

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.95, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 558.105 [Reserved]

§ 558.115 Carbadox.

(a) *Approvals.* Type A medicated articles: 2.2 percent (10 grams per pound) to 066104 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.100 of this chapter.

(c) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

(d) *Conditions of use.* It is used for swine as follows:

(1) *Amount per ton.* 10–25 grams (0.0011–0.00275 percent).

(i) *Indications for use.* For increase in rate of weight gain and improvement of feed efficiency.

(ii) *Limitations.* Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

(2) *Amount per ton.* 50 grams (0.0055 percent).

(i) *Indications for use.* For control of swine dysentery (vibronic dysentery, bloody scours, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

(3) *Amount per ton.* Carbadox 50 grams (0.0055 percent) plus pyrantel tartrate, 96 grams (0.0106 percent).

(i) *Indications for use.* For control of swine dysentery (vibronic dysentery, bloody scours, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections.

(ii) *Limitations.* Do not feed to swine over 75 pounds; do not feed within 10 weeks of slaughter; consult a veterinarian before feeding to severely de-

bilitated animals; feed continuously as sole ration. Do not use in complete feeds containing less than 15 percent crude protein.

(4) *Amount.* Carbadox, 10 to 25 grams per ton of feed; plus oxytetracycline, 10 milligrams per pound of body weight.

(i) *Indications for use.* For treatment of bacterial enteritis caused by *Escherichia coli* and *S. choleraesuis* susceptible to oxytetracycline, for treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline; and for increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Feed continuously for 7 to 14 days. Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

[40 FR 13959, Mar. 27, 1975, as amended at 40 FR 45164, Oct. 1, 1975; 40 FR 57798, Dec. 12, 1975; 42 FR 761, Jan. 4, 1977; 51 FR 7396, Mar. 3, 1986; 63 FR 59216, Nov. 3, 1998; 66 FR 47963, Sept. 17, 2001; 69 FR 51173, Aug. 18, 2004]

§ 558.128 Chlortetracycline.

(a) *Specifications.* Type A medicated articles containing either chlortetracycline calcium complex equivalent to chlortetracycline hydrochloride or, for products intended for use in milk replacer, chlortetracycline hydrochloride.

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) Nos. 054771, 048164, and 066104: 50 to 100 grams per pound (g/lb) of Type A medicated article.

(2) No. 012286: 50, 90, or 100 grams per pound of Type A medicated article.

(c) *Related tolerances.* See § 556.150 of this chapter.

(d) *Special considerations.* (1) In milk replacers or starter feed; include on labeling the warning: “A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.”

(2) Manufacture for use in free-choice feeds as in paragraph (e)(4)(iii) of this section must conform to § 510.455 of this chapter.

§ 558.128

21 CFR Ch. I (4–1–14 Edition)

(3) When manufactured for use as in paragraph (e)(5)(iv) of this section, include on labeling the warning: “Psittacosis, avian chlamydiosis, or ornithosis is a reportable communicable disease, transmissible between wild and

domestic birds, other animals, and man. Contact appropriate public health and regulatory officials.”

(e) Conditions of use—(1) *Chickens*. It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton	Chickens: For increased rate of weight gain and improved feed efficiency.. Do not feed to chickens producing eggs for human consumption..	054771 012286, 054771, 048164, 066104, 054771.
(ii) 100 to 200 g/ton	Chickens: For control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline..	1. Feed continuously for 7 to 14 d. 2. Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption..	012286, 054771, 048164, 066104, 054771.
(iii) 200 to 400 g/ton	Chickens: For the control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlortetracycline..	1. Feed continuously for 7 to 14 d. 2. Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption..	012286, 054771, 048164, 066104, 054771.
(iv) 500 g/ton	Chickens: For the reduction of mortality due to <i>E. coli</i> infections susceptible to chlortetracycline..	1. Feed for 5 d; 0-day withdrawal time when formulated from AUREOMYCIN Type A medicated articles or Type B medicated feeds under NADA 48–761.. 2. Feed for 5 d; withdraw 24 h prior to slaughter; do not feed to chickens producing eggs for human consumption..	012286, 054771, 048164, 066104.

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

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton	Growing turkeys: For increased rate of weight gain and improved feed efficiency..	Do not feed to turkeys producing eggs for human consumption..	012286, 054771, 048164, 066104.
(ii) 200 g/ton	Turkeys: For control of infectious synovitis caused by <i>M. synoviae</i> susceptible to chlortetracycline..	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption..	012286, 054771, 048164, 066104.
(iii) 400 g/ton	1. Turkeys: For control of hexamitiasis caused by <i>Hexamita meleagridis</i> susceptible to chlortetracycline..	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption..	012286, 054771, 048164, 066104.
.....	2. Turkey poults not over 4 weeks of age: For reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline..	012286, 054771, 048164, 066104.
(iv) 25 mg/lb of body weight.	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to chlortetracycline..	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption..	012286, 054771, 048164, 066104.

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

Food and Drug Administration, HHS

§ 558.128

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton	Growing swine: For increased rate of weight gain and improved feed efficiency..	012286, 054771, 048164, 066104.
(ii) 50 to 100 g/ton	Swine: For reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group <i>E. Streptococci</i> susceptible to chlortetracycline..	012286, 054771, 048164, 066104.
(iii) 400 g/ton	Breeding swine: For the control of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to chlortetracycline..	Feed continuously for not more than 14 d..	012286, 054771, 048164, 066104.
(iv) 10 mg/lb of body weight. 	1. Swine: For the treatment of bacterial enteritis caused by <i>E. coli</i> and <i>S. choleraesuis</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline.. 2. Swine: For the control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i> susceptible to chlortetracycline..	Feed approximately 400 g/t, varying with body weight and feed consumption to provide 10 mg/lb per day. Feed for not more than 14 d; withdraw 5 d prior to slaughter for sponsor 012286.. Feed for not more than 14 d.	012286, 054771, 048164, 066104. 054771.

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

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 0.1 mg/lb of body weight daily..	Calves (up to 250 lb): For increased rate of weight gain and improved feed efficiency..	See paragraph (d)(1) of this section. ..	012286, 054771, 048164, 066104.
(ii) 0.5 mg/lb of body weight daily..	Beef cattle (over 700 lb); control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline..	Withdraw 48 h prior to slaughter. To sponsor Nos. 054771 and 048164: zero withdrawal time..	012286, 054771, 048164, 066104.
(iii) 0.5 to 2.0 mg/lb of body weight daily..	Beef cattle and nonlactating dairy cattle: As an aid in the control of active infection of anaplasmosis caused by <i>A. marginale</i> susceptible to chlortetracycline..	In free-choice cattle feeds such as feed blocks or salt-mineral mixes manufactured from approved Type A articles. See paragraph (d)(2) of this section..	054771.
(iv) 10 mg/lb of body weight daily. 	1. Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline.. 2. Calves (up to 250 lb): For the treatment of bacterial enteritis caused by <i>E. coli</i> susceptible to chlortetracycline..	Feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb per day. Treat for not more than 5 d; in feed including milk replacers; withdraw 10 d prior to slaughter. To sponsor No. 048164: zero withdrawal time. See paragraph (d)(1) of this section.. See paragraph (d)(1) of this section. ..	012286, 048164, 066104. 012286, 054771, 048164, 066104.
(v) 500 to 4,000 g/ton	Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline..	Feed continuously for not more than 5 days to provide 10 mg/lb body weight per day. To sponsor No. 054771 under NADA 046-699: 24-h withdrawal time. To sponsor No. 054771 under NADA 048-761: zero withdrawal time..	054771.
(vi) 4,000 to 20,000 g/ton	Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline..	As a top dress, varying with body weight and feed consumption, to provide 10 mg/lb per day. Treat for not more than 5 days. See paragraph (d)(1) of this section..	054771.
(vii) 25 to 70 mg/head/day	Calves (250 to 400 lb): For increased rate of weight gain and improved feed efficiency..	See paragraph (d)(1) of this section. ..	012286, 054771, 048164, 066104.

§ 558.128

21 CFR Ch. I (4–1–14 Edition)

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(viii) 70 mg/head/day	Growing cattle (over 400 lb): For increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses..	See paragraph (d)(1) of this section. ..	012286, 054771, 048164, 066104.
(ix) 350 mg/head/day	1. Beef cattle: For control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline..	Withdraw 48 h prior to slaughter. To sponsor No. 054771 under NADA 046–699: 48-h withdrawal time. To sponsor No. 054771 under NADA 048–761 and No. 048164: zero withdrawal time..	012286, 054771, 048164, 066104.
.....	2. Beef cattle (under 700 lb): For control of active infection of anaplasmosis caused by <i>A. marginale</i> susceptible to chlortetracycline..	Withdraw 48 h prior to slaughter. To sponsor No. 054771 under NADA 046–699: 48-h withdrawal time. To sponsor No. 054771 under NADA 048–761 and No. 048164: zero withdrawal time..	012286, 054771, 048164, 066104.

(5) *Minor species*. It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 20 to 50 g/ton	Growing sheep; increased rate of weight gain and improved feed efficiency..	054771, 048164, 066104.
(ii) 80 mg/head/day	Breeding sheep; reducing the incidence of (vibronic) abortion caused by <i>Campylobacter fetus</i> infection susceptible to chlortetracycline..	054771, 048164, 066104.
(iii) 200 to 400 g/ton	Ducks: For the control and treatment of fowl cholera caused by <i>P. multocida</i> susceptible to chlortetracycline..	Feed in complete ration to provide from 8 to 28 mg/lb of body weight per day depending upon age and severity of disease, for not more than 21 d. Do not feed to ducks producing eggs for human consumption..	054771.
(iv) 10 mg/g of finished feed daily..	Psittacine birds (cockatoos, macaws, and parrots) suspected or known to be infected with psittacosis caused by <i>Chlamydia psittaci</i> sensitive to chlortetracycline..	Feed continuously for 45 d; each bird should consume daily an amount of medicated feed equal to one fifth of its body weight.. See paragraph (d)(3) of this section. ..	054771.

