

§ 529.1044

21 CFR Ch. I (4–1–13 Edition)

(iv) All finfish. For control of external protozoa *Ichthyophthirius* spp., *Chilodonella* spp., *Ichthyobodo* spp., *Ambiphrya* spp., *Epistylis* spp., and *Trichodina* spp., and monogenetic trematodes *Cleidodiscus* spp., *Gyrodactylus* spp., and *Dactylogyrus* spp.

(v) All finfish eggs: For control of fungi of the family Saprolegniaceae.

(2) *Amount*. The drug concentrations required are as follows:

(i) For control of external parasites on select finfish:

Fish	Concentration of formalin (microliters per liter)	
	Tanks and raceways (for up to 1 hour daily)	Earthen ponds (indefinitely)
Salmon and trout:		
Above 50 °F	Up to 170	15–25
Below 50 °F	Up to 250	15–25
Catfish, largemouth bass, and bluegill.	Up to 250	¹ 15–25

¹ Use the lower concentrations when pond is heavily loaded with fish or phytoplankton.

(ii) For control of fungi of the Saprolegniaceae on salmon, trout, and esocid eggs: Apply in constant flow water supply of incubating facilities for 15 minutes. Concentration of formalin used is 1,000 to 2,000 microliters per liter.

(iii) For control of external protozoan parasites on shrimp:

Shrimp	Concentration of formalin (microliters per liter)	
	Tanks and raceways (up to 4 hours daily)	Earthen ponds (single treatment)
Penaeid Shrimp ...	50 to 100 ¹	25 ²

¹ Treat for up to 4 hours daily. Treatment may be repeated daily until parasite control is achieved. Use the lower concentration when the tanks and raceways are heavily loaded.

² Single treatment. Treatment may be repeated in 5 to 10 days if needed.

(iv) For control of external parasites on all finfish:

Aquatic species	Administer in tanks and raceways for up to 1 hour (microliter/liter or part per million (µL/L or ppm))	Administer in earthen ponds indefinitely (µL/L or ppm)
Salmon and trout:		
Above 50 °F	Up to 170	15 to 25 ^{1,2}
Below 50 °F	Up to 250	15 to 25 ^{1,2}

Aquatic species	Administer in tanks and raceways for up to 1 hour (microliter/liter or part per million (µL/L or ppm))	Administer in earthen ponds indefinitely (µL/L or ppm)
All other finfish	Up to 250	15 to 25 ^{1,2}

¹ Use the lower concentration when ponds, tanks, or raceways are heavily loaded with phytoplankton or fish to avoid oxygen depletion due to the biological oxygen demand by decay of dead phytoplankton. Alternatively, a higher concentration may be used if dissolved oxygen is strictly monitored.

² Although the indicated concentrations are considered safe for cold and warm water finfish, a small number of each lot or pond to be treated should always be used to check for any unusual sensitivity to formalin before proceeding.

(v) For control of fungi of the family Saprolegniaceae on all finfish eggs: Eggs of all finfish except Acipenseriformes, 1,000 to 2,000 µL/L (ppm) for 15 minutes; eggs of Acipenseriformes, up to 1,500 µL/L (ppm) for 15 minutes.

(3) *Limitations*. Fish tanks and raceways may be treated daily until parasite control is achieved. Pond treatment may be repeated in 5 to 10 days if needed. However, pond treatments for *Ichthyophthirius* should be made at 2-day intervals until control is achieved. Egg tanks may be treated as often as necessary to prevent growth of fungi. Do not use formalin which has been subjected to temperatures below 40 °F, or allowed to freeze. Do not treat ponds containing striped bass. Treatments in tanks should never exceed 1 hour even if fish show no signs of stress. Do not apply formalin to ponds with water warmer than 27 °C (80 °F), when a heavy bloom of phytoplankton is present, or when the concentration of dissolved oxygen is less than 5 milligrams per liter.

[51 FR 11441, Apr. 3, 1986, as amended at 58 FR 59169, Nov. 8, 1993; 59 FR 60076, Nov. 22, 1994; 63 FR 38304, July 16, 1998; 68 FR 5563; Feb. 4, 2003; 72 FR 45158, Aug. 13, 2007; 76 FR 17339, Mar. 29, 2011]

§ 529.1044 Gentamicin sulfate in certain other dosage forms.

§ 529.1044a Gentamicin sulfate intrauterine solution.

(a) *Specifications*. Each milliliter of solution contains 50 or 100 milligrams gentamicin sulfate.

(b) *Sponsors*. See Nos. 000010, 000061, 000856, 000859 057561, 058005, and 061623 in § 510.600(c) of this chapter.