass dishes that are warmed on a hot plate and evaporate the solvent with the aid of a stream of filtered air. When the volume of the filtrate has been reduced to 10 to 15 milliliters, transfer the filtrate to tared 50-milliliter borosilicate glass beakers and complete evaporation to a constant weight in a 140 °F vacuum oven. Carry out a corresponding blank determination with each solvent. Determine the weight of the residue corrected for the

solvent blank and calculate the result as percent of the initial weight of the resin sample taken for analysis.

(e) *Other specifications and limitations.* The vinyl chloride-lauryl vinyl ether copolymers identified in and complying with this section, when used as components of the food-contact surface of any article that is subject to a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10110, Mar. 19, 1984]

§ 177.1980 Vinyl chloride-propylene copolymers.

The vinyl chloride-propylene copolymers identified in paragraph (a) of this section may be safely used as components of articles intended for contact with food, subject to the provisions of this section.

(a) For the purpose of this section, vinyl chloride-propylene copolymers consist of basic copolymers produced by the copolymerization of vinyl chloride and propylene such that the finished basic copolymers meet the specifications and extractives limitations prescribed in paragraph (c) of this section, when tested by the methods described in paragraph (d) of this section.

(b) The basic vinyl chloride-propylene copolymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic copolymers. The optional adjuvant substances required in the production of the basic vinyl chloride-propylene copolymers may include substances permitted for such use by regulations in parts 170 through 189 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) The vinyl chloride-propylene basic copolymers meet the following specifications and extractives limitations:

(1) *Specifications.* (i) Total chlorine content is in the range of 53 to 56 percent as determined by any suitable analytical procedure of generally accepted applicability.

(ii) Intrinsic viscosity in cyclohexanone at 30 °C is not less than 0.50 deciliter per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/code-of-federal-regulations/ibr-locations.html>.

(2) *Extractives limitations.* The following extractives limitations are determined by the methods described in paragraph (d) of this section:

(i) Total extractives do not exceed 0.10 weight-percent when extracted with *n*-heptane at 150 °F for 2 hours.

(ii) Total extractives do not exceed 0.03 weight-percent when extracted with water at 150 °F for 2 hours.

(iii) Total extractives obtained by extracting with water at 150 °F for 2 hours contain no more than 0.17 milligram of vinyl chloride-propylene copolymer per 100 grams of sample tested as determined from the organic chlorine content. For the purpose of this section, the organic chlorine content is the difference between the total chlorine and ionic chlorine contents determined as described in paragraph (d) of this section.

(d) *Analytical methods:* The analytical methods for determining whether vinyl chloride-propylene basic copolymers conform to the extractives limitations prescribed in paragraph (c) of this section are as follows and are applicable to the basic copolymers in powder form having a particle size such that 100 percent will pass through a U.S. Standard Sieve No. 40 and 80 percent will pass through a U.S. Standard Sieve No. 80:

(1) *Reagents*—(i) *Water.* All water used in these procedures shall be demineralized (deionized), freshly distilled water.

(ii) *n-Heptane.* Reagent grade, freshly distilled *n*-heptane shall be used.

(2) *Determination of total amount of extractives.* All determinations shall be done in duplicate using duplicate blanks. Approximately 400 grams of sample (accurately weighed) shall be placed in a 2-liter Erlenmeyer flask. Add 1,200 milliliters of solvent and cover the flask with aluminum foil. The covered flask and contents are suspended in a thermostated bath and are kept, with continual shaking, at 150 °F for 2 hours. The solution is then filtered through a No. 42 Whatman filter paper, and the filtrate is collected in a graduated cylinder. The total amount of filtrate (without washing) is measured and called *A* milliliters. The filtrate is transferred to a Pyrex (or equivalent) beaker and evaporated on a steam bath under a stream of nitrogen

to a small volume (approximately 50–60 milliliters). The concentrated filtrate is then quantitatively transferred to a tared 100-milliliter Pyrex beaker using small, fresh portions of solvent and a rubber policeman to effect the transfer. The concentrated filtrate is evaporated almost to dryness on a hotplate under nitrogen, and is then transferred to a drying oven at 230 °F in the case of the aqueous extract or to a vacuum oven at 150 °F in the case of the heptane extract. In the case of the aqueous extract the evaporation to constant weight is completed in 15 minutes at 230 °F; and in the case of heptane extract, it is overnight under vacuum at 150 °F. The residue is weighed and corrected for the solvent blank. Calculation:

$$\frac{\text{Grams of corrected residue}}{\text{Grams of sample}} \times \frac{1,200 \text{ milliliters}}{\text{Volume of filtrate } A \text{ in milliliters}} \times 100 = \text{Total extractives expressed as percent by weight of sample.}$$

(3) *Vinyl chloride-propylene copolymer content of aqueous extract*—(i) *Principle.* The vinyl chloride-propylene copolymer content of the aqueous extract can be determined by determining the organic chlorine content and calculating the amount of copolymer equivalent to the organic chlorine content. The organic chlorine content is the difference between the total chlorine content and the ionic chlorine content.

(ii) *Total chlorine content.* A weighed sample is extracted with water at 150 °F for 2 hours, filtered, and the volume of filtrate is measured (*A* milliliters) as described in paragraph (d)(2) of this section. Two drops of 50 percent by weight sodium hydroxide solution are added to prevent loss of chloride from ammonium chloride, if present, and the solution is evaporated to approximately 15 milliliters. The concentrated filtrate is quantitatively transferred to a 22-milliliter Parr bomb fusion cup and gently evaporated to dryness. To the contents of the cup are added 3.5 grams of granular sodium peroxide, 0.1 gram of powdered starch, and 0.02 gram potassium nitrate; and the contents are mixed thoroughly. The bomb is as-

sembled, water is added to the recess at the top of the bomb and ignition is conducted in the usual fashion using a Meeker burner. The heating is continued for 1 minute after the water at the top has evaporated. The bomb is quenched in water, rinsed with distilled water, and placed in a 400-milliliter beaker. The bomb cover is rinsed with water, catching the washings in the same 400-milliliter beaker. The bomb is covered with distilled water and a watch glass and heated until the melt has dissolved. The bomb is removed, rinsed, catching the rinsings in the beaker, and the solution is acidified with concentrated nitric acid using methyl purple as an indicator. The beaker is covered with a watch glass, and the contents are boiled gently for 10–15 minutes. After cooling to room temperature the solution is made slightly alkaline with 50 percent by weight sodium hydroxide solution, then acidified with dilute (1:5) nitric acid. Then 1.5 milliliters of 2 *N* nitric acid per 100 milliliters of solution is added and the solution is titrated with 0.005 *N* silver nitrate to the equivalence potential end point using an expanded

scale pH meter (Beckman Model 76, or equivalent). A complete blank must be run in duplicate. Calculation:

$$\frac{\text{Grams of sample}}{(B - C)} \times \frac{1,200 \text{ milliliters}}{\text{Volume of filtrate } A \text{ in milliliters}} \times 100 = \text{Milliequivalents of total chlorine in aqueous extract of 100 grams of sample}$$

where:

A = volume of filtrate obtained in extraction.
B = milliliters of silver nitrate solution used in sample titration \times normality of silver nitrate solution.

C = milliliters of silver nitrate solution used in blank titration \times normality of silver nitrate solution.

(iii) *Ionic chlorine content.* A weighed sample is extracted with water at 150 °F for 2 hours, filtered, and the volume of filtrate is measured (*A* milliliters) as in paragraph (d)(2) of this section. Two drops of 50 percent by weight sodium hydroxide solution are added and the

solution is evaporated to approximately 150 milliliters. The solution is quantitatively transferred to a 250-milliliter beaker, methyl purple indicator is added, and the solution is neutralized with 0.1 *N* nitric acid. For each 100 milliliters of solution is added 1.5 milliliters of 2 *N* nitric acid. The solution is titrated with 0.005 *N* silver nitrate to the equivalence potential end point, using the expanded scale pH meter described in paragraph (d)(3)(ii) of this section. A complete blank must be run in duplicate. Calculation:

$$\frac{D - E}{\text{Grams of sample}} \times \frac{1,200 \text{ milliliters}}{\text{Volume of filtrate } A \text{ in milliliters}} \times 100 = \text{Milliequivalents of ionic chlorine in aqueous extract of 100 grams of sample.}$$

where:

A = volume of filtrate obtained in extraction.
D = milliliters of silver nitrate solution used in sample titration \times normality of silver nitrate solution.

E = milliliters of silver nitrate solution used in blank titration \times normality of silver nitrate solution.

(iv) *Organic chlorine content and vinyl chloride-propylene copolymer content of aqueous extract.* The organic chlorine content and the vinyl chloride propylene copolymer content of the aqueous extract is calculated as follows:

(a) *Organic chlorine content.* Milliequivalents of organic chlorine in aqueous extract of 100 grams of sample equal milliequivalents of total chlorine in aqueous extract of 100 grams of sample (as calculated in paragraph (d)(3)(ii) of this section) minus milliequivalents of ionic chlorine in aqueous extract of 100 grams of sample (as calculated in paragraph (d)(3)(iii) of this section).

(b) *Vinyl chloride-propylene copolymer content.* Milligrams of vinyl chloride-propylene copolymer in aqueous extract of 100 grams of sample equal milliequivalents of organic chlorine in aqueous extract of 100 grams of sample (as calculated in paragraph (d)(3)(iv)(a) of this section) multiplied by 84.5.

NOTE: The conversion factor, 84.5, is derived from the equivalent weight of chlorine divided by the chlorine content of the heptane extractable fraction.)

(e) The vinyl chloride-propylene copolymers identified in and complying with this section, when used as components of the food-contact surface of any article that is the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(f) The provisions of this section are not applicable to vinyl chloride-propylene copolymers used in food-packaging adhesives complying with § 175.105 of this chapter.

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10111, Mar. 19, 1984]

§ 177.1990 Vinylidene chloride/methyl acrylate copolymers.

The vinylidene chloride/methyl acrylate copolymers (CAS Reg. No. 25038-72-6) identified in paragraph (a) of this section may be safely used as an article or as a component of an article intended for use in contact with food subject to the provisions of this section.

(a) *Identity.* For the purposes of this section vinylidene chloride/methyl acrylate copolymers consist of basic copolymers produced by the copolymerization of vinylidene chloride and methyl acrylate such that the copolymers contain not more than 15 weight-percent of polymer units derived from methyl acrylate.

(b) *Optional adjuvant substances.* The basic vinylidene chloride/methyl acrylate copolymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic copolymers. These optional adjuvant substances may include substances permitted for such use by regulations in parts 170 through 179 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) *Specifications.* (1) The methyl acrylate content is determined by an infrared spectrophotometric method titled "Determination of Copolymer Ratio in Vinylidene Chloride/Methyl Acrylate Copolymers," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(2) The weight average molecular weight of the copolymer is not less

than 50,000 when determined by gel permeation chromatography using tetrahydrofuran as the solvent. The gel permeation chromatograph is calibrated with polystyrene standards. The basic gel permeation chromatographic method is described in ANSI/ASTM D3536-76, "Standard Test Method for Molecular Weight Averages and Molecular Weight Distribution of Polystyrene by Liquid Exclusion Chromatography (Gel Permeation Chromatography-GPC)," which is incorporated by reference. Copies are available from University Microfilms International, 300 North Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(3) Residual vinylidene chloride and residual methyl acrylate in the copolymer in the form in which it will contact food (unsupported film, barrier layer, or as a copolymer for blending) will not exceed 10 parts per million and 5 parts per million, respectively, as determined by either a gas chromatographic method titled "Determination of Residual Vinylidene Chloride and Methyl Acrylate in Vinylidene Chloride/Methyl Acrylate Copolymer Resins and Films," or, alternatively, "Residual Methyl Acrylate and Vinylidene Chloride Monomers in Saran MA/VDC Resins and Pellets by Headspace Gas Chromatography," dated March 3, 1986, which are incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(d) *Extractives limitations.* The basic copolymer resin in the form of granules that will pass through a U.S. Standard

Sieve No. 45 (350 microns) shall meet the following extractives limitations:

(1) 10-gram samples of the resin, when extracted separately with 100 milliliters of distilled water at 121 °C (250 °F) for 2 hours, and 100 milliliters of *n*-heptane at 66 °C (150 °F) for 2 hours, shall yield total nonvolatile extractives not to exceed 0.5 percent by weight of the resin.

(2) The basic copolymer in the form of film when extracted separately with distilled water at 121 °C (250 °F) for 2 hours shall yield total nonvolatile extractives not to exceed 0.047 milligram per square centimeter (0.3 milligram per square inch).

(e) *Conditions of use.* The copolymers may be safely used as articles or components of articles intended for use in producing, manufacturing, processing, preparing, treating, packaging, transporting, or holding food, including processing of packaged food at temperatures not to exceed 135 °C (275 °F).

(f) *Other specifications and limitations.* The vinylidene chloride-methyl acrylate copolymers identified in and complying with this section, when used as components of the food contact surface of any article that is subject to a regulation in parts 174 through 178 and §179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

[48 FR 38605, Aug. 25, 1983; 48 FR 50077, Oct. 31, 1983, as amended at 53 FR 47185, Nov. 22, 1988; 54 FR 24898, June 12, 1989]

§ 177.2000 Vinylidene chloride/methyl acrylate/methyl methacrylate polymers.

The vinylidene chloride/methyl acrylate/methyl methacrylate polymers (CAS Reg. No. 34364-83-5) identified in paragraph (a) of this section may be safely used as articles or as a component of articles intended for use in contact with food subject to the provisions of this section.

(a) *Identity.* For the purpose of this section, vinylidene chloride/methyl acrylate/methyl methacrylate polymers consist of basic polymers produced by the copolymerization of vinylidene chloride/methyl acrylate/methyl methacrylate such that the basic polymers

or the finished food-contact articles meet the specifications prescribed in paragraph (d) of this section.

(b) *Optional adjuvant substances.* The basic vinylidene chloride/methyl acrylate/methyl methacrylate polymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic polymers. These optional adjuvant substances may include substances permitted for such use by regulations in parts 170 through 179 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction of approval.

(c) *Conditions of use.* The polymers may be safely used as articles or as components of articles intended for use in producing, manufacturing, processing, preparing, treating, packaging, transporting, or holding food, including processing of packaged food at temperatures up to 121 °C (250 °F).

(d) *Specifications and limitations.* The vinylidene chloride/methyl acrylate/methyl methacrylate basic polymers and/or finished food-contact articles meet the following specifications and limitations:

(1)(i) The basic vinylidene chloride/methyl acrylate/methyl methacrylate polymers contain not more than 2 weight percent of polymer units derived from methyl acrylate monomer and not more than 6 weight percent of polymer units derived from methyl methacrylate monomer.

(ii) The basic polymers are limited to a thickness of not more than 0.005 centimeter (0.002 inches).

(2) The weight average molecular weight of the basic polymer is not less than 100,000 when determined by gel permeation chromatography using tetrahydrofuran as the solvent. The gel permeation chromatography is calibrated with polystyrene standards. The basic gel permeation chromatographic method is described in ANSI/ASTM D3536-76, which is incorporated by reference. Copies are available from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or available for inspection at the National Archives and Records Administration (NARA). For information on

the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(3) The basic polymer or food-contact article described in paragraph (a) of this section, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of §176.170(c) of this chapter, yields net chloroform-soluble extractives in each extracting solvent not to exceed .08 milligram per square centimeter (0.5 milligram per square inch) of food-contact surface when tested by the methods described in §176.170(d). If the finished food-contact article is itself the subject of a regulation in parts 174 through 178 and §179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by the regulation.

[49 FR 29578, July 23, 1984]

Subpart C—Substances for Use Only as Components of Articles Intended for Repeated Use

§ 177.2210 Ethylene polymer, chlorosulfonated.

Ethylene polymer, chlorosulfonated as identified in this section may be safely used as an article or component of articles intended for use in contact with food, subject to the provisions of this section.

(a) Ethylene polymer, chlorosulfonated is produced by chlorosulfonation of a carbon tetrachloride solution of polyethylene with chlorine and sulfuryl chloride.

(b) Ethylene polymer, chlorosulfonated shall meet the following specifications:

(1) Chlorine not to exceed 25 percent by weight.

(2) Sulfur not to exceed 1.15 percent by weight.

(3) Molecular weight is in the range of 95,000 to 125,000.

Methods for the specifications in this paragraph (b), titled "Chlorine and Bromine—Coulometric Titration Meth-

od by Aminco Chloridometer," "Hypolon® Synthetic Rubber—Determination of Sulfur by Parr Bomb," and ASTM method D2857-70 (Reapproved 1977), "Standard Test Method for Dilute Solution Viscosity of Polymers," are incorporated by reference. Copies of the ASTM method may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959. Copies of the other two methods are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Copies of all three methods may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(c) The additive is used as the article, or a component of articles, intended for use as liners and covers for reservoirs intended for the storage of water for drinking purposes.

(d) Substances permitted by §177.2600 may be employed in the preparation of ethylene polymers, chlorosulfonated, subject to any limitations prescribed therein.

(e) The finished ethylene copolymers, chlorosulfonated shall conform to §177.2600(e) and (g).

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10111, Mar. 19, 1984; 54 FR 24898, June 12, 1989]

§ 177.2250 Filters, microporous polymeric.

Microporous polymeric filters identified in paragraph (a) of this section may be safely used, subject to the provisions of this section, to remove particles of insoluble matter in producing, manufacturing, processing, and preparing bulk quantities of liquid food.

(a) Microporous polymeric filters consist of a suitably permeable, continuous, polymeric matrix of polyvinyl chloride, vinyl chloride-propylene, or vinyl chloride-vinyl acetate, in which finely divided silicon dioxide is embedded. Cyclohexanone may be used as a solvent in the production of the filters.

(b) Any substance employed in the production of microporous polymeric filters that is the subject of a regulation in parts 170 through 189 of this chapter must conform with any specification in such regulation.

(c) Cyclohexanone when used as a solvent in the production of the filters shall not exceed 0.35 percent by weight of the microporous polymeric filters.

(d) The microporous polymeric filters may be colored with colorants used in accordance with § 178.3297 of this chapter.

(e) The temperature of food being processed through the microporous polymeric filters shall not exceed 180 °F.

(f) The microporous polymeric filters shall be maintained in a sanitary manner in accordance with good manufacturing practice so as to prevent potential microbial adulteration of the food.

(g) To assure safe use of the microporous polymeric filters, the label or labeling shall include adequate directions for a pre-use treatment, consisting of washing with a minimum of 2 gallons of potable water at a temperature of 180 °F for each square foot of filter, prior to the filter's first use in contact with food.

[42 FR 14572, Mar. 15, 1977, as amended at 56 FR 42933, Aug. 30, 1991]

§ 177.2260 Filters, resin-bonded.

Resin-bonded filters may be safely used in producing, manufacturing, processing, and preparing food, subject to the provisions of this section.

(a) Resin-bonded filters are prepared from natural or synthetic fibers to which have been added substances required in their preparation and finishing, and which are bonded with resins prepared by condensation or polymerization of resin-forming materials, together with adjuvant substances required in their preparation, application, and curing.

(b) The quantity of any substance employed in the production of the resin-bonded filter does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation further provided.

(c) Any substance employed in the production of resin-bonded filters that is the subject of a regulation in parts

174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the production of resin-bonded filters include the following, subject to any limitations provided:

LIST OF SUBSTANCES AND LIMITATIONS

(1) *Fibers:*

Cellulose pulp.

Cotton.

Nylon. (From nylon resins complying with the provisions of applicable regulations in subchapter B of this chapter.

Polyethylene terephthalate complying in composition with the provisions of § 177.1630; for use in inline filtration only as provided for in paragraphs (e) and (f) of this section.

Rayon (viscose).

(2) *Substances employed in fiber finishing:*

BHT.

Butyl (or isobutyl) palmitate or stearate.

2,5-Di-*tert*-butyl hydroquinone for use only in lubricant formulations for rayon fiber finishing and at a usage level not to exceed 0.1 percent by weight of the lubricant formulations.

Dimethylpolysiloxane.

4-Ethyl-4-hexadecyl morpholinium ethyl sulfate for use only as a lubricant in the manufacture of polyethylene terephthalate fibers specified in paragraph (d)(1) of this section at a level not to exceed 0.03 percent by weight of the finished fibers.

Fatty acid (C₁₀-C₁₈) diethanolamide condensates.

Fatty acids derived from animal or vegetable fats and oils, and salts of such acids, single or mixed, as follows:

Aluminum.

Ammonium.

Calcium.

Magnesium.

Potassium.

Sodium.

Triethanolamine.

Fatty acid (C₁₀-C₁₈) mono- and diesters of polyoxyethylene glycol (molecular weight 400-3,000).

Methyl esters of fatty acids (C₁₀-C₁₈).

Mineral oil.

Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740 (b) of this chapter.

Polyoxyethylene (4 mols) ethylenediamine monolauramide for use only in lubricant formulations for rayon fiber finishing and at a usage level not to exceed 10 percent by weight of the lubricant formulations.

Ricebran oil.

Titanium dioxide.

(3) *Resins:*

Acrylic polymers produced by polymerizing ethyl acrylate alone or with one or more of the monomers: Acrylic acid, acrylonitrile, *N*-methylolacrylamide, and styrene. The finished copolymers shall contain at least 70 weight percent of polymer units derived from ethyl acrylate, no more than 2 weight percent of total polymer units derived from acrylic acid, no more than 10 weight percent of total polymer units derived from acrylonitrile, no more than 2 weight percent of total polymer units derived from *N*-methylolacrylamide, and no more than 25 weight percent of total polymer units derived from styrene. For use only as provided in paragraph (m) of this section.

Melamine-formaldehyde.

Melamine-formaldehyde chemically modified with one or more of the amine catalysts identified in §175.300(b)(3)(xiii) of this chapter.

Melamine-formaldehyde chemically modified with methyl alcohol.

Melamine-formaldehyde chemically modified with urea; for use only as provided for in paragraphs (e), (f), (g), (h), and (i) of this section.

Phenol-formaldehyde resins.

Polyvinyl alcohol.

Polyvinyl alcohol with the copolymer of acrylic acid-allyl sucrose.

Polyvinyl alcohol with melamine formaldehyde.

Polyvinyl acetate with melamine formaldehyde.

p-Toluenesulfonamide-formaldehyde chemically modified with one or more of the amine catalysts identified in §175.300(b)(3)(xiii) of this chapter.

(4) *Adjuvant substances:*

Dimethyl polysiloxane with methylcellulose and sorbic acid (as an antifoaming agent).
Phosphoric acid.

(5) *Colorants:* Colorants used in accordance with §178.3297 of this chapter.

(e) Resin-bonded filters conforming with the specifications of paragraph (e)(1) of this section are used as provided in paragraph (e)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to distilled water at 100 °F for 2 hours, yields total extractives not to exceed 2.8 percent by weight of the filter.

(2) *Conditions of use.* It is used to filter milk or potable water at operating temperatures not to exceed 100 °F.

(f) Resin-bonded filters conforming with the specifications of paragraph

(f)(1) of this section are used as provided in paragraph (e)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to distilled water at 145 °F for 2 hours, yields total extractives not to exceed 4 percent by weight of the filter.

(2) *Conditions of use.* It is used to filter milk or potable water at operating temperatures not to exceed 145 °F.

(g) Resin-bonded filters conforming with the specifications of paragraph (g)(1) of this section are used as provided in paragraph (g)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to *n*-hexane at reflux temperature for 2 hours, yields total extractives not to exceed 0.5 percent by weight of the filter.

(2) *Conditions of use.* It is used to filter edible oils.

(h) Resin-bonded filters conforming with the specifications of paragraph (h)(1) of this section are used as provided in paragraph (h)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to distilled water at 212 °F for 2 hours, yields total extractives not to exceed 4 percent by weight of the filter.

(2) *Conditions of use.* It is used to filter milk, coffee, tea, and potable water at temperatures not to exceed 212 °F.

(i) Resin-bonded filters conforming with the specifications of paragraph (i)(1) of this section are used as provided in paragraph (i)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to distilled water for 2 hours at a temperature equivalent to, or higher than, the filtration temperature of the aqueous food, yields total extractives not to exceed 4 percent, by weight, of the filter.

(2) *Conditions of use.* It is used in commercial filtration of bulk quantities of nonalcoholic, aqueous foods having a pH above 5.0.

(j) Resin-bonded filters conforming with the specifications of paragraph (j)(1) of this section are used as provided in paragraph (j)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to 5 percent (by weight) acetic acid for 2 hours at a temperature equivalent to, or higher

§ 177.2280

than, the filtration temperature of the aqueous food, yields total extractives not to exceed 4 percent, by weight, of the filter.

(2) *Conditions of use.* It is used in commercial filtration of bulk quantities of nonalcoholic, aqueous foods having a pH of 5.0 or below.

