

(iv) *Grams per ton.* Roxarsone, 181.5 (0.02 percent) plus chlortetracycline, 10 to 50.

(A) *Indications for use.* For the treatment of swine dysentery; increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* See paragraph (d)(4)(iii)(B) of this section.

(v) *Grams per ton.* Roxarsone, 181.5 (0.02 percent) plus chlortetracycline, 400.

(A) *Indications for use.* For the treatment of swine dysentery; treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline.

(B) *Limitations.* See paragraph (d)(4)(iii)(B) of this section.

(5) *Permitted combinations.* It may be used in accordance with this section in combination as follows:

(i) Aklomide as in § 558.35.

(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) [Reserved]

(viii) Chlortetracycline as in § 558.128.

(ix) Clopidol as in § 558.175.

(x) Decoquinat as in § 558.195.

(xi) Monensin as in § 558.355.

(xii) Nequinat as in § 558.365.

(xiii) Nicarbazin as in § 558.366.

(xiv) Nitromide and sulfanitran as in § 558.376.

(xv) Robenidine hydrochloride as in § 558.515.

(xvi) Sulfadimethoxine, ormetoprim as in § 558.575.

(xvii) Zoalene as in § 558.680.

(xviii) Penicillin and zoalene as in § 558.680

(xix) Lasalocid as in § 558.311.

(xx) Lasalocid sodium and lincomycin as in § 558.311.

(xxi) Monensin and virginiamycin as in § 558.355.

(xxii) Monensin and bacitracin zinc as in § 558.355.

(xxiii) Narasin with bacitracin methylene disalicylate as in § 558.363.

(xxiv) Semduramicin with bacitracin methylene disalicylate as in § 558.555.

(6) *Additional combinations.* (i) Roxarsone may be used in combination "as an aid in the reduction of lesions due to *E. tenella*" as follows:

(A) Lasalocid as in § 558.311.

(B) Lasalocid plus bacitracin methylene disalicylate as in § 558.311.

(C) Lasalocid plus lincomycin as in § 558.311.

(D) Lasalocid and bacitracin zinc as in § 558.311.

(ii) Roxarsone may be used in combination with salinomycin as in § 558.550.

(iii) Roxarsone may be used in combination with salinomycin and bacitracin methylene disalicylate as in § 558.550.

(iv) Roxarsone may be used in combination with salinomycin and bacitracin zinc as in § 558.550.

(v) Roxarsone may be used in combination with halofuginone hydrobromide and bacitracin methylene disalicylate as in § 558.265.

(vi) Roxarsone may be used in combination with narasin as in § 558.363 of this part.

(vii) Roxarsone may be used in combination with salinomycin and chlortetracycline as in § 558.550.

[46 FR 52331, Oct. 27, 1981]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.530, see the List of CFR Sections Affected in the Finding Aids section of this volume.

#### § 558.550 Salinomycin.

(a) *Approvals.* Type A medicated articles—30 or 60 grams of salinomycin activity per pound from salinomycin sodium biomass:

(1) To 000004 in § 510.600(c) of this chapter for use of 30 and 60 grams per pound as in paragraph (b) of this section.

(2) To 012799 for use of 30 and 60 grams per pound as in paragraphs (b)(1)(i), (b)(1)(iii) through (b)(1)(xvi), and (b)(3)(i) through (b)(3)(iii) of this section.

(b)–(c) [Reserved]

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

(i)(a) *Narasin with bacitracin methylene disalicylate.* Salinomycin 40 to 60 grams.

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

(c) *Limitations.* Feed continuously as sole ration. Do not feed to layers. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses.

(ii)(a) *Amount per ton.* Salinomycin 40 to 60 grams and roxarsone 45.4 grams.

(b) *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.

(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.

(b) *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.

(b) *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 or-

ganic 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.

(b) *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 to horses. Withdraw 5 days before slaughter. Roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(vi)(a) *Amount per ton.* Salinomycin 40 to 60 grams and bacitracin methylene disalicylate 4 to 50 grams.

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

(c) *Limitations.* 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 MD as provided by No. 046573 in § 510.600(c) of this chapter.

(vii)(a) *Amount per ton.* Salinomycin 40 to 60 grams and bacitracin zinc 10 to 50 grams.

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

(c) *Limitations.* 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 zinc as provided by No. 000004 in § 510.600(c) of this chapter.

(viii)(a) *Amount per ton.* Salinomycin 40 to 60 grams with roxarsone 45.4 grams and bacitracin zinc 4 to 50 grams.

(b) *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 and improved feed efficiency.

