

§ 558.625

21 CFR Ch. I (4–1–01 Edition)

by or upon a lawful veterinary feed directive (VFD) issued by a licensed veterinarian in the course of the veterinarian's professional practice. VFD's for tilmicosin phosphate shall not be refilled.

[61 FR 68148, Dec. 27, 1996; 62 FR 15391, Apr. 1, 1997, as amended at 64 FR 13679, Mar. 22, 1999; 65 FR 76930, Dec. 8, 2000]

§ 558.625 Tylosin.

(a) *Specifications.* Tylosin is the antibiotic substance produced by growth of *Streptomyces fradiae* or the same antibiotic substance produced by any other means. Tylosin, present as the phosphate salt, conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled "Determination of Factor Content in Tylosin by High Performance Liquid Chromatography," which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001.

(b) *Approvals.* Type A medicated article levels of tylosin granted to firms as sponsor(s) and identified by drug listing numbers in §510.600(c) of this chapter for the specific usage indicated in paragraph (f) of this section.

(1) To 000986: 10, 40, 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(2) To 051359: 1, 2, 4, 5, 8, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(3) To 043733: 20 and 40 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(4) [Reserved]

(5) To 017800: 0.4, 0.8, 1, and 8 grams per pound, paragraph (f)(1)(vi)(a) of this section; 10 and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(6)–(7) [Reserved]

(8) To 035369: 4 and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section; 10 grams per pound, para-

graphs (f)(1) (i) through (vi) of this section.

(9) To 043727: 4 grams per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(10) To 017519: 0.4, 0.8, and 1.6 grams per pound, paragraph (f)(1)(vi)(a) of this section; 20, 40, and 100 grams per pound, paragraphs (f)(1)(i) through (f)(1)(vi) of this section.

(11) [Reserved]

(12) To 021930: 2 grams per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(13) To 035393: 0.4 and 2 grams per pound; paragraph (f)(1)(vi)(a) of this section.

(14) To 016968: 1, 2, 4, 8, and 10 grams per pound, paragraphs (f)(1) (i), (iii), (iv), and (vi) of this section; 20, 25, 40, and 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(15) [Reserved]

(16) To 049768: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(17) To 021780: 0.8 gram per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(18) [Reserved]

(19) To 033999: 10 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(20)–(21) [Reserved]

(22) To 026282: 10 grams per pound; paragraph (f)(1)(vi)(a) of this section.

(23)–(24) [Reserved]

(25) To 000069: 4, 8, and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section; 20 and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(26)–(30) [Reserved]

(31) To 029341: 5 grams per pound; paragraph (f)(1)(vi)(a) of this section.

(32) [Reserved]

(33) To 034936: 0.8 and 2 grams per pound, paragraph (f)(1)(vi)(a) of this section; 4, 8, and 10 grams per pound, paragraphs (f)(1)(i), (iii), (iv), and (vi) of this section; 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section; 100 grams per pound, paragraphs

(f)(1) (i), (ii), (iii), (iv), and (vi) of this section.

(34) To 028260: 0.8 gram per pound, paragraph (f)(1)(vi)(a) of this section.

(35) To 039741: 2 and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(36)–(37) [Reserved]

(38) To 053740: 1 gram per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(39) To 061133: 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(40) To 035955: 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(41) [Reserved]

(42) To 010439: 0.4, 0.5, and 2 grams per pound, paragraph (f)(1)(vi) (a) of this section; 5, 10, 20, and 40 grams per pound, paragraph (f)(1)(i) through (vi) of this section.

(43)–(44) [Reserved]

(45) To 017139: 4 and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(46)–(47) [Reserved]

(48) To 017790: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(49)–(51) [Reserved]

(52) To 017519: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(53) [Reserved]

(54) To 046573: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(55)–(56) [Reserved]

(57) To 028459: 0.4 and 10 grams per pound; paragraph (f)(1)(vi)(a) of this section.

(58)–(62) [Reserved]

(63) To 046987: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(64)–(65) [Reserved]

(66) To 024174: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(67) To 027190: 2 grams per pound; paragraph (f)(1)(vi)(a) of this section.

(68) To 017473: 10 and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(69)–(72) [Reserved]

(73) To 035098: 0.33 and 0.67 gram per pound, paragraph (f)(1)(vi)(a) of this section; 0.8, 1, 2, and 10 grams per

pound, paragraphs (f)(1) (i) and (vi) (a), (b) and (d) of this section; 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(74)–(76) [Reserved]

(77) To 050639: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(78) To 050972: 0.36, 0.4, 0.72, and 0.8 gram per pound, paragraph (f)(1)(vi)(a) of this section; 1 gram per pound, paragraphs (f)(1)(vi) (a), (b), and (d) of this section.

