

§ 177.2280

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°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 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 <sub>18</sub> 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 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.

(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, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(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: