§ 529.400 Chlorhexidine tablets and suspension.

(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

[43 FR 10705, Feb. 23, 1979]

§ 529.469 Competitive exclusion culture.

(a) **Specifications.** Each packet of lyophilized culture contains either 2,000 or 5,000 doses in frozen pellets to be reconstituted for use.

(1) For 2,000-dose packet, add contents of one 2,000-dose packet of reconstitution powder to 490 milliliters of deionized water. Mix. Add contents of one 2,000-dose packet of lyophilized culture. Mix thoroughly.

(2) For 5,000-dose packet, add contents of one 5,000-dose packet of reconstitution powder to 1,250 milliliters of deionized water. Mix. Add contents of one 5,000-dose packet of lyophilized culture. Mix thoroughly. Allow to stand for 45 minutes before use. Use within 5 hours of reconstitution.

(b) **Sponsor.** See No. 032761 in § 510.600(c) of this chapter.

(c) **Conditions of use**—(1) **Indications for use.** For early establishment of intestinal microflora in chickens to reduce *Salmonella* colonization.

(3) **Limitations.** Administer as soon as possible after hatch, preferably at less than 1 day of age. Expose chicks to light for at least 5 minutes after spray treatment to encourage preening for oral uptake of the organisms. Provide access to feed and water as soon as possible after treatment. Do not administer antibiotics to treated chickens.

[63 FR 25164, May 7, 1998]

§ 529.1003 Flurogestone acetate-impregnated vaginal sponge.

(a) **Specifications.** Each vaginal sponge contains 20 milligrams of flurogestone acetate.

(b) **Sponsor.** See No. 000014 in § 510.600(c) of this chapter.

(c) **Conditions of use**—(1) **Indications for use.** For synchronizing estrus/ovulation in cycling adult ewes during their normal breeding season.

(2) **Limitations.** Using applicator provided, insert sponge into ewe’s vagina 13 days before desired start of breeding. For intravaginal use in sheep only. Do not use in young ewes that have not 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.

(a) **Specifications.** Formalin is an aqueous solution containing approximately 37 percent by weight of form- aldehyde 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)(2)(v), (d)(2)(v), and (d)(3).

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.
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(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., Costia spp., Scyphidia spp., Epistylis spp., and Trichodina spp., and monogenetic trematodes Cleidodiscus spp., Gyrodactylus spp., and Dactylogyra spp., on salmon, trout, and esocid eggs.

(ii) Select finfish eggs. For control of external protozoan parasites Bodo spp., Epistylis spp., and Zoothamnium spp.

(iii) All finfish. For control of external protozoa Ichthyophthirius spp., Chilodonella spp., Costia spp., Scyphidia spp., Epistylis spp., and Trichodina spp., and monogenetic trematodes Cleidodiscus spp., Gyrodactylus spp., and Dactylogyra spp.

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

(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:

<table>
<thead>
<tr>
<th>Fish</th>
<th>Concentration of formalin (microliters per liter)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tanks and raceways (up to 1 hour daily)</td>
</tr>
<tr>
<td>Salmon and trout:</td>
<td></td>
</tr>
<tr>
<td>Above 50 °F</td>
<td>Up to 170</td>
</tr>
<tr>
<td>Below 50 °F</td>
<td>Up to 250</td>
</tr>
<tr>
<td>Catfish, largemouth bass, and bluegill.</td>
<td>Up to 250</td>
</tr>
</tbody>
</table>

(2) Use the lower concentrations when pond is heavily loaded with fish or phytoplankton.

(ii) For control of fungi of the family 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:

<table>
<thead>
<tr>
<th>Shrimp</th>
<th>Concentration of formalin (microliters per liter)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penaeid Shrimp</td>
<td>50 to 100</td>
</tr>
</tbody>
</table>

(i) 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.

(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 fungi is unusual sensitivity to formalin before proceeding.
§ 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, 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.

§ 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.

§ 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

§ 529.1150 Hydrogen peroxide.

(a) Specifications. Each milliliter of solution contains 396.1 milligrams (mg) dissolved oxygen is less than 5 milligrams per liter.


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.