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SOURCE: 42 FR 14609, Mar. 15, 1977, unless otherwise noted.

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Subpart A [Reserved]

Subpart B—Substances Utilized To Control the Growth of Microorganisms

§ 178.1005 Hydrogen peroxide solution.

Hydrogen peroxide solution identified in this section may be safely used to sterilize polymeric food-contact surfaces identified in paragraph (e)(1) of this section.

(a) *Identity.* For the purpose of this section, hydrogen peroxide solution is an aqueous solution containing not more than 35 percent hydrogen peroxide (CAS Reg. No. 7722–84–1) by weight, meeting the specifications prescribed in paragraph (c) of this section.

(b) *Optional adjuvant substances.* Hydrogen peroxide solution identified in paragraph (a) of this section may contain substances generally recognized as safe in or on food, substances generally recognized for their intended use in food packaging, substances used in accordance with a prior sanction or approval, and substances permitted by applicable regulations in parts 174 through 179 of this chapter.

(c) *Specifications.* Hydrogen peroxide solution shall meet the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 496–497, which is incorporated by reference. Hydrogen peroxide solution shall also meet the specifications for ''Acidity,'' ''Chloride,'' and ''Other requirements'' for Hydrogen Peroxide Concentrate in the United States Pharmacopeia 36th Revision (2013), pp. 3848–3849, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address http://www.usp.org). Copies 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/cfr/ibr-locations.html.*

(d) *Limitations.* No use of hydrogen peroxide solution in the sterilization of food packaging material shall be considered to be in compliance if more than 0.5 part per million of hydrogen peroxide can be determined in distilled water packaged under production conditions (assay to be performed immediately after packaging).

(e) *Conditions of use.* (1) Hydrogen peroxide solution identified in and complying with the specifications in this section may be used by itself or in combination with other processes to treat food-contact surfaces to attain commercial sterility at least equivalent to that attainable by thermal processing for metal containers as provided for in part 113 of this chapter. Food-contact surfaces include the following:

Substances	Limitations
Ethylene-acrylic acid copolymers.	Complying with §177.1310 of this chapter.
Ethylene-carbon monoxide copolymers.	Complying with §177.1312 of this chapter.
Ethylene-methyl acrylate copolymer resins.	Complying with §177.1340 of this chapter.
Ethylene-vinyl acetate copolymers.	Complying with §177.1350 of this chapter.
Ionomeric resins	Complying with §177.1330 of this chapter.
Isobutylene polymers	Complying with §177.1420 (a)(1) and (a)(2) of this chapter.
Olefin polymers	Complying with §177.1520 of this chapter.
Polycarbonate resins	Complying with §177.1580 of this chapter.
Polyethylene-terephthalate polymers.	Complying with §177.1630 of this chapter (excluding polymers described in §177.1630(c) of this chapter.
Poly-l-butene resins and butene/ethylene copolymers.	Complying with §177.1570 of this chapter.
Polystryrene and rubber-modified polystyrene polymers.	Complying with §177.1640 of this chapter.
Vinylidene chloride/methyl acrylate copolymers.	Complying with §177.1990 of this chapter.

(2) The packaging materials identified in paragraph (e)(1) of this section may be used for packaging all commercially sterile foods except that the olefin polymers may be used in articles for packaging foods only of the types identified in §176.170(c) of this chapter, table 1, under Categories I, II, III, IV-B, V, and VI.

(3) Processed foods packaged in the materials identified in paragraph (e)(1) of this section shall conform with parts

108, 110, 113, and 114 of this chapter as applicable.

§ 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 lauryl 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*-hydroxypoly-(oxyethylene) (complying with the identity prescribed in §178.3400(c) and having a maximum average molecular weight of 748) and/or polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular