

## § 558.95

## 21 CFR Ch. I (4–1–11 Edition)

(vi) Hygromycin B alone and with penicillin as in § 558.274.

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

(viii) Monensin alone and with roxarsone as in § 558.355.

(ix) Naracin as in § 558.363.

(x) Nitarsone as in § 558.369.

(xi) Robenidine as in § 558.515.

(xii) Salinomycin alone and with roxarsone as in § 558.550.

(xiii) Zoalene alone and with arsanilic acid or roxarsone as in § 558.680.

[41 FR 10994, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.78, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at [www.fdsys.gov](http://www.fdsys.gov).

### § 558.95 Bambermycins.

(a) *Approvals.* To sponsors identified by drug labeler codes in § 510.600(c) of this chapter for use of bambermycins Type A medicated articles as bambermycins activity per pound in paragraph (d) of this section as follows:

(1) To 016592: 2, 4, and 10 grams for use as in paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) of this section.

(2) To 016592: 0.4 gram for use as in paragraph (d)(2) of this section.

(3) [Reserved]

(4) To Nos. 012286, 016968, and 017790: 0.4 and 2 grams for use as in paragraph (d)(2) and 2 grams for use as in paragraph (d)(3) of this section.

(5) To 016592: 10 grams to make 40 to 800 grams per ton Type B feed for use as in paragraph (d)(4) of this section.

(b) *Special considerations.* (1) Bambermycins liquid Type B feeds may be manufactured from dry bambermycins Type A articles. The liquid Type B feeds must have a pH of 3.8 to 7.5, moisture content of 30 to 45 percent.

(2) The expiration date for the liquid Type B feed is 8 weeks after date of manufacture. The expiration date for the dry Type C feed made from the liquid Type B feed is 1 week after date of manufacture.

(c) [Reserved]

(d) *Conditions of use—(1) Broiler chickens.* It is used as follows:

(i) *Amount per ton.* 1 to 2 grams.

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

(b) *Limitations.* Feed continuously as the sole ration.

(ii) [Reserved]

(2) *Growing-finishing swine.* It is used as follows:

(i) *Amount per ton.* 2 grams.

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

(b) *Limitations.* Feed continuously as sole ration.

(ii) *Amount per ton.* 2 to 4 grams.

(a) *Indications for use.* For increased rate of weight gain.

(b) *Limitations.* Feed continuously as sole ration.

(3) *Growing turkeys.* It is used as follows:

(i) *Amount per ton.* 1 to 2 grams.

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

(b) *Limitations.* Feed continuously as the sole ration.

(ii) *Amount per ton.* 2 grams.

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

(b) *Limitations.* Feed continuously as sole ration.

(4) *Cattle—(i) Amount per ton.* 1 to 4 grams.

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

(b) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously in a Type C medicated feed at a rate of 10 to 20 milligrams of bambermycins per head per day. Liquid Type B feeds containing bambermycins may be used in the preparation of dry complete ration Type C feeds.

(ii) *Amount per ton.* 2 to 40 grams.

(a) *Indications for use.* For increased rate of weight gain.

(b) *Limitations.* Feed continuously to pasture cattle (slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers) at a rate of 10 to 40 milligrams of bambermycins per head per day in at least 1 pound and not more than 10 pounds of Type C medicated feed. Daily bambermycins intakes in excess of 20 mg/head/day have

**Food and Drug Administration, HHS**

**§ 558.115**

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: