

Exhibit 9

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

(b) *Sponsor*. See No. 000856 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.¹

(2) *Indications for use*. For prevention or treatment of metritis and vaginitis in cows and mares when caused by pathogens sensitive to chlorhexidine dihydrochloride.¹

(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.¹

¹These 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.

[43 FR 10705, Feb. 23, 1979]

Sec. 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]

Sec. 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 sponsors in 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) Nos. 049968, 050378, and 067188 for use as in paragraphs (d) (1) (iii), (d) (1) (iv), (d) (1) (v), (d) (2) (iii), (d) (2) (iv), (d) (2) (v), and (d) (3).

(2) No. 051212 for use as in paragraphs (d) (1) (i), (d) (1) (ii), (d) (2) (i), (d) (2) (ii), and (d) (3).

(c) [Reserved]

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

(1) *Indications for use*. (i) Select finfish. For control of external protozoa *Ichthyophthirius* spp., *Chilodonella* spp., *Ichthyobodo* spp., *Ambiphraya* 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., *Ambiphraya* 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 deg. F	Up to 170	15-25
Below 50 deg. F	Up to 250	15-25
Catfish, largemouth bass, and bluegill	Up to 250	¹ 15-25

¹Use 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

¹Treat 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.

²Single 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 ([micro]L/L or ppm))	Administer in earthen ponds indefinitely ([micro]L/L or ppm)
Salmon and trout:		
Above 50 deg. Up to 170 F		15 to 25 ^{1,2}
Below 50 deg. Up to 250 F		15 to 25 ^{1,2}
All other finfish	Up to 250	15 to 25 ^{1,2}

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.

²Although 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 [micro]L/L (ppm) for 15 minutes; eggs of Acipenseriformes, up to 1,500 [micro]L/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 deg. 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 deg. C (80 deg. 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]

Sec. 529.1044 Gentamicin sulfate in certain other dosage forms.

Sec. 529.1044a Gentamicin sulfate intrauterine solution.

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

(b) *Sponsors*. See Nos. 000061, 000856, 000859, 054628, 057561, 058005, 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, as amended at 78 FR 17597, Mar. 22, 2013; 78 FR 21060, Apr. 9, 2013]

Sec. 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*.