

(ii) *Limitations.* For use in swine feed only. Feed as the only feed for 7 consecutive days. For weaned growing and finishing swine, feed bacitracin methylene disalicylate Type C medicated feed from weaning to market weight for increased rate of weight gain and improved feed efficiency. For pregnant sows, feed bacitracin methylene disalicylate to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours. Withdraw ivermectin-containing feeds 5 days before slaughter.

[58 FR 58653, Nov. 3, 1993, as amended at 60 FR 39848, Aug. 4, 1995; 61 FR 32652, June 25, 1996; 62 FR 63271, Nov. 28, 1997; 63 FR 54353, Oct. 9, 1998; 64 FR 13342, Mar. 18, 1999]

§ 558.305 Laidlomycin propionate potassium.

(a) *Approvals.* Type A medicated articles: 50 grams per pound to 063238 in § 510.600(c) of this chapter.

(b) *Special considerations.* (1) Laidlomycin liquid Type B feeds may be manufactured from dry laidlomycin Type A articles. The liquid Type B feeds must have a pH of 6.0 to 8.0, dry matter of 62 to 75 percent, and bear appropriate mixing directions as follows:

(i) For liquid Type B feeds stored in recirculating tank systems: Recirculate immediately prior to use for no less 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 not less 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) The expiration date for the liquid Type B feed is 21 days after date of manufacture. The expiration date for the dry Type C feed made from the liquid Type B feed is 7 days after date of manufacture.

(c) [Reserved]

(d) *Conditions of use.* Used in cattle feed as follows:

(1) *Amount.* Laidlomycin propionate potassium, 5 grams per ton.

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

(ii) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously in a Type C feed at a rate of 30 to 75 milligrams per head per day.

(2) *Amount.* Laidlomycin propionate potassium, 5 to 10 grams per ton.

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

(ii) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously in a Type C feed at a rate of 30 to 150 milligrams per head per day.

(3) *Additional limitations.* (i) Do not allow horses or other equines access to feeds containing laidlomycin propionate potassium.

(ii) The safety of laidlomycin propionate potassium in unapproved species has not been established.

(iii) Not for use in animals intended for breeding.

[59 FR 18297, Apr. 18, 1994, as amended at 60 FR 53509, Oct. 16, 1995; 62 FR 9929, Mar. 5, 1997; 63 FR 27845, May 21, 1998]

§ 558.311 Lasalocid.

(a) *Specifications.* A minimum of 90 percent of lasalocid activity is derived from lasalocid A.

(b) *Approvals.* Type A medicated articles approved for sponsors identified in § 510.600(c) of this chapter for use as in paragraph (e) of this section as follows:

(1) 3.0, 3.3, 3.8, 4.0, 4.3, 4.4, 5.0, 5.1, 5.5, 5.7, 6.0, 6.3, 6.7, 7.2, 7.5, 8.0, 8.3, 10.0, 12.5, 15, 20, and 50 percent activity to No. 000004 for use as in paragraphs (e)(1)(i), (ii), (iii), (iv), and (x) of this section.

(2) 15 percent activity to No. 000069 as provided by No. 063238 for use as in paragraph (e)(1)(v) of this section.

(3) 15, 20, 33.1, and 50 percent activity to No. 063238 for use in cattle feeds as in paragraphs (e)(1)(vi), (vii), (ix), (xi), (xii), and (xv) of this section, and for use in sheep as in paragraph (e)(1)(viii) of this section.

(4) 15 percent activity to No. 063238 for use in Type C rabbit feeds as in paragraph (e)(1)(xvi) of this section and for use in ruminant free-choice Type C feeds as in paragraphs (e)(2) and (e)(3) of this section.

(5) 15 percent activity to 021930 (Type A article provided by 063238) for use in free-choice vitamin-mineral Type C cattle feeds as in paragraph (e)(1)(xi).

(6) 20 percent activity as a liquid Type A article to No. 063238 for use in cattle feeds as in paragraphs (e)(1)(vi), (e)(1)(vii), (e)(1)(ix), (e)(1)(xi), (e)(1)(xii), and (e)(3) of this section, and for use in sheep feeds as in paragraph (e)(1)(viii) of this section.

(7) 20 percent activity to No. 063238 for use as follows:

(i) Chukar partridges as in paragraph (e)(1)(xiii).

(ii) Turkeys as in paragraph (e)(1)(xiv).

(iii) Rabbits as in paragraph (e)(1)(xvi).

(c) *Related tolerance.* See § 556.347 of this chapter.

(d) *Special considerations.* (1) Type C cattle and sheep feeds may be manufactured from lasalocid liquid Type B feeds which have a pH of 4.0 to 8.0 and bear appropriate mixing directions as follows:

(i) For liquid Type B feeds stored in recirculating tank systems: Recirculate immediately prior to use for no less 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 not less 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) A positionally stable lasalocid liquid Type B feed will not be subject to the requirements for mixing directions prescribed in paragraph (d)(1) of this section provided it has a pH of 4.0 to 8.0 and contains a suspending agent(s) sufficient to maintain a viscosity of not less than 300 centipoises per second for 3 months. Form FDA 1900 must indicate the pH and centipoises per second for such lasalocid liquid Type B feed.

(3) If a manufacturer is unable to meet the requirements of paragraph (d)(1) or (2) of this section, the manufacturer may secure approval of a positionally stable liquid Type B feed

by (i) either filing a new animal drug application for the product or establishing a master file containing data to support the stability of its product; (ii) authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental new animal drug application to establish positional stability; and (iii) requesting the sponsor of an approved new animal drug application to file a supplement to provide for use of its lasalocid Type A article in the manufacture of the liquid Type B feed specified in the appropriate master file. If the data demonstrate the stability of the liquid Type B feed described in the master file, the supplement new animal drug application will be approved. Approval of the supplement will not be published in the FEDERAL REGISTER because such approval will not affect or alter conditions or use of the product in the new animal drug application or the regulation. The approval will, however, provide a basis for the individual liquid feed manufacturer to submit, and for the agency to approve, a medicated feed application under section 512(m) of the act for liquid Type B feed. A manufacturer who seeks to market a positionally unstable lasalocid liquid Type B feed with mixing directions different from the standard directions established in paragraph (d)(1) of this section may also follow this procedure.

(4) If adequate information is submitted to show that a particular liquid Type B feed containing lasalocid is stable outside the pH of 4.0 to 8.0, the pH restriction described in paragraphs (d)(1) and (2) of this section may be waived.

(5) Required label statements:

(i) For liquid Type B feed (cattle and sheep): Mix thoroughly with grain and/or roughage prior to feeding. Feeding undiluted, mixing errors, or inadequate mixing (recirculation or agitation) may result in an excess lasalocid concentration which could be fatal to cattle and sheep. Do not allow horses or other equines access to Type A articles or Type B feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid for use in unapproved species has not been established.

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(ii) For Type A articles or Type B feeds (cattle and sheep): Feeding undiluted or mixing errors may result in an excess lasalocid concentration which could be fatal to cattle and sheep. Do not allow horses or other equines access to Type A articles or Type B feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid for use in

unapproved species has not been established.

(6) Lasalocid Type A medicated articles containing lasalocid dried fermentation residue are for use in cattle and sheep feed only.

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

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 68 (0.0075 pct) to 113 (0.0125 pct).	For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> .	For broiler or fryer chickens only; feed continuously as the sole ration.	000004
(ii) 68 (0.0075 pct) to 113 (0.0125 pct).	Roxarsone 45.4 (0.005 pct).	Broiler or fryer chickens; for the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> and as an aid in the reduction of lesions due to <i>E. tenella</i> .	For broiler or fryer chickens only; feed continuously as the sole ration; as sole source of organic arsenic; withdraw 5 d before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter.	000004
	Roxarsone 45.4 plus bambermycins 1 (0.00011 pct).	For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; as an aid in the reduction of lesions due to <i>E. tenella</i> ; and for increased rate of weight gain.	For broiler chickens only; feed continuously as sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter, bambermycins provided by No. 012799.	000004
	Roxarsone 45.4 plus lincomycin 2.0.	For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; as an aid in the reduction of lesions due to <i>E. tenella</i> ; and for increased rate of weight gain and improved feed efficiency.	For broiler chickens only; feed continuously as sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter, lincomycin provided by No. 000009.	000004
	Roxarsone 45.4 plus bacitracin 10 to 25.	For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; as an aid in the reduction of lesions due to <i>E. tenella</i> ; and for increased rate of weight gain.	For broiler or fryer chickens only; feed continuously as the sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter, bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.	000004
	Roxarsone 45.4 plus bacitracin 10 or 30.	For prevention of coccidiosis caused by <i>E. tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> and <i>E. maxima</i> ; as an aid in the reduction of lesions due to <i>E. tenella</i> ; and for increased rate of weight gain (10 grams per ton) or improved feed efficiency (30 grams per ton).	For broiler chickens only; feed continuously as sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter, bacitracin zinc provided by No. 000004.	000004
	Roxarsone 45.5 plus bacitracin methylene disalicylate 50.	Prevention of coccidiosis caused by <i>Eimeria necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; reduction of lesions due to <i>E. tenella</i> ; prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other susceptible organisms.	Feed continuously as sole ration; as sole source of organic arsenic; withdraw 5 days before slaughter.	046573

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Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(iii) 68 (0.0075 pct)	Lincomycin 2 (0.00022 pct).	Broiler or fryer chickens; for the prevention of coccidiosis caused by <i>Eimeria mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> ; for increased rate of weight gain and improved feed efficiency.	For broiler and fryer chickens only; feed continuously as sole ration; withdraw 5 d before slaughter; Type C feed must be used within 4 weeks of manufacture; as lincomycin hydrochloride monohydrate.	000004
(iv) 68 (0.0075 percent).	Bacitracin 10 to 50 ..	For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency.	For broiler or fryer chickens only; feed continuously as the sole ration; withdraw 3 days before slaughter bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.	000004
(v) 68 (0.0075 pct) to 113 (0.0125 pct).	Virginiamycin 20	For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency.	For broiler and fryer chickens only; feed continuously as sole ration; do not feed to laying chickens; lasalocid sodium provided by No. 063238 in § 510.600(c) of this chapter.	063238
(vi) 10 (0.0011 pct) to 30 (0.0033 pct).	Cattle; for improved feed efficiency.	In Type C feeds; for cattle fed in confinement for slaughter only; feed continuously in complete feed to provide not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day.	000004
	Oxytetracycline 7.5 ..	Cattle: for improved feed efficiency and reduction of incidence and severity of liver abscesses.	In Type C feeds, for beef cattle fed in confinement for slaughter; feed continuously at 100 to 360 mg/head/day lasalocid and 75 mg/head/day oxytetracycline. As monoalkyl (C ₈ –C ₁₈) trimethyl ammonium oxytetracycline.	000004
(vii) 25 (0.0027 pct) to 30 (0.0033 pct).	Cattle; for improved feed efficiency and increased rate of weight gain.	In Type C feeds; for cattle fed in confinement for slaughter only; feed continuously in complete feed to provide not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day.	000004
	Oxytetracycline 7.5 ..	Cattle: for improved feed efficiency, increased rate of weight gain, and reduction of incidence and severity of liver abscesses.	In Type C feeds, for beef cattle fed in confinement for slaughter; feed continuously at 250 to 360 mg/head/day lasalocid and 75 mg/head/day oxytetracycline. As monoalkyl (C ₈ –C ₁₈) trimethyl ammonium oxytetracycline.	000004
(viii) 20 (0.0022 pct) to 30 (0.0033 pct).	Sheep; for the prevention of coccidiosis caused by <i>Eimeria ovina</i> , <i>E. crandallis</i> , <i>E. ovinoidalis</i> (<i>E. ninakohlyakimovae</i>), <i>E. parva</i> , and <i>E. intricata</i> .	In Type C feeds; for sheep maintained in confinement; feed continuously in complete feed to provide not less than 15 mg nor more than 70 mg of lasalocid sodium activity per head per day depending on body weight.	000004
(ix)	Cattle; for increased rate of weight gain.	For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) only; feed continuously at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day when on pasture; the drug must be contained in at least 1 pound of feed.	000004

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(x) 68 (0.0075 pct) to 113 (0.0125 pct).	Bacitracin 4 to 50	Broiler chickens; for prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; and for improved feed efficiency.	For broiler chickens only; feed continuously as the sole ration; withdraw 3 days before slaughter; bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.	000004
(xi)	Cattle; for increased rate of weight gain.	For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) only; feed continuously on a free-choice basis at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day. Each use in a free-choice Type C feed must be the subject of an approved NADA or supplemental NADA as provided in § 510.455 of this chapter.	000004, 021930
(xii)	Cattle; for control of coccidiosis caused by <i>Eimeria bovis</i> and <i>Eimeria zuernii</i> .	For cattle; hand feed at a rate of 1 mg of lasalocid per 2.2 pounds body weight per day to cattle weighing up to 800 pounds with a maximum of 360 mg of lasalocid per head per day.	000004
(xiii) 113 (0.0125 pct).	Chukar partridges; for prevention of coccidiosis caused by <i>Eimeria legionensis</i> .	Feed continuously as sole ration up to 8 weeks of age.	000004
(xiv) 68 (0.0075 pct) to 113 (0.0125 pct).	Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoeides</i> .	Feed continuously as sole ration	000004
.....	Bacitracin 4 to 50	Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoeides</i> ; for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration	063238
.....	Virginiamycin 10 to 20.	Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoeides</i> , and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. As lasalocid sodium provided by 063238 and virginiamycin provided by 000069..	063238
(xv)	Replacement calves; for control of coccidiosis caused by <i>E. bovis</i> and <i>E. zuernii</i> ..	In milk replacer powder; hand feed at a rate of 1 mg of lasalocid per 2.2 lb body weight per day; include on labeling warning: "A withdrawal period has not been established for lasalocid in pre-ruminating calves. Do not use in calves to be processed for veal".	000004
(xvi) 113 (0.0125 pct).	Rabbits; for prevention of coccidiosis caused by <i>Eimeria stiedae</i> .	Feed continuously as sole ration up to 6 1/2 weeks of age.	000004

(2) It is used as a free-choice mineral Type C feed as follows:
 (i) *Specifications.*

Ingredient	Per-cent	Inter-national feed No.
Defluorinated Phosphate (20.5 percent Calcium, 18.5 percent Phosphorus)	35.9	6-01-080
Sodium Chloride (Salt)	20.0	6-04-152
Calcium Carbonate (38 percent Calcium)	18.0	6-01-069
Cottonseed Meal	10.0	5-01-621

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Ingredient	Per-cent	Inter-national feed No.
Potassium Chloride	3.0	6-03-755
Selenium Premix (0.02 percent Selenium) ¹	3.0
Dried Cane Molasses	2.5	4-04-695
Magnesium Sulfate	1.7	6-02-758
Vitamin Premix ¹	1.4
Magnesium Oxide	1.2	6-02-756
Potassium Sulfate	1.2	6-06-098
Trace Mineral Premix ¹	1.04
Bovatec Premix (68 grams per pound) ...	1.06

¹ Content of the vitamin and trace mineral premixes may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. The amount of selenium and ethylenediamine dihydroiodide (EDDI) must comply with published regulations. For selenium (21 CFR 573.920): up to 120 parts per million in a mixture for free-choice feeding at a rate not to exceed an intake of 3 milligrams per head per day.

Ingredient	Percent	International feed No.
Cane Molasses	55.167	4-13-241
Condensed Molasses Fermentation Solubles	24.0	N/A
50% Urea Solution (23% N)	12.0	N/A
Ammonium Polyphosphate Solution	1.0	6-08-42
Phosphoric Acid (54%)	3.0	6-03-707
Xanthan Gum	0.05	8-15-818
Water	4.0	N/A
Trace Mineral Mix ¹	0.5	N/A
Vitamin Premix ¹	0.2	N/A
Bovatec Liquid 20 (90.8 gm/lb) ²	0.083	N/A

¹ Content of vitamin and trace mineral premixes may be varied. However, they should be comparable to those used for other free-choice liquid feeds. Formulation modifications require FDA approval prior to marketing. The amount of selenium and ethylenediamine dihydroiodide (EDDI) must comply with published regulations (for selenium see 21 CFR 573.920; for EDDI see 51 FR 11483, April 3, 1986).

² To provide 150 gm lasalocid per ton, use 1.652 lb (0.083%) of Bovatec Liquid 20 (90.8 gm/lb). If dry Bovatec-68 (68 gm/lb) is used, use 2.206 lbs per ton (0.111%), replacing molasses.

(ii) *Amount.* 150 grams per ton (.017 percent).

(iii) *Indications for use.* Cattle: for increased rate of weight gain.

(iv) *Limitations.* For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers). Feed continuously on a free-choice basis at a rate of 60 to 200 milligrams lasalocid per head per day. Each use of this free-choice liquid Type C feed must be the subject of an approved FD-1900 as in § 510.455 of this chapter.

(v) *Sponsor.* See No. 063238 in § 510.600(c) of this chapter.

(4) *Additional combinations.* Lasalocid may be used in accordance with the provisions of this section in combination as follows:

(i) Melengestrol acetate alone or in combination with tylosin in accordance with § 558.342.

(ii) *Amount.* 1,440 grams per ton (0.16 percent).

(iii) *Indications for use.* Cattle, for increased rate of weight gain.

(iv) *Limitations.* For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers); feed continuously on a free-choice basis at a rate of 60 to 200 milligrams lasalocid per head per day; each use of this Type C free-choice feed must be the subject of an approved FD-1900 as provided in § 510.455 of this chapter.

(v) *Sponsor.* See No. 063238 in § 510.600(c) of this chapter.

(3) It is used as a ruminant free-choice liquid Type C feed as follows:

(i) *Specifications.*

(ii) Bambermycins as in § 558.95 of this chapter.

[41 FR 44382, Oct. 8, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.311, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 558.315 Levamisole hydrochloride (equivalent).

(a) *Approvals.* Type A medicated articles: 227 grams per pound to 043781 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.350 of this chapter.

(c) *Conditions of use.* It is used in Type C medicated feed as follows:

(1) *Cattle*—(i) *Amount per pound.* 0.36–3.6 grams (0.08–0.8 percent).

(ii) *Indications for use.* Treatment of the following gastrointestinal worms and lung worm infections; stomach worms (*Haemonchus*, *Trichostrongylus*,