

§ 173.340

21 CFR Ch. I (4–1–11 Edition)

that result in sodium chlorite concentrations between 500 and 1,200 ppm, in combination with any GRAS acid at a level sufficient to achieve a solution pH of 2.3 to 2.9.

(h) The concentration of sodium chlorite is determined by a method entitled “Determination of Sodium Chlorite: 50 ppm to 1500 ppm Concentration,” September 13, 1995, developed by Alcide Corp., Redmond, WA, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available 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 20204-0001, 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](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

[61 FR 17829, Apr. 23, 1996, as amended at 63 FR 11119, Mar. 6, 1998; 64 FR 44123, Aug. 13, 1999; 64 FR 49982, Sept. 15, 1999; 65 FR 1776, Jan. 12, 2000; 65 FR 16312, Mar. 28, 2000; 66 FR 22922, May 7, 2001; 66 FR 31841, June 13, 2001; 67 FR 15720, Apr. 3, 2002; 69 FR 78304, Dec. 30, 2004]

§ 173.340 Defoaming agents.

Defoaming agents may be safely used in processing foods, in accordance with the following conditions:

(a) They consist of one or more of the following:

(1) Substances generally recognized by qualified experts as safe in food or covered by prior sanctions for the use prescribed by this section.

(2) Substances listed in this paragraph (a)(2) of this section, subject to any limitations imposed:

Substances	Limitations
Dimethylpolysiloxane (substantially free from hydrolyzable chloride and alkoxy groups; no more than 18 percent loss in weight after heating 4 hours at 200 °C; viscosity 300 to 1,050 centistokes at 25 °C; refractive index 1.400–1.404 at 25 °C).	10 parts per million in food, or at such level in a concentrated food that when prepared as directed on the labels, the food in its ready-for-consumption state will have not more than 10 parts per million except as follows: Zero in milk; 110 parts per million in dry gelatin dessert mixes labeled for use whereby no more than 16 parts per million is present in the ready-to-serve dessert; 250 parts per million in salt labeled for cooking purposes, whereby no more than 10 parts per million is present in the cooked food.
Formaldehyde .....	As a preservative in defoaming agents containing dimethylpolysiloxane, in an amount not exceeding 1.0 percent of the dimethylpolysiloxane content.
α-Hydro-omega-hydroxy-poly (oxyethylene)/poly(oxypropylene) (minimum 15 moles/poly(oxyethylene) block copolymer (CAS Reg. No. 9003-11-6) as defined in § 172.808(a)(3) of this chapter.	For use as prescribed in § 172.808(b)(3) of this chapter.
Polyacrylic acid, sodium salt .....	As a stabilizer and thickener in defoaming agents containing dimethylpolysiloxane in an amount reasonably required to accomplish the intended effect.
Polyethylene glycol .....	As defined in § 172.820 of this chapter.
Polyoxyethylene 40 monostearate .....	As defined in U.S.P. XVI.
Polysorbate 60 .....	As defined in § 172.836 of this chapter.
Polysorbate 65 .....	As defined in § 172.838 of this chapter.
Propylene glycol alginate .....	As defined in § 172.858 of this chapter.
Silicon dioxide .....	As defined in § 172.480 of this chapter.
Sorbitan monostearate .....	As defined in § 172.842 of this chapter.
White mineral oil: Conforming with § 172.878 of this chapter .....	As a component of defoaming agents for use in wash water for sliced potatoes at a level not to exceed 0.008 percent of the wash water.

(3) Substances listed in this paragraph (a)(3), provided they are components of defoaming agents limited to

use in processing beet sugar and yeast, and subject to any limitations imposed:

Substances	Limitations
Aluminum stearate .....	As defined in § 172.863 of this chapter.

