Food and Drug Administration, HHS

§ 529.778

(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 administrating solutions and suspensions. Treatment may be repeated in 48 to 72 hours.


§ 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.


§ 529.400 Chlorhexidine tablets and suspension.

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

1 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.
§ 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) 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.

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§ 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) Panaeid shrimp. For control of external protozoan parasites Bodo spp., Epistyli s spp., and Zoothamnium spp.

(ii) All finfish. For control of external protozoa Ichthyophthirius spp., Chilodonella spp., Ichthyobodo spp., Ambiphrya spp., Epistyli s spp., and Trichodina spp., and monogenetic trematodes Cladodiscus 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:

<table>
<thead>
<tr>
<th>Shrimp</th>
<th>Concentration of formalin (microliters per liter)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tanks and raceways (up to 4 hours daily)</td>
</tr>
<tr>
<td>Panaeid Shrimp</td>
<td>50 to 100 μL/L</td>
</tr>
</tbody>
</table>

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.

(ii) For control of external parasites on finfish:

<table>
<thead>
<tr>
<th>Aquatic species</th>
<th>Administer in tanks and raceways for up to 1 hour (microliter/liter or part per million (μL/L or ppm))</th>
<th>Administer in earthen ponds indefinitely (μL/L or ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmon and trout: Above 50 °F</td>
<td>Up to 170</td>
<td>15 to 25 1 2</td>
</tr>
</tbody>
</table>

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.

(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.


§ 529.1044 Gentamicin in certain other dosage forms.

(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.