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(ii) The safety of laidlomycin propionate potassium in unapproved species has not been established.

(iii) Not for use in animals intended for breeding.

(e) *Conditions of use.* It is used in cattle being fed in confinement for slaughter as follows:

| Laidlomycin in grams per ton | Combination in grams per ton | Indications for use | Limitations | Sponsor |
|------------------------------|--|---|---|---------|
| (1) 5 | | For improved feed efficiency and increased rate of weight gain.. | Feed continuously in a Type C feed at a rate of 30 to 75 mg/head/day.. | 046573 |
| (2) 5 | Chlortetracycline 10 mg/lb body weight. | For improved feed efficiency and increased rate of weight gain; and for treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> organisms susceptible to chlortetracycline.. | Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.. | 046573 |
| (3) 5 | Chlortetracycline 350 mg/head/day. | For improved feed efficiency and increased rate of weight gain; and for control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.. | Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.. | 046573 |
| (4) 5 to 10 | | For improved feed efficiency. | Feed continuously in a Type C feed at a rate of 30 to 150 milligrams/head/day.. | 046573 |
| (5) 5 to 10 | Chlortetracycline 10 mg/pound body weight. | For improved feed efficiency; and for treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline.. | Feed continuously at a rate of 30 to 150 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.. | 046573 |
| (6) 5 to 10 | Chlortetracycline 350 mg/head/day. | For improved feed efficiency; and for control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.. | Feed continuously at a rate of 30 to 150 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.. | 046573 |

[59 FR 18297, Apr. 18, 1994, as amended at 60 FR 53509, Oct. 16, 1995; 62 FR 9929, Mar. 5, 1997; 63 FR 27845, May 21, 1998; 66 FR 46706, Sept. 7, 2001; 68 FR 13839, Mar. 21, 2003; 68 FR 42590, July 18, 2003; 69 FR 30198, May 27, 2004]

§ 558.311 Lasalocid.

(a) *Specifications.* A minimum of 90 percent of lasalocid activity is derived from lasalocid A.

(b) *Approvals.* Type A medicated articles approved for sponsors identified in § 510.600(c) of this chapter for use as in paragraph (e) of this section as follows:

(1) 3.0, 3.3, 3.8, 4.0, 4.3, 4.4, 5.0, 5.1, 5.5, 5.7, 6.0, 6.3, 6.7, 7.2, 7.5, 8.0, 8.3, 10.0, 12.5, 15, 20, and 50 percent activity to No.

046573 for use as in paragraphs (e)(1) (i), (ii), (iii), (iv), and (x) of this section.

(2) 15 percent activity to No. 066104 as provided by No. 046573 for use as in paragraph (e)(1)(v) of this section.

(3) 15, 20, 33.1, and 50 percent activity to No. 046573 for use in cattle feeds as in paragraphs (e)(1)(vi), (vii), (ix), (xi), (xii), and (xv) of this section, and for use in sheep as in paragraph (e)(1)(viii) of this section.

(4) 15 percent activity to No. 046573 for use in Type C rabbit feeds as in paragraph (e)(1)(xvi) of this section and for use in ruminant free-choice Type C feeds as in paragraphs (e)(2), (e)(3), and (e)(4) of this section.

(5) 15 and 20 percent activity to Nos. 012286 and 017800 for use in free-choice mineral feeds for cattle as in paragraph (e)(1)(xviii) of this section.

(6) 20 percent activity as a liquid Type A article to No. 046573 for use in cattle feeds as in paragraphs (e)(1)(vi), (e)(1)(vii), (e)(1)(ix), (e)(1)(xi), (e)(1)(xii), and (e)(3) of this section, and for use in sheep feeds as in paragraph (e)(1)(viii) of this section.

(7) 20 percent activity to No. 046573 for use as follows:

(i) Chukar partridges as in paragraph (e)(1)(xiii).

(ii) Turkeys as in paragraph (e)(1)(xiv).

(iii) Rabbits as in paragraph (e)(1)(xvi).

(8) [Reserved]

(9) 15 percent activity to No. 068287 for use in free-choice protein blocks for cattle as in paragraphs (e)(1)(xix) of this section.

(c) *Related tolerance.* See § 556.347 of this chapter.

(d) *Special considerations.* (1) Type C cattle and sheep feeds may be manufactured from lasalocid liquid Type B 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 lasalocid liquid 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) If a manufacturer is unable to meet the requirements of paragraph (d)(1) or (d)(2) of this section, the manufacturer may secure approval of a positionally stable liquid feed by:

(i) Either filing a new animal drug application for the product or establishing a master file containing data to support the stability of its product;

(ii) Authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental new animal drug application to establish physical stability; and

(iii) Requesting the sponsor of an approved new animal drug application to file a supplement to provide for use of its lasalocid Type A article in the manufacture of the liquid feed specified in the appropriate master file. If the data demonstrate the stability of the liquid feed described in the master file, the supplemental new animal drug application will be approved. The approval will provide a basis for the individual liquid feed manufacturer to manufacture under a medicated feed license the liquid mediated feed described in the master file. A manufacturer who seeks to market a physically unstable lasalocid liquid feed with mixing directions different from the standard directions established in paragraph (d)(1) of this section may also follow this procedure.

(4) If adequate information is submitted to show that a particular liquid feed containing lasalocid is stable outside the pH of 4.0 to 8.0, the pH restriction described in paragraphs (d)(1) and (d)(2) of this section may be waived.

(5) Required label statements:

(i) For liquid Type B feed (cattle and sheep): Mix thoroughly with grain and/or roughage prior to feeding. Feeding undiluted, mixing errors, or inadequate mixing (recirculation or agitation) may result in an excess lasalocid concentration which could be fatal to cattle and sheep. Do not allow horses or other equines access to Type A articles or Type B feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid for use in unapproved species has not been established.

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(ii) For Type A articles or Type B feeds (cattle and sheep): Feeding undiluted or mixing errors may result in an excess lasalocid concentration which could be fatal to cattle and sheep. Do not allow horses or other equines access to Type A articles or Type B feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid for use in unapproved species has not been established.

(iii) For Type A articles, Type B or Type C feeds (cattle): A withdrawal period has not been established for this product in preruminating calves. Do

not use in calves to be processed for veal.

(6) Lasalocid Type A medicated articles containing lasalocid dried fermentation residue are for use in cattle and sheep feed only.

(7) Each use in a free-choice Type C cattle feed as in paragraphs (e)(1)(xii) and (e)(1)(xviii) of this section must be the subject of an approved NADA or supplemental NADA as provided in §510.455 of this chapter.

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

| Lasalocid sodium activity in grams per ton | Combination in grams per ton | Indications for use | Limitations | Sponsor |
|--|---|--|---|---------|
| (i) 68 (0.0075 pct) to 113 (0.0125 pct). | | For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> . | For broiler or fryer chickens only; feed continuously as the sole ration. | 046573 |
| (ii) 68 (0.0075 pct) to 113 (0.0125 pct). | Roxarsone 45.4 (0.005 pct). | Broiler or fryer chickens; for the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> and as an aid in the reduction of lesions due to <i>E. tenella</i> . | For broiler or fryer chickens only; feed continuously as the sole ration; as sole source of organic arsenic; withdraw 5 d before slaughter; roxarsone provided by Nos. 046573 and 011526 in §510.600(c) of this chapter. | 046573 |
| | Roxarsone 45.4 plus bambermycins 1 (0.00011 pct). | For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; as an aid in the reduction of lesions due to <i>E. tenella</i> ; and for increased rate of weight gain. | For broiler chickens only; feed continuously as sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in §510.600(c) of this chapter, bambermycins provided by No. 016592. | 046573 |
| | Bambermycins 1 to 2 | Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; and for increased rate of weight gain and improved feed efficiency. | Feed continuously as sole ration. Bambermycins provided by No. 016592 in §510.600(c) of this chapter. | 016592 |
| | Roxarsone 45.4 plus lincomycin 2.0. | For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; as an aid in the reduction of lesions due to <i>E. tenella</i> ; and for increased rate of weight gain and improved feed efficiency. | For broiler chickens only; feed continuously as sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in §510.600(c) of this chapter, lincomycin provided by No. 000009. | 046573 |
| | Roxarsone 45.4 plus bacitracin 10 to 25. | For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; as an aid in the reduction of lesions due to <i>E. tenella</i> ; and for increased rate of weight gain. | For broiler or fryer chickens only; feed continuously as the sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in §510.600(c) of this chapter, bacitracin methylene disalicylate provided by No. 046573 in §510.600(c) of this chapter. | 046573 |

