

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).

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely, *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli* (colibacillosis) and *P. multocida* (fowl cholera).

(b) *Limitations.* Feed as sole ration; withdraw 5 days before slaughter.

(ii) *Amount per ton.* Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent) plus roxarsone, 22.7 grams (0.0025 percent).

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli* (colibacillosis); and *P. multocida* (fowl cholera); growth promotion and feed efficiency; improving pigmentation.

(b) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic.

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

(ii) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and bacterial infections due to *H. galmaxima*, and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli* (colibacillosis) and *P. multocida* (fowl cholera).

(iii) *Limitations.* Feed as a sole ration; do not feed to chickens over 16 weeks (112 days) of age; withdraw 5 days before slaughter.

(3) *Turkeys*—(i) *Amount per ton.* Sulfadimethoxine, 56.75 grams (0.00625 percent) plus ormetoprim, 34.05 grams (0.00375 percent).

(ii) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to turkeys, namely, *E.*

*adenoeides*, *E. gallopavonis*, and *E. meleagrimitis* and bacterial infection due to *P. multocida* (fowl cholera).

(iii) *Limitations.* Do not feed to turkeys producing eggs for food; withdraw 5 days before slaughter.

(4) *Ducks*—(i) *Amount per ton.* Sulfadimethoxine, 227 grams (0.025 percent) plus ormetoprim, 136.2 grams (0.015 percent).

(a) *Indications for use.* As an aid in the control of bacterial infections due to *P. multocida* (fowl cholera) in ducks, including breeding ducks.

(b) *Limitations.* Feed as sole ration for 7 days; withdraw 5 days before slaughter; medication should be started at the first signs of infection; do not feed to ducks producing eggs for food.

(ii) *Amount per ton.* Sulfadimethoxine, 454 grams (0.05 percent) plus ormetoprim, 272.4 grams (0.03 percent).

(a) *Indications for use.* As an aid in the control of bacterial infections due to *E. coli*, *P. anatipestifer*, and severe challenge of *P. multocida* (fowl cholera) in ducks.

(b) *Limitations.* Feed as a sole ration for 7 days; withdraw 5 days before slaughter; medication should be started at the first signs of infection; not for breeding ducks; do not feed to ducks producing eggs for food.

(5) *Salmonids*—(i) *Amount.* 50 milligrams of active ingredients per kilogram of body weight per day.

(ii) *Indications of use.* For the control of furunculosis in salmonids (trout and salmon) caused by *Aeromonas salmonicida* strains susceptible to sulfadimethoxine and ormetoprim combination.

(iii) *Limitations.* Administer for 5 consecutive days; withdraw 42 days before release as stocker fish or slaughter.

(6) *Catfish*—(i) *Amount.* 50 milligrams of active ingredients per kilogram of body weight per day.

(ii) *Indications for use.* For control of enteric septicemia of catfish caused by *Edwardsiella ictaluri* strains susceptible to sulfadimethoxine and ormetoprim combination.

(iii) *Limitations.* Administer for 5 consecutive days; withdraw 3 days before slaughter or release as stocker fish.

[40 FR 13959, Mar. 27, 1975, as amended at 42 FR 13550, Mar. 11, 1977; 49 FR 33442, Aug. 23, 1984; 49 FR 46371, Nov. 26, 1984; 51 FR 7400, Mar. 3, 1986; 51 FR 18884, May 23, 1986; 52 FR 2686, Jan. 26, 1987; 54 FR 1686, Jan. 17, 1989]

#### § 558.579 Sulfaethoxyypyridazine.

(a) *Approvals.* Type A medicated articles: 5.5 percent for swine, and 5.5 and 11 percent for cattle to 010042 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.650 of this chapter.

(c) *Conditions of use.* It is used in animal feed as follows:

(1) *Swine*—(i) *Amount.* 25 milligrams per pound body weight per day.

(ii) *Indications for use.* For treatment of bacterial scours, pneumonia, enteritis, bronchitis, septicemia accompanying *Salmonella choleraesuis* infection.

(iii) *Limitations.* Administer 1,000 grams per ton (0.11 percent) for not less than 4 days nor more than 10 days; do not treat within 10 days of slaughter; as sole source of sulfonamide; for use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount.* 25 milligrams per pound body weight per day.

(ii) *Indications for use.* For treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; as adjunctive therapy in septicemia accompanying mastitis and metritis.

(iii) *Limitations.* Administer as a top dressing or in mixed feed for 4 days; do not treat within 16 days of slaughter; as sole source of sulfonamide; milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food; for use by or on the order of a licensed veterinarian.

[41 FR 11005, Mar. 15, 1976, as amended at 51 FR 7400, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987]

#### § 558.582 Sulfamerazine.

(a) *Approvals.* Type A medicated articles: 99 percent to 000004 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.660 of this chapter.

(c) *Conditions of use.* It is used in fish feed for rainbow trout, brook trout, and brown trout as follows:

(1) *Amount.* 10 grams of sulfamerazine per 100 pounds of fish per day.

(2) *Indications for use.* Control of furunculosis.

(3) *Limitations.* Treat for not more than 14 days; do not treat within 3 weeks of marketing or stocking in stream open to fishing.

[41 FR 11005, Mar. 15, 1976, as amended at 51 FR 7400, Mar. 3, 1986; 61 FR 18082, Apr. 24, 1996]

#### § 558.586 Sulfaquinoxoline.

(a) *Approvals.* Type A medicated articles: 40 percent to 050749 in § 510.600(c) of this chapter.

(b)–(c) [Reserved]

(d) *NAS/NRC status.* The conditions of use specified in this section have been reviewed by NAS/NRC and are found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency information. Applications must be accompanied by a written commitment to undertake the human safety studies required by FDA.

(e) *Special considerations.* (1) For control of outbreaks of disease, medication should be initiated as soon as the diagnosis is determined. Medicated chickens, turkeys, and rabbits must actually consume enough medicated feed which provides a recommended dose of approximately 3.5 to 60 milligrams per pound per day in chickens, 2.5 to 100 milligrams per pound per day in turkeys, and 2.8 to 68 milligrams per pound per day in rabbits depending upon age and class of animal, ambient temperature, and other factors. Consult a veterinarian or poultry pathologist for diagnosis.

(2) [Reserved]

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

(1) *Chickens*—(i) *Amount.* 0.015 percent.

(a) *Indications for use.* As an aid in preventing outbreaks of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, and *E. brunetti* under average conditions of exposure.

(b) *Limitations.* Feed continuously from the time birds are placed on litter and continue past the age when coccidiosis is ordinarily a hazard. If death