§ 178.1010 Sanitizing solutions.

Sanitizing solutions may be safely used on food-processing equipment and utensils, and on other food-contact articles as specified in this section, within the following prescribed conditions:

(a) Such sanitizing solutions are used, followed by adequate draining, before contact with food.

(b) The solutions consist of one of the following, to which may be added components generally recognized as safe and components which are permitted by prior sanction or approval.

(1) An aqueous solution containing potassium, sodium, or calcium hypochlorite, with or without the bromides of potassium, sodium, or calcium.

(2) An aqueous solution containing dichloroisocyanuric acid, trichloroisocyanuric acid, or the sodium or potassium salts of these acids, with or without the bromides of potassium, sodium, or calcium.

(3) An aqueous solution containing potassium iodide, sodium p-toluenesulfonchloroamide, and sodium laurel sulfate.

(4) An aqueous solution containing iodine, butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol having a cloudpoint of 90–100 °C in 0.5 percent aqueous solution and an average molecular weight of 3,300, and ethylene glycol monobutyl ether. Additionally, the aqueous solution may contain diethylene glycol monoethyl ether as an optional ingredient.

(5) An aqueous solution containing elemental iodine, hydriodic acid, a-[p-
nonylphenyl)-omega-hydroxy(poly(oxyethylene) (complying with the identity prescribed in §178.3400(c) and having a maximum average molecular weight of 748) and/or polyoxyethylene-poloxypolypropylene block polymers (having a minimum average molecular weight of 1,900). Additionally, the aqueous solution may contain isopropyl alcohol as an optional ingredient.

(6) An aqueous solution containing elemental iodine, sodium iodide, sodium dioctylsulfosuccinate, and polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 1,900).

(7) An aqueous solution containing dodecylbenzenesulfonic acid and either isopropyl alcohol or polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,800). In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk.

(8) An aqueous solution containing elemental iodine, butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol having a minimum average molecular weight of 2,400 and nu-lauroyl-omega-hydroxy(poly(oxyethylene) with an average 8-9 moles of ethylene oxide and an average molecular weight of 400. In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk.

(9) An aqueous solution containing n-alkyl (C12-C18) benzyl dimethylammonium chloride compounds having average molecular weights of 351 to 380. The alkyl groups consist principally of groups with 12 to 16 carbon atoms and contain not more than 1 percent each of groups with 8 and 10 carbon atoms. Additionally, the aqueous solution may contain either ethyl alcohol or isopropyl alcohol as an optional ingredient.

(10) An aqueous solution containing trichlororomelamine and either sodium lauryl sulfate or dodecylbenzenesulfonic acid. In addition to use on food-processing equipment and utensils and other food-contact articles, this solution may be used on beverage containers except milk containers or equipment.

(11) An aqueous solution containing equal amounts of n-alkyl (C12-C18) benzyl dimethyl ammonium chloride and n-alkyl (C12-C18) dimethyl ethylbenzyl ammonium chloride (having an average molecular weight of 384). In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(12) An aqueous solution containing the sodium salt of sulfonated oleic acid, polyoxyethylene-polyoxypropylene block polymers (having an average molecular weight of 2,000 and 27 to 31 moles of polyoxypropylene). In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk. All equipment, utensils, glass bottles, and other glass containers treated with this sanitizing solution shall have a drainage period of 15 minutes prior to use in contact with food.

(13) An aqueous solution containing elemental iodine and alkyl (C12-C15) monoether of mixed (ethylene-propylene) polyalkylene glycol, having a cloud-point of 70°–77 °C in 1 percent aqueous solution and an average molecular weight of 807.

(14) An aqueous solution containing iodine, butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol, having a cloud-point of 90°–100 °C in 0.5 percent aqueous solution and an average molecular weight of 3,300, and polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,000).

(15) An aqueous solution containing lithium hypochlorite.