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| Lasalocid sodium activity in grams per ton | Combination in grams per ton | Indications for use | Limitations | Sponsor |
|--|---|--|---|---------|
| | Roxarsone 45.4 plus bacitracin 10 or 30. | For prevention of coccidiosis caused by <i>E. tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> and <i>E. maxima</i> ; as an aid in the reduction of lesions due to <i>E. tenella</i> ; and for increased rate of weight gain (10 grams per ton) or improved feed efficiency (30 grams per ton). | For broiler chickens only; feed continuously as sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in §510.600(c) of this chapter, bacitracin zinc provided by No. 000004. | 046573 |
| | Roxarsone 45.5 plus bacitracin methylene disalicylate 50. | Prevention of coccidiosis caused by <i>Eimeria necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> ; <i>E. mivati</i> , and <i>E. maxima</i> ; reduction of lesions due to <i>E. tenella</i> ; prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other susceptible organisms. | Feed continuously as sole ration; as sole source of organic arsenic; withdraw 5 days before slaughter. | 046573 |
| (iii) 68 (0.0075 pct). | Lincomycin 2 (0.00022 pct). | Broiler or fryer chickens; for the prevention of coccidiosis caused by <i>Eimeria mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> ; for increased rate of weight gain and improved feed efficiency. | For broiler and fryer chickens only; feed continuously as sole ration; withdraw 5 d before slaughter; Type C feed must be used within 4 weeks of manufacture; as lincomycin hydrochloride monohydrate. | 046573 |
| (iv) 68 (0.0075 percent). | Bacitracin 10 to 50 .. | For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency. | For broiler or fryer chickens only; feed continuously as the sole ration; bacitracin methylene disalicylate provided by No. 046573 in §510.600(c) of this chapter. | 046573 |
| (v) 68 (0.0075 pct) to 113 (0.0125 pct). | Virginiamycin 20 | For prevention of coccidiosis caused by <i>Eimeria tenella</i> <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency. | For broiler and fryer chickens only; feed continuously as sole ration; do not feed to laying chickens; lasalocid sodium provided by No. 046573 in §510.600(c) of this chapter. | 046573 |
| (vi) 10 (0.0011 pct) to 30 (0.0033 pct). | | Cattle; for improved feed efficiency | In Type C feeds; for cattle fed in confinement for slaughter only; feed continuously in complete feed to provide not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day. | 046573 |
| | Oxytetracycline 7.5 .. | Cattle: for improved feed efficiency and reduction of incidence and severity of liver abscesses. | In Type C feeds, for beef cattle fed in confinement for slaughter; feed continuously at 100 to 360 mg/head/day lasalocid and 75 mg/head/day oxytetracycline. As monoalkyl (C ₈ - C ₁₈) trimethyl ammonium oxytetracycline. | 046573 |
| (vii) 25 (0.0027 pct) to 30 (0.0033 pct). | | Cattle; for improved feed efficiency and increased rate of weight gain. | In Type C feeds; for cattle fed in confinement for slaughter only; feed continuously in complete feed to provide not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day. | 046573 |
| | Oxytetracycline 7.5 .. | Cattle: for improved feed efficiency, increased rate of weight gain, and reduction of incidence and severity of liver abscesses. | In Type C feeds, for beef cattle fed in confinement for slaughter; feed continuously at 250 to 360 mg/head/day lasalocid and 75 mg/head/day oxytetracycline. As monoalkyl (C ₈ - C ₁₈) trimethyl ammonium oxytetracycline. | 046573 |