(c) *Limitations.* See paragraph (b)(1)(iv)(c) of this section.

(ix)(a) *Amount per ton.* Salinomycin 40 to 60 grams with roxarsone 34.1 grams and bacitracin zinc 10 to 50 grams.

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

(c) *Limitations.* Feed continuously as sole ration. Use as sole source of organic arsenic. 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 and bacitracin as provided by No. 000004 in § 510.600(c) of this chapter.

(x)(a) *Amount per ton.* Salinomycin 40 to 60 grams and virginiamycin 5 grams.

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

(c) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers or to chickens over 16 weeks of age. May be fatal if accidentally fed to adult turkeys or horses. Virginiamycin as provided by No. 053571 in § 510.600(c) of this chapter.

(xi)(a) *Amount per ton.* Salinomycin 40 to 60 grams and virginiamycin 5 to 15 grams.

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

(c) *Limitations.* See paragraph (b)(1)(x)(c) of this section.

(xii) (a) *Amount per ton.* Salinomycin 40 to 60 grams, virginiamycin 5 grams, and roxarsone 45.4 grams.

(b) *Indications for use.* For 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, and for improved feed efficiency.

(c) *Limitations.* Feed continuously as sole ration. Withdraw 5 days prior to slaughter. 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. Virginiamycin as provided by No. 053571 in § 510.600(c) of this chapter. Roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(xiii)(a) *Amount per ton.* Salinomycin 40 to 60 grams and lincomycin 2 to 4 grams.

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

(c) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers. Do not allow horses, adult turkeys, guinea pigs, rabbits, hamsters, or ruminants access to this feed. Ingestion by these species may result in severe gastrointestinal effects or may be fatal. Lincomycin hydrochloride monohydrate as provided by No. 000009 in § 510.600(c) of this chapter.

(xiv)(a) *Amount per ton.* Salinomycin 40 to 60 grams, roxarsone 45.4 grams, and lincomycin 2 grams.

(b) *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* that are more susceptible to roxarsone combined with salinomycin than to salinomycin alone, and for improved feed efficiency.

(c) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. Drug overdose or lack of water may result in leg weakness. Do not feed to layers. Do not allow horses, adult turkeys, guinea pigs, rabbits,

hamsters, or ruminants access to this feed. Ingestion by these species may result in severe gastrointestinal effects or may be fatal. Withdraw 5 days before slaughter. Lincomycin hydrochloride monohydrate as provided by No. 000009 in § 510.600(c) of this chapter. Roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(xv)(a) *Amount per ton.* Salinomycin 40 to 60 grams, chlortetracycline 500 grams, and roxarsone 45.4 grams.

(b) *Indications for use.* For 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, and as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatment.

(c) *Limitations.* Do not feed to layers. In feeds containing 0.8 percent dietary calcium, not to be fed for more than 5 days. Not approved for use with pellet binders. Withdraw 5 days before slaughter. May be fatal if accidentally fed to adult turkeys or to horses. Chlortetracycline as provided by No. 000004 and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(xvi)(a) *Amount per ton.* Salinomycin 40 to 60 grams and chlortetracycline 500 grams.

(b) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatment.

(c) *Limitations.* Do not feed to layers. In feeds containing 0.8 percent dietary calcium. Not to be fed for more than 5 days. Not approved for use with pellet binders. Withdraw 24 hours before slaughter. May be fatal if accidentally fed to adult turkeys or horses. Chlortetracycline as provided by No. 000004 in § 510.600(c) of this chapter.

(xvii)(A) *Amount per ton.* Salinomycin 40 to 60 grams with roxarsone 34.1 or 45.4 grams and bacitracin methylene disalicylate 4 to 50 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, in-

cluding some field strains of *E. tenella* that are more susceptible to roxarsone combined with salinomycin than to salinomycin alone; for increased rate of weight gain. Use of 34.1 or 45.4 grams per ton roxarsone is indicated to meet the *E. tenella* challenge which varies with environmental and management conditions.

(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 laying chickens. May be fatal if accidentally fed to adult turkeys or horses. Poultry should have access to drinking water at all times. Overdosage or lack of water may result in leg weakness or paralysis. Withdraw 5 days before slaughter. Salinomycin as provided by No. 000004 in § 510.600(c) of this chapter. Roxarsone and bacitracin as provided by No. 046573 in § 510.600(c) of this chapter.

(2) *Quail—(i)(a) Amount per ton.* Salinomycin 50 grams.

(b) *Indications for use.* For the prevention of coccidiosis caused by *E. dispersa* and *E. lettyae*.

(c) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses.

(ii) [Reserved]

(3) *Roaster and replacement (breeder and layer) chickens:* It is used as follows:

(i) *Amount per ton.* Salinomycin 40 to 60 grams.

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

(iii) *Limitations.* Feed continuously as sole ration. Do not feed to laying hens producing eggs for human consumption. Not approved for use with pellet binders. May be fatal if accidentally fed to horses or adult turkeys.

(4) *Permitted combinations.* Salinomycin may be used as in this section in combinations as follows:

(i) Bambermycins and roxarsone as in § 558.95.

(ii) Bambermycins as in § 558.95.

(iii) Oxytetracycline as in § 558.450.

[48 FR 30616, July 5, 1983]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.550, see the List of CFR

Sections Affected in the Finding Aids section of this volume.

EDITORIAL NOTE: At 62 FR 29014, May 29, 1997, in § 558.550, paragraph (b) was redesignated as paragraph (d). At 62 FR 60781, Nov. 13, 1997, paragraph (b)(1)(vii)(c) was amended by removing "No. 000004" and adding in its place "Nos. 000004 and 046573" and at 62 FR 66985, Dec. 23, 1997, paragraph (b)(1)(ix)(c) was amended by removing "No. 000004" and adding in its place "Nos. 000004 and 046573". Since § 558.550(b) does not exist, these amendments could not be incorporated.

#### § 558.555 Semduramicin.

(a) *Approvals.* Type A medicated article containing 5.13 percent semduramicin sodium (equivalent to 50 grams semduramicin per kilogram or 22.7 grams per pound) to 000069 in § 510.600(c) of this chapter.

(b) *Conditions of use.* (1) Broilers:

(i) *Amount.* Semduramicin: 25 parts per million.

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

(iii) *Limitations.* Do not feed to laying hens.

(2) *Amount.* Semduramicin 22.7 grams with bacitracin methylene disalicylate 10 to 50 grams and roxarsone 45.4 grams per ton.

(i) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati/E. mitis*, *E. necatrix*, and *E. tenella*, including some field strains of *E. tenella* that are more susceptible to semduramicin combined with roxarsone than semduramicin alone, and for improved feed efficiency.

(ii) *Limitations.* Feed continuously as sole ration. Use feed within 2 weeks of production. Withdraw 5 days before slaughter. Do not feed to laying hens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdose or lack of water intake may result in leg weakness or paralysis. Semduramicin as provided by 000069 in § 510.600(c) of this chapter, bacitracin methylene disalicylate and roxarsone as provided by 046573.

(3) *Amount.* Semduramicin 22.7 grams with bacitracin methylene disalicylate 10 to 50 grams per ton.

(i) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati/E. mitis*, *E. necatrix*, and *E. tenella*, and for improved feed efficiency in broiler chickens.

(ii) *Limitations.* Feed continuously as sole ration. Use feed within 2 weeks of production. Do not feed to laying hens. Semduramicin as provided by 000069, bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(4) *Amount.* Semduramicin 22.7 grams with roxarsone 45.4 grams per ton.

(i) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati/E. mitis*, *E. necatrix*, and *E. tenella*, including some field strains of *E. tenella* that are more susceptible to semduramicin combined with roxarsone than semduramicin alone.

(ii) *Limitations.* Feed continuously as sole ration. Withdraw 5 days before slaughter. For broiler chickens only. Do not feed to laying hens. Use as sole source of organic arsenic. Roxarsone as provided by 046573, semduramicin as provided by 000069 in § 510.600(c) of this chapter.

[59 FR 17477, Apr. 13, 1994, as amended at 60 FR 57928, Nov. 24, 1995; 61 FR 29481, June 11, 1996; 61 FR 43451, Aug. 23, 1996; 61 FR 66584, Dec. 18, 1996; 62 FR 66985, Dec. 23, 1997]

#### § 558.575 Sulfadimethoxine, ormetoprim.

(a) *Approvals.* Type A medicated articles to sponsors as identified in § 510.600(c) of this chapter for uses as in paragraph (c) of this section as follows:

(1) 25 percent sulfadimethoxine and 15 percent ormetoprim to 000004 for use for poultry as in paragraphs (c)(1), (2), (3), and (4) of this section.

(2) 25 percent sulfadimethoxine and 5 percent ormetoprim to 000004 for use for fish as in paragraphs (c)(5) and (6) of this section.

(b) *Related tolerances.* See §§ 556.490 and 556.640 of this chapter.

(c) *Conditions of use.* It is used in feeds for animals as follows:

(1) *Broiler chickens*—(i) *Amount per ton.* Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent).