

had lambs. Use plastic or rubber gloves when handling large numbers of sponges to minimize exposure to drug. Do not leave sponge in the vagina for more than 21 days. Ewes must not be slaughtered for food within 30 days of sponge removal.

[49 FR 45420, Nov. 16, 1984]

**§ 529.1030 Formalin solution.**

(a) *Specifications.* Formalin solution is an aqueous solution containing approximately 37 percent by weight of formaldehyde gas, U.S.P.

(b) *Sponsor.* Approval to firms identified in § 510.600(c) of this chapter for use as indicated:

(1) No. 050378 for use as in paragraph (c) of this section.

(2) Nos. 049968 and 051212 for use as in paragraphs (c)(1)(i), (c)(1)(ii), (c)(2)(i), (c)(2)(ii), and (c)(3) of this section.

(c) *Conditions of use—(1) Indications for use.* The drug is added to the environmental water as follows:

(i) For control of the protozoa: *Ichthyophthirius* spp., *Chilodonella* spp., *Costia* spp., *Scyphidia* spp., *Epistylis* spp., and *Trichodina* spp.; and the monogenetic trematodes: *Cleidodiscus* spp., *Gyrodactylus* spp., and *Dactylogyrus* spp. on salmon, trout, catfish, largemouth bass, and bluegill.

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

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

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

(i) For control of external parasites on fish:

Fish	Concentration of formalin (microliters per liter)	
	Tanks and raceways (for up to 1 hour)	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 .....	<sup>1</sup> 15–25

<sup>1</sup> 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 <sup>1</sup> .....	25 <sup>2</sup>

<sup>1</sup>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.

<sup>2</sup>Single treatment. Treatment may be repeated in 5 to 10 days if needed.

(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]

**§ 529.1044 Gentamicin sulfate in certain other dosage forms.**

**§ 529.1044a Gentamicin sulfate intrauterine solution.**

(a) *Specifications.* Each milliliter of the drug contains 50 or 100 milligrams of gentamicin (as the sulfate) in sterile aqueous solution.

(b) *Sponsor.* See Nos. 000010, 000061, 000856, 000864, 057561, and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for use for control of bacterial infections of the uterus in horses (metritis) and as an aid in improving

conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

(2) It is administered at a dosage level of 2 to 2.5 grams per day for 3 to 5 days during estrus, each dose being diluted with 200 to 500 milliliters of sterile physiological saline before aseptic infusion into the uterus.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) Not for use in horses intended for food.

[40 FR 13881, Mar. 27, 1975, as amended at 40 FR 48676, Oct. 17, 1975; 48 FR 31386, July 8, 1983; 52 FR 7833, Mar. 13, 1987; 58 FR 14314, Mar. 17, 1993; 59 FR 31140, June 17, 1994; 60 FR 45042, Aug. 30, 1995; 60 FR 48894, Sept. 21, 1995; 61 FR 17830, Apr. 23, 1996; 62 FR 611, Jan. 6, 1997; 62 FR 35077, June 30, 1997; 63 FR 6644, Feb. 10, 1998]

#### § 529.1044b Gentamicin sulfate solution.

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

(b) *Sponsor.* See Nos. 000061 and 051259 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]

#### § 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.<sup>1</sup>

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

(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.<sup>1</sup>

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

#### § 529.1186 Isoflurane.

(a) *Specifications.* The drug is a clear, colorless, stable liquid containing no additives or chemical stabilizers. It is nonflammable and nonexplosive.

(b) *Sponsors.* See Nos. 000074, 010019, 012164, and 059258 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount—(i) Horses:* For induction of surgical anesthesia: 3 to 5 percent isoflurane (with

<sup>1</sup>These 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.