(16) An aqueous solution containing equal amounts of n-alkyl (C12-C18) benzyl dimethyl ammonium chloride and n-alkyl (C12-C18) dimethyl ethylbenzyl ammonium chloride (having average molecular weights of 377 to 384), with the optional adjuvant substances tetrasodium ethylenediaminetetraacetate and alpha-(p-nonylphenol)-
§ 178.1010

omega-hydroxy poly (oxyethylene) having an average poly- (oxyethylene) content of 11 moles. Alpha-hydro-omega-hydroxypoly-(oxyethylene) poly(oxypropylene) (15 to 18 mole minimum) poly (oxyethylene) block copolymer, having a minimum molecular weight of 1,900 (CAS Registry No. 9006–11–6) may be used in lieu of alpha- (p-nonylphenol)-omega-hydroxy-poly(oxyethylene) having an average poly(oxyethylene) content of 11 moles. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(17) An aqueous solution containing di- n-alkyl[C_{12–C_{16}}]dimethyl ammonium chloride, sodium metaborate, alpha-terpineol and alpha[p-(1,1,3,3-tetramethylbutyl)phenyl] -omega-hydroxy-poly (oxyethylene) produced with one mole of the phenol and 4 to 14 moles ethylene oxide, and alpha-alkyl[C_{12–C_{16}}]-omega-hydroxy[poly(oxyethylene) poly(oxypropylene)] (having an average molecular weight of 965).

(18) An aqueous solution containing alpha-hydro-omega-poly(oxyethylene) having an average poly(oxyethylene) content averaging an average poly- (oxyethylene) content of 11 moles. Alpha-hydro-omega-hydroxypoly-(oxyethylene) poly(oxypropylene) (15 to 18 mole minimum) poly (oxyethylene) block copolymer, having a minimum molecular weight of 1,900 (CAS Registry No. 9006–11–6) may be used in lieu of alpha- (p-nonylphenol)-omega-hydroxy-poly(oxyethylene) having an average poly(oxyethylene) content of 11 moles. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(19) An aqueous solution containing sodium dichloroisocyanurate and tetrasodium ethylenediaminetetraacetate. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(20) An aqueous solution containing ortho-phenylphenol, ortho-benzyl-para-chlorophenol, para-tertiaryaminophenol, sodium -alpha-alkyl[C_{12–C_{16}}]-omega-hydroxypoly (oxyethylene) sulfate with the poly(oxyethylene) content averaging one mole, potassium salts of coconut oil fatty acids, and isopropyl alcohol or hexylene glycol.

(21) An aqueous solution containing sodium dodecybenzenesulfonate. In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk.

(22) An aqueous solution containing (1) di- n-alkyl[C_{12–C_{16}}] dimethylammonium chloride compounds having average molecular weights of 332–361, (2) n-alkyl (C_{12–C_{16}}) benzyldimethylammonium chloride compounds having average molecular weights of 351–380 and consisting principally of alkyl groups with 12 to 16 carbon atoms with or without not over 1 percent each of groups with 8 and 10 carbon atoms, and (3) ethyl alcohol. The ratio of compound (1) to compound (2) is 60 to 40.

(23) An aqueous solution containing n-alkyl (C_{12–C_{16}}) benzyl- dimethylammonium chloride and didecyl(dimethylammonium chloride.

(24) An aqueous solution containing elemental iodine (CAS Reg. No. 7553–56–2), alpha-[p-(1,1,3,3-tetramethylbutyl)phenyl]-omega-hydroxy-poly(oxyethylene) produced with one mole of the phenol and 4 to 14 moles ethylene oxide, and alpha-alkyl[C_{12–C_{16}}]-omega-hydroxy[poly(oxyethylene) poly(oxypropylene)] (having an average molecular weight of 965).

(25) An aqueous solution containing n-alkyl (C_{12–C_{16}}) benzyl- dimethylammonium chloride and didecyl(dimethylammonium chloride.

(26) [Reserved]


(29) An aqueous solution containing dodecyldiphenoxydisulfonic acid (CAS Reg. No. 39269–73–2), sulfonated tall oil fatty acid (CAS Reg. No. 68309–27–3), and neo-decanoic acid (CAS Reg. No. 26896–20–8). In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk.
(30) An aqueous solution containing hydrogen peroxide (CAS Reg. No. 7722-84-1), peracetic acid (CAS Reg. No. 79-21-0), acetic acid (CAS Reg. No. 64-19-7), and 1-hydroxyethyldiene-1,1-diphosphonic acid (CAS Reg. No. 2809-21-4).

(31) An aqueous solution containing elemental iodine, alpha-alkyl(C<sub>8</sub>-C<sub>14</sub>)-omega-hydroxy(poly(oxyethylene)poly(oxypropylene) of average molecular weight between 768 and 837, and alpha-alkyl(C<sub>12</sub>-C<sub>18</sub>)-omega-hydroxy(poly(oxyethylene)poly(oxypropylene) of average molecular weight between 950 and 1,120. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(32) An aqueous solution containing (i) di-n-alkyl(C<sub>6</sub>-C<sub>10</sub>)dimethyl ammonium chloride compounds having average molecular weights of 332 to 361, (ii) n-alkyl(C<sub>12</sub>-C<sub>18</sub>)benzylidimethyl- ammonium chloride compounds having average molecular weights of 351 to 380 and consisting principally of alkyl groups with 12 to 16 carbon atoms with no more than 1 percent of groups with 8 and 10, (iii) ethyl alcohol, and (iv) alpha-(p-nonylphenyl)-omega-hydroxy(poly(oxyethylene) produced by the condensation of 1 mole of p-nonylphenol with 9 to 12 moles of ethylene oxide. The ratio of compound (i) to compound (ii) is 3 to 2.

(33) An aqueous solution containing (i) di-n-alkyl -(C<sub>6</sub>-C<sub>10</sub>)dimethylammonium chloride compounds having average molecular weights of 332 to 361; (ii) n-alkyl(C<sub>12</sub>-C<sub>18</sub>) -benzylidimethylammonium chloride compounds having molecular weights of 351 to 380 and consisting principally of alkyl groups with 12 to 16 carbon atoms with no more than 1 percent of the groups with 8 to 10; and (iii) tetrasodium ethylenediamine tetracetate. Additionally, the aqueous solution contains either alpha-(p-nonylphenyl)-omega-hydroxy(poly(oxyethylene) or alpha-alkyl(C<sub>12</sub>-C<sub>18</sub>)-omega-hydroxy(poly(oxyethylene), each produced with 9 to 13 moles of ethylene oxide. The ratio of compound (i) to compound (ii) is 3 to 2.

(34) An aqueous solution of an equilibrium mixture of oxychloro species (predominantly chlorite, chlorate, and chlorine dioxide) generated either (i) by directly metering a concentrated chlorine dioxide solution, prepared just prior to use, into potable water to provide the concentration of available chlorine dioxide stated in paragraph (c)(29) of this section, or (ii) by acidification of an aqueous alkaline solution of oxychloro species (predominantly chlorite and chlorate) followed by dilution with potable water to provide the concentration of available chlorine dioxide described in paragraph (c)(29) of this section.

(35) An aqueous solution containing decanoic acid (CAS Reg. No. 334-48-5), octanoic acid (CAS Reg. No. 124-07-2), lactic acid (CAS Reg. No. 50-21-5), phosphoric acid (CAS Reg. No. 7664-38-2) and a mixture of the sodium salt of naphthalenesulfonic acid (CAS Reg. No. 1321-69-3); the methyl, dimethyl, and trimethyl derivatives of the sodium salt of naphthalenesulfonic acid; and a mixture of the sodium salt of naphthalenesulfonic acid, and the methyl, dimethyl, and trimethyl derivatives of the sodium salt of naphthalenesulfonic acid alkylated at 3 percent by weight with C<sub>6</sub>-C<sub>8</sub> linear olefins, as components of a sanitizing solution to be used on food-processing equipment and utensils. The methyl and dimethyl substituted derivatives (described within this paragraph (b)(35)) constitute no less than 70 percent by weight of the mixture of naphthalenesulfonates.

(36) The sanitizing solution contains decanoic acid (CAS Reg. No. 334-48-5); octanoic acid (CAS Reg. No. 124-07-2); lactic acid (CAS Reg. No. 50-21-5); phosphoric acid (CAS Reg. No. 7664-38-2); a mixture of 1-octanesulfonic acid (CAS Reg. No. 3944-72-7), and 1-octanesulfonic-2-sulfinic acid (CAS Reg. No. 113652-56-5) or 1,2-octanesulfonic acid (CAS Reg. No. 113669-38-2); the condensate of four moles of poly(oxyethylene)poly(oxypropylene) block copolymers with one mole of ethylenediamine (CAS Reg. No. 11111-34-5); and the optional ingredient FD&C Yellow No. 5 (CAS Reg. No. 001934210). In addition to use on food-processing equipment and utensils, this...
solution may be used on dairy-processing equipment.

(37) The sanitizing solution contains sodium hypochlorite (CAS Reg. No. 7681–52–9), trisodium phosphate (CAS Reg. No. 7601–54–9), sodium lauryl sulfate (CAS Reg. No. 151–21–3), and potassium permanganate (CAS Reg. No. 7722–64–7). Magnesium oxide (CAS Reg. No. 1309–48–4) and potassium bromide (CAS Reg. No. 7758–02–3) may be added as optional ingredients to this sanitizing solution. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(38) An aqueous solution containing hydrogen peroxide (CAS Reg. No. 7722–84–1); peroxyacetic acid (CAS Reg. No. 79–21–0); acetic acid (CAS Reg. No. 64–19–7); sulfuric acid (CAS Reg. No. 7664–93–9); and 2,6-pyridinedicarboxylic acid (CAS Reg. No. 499–83–2). In addition to use on food-processing equipment and utensils, this solution may be used on dairy-processing equipment.

(39) An aqueous solution containing phosphoric acid (CAS Reg. No. 7664–38–2); octenyl succinic acid (CAS Reg. No. 28805–58–5); \(N,N\)-dimethyloctanamine (CAS Reg. No. 7378–99–6); and a mixture of \(n\)-carboxylic acids (C\(_6\)-C\(_{12}\), consisting of not less than 56 percent octanoic acid and not less than 40 percent decanoic acid). This solution may be used on food-processing equipment and utensils, including dairy-processing equipment.

(40) An aqueous solution prepared by combining elemental iodine (CAS Reg. No. 7553–56–2); hydriodic acid (CAS Reg. No. 10034–85–2); sodium \(N\)-cyclohexyl-\(N\)\(-\)palmitoyl taurate (CAS Reg. No. 132–33–4); chloroacetic acid, sodium salt reaction products with 4,5-dihydro-2-undecyl-1H-imidazole-1-ethanol and sodium hydroxide (CAS Reg. No. 68608–66–2); dodecylbenzene sulfonic acid (CAS Reg. No. 27176–87–0); phosphoric acid (CAS Reg. No. 7664–38–2); isopropyl alcohol (CAS Reg. No. 67–63–0); and calcium chloride (CAS Reg. No. 10043–52–4). In addition to use on food-processing equipment and utensils, this solution may be used on dairy-processing equipment.

(41) An aqueous solution containing \(n\)-alkyl(C\(_{12}-\)C\(_{16}\))benzyldimethylammonium chloride, having average molecular weights ranging from 351 to 380 wherein the alkyl groups contain principally 12 to 16 carbons and not more than 1 percent of each of the groups with 8 and 10 carbon atoms; ammonium chloride (CAS Reg. No. 12125–02–9); calcium stearate (CAS Reg. No. 1592–23–0); sodium bicarbonate (CAS Reg. No. 144–55–8); starch or dextrin, or both starch and dextrin (CAS Reg. No. 9004–53–9); and the optional ingredient methylene blue (CAS Reg. No. 61–73–4). In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(42) An aqueous solution containing decanoic acid (CAS Reg. No. 334–48–5), nonanoic acid (CAS Reg. No. 112–05–0), phosphoric acid (CAS Reg. No. 7664–38–2), propionic acid (CAS Reg. No. 79–09–04), and sodium 1-octanesulfonate (CAS Reg. No. 5324–84–5). Sulfuric acid (CAS Reg. No. 7664–38–9) may be added as an optional ingredient. In addition to use on food-processing equipment and utensils, this solution may be used on dairy-processing equipment.

(43) An aqueous solution of iodine and hypochlorous acid generated by the dilution of an aqueous acidic (21.5 percent nitric acid) solution of iodine monochloride. In addition to use on food-processing equipment and utensils, this solution may be used on dairy-processing equipment.

(44) An aqueous solution of citric acid, disodium ethylenediaminetetraacetate, sodium lauryl sulfate, and monosodium phosphate. In addition to use on food-processing equipment and utensils, this solution may be used on dairy-processing equipment.

(45) An aqueous solution of hydrogen peroxide, acetic acid, peroxyacetic acid, octanoic acid, peroxyoctanoic acid, sodium 1-octanesulfonate, and 1-hydroxyethyldiene-1,1-diphosphonic acid. In addition to use on food-processing equipment and utensils, this solution may be used on dairy-processing equipment.

(46) An aqueous solution of hydrogen dioxide and related oxychloro species
Food and Drug Administration, HHS § 178.1010

generated by acidification of an aqueous solution of sodium chlorite with a solution of sodium gluconate, citric acid, phosphoric acid, and sodium mono- and didodecylphenoxybenzenesulfonate. In addition to use on food-processing equipment and utensils, this solution may be used on dairy-processing equipment.

(c) The solutions identified in paragraph (b) of this section will not exceed the following concentrations:

1. Solutions identified in paragraph (b)(1) of this section will provide not more than 200 parts per million of available halogen determined as available chlorine.

2. Solutions identified in paragraph (b)(2) of this section will provide not more than 100 parts per million of available halogen determined as available chlorine.

3. Solution identified in paragraph (b)(3) of this section will provide not more than 25 parts per million of titratable iodine. The solutions will contain the components potassium iodide, sodium p-toluenesulfonchloramide and sodium lauryl sulfate at a level not in excess of the minimum required to produce their intended functional effect.

4. Solutions identified in paragraph (b)(4), (5), (6), (8), (13), and (14) of this section will contain iodine to provide not more than 25 parts per million of titratable iodine. The adjuvants used with the iodine will not be in excess of the minimum amounts required to accomplish the intended technical effect.

5. Solutions identified in paragraph (b)(7) of this section will provide not more than 400 parts per million dodecylbenzenesulfonic acid and not more than 80 parts per million of polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,800) or not more than 40 parts per million of isopropyl alcohol.

6. Solutions identified in paragraph (b)(9) of this section shall provide when ready to use no more than 200 parts per million of the active quaternary compound.

7. Solutions identified in paragraph (b)(10) of this section shall provide not more than sufficient trichloromelamine to produce 200 parts per million of available chlorine and either sodium lauryl sulfate at a level not in excess of the minimum required to produce its intended functional effect or not more than 400 parts per million of dodecylbenzenesulfonic acid.

8. Solutions identified in paragraph (b)(11) of this section shall provide, when ready to use, not more than 200 parts per million of active quaternary compound.

9. The solution identified in paragraph (b)(12) of this section shall provide not more than 200 parts per million of sulfurated oleic acid, sodium salt.

10. Solutions identified in paragraph (b)(15) of this section will provide not more than 200 parts per million of available chlorine and not more than 30 ppm lithium.

11. Solutions identified in paragraph (b)(16) of this section shall provide not more than 200 parts per million of active quaternary compound.

12. Solutions identified in paragraph (b)(17) of this section shall provide, when ready to use, a level of 150 parts per million of the active quaternary compound.

13. Solutions identified in paragraph (b)(18) of this section shall provide not more than 200 parts per million of active quaternary compound and not more than 66 parts per million of alpha-[p-(1,1,3,3-tetramethylbutyl)-phenyl]-omega-hydroxypropyloxethyene.

14. Solutions identified in paragraph (b)(19) of this section shall provide, when ready to use, a level of 100 parts per million of available chlorine.

15. Solutions identified in paragraph (b)(20) of this section are for single use applications only and shall provide, when ready to use, a level of 800 parts per million of total active phenols consisting of 400 parts per million ortho-phenylphenol, 320 parts per million ortho-benzyl-para-chlorophenol and 80 parts per million para-tertiaryamylphenol.

16. Solution identified in paragraph (b)(21) of this section shall provide not more than 400 parts per million and not less than 25 parts per million of sodium dodecylbenzenesulfonate.
(17) Solutions identified in paragraph (b)(22) of this section shall provide, when ready to use, at least 150 parts per million and not more than 400 parts per million of active quaternary compound.

(18) Solutions identified in paragraph (b)(23) of this section shall provide at least 150 parts per million and not more than 200 parts per million of the active quaternary compound.

(19) Solutions identified in paragraphs (b)(24), (b)(25), and (b)(43) of this section shall provide at least 12.5 parts per million and not more than 25 parts per million of titratable iodine. The adjuvants used with the iodine shall not be in excess of the minimum amounts required to accomplish the intended technical effect.

(20)–(21) [Reserved]

(22) Solutions identified in paragraph (b)(27) of this section shall provide, when ready to use, at least 109 parts per million and not more than 218 parts per million of total active fatty acids and at least 156 parts per million and not more than 312 parts per million of the sodium 1-octanesulfonate.

(23) Solutions identified in paragraph (b)(28) of this section shall provide, when ready to use, at least 156 parts per million and not more than 312 parts per million of sulfonated 9-octadecenoic acid, at least 31 parts per million and not more than 62 parts per million of sodium xylenesulfonate.

(24) Solutions identified in paragraph (b)(29) of this section will provide at least 237 parts per million and not more than 474 parts per million dodecylphenyloxidisedisulfonic acid, at least 33 parts per million and not more than 66 parts per million sulfonated tall oil fatty acid, and at least 87 parts per million and not more than 174 parts per million neo-decanolic acid.

(25) Solutions identified in paragraph (b)(30) of this section shall provide, when ready to use, not less than 550 parts per million and not more than 1,100 parts per million hydrogen peroxide, not less than 100 parts per million and not more than 200 parts per million peracetic acid, not less than 15 parts per million and not more than 300 parts per million acetic acid, and not less than 15 parts per million and not more than 30 parts per million 1-hydroxyethylidene-1,1-diphosphonic acid.

(26) The solution identified in paragraph (b)(31) of this section shall provide, when ready to use, at least 12.5 parts per million and not more than 25 parts per million of titratable iodine. The adjuvants used with the iodine will not be in excess of the minimum amounts required to accomplish the intended technical effect.

(27) Solutions identified in paragraph (b)(32) of this section shall provide, when ready to use, at least 150 parts per million and not more than 400 parts per million of active quaternary compounds in solutions containing no more than 600 parts per million water hardness. The adjuvants used with the quaternary compounds will not exceed the amounts required to accomplish the intended technical effect.

(28) Solutions identified in paragraph (b)(33) of this section shall provide, when ready to use, at least 150 parts per million and not more than 400 parts per million of active quaternary compounds. The adjuvants used with the quaternary compounds shall not exceed the amounts required to accomplish the intended technical effect. Tetrasodium ethylenediaminetetraacetate shall be added at a minimum level of 60 parts per million. Use of these sanitizing solutions shall be limited to conditions of water hardness not in excess of 300 parts per million.

(29) Solutions identified in paragraph (b)(34) of this section should provide, when ready to use, at least 100 parts per million and not more than 200 parts per million available chlorine dioxide as determined by the method titled “Iodometric Method for the Determination of Available Chlorine Dioxide (50–250 ppm available ClO₂),” which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., 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.
(30) Solutions identified in paragraph (b)(35) of this section shall provide, when ready for use, at least 117 parts per million and not more than 234 parts per million of total fatty acids and at least 166 parts per million and not more than 332 parts per million of a mixture of naphthalenesulfonates. The adjuvants phosphoric acid and lactic acid, used with decanoic acid, octanoic acid, and sodium naphthalenesulfonate and its alkylated derivatives, will not be in excess of the minimum amounts required to accomplish the intended technical effects.

(31) Solutions identified in paragraph (b)(36) of this section shall provide, when ready for use, at least 29 parts per million and not more than 58 parts per million decanoic acid; at least 88 parts per million and not more than 176 parts per million of octanoic acid; at least 69 parts per million and not more than 138 parts per million of lactic acid; at least 256 parts per million and not more than 512 parts per million of phosphoric acid; at least 86 parts per million and not more than 172 parts per million of 1-octanesulfonic acid; at least 51 parts per million and not more than 102 parts per million of 1-octanesulfonic-2-sulfinic acid or 1,2-octanedisulfonic acid; and at least 10 parts per million of the condensate of four moles of poly(oxyethylene)poly(oxypropylene) block copolymer with one mole of ethylenediamine. The colorant adjuvant FD&C Yellow No. 5 shall not be used in excess of the minimum amount required to accomplish the intended technical effect.

(32)(i) The solution identified in paragraph (b)(37) of this section without potassium bromide shall provide, when ready to use, at least 100 parts per million and not more than 200 parts per million of available halogen determined as available chlorine; at least 2,958 parts per million and not more than 5,916 parts per million of trisodium phosphate; at least 690 parts per million and not more than 2,072 parts per million of potassium bromide; at least 0.3 part per million and not more than 1 part per million of sodium lauryl sulfate; and at least 0.1 part per million and not more than 0.3 part per million of potassium permanganate.

(ii) Magnesium oxide when used in paragraph (c)(32)(i) or (ii) of this section shall not be used in excess of the minimum amount required to accomplish its intended technical effect.

(33) Solutions identified in paragraph (b)(38) of this section shall provide when ready for use not less than 300 parts per million and not more than 465 parts per million of hydrogen peroxide; not less than 200 parts per million and not more than 315 parts per million of peroxyacetic acid; not less than 200 parts per million and not more than 340 parts per million of peracetic acid; not less than 10 parts per million and not more than 20 parts per million of sulfuric acid; and not less than 0.75 parts per million and not more than 1.2 parts per million of 2,6-pyridinedicarboxylic acid.

(34) Solutions identified in paragraph (b)(39) of this section shall provide when ready for use not less than 460 parts per million and not more than 625 parts per million of phosphoric acid, and all components shall be present in the following proportions: 1 part phosphoric acid to 0.25 octenyl succinic acid to 0.18 part N,N-dimethylectanamide to 0.062 part of a mixture of \( C_6-C_{12} \) acids (consisting of not less than 56 percent octanoic acid and not less than 40 percent decanoic acid).

(35) Solutions identified in paragraph (b)(40) of this section shall provide when ready for use not less than 12.5 parts per million and not more than 25.0 parts per million of titratable iodine; and not less than 2.7 parts per million and not more than 5.5 parts per million of dodecylbenzene sulfonic acid. All components shall be present in the following proportions: 1.0 part...
dodecylbenzene sulfonic acid to 43 parts sodium N-cyclohexyl-N-
palmitoyltaurate to 7.7 parts chloroacetic acid, sodium salt, reaction products with 4,5-
dihydro-2-undecyl-1H-imidazole-1-ethanol and sodium hydroxide to 14 parts
phosphoric acid to 57 parts isopropyl alcohol to 3.0 parts calcium chloride.

(36) Solutions identified in paragraph (b)(41) of this section shall provide,
when ready for use, not less than 150 parts per million and not more than 200
parts per million of \( \text{n-alkyl(C}_{12}-\text{C}_{16}) \)benzyldimethylammonium chloride; and not more than 0.4 part per
million of the colorant methylene blue. Components shall be present in the
product used to prepare the solution in the following proportions: 1 part \( \text{n-}
\text{alkyl(C}_{12}-\text{C}_{16}) \)benzyldimethylammonium chloride to 0.24 part ammonium chloride to 0.08
part calcium stearate to 0.60 part sodium bicarbonate to 0.08 part starch or
dextrin, or a combination of starch and dextrin.

(37)(i) The solution identified in paragraph (b)(42) of this section not con-
taining sulfuric acid shall provide when ready for use not less than 45 parts per
million and not more than 90 parts per million of decanoic acid; and all com-
ponents shall be present in the following proportions (weight/weight (w/
w)): 1 part decanoic acid to 1 part nonanoic acid to 9.5 parts phosphoric acid to
3.3 parts propionic acid to 3.3 parts sodium 1-octanesulfonate.

(ii) The solution identified in paragraph (b)(42) of this section containing
sulfuric acid shall provide when ready for use not less than 45 parts per
million and not more than 90 parts per million of decanoic acid; and all com-
ponents shall be present in the following proportions (w/w): 1 part decanoic acid to 1 part nonanoic acid to 9.5 parts phosphoric acid to
3.3 parts propionic acid to 3.3 parts sodium 1-octanesulfonate.

(38) The solution identified in paragraph (b)(44) of this section shall pro-
vide, when ready for use, at least 16,450 parts per million and not more than
32,900 parts per million of citric acid; at least 700 parts per million and not
more than 1,400 parts per million of disodium ethylenediaminetetraacetate;
at least 175 parts per million and not more than 350 parts per million of so-
dium lauryl sulfate; and at least 175 parts per million and not more than 350
parts per million of monosodium phosphate.

(39)(i) The solution identified in para-
graph (b)(45) of this section, when used
on food processing equipment and uten-
sils, including dairy and beverage-proc-
essing equipment but excluding food-
contact surfaces in public eating places
and dairy and beverage containers,
shall provide when ready for use at
least 72 parts per million and not more
than 216 parts per million of hydrogen
peroxide; at least 46 parts per million
and not more than 138 parts per million
of peroxyacetic acid; at least 40 parts
per million and not more than 122 parts
per million of octanoic acid (including
peroxyoctanoic acid); at least 281 parts
per million and not more than 686 parts
per million of acetic acid; at least 7
parts per million and not more than 34
parts per million of 1-
hydroxyethylidene-1,1-diphosphonic
acid; and at least 36 parts per million
and not more than 109 parts per million
of sodium 1-octanesulfonate.

(ii) The solution identified in para-
graph (b)(45) of this section, when used
on food-contact equipment and utensils
in warewashing machines, including
warewashing machines in public eating
places, at temperatures no less than 120
\( ^\circ \text{F} \) (49 \( ^\circ \text{C} \)) shall provide when ready for
use at least 30 parts per million and
not more than 91 parts per million of
hydrogen peroxide; at least 19 parts per
million and not more than 58 parts per
million of peroxyacetic acid; at least 17
parts per million and not more than 52
parts per million of octanoic acid (in-
cluding peroxyoctanoic acid); at least
119 parts per million and not more than
290 parts per million of acetic acid; at
least 3 parts per million and not more
than 14 parts per million of 1-
hydroxyethylidene-1,1-diphosphonic
acid; and at least 15 parts per million
and not more than 46 parts per million
of sodium 1-octanesulfonate.

(iii) The solution identified in para-
graph (b)(45) of this section, when used
on dairy or beverage containers, shall
provide when ready for use at least 36
parts per million and not more than 108
parts per million of hydrogen peroxide;
Food and Drug Administration, HHS § 178.2010

at least 23 parts per million and not more than 69 parts per million of peroxycetic acid; at least 20 parts per million and not more than 61 parts per million of octanoic acid (including peroxycetanoic acid); at least 140 parts per million and not more than 343 parts per million of acetic acid; at least 3 parts per million and not more than 17 parts per million of 1-hydroxyethylidene-1,1-diphosphonic acid; and at least 18 parts per million and not more than 55 parts per million of sodium 1-octanesulfonate.

(40) The solution identified in paragraph (b)(46) of this section shall provide, when ready for use, at least 100 parts per million and not more than 200 parts per million of chlorine dioxide as determined by the method developed by Bio-cide International, Inc., entitled, “Iodometric Method for the Determination of Available Chlorine Dioxide (50–250 ppm Available ClO₂),” dated June 11, 1987, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this method are available from the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200, and may be examined at the Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, 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; at least 380 parts per million and not more than 760 parts per million of sodium gluconate; and at least 960 parts per million and not more than 1,920 parts per million of sodium mono- and didodecylphenoxybenzenesulfonate.

Other components listed under paragraph (b)(46) of this section shall be used in the minimum amount necessary to produce the intended effect.

(d) Sanitizing agents for use in accordance with this section will bear labeling meeting the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act.

[42 FR 14609, Mar. 16, 1977]

EDITORIAL NOTE: For Federal Register citations affecting § 178.1010, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

Subpart C—Antioxidants and Stabilizers

§ 178.2010 Antioxidants and/or stabilizers for polymers.

The substances listed in paragraph (b) of this section may be safely used as antioxidants and/or stabilizers in polymers used in the manufacture of 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 quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect.

(b) List of substances:

<table>
<thead>
<tr>
<th>Substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-n-Alkyl-N’-(carboxymethyl)-N,N’-trimethylene-diglycine; the alkyl group is even numbered in the range C₁₄–C₁₈ and the nitrogen content is in the range 5.4–5.6 weight percent.</td>
<td>For use only: 1. As component of nonfood articles complying with §§ 175.105 and 177.2600 of this chapter. 2. At levels not to exceed 1.35 percent by weight of natural rubber, butadiene-acrylonitrile, butadiene-acrylonitrile-styrene, and butadiene-styrene polymers that are used in contact with nonalcoholic food at temperatures not to exceed room temperature and that are employed in closure-sealing gaskets complying with § 177.1210 of this chapter or in coatings complying with §§ 175.300, § 176.170, or § 175.320 of this chapter. The average thickness of such coatings and closure-sealing gaskets shall not exceed 0.004 inch. For use only: 1. At levels not to exceed 2 percent by weight of adhesives complying with § 175.105 of this chapter, of pressure-sensitive adhesives complying with § 175.125 of this chapter, and of rubber articles complying with § 177.2600 of this chapter.</td>
</tr>
</tbody>
</table>

Alkylthiophenolics:

1. Acid-catalyzed condensation reaction products of 4-nonylphenol, formaldehyde, and 1-dodecanethiol (CAS Reg. No. 164907–73–7).