

Substances	Limitations
Tris(2-methyl-4-hydroxy-5- <i>tert</i> -butylphenyl)butane (CAS Reg. No. 1843–03–4).	For use only: 1. At levels not to exceed 0.25 percent by weight of polymers used as provided in § 176.180 of this chapter. 2. At levels not to exceed 0.25 percent by weight of the following polymers when used in articles that contact food of Types I, II, IV-B, VI-B, VII-B, and VIII described in table 1 of § 176.170(c) of this chapter: Olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4 or complying with other sections in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter; vinyl chloride polymers; and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. 3. At levels not to exceed 0.1 percent by weight of the following polymers when used in articles that contact food of Types III, IV-A, V, VI-A, VI-C, VII-A, and IX described in table 1 of § 176.170(c) of this chapter: Olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4 or complying with other sections in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter; vinyl chloride polymers; and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. 4. As provided in § 175.105 of this chapter. 5. At levels not to exceed 0.2 percent by weight of polystyrene and/or modified polystyrene polymers identified in § 177.1640 of this chapter. 6. At levels not to exceed 0.25 percent by weight of acrylonitrile-butadiene-styrene copolymers used in contact with nonalcoholic foods. 7. At levels not to exceed 1 percent by weight of closure-sealing gasket compositions complying with § 177.1210(b) of this chapter.
Zinc dibutyldithiocarbamate (CAS Reg. No. 136–23–2).	For use only: 1. At levels not to exceed 0.2 percent by weight of isobutyleneisoprene copolymers complying with § 177.1420 of this chapter: <i>Provided</i> , That the finished copolymers contact food only of the types identified in § 176.170(c) of this chapter, table 1, under Types V, VII, VIII, and IX. 2. At levels not to exceed 0.02 percent by weight of polypropylene polymers complying with § 177.1520(c), item 1.1 of this chapter.
Zinc palmitate. Zinc salicylate	For use only in rigid polyvinyl chloride and/or in rigid vinyl chloride copolymers complying with § 177.1980 of this chapter: <i>Provided</i> , That total salicylates (calculated as the acid) do not exceed 0.3 percent by weight of such polymers.
Zinc stearate.	

¹ Copies are available from the American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pa. 19103.

[42 FR 14609, Mar. 15, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §178.2010, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 178.2550 4-Hydroxymethyl-2,6-di-*tert*-butylphenol.

4-Hydroxymethyl-2,6-di-*tert*-butylphenol may be safely used as an antioxidant in articles intended for use in contact with food, in accordance with the following prescribed conditions:

- (a) The additive has a solidification point of 140°–141 °C.
- (b) The concentration of the additive and any other permitted antioxidants in the finished food-contact article does not exceed a total of 0.5 milligram per square inch of food-contact surface.

§ 178.2650 Organotin stabilizers in vinyl chloride plastics.

The organotin chemicals identified in paragraph (a) of this section may be safely used alone or in combination, at levels not to exceed a total of 3 parts per hundred of resin, as stabilizers in vinyl chloride homopolymers and copolymers complying with the provisions of §177.1950 or §177.1980 of this chapter and that are identified for use in contact with food of types I, II, III, IV (except liquid milk), V, VI (except malt beverages and carbonated non-alcoholic beverages), VII, VIII, and IX described in table 1 of § 176.170(c) of this chapter, except for the organotin chemical identified in paragraph (a)(3)

of this section, which may be used in contact with food of types I through IX at temperatures not exceeding 75 °C (167 °F), and further that the organotin chemicals identified in paragraphs (a)(5) and (6) of this section may be used in contact with food of types I through IX at temperatures not exceeding 66 °C (150 °F), conditions of use D through G described in table 2 of §176.170(c) of this chapter, and further that dodecyltin chemicals identified in paragraph (a)(7) of this section which may be used in contact with food of types I, II, III, IV (except liquid milk), V, VI (except malt beverages and carbonated nonalcoholic beverages), VII, VIII, and IX described in table 1 of §176.170(c) of this chapter at temperatures not exceeding 71 °C (160 °F), in accordance with the following prescribed conditions:

(a) For the purpose of this section, the organotin chemicals are those listed in paragraphs (a)(1), (2), (3), (4), (5), (6), and (7) of this section.

(1) Di(*n*-octyl)tin S,S'-bis(isooctylmercaptoacetate) is an octyltin chemical having 15.1 to 16.4 percent by weight of tin (Sn) and having 8.1 to 8.9 percent by weight of mercapto sulfur. It is made from di(*n*-octyl)tin dichloride or di(*n*-octyl)tin oxide. The isooctyl radical in the mercaptoacetate is derived from oxo process isooctyl alcohol. Di(*n*-octyl)tin dichloride has an organotin composition that is not less than 95 percent by weight of di(*n*-octyl)tin dichloride and not more than 5 percent by weight of tri(*n*-octyl)tin chloride. Di(*n*-octyl)tin oxide has an organotin composition that is not less than 95 percent by weight of di(*n*-octyl)tin oxide and not more than 5 percent by weight of bis[tri(*n*-octyl)tin] oxide, and/or mono *n*-octyltin oxide.