(k) Resin-bonded filters conforming with the specifications of paragraph (k)(1) of this section are used as provided in paragraph (k)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to 8 percent (by volume) ethyl alcohol in distilled water for 2 hours at a temperature equivalent to, or higher than, the filtration temperature of the alcoholic beverage, yields total extractives not to exceed 4 percent, by weight, of the filter.

(2) *Conditions of use.* It is used in commercial filtration of bulk quantities of alcoholic beverages containing not more than 8 percent alcohol.

(l) Resin-bonded filters conforming with the specifications of paragraph (l)(1) of this section are used as provided in paragraph (l)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to 50 percent (by volume) ethyl alcohol in distilled water for 2 hours at a temperature equivalent to, or higher than, the filtration temperature of the alcoholic beverage, yields total extractives not to exceed 4 percent, by weight, of the filter.

(2) *Conditions of use.* It is used in commercial filtration of bulk quantities of alcoholic beverages containing more than 8 percent alcohol.

(m) Resin-bonded filters fabricated from acrylic polymers as provided in paragraph (d)(3) of this section together with other substances as provided in paragraph (d), (1), (2), and (4) of this section may be used as follows:

(1) The finished filter may be used to filter milk or potable water at operating temperatures not to exceed 100 °F, provided that the finished filter when exposed to distilled water at 100 °F for 2 hours yields total extractives not to exceed 1 percent by weight of the filter.

(2) The finished filter may be used to filter milk or potable water at operating temperatures not to exceed 145 °F, provided that the finished filter

21 CFR Ch. I (4–1–25 Edition)

when exposed to distilled water at 145 °F for 2 hours yields total extractives not to exceed 1.2 percent by weight of the filter.

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

[42 FR 14572, Mar. 15, 1977, as amended at 56 FR 42933, Aug. 30, 1991]

§ 177.2280 4,4'-Isopropylidenediphenol-epichlorohydrin thermosetting epoxy resins.

4,4'-Isopropylidenediphenol-epichlorohydrin thermosetting epoxy resins may be safely used as articles or components of articles intended for repeated use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The basic thermosetting epoxy resin is made by reacting 4,4'-isopropylidenediphenol with epichlorohydrin.

(b) The resin may contain one or more of the following optional substances provided the quantity used does not exceed that reasonably required to accomplish the intended effect:

Allyl glycidyl ether	As curing system additive.
Di- and tri-glycidyl ester mixture resulting from the reaction of epichlorohydrin with mixed dimers and trimers of unsaturated C ₁₈ monobasic fatty acids derived from animal and vegetable fats and oils.	As modifier at levels not to exceed equal parts by weight of the 4,4'-isopropylidenediphenol-epichlorohydrin basic resin and limited to use in contact with alcoholic beverages containing not more than 8 percent of alcohol.
1,2-Epoxy-3-phenoxypropane	As curing system additive.
Glyoxal	Do.
4,4'-Isopropylidenediphenol ...	Do.
4,4'-Methylenedianiline	Do.
m-Phenylenediamine	Do.
Tetrahydrophthalic anhydride	Do.

(c) In accordance with good manufacturing practice, finished articles containing the resins shall be thoroughly cleansed prior to their first use in contact with food.

(d) The provisions of this section are not applicable to 4,4'-isopropylidenediphenol-epichlorohydrin resins listed in

Food and Drug Administration, HHS

§ 177.2400

other sections of parts 174, 175, 176, 177, 178 and 179 of this chapter.

[42 FR 14572, Mar. 15, 1977; 49 FR 5748, Feb. 15, 1984]

§ 177.2355 Mineral reinforced nylon resins.

Mineral reinforced nylon resins identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with nonacidic food (pH above 5.0) and at use temperatures not exceeding 212 °F. in accordance with the following prescribed conditions:

(a) For the purpose of this section the mineral reinforced nylon resins consist of nylon 66, as identified in and complying with the specifications of § 177.1500, reinforced with up to 40 weight percent of calcium silicate and up to 0.5 weight percent 3-(triethoxysilyl) propylamine (Chemical Abstracts Service Registry No. 000919302) based on the weight of the calcium silicate.

(b) The mineral reinforced nylon resins may contain up to 0.2 percent by weight of titanium dioxide as an optional adjuvant substance.

(c) The mineral reinforced nylon resins with or without the optional substance described in paragraph (b) of this section, and in the form of 1/8-inch molded test bars, when extracted with the solvents, i.e., distilled water and 50 percent (by volume) ethyl alcohol in distilled water, at reflux temperature for 24 hours using a volume-to-surface ratio of 2 milliliters of solvent per square inch of surface tested, shall meet the following extractives limitations:

(1) Total extractives not to exceed 5.0 milligrams per square inch of food-contact surface tested for each solvent.

(2) The ash after ignition of the extractives described in paragraph (c)(1) of this section, not to exceed 0.5 milligram per square inch of food-contact surface tested.

(d) In accordance with good manufacturing practice, finished articles containing the mineral reinforced nylon resins shall be thoroughly cleansed

prior to their first use in contact with food.

[42 FR 54533, Oct. 7, 1977, as amended at 42 FR 61594, Dec. 6, 1977]

§ 177.2400 Perfluorocarbon cured elastomers.

Perfluorocarbon cured elastomers identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with nonacid food (pH above 5.0), subject to the provisions of this section.

(a) *Identity.* (1) For the purpose of this section, perfluorocarbon cured elastomers are produced by terpolymerizing tetrafluoroethylene (CAS Reg. No. 116-14-3), perfluoromethyl vinyl ether (CAS Reg. No. 1187-93-5), and perfluoro-2-phenoxypropyl vinyl ether (CAS Reg. No. 24520-19-2) and subsequent curing of the terpolymer (CAS Reg. No. 26658-70-8) using the crosslinking agent, phenol, 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl) ethylidene] bis-, dipotassium salt (CAS Reg. No. 25088-69-1) and accelerator, 1,4,7,10,13,16-hexaoxacyclooctadecane (CAS Reg. No. 17455-13-9).

(2) The perfluorocarbon base polymer shall contain no less than 40 weight-percent of polymer units derived from tetrafluoroethylene, no less than 40 weight-percent of polymer units derived from perfluoromethyl vinyl ether and no more than 5 weight-percent polymer units derived from perfluoro-2-phenoxy-propyl vinyl ether.

(3) The composition limitations of the cured elastomer, calculated as parts per 100 parts of terpolymer, are as follows:

Phenol, 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)-ethylidene] bis-, dipotassium salt—not to exceed 5 parts.
1,4,7,10,13,16-Hexaoxacyclo-octadecane—not to exceed 5 parts.

(b) *Optional adjuvant substances.* The perfluorocarbon cured elastomer identified in paragraph (a) of this section may contain the following optional adjuvant substances, subject to any limitations cited on their use:

(1) Substances generally recognized as safe (GRAS) in food or food packaging.

§ 177.2410

21 CFR Ch. I (4–1–25 Edition)

(2) Substances used in accordance with a prior sanction.

(3) Substances authorized under applicable regulations in this part and in parts 175 and 178 of this chapter and subject to any limitations prescribed therein.

(4) Substances identified in this paragraph (b)(4) subject to such limitations as are provided:

Substances	Limitations
Carbon black (channel process of furnace combustion process) (CAS Reg. No. 1333–86–4).	Not to exceed 15 parts per 100 parts of the terpolymer.
Magnesium oxide (CAS Reg. No. 1309–48–4).	Not to exceed 5 parts per 100 parts of the terpolymer.

(c) *Specifications*—(1) *Infrared identification*. Perfluorocarbon cured elastomers may be identified by the characteristic infrared spectra of the pyrolysate breakdown product that is obtained by heating and decomposing the elastomer using the method entitled “Qualitative Identification of Kalrez® by Infrared Examination of Pyrolysate.” This method is incorporated by reference. Copies of the method are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(2) *Thermogravimetry*. Perfluorocarbon cured elastomers have a major decomposition peak occurring at 490° ±15 °C (914 °F). Less than 1.5 percent of the elastomers will volatilize below 400 °C (752 °F) when run under nitrogen at a 10 °C or 18 °F per minute heating rate using a Du Pont Thermal Analyzer Model 1099 with Model 951 TGA unit or the equivalent.

(d) *Extractive limitations*. Articles fabricated from perfluorocarbon cured elastomers having a thickness of at least 1.0 millimeter (0.039 inch) when extracted at reflux temperatures for 2 hours separately with distilled water, 50 percent ethanol, and *n*-heptane,

shall meet the following extractability limits:

(1) Total extractives not to exceed 3.1 milligrams per square decimeter (0.2 milligrams per square inch).

(2) Fluoride extractives calculated as fluorine not to exceed 0.47 milligram per square decimeter (0.03 milligram per square inch).

(e) *Conditions of use*. In accordance with current good manufacturing practice, finished food contact articles containing the perfluorocarbon cured elastomers shall be thoroughly cleaned prior to their first use in contact with food.

[49 FR 43050, Oct. 26, 1984]

§ 177.2410 Phenolic resins in molded articles.

Phenolic resins identified in this section may be safely used as the food-contact surface of molded articles intended for repeated use in contact with nonacid food (pH above 5.0), in accordance with the following prescribed conditions:

(a) For the purpose of this section, the phenolic resins are those produced when one or more of the phenols listed in paragraph (a)(1) of this section are made to react with one or more of the aldehydes listed in paragraph (a)(2) of this section, with or without aniline and/or anhydro-formaldehyde aniline (hexahydro-1, 3,5-triphenyl-s-triazine):

(1) *Phenols*:

p-tert-Amylphenol.
p-tert-Butylphenol.
o-, *m*-, and *p*-Cresol.
p-Octylphenol.
 Phenol.

o- and *p*-Phenylethylphenol mixture produced when phenol is made to react with styrene in the presence of sulfuric acid catalyst.

(2) *Aldehydes*:

Acetaldehyde.
 Formaldehyde.
 Paraldehyde.

(b) Optional adjuvant substances employed in the production of the phenolic resins or added thereto to impart desired technical or physical properties include the following:

Asbestos fiber.	
Barium hydroxide	For use as catalyst.
Calcium stearate	For use as lubricant.

Food and Drug Administration, HHS

§ 177.2420

Carbon black (channel process).	
Diatomaceous earth.	
Glass fiber.	
Hexamethylenetetramine	For use as curing agent.
Mica.	
Oxalic acid	For use as catalyst.
Zinc stearate	For use as lubricant.

(c) The finished food-contact article, when extracted with distilled water at reflux temperature for 2 hours, using a volume-to-surface ratio of 2 milliliters of distilled water per square inch of surface tested, shall meet the following extractives limitations:

(1) Total extractives not to exceed 0.15 milligram per square inch of food-contact surface.

(2) Extracted phenol not to exceed 0.005 milligram per square inch of food-contact surface.

(3) No extracted aniline when tested by a spectrophotometric method sensitive to 0.006 milligram of aniline per square inch of food-contact surface.

(d) In accordance with good manufacturing practice, finished molded articles containing the phenolic resins shall be thoroughly cleansed prior to their first use in contact with food.

§ 177.2415 Poly(aryletherketone) resins.

Poly(aryletherketone) resins identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with food subject to the provisions of this section.

(a) *Identity.* For the purposes of this section, poly(aryletherketone) resins are poly(*p*-oxyphenylene *p*-oxyphenylene *p*-carboxyphenylene) resins (CAS Reg. No. 29658-26-2) produced by the polymerization of hydroquinone and 4,4'-difluorobenzophenone, and have a minimum weight-average molecular weight of 12,000, as determined by gel permeation chromatography in comparison with polystyrene standards, and a minimum mid-point glass transition temperature of 142 °C, as determined by differential scanning calorimetry.

(b) *Optional adjuvant substances.* The basic resins identified in paragraph (a) may contain optional adjuvant substances used in their production. These adjuvants may include substances de-

scribed in §174.5(d) of this chapter and the following:

Substance	Limitations
Diphenyl sulfone	Not to exceed 0.2 percent by weight as a residual solvent in the finished basic resin.

(c) *Extractive limitations.* The finished food contact article, when extracted at reflux temperatures for 2 hours with the following four solvents, yields in each extracting solvent net chloroform soluble extractives not to exceed 0.05 milligrams per square inch of food contact surface: Distilled water, 50 percent (by volume) ethanol in distilled water, 3 percent acetic acid in distilled water, and *n*-heptane. In testing the final food contact article, a separate test sample shall be used for each extracting solvent.

[63 FR 20315, Apr. 24, 1998]

§ 177.2420 Polyester resins, cross-linked.