| Lasalocid sodium activity in grams per ton | Combination in grams per ton | Indications for use | Limitations | Sponsor |
|--|--|--|---|---------|
| (viii) 20 (0.0022 pct) to 30 (0.0033 pct). | | Sheep; for the prevention of coccidiosis caused by <i>Eimeria ovina</i> , <i>E. crandallis</i> , <i>E. ovinoidalis</i> (<i>E. ninakohlyakimovae</i>), <i>E. parva</i> , and <i>E. intricata</i> . | In Type C feeds; for sheep maintained in confinement; feed continuously in complete feed to provide not less than 15 mg nor more than 70 mg of lasalocid sodium activity per head per day depending on body weight. | 046573 |
| (ix) | | 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.. | Feed continuously at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day when on pasture; the drug must be contained in at least 1 pound of feed.. | 046573 |
| (x) 68 (0.0075 pct) to 113 (0.0125 pct). | Bacitracin 4 to 50 | Broiler chickens; for prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; and for improved feed efficiency. | For broiler chickens only; feed continuously as the sole ration; bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter. | 046573 |
| (xi) 68 (0.0075 pct) to 113 (0.0125 pct). | Bacitracin zinc 4 to 50. | Broiler chickens. For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency.. | Feed continuously as sole ration. Bacitracin zinc and lasalocid sodium as provided by No. 046573 in § 510.600(c) of this chapter.. | 046573 |
| (xii) | | 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.. | Feed continuously on a free-choice basis at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day.. | 046573 |
| (xiii) | | Cattle; for control of coccidiosis caused by <i>Eimeria bovis</i> and <i>Eimeria zuernii</i> . | For cattle; hand feed at a rate of 1 mg of lasalocid per 2.2 pounds body weight per day to cattle weighing up to 800 pounds with a maximum of 360 mg of lasalocid per head per day. | 046573 |
| (xiv) 113 (0.0125 pct). | | Chukar partridges; for prevention of coccidiosis caused by <i>Eimeria legionensis</i> . | Feed continuously as sole ration up to 8 weeks of age. | 046573 |
| (xv) 68 (0.0075 pct) to 113 (0.0125 pct). | | Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoeides</i> .. | Feed continuously as sole ration. | 046573 |
| | Bacitracin 4 to 50 | Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoeides</i> ; for increased rate of weight gain and improved feed efficiency.. | Feed continuously as sole ration. | 046573 |
| | Bacitracin methylene disalicylate 4 to 50. | Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoeides</i> ; for increased rate of weight gain and improved feed efficiency.. | Feed continuously as sole ration. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.. | 046573 |
| | Roxarsone 22.7 to 45.4. | Growing turkeys: For prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoeides</i> , increased rate of weight gain, improved feed efficiency, and improved pigmentation.. | Feed continuously as the sole ration. Roxarsone provided by No. 046573 in § 510.600(c) in this chapter.. | 046573 |

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| Lasalocid sodium activity in grams per ton | Combination in grams per ton | Indications for use | Limitations | Sponsor |
|--|--------------------------------|--|--|------------------|
| | Virginiamycin 10 to 20. | Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoides</i> , and for increased rate of weight gain and improved feed efficiency.. | Feed continuously as sole ration. As lasalocid sodium provided by 063238 and virginiamycin provided by 066104.. | 046573 |
| (xvi) | | Replacement calves; for control of coccidiosis caused by <i>E. bovis</i> and <i>E. zuernii</i> .. | In milk replacer powder; hand feed at a rate of 1 mg of lasalocid per 2.2 lb body weight per day; include on labeling warning: "A withdrawal period has not been established for lasalocid in pre-ruminating calves. Do not use in calves to be processed for veal". | 046573 |
| (xvii) 113 (0.0125 pct). | | Rabbits; for prevention of coccidiosis caused by <i>Eimeria stiedae</i> . | Feed continuously as sole ration up to 6 1/2 weeks of age. | 046573 |
| (xviii) 1440 | | Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain.. | Feed continuously on a free-choice basis at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day.. | 021930 017800 |
| (xix) 300 | | Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain.. | Feed continuously on a free-choice basis at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day.. | 068287 |
| (xx) 10 to 30 | Chlortetracycline 25 to 100. | 1. Cattle fed in confinement for slaughter: For improved feed efficiency; and for control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.. | Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day.. | 046573 |
| | | 2. Cattle under 700 pounds fed in confinement for slaughter: For improved feed efficiency; and for control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.. | Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day.. | 046573 |
| (xxi) 10 to 30 | Chlortetracycline 500 to 2000. | Cattle fed in confinement for slaughter: For improved feed efficiency; and for treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline.. | Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb body weight per day and not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day.. | 046573 |
| (xxii) 25 to 30 | Chlortetracycline 25 to 42.2. | 1. Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency; and for control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.. | Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day.. | 046573 |
| | | 2. Cattle under 700 pounds fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency; and for control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.. | Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day.. | 046573 |

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|--|--------------------------------|---|--|---------|
| (xxiii) 25 to 30 | Chlortetracycline 500 to 1200. | Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency; and for treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline.. | Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb body weight per day and not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day.. | 046573 |
| (xxiv) 30 to 181.8 | Chlortetracycline 25 to 2800. | 1. Beef cattle under 700 pounds: For control of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> ; and for control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.. | Hand feed continuously at a rate of 350 mg chlortetracycline per head per day and 1 mg lasalocid per 2.2 lb body weight per day with a maximum of 360 mg lasalocid per head per day.. | 046573 |
| | | 2. Beef cattle up to 800 pounds: For control of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> ; and for control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.. | Hand feed continuously at a rate of 350 mg chlortetracycline per head per day and 1 mg lasalocid per 2.2 lb body weight per day with a maximum of 360 mg lasalocid per head per day.. | 046573 |
| (xxv) 30 to 181.8 | Chlortetracycline 500 to 4000. | Cattle up to 800 pounds: For control of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> ; and for treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline.. | Hand feed continuously for not more than 5 days to provide 10 mg chlortetracycline per lb body weight per day and 1 mg lasalocid per 2.2 lb body weight per day with a maximum of 360 mg lasalocid per head per day.. | 046573 |
| (xxvi) 30 to 600 .. | Chlortetracycline 25 to 700. | 1. Pasture cattle (slaughter, stocker, feeder cattle, and beef replacement heifers): for increased rate of weight gain; and for control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.. | Hand feed continuously at a rate of 350 mg chlortetracycline and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 lb of feed. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.. | 046573 |
| | | 2. Pasture cattle under 700 pounds (slaughter, stocker, feeder cattle, and beef replacement heifers): for increased rate of weight gain; and for control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.. | Hand feed continuously at a rate of 350 mg chlortetracycline and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 lb of feed. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.. | 046573 |
| (xxvii) 30 to 600 .. | Chlortetracycline 25 to 1100. | Pasture cattle over 700 pounds (slaughter, stocker, feeder cattle, and beef replacement heifers): For increased rate of weight gain; and for control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.. | Hand feed continuously at a rate of 0.5 mg chlortetracycline per lb body weight per day and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 lb of feed. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.. | 046573 |

| Lasalocid sodium activity in grams per ton | Combination in grams per ton | Indications for use | Limitations | Sponsor |
|--|---------------------------------|---|--|---------|
| (xxviii) 30 to 600. | Chlortetracycline 500 to 4000.. | Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain; and for treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline.. | Hand feed continuously for not more than 5 days to provide 10 mg chlortetracycline per lb body weight per day and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 lb of feed. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.. | 046573 |

