

(b) *Approvals.* See No. 000010 in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(c) *Conditions of use*—(1) *Amount.* Each valve actuation (puff) of the device delivers 120 micrograms (mcg) of albuterol sulfate. One dose is three (3) puffs, totaling 360 mcg.

(2) *Indications for use.* For the immediate relief of bronchospasm and bronchoconstriction associated with reversible airway obstruction in horses.

(3) Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[67 FR 7072, Feb. 15, 2002, as amended at 79 FR 10973, Feb. 27, 2014]

#### § 529.56 Amikacin.

(a) *Specifications.* Each milliliter (mL) of solution contains 250 milligrams of amikacin as amikacin sulfate.

(b) *Sponsors.* See Nos. 000859 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 2 grams (8 mL) diluted with 200 mL of sterile physiological saline by intrauterine infusion daily for 3 consecutive days.

(2) *Indications for use.* For treating genital tract infections (endometritis, metritis, and pyometra) in mares caused by susceptible organisms including *Escherichia coli*, *Pseudomonas* spp., and *Klebsiella* spp.

(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.

[76 FR 17339, Mar. 29, 2011, as amended at 78 FR 17597, Mar. 22, 2013; 79 FR 10973, Feb. 27, 2014]

#### § 529.400 Chlorhexidine tablets and suspension.

(a) *Specification.* Each tablet and each 28-milliliter syringe of suspension contain 1 gram of chlorhexidine dihydrochloride.<sup>1</sup>

<sup>1</sup>These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Place 1 or 2 tablets deep in each uterine horn; or infuse a solution of 1 tablet dissolved in an appropriate amount of clean boiled water; or infuse one syringe of suspension into the uterus.

(2) *Indications for use.* For prevention or treatment of metritis and vaginitis in cows and mares when caused by pathogens sensitive to chlorhexidine dihydrochloride.

(3) *Limitations.* Prior to administration, remove any unattached placental membranes, any excess uterine fluid or debris, and carefully clean external genitalia. Use a clean, sterile inseminating pipette for administering solutions and suspensions. Treatment may be repeated in 48 to 72 hours.

[43 FR 10705, Feb. 23, 1979, as amended at 79 FR 10973, Feb. 27, 2014]

EDITORIAL NOTE: At 79 FR 10973, Feb. 27, 2014, § 529.400 was amended to revise the section heading, however, the section heading was not provided, therefore, the amendment could not be incorporated due to inaccurate amendatory instruction.

#### § 529.536 Detomidine.

(a) *Specifications.* Each milliliter of gel contains 7.6 milligrams (mg) of detomidine hydrochloride.

(b) *Sponsor.* See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 0.018 mg per pound (mg/lb) (0.040 mg/kilogram (kg) sublingually.

(2) *Indications for use.* For sedation and restraint.

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

[75 FR 21163, Apr. 23, 2010, as amended at 76 FR 16533, Mar. 24, 2011]

#### § 529.778 Doxycycline.

(a) *Specifications.* Doxycycline hyclate solution contains 8.5 percent doxycycline activity. A syringe of N-methyl-2-pyrrolidone and poly (DL-lactide) mixed with a syringe of doxycycline produces 0.5 milliliter of solution.

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(b) *Sponsor*. See 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Apply subgingivally to periodontal pocket(s) of affected teeth.

(2) *Indications for use*. For treatment and control of periodontal disease.

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

[79 FR 10973, Feb. 27, 2014]

§ 529.1030 **Formalin.**

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

(b) *Sponsors*. See Nos. 049968, 050378, and 067188 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*. It is added to environmental water as follows:

(1) *Indications for use*. (i) Penaeid shrimp. For control of external protozoan parasites *Bodo* spp., *Epistylis* spp., and *Zoothamnium* spp.

(ii) 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.

(iii) 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 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.

(ii) For control of external parasites on 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 <sup>1 2</sup>

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)
Below 50 °F	Up to 250	15 to 25 <sup>1 2</sup>
All other finfish	Up to 250	15 to 25 <sup>1 2</sup>

<sup>1</sup> 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.

<sup>2</sup> 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.

(iii) For control of fungi of the family Saprolegniaceae on 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; 79 FR 2786, Jan. 16, 2014]

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

§ 529.1044a **Gentamicin solution for infusion.**

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

(b) *Sponsors*. See Nos. 000061, 000859, 054628, 054771, 057561, 058005, and 061623 in § 510.600(c) of this chapter.