Cross-linked polyester resins may be safely used as articles or components of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions:

(a) The cross-linked polyester resins are produced by the condensation of one or more of the acids listed in paragraph (a)(1) of this section with one or more of the alcohols or epoxides listed in paragraph (a)(2) of this section, followed by copolymerization with one or more of the cross-linking agents listed in paragraph (a)(3) of this section:

(1) Acids:

Adipic.
Fatty acids, and dimers thereof, from natural sources.
Fumaric.
Isophthalic.
Maleic.
Methacrylic.
Orthophthalic.
Sebacic.
Terephthalic.
Trimellitic.

(2) Polyols and polyepoxides:

Butylene glycol.
Diethylene glycol.
2,2-Dimethyl-1,3-propanediol.
Dipropylene glycol.
Ethylene glycol.
Glycerol.

§ 177.2420

21 CFR Ch. I (4–1–25 Edition)

4,4'-Isopropylidenediphenol-epichlorohydrin.
Mannitol.
 α -Methyl glucoside.
Pentaerythritol.
Polyoxypropylene ethers of 4,4'-isopropylidenediphenol (containing an average of 2–7.5 moles of propylene oxide).
Propylene glycol.
Sorbitol.
Trimethylol ethane.
Trimethylol propane.
2,2,4-Trimethyl-1,3-pentanediol.

(3) Cross-linking agents:

Butyl acrylate.
Butyl methacrylate.
Ethyl acrylate.
Ethylhexyl acrylate.
Methyl acrylate.

Methyl methacrylate.
Styrene.
Triglycidyl isocyanurate (CAS Reg. No. 2451–62–9), for use only in coatings contacting bulk quantities of dry food of the type identified in §176.170(c) of this chapter, table 1, under type VIII.
Vinyl toluene.

(b) Optional adjuvant substances employed to facilitate the production of the resins or added thereto to impart desired technical or physical properties include the following, provided that the quantity used does not exceed that reasonably required to accomplish the intended physical or technical effect and does not exceed any limitations prescribed in this section:

List of substances	Limitations (limits of addition expressed as percent by weight of finished resin)
1. Inhibitors: Benzoquinone <i>tert</i> -Butyl catechol. TBHQ. Di- <i>tert</i> -butyl hydroquinone. Hydroquinone.	Total not to exceed 0.08 percent. 0.01 percent.
2. Accelerators: Benzyl trimethyl ammonium chloride Calcium naphthenate. Cobalt naphthenate. Copper naphthenate. <i>N, N</i> -Diethylaniline <i>N, N</i> -Dimethylaniline Ethylene guanidine hydrochloride	Total not to exceed 1.5 percent. 0.05 percent. 0.4 percent. Do. 0.05 percent.
3. Catalysts: Azo-bis-isobutyronitrile. Benzoyl peroxide. <i>tert</i> -Butyl perbenzoate. Chlorobenzoyl peroxide. Cumene hydroperoxide. Dibutyltin oxide (CAS Reg. No. 818–08–6) Dicumyl peroxide. Hydroxybutyltin oxide (CAS Reg. No. 2273–43–0) Lauroyl peroxide. <i>p</i> -Menthane hydroperoxide. Methyl ethyl ketone peroxide. Monobutyltin tris(2-ethylhexoate) (CAS Reg. No. 23850–94–4).	Total not to exceed 1.5 percent, except that methyl ethyl ketone peroxide may be used as the sole catalyst at levels not to exceed 2 percent. For use in the polycondensation reaction at levels not to exceed 0.2 percent of the polyester resin. For use in the polycondensation reaction at levels not to exceed 0.2 percent of the polyester resin.
4. Solvents for inhibitors, accelerators, and catalysts: Diethylene glycol Methyl alcohol. Styrene. Triphenyl phosphate.	For use in the polycondensation reaction at levels not to exceed 0.2 percent of the polyester resin. As a solvent for benzyl trimethyl ammonium chloride or ethylene guanidine hydrochloride only.
5. Reinforcements: Asbestos. Glass fiber. Polyester fiber produced by the condensation of one or more of the acids listed in paragraph (a)(1) of this section with one or more of the alcohols listed in paragraph (a)(2) of this section.	
6. Miscellaneous materials: Castor oil, hydrogenated. α -Methylstyrene. Polyethylene glycol 6000. Silicon dioxide.	

List of substances	Limitations (limits of addition expressed as percent by weight of finished resin)
Wax, petroleum	Complying with § 178.3710 of this chapter.

(c) The cross-linked polyester resins, with or without the optional substances described in paragraph (b) of this section, and in the finished form in which they are to contact food, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of their intended use, as determined from tables 1 and 2 of §176.170(c) of this chapter, shall meet the following extractives limitations:

(1) Net chloroform-soluble extractives not to exceed 0.1 milligram per square inch of food-contact surface tested when the prescribed food-simulating solvent is water or 8 or 50 percent alcohol.

(2) Total nonvolatile extractives not to exceed 0.1 milligram per square inch of food-contact surface tested when the prescribed food-simulating solvent is heptane.

(d) In accordance with good manufacturing practice, finished articles containing the cross-linked polyester resins shall be thoroughly cleansed prior to their first use in contact with food.

[42 FR 14572, Mar. 15, 1977, as amended at 48 FR 37618, Aug. 19, 1983; 54 FR 48858, Nov. 28, 1989; 87 FR 31089, May 20, 2022]

§ 177.2430 Polyether resins, chlorinated.

Chlorinated polyether resins may be safely used as articles or components of articles intended for repeated use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The chlorinated polyether resins are produced by the catalytic polymerization of 3,3-bis(chloromethyl)-oxetane, and shall contain not more than 2 percent residual monomer.

(b) In accordance with good manufacturing practice, finished articles containing the chlorinated polyether resins shall be thoroughly cleansed prior to their first use in contact with food.

§ 177.2440 Polyethersulfone resins.

Polyethersulfone resins identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with food in accordance with the following prescribed conditions:

(a) For the purpose of this section, polyethersulfone resins are:

(1) Poly(oxy-*p*-phenylenesulfonyl-*p*-phenylene) resins (CAS Reg. No. 25667-42-9), which have a minimum number average molecular weight of 16,000.

(2) 1,1'-sulfonylbis[4-chlorobenzene] polymer with 4,4'-(1-methylethylidene)bis[phenol] (maximum 8 percent) and 4,4'-sulfonylbis[phenol] (minimum 92 percent) (CAS Reg. No. 88285-91-0), which have a minimum number average molecular weight of 26,000.

(3) In paragraphs (a)(1) and (a)(2) of this section, the minimum number average molecular weight is determined by reduced viscosity in dimethyl formamide in accordance with ASTM method D2857-70 (Reapproved 1977), "Standard Test Method for Dilute Solution Viscosity of Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) The basic resins identified in paragraphs (a)(1) and (a)(2) of this section may contain optional adjuvant substances described in §174.5(d) of this chapter and the following:

§ 177.2450

21 CFR Ch. I (4–1–25 Edition)

List of substances	Limitations
Diphenylsulfone	Not to exceed 0.2 percent as residual solvent in the finished basic resin described in paragraph (a)(1) of this section.
Dimethyl sulfoxide	Not to exceed 0.01 percent as residual solvent in the finished basic resin described in paragraph (a)(1) of this section.
N-methyl-2-pyrrolidone	Not to exceed 0.01 percent as residual solvent in the finished basic resin described in paragraph (a)(2) of this section.

(c) The finished food-contact article, when extracted at reflux temperatures for 2 hours with the following four solvents, yields net chloroform-soluble extractives in each extracting solvent not to exceed 0.02 milligram per square inch of food-contact surface: distilled water, 50 percent (by volume) ethyl alcohol in distilled water, 3 percent acetic acid in distilled water, and *n*-heptane. (Note: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.)

(d) In accordance with good manufacturing practice, finished food-contact articles containing the polyethersulfone resins shall be thoroughly cleansed before their first use in contact with food.

[44 FR 34493, June 15, 1979, as amended at 47 FR 38885, Sept. 3, 1982; 49 FR 10111, Mar. 19, 1984; 50 FR 47211, Nov. 15, 1985; 60 FR 48648, Sept. 20, 1995; 78 FR 14666, Mar. 7, 2013]

§ 177.2450 Polyamide-imide resins.

Polyamide-imide resins identified in paragraph (a) of this section may be safely used as components of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions:

(a) *Identity.* (1) For the purpose of this section the polyamide-imide resins are derived from the condensation reaction of substantially equimolar parts of trimellitic anhydride and *p,p'*-diphenylmethane diisocyanate.

(2) The polyamide-imide resins (CAS Reg. No. 31957–38–7) derived from the condensation reaction of equimolar parts of benzoyl chloride-3,4-dicarboxylic anhydride and 4,4'-diphenylmethanediamine.

(b) *Specifications.* (1) Polyamide-imide resins identified in paragraph (a)(1) of this section shall have a nitrogen con-

tent of not less than 7.8 weight percent and not more than 8.2 weight percent. Polyamide-imide resins identified in paragraph (a)(2) of this section shall have a nitrogen content of not less than 7.5 weight percent and not more than 7.8 weight percent. Nitrogen content is determined by the Dumas Nitrogen Determination as set forth in the “Official Methods of Analysis of the Association of Official Analytical Chemists,” 13th Ed. (1980), sections 7.016–7.020, which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(2) Polyamide-imide resins identified in paragraph (a)(1) of this section shall have a solution viscosity of not less than 1.200. Polyamide-imide resins identified in paragraph (a)(2) of this section shall have a solution viscosity of not less than 1.190. Solution viscosity shall be determined by a method titled “Solution Viscosity” which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(3) The polyamide-imide resins identified in paragraph (a)(1) of this section are heat cured at 600 °F for 15 minutes when prepared for extraction tests and the residual monomers: *p,p'*-diphenylmethane diisocyanate should not be present at greater than 100 parts per million and trimellitic anhydride should not be present at greater than

500 parts per million. Residual monomers are determined by gas chromatography (the gas chromatography method titled "Amide-Imide Polymer Analysis—Analysis of Monomer Content," is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(c) Extractive limitations are applicable to the polyamide-imide resins identified in paragraphs (a)(1) and (2) of this section in the form of films of 1 mil uniform thickness after coating and heat curing at 600 °F for 15 minutes on stainless steel plates, each having such resin-coated surface area of 100 square inches. The cured-resin film coatings shall be extracted in accordance with the method described in §176.170(d)(3) of this chapter, using a plurality of spaced, coated stainless steel plates, exposed to the respective food simulating solvents. The resin shall meet the following extractive limitations under the corresponding extraction conditions:

(1) Distilled water at 250 °F for 2 hours: Not to exceed 0.01 milligram per square inch.

(2) Three percent acetic acid at 212 °F for 2 hours: Not to exceed 0.05 milligram per square inch.

(3) Fifty percent ethyl alcohol at 160 °F for 2 hours: Not to exceed 0.03 milligram per square inch.

(4) *n*-Heptane at 150 °F for 2 hours: Not to exceed 0.05 milligram per square inch.

(d) In accordance with good manufacturing practice, those food contact articles, having as components the polyamide-imide resins identified in paragraph (a) of this section and intended for repeated use shall be thoroughly

cleansed prior to their first use in contact with food.

[42 FR 14572, Mar. 15, 1977, as amended at 47 FR 11845, Mar. 19, 1982; 49 FR 10111, Mar. 19, 1984; 54 FR 24898, June 12, 1989; 54 FR 43170, Oct. 23, 1989; 61 FR 14481, Apr. 2, 1996; 70 FR 40880, July 15, 2005; 70 FR 67651, Nov. 8, 2005]

§ 177.2460 Poly(2,6-dimethyl-1,4-phenylene) oxide resins.

The poly(2,6-dimethyl-1,4-phenylene) oxide resins identified in paragraph (a) of this section may be used as an article or as a component of an article intended for use in contact with food subject to the provisions of this section.

(a) *Identity.* For the purposes of this section, poly(2,6-dimethyl-1,4-phenylene) oxide resins consist of basic resins produced by the oxidative coupling of 2,6-xylenol such that the finished basic resins meet the specifications and extractives limitations prescribed in paragraph (c) of this section.

(b) *Optional adjuvant substances.* The basic poly(2,6-dimethyl-1,4-phenylene) oxide resins identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic resins. The optional adjuvant substances required in the production of the basic poly(2,6-dimethyl-1,4-phenylene) oxide resins may include substances permitted for such use by regulations in parts 170 through 189 of this chapter, substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, and the following:

List of substances	Limitations (expressed as percent by weight of finished basic resin)
Diethylamine	Not to exceed 0.16 percent as residual catalyst.
Methyl alcohol	Not to exceed 0.02 percent as residual solvent.
Toluene	Not to exceed 0.2 percent as residual solvent.

