

21 CFR Part 177.2600

21 - Food and Drug

Part 177 - Indirect Additive: Polymer

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 regulation 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 Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., 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. 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* - lauro lactam 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- ω -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 fluoride-hexafluoropropylene-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 fluoride-hexafluoropropylene copolymer and vinylidene fluoride-hexafluoropropylene-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.

Diphenylguanidine phthalate.

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 xanathate.

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 (C₄and/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 xylyl.

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*-butylphenol).

2,2'-Methylenebis(4-methyl-6-nonylphenol).

2,2'-Methylenebis(4-methyl-6-*tert*-octylphenol).

Monooctyl- 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- Toly- *N'*- phenyl -*p*- phenylenediamine.

p(*p*- Toly)sufanilamide) 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) .

n -Amyl *n* -decyl phthalate.

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 phthalate.

Dibutyl sebacate.

Didecyl adipate.

Didecyl phthalate.

Diisodecyl adipate.

Diisodecyl phthalate.

Diisooctyl adipate.

Diisooctyl sebacate.

Dioctyl adipate.

Dioctyl phthalate.

Dioctyl sebacate.

Dipentene resin.

Diphenyl ketone.

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.

n-Octyl *n*-decyl phthalate.

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

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.

α-(*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* -butylthiophenate 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 on GPO Access.