

(3) No. 051311: 40 grams per pound each for use as in paragraph (e)(2)(ii) of this section.

(4) [Reserved]

(5) Nos. 000986, 012286, 034936, and 054771: 5, 10, 20, or 40 grams per pound each for use as in paragraph (e)(2)(ii) of this section.

(6) No. 000986: 40 grams per pound each for use as in paragraph (e)(2)(iii) of this section.

(c) *Special considerations.* Labeling shall bear the statement: “Do not use in medicated feeds containing in excess of 2% bentonite.”

(d) *Related tolerances.* See §§ 556.670 and 556.740 of this chapter.

(e) *Conditions of use.* It is used in feed for swine as follows:

(1) *Amount per ton.* 100 grams tylosin and 100 grams sulfamethazine.

(2) *Indications for use—*(i) Maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery (vibrionic); control of swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Corynebacterium pyogenes*); for reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E *Streptococci*. Only the sulfamethazine portion of this combination is active in controlling jowl abscesses.

(ii) Maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery (vibrionic); control of swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Corynebacterium pyogenes*).

(iii) For maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery associated with *Brachyspira hyodysenteriae*; and control of swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Arcanobacterium pyogenes*).

(3) *Limitations.* Withdraw 15 days before swine are slaughtered.

[73 FR 34185, June 17, 2008, as amended at 73 FR 35341, June 23, 2008; 75 FR 55677, Sept. 14, 2010; 76 FR 17778, Mar. 31, 2011; 77 FR 4897, Feb. 1, 2012; 78 FR 14669, Mar. 7, 2013; 79 FR 13546, Mar. 11, 2014]

§ 558.635 Virginiamycin.

(a) *Approvals.* Type A medicated articles. (1) 1.1 percent activity (5 grams per pound), 2.2 percent activity (10 grams per pound), 4.4 percent activity (20 grams per pound), 11 percent activity (50 grams per pound), and 50 percent activity (227 grams per pound) used as in paragraph (d) of this section; and 30 percent activity (136.2 grams per pound) for the manufacture of Type C medicated feed for cattle used as in paragraph (d)(3); to 066104 in § 510.600(c) of this chapter.

(2) 2.2 percent activity (10 grams per pound) to 054771 and 017790 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(iv) and (d)(1)(v) of this section.

(b) *Related tolerances.* See § 556.750 of this chapter.

(c) *Special considerations.* (1) Not for use in breeding swine over 120 pounds.

(2) Dilute Type A article with at least 10 pounds of a feed ingredient prior to final mixing in 1 ton of Type C feed.

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

(i) 100 grams per ton for 2 weeks, for treatment of swine dysentery in non-breeding swine over 120 pounds.

(ii) 100 grams per ton for 2 weeks, 50 grams per ton thereafter, for treatment and control of swine dysentery in swine up to 120 pounds.

(iii) 25 grams per ton, as an aid in control of dysentery in swine up to 120 pounds. For use in animals or on premises with a history of swine dysentery but where symptoms have not yet occurred.

(iv) 10 grams per ton from weaning up to 120 pounds for increased rate of weight gain and improved feed efficiency, followed by 5 grams per ton to market weight for increased rate of weight gain and improved feed efficiency. For continuous use from weaning to market weight.

(v) 10 grams per ton from weaning up to 120 pounds for increased rate of

§ 558.665

21 CFR Ch. I (4–1–14 Edition)

weight gain and improved feed efficiency, followed by 5 to 10 grams per ton to market weight for increased rate of weight gain. For continuous use from weaning to market weight.

(2) *Poultry*. It is used as follows:

(i) 5 to 15 grams per ton for increased rate of weight gain, for use in broiler chickens, not for use in layers.

(ii) 5 grams per ton for increased rate of weight gain and improved feed efficiency in broiler chickens, not for use in layers.

(iii) 20 grams per ton for prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin in broiler chickens; not for use in layers.

(iv) 10 to 15 grams per ton for increased rate of weight gain and improved feed efficiency in growing turkeys.

(3) *Cattle*. It is used as follows:

(i) 16.0 to 22.5 grams per ton to provide 100 to 340 milligrams per head per day for increased rate of weight gain.

(ii) 13.5 to 16.0 grams per ton to provide 85 to 240 milligrams per head per day for reduction of incidence of liver abscesses.

(iii) 11.0 to 16.0 grams per ton to provide 70 to 240 milligrams per head per day for improved feed efficiency.

(iv) Feed continuously as sole ration to cattle fed in confinement for slaughter. Not for use in animals intended for breeding.

(4) Virginiamycin may be used in combination with:

(i) Amprolium and ethopabate as in § 558.58.

(ii) Diclazuril as in § 558.198.

(iii) Halofuginone as in § 558.265.

(iv) Lasalocid as in § 558.311.

(v) Monensin as in § 558.355.

(vi) Salinomycin as in § 558.550.

(vii) Semduramicin as in § 558.555.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.635, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 558.665 Zilpaterol.

(a) *Specifications*. Type A medicated articles containing 21.77 grams (g) zilpaterol hydrochloride per pound.

(b) *Approvals*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Tolerances*. See § 556.765 of this chapter.

(d) *Special considerations*—(1) Labeling of Type B and Type C cattle feeds shall bear the following:

(i) Do not allow horses or other equines access to feed containing zilpaterol.

(ii) Not for use in animals intended for breeding.

(iii) Do not use in veal calves.

(2) Type B Liquid Feeds can be manufactured containing 68 to 680 g zilpaterol hydrochloride/ton. The liquid Type B feeds must be maintained at a pH of 3.8 to 7.5. For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used. For liquid feeds stored in mechanical, air or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(e) *Conditions of use in cattle*. It is administered in feed as follows:

Zilpaterol in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(1) 6.8 to provide 60 to 90 mg/head/day		Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed.	Feed continuously as the sole ration during the last 20 to 40 days on feed. Withdrawal period: 3 days.	000061