(6) It is used as a free-choice, loose mineral Type C feed as follows:

(i) *Specifications*.

Ingredient	Percent	International Feed No.
Dicalcium Phosphate	46.20	6–26–335
Sodium Chloride (Salt)	15.00	6–04–152
Magnesium Oxide	10.67	6–02–756
Cottonseed Meal	10.00	5–01–625
Trace Mineral/Vitamin Premix ¹	3.80	
Calcium Carbonate	3.50	6–01–069
Dried Cane Molasses	3.00	4–04–695
Potassium Chloride	2.00	6–03–755
Mineral Oil	2.00	8–03–123
Iron Oxide	0.50	6–02–431
Chlortetracycline Type A medicated article (90 gram/lb)	3.33	

¹Content of vitamin and trace mineral premixes may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

(ii) *Amount*. 6,000 grams per ton.

(iii) *Indications for use*. Beef and non-lactating dairy cattle: As an aid in the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.

(iv) *Limitations*. Feed continuously on a free-choice basis at a rate of 0.5 to 2.0 mg chlortetracycline per pound of body weight per day.

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

(7) Chlortetracycline may also be used in combination with:

(i) Amprolium and ethopabate as in § 558.58.

(ii) Bacitracin methylene disalicylate as in § 558.76.

(iii) Clopidol as in § 558.175.

(iv) Decoquinatate as in § 558.195.

- (v) Hygromycin B as in § 558.274.
- (vi) Laidlomycin as in § 558.305.
- (vii) Lasalocid as in § 558.311.
- (viii) Monensin as in § 558.355.
- (ix) Robenidine as in § 558.515.
- (x) Salinomycin as in § 558.550.
- (xi) Tiamulin as in § 558.600.

[41 FR 10995, Mar. 15, 1976]

EDITORIAL NOTE: FOR FEDERAL REGISTER citations affecting § 558.128, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 558.140 Chlortetracycline and sulfamethazine.

(a) *Approvals.* Type A medicated articles: 35 grams of chlortetracycline per pound with 7.7 percent (35 grams) of sulfamethazine to Nos. 054771 and 048164 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See §§ 556.150 and 556.670 of this chapter.

(c) It is used in feed for beef cattle as follows:

(1) *Amount per head per day.* Chlortetracycline, 350 milligrams plus sulfamethazine, 350 milligrams.

(2) *Indications for use.* Aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.

(3) *Limitations.* Feed for 28 days, withdraw 7 days prior to slaughter. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

[61 FR 35954, July 9, 1996, as amended at 64 FR 15684, Apr. 1, 1999; 66 FR 46706, Sept. 7, 2001; 68 FR 22294, Apr. 28, 2003; 69 FR 62407, Oct. 26, 2004; 79 FR 13544, Mar. 11, 2014]

§ 558.145 Chlortetracycline, procaine penicillin, and sulfamethazine.

(a) *Approvals.* Type A medicated articles: (1) 20 grams of chlortetracycline per pound, 4.4 percent (20 grams) of sulfamethazine, and procaine penicillin equivalent in activity to 10 grams of penicillin per pound to 054771 in § 510.600(c) of this chapter.

(2) 40 grams of chlortetracycline per pound, 8.8 percent of sulfamethazine, and penicillin procaine equivalent in activity to 20 grams of penicillin per pound to Nos. 048164 and 054771 in § 510.600(c) of this chapter.

(b) *Specifications.* (1) The antibiotic substance refers to the antibiotic or feed-grade antibiotic.

(2) The antibiotic activities are expressed in terms of the appropriate antibiotic standards.

(3) Type C medicated feed contains in each ton, 100 grams of chlortetracycline, 50 grams of penicillin as procaine penicillin, and 100 grams of sulfamethazine.

(c) *Related tolerances.* See §§ 556.150, 556.510, and 556.670 of this chapter.

(d) *Conditions of use.* (1) It is administered to swine in a Type C feed for reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibronic dysentery); prevention of these diseases during times of stress; maintenance of weight gains in the presence of atrophic rhinitis; growth promotion and increased feed efficiency in swine weighing up to 75 pounds.

(2) Withdraw 15 days prior to slaughter.

[40 FR 13959, Mar. 27, 1975, as amended at 43 FR 19385, May 5, 1978; 47 FR 39814, Sept. 10, 1982; 48 FR 30615, July 5, 1983; 51 FR 7396, Mar. 3, 1986; 52 FR 2684, Jan. 26, 1987; 56 FR 14019, Apr. 5, 1991; 61 FR 18082, Apr. 24, 1996; 62 FR 14300, Mar. 26, 1997; 63 FR 27845, May 21, 1998; 66 FR 46706, Sept. 7, 2001; 68 FR 47237, Aug. 8, 2003; 69 FR 62407, Oct. 26, 2004; 79 FR 13544, Mar. 11, 2014]

§ 558.175 Clopidol.

(a) *Specifications.* Type A medicated article containing 25 percent clopidol.

(b) *Approvals.* See No. 016592 in § 510.600(c) of this chapter.

(c) [Reserved]

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