

(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:

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(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.
Carbon black (channel process).	
Diatomaceous earth.	

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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 described in §174.5(d) of this chapter and the following: