### Food and Drug Administration, HHS § 558.530

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#### Roxarsone.

(a) **Specifications.** Type A medicated articles containing 10, 20, 50, or 80 percent roxarsone.

(b) **Approvals.** See sponsors in §510.600(c) of this chapter for use as in paragraphs (d)(1) through (d)(3) of this section.

(1) No. 046573 for use of 10, 20, and 50 percent Type A medicated articles as in paragraph (d)(1)(i) of this section.

(2) No. 046573 for use of 10, 20, 50, and 80 percent Type A medicated articles as in paragraphs (d)(1) through (d)(3) of this section.

(c) **Related tolerances.** See §556.60 of this chapter.

(d) **Conditions of use.**

- **(1) Chickens.** It is used in chicken feed as follows:

<table>
<thead>
<tr>
<th>Roxarsone in grams per ton</th>
<th>Combinations in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 22.7 to 45.4</td>
<td></td>
<td>Growing chickens: For increased rate of weight gain, improved feed efficiency, and improved pigmentation.</td>
<td>Feed continuously throughout growing period; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs.</td>
<td>046573</td>
</tr>
<tr>
<td>(ii) 22.7 to 45.4</td>
<td>Chlortetracycline 10 to 50</td>
<td>Growing chickens: As in paragraph (d)(1)(i) of this section.</td>
<td>As in paragraph (d)(1)(i) of this section. Chlortetracycline as provided by No. 046573 in §510.600(c) of this chapter.</td>
<td>046573</td>
</tr>
</tbody>
</table>

(40 FR 13959, Mar. 27, 1975)

**EDITORIAL NOTE:** For Federal Register citations affecting §558.515, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.
(iii) 22.7 to 45.4
Chlortetracycline 100 to 200
Growing chickens: As in paragraph (d)(1)(i) of this section; and for control of infectious synovitis caused by Mycoplasma synoviae susceptible to chlortetracycline.
As in paragraph (d)(1)(i) of this section except feed continuously for 7 to 14 days. Chlortetracycline as provided by No. 046573 in §510.600(c) of this chapter.

(iv) 22.7 to 45.4
Chlortetracycline 200 to 400
Growing chickens: As in paragraph (d)(1)(i) of this section; and for control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.
As in paragraph (d)(1)(i) of this section except feed continuously for 7 to 14 days. Chlortetracycline as provided by No. 046573 in §510.600(c) of this chapter.

(v) 22.7 to 45.4
Chlortetracycline 500
Growing chickens: As in paragraph (d)(1)(i) of this section; and for reduction of mortality due to *E. coli* infections susceptible to chlortetracycline.
As in paragraph (d)(1)(i) of this section except feed continuously for 5 days. Chlortetracycline as provided by No. 046573 in §510.600(c) of this chapter.

(2) *Turkeys.* It is used in turkey feed as follows:

<table>
<thead>
<tr>
<th>Roxarsone in grams per ton</th>
<th>Combinations in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 22.7 to 45.4</td>
<td></td>
<td>Growing turkeys: For increased rate of weight gain, improved feed efficiency, and improved pigmentation.</td>
<td>Feed continuously throughout growing period; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs.</td>
<td>046573</td>
</tr>
<tr>
<td>(ii) 22.7 to 45.4</td>
<td>Chlortetracycline 10 to 50</td>
<td>Growing turkeys: As in paragraph (d)(2)(i) of this section.</td>
<td>As in paragraph (d)(2)(i) of this section. Chlortetracycline as provided by No. 046573 in §510.600(c) of this chapter.</td>
<td></td>
</tr>
<tr>
<td>(iii) 22.7 to 45.4</td>
<td>Chlortetracycline 200</td>
<td>Growing turkeys: As in paragraph (d)(2)(i) of this section; and for control of infectious synovitis caused by <em>Mycoplasma synoviae</em> susceptible to chlortetracycline.</td>
<td>As in paragraph (d)(2)(i) of this section except feed continuously for 7 to 14 days. Chlortetracycline as provided by No. 046573 in §510.600(c) of this chapter.</td>
<td></td>
</tr>
<tr>
<td>(iv) 22.7 to 45.4</td>
<td>Chlortetracycline 400</td>
<td>1. Growing turkeys: As in paragraph (d)(2)(i) of this section; and for control of <em>Hexamitidae meleagridis</em> susceptible to chlortetracycline. 2. Turkey pouls not over 4 weeks of age: Reduction of mortality due to paratyphoid caused by <em>Salmonella typhimurium</em> susceptible to chlortetracycline.</td>
<td>As in paragraph (d)(2)(i) of this section except feed continuously for 7 to 14 days. Chlortetracycline as provided by No. 046573 in §510.600(c) of this chapter.</td>
<td></td>
</tr>
<tr>
<td>(v) 22.7 to 45.4</td>
<td>Chlortetracycline 25 mg/kg body weight daily</td>
<td>Growing turkeys: As in paragraph (d)(2)(i) of this section; and for control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline.</td>
<td>As in paragraph (d)(2)(i) of this section except feed continuously for 7 to 14 days. Chlortetracycline as provided by No. 046573 in §510.600(c) of this chapter.</td>
<td></td>
</tr>
</tbody>
</table>
(3) Swine. It is used in swine feed as follows:

<table>
<thead>
<tr>
<th>Roxarsone in grams per ton</th>
<th>Combinations in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 22.7 to 34.1</td>
<td></td>
<td>Growing and finishing swine: For increased rate of weight gain and improved feed efficiency.</td>
<td>Feed continuously throughout growing period; withdraw 5 days before slaughter; as sole source of organic arsenic.</td>
<td>046573</td>
</tr>
<tr>
<td>(ii) 22.7 to 34.1</td>
<td>Chlortetracycline 400 (to administer 10 mg/lb body weight)</td>
<td>Growing and finishing swine: As in paragraph (d)(3)(i) of this section; and for treatment of bacterial enteritis caused by <em>E. coli</em> and <em>S. choleraesuis</em> and bacterial pneumonia caused by <em>Pasteurella multocida</em> susceptible to chlortetracycline.</td>
<td>Feed for not more than 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic.</td>
<td></td>
</tr>
<tr>
<td>(iii) 181.5</td>
<td></td>
<td>Growing and finishing swine: For the treatment of swine dysentery.</td>
<td>Feed for not more than 6 consecutive days; if improvement is not observed, consult a veterinarian; withdraw 5 days before slaughter; as a sole source of organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.</td>
<td>046573</td>
</tr>
<tr>
<td>(iv) 181.5</td>
<td>Chlortetracycline 10 to 50</td>
<td>Growing and finishing swine: As in paragraph (d)(3)(i) of this section; and for treatment of swine dysentery.</td>
<td>Feed for not more than 6 consecutive days; if improvement is not observed, consult a veterinarian; withdraw 5 days before slaughter; as a sole source of organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.</td>
<td></td>
</tr>
<tr>
<td>(v) 181.5</td>
<td>Chlortetracycline 400 (to administer 10 mg/lb body weight)</td>
<td>Growing and finishing swine: As in paragraph (d)(3)(iii) of this section; and for treatment of bacterial enteritis caused by <em>E. coli</em> and <em>S. choleraesuis</em> and bacterial pneumonia caused by <em>P. multocida</em> susceptible to chlortetracycline.</td>
<td>Feed for not more than 6 consecutive days; if improvement is not observed, consult a veterinarian; withdraw 5 days before slaughter; as a sole source of organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.</td>
<td></td>
</tr>
</tbody>
</table>

(4) Permitted combinations. It may be used in accordance with this section in combination with:

- (i) [Reserved]
- (ii) Amprolium as in §558.55.
- (iii) Amprolium and ethopabate as in §558.58.
- (iv) Bacitracin methylene disalicylate as in §558.76.
- (v) Bacitracin zinc as in §558.78.
- (vi) Bambermycins and bambermycins plus certain anticoccidials as in §558.95.
- (vii) Chlortetracycline as in §558.128.
- (viii) Clopidol as in §558.175.
- (ix) Decoquinate alone or in combination as in §558.195.
- (x) Diclazuril alone or in combination as in §558.198.
- (xi) Halofuginone alone or in combination as in §558.265.
- (xii) Lasalocid alone or in combination as in §558.311.
- (xiii) Monensin alone or in combination as in §558.355.
- (xiv) Narasin alone or in combination as in §558.363.
- (xv) Nequinate as in §558.365.
- (xvi) Nicarbazin alone or in combination as in §558.366.
- (xvii) [Reserved]
- (xviii) Penicillin and zoalene as in §558.680.
- (xix) Robenidine hydrochloride as in §558.515.
- (xx) Salinomycin alone or in combination as in §558.550.
§ 558.550  Salinomycin.

(a) Specifications. Type A medicated articles containing 30 or 60 grams of salinomycin activity per pound (as salinomycin sodium biomass).

(b) Approvals. See sponsors in §510.600(c) of this chapter for use as in paragraph (d) of this section:

(1) No. 046573 for use as in paragraph (d) of this section.
(2) No. 011526 or 046573 in §510.600(c) of this chapter.
(3) No. 048164 for use as in paragraphs (d)(1)(v), (d)(1)(vi) through (d)(1)(xvi), (d)(1)(xxii) and (d)(1)(xxiv), (d)(2)(ii), (d)(3)(i), and (d)(4) of this section.

(c) Limitations. Feed continuously as sole ration. Use as sole source of organic arsenic. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Bacitracin methylene disalicylate as provided by No. 046573 in §510.600(c) of this chapter.

(ii)(a) Amount per ton. Salinomycin 40 to 60 grams and bacitracin methylene disalicylate 4 to 30 grams.

(ii) Indications for use. For the prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati for increased rate of weight gain and improved feed efficiency.

(c) Limitations. Feed continuously as sole ration. Use as sole source of organic arsenic. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Withdraw 5 days before slaughter. Roxarsone as provided by No. 011526 or 046573 in §510.600(c) of this chapter.

(iii)(a) Amount per ton. Salinomycin 40 to 60 grams and bacitracin methylene disalicylate 4 to 30 grams.

(ii) Indications for use. For the prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati for increased rate of weight gain and improved feed efficiency.

(c) Limitation. Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Bacitracin methylene disalicylate as provided by No. 046573 in §510.600(c) of this chapter.

(iv)(a) Amount per ton. Salinomycin 40 to 60 grams with roxarsone 45.4 grams and bacitracin methylene disalicylate 4 to 50 grams.

(ii) Indications for use. For the prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati, including some field strains of E. tenella which are more susceptible to roxarsone combined with salinomycin than to salinomycin alone; for increased rate of weight gain.

(c) Limitations. Feed continuously as sole ration. Use as sole source of organic arsenic. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Withdraw 5 days before slaughter. Roxarsone and bacitracin as provided by No. 046573 in §510.600(c) of this chapter.

(v)(a) Amount per ton. Salinomycin 40 to 60 grams per ton with roxarsone 22.7 to 45.4 grams per ton.

(ii) Indications for use. For the prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati, and E. maxima and for improved feed efficiency.

(c) Limitations. Feed continuously as sole ration. Use as sole source of organic arsenic. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Withdraw 5 days before slaughter. Roxarsone as provided by No. 046573 in §510.600(c) of this chapter.