

§ 558.575

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

provided by 046573, semduramicin as provided by 000069 in § 510.600(c) of this chapter.

(5) *Amount.* Semduramicin 22.7 grams with virginiamycin 20 grams per ton.

(i) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, *E. necatrix*, and *E. mivati/mitis*, and for prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin.

(ii) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Semduramicin and virginiamycin as provided by 000069 in § 510.600(c) of this chapter.

(6) *Amount.* Semduramicin 22.7 grams with virginiamycin 5 to 15 grams per ton.

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

(ii) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Semduramicin and virginiamycin as provided by 000069 in § 510.600(c) of this chapter.

(7) *Amount.* Semduramicin 22.7 grams with virginiamycin 5 grams per ton.

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

(ii) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Semduramicin and virginiamycin 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; 64 FR 48296, Sept. 3, 1999]

§ 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 (d) of this section as follows:

(1) 25 percent sulfadimethoxine and 15 percent ormetoprim to 000004 for use for poultry as in paragraphs (d)(1), (d)(2), (d)(3), (d)(4), and (d)(7) of this section.

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

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

(c) [Reserved]

(d) *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*, *Riemerella 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 for 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.

(7) *Chukar partridges*—(i) *Amount per ton*. Sulfadimethoxine 113.5 grams (0.0125 percent) plus ormetoprim 68.1 grams (0.0075 percent).

(ii) *Indications for use*. For prevention of coccidiosis caused by *Eimeria kofoidi* and *E. legionensis*.

(iii) *Limitations*. Feed continuously to young birds up to 8 weeks of age as sole ration.

[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; 63 FR 27846, May 21, 1998; 64 FR 26672, May 17, 1999; 64 FR 43910, Aug. 12, 1999]

#### § 558.579 Sulfaethoxy pyridazine.

(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.