Food and Drug Administration, HHS

§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—(a) Amount. 3 grams per 100 lb. body weight.

(i) Tiamulin in grams per ton

<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>
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<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>
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<td>2. For control of porcine proliferative enteropathies (ileitis) associated with Lawsonia intracellularis. For treatment of swine bacterial enteritis caused by Escherichia coli and Salmonella choleraesuis and bacterial pneumonia caused by Pasteurella multocida susceptible to chlorotetracycline, and control of swine dysentery associated with Brachyspira (formerly Serpulina or Treponema) hyodysenteriae susceptible to tiamulin.</td>
<td>Feed continuously as sole ration for not less than 10 days. Withdraw 2 days before slaughter.</td>
<td>048164, 058198</td>
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<tr>
<td>(iii) 35</td>
<td>Chlorotetracycline, 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 chlorotetracycline, and control of swine dysentery associated with Brachyspira (formerly Serpulina or Treponema) hyodysenteriae susceptible to tiamulin.</td>
<td>Feed continuously as sole ration for 14 days. Use as only source of chlorotetracycline. Withdraw 2 days before slaughter.</td>
<td>048164, 058198</td>
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<td></td>
<td>mately 400 (varying with body</td>
<td></td>
<td>As chlorotetracycline calcium complex. Type A medicated articles containing the equivalent of 50 to 100 grams per pound of chlorotetracycline hydrochloride provided by 046573 and 048164 in §510.600(c) of this chapter.</td>
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<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]

Nematodirus spp., Oesophagostomum radiatum).

(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; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(2) Goats—(i) Amount. 3 grams per 100 lb. body weight.


(iii) Limitations. 3 grams per 100 lb. body weight at a single dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(3) Sheep and goats—(i) Amount. 2 grams per 100 lb. body weight.

(ii) Indications for use. Control of infections of gastrointestinal roundworms (Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp., and Oesophagostomum spp.); also active against ova and larvae passed by sheep from 3 hours to 3 days after the feed is consumed (good activity against ova and larvae of T. colubriformis and azei, Ostertagia spp., Nematodirus spp., Strongyloides spp.; less effective against those of Haemonchus contortus and Oesophagostomum spp.).

(iii) Limitations. Use 2 grams per 100 lb. body weight at a single dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(4) For swine—(i) Amount. 45.4–908 grams per ton (0.005–0.1 percent).

(ii) Indications for use. Aid in the prevention of infections of large roundworms (genus Ascaris).

(iii) Limitations. Administer continuously feed containing 0.05–0.1 percent thiabendazole per ton for 2 weeks followed by feed containing 0.005–0.02 percent thiabendazole per ton for 8–14 weeks; do not treat animals within 30 days of slaughter.

(5) Pheasants—(i) Amount. 454 grams per ton (0.05 percent) continuously for 2 weeks (14 days).

(ii) Indications for use. For the treatment of gapeworms (Syngamus trachea) in pheasants.

(iii) Limitations. Do not use treated pheasants for food for 21 days after last day of treatment. Fertility, hatchability, and other reproductive data are not available on use in breeding animals.

§ 558.618 Tilmicosin.

(a) Specifications. Type A medicated article containing 90.7 grams (g) per pound tilmicosin as tilmicosin phosphate (200 g per kilogram).

(b) Approvals. See No. 000986 in § 510.600(c) of this chapter.

(c) Special considerations—(1) Tilmicosin medicated feeds are restricted to use under a veterinary feed directive (VFD). See § 558.6 of this chapter for required label statements and other limitations.

(2) VFDs for tilmicosin phosphate shall not be refilled.

(3) Labeling of tilmicosin Type B or Type C medicated feeds must bear the following warnings:

(i) Do not allow horses or other equines access to feeds containing tilmicosin.