

(B) *Limitations.* See paragraph (d)(3)(i)(B) of this section except that the drug should only be fed continuously for 7 to 14 days.

(4) *Growing-finishing swine*—(i) *Grams per ton.* Roxarsone 22.7 to 34.1 (0.0025 to 0.00375 percent).

(A) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic; feed continuously throughout growing season.

(ii) *Grams per ton.* Roxarsone 22.7 to 34.1 (0.0025 to 0.00375 percent) plus chlortetracycline, 400 (to administer 10 milligrams per pound of body weight).

(A) *Indications for use.* For increased rate of weight gain and improved feed efficiency; treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline.

(B) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic; feed for not more than 14 days.

(iii) *Grams per ton.* Roxarsone 181.5 (0.02 percent).

(A) *Indications for use.* For the treatment of swine dysentery.

(B) *Limitations.* 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 or organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.

(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 with:

(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) Chlortetracycline as in § 558.128.

(viii) Clopidol as in § 558.175.

(ix) Decoquinatone alone or in combination as in § 558.195.

(x) [Reserved]

(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) Nequinatone as in § 558.365.

(xvi) Nicarbazine alone or in combination as in § 558.366.

(xvii) Nitromide and sulfanitran as in § 558.376.

(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.

(xxi) Sempduramicin alone or in combination as in § 558.555.

(xxii) Sulfadimethoxine, ormetoprim as in § 558.575.

(xxiii) Zoalene alone or in combination as in § 558.680.

[46 FR 52331, Oct. 27, 1981]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.530, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 558.550 Salinomycin.

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

§ 558.550

21 CFR Ch. I (4-1-01 Edition)

(1) To 063238 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(2) To 012799 for use as in paragraphs (d)(1)(i), (d)(1)(iii) through (d)(1)(xvi), and (d)(3)(i) of this section.

(3) To 046573 for use as in paragraphs (d)(1)(xv), (d)(1)(xvi), (d)(1)(xviii) through (d)(1)(xxi), and (d)(3)(ii) through (d)(3)(vii) of this section.

(b)-(c) [Reserved]

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

(i)(a) *Amount per ton.* 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 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.

(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. 063238 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. 063238 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 pro-

vided 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 Nos. 046573 and 063238; roxarsone as provided by No. 046573; and salinomycin as provided by Nos. 012799 and 063238 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 Nos. 046573 and 063238; salinomycin as provided by Nos. 012799 and 063238 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*, including 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.

(xviii)(A) *Amount per ton*. Salinomycin, 40 to 60 grams; bacitracin methylene disalicylate, 50 grams; and roxarsone, 22.7 to 45.4 grams.

(B) *Indications for use*. For the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(C) *Limitations*. Feed continuously as sole ration. Do not feed to laying chickens. Use as sole source of organic arsenic. Poultry should have access to

drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. May be fatal if fed to adult turkeys or to horses. Withdraw 5 days before slaughter. Salinomycin as provided by Nos. 063238; bacitracin methylene disalicylate and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(xix)(A) *Amount per ton.* Salinomycin, 40 to 60 grams; bacitracin methylene disalicylate, 100 to 200 grams; and roxarsone, 22.7 to 45.4 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(C) *Limitations.* Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Do not feed to laying chickens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. May be fatal if fed to adult turkeys or to horses. Withdraw 5 days before slaughter. Salinomycin as provided by No. 063238; bacitracin methylene disalicylate and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(xx)(A) *Amount per ton.* Salinomycin, 40 to 60 grams; and bacitracin methylene disalicylate, 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 as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(C) *Limitations.* Feed continuously as sole ration. Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by 063238; bacitracin meth-

ylene disalicylate as provided by 046573 in § 510.600(c) in this chapter.

(xxi)(A) *Amount per ton.* Salinomycin, 40 to 60 grams; and bacitracin methylene disalicylate, 100 to 200 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 control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(C) *Limitations.* Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton). Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by 063238; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) in 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)(A) *Amount per ton.* Salinomycin 40 to 60 grams.

(B) *Indications for use.* For 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 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.

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

(A) *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.

(B) *Limitations.* Feed continuously as sole ration. Discontinue use prior to sexual maturity. Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by 063238; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(iii) *Amount per ton.* Salinomycin, 40 to 60 grams, and bacitracin methylene disalicylate, 50 grams.

(A) *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 prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(B) *Limitations.* Feed continuously as sole ration. Discontinue use prior to sexual maturity. Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by 063238; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(iv)(A) *Amount per ton.* Salinomycin, 40 to 60 grams; bacitracin methylene disalicylate, 50 grams; and roxarsone, 22.7 to 45.4 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(C) *Limitations.* Feed continuously as sole ration. Discontinue use prior to sexual maturity. Do not feed to laying chickens. 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. May be fatal if fed to adult turkeys or to horses. Withdraw 5 days before slaughter. Salinomycin as provided by No. 063238; bacitracin methylene disalicylate and roxarsone as provided by No. 046573 in § 510.600(c).

(v) *Amount per ton.* Salinomycin, 40 to 60 grams, and bacitracin methylene disalicylate, 100 to 200 grams.

(A) *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 control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(B) *Limitations.* Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton). Discontinue use prior to sexual maturity. Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by 063238; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(vi)(A) *Amount per ton.* Salinomycin, 40 to 60 grams; bacitracin methylene disalicylate, 100 to 200 grams; and roxarsone, 22.7 to 45.4 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(C) *Limitations.* Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Discontinue use prior to sexual maturity. Do not feed to laying chickens. 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. May be fatal if fed to adult turkeys or to horses. Withdraw 5 days before slaughter. Salinomycin as provided by No.

063238; bacitracin methylene disalicylate and roxarsone as provided by No. 046573 in § 510.600(c).

(vii) *Amount per ton.* Salinomycin, 40 to 60 grams; and roxarsone, 22.7 to 45.4 grams.

(A) *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 increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations.* Feed continuously as sole ration. Discontinue use prior to sexual maturity. Do not feed to laying chickens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. May be fatal if fed to adult turkeys or to horses. Withdraw 5 days before slaughter. Salinomycin as provided by No. 063238 and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(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, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 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) *Related tolerances.* See § 556.597 of this chapter.

(c) [Reserved]

(d) *Conditions of use in broiler chickens.* (1)(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 overdosage 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