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

(i) *Specifications.*

| Ingredient | Percent | International feed No. |
|---|---------|------------------------|
| Defluorinated phosphate (20.5% Ca, 18.5% P) | 35.9 | 6-01-080 |
| Sodium chloride (salt) | 20.0 | 6-04-152 |
| Calcium carbonate (38% Ca) | 18.0 | 6-01-069 |
| Cottonseed meal | 10.0 | 5-01-621 |
| Potassium chloride | 3.0 | 6-03-755 |
| Selenium premix (0.02 percent Se) ¹ | 3.0 | |
| Dried cane molasses (46% sugars) | 2.5 | 4-04-695 |
| Magnesium sulfate | 1.7 | 6-02-758 |
| Vitamin premix ¹ | 1.4 | |
| Magnesium oxide (58% Mg) | 1.2 | 6-02-756 |
| Potassium sulfate | 1.2 | 6-06-098 |
| Trace mineral premix ¹ | 1.04 | |
| Lasalocid Type A medicated article (68 g/lb) ² | 1.06 | |

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 FDA 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 1,440 g lasalocid per ton, use 21.2 lbs (1.06%) of a lasalocid Type A medicated article containing 68 g/lb. If using a lasalocid Type A medicated article containing 90.7 g/lb, use 15.88 lbs per ton (0.794%), adding molasses.

(ii) *Amount.* 1,440 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.

(3) It is used as a ruminant free-choice liquid Type C feed as follows:

(i) *Specifications.*

| Ingredient | Percent | International feed No. |
|---|---------|------------------------|
| Cane molasses | 55.167 | 4-13-241 |
| Condensed molasses fermentation solubles | 24.0 | |
| 50% Urea Solution (23% N) | 12.0 | |
| Ammonium polyphosphate solution | 1.0 | 6-08-42 |
| Phosphoric acid (54%) | 3.0 | 6-03-707 |
| Xanthan gum | 0.05 | 8-15-818 |
| Water | 4.0 | |
| Trace mineral premix ¹ | 0.5 | |
| Vitamin premix ¹ | 0.2 | |
| Lasalocid Type A medicated article (90.7 g/lb) ² | 0.083 | |

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 FDA 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).

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²To 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, 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:
 - (i) *Specifications.*

| Ingredient | Percent | International feed No. |
|---|---------|------------------------|
| Monocalcium phosphate (21% P) | 57.70 | 6-01-082 |
| Salt | 17.55 | 6-04-152 |
| Distillers dried grains w/ solubles | 5.40 | 5-28-236 |
| Dried cane molasses (46% Sugars) | 5.20 | 4-04-695 |
| Potassium chloride | 4.90 | 6-03-755 |
| Trace mineral/vitamin premix ¹ | 3.35 | |
| Calcium carbonate (38% Ca) | 2.95 | 6-01-069 |
| Mineral oil | 1.05 | 8-03-123 |
| Magnesium oxide (58% Mg) | 1.00 | 6-02-756 |
| Iron oxide (52% Fe) | 0.10 | 6-02-431 |
| Lasalocid Type A medicated article (68 g/lb) ² | 0.80 | |

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 FDA 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).

²To provide 1,088 g lasalocid per ton, use 16 lbs (0.80%) of a lasalocid Type A medicated article containing 68 g/lb. If using a lasalocid Type A medicated article containing 90.7 g/lb, use 12 lbs per ton (0.6%), adding molasses.

- (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 on GPO Access.

§ 558.315 Levamisole hydrochloride (equivalent).

- (a) *Approvals.* Type A medicated articles: 227 grams per pound to No. 053501 in § 510.600(c) of this chapter.
- (b) *Related tolerances.* See § 556.350 of this chapter.
- (c) *Conditions of use.* It is used in Type C medicated feed as follows:
 - (1) *Cattle*—(i) *Amount per pound.* 0.36-3.6 grams (0.08-0.8 percent).
 - (ii) *Indications for use.* Treatment of the following gastrointestinal worms and lung worm infections; stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*), and lungworms (*Dictyocaulus*).
 - (iii) *Limitations.* Administer medicated feed mixed thoroughly in one half the usual amount of morning feed; the medicated feed mix should be consumed within 6 hours; when medicated feed is consumed resume normal feeding; medicated feed is to be fed at the