

§ 558.555 Semduramicin.

(a) *Specifications.* Type A medicated article containing 22.7 grams per pound (50 grams per kilogram) semduramicin sodium.

(b) *Approvals.* See No. 066104 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

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

(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 overdose or lack of water intake may result in leg weakness or paralysis. Semduramicin as provided by 066104 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 066104,

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 066104 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 066104 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 066104 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 066104 in §510.600(c) of this chapter.

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§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 046573 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 046573 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