(79) To 012286: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(80) To 049685: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(81)–(82) [Reserved]

(83) To 046573: 5-, 10-, 20-, and 40-grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(84) [Reserved]

(85) To 047126: 10, 40, and 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(86)–(88) [Reserved]

(89) To 053389: 5, 10, 20, and 40 grams per pound, paragraph (f)(1) (i) through (vi) of this section.

(c) *Special considerations.* (1) Type C medicated feeds for cattle may be manufactured from tylosin liquid Type B medicated feeds which have a pH between 4.5 and 6.0 and which bear appropriate mixing directions as follows:

(i) For liquid Type B feeds stored in recirculating tank systems: Recirculate immediately prior to use for no fewer 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.

(ii) For liquid Type B feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for no fewer 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.

(2) Tylosin liquid Type B medicated feeds used to make Type C medicated feeds for cattle may be manufactured from tylosin Type A medicated articles according to the following mixing directions:

(i) Presolubilize tylosin in 50 percent urea for approximately 1 hour prior to adding any feed components or other active ingredients.

(ii) Maintain a pH between 4.5 and 6.0.

(3) Tylosin liquid Type B medicated feeds must bear an expiration date of 8 weeks after the date of manufacture.

(d) [Reserved]

(e) *Related tolerances.* See § 556.740 of this chapter.

(f) *Conditions of use.* (1) It is used in animal feeds as follows:

(i) *For beef cattle—(a) Amount per ton.* 8-10 grams.

(b) *Indications for use.* For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*.

(c) *Limitations.* As tylosin phosphate; each animal must receive not more than 90 milligrams per day and not less than 60 milligrams per day; feed continuously as sole ration.

(ii) *Broiler chickens—(a) Amount per ton.* Tylosin, 800-1000 grams.

(b) *Indications for use.* To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum*.

(c) *Limitations.* As tylosin phosphate; withdraw 5 days before slaughter; administer in feed to chickens 0 to 5 days of age, follow with second administration in feed for 24-48 hours at 3 to 5 weeks of age.

(iii) *Chickens—(a) Amount per ton.* Tylosin, 4-50 grams.

(1) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(2) *Limitations.* As tylosin phosphate.

(iv) *Laying chickens—(a) Amount per ton.* Tylosin, 20-50 grams.

(b) *Indications for use.* For improved feed efficiency.

(c) *Limitations.* As tylosin phosphate.

(v) *Replacement chickens—(a) Amount per ton.* Tylosin, 1,000 grams.

(b) *Indications for use.* To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum*.

(c) *Limitations.* As tylosin phosphate; withdraw 5 days before slaughter; administer in feed to chickens 0 to 5 days of age, follow with second administration in feed for 24 to 48 hours at 3 to 5 weeks of age.

(vi) *Swine—(a) Amount per ton.* Tylosin, 10-100 grams.

(1) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(2) *Limitations.* As tylosin phosphate; continuous use as follows: *Grams per ton:* 20-100, prestarter or starter; 20-40, grower; 10-20, finisher.

(b) *Amount per ton.* Tylosin, 40-100 grams.

(1) *Indications for use.* Prevention of swine dysentery (vibrionic).

(2) *Limitations.* Use 100 grams per ton for at least 3 weeks followed by 40 grams per ton until market weight; as tylosin phosphate.

(c) *Amount per ton.* Tylosin, 40-100 grams.

(1) *Indications for use.* Treatment and control of swine dysentery (vibrionic).

(2) *Limitations.* Administer in feed as tylosin phosphate after treatment with tylosin in drinking water as tylosin base; 0.25 gram per gallon in drinking water for 3-10 days, 40-100 grams per ton in feed for 2-6 weeks.

(d) *Amount per ton.* Tylosin, 100 grams.

(1) *Indications for use.* Maintaining weight gains and feed efficiency in presence of atrophic rhinitis.

(2) *Limitations.* As tylosin phosphate.

(vi) Pyrantel tartrate in accordance with § 558.485.

(e) *Amount per ton.* Tylosin 100 grams.

(1) *Indications for use.* Prevention and/or control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*.

(2) *Limitations.* As tylosin phosphate, administer for 21 days.

(2) Tylosin may also be used in combination with:

(i) Decoquinat and monensin as in § 558.195.

(ii) Hygromycin B as in § 558.274.

(iii) Melengestrol acetate alone or in combination with certain ionophores as in § 558.342.

(iv) Monensin as in § 558.355.

(v) Narasin as in § 558.363.

(vi) Pyrantel tartrate as in § 558.485.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.625, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.