(c) *Specifications and extractives limitations.* The poly(2,6-dimethyl-1,4-phenylene) oxide basic resins meet the following:

(1) *Specifications.* Intrinsic viscosity is not less than 0.30 deciliter per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by

reference, modified as follows. Copies of the incorporation by reference may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(i) *Solvent*: Chloroform, reagent grade containing 0.01 percent *tert*-butylcatechol.

(ii) *Resin sample*: Powdered resin obtained from production prior to molding or extrusion.

(iii) *Viscometer*: Cannon-Ubbelohde series 25 dilution viscometer (or equivalent).

(iv) *Calculation*: The calculation method used is that described in appendix X.1.3 (ASTM method D1243-79, cited and incorporated by reference in paragraph (c)(1) of this section) with the reduced viscosity determined for three concentration levels (0.4, 0.2, and 0.1 gram per deciliter) and extrapolated to zero concentration for intrinsic viscosity. The following formula is used for determining reduced viscosity:

$$\text{Reduced viscosity in terms of deciliters per gram} = \frac{t - t_o}{t_o \times c}$$

where:

t = Solution efflux time.

t_o = Solvent efflux time.

c = Concentration of solution in terms of grams per deciliter.

(2) *Extractives limitations*. Total resin extracted not to exceed 0.02 weight-percent when extracted with *n*-heptane at 160 °F for 2 hours as determined using 200 milliliters of reagent grade *n*-heptane which has been freshly distilled before use and 25 grams of poly(2,6-dimethyl-1,4-phenylene) oxide resin. The resin as tested is in pellet form having a particle size such that 100 percent of the pellets will pass through a U.S. Standard Sieve No. 6 and 100 percent of the pellets will be held on a U.S. Standard Sieve No. 10.

(d) *Other limitations*. The poly(2,6-dimethyl-1,4-phenylene) oxide resins identified in and complying with this

section, when used as components of the food-contact surface of any article that is the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(e) *Uses*. The poly(2,6-dimethyl-1,4-phenylene) oxide resins identified in and complying with the limitations in this section may be used as articles or components of articles intended for repeated food-contact use or as articles or components of articles intended for single-service food-contact use only under the conditions described in §176.170(c) of this chapter, table 2, conditions of use H.

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10111, Mar. 19, 1984; 63 FR 8852, Feb. 23, 1998]

§ 177.2465 Polymethylmethacrylate/poly(trimethoxysilylpropyl)methacrylate copolymers.

Polymethylmethacrylate/poly(trimethoxysilylpropyl) methacrylate copolymers (CAS Reg. No. 26936-30-1) may be safely used as components of surface primers used in conjunction with silicone polymers intended for repeated use and complying with §175.300 of this chapter and §177.2600, in accordance with the following prescribed conditions.

(a) *Identity*. For the purpose of this section, polymethylmethacrylate/poly(trimethoxysilylpropyl)methacrylate copolymers are produced by the polymerization of methylmethacrylate and trimethoxysilylpropylmethacrylate.

(b) *Conditions of use*. (1) The polymethylmethacrylate/poly(trimethoxysilylpropyl)methacrylate copolymers are used at levels not to exceed 6.0 percent by weight of the primer formulation.

(2) The copolymers may be used in food contact applications with all food types under conditions of use B through H as described in table 2 of §176.170(c) of this chapter.

[59 FR 5948, Feb. 9, 1994]

§ 177.2470 Polyoxymethylene copolymer.

Polyoxymethylene copolymer identified in this section may be safely used as an article or component of articles intended for food-contact use in accordance with the following prescribed conditions:

(a) *Identity.* For the purpose of this section, polyoxymethylene copolymers are identified as the following: The reaction product of trioxane (cyclic trimer of formaldehyde) and ethylene oxide (CAS Reg. No. 24969-25-3) or the reaction product of trioxane (cyclic trimer of formaldehyde) and a maximum of 5 percent by weight of butanediol formal (CAS Reg. No. 25214 85-1). Both copolymers may have certain optional substances added to impart desired technological properties to the copolymer.

(b) *Optional adjuvant substances.* The polyoxymethylene copolymer identified in paragraph (a) of this section may contain optional adjuvant substances required in its production. The quantity of any optional adjuvant substance employed in the production of the copolymer does not exceed the amount reasonably required to accomplish the intended technical or physical effect. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted under applicable regulations in parts 170 through 189 of this chapter, and the following:

(1) Stabilizers (total amount of stabilizers not to exceed 2.0 percent and amount of any one stabilizer not to exceed 1.0 percent of polymer by weight)

Calcium ricinoleate.

Cyanoguanidine.

Hexamethylene bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate) (CAS Reg. No. 35074-77-2).

Melamine-formaldehyde resin.

2,2'-Methylenebis(4-methyl-6-*tert*-butylphenol).

Nylon 6/66, weight ratio 2/3.

Tetrakis [methylene (3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate)] methane.

(2) Lubricant: N,N'-Distearoylethylenediamine.

(c) *Specifications.* (1) Polyoxymethylene copolymer can be identified by its characteristic infrared spectrum.

(2) Minimum number average molecular weight of the copolymer is 15,000 as determined by a method titled "Number Average Molecular Weight," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(d) *Extractive limitations.* (1) Polyoxymethylene copolymer 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 as determined from tables 1 and 2 of §175.300(d) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface.

(2) Polyoxymethylene copolymer with or without the optional substances described in paragraph (b) of this section, when ground or cut into particles that pass through a U.S.A. Standard Sieve No. 6 and that are retained on a U.S.A. Standard Sieve No. 10, shall yield total extractives as follows:

(i) Not to exceed 0.20 percent by weight of the copolymer when extracted for 6 hours with distilled water at reflux temperature.

(ii) Not to exceed 0.15 percent by weight of the copolymer when extracted for 6 hours with n-heptane at reflux temperature.

(e) *Conditions of use.* (1) The polyoxymethylene copolymer is for use as articles or components of articles intended for repeated use.

(2) Use temperature shall not exceed 250 °F.

(3) In accordance with good manufacturing practice, finished articles containing polyoxymethylene copolymer

§ 177.2480

shall be thoroughly cleansed before their first use in contact with food.

[42 FR 14572, Mar. 15, 1977, as amended at 48 FR 56204, Dec. 20, 1983; 49 FR 5748, Feb. 15, 1984; 50 FR 1842, Jan. 14, 1985; 50 FR 20560, May 17, 1985; 52 FR 4493, Feb. 12, 1987, 54 FR 24898, June 12, 1989]

§ 177.2480 Polyoxymethylene homopolymer.

Polyoxymethylene homopolymer identified in this section may be safely used as articles or components of articles intended for food-contact use in accordance with the following prescribed conditions:

(a) *Identity.* For the purpose of this section, polyoxymethylene homopolymer is polymerized formaldehyde [Chemical Abstracts Service Registry No. 9002-81-7]. Certain optional adjuvant substances, described in paragraph (b) of this section, may be added to impart desired technological properties to the homopolymer.

(b) *Optional adjuvant substances.* The polyoxymethylene homopolymer identified in paragraph (a) of this section may contain optional adjuvant substances in its production. The quantity of any optional adjuvant substance employed in the production of the homopolymer does not exceed the amount reasonably required to accomplish the intended effect. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted under applicable regulations in this part, and the following:

(1) *Stabilizers.* The homopolymer may contain one or more of the following stabilizers. The total amount of stabilizers shall not exceed 1.9 percent of homopolymer by weight, and the quantity of individual stabilizer used shall not exceed the limitations set forth below:

Substances	Limitations
Hexamethylenebis(3,5-di-tert-butyl-4-hydroxy-hydrocinnamate) (CAS Reg. No. 35074-77-2).	At a maximum level of 1 percent by weight of homopolymer. The finished articles shall not be used for foods containing more than 8 percent alcohol.
2,2'-Methylenebis(4-methyl-6-tert-butylphenol).	At a maximum level of 0.5 percent by weight of homopolymer.

21 CFR Ch. I (4-1-25 Edition)

Substances	Limitations
Nylon 66/610/6 terpolymer, respective proportions of nylon polymers by weight are: 3/2/4.	At a maximum level of 1.5 percent by weight of homopolymer.
Nylon 612/6 copolymer (CAS Reg. No. 51733-10-9), weight ratio 6/1.	Do.
Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxy-hydrocinnamate)] methane.	At a maximum level of 0.5 percent by weight of homopolymer.

(2) *Lubricant.* *N,N'*-Distearoyl-ethylenediamine.

(3) *Molding assistant.* Polyethylene glycol 6,000.

(c) *Specifications.* (1) Polyoxymethylene homopolymer can be identified by its characteristic infrared spectrum.

(2) Minimum number average molecular weight of the homopolymer is 25,000.

(3) Density of the homopolymer is between 1.39 and 1.44 as determined by ASTM method D1505-68 (Reapproved 1979), "Standard Test Method for Density of Plastics by the Density-Gradient Technique," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(4) Melting point is between 172 °C and 184 °C as determined by ASTM method D2133-66, "Specifications for Acetal Resin Injection Molding and Extrusion Materials" (Revised 1966), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(d) *Extractive limitations.* (1) Polyoxymethylene homopolymer, in

the finished form which 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 intended use under paragraphs (c)(3) and (d) of §175.300 of this chapter and as limited by paragraph (e) of this section, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface.

(2) Polyoxymethylene homopolymer, with or without the optional adjuvant substances described in paragraph (b) of this section, when ground or cut into particles that pass through a U.S.A. Standard Sieve No. 6 and that are retained on a U.S.A. Standard Sieve No. 10, shall yield extractives as follows:

(i) Formaldehyde not to exceed 0.0050 percent by weight of homopolymer as determined by a method titled "Formaldehyde Release and Formaldehyde Analysis," which is incorporated by reference. Copies are available from Center for Food Safety and Applied Nutrition (HFS-200) Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal-register/code_of_federal_regulations/ibr_locations.html.

(ii) Total extractives not to exceed 0.20 percent by weight of homopolymer when extracted for 6 hours with distilled water at reflux temperature and 0.15 percent by weight of homopolymer when extracted for 6 hours with *n*-heptane at reflux temperature.

(e) *Conditions of use.* (1) Polyoxymethylene homopolymer is for use as articles or components of articles intended for repeated use.

(2) Use temperature shall not exceed 250 °F.

(3) In accordance with good manufacturing practice, finished articles containing polyoxymethylene homopolymer shall be thoroughly

cleansed prior to first use in contact with food.

[42 FR 14572, Mar. 15, 1977, as amended at 43 FR 44835, Sept. 29, 1978; 47 FR 11846, Mar. 19, 1982; 47 FR 51562, Nov. 16, 1982; 49 FR 10111, Mar. 19, 1984; 54 FR 24898, June 12, 1989]

§ 177.2490 Polyphenylene sulfide resins.

Polyphenylene sulfide resins (poly(1,4-phenylene sulfide) resins) may be safely used as coatings or components of coatings of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions.

(a) Polyphenylene sulfide resins consist of basic resins produced by the reaction of equimolar parts of *p*-dichlorobenzene and sodium sulfide, such that the finished resins meet the following specifications as determined by methods titled "Oxygen Flask Combustion-Gravimetric Method for Determination of Sulfur in Organic Compounds," "Determination of the Inherent Viscosity of Polyphenylene Sulfide," and "Analysis for Dichlorobenzene in Ryton Polyphenylene Sulfide," which are incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal-register/code_of_federal_regulations/ibr_locations.html.

(1) Sulfur content: 28.2-29.1 percent by weight of finished resin.

(2) Minimum inherent viscosity: 0.13 deciliters per gram.

(3) Maximum residual *p*-dichlorobenzene: 0.8 ppm.

(b) Subject to any limitations prescribed in parts 170 through 189 of this chapter, the following optional substances may be added to the polyphenylene sulfide basic resins in an amount not to exceed that reasonably required to accomplish the intended physical or technical effect.

(1) Substances generally recognized as safe in food.

§ 177.2500

(2) Substances used in accordance with prior sanction or approval.

(3) Substances the use of which is permitted in coatings under regulations in parts 170 through 189 of this chapter.

(c) The finished coatings are thermally cured at temperatures of 700 °F and above.

(d) Polyphenylene sulfide resin coatings may be used in contact with food at temperatures not to exceed the boiling point of water; provided that the finished cured coating, when extracted at reflux temperatures for 8 hours separately with distilled water, 50 percent ethanol in water, and 3 percent acetic acid, yields total extractives in each extracting solvent not to exceed 0.02 milligram per square inch of surface and when extracted at reflux temperature for 8 hours with heptane yields total extractives not to exceed 0.1 milligram per square inch of surface.

(e) Polyphenylene sulfide resin coatings containing perfluorocarbon resins complying with §177.1550 may be used in contact with food at temperatures up to and including normal baking and frying temperatures; provided that the finished cured coating, when extracted at reflux temperatures for 2 hours separately with distilled water, 50 percent ethanol in water, 3 percent acetic acid and heptane, yields total extractives in each extracting solvent not to exceed 0.2 milligram per square inch of surface and when extracted at reflux temperature for 1 hour with diphenyl ether yields total extractives not to exceed 4.5 milligrams per square inch of surface.

[42 FR 14572, Mar. 15, 1977, as amended at 47 FR 11846, Mar. 19, 1982; 54 FR 24898, June 12, 1989]

§ 177.2500 Polyphenylene sulfone resins.

The polyphenylene sulfone resins (CAS Reg. No. 31833-61-1) identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with food, subject to the provisions of this section.

(a) *Identity.* For the purpose of this section, polyphenylene sulfone resins consist of basic resin produced by reacting polyphenylene sulfide with per-

21 CFR Ch. I (4-1-25 Edition)

acetic acid such that the finished resins meet the specifications set forth in paragraph (c) of this section. The polyphenylene sulfide used to manufacture polyphenylene sulfone is prepared by the reaction of sodium sulfide and *p*-dichlorobenzene, and has a minimum weight average molecular weight of 5,000 Daltons.

(b) *Optional adjuvant substances.* The basic polyphenylene sulfone resins identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic resins. These optional adjuvant substances may include substances permitted for such use by regulations in parts 170 through 189 of this chapter, substances generally recognized as safe in food, or substances used in accordance with a prior sanction or approval.

(c) *Specifications.* The glass transition temperature of the polymer is 360±5 °C as determined by the use of differential scanning calorimetry.

[65 FR 15053, Mar. 21, 2000]

§ 177.2510 Polyvinylidene fluoride resins.

Polyvinylidene fluoride resins may be safely used as articles or components of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions:

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

(b) The finished food-contact article, when extracted at reflux temperatures for 2 hours with the solvents distilled water, 50 percent (by volume) ethyl alcohol in distilled water, and *n*-heptane, yields total extractives in each extracting solvent not to exceed 0.01 milligram per square inch of food-contact surface tested; and if the finished food-contact article is itself the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation. (NOTE: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.)

(c) In accordance with good manufacturing practice, finished food-contact articles containing the polyvinylidene fluoride resins shall be thoroughly cleansed prior to their first use in contact with food.

§ 177.2550 Reverse osmosis membranes.

Substances identified in paragraph (a) of this section may be safely used as reverse osmosis membranes intended for use in processing bulk quantities of liquid food to separate permeate from food concentrate or in purifying water for food manufacturing under the following prescribed conditions:

(a) *Identity.* For the purpose of this section, reverse osmosis membranes may consist of either of the following formulations:

(1) A cross-linked high molecular weight polyamide reaction product of 1,3,5-benzenetricarbonyl trichloride with 1,3-benzenediamine (CAS Reg. No. 83044-99-9) or piperazine (CAS Reg. No. 110-85-0). The membrane is on the food-contact surface, and its maximum weight is 62 milligrams per square decimeter (4 milligrams per square inch) as a thin film composite on a suitable support.

(2) A cross-linked polyetheramine (CAS Reg. No. 101747-84-6), identified as the copolymer of epichlorohydrin, 1,2-ethanediamine and 1,2-dichloroethane, whose surface is the reaction product of this copolymer with 2,4-toluenediisocyanate (CAS Reg. No. of the final polymer is 99811-80-0) for use as the food-contact surface of reverse osmosis membranes used in processing liquid food. The composite membrane is on the food-contact surface and its maximum weight is 4.7 milligrams per square decimeter (0.3 milligrams per square inch) as a thin film composite on a suitable support. The maximum weight of the 2,4-toluenediisocyanate component of the thin film composite is 0.47 milligrams per square decimeter (0.03 milligrams per square inch).

(3) For the purpose of this section, the reverse osmosis membrane consists of a polyamide identified as 2,4-diaminobenzenesulfonic acid, calcium salt (2:1) polymer with 1,3-benzenediamine, 1,3-benzenedicarbonyl dichloride, and 1,4-benzenedicarbonyl

dichloride (CAS Reg. No. 39443-76-0). The membrane is the food contact surface and may be applied as a film on a suitable support. Its maximum weight is 512 milligrams per square decimeter (33 milligrams per square inch).

(4) A cross-linked high molecular weight polyamide reaction product of poly(*N*-vinyl-*N*-methylamine) (CAS Reg. No. 31245-56-4), *N,N'*-bis(3-aminopropyl)ethylenediamine (CAS Reg. No. 10563-26-5), 1,3-benzenedicarbonyl dichloride (CAS Reg. No. 99-63-8) and 1,3,5-benzenetricarbonyl trichloride (CAS Reg. No. 4422-95-1). The membrane is the food-contact surface. Its maximum weight is 20 milligrams per square decimeter (1.3 milligrams per square inch) as a thin film composite on a suitable support.

(5) A polyamide reaction product of 1,3,5-benzenetricarbonyl trichloride polymer (CAS Reg. No. 4422-95-1) with piperazine (CAS Reg. No. 110-85-0) and 1,2-diaminoethane (CAS Reg. No. 107-15-3). The membrane is the food-contact layer and may be applied as a film on a suitable support. Its maximum weight is 15 milligrams per square decimeter (1 milligram per square inch).

(b) *Optional adjuvant substances.* The basic polymer identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic polymer. These optional adjuvant substances may include substances permitted for such use by regulations in parts 170 through 186 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) *Supports.* Suitable supports for reverse osmosis membranes are materials permitted for such use by regulations in parts 170 through 186 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(d) *Conditions of use.* (1) Reverse osmosis membranes described in paragraphs (a)(1), (a)(2), (a)(3), and (a)(5) of this section may be used in contact with all types of liquid food at temperatures up to 80 °C (176 °F).

§ 177.2600

(2) Reverse osmosis membranes described in paragraph (a)(4) of this section may be used in contact with all types of liquid food, except food containing more than 8 percent alcohol, at temperatures up to 80 °C (176 °F).

(3) Reverse osmosis membranes shall be maintained in a sanitary manner in accordance with current good manufacturing practice so as to prevent microbial adulteration of food.

(4) To assure their safe use, reverse osmosis membranes and their supports shall be thoroughly cleaned prior to their first use in accordance with current good manufacturing practice.

[49 FR 49448, Dec. 20, 1984, as amended at 52 FR 29668, Aug. 11, 1987; 53 FR 31835, Aug. 22, 1988; 53 FR 32215, Aug. 24, 1988; 55 FR 8139, Mar. 7, 1990; 59 FR 9925, Mar. 2, 1994]

§ 177.2600 Rubber articles intended for repeated use.

Rubber articles intended for repeated use may be safely used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The rubber articles are prepared from natural and/or synthetic polymers and adjuvant substances as described in paragraph (c) of this section.

(b) The quantity of any substance employed in the production of rubber articles intended for repeated use shall not exceed the amount reasonably required to accomplish the intended effect in the rubber article and shall not be intended to accomplish any effect in food.

(c) Substances employed in the preparation of rubber articles include the following, subject to any limitations prescribed:

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

(2) Substances used in accordance with the provisions of a prior sanction or approval.

(3) Substances that by regulation in parts 170 through 189 of this chapter may be safely used in rubber articles, subject to the provisions of such regulation.

(4) Substances identified in this paragraph (c)(4), provided that any substance that is the subject of a regula-

21 CFR Ch. I (4–1–25 Edition)

tion in parts 174, 175, 176, 177, 178 and §179.45 of this chapter conforms with any specification in such regulation.

(i) *Elastomers.*

Acrylonitrile-butadiene copolymer.

Brominated isobutylene-isoprene copolymers complying with §177.1210.

Butadiene-acrylonitrile-ethylene glycol dimethacrylate copolymers containing not more than 5 weight percent of polymer units derived from ethylene glycol dimethacrylate.

Butadiene-acrylonitrile-methacrylic acid copolymer.

Butadiene-styrene-methacrylic acid copolymer.

Chloroprene polymers.

Chlorotrifluoroethylene-vinylidene fluoride copolymer.

Ethylene-propylene copolymer elastomers which may contain not more than 5 weight-percent of total polymer units derived from 5-methylene-2-norbornene and/or 5-ethylidene-2-norbornene.

Ethylene-propylene-dicyclopentadiene copolymer.

Ethylene-propylene-1,4-hexadiene copolymers containing no more than 8 weight percent of total polymer units derived from 1,4-hexadiene.

Hydrogenated butadiene/acrylonitrile copolymers (CAS Reg. No. 88254-10-8) produced when acrylonitrile/butadiene copolymers are modified by hydrogenation of the olefinic unsaturation to leave either: (1) Not more than 10 percent *trans* olefinic unsaturation and no α , β -olefinic unsaturation as determined by a method entitled "Determination of Residual α , β -Olefinic and Trans Olefinic Unsaturation Levels in HNBR," developed October 1, 1991, by Polysar Rubber Corp., 1256 South Vidal St., Sarnia, Ontario, Canada N7T 7M1; or (2) 0.4 percent to 20 percent olefinic unsaturation and Mooney viscosities greater than 45 (ML 1 + 4 @ 100 °C), as determined by ASTM Standard Method D1646-92, "Standard Test Method for Rubber—Viscosity and Vulcanization Characteristics (Mooney Viscometer)," which are both incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of these methods may be obtained from the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/

code_of_federal_regulations/

ibr_locations.html. A copy of ASTM Standard Method D1646-92 may also be obtained from the American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428-2959.

Isobutylene-isoprene copolymer.

Polyamide/polyether block copolymers (CAS Reg. No. 77402-38-1 prepared by reacting a copolymer of *omega*-laurolactam and adipic acid with poly(tetramethylene ether glycol). The polyamide and polyether components are reacted in ratios such that the polyamide component constitutes a minimum of 30 weight-percent of total polymer units. The copolymers may be used in contact with foods of Types I, II, III, IV, V, VI, VII, VIII, and IX identified in table 1 of §176.170(c) of this chapter at temperatures not to exceed 150 °F except that those copolymers prepared with less than 50 weight-percent of polyamide are limited to use in contact with such foods at temperatures not to exceed 100 °F.

Polybutadiene.

Polyester elastomers derived from the reaction of dimethyl terephthalate, 1,4-butanediol, and α -hydro-*omega*-hydroxypoly (oxytetramethylene). Additionally, trimethyl trimellitate may be used as a reactant. The polyester elastomers may be used only in contact with foods containing not more than 8 percent alcohol and limited to use in contact with food at temperatures not exceeding 150 °F.

Polyisoprene.

Polyurethane resins (CAS Reg. Nos. 37383-28-1 or 9018-04-6) derived from the reaction of diphenylmethane diisocyanate with 1,4-butanediol and polytetramethylene ether glycol.

Polyurethane resins derived from reactions of diphenylmethane diisocyanate with adipic acid and 1,4-butanediol.

Rubber, natural.

Silicone basic polymer as described in ASTM method D1418-81, "Standard Practice for Rubber and Rubber Latices—Nomenclature," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Silicone (Si) elastomers containing methyl groups.

Silicone (Psi) elastomers containing methyl and phenyl groups.

Silicone (Vsi) elastomers containing methyl and vinyl groups.

Silicone (Fsi) elastomers containing methyl and fluorine groups.

Silicone (PVsi) elastomers containing phenyl, methyl, and vinyl groups.

Styrene-butadiene copolymer.

Vinylidene fluoride-hexafluoropropylene copolymers (minimum number average molecular weight 70,000 as determined by osmotic pressure in methyl ethyl ketone).

Vinylidene fluoride-hexafluoropropylene-tetrafluoroethylene copolymers (minimum number average molecular weight 100,000 as determined by osmotic pressure in methyl ethyl ketone).

(ii) *Vulcanization materials—(a) Vulcanizing agents.*

4,4'-Bis(aminocyclohexyl)methane carbamate for use only as cross-linking agent in the vulcanization of vinylidene fluoridehexafluoropropylene copolymer and vinylidene fluoridehexafluoropropylene-tetrafluoroethylene copolymer elastomers identified under paragraph (c)(4)(i) of this section and limited to use at levels not to exceed 2.4 percent by weight of such copolymers.

Diisopropyl xanthogen polysulfide (a 1:2:1 mixture of O,O-di(1-methylethyl)trithio-bis-thioformate, O,O-di(1-methylethyl)tetrathio-bis-thioformate, and O,O-di(1-methylethyl)pentathio-bis-thioformate) for use as a cross linking agent in the vulcanization of natural rubber, styrene-butadiene copolymer, acrylonitrile-butadiene copolymer, and ethylene-propylene terpolymers identified under paragraph (c)(4)(i) of this section and limited to use at levels not to exceed 2.4 percent by weight of such copolymers.

Hexamethylenediamine carbamate for use only as cross-linking agent in the vulcanization of vinylidene fluoridehexafluoropropylene copolymer and vinylidene fluoridehexafluoropropylene-tetrafluoroethylene copolymer elastomers identified under paragraph (c)(4)(i) of this section and limited to use at levels not to exceed 1.5 percent by weight of such copolymers.

Sulfur, ground.

(b) *Accelerators (total not to exceed 1.5 percent by weight of rubber product).*

2-Benzothiazyl-N,N-diethylthiocarbamyl-sulfide.

Benzoyl peroxide.

1,3-Bis(2-benzothiazolylmercaptomethyl)urea.

N-tert-Butyl-2-benzothiazole sulfenamide.

Butyraldehyde-aniline resin (iodine number 670-705).

Carbon disulfide-1,1'-methylenedipiperidine reaction product.

Copper dimethyldithiocarbamate.

N-Cyclohexyl-2-benzothiazole sulfenamide.

Dibenzoyl-*p*-quinone dioxime.
 Dibenzylamine.
 Diisopropyl xanthogen polysulfide (a 1:2:1 mixture of O,O-di(1-methylethyl)trithio-bis-thioformate, O,O-di(1-methylethyl)tetrathio-bis-thioformate, and O,O-di(1-methylethyl)pentathio-bis-thioformate).
 Di(4-methylbenzoyl) peroxide (CAS Reg. No. 895-85-2) for use only as a crosslinking agent in silicone polymers and elastomers identified under paragraph (c)(4)(i) of this section at levels not to exceed 1 percent by weight of such polymers and elastomers where the total of all accelerators does not exceed 1.5 percent by weight of rubber product.
 Di-*tert*-butyl peroxide.
 Dibutyl xanthogen disulfide.
 2,4-Dichlorobenzoyl peroxide.
 Dicumyl peroxide.
N,N-Dimethylcyclohexylamine salt of dibutyldithiocarbamic acid.
 2,6-Dimethylmorpholine thiobenzothiazol.
 Dipentamethylenethiuram hexasulfide (CAS Reg. No. 971-15-3).
 Diphenylguanidine.
 1,3-Diphenyl-2-thiourea.
 2,2'-Dithiobis[benzothiazole].
 4,4'-Dithiodimorpholine.
N,N-Di-*o*-tolylguanidine.
 Di-*o*-tolylguanidine salt of pyrocatecholborate.
 Ethylenediamine carbamate.
 Heptaldehyde-aniline resin (iodine number 430-445).
 Hexamethylenetetramine.
 2-Mercaptobenzothiazole.
 2-Mercaptothiazoline.
N-Oxydiethylene-benzothiazole-2-sulfenamide.
 Piperidinium pentamethylenedithiocarbamate.
 Potassium pentamethylenedithiocarbamate.
p-Quinone dioxime.
 Sodium dibutyldithiocarbamate.
 Sodium dimethyldithiocarbamate.
 Stannous oleate for use only as an accelerator for silicone elastomers.
 Tetrabutylthiuram monosulfide.
 Tetraethylthiuram disulfide.
 (1,1,4,4-Tetramethyltetramethylene)bis [*tert*-butyl peroxide].
 Tetramethylthiuram monosulfide.
 Thiram (tetramethylthiuram disulfide).
 Triallyl cyanurate.
 Triethylenetetramine.
 1,3,5-Triethyl-hexahydro-*s*-triazine (triethyltrimethylenetriamine).
 Triphenylguanidine.
 Zinc butyl xanthate.
 Zinc dibenzyl dithiocarbamate.
 Zinc dibutyldithiocarbamate.
 Zinc diethyldithiocarbamate.
 Zinc 2-mercaptobenzothiazole.
 Ziram (zinc dimethyldithiocarbamate).

(c) *Retarders (total not to exceed 10 percent of weight of rubber product).*

Cyanoguanidine.
 Phthalic anhydride.
 Salicylic acid.

(d) *Activators (total not to exceed 5 percent by weight of rubber product except magnesium oxide may be used at higher levels).*

Diethylamine.
 Fatty acid amines, mixed.
 Fatty acids.
 Magnesium carbonate.
 Magnesium oxide, light and heavy.
 Oleic acid, dibutylamine salt (dibutylammonium oleate).
 Stannous chloride.
 Tall oil fatty acids.
 Tetrachloro-*p*-benzoquinone.
 Triethanolamine.
 Zinc salts of fatty acids.

(iii) *Antioxidants and antiozonants (total not to exceed 5 percent by weight of rubber product).*

Aldol- α -naphthylamine.
 Alkylated (C₄ and/or C₈) phenols.
 BHT (butylated hydroxytoluene).
 4-[[4,6-bis(octylthio)-*s*-triazin-2-yl]amino]-2,6-di-*tert*-butylphenol (CAS Reg. No. 991-84-4) for use only as a stabilizer at levels not to exceed 0.5 percent by weight of the finished rubber product.
 Butylated reaction product of *p*-cresol and dicyclopentadiene as identified in § 178.2010(b) of this chapter.
 Butylated, styrenated cresols identified in § 178.2010(b) of this chapter.
 4,4'-Butylidenebis(6-*tert*-butyl-*m*-cresol).
N-Cyclohexyl-*N'*-phenylphenylenediamine.
p,p'-Diaminodiphenylmethane.
 2,5-Di-*tert*-amylhydroquinone.
 Diaryl-*p*-phenylenediamine, where the aryl group may be phenyl, tolyl, or xylol.
 2,6-Di-*tert*-butyl-*p*-phenylphenol.
 1,2-Dihydro-2,2,4-trimethyl-6-dodecylquinoline.
 1,2-Dihydro-2,2,4-trimethyl-6-ethoxyquinoline.
 1,2-Dihydro-2,2,4-trimethyl-6-phenylquinoline.
 4,4'-Dimethoxydiphenylamine.
 4,6-Dinonyl-*o*-cresol.
N,N'-Dioctyl-*p*-phenylenediamine.
 Diphenylamine-acetone resin.
 Diphenylamine-acetone-formaldehyde resin.
N,N'-Diphenylethylenediamine.
N,N'-Disalicylalpropylenediamine.
N,N'-Di-*o*-tolylethylenediamine.
 Hydroquinone monobenzyl ether.
 Isopropoxydiphenylamine.
N-Isopropyl-*N'*-phenyl-*p*-phenylenediamine.
 2,2'-Methylenebis(6-*tert*-butyl-4-ethylphenol).

2,2'-Methylenebis(4-methyl-6-*tert*-butyl-phenol).
 2,2'-Methylenebis(4-methyl-6-nonylphenol).
 2,2'-Methylenebis(4-methyl-6-*tert*-octylphenol).
 Mono-octyl- and dioctyldiphenylamine.
N,N'-Di- β -naphthyl-*p*-phenylenediamine.
 Phenyl- α -naphthylamine.
 Phenyl- β -naphthylamine.
 Phenyl- β -naphthylamine-acetone aromatic amine resin (average molecular weight 600; nitrogen content 5.3 percent).
o- and *p*-Phenylphenol.
 Polybutylated (mixture) 4,4'-isopropylidenediphenol.
 Sodium pentachlorophenate.
 Styrenated cresols produced when 2 moles of styrene are made to react with 1 mole of a mixture of phenol and *o*-, *m*-, and *p*-cresols so that the final product has a Brookfield viscosity at 25 °C of 1400 to 1700 centipoises.
 Styrenated phenol.
 4,4'-Thiobis (6-*tert*-butyl-*m*-cresol).
 Toluene-2,4-diamine.
N-o-Tolyl-*N'*-phenyl-*p*-phenylenediamine.
p(*p*-Tolylsulfanilamide) diphenylamine.
 Tri(mixed mono- and dinonylphenyl) phosphite.
 Tri(nonylphenyl) phosphite-formaldehyde resins produced when 1 mole of tri(nonylphenyl) phosphite is made to react with 1.4 moles of formaldehyde or produced when 1 mole of nonylphenol is made to react with 0.36 mole of formaldehyde and the reaction product is then further reacted with 0.33 mole of phosphorus trichloride. The finished resins have a minimum viscosity of 20,000 centipoises at 25 °C, as determined by LV-series Brookfield viscometer (or equivalent) using a No. 4 spindle at 12 r.p.m., and have an organic phosphorus content of 4.05 to 4.15 percent by weight.

(iv) *Plasticizers (total not to exceed 30 percent by weight of rubber product unless otherwise specified).*

Butylacetyl ricinoleate.
n-Butyl ester of tall oil fatty acids.
 Butyl laurate.
 Butyl oleate.
 Butyl stearate.
 Calcium stearate.
 Castor oil.
 Coumarone-indene resins.
 2,2'-Dibenzamidodiphenyl disulfide.
 Dibenzyl adipate.
 Dibutoxyethoxyethyl adipate.
 Dibutyl sebacate.
 Didecyl adipate.
 Diisodecyl adipate.
 Diisodecyl phthalate.
 Diisooctyl adipate.
 Diisooctyl sebacate.
 Dioctyl adipate.
 Dioctyl sebacate.

Dipentene resin.
 Fatty acids.
 Fatty acids, hydrogenated.
 Isooctyl ester of tall oil fatty acids.
 Lanolin.
α-Methylstyrene-vinyltoluene copolymer resins (molar ratio 1 *α*-methylstyrene to 3 vinyltoluene).
 Mineral oil; (1) In rubber articles complying with this section, not to exceed 30 percent by weight; (2) Alone or in combination with waxes, petroleum, total not to exceed 45 percent by weight of rubber articles that contain at least 20 percent by weight of ethylene-propylene copolymer elastomer complying with paragraph (c)(4)(i) of this section, in contact with foods of Types I, II, III, IV, VI, VII, VIII, and IX identified in table 1 of §176.170(c) of this chapter.
 Montan wax.
n-Octyl *n*-decyl adipate.
 Petrolatum.
 Petroleum hydrocarbon resin (cyclopentadiene type), hydrogenated.
 Petroleum hydrocarbon resin (produced by the homo- and copolymerization of dienes and olefins of the aliphatic, alicyclic, and monobenzenoid arylalkene types from distillates of cracked petroleum stocks).
 Petroleum hydrocarbon resin (produced by the catalytic polymerization and subsequent hydrogenation of styrene, vinyltoluene, and indene types from distillates of cracked petroleum stocks).
 Petroleum oil, sulfonated.
 Phenol-formaldehyde resin.
 Pine tar.
 Polybutene.
 Polystyrene.
 Propylene glycol.
n-Propyl ester of tall oil fatty acids.
 Rapeseed oil vulcanized with rubber maker's sulfur.
 Rosins and rosin derivatives identified in §175.105(c)(5) of this chapter.
 Soybean oil vulcanized with rubber maker's sulfur.
 Styrene-acrylonitrile copolymer.
 Terpene resins.
 Triethylene glycol dicaprate.
 Triethylene glycol dicaprylate.
 Waxes, petroleum.
 Xylene (or toluene) alkylated with dicyclopentadiene.
 Zinc 2-benzamidothiophenate.

(v) *Fillers.*

Aluminum hydroxide.
 Aluminum silicate.
 Asbestos fiber, chrysotile or crocidolite.
 Barium sulfate.
 Carbon black (channel process or furnace combustion process; total carbon black not to exceed 50 percent by weight of rubber product; furnace combustion black content

not to exceed 10 percent by weight of rubber products intended for use in contact with milk or edible oils).

Cork.
Cotton (floc, fibers, fabric).
Mica.
Nylon (floc, fibers, fabric).
Silica.
Titanium dioxide.
Zinc carbonate.
Zinc sulfide.

(vi) *Colorants*. Colorants used in accordance with § 178.3297 of this chapter.

(vii) *Lubricants* (total not to exceed 2 percent by weight of rubber product).

Polyethylene.
Sodium stearate.

(viii) *Emulsifiers*.

Fatty acid salts, sodium or potassium.
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt.
Rosins and rosin-derivatives identified in § 175.105(c)(5) of this chapter.
Sodium decylbenzenesulfonate
Sodium dodecylbenzenesulfonate
Sodium lauryl sulfate.
Tall oil mixed soap (calcium, potassium, and sodium).

(ix) *Miscellaneous* (total not to exceed 5 percent by weight of rubber product).

Animal glue as described in § 178.3120 of this chapter.
Azodicarbonamide as chemical blowing agent.
2-Anthraquinone sulfonic acid sodium salt for use only as polymerization inhibitor in chloroprene polymers and not to exceed 0.03 percent by weight of the chloroprene polymers.
1,2-Benzisothiazolin-3-one (CAS Reg. No. 2634-33-5) for use as a biocide in uncured liquid rubber latex not to exceed 0.02 percent by weight of the latex solids, where the total of all items listed in paragraph (c)(4)(ix) of this section does not exceed 5 percent of the rubber product.
n-Butyllithium for use only as polymerization catalyst for polybutadiene.
4-*tert*-Butyl-*o*-thiocresol as peptizing agent.
tert-Butyl peracetate.
p-*tert*-Butylpyrocatechol.
Dialkyl (C₈–C₁₈) dimethylammonium chloride for use only as a flocculating agent in the manufacture of silica.
Di- and triethanolamine.
Diethyl xanthogen disulfide.
4-(Diiodomethylsulfonyl) toluene, Chemical Abstracts Service Registry No. 20018-09-01, for use as an antifungal preservative at levels not to exceed 0.3 percent by weight of the sealants and caulking materials.
Dodecyl mercaptan isomers, single or mixed.
2-Ethoxyethanol.

Iodoform.

p-Menthane hydroperoxide.

a-(*p*-Nonylphenyl)-*omega*-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters, barium salt; the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content averages 9 moles; for use only as residual polymerization emulsifier at levels not to exceed 0.7 percent by weight of ethylene-propylene-1,4-hexadiene copolymers identified under paragraph (c)(4)(i) of this section.

4,4'-Oxybis (benzenesulfonhydrazide) as chemical blowing agent.

Phenothiazine.

Potassium persulfate.

Sodium formaldehyde sulfoxylate.

Sodium polysulfide.

Sodium nitrite.

Sodium salt of ethylenediamine tetraacetic acid and glycine.

Sodium sulfide.

Styrene monomer.

Tall oil.

Thioxyleneis as peptizing agents.

Tridecyl mercaptan.

Zinc 4-*tert*-butylthiophenolate as peptizing agent.

(d) Rubber articles intended for use with dry food are so formulated and cured under conditions of good manufacturing practice as to be suitable for repeated use.

(e) Rubber articles intended for repeated use in contact with aqueous food shall meet the following specifications: The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with distilled water at reflux temperature, shall yield total extractives not to exceed 20 milligrams per square inch during the first 7 hours of extraction, nor to exceed 1 milligram per square inch during the succeeding 2 hours of extraction.

(f) Rubber articles intended for repeated use in contact with fatty foods shall meet the following specifications: The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with *n*-hexane at reflux temperature, shall yield total extractives not to exceed 175 milligrams per square inch during the first 7 hours of extraction, nor to exceed 4 milligrams per square inch during the succeeding 2 hours of extraction.

(g) In accordance with good manufacturing practice finished rubber articles

intended for repeated use in contact with food shall be thoroughly cleansed prior to their first use in contact with food.

(h) The provisions of this section are not applicable to rubber nursing-bottle nipples.

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

[42 FR 14572, Mar. 15, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §177.2600, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 177.2710 Styrene-divinylbenzene resins, cross-linked.

Styrene-divinylbenzene cross-linked copolymer resins may be safely used as articles or components of articles intended for repeated use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The resins are produced by the copolymerization of styrene with divinylbenzene.

(b) The resins meet the extractives limitations prescribed in this paragraph:

(1) The resins to be tested are ground or cut into small particles that will pass through a U.S. standard sieve No. 3 and that will be held on a U.S. standard sieve No. 20.

(2) A 100-gram sample of the resins, when extracted with 100 milliliters of ethyl acetate at reflux temperature for 1 hour, yields total extractives not to exceed 1 percent by weight of the resins.

(c) In accordance with good manufacturing practice, finished articles containing the resins shall be thoroughly cleansed prior to their first use in contact with food.

§ 177.2800 Textiles and textile fibers.

Textiles and textile fibers may safely be used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The textiles and textile fibers are prepared from one or more of the fibers identified in paragraph (d) of this section and from certain other adjuvant substances required in the production of the textiles or textile fibers or added to impart desired properties.

(b) The quantity of any adjuvant substance employed in the production of textiles or textile fibers does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation further provided.

(c) Any substance employed in the production of textiles or textile fibers that is the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the production of or added to textiles and textile fibers may include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in textiles and textile fibers and used in accordance with such sanction or approval.

(3) Substances generally recognized as safe for use in cotton and cotton fabrics used in dry-food packaging.

(4) Substances that by regulation in this part may safely be used in the production of or as a component of textiles or textile fibers and subject to provisions of such regulation.

(5) Substances identified in this paragraph (d)(5), subject to such limitations as are provided:

List of substances	Limitations
(i) Fibers: Cotton. Polyethylene terephthalate complying in composition with the provisions of § 177.1630(e)(4)(ii). Rayon. (ii) Adjuvant substances: Aluminum stearate.	For use only in the manufacture of items for repeated use.

List of substances	Limitations
<p>Borax</p> <p>Butyl-acetyl ricinoleate.</p> <p>Colorants used in accordance with § 178.3297 of this chapter..</p> <p>Di-<i>tert</i>-butyl hydroquinone.</p> <p>Dimethylpolysiloxane.</p> <p>Ethylenediaminetetraacetic acid, sodium salt.</p> <p>4-Ethyl-4-hexadecyl morpholinium ethyl sulfate</p>	<p>For use as preservative only.</p>
<p>Eugenol.</p> <p>Fats, oils, fatty acids, and fatty alcohols derived from castor, coconut, cottonseed, fish, mustardseed, palm, peanut, rapeseed, ricebran, soybean, sperm, and tall oils and tallow.</p> <p>Fats, oils, fatty acids, and fatty alcohols described in the preceding item reacted with one or more of the following substances:</p> <p> <i>n</i>-Butyl and isobutyl alcohol.</p> <p> Diethylene glycol.</p> <p> Diethanolamine.</p> <p> Glycerol.</p> <p> Hexylene glycol (2-methyl-2,4-pentanediol).</p> <p> Hydrogen.</p> <p> Isopropyl alcohol.</p> <p> Methyl alcohol.</p> <p> Oxygen.</p> <p> Polyethylene glycol (molecular weight 400–3,000).</p> <p> Potassium hydroxide.</p> <p> Propylene glycol.</p> <p> Sodium hydroxide.</p> <p> Sulfuric acid.</p>	<p>For use only as a lubricant in the manufacture of polyethylene terephthalate fibers specified in paragraph (d)(5)(i) of this section at a level not to exceed 0.03 percent by weight of the finished fibers.</p>
<p>Formaldehyde</p> <p>Glyceryl mono-12-hydroxystearate.</p> <p>2-(9-Heptadecenyl)-1-[2-(10-octadecenamido)ethyl-2-imidazolinium ethyl sulfate.</p> <p>Hexylene glycol (2-methyl,-2,4-pentanediol).</p> <p>Isobutyl alcohol.</p> <p>Isopropyl alcohol.</p> <p>Kerosene.</p> <p>Methyl ester of sulfated ricebran oil.</p> <p>Mineral oil</p>	<p>For use as preservative only.</p>
<p>Mono- and diisopropylated <i>m</i>- and <i>p</i>-cresols (isothymol derivative).</p> <p><i>N</i>-Oleyl, <i>N</i>-acetyl, <i>N</i>-β-hydroxy-ethylenediamine.</p> <p>Petrolatum.</p> <p>Petroleum sulfonate.</p> <p>Pine oil.</p> <p>Polybutene, hydrogenated; complying with the identity prescribed under 21 CFR 178.3740(b) of this chapter.</p> <p>Polyethylene, oxidized (air blown).</p> <p>Polyvinyl acetate.</p> <p>Polyvinyl alcohol.</p> <p>Potassium soap of a saponified sulfated castor oil.</p> <p>Sodium bis(2,6-dimethylheptyl-4) sulfosuccinate.</p> <p>Sodium dioctyl sulfosuccinate.</p> <p>Sodium dodecyl benzenesulfonate.</p>	<p>For use only at a level not to exceed 0.15 percent by weight of finished fibers.</p>
<p>Sodium fluoride</p> <p>Sodium hydrosulfite.</p> <p>Sodium hypochlorite.</p> <p>Sodium lauryl sulfate.</p> <p>Sodium 2-mercaptobenzothiazole</p> <p>Sodium pentachlorophenate</p> <p>Styrene-butadiene copolymer.</p> <p>Sulfated butyl, isobutyl and propyl oleate.</p> <p>Tallow.</p> <p>Tallow, sulfonated.</p> <p>Titanium dioxide.</p> <p>Triethanolamine.</p> <p>Ultramarine blue.</p> <p>Waxes, petroleum.</p> <p>Zinc hydrosulfite.</p>	<p>For use as preservative only.</p> <p>Do.</p> <p>Do.</p>

(e) Textile and textile fibers are used as articles or components of articles that contact dry food only.

(f) The provisions of this section are not applicable to jute fibers used as prescribed by §178.3620(d)(2) of this chapter.

[42 FR 14572, Mar. 15, 1977, as amended at 46 FR 37042, July 17, 1981; 49 FR 4372, Feb. 6, 1984; 49 FR 5748, Feb. 15, 1984; 56 FR 42933, Aug. 30, 1991]

§ 177.2910 Ultra-filtration membranes.

Ultra-filtration membranes identified in paragraphs (a)(1), (a)(2), (a)(3), and (a)(4) of this section may be safely used in the processing of food, under the following prescribed conditions;

(a)(1) Ultra-filtration membranes that consist of paper impregnated with cured phenol-formaldehyde resin, which is used as a support and is coated with a vinyl chloride-acrylonitrile copolymer.

(2) Ultra-filtration membranes that consist of a sintered carbon support that is coated with zirconium oxide (CAS Reg. No. 1314-23-4) containing up to 12 percent yttrium oxide (CAS Reg. No. 1314-36-9).

(3) Ultra-filtration membranes that consist of an aluminum oxide support that is coated with zirconium oxide (CAS Reg. No. 1314-23-4) containing up to 5 percent yttrium oxide (CAS Reg. No. 1314-36-9).

(4) Ultrafiltration membranes that consist of a microporous poly(vinylidene fluoride) membrane with a hydrophilic surface modifier consisting of hydroxypropyl acrylate/tetraethylene glycol diacrylate copolymer.

(b) Any substance employed in the production of ultra-filtration membranes that is the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter conforms with the specifications of such regulation.

(c) Ultra-filtration membranes are used in the physical separation of dissolved or colloiddally suspended varying molecular size components of liquids during the commercial processing of bulk quantities of food.

(d) Ultra-filtration membranes shall be maintained in a sanitary manner in accordance with good manufacturing

practice so as to prevent potential microbial adulteration of the food.

(e) Ultrafiltration membranes identified in paragraph (a)(4) may be used to filter aqueous or acidic foods containing up to 13 percent of alcohol at temperatures not to exceed 21 °C (70 °F).

(f) To assure safe use of the ultra-filtration membranes, the label or labeling shall include adequate directions for a pre-use treatment, consisting of conditioning and washing with a minimum of 8 gallons of potable water prior to their first use in contact with food.

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

[42 FR 14572, Mar. 15, 1977, as amended at 53 FR 17925, May 19, 1988; 58 FR 48599, Sept. 17, 1993; 60 FR 54426, Oct. 24, 1995]

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

Subpart A [Reserved]

Subpart B—Substances Utilized To Control the Growth of Microorganisms

Sec.

178.1005 Hydrogen peroxide solution.

178.1010 Sanitizing solutions.

Subpart C—Antioxidants and Stabilizers

178.2010 Antioxidants and/or stabilizers for polymers.

178.2550 4-Hydroxymethyl-2,6-di-*tert*-butylphenol.

178.2650 Organotin stabilizers in vinyl chloride plastics.

Subpart D—Certain Adjuvants and Production Aids

178.3010 Adjuvant substances used in the manufacture of foamed plastics.

178.3120 Animal glue.

178.3125 Anticorrosive agents.

178.3130 Antistatic and/or antifogging agents in food-packaging materials.

178.3280 Castor oil, hydrogenated.

178.3290 Chromic chloride complexes.

178.3295 Clarifying agents for polymers.

178.3297 Colorants for polymers.

178.3300 Corrosion inhibitors used for steel or tinplate.

178.3400 Emulsifiers and/or surface-active agents.