Food and Drug Administration, HHS

§ 173.340

Substances	Limitations
Butyl stearate.	
BHA .....	As an antioxidant, not to exceed 0.1 percent by weight of defoamer.
BHT .....	Do.
Calcium stearate .....	As defined in § 172.863 of this chapter.
Fatty acids .....	As defined in § 172.860 of this chapter.
Formaldehyde .....	As a preservative.
Hydroxylated lecithin .....	As defined in § 172.814 of this chapter.
Isopropyl alcohol.	
Magnesium stearate .....	As defined in § 172.863 of this chapter.
Mineral oil: Conforming with § 172.878 of this chapter .....	Not more than 150 p.p.m. in yeast, measured as hydrocarbons.
Odorless light petroleum hydrocarbons: Conforming with § 172.884 of this chapter.	
Petrolatum: Conforming with § 172.880 of this chapter .....	
Petroleum wax: Conforming with § 172.886 of this chapter.	
Petroleum wax, synthetic.	
Polyethylene glycol (400)dioleate: Conforming with § 172.820(a)(2) of this chapter and providing the oleic acid used in the production of this substance complies with § 172.860 or § 172.862 of this chapter.	As an emulsifier not to exceed 10 percent by weight of defoamer formulation.
Synthetic isoparaffinic petroleum hydrocarbons: Conforming with § 172.882 of this chapter.	
Oleic acid derived from tall oil fatty acids .....	Complying with § 172.862 of this chapter.
Oxystearin .....	As defined in § 172.818 of this chapter.
Polyoxyethylene (600) dioleate.	
Polyoxyethylene (600) monoricinoleate.	
Polypropylene glycol .....	Molecular weight range, 1,200–3,000.
Polysorbate 80 .....	As defined in § 172.840 of this chapter.
Potassium stearate .....	As defined in § 172.863 of this chapter.
Propylene glycol mono- and diesters of fats and fatty acids .....	As defined in § 172.856 of this chapter.
Soybean oil fatty acids, hydroxylated.	
Tallow, hydrogenated, oxidized or sulfated.	
Tallow alcohol, hydrogenated.	

§ 173.342

21 CFR Ch. I (4-1-11 Edition)

(4) The substances listed in this paragraph (a)(4), provided they are components of defoaming agents limited to use in processing beet sugar only, and subject to the limitations imposed:

Substances	Limitations
<p><i>n</i>-Butoxypoly(oxyethylene)-poly(oxypropylene)glycol.</p>	<p>Viscosity range, 4,850–5,350 Saybolt Universal Seconds (SUS) at 37.8 °C (100 °F). The viscosity range is determined by the method “Viscosity Determination of <i>n</i>-butoxypoly(oxyethylene)-poly(oxypropylene) glycol” dated April 26, 1995, developed by Union Carbide Corp., P.O. Box 670, Bound Brook, NJ 08805, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the material incorporated by reference are available from the Division of Petition Control, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and 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: <a href="http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html">http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html</a>.</p>
<p>Monoester of alpha-hydroxy-omega-hydroxy-poly(oxyethylene) poly(oxypropylene) poly(oxyethylene) (15 mole minimum) blocked copolymer derived from low erucic acid rapeseed oil.</p>	

(b) They are added in an amount not in excess of that reasonably required to inhibit foaming.

[42 FR 14526, Mar. 15, 1977, as amended at 43 FR 2872, Jan. 20, 1978; 46 FR 30493, June 9, 1981; 46 FR 57476, Nov. 24, 1981; 60 FR 54036, Oct. 19, 1995; 61 FR 632, Jan. 9, 1996; 63 FR 29134, May 28, 1998]

§ 173.342 Chlorofluorocarbon 113 and perfluorohexane.

A mixture of 99 percent chlorofluorocarbon 113 (1,1,2-trichloro-

1,2,2-trifluoroethane) (CAS Reg. No. 76–13–1, also known as fluorocarbon 113, CFC 113 and FC 113) and 1 percent perfluorohexane (CAS Reg. No. 355–42–0) may be safely used in accordance with the following prescribed conditions:

(a) The additive chlorofluorocarbon 113 has a purity of not less than 99.99 percent.

(b) The additive mixture is intended for use to quickly cool or crust-freeze chickens sealed in intact bags composed of substances regulated in parts 174, 175, 177, 178, and §179.45 of this chapter and conforming to any limitations or specifications in such regulations.

[55 FR 8913, Mar. 9, 1990]

§ 173.345 Chloropentafluoroethane.

The food additive chloropentafluoroethane may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive has a purity of not less than 99.97 percent, and contains not more than 200 parts per million saturated fluoro compounds and 10 parts per million unsaturated fluoro compounds as impurities.

(b) The additive is used or intended for use alone or with one or more of the following substances: Carbon dioxide, nitrous oxide, propane, and octafluorocyclobutane complying with §173.360, as an aerating agent for foamed or sprayed food products, with any propellant effect being incidental and no more than is minimally necessary to achieve the aerating function, except that use is not permitted for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive

(1) The label of the food additive container shall bear, in addition to the other information required by the act, the following:

- (i) The name of the additive, chloropentafluoroethane.
- (ii) The percentage of the additive present in the case of a mixture.
- (iii) The designation “food grade”.