§ 558.600 Tiamulin.

(a) Specifications. Type A article containing 5, 10, or 113.4 grams of tiamulin (as tiamulin hydrogen fumarate) per pound.

(b) Approvals. See No. 058198 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.738 of this chapter.

(d) Special considerations—(1) Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., lasalocid, monensin, narasin, salinomycin, or semduramycin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.

(2) The effects of tiamulin on swine reproductive performance, pregnancy, and lactation have not been determined.

(3) Use as sole source of tiamulin.

(e) Conditions of use—(1) Swine. It is used as follows:

(i) [Reserved]

(ii) [Reserved]

(iii) Indications for use. As an aid in controlling outbreaks of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. maxima, and E. brunetti.

(b) Limitations. Feed 0.1 percent level for first 48 to 72 hours. Skip 3 days; 0.05 percent for 2 days, skip 3 days; 0.05 percent for 2 days. If bloody droppings recur, give 0.05 percent for another 2 days. Do not treat chickens within 10 days of slaughter. Do not medicate chickens producing eggs for human consumption.

(ii) [Reserved]

(iii) Indications for use. As an aid in controlling outbreaks of coccidiosis caused by Eimeria meleagrimitis and E. adenoeides.

(b) Limitations. Feed 0.0175 percent continuously during time birds are closely confined. May be continued for week to 10 days after flock is transferred to range to reduce danger of an outbreak following moving of the flock. Do not treat turkeys within 10 days of slaughter. Do not medicate turkeys producing eggs for human consumption.

(iv) Indications for use. Preventing outbreaks of coccidiosis caused by Eimeria stiedae.

(b) Limitations. Treatment to be started after weaning. Feed continuously for 30 days or feed medicated feed for 2 days out of every week until marketing. Do not treat within 10 days of slaughter.

(iv) Use as sole source of tiamulin.

(a) Indications for use. As an aid in controlling outbreaks of coccidiosis caused by Eimeria meleagrimitis and E. adenoeides.

(b) Limitations. Feed 0.05 percent for 2 days. Follow with 3 days on regular feed and 2 more days on 0.05 percent sulfonquinoxaline feed. Again follow with 3 days on regular feed and 2 more days on 0.05 percent sulfonquinoxaline feed. Continue this schedule if necessary till all signs of the outbreaks have subsided. Do not treat turkeys within 10 days of slaughter. Do not medicate turkeys producing eggs for human consumption.

(i) Indications for use. As an aid in the control of acute fowl cholera caused by Pasteurella multocida susceptible to sulfonquinoxaline and fowl typhoid caused by Salmonella gallinarum susceptible to sulfonquinoxaline.

(b) Limitations. Feed 0.1 percent for 48 to 72 hours. Mortality should be brought under control. After medication, move birds to clean ground or to a clean house. If disease recurs, use 0.05 percent in feed again for 2 days. Do not treat chickens or turkeys within 10 days of slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption.

(i) [Reserved]
Food and Drug Administration, HHS § 558.615

<table>
<thead>
<tr>
<th>Tiamulin in grams per ton</th>
<th>Combination in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 10</td>
<td></td>
<td>For increased rate of weight gain and improved feed efficiency.</td>
<td>Feed continuously as the sole ration. Not for use in swine weighing over 250 pounds.</td>
<td>058198</td>
</tr>
<tr>
<td>(ii) 35</td>
<td></td>
<td>1. For control of swine dysentery associated with Brachyspira (formerly Serpulina or Treponema) hyodysenteriae susceptible to tiamulin.</td>
<td>Feed continuously as sole ration on premises with a history of swine dysentery but where signs of disease have not yet occurred or following approved treatment of disease. Withdraw 2 days before slaughter.</td>
<td>058198</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. For control of porcine proliferative enteropathies (ileitis) associated with Lawsonia intracellularis.</td>
<td>Feed continuously as the sole ration for not less than 14 days. Use as only source of chlortetracycline. Withdraw 2 days before slaughter.</td>
<td>048164, 008198</td>
</tr>
<tr>
<td>(iii) 35</td>
<td>Chlortetracycline, approxi-</td>
<td>For treatment of swine bacterial enteritis caused by Escherichia coli and Salmonella choleraesuis and bacterial pneumonia caused by Pasteurella multocida susceptible to chlortetracycline, and control of swine dysentery associated with Brachyspira (formerly Serpulina or Treponema) hyodysenteriae susceptible to tiamulin.</td>
<td>Feed continuously as the sole feed for 14 consecutive days. Use as only source of chlortetracycline calcium complex. Type A medicated articles containing the equivalent of 50 to 100 grams per pound of chlortetracycline hydrochloride provided by 046573 and 048164 in § 510.600(c) of this chapter.</td>
<td>058198</td>
</tr>
<tr>
<td>(iv) 200</td>
<td></td>
<td>For treatment of swine dysentery associated with Brachyspira (formerly Serpulina or Treponema) hyodysenteriae susceptible to tiamulin.</td>
<td>Feed continuously as the sole feed for 14 consecutive days. Withdraw feed 7 days before slaughter.</td>
<td>058198</td>
</tr>
</tbody>
</table>

(2) [Reserved]

§ 558.615 Thiabendazole.

(a) Approvals. Dry Type A medicated articles: 22, 44.1, 66.1, and 88.2 percent to 050604 in § 510.600(c) of this chapter. The 66.1 percent Type A is solely for the manufacture of cane molasses liquid Type B feed which is mixed in dry feeds. The 88.2 percent Type A is used solely for the manufacture of an aqueous slurry for adding to a Type C dry cattle feed.

(b) Special considerations. Do not use in Type B or Type C medicated feed containing bentonite.

(c) Related tolerances. See §556.730 of this chapter.

(d) Conditions of use. It is used in feed for animals as follows:

(1) Cattle—(i) Amount. 3 grams per 100 lb. body weight.


(b) Limitations. Use 3 grams per 100 lb. body weight at a single dose; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(ii) Amount. 5 grams per 100 lb. body weight.

(a) Indications for use. Control of severe infections of gastrointestinal roundworms (Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Nematodirus spp., Oesophagostomum radiatum); control of infections of Cooperia spp.

(b) Limitations. 5 grams per 100 lb. body weight at a single dose or divided into 3 equal doses, administered 1 dose each day, on succeeding days; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter;