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21 CFR Ch. I (4–1–13 Edition)

To provide 150 gm lasalocid per ton, use 1.652 lb (0.083%) of a lasalocid liquid Type A medicated article containing 90.7 g/lb. If using a dry lasalocid Type A medicated article containing 68 g/lb, use 2.206 lbs per ton (0.111%), replacing molasses.

If using a dry lasalocid Type A medicated article containing 90.7 g/lb, use 1.652 lbs per ton (0.083%), adding molasses.

(ii) Amount. 150 grams per ton.

(iii) Indications for use. Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers); for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.

(iv) Limitations. For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers). Feed continuously on a free-choice basis at a rate of 60 to 300 milligrams lasalocid per head per day.

(v) Sponsor. See No. 046573 in §510.600(c) of this chapter.

(4) It is used as a free-choice, loose mineral Type C feed as follows:

(1) Specifications.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Percent</th>
<th>International feed No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monocalcium phosphate (21% P)</td>
<td>57.70</td>
<td>6–01–082</td>
</tr>
<tr>
<td>Salt</td>
<td>17.55</td>
<td>6–04–152</td>
</tr>
<tr>
<td>Distillers dried grains w/solubles</td>
<td>5.40</td>
<td>5–02–236</td>
</tr>
<tr>
<td>Dried cane molasses (46% Sugars)</td>
<td>5.20</td>
<td>4–04–695</td>
</tr>
<tr>
<td>Potassium chloride</td>
<td>4.90</td>
<td>6–03–755</td>
</tr>
<tr>
<td>Trace mineral/vitamin premix</td>
<td>3.35</td>
<td></td>
</tr>
<tr>
<td>Calcium carbonate (38% Ca)</td>
<td>2.95</td>
<td>6–01–069</td>
</tr>
<tr>
<td>Mineral oil</td>
<td>1.05</td>
<td>6–03–123</td>
</tr>
<tr>
<td>Magnesium oxide (58% Mg)</td>
<td>1.00</td>
<td>6–02–756</td>
</tr>
<tr>
<td>Iron oxide (52% Fe)</td>
<td>0.10</td>
<td>6–02–431</td>
</tr>
<tr>
<td>Lasalocid Type A medicated article (68 g/lb)</td>
<td>0.80</td>
<td></td>
</tr>
</tbody>
</table>

1 Content of the vitamin and trace mineral premixes may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDFA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

2 To provide 1,088 g lasalocid per ton, use 16 lbs (0.80%) of a lasalocid Type A medicated article containing 68 g/lb.

(ii) Amount. 1,088 grams per ton.

(iii) Indications for use. Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.

(iv) Limitations. Feed continuously on a free-choice basis at a rate of 60 to 300 mg lasalocid per head per day.

(v) Sponsor. See No. 046573 in §510.600(c) of this chapter.

(5) Additional combinations. Lasalocid may be used in accordance with the provisions of this section in combination as follows:

(i) Melengestrol acetate alone or in combination with tylosin in accordance with §558.342.

(ii) [Reserved]

(41 FR 44382, Oct. 8, 1976)

EDITORIAL NOTE: For Federal Register citations affecting §558.311, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.
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following directions: “CAUTION: Occasionally, swine fed lincomycin may within the first 2 days after the onset of treatment develop diarrhea and/or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within 5 to 8 days without discontinuing the lincomycin treatment.”

(3) Labeling of Type A medicated articles and single-ingredient Type B and Type C medicated feeds containing lincomycin intended for use in swine shall bear the following directions:

(i) No. 000009: “CAUTION: The effects of lincomycin on swine reproductive performance, pregnancy, and lactation have not been determined. Not for use in swine intended for breeding when lincomycin is fed at 20 grams per ton of complete feed.”

(ii) No. 051311: “CAUTION: Not to be fed to swine that weigh more than 250 lb.”

(d) Conditions of use—(1) Chickens. It is used in feed as follows:

<table>
<thead>
<tr>
<th>Lincomycin grams/ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 2 ..................</td>
<td>Broilers: For control of necrotic enteritis caused by Clostridium spp. or other susceptible organisms.</td>
<td>As lincomycin hydrochloride monohydrate. ...........................................</td>
<td>000009</td>
</tr>
<tr>
<td>(ii) 2 to 4 ...........</td>
<td>Broilers: For increased rate of weight gain and improved feed efficiency.</td>
<td></td>
<td>000009</td>
</tr>
</tbody>
</table>

(2) Swine. It is used in feed as follows:

<table>
<thead>
<tr>
<th>Lincomycin grams/ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 20 ..................</td>
<td>Growing-finishing swine: For increased rate of weight gain</td>
<td>Feed as sole ration. ..................................................................................</td>
<td>000009</td>
</tr>
<tr>
<td>(ii) 40 ..................</td>
<td>1. For control of swine dysentery. .......................................................................</td>
<td>Feed as sole ration; for use in swine on premises with a history of swine dysentery but where symptoms have not yet occurred, or following use of lincomycin at 100 grams (g)/ton for treatment of swine dysentery..</td>
<td>000009</td>
</tr>
<tr>
<td>(iii) 100 ..............</td>
<td>2. For control of porcine proliferative enteropathies (ileitis) caused by Lawsonia intracellularis..</td>
<td>Feed as sole ration, or following use of lincomycin at 100 g/ton for control of porcine proliferative enteropathies (ileitis) ..</td>
<td>000009</td>
</tr>
<tr>
<td>(iv) 200 ..............</td>
<td>For reduction in the severity of swine mycoplasmal pneumonia caused by Mycoplasma hyopneumoniae.</td>
<td>Feed as sole ration for 3 weeks or until signs of disease disappear. ..........</td>
<td>000009</td>
</tr>
</tbody>
</table>

(3) Lincomycin may also be used in combination with:

(i) Amprolium and ethopabate or amprolium and ethopabate with roxarsone in accordance with §558.58.

(ii) Clopidol in accordance with §558.175.

(iii) Dequinate in accordance with §558.195.

(iv) Fenbendazole as provided in §558.258.

(v) Halofuginone in accordance with §558.265.

(vi) Ivermectin as in §558.300.

(vii) Lasalocid alone or with roxarsone in accordance with §558.311.

(viii) Monensin alone or with roxarsone in accordance with §558.355.

(ix) Narcan alone or with narasin or roxarsone as in §558.366.

(x) Pyrantel as in §558.485.

(xi) Robenidine in accordance with §558.515.

(xii) Roxarsone in accordance with §558.530.

(xiii) Salinomycin with or without roxarsone as in §558.550.

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§ 558.340 Maduramicin ammonium.

(a) Approvals. Type A medicated articles: 4.54 grams per pound to 046573 in § 510.600(c) of this chapter.

(b) Tolerances. See § 556.375 of this chapter.

(c) Conditions of use—(1) Amount. 4.54 to 5.45 grams per ton (5 to 6 parts per million) (1 to 1.2 pounds per ton).

(i) Indications for use. For prevention of coccidiosis caused by Eimeria acervulina, E. tenella, E. brunetti, E. maxima, E. necatrix, and E. mivati.

(ii) Limitations. For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter.

(2) [Reserved]

§ 558.342 Melengestrol.

(a) Specifications. (1) Dry Type A medicated articles containing 100 or 200 milligrams (mg) melengestrol acetate per pound.

(2) Liquid Type A medicated article containing 500 mg melengestrol acetate per pound.

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

(1) No. 000009 for use of products described in paragraph (a) of this section.

(2) No. 000986 for use of product described in paragraph (a)(2) of this section.

(c) Related tolerances. See § 556.380 of this chapter.

(d) Special considerations. (1) Type B or C medicated feeds may be manufactured from melengestrol acetate liquid Type A articles or Type B or C medicated feeds which have a pH of 4.0 to 8.0 and bear appropriate mixing directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for no less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(2) A physically stable melengestrol acetate liquid Type B or C feed will not be subject to the requirements for mixing directions prescribed in paragraph (d)(1) of this section provided it has a pH of 4.0 to 8.0 and contains a suspending agent(s) sufficient to maintain a viscosity of not less than 300 centipoises per second for 3 months.

(3) Combination Type B or C medicated feeds containing lasalocid must be labeled in accordance with § 558.311(d)(5) of this chapter.

(4) Liquid combination Type B or C medicated feeds containing melengestrol acetate and lasalocid must be manufactured in accordance with § 558.311(d) of this chapter.

(5) Combination Type B or C medicated feeds containing monensin must be labeled in accordance with § 558.355(d) of this chapter.

(6) Liquid combination Type B or C medicated feeds containing melengestrol acetate and monensin must be manufactured in accordance with § 558.355(f)(3)(i) of this chapter.

(7) Liquid combination Type B or C medicated feeds containing melengestrol acetate and tylosin must be manufactured in accordance with § 558.625(c) of this chapter.

(8) Liquid melengestrol acetate may not be mixed with oxytetracycline in a common liquid feed supplement.

(e) Conditions of use—(1) Cattle.