

Ingredient	International Feed No.	Percent
Potassium sulfate (0.33%)	6-06-098	0.16

*Content of vitamin/trace mineral premix 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).

- (b) *Amount per ton.* 120 grams.
- (c) *Indications for use.* For increased rate of weight gain.
- (d) *Limitations.* For free-choice feeding to pasture cattle (slaughter, stocker, and feeder). Feed a nonmedicated commercial mineral product for 6 weeks to stabilize consumption between 2.66 and 5.33 ounces per head per day. Feed continuously to provide 10- to 20-milligrams bambermycins per head per day. Each use of this free-choice Type C medicated feed must be the subject of an approved Form FDA 1900 as required by 21 CFR 510.455.
- (iv) Use free-choice Type C medicated feeds for pasture cattle (slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers) as follows:
 - (a) *Amount.* Feed continuously to provide 10 to 20 milligrams of bambermycins per head per day.
 - (b) *Indications for use.* For increased rate of weight gain.
 - (c) *Limitations.* Each use in a free-choice Type C medicated feed must be the subject of an approved new animal drug application (NADA) or supplemental NADA as required by 21 CFR 510.455.
- (5) Bambermycins may be used in combination with:
 - (i) Diclazuril as in § 558.198.
 - (ii) Halofuginone as in § 558.265.
 - (iii) Monensin as in § 558.355.
 - (iv) Narasin alone or with nicarbazin or roxarsone as in § 558.363.
 - (v) Nicarbazin as in § 558.366.

[40 FR 13959, Mar. 27, 1975]

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 on GPO Access.

§ 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 debilitated animals; feed continuously as sole ration. Do not use in complete

Food and Drug Administration, HHS

§ 558.128

feeds containing less than 15 percent crude protein.

[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]

§ 558.120 Carbarsonone (not U.S.P.).

(a) *Approvals.* Type A medicated articles: (1) 37.5 percent to 046573 in § 510.600(c) of this chapter.

(2) 25 percent carbarsonone and 5 grams per pound bacitracin (as bacitracin methylene disalicylate) to 046573 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.60 of this chapter.

(c) [Reserved]

(d) *Conditions of use.* (1) It is used for turkeys as follows:

(i) *Grams per ton.* 227 to 340.5 (0.025 to 0.0375 percent).

(a) *Indications for use.* As an aid in the prevention of blackhead.

(b) *Limitations.* Feed continuously beginning 2 weeks before blackhead is expected and continue as long as prevention is needed; withdraw 5 days before slaughter; as sole source of organic arsenic.

(ii) *Grams per ton.* 227 to 340.5 (0.025 to 0.0375 percent) carbarsonone plus 10 grams per ton bacitracin from bacitracin methylene disalicylate.

(a) *Indications for use.* As an aid in the prevention of blackhead; for increased rate of weight gain.

(b) *Limitations.* Feed continuously beginning 2 weeks before blackhead is expected and continue as long as prevention is needed; withdraw 5 days before slaughter; as sole source of organic arsenic.

(iii) *Grams per ton.* 227 to 340.5 (0.025 to 0.0375 percent) carbarsonone plus 4 to 45 grams per ton bacitracin from bacitracin zinc.

(a) *Indications for use.* As an aid in the prevention of blackhead, increased rate of weight gain, and improved feed efficiency.

(b) *Limitations.* Feed continuously as sole ration. Withdraw 5 days before slaughter. As sole source of organic arsenic; as bacitracin zinc provided by No. 046573 in § 510.600(c) of this chapter.

(2) Carbarsonone (not U.S.P.) may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Zoalene in accordance with § 558.680.

(ii) Amprolium as in § 558.55.

(iii) Bambermycins as in § 558.95.

[41 FR 10995, Mar. 15, 1976, as amended at 42 FR 18617, Apr. 8, 1977; 46 FR 46797, Sept. 22, 1981; 48 FR 2758, Jan. 21, 1983; 51 FR 7396, Mar. 3, 1986; 52 FR 2687, Jan. 26, 1987; 53 FR 20843, June 7, 1988; 57 FR 7652, Mar. 4, 1992; 61 FR 515, Jan. 8, 1996; 61 FR 18082, Apr. 24, 1996; 62 FR 61011, Nov. 14, 1997; 63 FR 27845, May 21, 1998; 66 FR 46706, Sept. 7, 2001]

§ 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. 046573, 053389, and 066104: 50 to 100 grams per pound (g/lb) of Type A medicated article.

(2) No. 017519: 50 g/lb 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.

(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: