

§ 529.1044

21 CFR Ch. I (4–1–12 Edition)

spp., *Ichthyobodo* spp., *Ambiphrya* spp., *Epistylis* spp., and *Trichodina* spp., and monogenetic trematodes *Cleidodiscus* spp., *Gyrodactylus* spp., and *Dactylogyrus* spp., on salmon, trout, catfish, largemouth bass, and bluegill.

(ii) Select finfish eggs. For control of fungi of the family Saprolegniaceae on salmon, trout, and esocid eggs.

(iii) Penaeid shrimp. For control of external protozoan parasites *Bodo* spp., *Epistylis* spp., and *Zoothamnium* spp.

(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}
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 intraveterine solution.

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

(b) *Sponsors*. See Nos. 000010, 000061, 000856, 057561, 058005, 059130, and 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. Infuse 2 to 2.5 grams per day for 3 to 5 days during estrus.

(2) *Indications for use*. For control of bacterial infections of the uterus (metritis) and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

(3) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 51727, Aug. 31, 2006]

§ 529.1044b Gentamicin sulfate solution.

(a) *Specifications*. Each milliliter of solution contains gentamicin sulfate equivalent to 50 milligrams of gentamicin base.

(b) *Sponsors*. See Nos. 000061 and 054925 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is recommended as an aid in the reduction or elimination of the following microorganisms from turkey-hatching eggs: *Arizona hinshawii* (paracolon), *Salmonella st. paul*, and *Mycoplasma meleagridis*.

(2) The drug is added to clean water to provide a dip solution with a gentamicin concentration of 250 to 1,000 parts per million. A concentration of 500 parts per million is recommended. Clean eggs should be held submerged in the gentamicin solution under a vacuum of about 27.5 to 38 centimeters of mercury for 5 minutes followed by additional soaking in gentamicin solution for approximately 10 minutes at atmospheric pressure. Eggs can also be treated by warming them for 3 to 6 hours at approximately 100 °F. then immediately submerging them in gentamicin solution maintained at about 40 °F., keeping the eggs submerged for 10 to 15 minutes.

(3) For use in the dipping treatment of turkey-hatching eggs only. Eggs which have been dipped in the drug shall not be used for food.

[40 FR 13881, Mar. 27, 1975, as amended at 52 FR 7833, Mar. 13, 1987; 62 FR 22889, Apr. 28, 1997; 71 FR 13543, Mar. 16, 2006]

§ 529.1115 Halothane.

(a) *Specifications*. The drug is a colorless, odorless, nonflammable, nonexplosive, heavy liquid containing 0.01 percent thymol as a preservative.

(b) *Sponsor*. See 000856 and 012164 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Two to 5 percent of inhaled atmosphere for induction of anesthesia; 0.5 to 2 percent for maintenance of anesthesia.¹

(2) *Indications for use*. For nonfood animals for the induction and maintenance of anesthesia.¹

(3) *Limitations*. Administered by inhalation. May be administered with either oxygen or a mixture of oxygen and nitrous oxide. Place drug vaporizer between the gas supply and breathing bag to prevent overdosage. Not recommended for obstetrical anesthesia except when uterine relaxation is required. Do not use in pregnant animals; information on possible adverse effects on fetal development is not available. Operating rooms should have adequate ventilation to prevent accumulation of anesthetic gases. Not for use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[46 FR 27915, May 22, 1981, as amended at 62 FR 29014, May 29, 1997]

§ 529.1150 Hydrogen peroxide.

(a) *Specifications*. Each milliliter of solution contains 396.1 milligrams (mg) hydrogen peroxide (a 35% w/w solution).

(b) *Sponsor*. See No. 061088 in § 510.600(c) of this chapter.

(c) *Conditions of use in finfish*—(1) *Amount*—(i) Freshwater-reared finfish eggs: 500 to 1,000 mg per liter (L) of culture water for 15 minutes in a continuous flow system once per day on consecutive or alternate days until hatch for all coldwater and coolwater species of freshwater-reared finfish eggs or 750 to 1,000 mg/L for 15 minutes in a continuous flow system once per day on consecutive or alternate days

¹These conditions have been reviewed by FDA and found effective. NADA's for similar products for these conditions of use need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.