

Food and Drug Administration, HHS

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not been shown to be more effective than 20 mg/head/day.

(iii) Used as a free-choice Type C medicated loose mineral feed for pas-

ture cattle (slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers) as follows:

(a) *Specifications.*

Ingredient	International Feed No.	Percent
Deflorinated phosphate (20.5% calcium, 18.5% phosphorus)	6-01-080	42.50
Sodium chloride (salt)	6-04-152	20.10
Calcium carbonate (38% calcium)	6-01-069	15.24
Corn distillers dried grains w/solubles	5-28-236	9.57
Magnesium oxide	6-02-756	5.15
Vitamin and trace mineral premix *	3.72
Mineral oil	1.00
Yeast (primary dehydrated yeast)	7-05-533	0.75
Bambermycins Type A article (10 g/lb)	0.60
Iron oxide	6-02-431	0.50
Magnesium sulfate (67%)	6-02-758	0.32
Selenium premix (270 mg/lb) *	0.21
Copper sulfate	6-01-720	0.18
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 cattle, and dairy and beef replacement heifers). Feed a nonmedicated commercial mineral product for 6 weeks to stabilize consumption between 2.66 and 10.66 ounces per head per day. Feed continuously to provide 10 to 40 milligrams bambermycins per head per day. Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.

(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 40 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. Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.

(5) Bambermycins may also be used in combination with:

(i) Amprolium alone or with roxarsone as in § 558.55.

(ii) Amprolium and ethopabate alone or with roxarsone as in § 558.58.

(iii) Diclazuril as in § 558.198.

(iv) Halofuginone as in § 558.265.

(v) Lasalocid alone or with roxarsone as in § 558.311.

(vi) Monensin alone or with roxarsone as in § 558.355.

(vii) Narasin alone or with nicarbazin or roxarsone as in § 558.363.

(viii) Nicarbazin as in § 558.366.

(ix) Salinomycin alone or with roxarsone as in § 558.550.

(x) Zoalene alone or with roxarsone as in § 558.680.

[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 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:

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(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 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

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swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

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§ 558.120 Carbarstone (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 carbarstone 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) carbarstone 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) carbarstone 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.