(2) Di(*n*-octyl) tin maleate polymer is an octyltin chemical having the formula $[(C_8H_{17})_2SnC_4H_2O_4]_n$ (where *n* is between 2 and 4 inclusive), having 25.2 to 26.6 percent by weight of tin (Sn) and having a saponification number of 225 to 255. It is made from di(*n*-octyl)tin dichloride or di(*n*-octyl)tin oxide meeting the specifications prescribed for di(*n*-octyl) tin dichloride or di(*n*-octyl) tin oxide in paragraph (a)(1) of this section.

(3) C₁₀₋₁₆-Alkyl mercaptoacetates reaction products with dichlorodioctylstannane and trichlorooctylstannane (CAS Reg. No. 83447-69-2) is an organotin chemical mixture having 10.8 to 11.8 percent by weight of tin (Sn) and having 8.0 to 8.6 percent by weight of mercapto sulfur. It is made from a mixture of di(*n*-octyl)tin dichloride and (*n*-octyl)tin trichloride which has an organotin composition that is not less than 95 percent by weight di(*n*-octyl)tin dichloride/(*n*-octyl)tin trichloride, and not more than 1.5 percent by weight of tri(*n*-octyl)tin chloride. The alkyl radical in the mercaptoacetate is derived from a mixture of saturated *n*-alcohols which has a composition that is not less than 50 percent by weight tetradecyl alcohol, and that is not more than 50 percent by weight total of decyl alcohol and/or dodecyl alcohol, and/or hexadecyl alcohol.

(4) (*n*-Octyl)tin S,S' tris(isooctylmercaptoacetate) is an octyltin chemical having the formula $n-C_8H_{17}Sn(SCH_2CO_2C_8H_{17})_3$ (CAS Reg. No. 26401-86-5) having 13.4 to 14.8 percent by weight of tin (Sn) and having 10.9 to 11.9 percent by weight of mercapto sulfur. It is made from (*n*-octyl)tin trichloride. The isooctyl radical in the mercaptoacetate is derived from oxo process isooctyl alcohol. The (*n*-octyl)tin trichloride has an organotin composition that is not less than 95 percent by weight of (*n*-octyl)tin trichloride and not more than 5 percent by weight of tri(*n*-octyl)tin chloride.

(5) Bis(*beta*-carboboxyethyl)tin bis(isooctylmercaptoacetate) (CAS Reg. No. 63397-60-4) is an estertin chemical having 14.0 to 15.0 percent by weight of tin (Sn) and having 7.5 to 8.5 percent by weight of mercapto sulfur. It is made from bis(*beta*-carboboxyethyl)tin dichloride. The isooctyl radical in the mercaptoacetate is derived from oxo process primary octyl alcohols. The bis(*beta*-carboboxyethyl)tin dichloride has an organotin composition that is not less than 95 percent by weight of bis(*beta*-carboboxyethyl)tin dichloride and not more than 5 percent by weight of bis(*beta*-carboboxyethyl)tin trichloride. The triestertin chloride content of bis(*beta*-carboboxyethyl)tin

dichloride shall not exceed 0.02 percent.
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(6) *Beta*-carboboxyethyltin tris(isooctylmercaptoacetate) (CAS Reg. No. 63438-80-2) is an estertin chemical having 13.0 to 14.0 percent by weight of tin (Sn) and having 10.5 to 11.5 percent by weight of mercapto sulfur. It is made from *beta*-carboboxyethyltin trichloride. The isooctyl radical in the mercaptoacetate is derived from oxo process primary octyl alcohol. The *beta*-carboboxyethyltin trichloride has an organotin composition that is not less than 95 percent by weight of *beta*-carboboxyethyltin trichloride and not more than 5 percent total of triestertin chloride and diestertin chloride.

(7) The dodecyltin stabilizer is a mixture of 50 to 60 percent by weight of *n*-dodecyltin S,S',S''-tris(isooctylmercaptoacetate) (CAS Reg. No. 67649-65-4) and 40 to 50 percent by weight of di(*n*-dodecyl)tin S,S'-di(isooctylmercaptoacetate) (CAS Reg. No. 84030-61-5) having 13 to 14 percent by weight of tin (Sn) and having 8 to 9 percent by weight of mercapto sulfur. It is made from a mixture of dodecyltin trichloride and di(dodecyl)tin dichloride which has not more than 0.2 percent by weight of dodecyltin trichloride, not more than 2 percent by weight of dodecylbutyltin dichloride and not more than 3 percent by weight of tri(dodecyl)tin chloride. The isooctyl radical in the mercaptoacetate is derived from oxo process primary octyl alcohols.

(b) The vinyl chloride plastic containers, film or panels in the finished form in which they are to contact food, shall meet the following limitations:

(1) The finished plastics intended for contact with foods of the types listed in this section shall be extracted with the solvent or solvents characterizing those types of foods as determined from table 2 of §176.170(c) of this chapter at the temperature reflecting the conditions of intended use as determined therein. Additionally, extraction tests for acidic foods shall be included and simulated by 3-percent acetic acid at temperatures specified for water in table 2 of §176.170(c) of this chapter. The extraction tests shall

cover at least three equilibrium periodic determinations, as follows:

(i) The exposure time for the first determination shall be at least 72 hours for aqueous solvents, and at least 6 hours for heptane.

(ii) Subsequent determinations shall be at a minimum of 24-hour intervals for aqueous solvents, and 2-hour intervals for heptane. These tests shall yield total octyltin stabilizers not to exceed 0.5 parts per million as determined by analytical method entitled "Atomic Absorption Spectrometric Determination of Sub-part-per-Million Quantities of Tin in Extracts and Biological Materials with Graphite Furnace," *Analytical Chemistry*, Vol. 49, p. 1090-1093 (1977), 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>.

(iii) Subsequent determinations for the dodecyltin mixture described in paragraph (a)(7) of this section shall be at a minimum of 24-hour intervals for aqueous solvents and 2-hour intervals for heptane. These tests shall yield di(*n*-octyl)tin S,S'-bis(isooctylmercaptoacetate), or di(*n*-octyl)tin maleate polymer, or (C₁₀-C₁₆)-alkylmercaptoacetate reaction products with dichlorodioctylstannane and trichlorooctylstannane, or *n*-octyltin S,S',S''-tris(isooctylmercaptoacetate), tris(isooctylmercaptoacetate) and di(*n*-dodecyl)tin bis(isooctylmercaptoacetate) or any combination thereof, not to exceed 0.5 parts per million as determined by an analytical method entitled "Atomic Absorption Spectrophotometric Determination of Sub-part-per-Million Quantities of Tin in Extracts and Biological Materials with Graphite Furnace," *Analytical Chemistry*, Vol. 49, pp. 1090-1093 (1977), which is incorporated by reference in accordance with 5 U.S.C.

Food and Drug Administration, HHS

§ 178.3120

552(a). The availability of this incorporation by reference is given in paragraph (b)(1)(ii) of this section.

(2) In lieu of the tests prescribed in paragraph (b)(1) of this section, the finished plastics intended for contact with foods only of Types II, V, VI-A (except malt beverages), and VI-C may be end-tested with food-simulating solvents, under conditions of time and temperature, as specified below, whereby such tests shall yield the octyltin residues cited in paragraph (b)(1) of this section not in excess of 0.5 ppm:

	Food-simulating solvent	Time (hours)	Temperature (degrees Fahrenheit)
Type II	Acetic acid, 3 pct	48	135
Type V	Heptane	2	100
Type VI-A	Ethyl alcohol, 8 pct	24	120
Type VI-C	Ethyl alcohol, 50 percent.	24	120

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11847, Mar. 19, 1982; 48 FR 7170, Feb. 18, 1983; 48 FR 42972, Sept. 21, 1983; 48 FR 51612, Nov. 10, 1983; 49 FR 8432, Mar. 7, 1984; 50 FR 62, Jan. 2, 1985; 50 FR 3510, Jan. 25, 1985; 50 FR 37998, Sept. 19, 1985; 50 FR 47212, Nov. 15, 1985; 54 FR 24898, June 12, 1989]

Subpart D—Certain Adjuvants and Production Aids

§ 178.3010 Adjuvant substances used in the manufacture of foamed plastics.

The following substances may be safely used as adjuvants in the manufacture of foamed plastics intended for use in contact with food, subject to any prescribed limitations:

List of substances	Limitations
Azodicarbonamide	For use as a blowing agent in polyethylene complying with item 2.1 in § 177.1520(c) of this chapter at a level not to exceed 5 percent by weight of finished foamed polyethylene.
1,1-Difluoroethane (CAS Reg. No. 75-37-6).	For use as a blowing agent in polystyrene.
Isopentane	For use as a blowing agent in polystyrene.
n-Pentane	Do.

List of substances	Limitations
1,1,2,2-Tetrachloroethylene.	For use only as a blowing agent adjuvant in polystyrene at a level not to exceed 0.3 percent by weight of finished foamed polystyrene intended for use in contact with food only of the types identified in § 176.170(c) of this chapter, table 1, under Categories I, II, VI, and VIII.
Toluene	For use only as a blowing agent adjuvant in polystyrene at a level not to exceed 0.35 percent by weight of finished foamed polystyrene.

[47 FR 22090, May 21, 1982, as amended at 58 FR 64895, Dec. 10, 1993]

§ 178.3120 Animal glue.

Animal glue 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) Animal glue consists of the proteinaceous extractives obtained from hides, bones, and other collagen-rich substances of animal origin (excluding diseased or rotted animals), to which may be added other optional adjuvant substances required in its production or added to impart desired properties.

(b) The quantity of any substance employed in the production of animal glue does not exceed the amount reasonably required to accomplish the intended physical or technical effect nor any limitation further provided.

(c) Any substance employed in the production of animal glue and which 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) Optional adjuvant substances employed in the production of animal glue include:

(1) Substances generally recognized as safe in food.

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

(3) Substances identified in this paragraph (d)(3) and subject to such limitations as are provided: