Food and Drug Administration, HHS

§ 177.2600 Rubber articles intended for repeated use.

Rubber articles intended for repeated use may be safely used in producing, manufacturing, packaging, 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.

(1) 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-Olefinc and ‘Trans Olefinic Saturation Levels in HNBR,'” developed October 1, 1991, by Polysar Rubber Corp., 1236 South Vidal St., Sarnia, Ontario, Canada N7T 7MI; 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/
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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. 77902–38–1) 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-butandioi, and ε-hydro-omega-hydroxy poly (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. No. 37383–28–6) 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-butandioi.

Rubber, natural.  
Silicone basic polymer as described in ASTM method D1418–81, “Standard Practice for Rubber and Rubber Latexes—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 (Ps) elastomers containing methyl and phenyl groups.

Silicone (Vs) elastomers containing methyl and vinyl groups.

Silicone (Ps) elastomers containing methy1 and fluorine groups.

Silicone (FSi) elastomers containing phenyl, methyl, and vinyl groups.

Styrene-butadiene copolymer.

Vinyldiene fluoride-hexafluoropropylene copolymers (minimum number average molecular weight 70,000 as determined by osmotic pressure in methyl ethyl ketone).

Vinyldiene 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′-Risaminocyclohexylmethane carbamate for use only as a cross-linking agent in the vulcanization of vinyldiene fluoride-hexafluoropropylene copolymer and vinyldiene 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.

Disopropyl xanthogen polysulfide (a 1:2:1 mixture of O,O-di(1-methylethyl)trithio-bis-thioformate, O,O-di(1-methylethyl)tetraethio-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.

Hexamethylene diamine carbamate for use only as a cross-linking agent in the vulcanization of vinyldiene fluoride-hexafluoropropylene copolymer and vinyldiene 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.

Benzyol peroxide.

1,3-Bis(2-benzothiazoylmercaptomethyl) urea.

N-tert-Butyl-2-benzothiazole sulfenamide.

Butyraldehyde-aniline resin (iodine number 670–756).

Carbon disulfide-1,1′-methylene diphosphine reaction product.

Copper dimethylthiocarbamate.

N-Cyclohexyl-2-benzothiazole sulfenamide.
Dibenzyl-\(p\)-quinite dioxime.
Dibenzylamine.
Ditospropyl xanthogen polysulfide (a 1:2:1 mixture of \(\text{O},\text{O-di(1-methylethyl)trithio-bis-thioformate}\), \(\text{O},\text{O-di(1-methylethyl)trithio-bis-thioformate}\), and \(\text{O},\text{O-di(1-methylethyl)pentathio-bis-thioformate}\)).
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-\(\text{t}ert\)-butyl peroxide.
Dibutyl xanthogen disulfide.
2,4-Dichlorobenzyl peroxide.
Dicyclopentadiene as identified in §178.2010(b) of this chapter.

(3) Phosphorus compounds.

(c) Retarders (total not to exceed 10 percent of weight of rubber product).
Cyanoguanidine.
Phthalein anhydride.
Salsicylic 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.
Stannous chloride.
Tall oil fatty acids.
Tetrachloro-\(p\)-benzoquinone.
Triethanolamine.
Zinc salts of fatty acids.

(iii) Antiromodants and antiozonants (total not to exceed 5 percent by weight of rubber product).
Aldol-\(\text{o}\)-napthylamine.
Alkylated (\(\text{C}_1\) and/or \(\text{C}_2\)) phenols.
BHT (butylated hydroxytoluene).

BHT (butylated hydroxytoluene).

4-\{[4,6-bis(octyloxy)-\text{O}-\text{triazin-2-yl]amino}-2,6-di-\(\text{t}ert\)-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′-\text{Butylidinebis(6-\(\text{t}ert\)-butyl-m-cresol)}.
\(N\)-\text{Cyclohexyl-\text{o}}-phenylenediamine.

\(p\),\(p\)′-\text{Diaminodiphenylmethane}.

2,5-Di-\(\text{t}ert\)-amylohydroquinone.
Diaryl-\(p\)-phenylenediamine, where the aryl group may be phenyl, tolyl, or xylyl.

2,6-Di-\(\text{t}ert\)-butyl-\(p\)-phenylenol.

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-phenyquinoline.

4,4′-\text{Dimethoxydiphenylamine}.

4,6-Dimethyl-\(p\)-cresol.

\(N\),\(N\)′-\text{Diocetyl-\text{p}}-phenylenediamine.

Diphenylamine-acetone resin.

Diphenylamine-acetone-formaldehyde resin.

\(N\),\(N\)′-\text{Diphenylethylene diamine}.

\(N\),\(N\)′-Disalicylalpropylenediamine.

Hydroquinone monobenzyl ether.

Isopropoxydiphenylamine.

\(N\)-Isopropyl-\(N\)′-phenyl-\(p\)-phenylenediamine.

2,2′-Methylenbis(\(6\)-\(\text{t}ert\)-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).
Monoctyl- and dioctyldiphenylamine.
\(N,N'\)-Di-\(p\)-napthyl-\(p\)-phenylenediamine.
Phenyl-\(p\)-napthylamine.
Phenyl-\(p\)-napthylamine-acetone aromatic amine resin (average molecular weight 600; nitrogen content 5.3 percent).
\(o\)- and \(p\)-Phenylenediamine.
Polybutylated (mixture) 4,4'-isopropylidendiphenyl.
Sodium pentachlorophenate.
Styrenated cresols produced when 2 moles of sodium pentachlorophenate react with 0.33 mole of phosphorus trichloride. The finished resins have a minimum viscosity of 20,000 centipoises at 25 °C of 1400 to 1700 centipoises.
Styrenated phenol.
4,4'-Thiobis(6-tert-butyl-m-cresol).
Toluene-2,4-diamine.
\(p\)-(p-Tolylsufanilamide) diphenylamine.
Tri[mixed mono- and dinonylphenyl] phosphite.
Tri(nonylphenyl) phosphite-formaldehyde resins 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.

(1v) 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.
Dilinoleyl adipate.
Dilinoleyl phthalate.
Disoctyl adipate.
Disoctyl sebacate.
Diocytl adipate.
Diocytl phthalate.
Diocytl sebacate.
Dipentene resin.
Diphenyl ketone.
Fatty acids.
Fatty acids, hydrogenated.
Isooctyl ester of tall oil fatty acids.
Lanolin.
\(a\)-Methylstyrane-vinyltoluene copolymer resins (molar ratio 1 \(a\)-methylstyrane 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, sulphonated.
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.
Resins and resin 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 dicaprylate.
Triethylene glycol dicaprate.
Waxes, petroleum.
Xylene (or toluene) alkylated with dicyclopentadiene.
Zinc 2-benzamidodithiophenate.

(v) Fillers.
Aluminum hydroxide.
Aluminum silicate.
Asbestos fiber, chrysotile or crocidolite.
Barium sulfate.
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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 0.85 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.

t-Butyl peracetate.

p-tert-Butylproocatechol.

Dialkyl (C₈–C₁₀) Di- and triethanolamine.

Dichlorodimethylsilane.

2,6-Di(3-tert-butyl-4-hydroxyphenyl)imidazoline, Chemical Abstracts Service Registry No. 20018–09–01, for use as an antifungal preservative at levels not to exceed 0.1 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 formalddehyde sulfoxylate.

Sodium polysulfide.

Sodium nitrite.

Sodium salt of ethylenediamine tetraacetic acid and glycine.

Sodium sulfide.

Tall oil.

Thioxylenois 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 1 milligram per square inch during the succeeding 2 hours of extraction.
§ 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:

<table>
<thead>
<tr>
<th>List of substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) Fibers:</td>
<td></td>
</tr>
<tr>
<td>Cotton</td>
<td>For use only in the manufacture of items for repeated use.</td>
</tr>
<tr>
<td>Polyethylene terephthalate complying in composition with the provisions of §177.1630(e)(4)(ii). Rayon.</td>
<td></td>
</tr>
<tr>
<td>(ii) Adjuvant substances:</td>
<td></td>
</tr>
<tr>
<td>Aluminum stearate.</td>
<td></td>
</tr>
</tbody>
</table>

[42 FR 14572, Mar. 15, 1977]