

Bottled Water/Carbonated Soft Drinks Guidance Documents & Regulatory Information

U.S. Department of Health and Human Services

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§165.110 Bottled water.

Description. Bottled water is water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents. Fluoride may be optionally added within the limitations established in §165.110(b)(4)(ii). Bottled water may be used as an ingredient in beverages (e.g., diluted juices, flavored bottled waters). It does not include those food ingredients that are declared in ingredient labeling as “water,” “carbonated water,” “disinfected water,” “filtered water,” “seltzer water,” “soda water,” “sparkling water,” and “tonic water.”

Physical quality. Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the method described in applicable sections of “Standard Methods for the Examination of Water and Wastewater,” 15th Ed. (1980), American Public Health Association, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (copies may be obtained from the American Public Health Association, 800 I St. NW., Washington, DC 20001, 202-777-2742 (APHA), or a copy may be examined at the National Archives and Records Administration (NARA), or at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, 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), meet the following standards of physical quality:

- (i) The turbidity shall not exceed 5 units.
- (ii) The color shall not exceed 15 units.¹

¹Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

- (iii) The odor shall not exceed threshold odor No. 3.¹

Chemical quality. Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (b)(4)(i)(B) of this section, meet standards of chemical quality and shall not contain chemical substances in excess of the following concentrations:

Substance	Concentration in milligrams per liter
Chloride ¹	250.0
Iron ¹	0.3
Manganese ¹	0.05
Phenols	0.001
Total dissolved solids ¹	500.0
Zinc ¹	5.0

¹Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

(A) Bottled water packaged in the United States to which no fluoride is added shall not contain fluoride in excess of the levels in Table 1 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 1

Annual average of maximum daily air temperatures (°F)	Fluoride concentration in milligrams per liter
53.7 and below	2.4
53.8-58.3	2.2
58.4-63.8	2.0
63.9-70.6	1.8
70.7-79.2	1.6
79.3-90.5	1.4

(B) Imported bottled water to which no fluoride is added shall not contain fluoride in excess of 1.4 milligrams per liter.

(C) Bottled water packaged in the United States to which fluoride is added shall not contain fluoride in excess of levels in Table 2 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 2

Annual average of maximum daily air temperatures (°F)	Fluoride concentration in milligrams per liter
53.7 and below	1.7
53.8-58.3	1.5
58.4-63.8	1.3
63.9-70.6	1.2
70.7-79.2	1.0
79.3-90.5	0.8

(D) Imported bottled water to which fluoride is added shall not contain fluoride in excess of 0.8 milligram per liter.

The allowable levels for inorganic substances are as follows:

Contaminant	Concentration in milligrams per liter (or as specified)
Arsenic	0.010
Antimony	.006
Barium	2
Beryllium	0.004
Cadmium	0.005
Chromium	0.1
Copper	1.0
Cyanide	0.2
Lead	0.005
Mercury	0.002
Nickel	0.1
Nitrate	10 (as nitrogen)
Nitrite	1 (as nitrogen)
Total Nitrate and Nitrite	10 (as nitrogen)
Selenium	0.05
Thallium	0.002

The allowable levels for volatile organic chemicals (VOC's) are as follows:

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
Benzene (71-43-2)	0.005
Carbon tetrachloride (56-23-5)	0.005
<i>o</i> - Dichlorobenzene (95-50-1)	0.6
<i>p</i> - Dichlorobenzene (106-46-7)	0.075
1,2-Dichloroethane (107-06-2)	0.005
1,1-Dichloroethylene (75-35-4)	0.007
<i>cis</i> -1,2-Dichloroethylene (156-59-2)	0.07
<i>trans</i> -1,2-Dichloroethylene (156-60-5)	0.1
Dichloromethane (75-09-2)	0.005
1,2-Dichloropropane (78-87-5)	0.005
Ethylbenzene (100-41-4)	0.7
Monochlorobenzene (108-90-7)	0.1
Styrene (100-42-5)	0.1
Tetrachloroethylene (127-18-4)	0.005
Toluene (108-88-3)	1
1,2,4-Trichlorobenzene (120-82-1)	0.07
1,1,1-Trichloroethane (71-55-6)	0.20
1,1,2-Trichloroethane (79-00-5)	0.005
Trichloroethylene (79-01-6)	0.005
Vinyl chloride (75-01-4)	0.002
Xylenes (1330-20-7)	10

The allowable levels for pesticides and other synthetic organic chemicals (SOC's) are as follows:

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
Alachlor (15972-60-8)	0.002
Atrazine (1912-24-9)	0.003
Benzo(a)pyrene (50-32-8)	0.0002
Carbofuran (1563-66-2)	0.04
Chlordane (57-74-9)	0.002
Dalapon (75-99-0)	0.2
1,2-Dibromo-3-chloropropane (96-12-8)	0.0002
2,4-D (94-75-7)	0.07
Di(2-ethylhexyl)adipate (103-23-1)	0.4
Di(2-ethylhexyl)phthalate (117-81-7)	0.006
Dinoseb (88-85-7)	0.007
Diquat (85-00-7)	0.02
Endothall (145-73-3)	0.1
Endrin (72-20-8)	0.002
Ethylene dibromide (106-93-4)	0.00005
Glyphosate (1071-53-6)	0.7
Heptachlor (76-44-8)	0.0004
Heptachlor epoxide (1024-57-3)	0.0002
Hexachlorobenzene (118-74-4)	0.001
Hexachlorocyclopentadiene (77-47-4)	0.05
Lindane (58-89-9)	0.0002
Methoxychlor (72-43-5)	0.04
Oxamyl (23135-22-0)	0.2
Pentachlorophenol (87-86-5)	0.001
PCB's (as decachlorobiphenyl) (1336-36-3)	0.0005
Picloram (1918-02-1)	0.5
Simazine (122-34-9)	0.004
2,3,7,8-TCDD (Dioxin) (1746-01-6)	3×10^{-8}

Toxaphene (8001-35-2)	0.003
2,4,5-TP (Silvex) (93-72-1)	0.05

The allowable levels for certain chemicals for which EPA has established secondary maximum contaminant levels in its drinking water regulations (40 CFR part 143) are as follows:

Contaminant	Concentration in milligrams per liter
Aluminum	0.2
Silver	0.1
Sulfate ¹	250.0

¹Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

The allowable levels for residual disinfectants and disinfection byproducts are as follows:

Substance	Concentration in milligrams per liter
Disinfection byproducts	
Bromate	0.010
Chlorite	1.0
Haloacetic acids (five) (HAA5)	0.060
Total Trihalomethanes (TTHM)	0.080
Residual disinfectants	
Chloramine	4.0 (as Cl ₂)
Chlorine	4.0 (as Cl ₂)
Chlorine dioxide	0.8 (as ClO ₂)

Radiological quality. Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (b)(5)(ii) of this section, meet standards of radiological quality as follows:

(A) The bottled water shall not contain a combined radium-226 and radium-228 activity in excess of 5 picocuries per liter of water.

(B) The bottled water shall not contain a gross alpha particle activity (including radium-226, but excluding radon and uranium) in excess of 15 picocuries per liter of water.

(C) The bottled water shall not contain beta particle and photon radioactivity from manmade radionuclides in excess of that which would produce an annual dose equivalent to the total body or any internal organ of 4 millirems per year calculated on the basis of an intake of 2 liters of the water per day. If two or more beta or photon-emitting radionuclides are present, the sum of their annual dose equivalent to the total body or to any internal organ shall not exceed 4 millirems per year.

(D) The bottled water shall not contain uranium in excess of 30 micrograms per liter of water.