

§ 558.500

21 CFR Ch. I (4–1–23 Edition)

Pyrantel grams/ton	Indications for use	Limitations	Sponsor
(iii) 800	Swine: For the removal and control of large roundworm (<i>Ascaris suum</i>) and nodular worm (<i>Oesophagostomum</i>) infections.	Feed as the sole ration for a single therapeutic treatment in Type C feed at a rate of 1 lb of feed per 40 lb of body weight for animals up to 200 lb, and 5 lb of feed per head for animals 200 lb or over. Withdraw 24 hours prior to slaughter.	066104

(2) Horses—

Pyrantel grams/ton	Indications for use	Limitations	Sponsor
To provide 1.2 mg/lb body weight.	Prevention of <i>Strongylus vulgaris</i> larval infections; control of adult large strongyles (<i>S. vulgaris</i> , and <i>S. edentatus</i>), adult and 4th stage larvae small strongyles (<i>Cyathostomum</i> spp., <i>Cylicocyclus</i> spp., <i>Cylicostephanus</i> spp., <i>Cylicodontophorus</i> spp., <i>Poteriosomum</i> spp., and <i>Triodontophorus</i> spp.), adult and 4th stage larvae pinworms (<i>Oxyuris equi</i>), and adult and 4th stage larvae ascarids (<i>Parascaris equorum</i>).	Feed continuously. Administer either as a top-dress (not to exceed 20,000 g/ton) or mixed in the horse's daily grain ration (not to exceed 1,200 g/ton) during the time that the animal is at risk of exposure to internal parasites. Do not use in horses intended for human consumption. Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.	017135 054771

(3) Pyrantel may also be used in combination with:

- (i) Carbadox as in § 558.115.
- (ii) Lincomycin as in § 558.325.
- (iii) Tylosin as in § 558.625.

[83 FR 48948, Sept. 28, 2018, as amended at 83 FR 64744, Dec. 18, 2018; 86 FR 14826, Mar. 19, 2021]

§ 558.500 Ractopamine.

(a) *Specifications.* Type A medicated articles containing 9 or 45.4 grams of ractopamine hydrochloride per pound.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 058198: Type A medicated articles containing 9 or 45.4 grams per pound (g/lb) ractopamine hydrochloride.

(2) Nos. 016592, 051311, and 054771: Type A medicated articles containing 45.4 g/lb ractopamine hydrochloride.

(c) *Related tolerances.* See § 556.570 of this chapter.

(d) *Special considerations.* (1) Labeling of Type B and Type C feeds shall bear the following: “Not for animals intended for breeding.”

(2) Labeling of Type B and Type C swine feeds shall bear the following:

(i) “No increased benefit has been shown when ractopamine concentrations in the diet are greater than 4.5 g/ton.”

(ii) “Ractopamine may increase the number of injured and/or fatigued pigs during marketing.”

(3) Labeling of Type B and Type C tom turkey feeds shall bear the following: “No increased benefit has been shown when ractopamine concentrations in the diet are greater than 4.6 g/ton.”

(4) Tylosin in combinations as tylosin phosphate.

(5) Ractopamine liquid Type B cattle feeds may be manufactured from dry ractopamine Type A articles. The liquid Type B feeds must be maintained

Food and Drug Administration, HHS

§ 558.500

at a pH of 4.5 to 7.5 or, if in combination with monensin and/or tylosin, at a pH of 4.5 to 6.0. Mixing directions for liquid Type B feeds requiring recirculation or agitation: 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.

(e) *Conditions of use*—(1) *Swine*—

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 4.5 to 9.0	For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter.	Feed continuously as sole ration.	058198, 054771
(ii) [Reserved].				

(2) *Cattle*.

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 8.2 to 24.6	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding.	016592 051311 054771 058198
(ii) 8.2 to 24.6 to provide 70 to 430 mg/head/day.	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding. See special labeling considerations in § 558.355(d) of this chapter. Ractopamine as provided by No. 016592, 054771, or 058198; monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter.	016592 054771 058198
(iii) 9.8 to 24.6	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding.	016592 051311 054771 058198
(iv) 9.8 to 24.6 to provide 90 to 430 mg/head/day.	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, increased carcass leanness, and prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding. See special labeling considerations in § 558.355(d) of this chapter. Ractopamine as provided by No. 016592, 054771, or 058198; monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter.	016592 054771 058198

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(v) 9.8 to 24.6 to provide 90 to 430 mg/head/day.	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> , and suppression of estrus (heat) during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding. See special labeling considerations in §§ 558.342(d) and 558.355(d) of this chapter. Ractopamine as provided by No. 016592, 054771, or 058198; monensin as provided by No. 016592 or 058198; melengestrol acetate as provided by No. 016592, 054771 or 058198 in § 510.600(c) of this chapter.	016592 054771 058198
(vi) Not to exceed 800; to provide 70 to 400 mg/head/day.	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed.	Top dress ractopamine at a minimum of 1.0 lb/head/day of medicated feed continuously during the last 28 to 42 days on feed. Not for animals intended for breeding.	016592 051311 054771 058198
(vii) Not to exceed 800; to provide 70 to 400 mg/head/day.	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> during the last 28 to 42 days on feed.	Top dress ractopamine at a minimum of 1.0 lb/head/day of medicated feed continuously during the last 28 to 42 days on feed. Not for animals intended for breeding. See special labeling considerations in § 558.355(d) of this chapter. Ractopamine as provided by No. 016592, 054771, or 058198; monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter.	016592 054771 058198

(3) *Turkeys—*

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 4.6 to 11.8 (5 to 13 ppm).	Finishing hen turkeys: For increased rate of weight gain and improved feed efficiency when fed for the last 7 to 14 days prior to slaughter..	Feed continuously as sole ration during the last 7 to 14 days prior to slaughter..	058198
(ii) 4.6 to 11.8 (5 to 13 ppm).	Finishing tom turkeys: For increased rate of weight gain and improved feed efficiency when fed for the last 14 days prior to slaughter..	Feed continuously as sole ration during the last 14 days prior to slaughter. Feeding ractopamine to tom turkeys during periods of excessive heat can result in increased mortality..	058198
(iii) 4.6 to 11.8 (5 to 13 ppm).	Monensin 54 to 90 ...	Finishing hen turkeys: As in paragraph (e)(3)(i) of this section; and for the prevention of coccidiosis in growing turkeys caused by <i>Eimeria adenoides</i> , <i>E. meleagris</i> and <i>E. gallopavonis</i> ..	Feed continuously as sole ration during the last 7 to 14 days prior to slaughter. See § 558.355(d)..	058198
(iv) 4.6 to 11.8 (5 to 13 ppm).	Monensin 54 to 90 ...	Finishing tom turkeys: As in paragraph (e)(3)(ii) of this section; and for the prevention of coccidiosis in growing turkeys caused by <i>Eimeria adenoides</i> , <i>E. meleagris</i> and <i>E. gallopavonis</i> ..	Feed continuously as sole ration during the last 14 days prior to slaughter. Feeding ractopamine to tom turkeys during periods of excessive heat can result in increased mortality. See § 558.355(d)..	058198

Food and Drug Administration, HHS

§ 558.515

(4) Ractopamine may also be used in combination with tylosin in as in § 558.625.

[67 FR 71820, Dec. 3, 2002, as amended at 68 FR 54659, Sept. 18, 2003; 69 FR 12068, Mar. 15, 2004; 69 FR 51174, Aug. 18, 2004; 71 FR 31074, June 1, 2006; 71 FR 67301, Nov. 21, 2006; 72 FR 10358, Mar. 8, 2007; 72 FR 41619, July 31, 2007; 72 FR 56897, Oct. 5, 2007; 72 FR 62571, Nov. 6, 2007; 72 FR 65667, Nov. 23, 2007; 72 FR 70777, Dec. 13, 2007; 73 FR 72715, Dec. 1, 2008; 73 FR 75323, Dec. 11, 2008; 74 FR 66914, Dec. 17, 2009; 75 FR 1276, Jan. 11, 2010; 75 FR 5888, Feb. 5, 2010; 75 FR 20917, Apr. 22, 2010; 75 FR 54018, Sept. 3, 2010; 77 FR 31724, May 30, 2012; 78 FR 63872, Oct. 25, 2013; 79 FR 13546, Mar. 11, 2014; 79 FR 37621, July 2, 2014; 79 FR 44278, July 31, 2014; 79 FR 53136, Sept. 8, 2014; 80 FR 61298, Oct. 13, 2015; 81 FR 48703, July 26, 2016; 81 FR 95013, Dec. 27, 2016; 85 FR 18122, Apr. 1, 2020; 85 FR 45311, July 28, 2020; 86 FR 58013, Oct. 20, 2021; 87 FR 17947, Mar. 29, 2022]

§ 558.515 Robenidine.

(a) *Specifications.* Type A medicated articles containing 30 grams per pound.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.580 of this chapter.

(d) *Special considerations.* Type C feed containing robenidine hydrochloride must be fed within 50 days from the date of manufacture. Do not use in Type B or Type C medicated feeds containing bentonite.

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

Robenidine hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
30 (0.0033 pct)	Broiler chickens: As an aid in the prevention of coccidiosis caused by <i>E. mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> ..	Feed continuously as sole ration. Do not feed to chickens producing eggs for food. Withdraw 5 days prior to slaughter..	054771
.....	Bacitracin (as bacitracin methylenedisalicylate) 4 to 30.	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by <i>E. mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> . For increased rate of weight gain..	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter..	054771
.....	Bacitracin (as bacitracin methylenedisalicylate) 27 to 50.	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by <i>E. mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> . For improved feed efficiency..	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter..	054771
.....	Bacitracin (as bacitracin methylenedisalicylate) 50.	For broiler and fryer chickens: As an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin..	Feed continuously as sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter..	054771
.....	Bacitracin (as bacitracin methylenedisalicylate) 100 to 200.	For broiler and fryer chickens: As an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin..	To control a necrotic enteritis outbreak, start medication at first clinical signs of disease; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin methylenedisalicylate to prevention level (50 g/ton). Do not feed to laying hens. Withdraw 5 days before slaughter..	054771
.....	Bacitracin (as bacitracin zinc) 4 to 30.	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by <i>E. mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> . For increased rate of weight gain..	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter..	054771 054771