

§ 558.315

21 CFR Ch. I (4-1-01 Edition)

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*,

Ostertagia), intestinal worms (*Trichostrongylus Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*), and lungworms (*Dictyocaulus*).

(iii) *Limitations*. Administer medicated feed mixed thoroughly in one half the usual amount of morning feed; the medicated feed mix should be consumed within 6 hours; when medicated feed is consumed resume normal feeding; medicated feed is to be fed at the rate of 0.36 gram of levamisole hydrochloride (equivalent) per 100 lb. of body weight; conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment; do not slaughter for food within 48 hours of treatment; consult veterinarian before using in severely debilitated animals; do not administer to dairy animals of breeding age; for use in pelleted or meal feeds only; the label shall bear the caution, "Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully."

(2) *Swine*—(i) *Amount per pound*. 0.36 grams (0.08 percent).

(ii) *Indications for use*. Treatment of the following nematode infections: large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum* spp.), lungworms (*Metastrongylus* spp.), intestinal threadworms (*Strongyloides ransomi*), swine kidney worms (*Stephanurus dentatus*).

(iii) *Limitations*. It is recommended that regular feed be withheld overnight and worming feed administered the following morning; dilute supplement with nonmedicated feed as directed; feed the equivalent of 1 lb. of 0.08 percent worming feed per 100 lbs. of body weight of pigs to be treated; may be fed as sole feed or thoroughly mixed with 1 to 2 parts of regular feed prior to feeding; when medicated feed is consumed, resume normal feeding. Pigs maintained under conditions of constant worm exposure may require retreatment within 4 to 5 weeks after the first treatment due to reinfection; do not slaughter for food within 72 hours of treatment; the label shall bear the caution, "Excessive salivation or muzzle foam may be observed. This reaction is

occasionally seen and will disappear in a short time after medication. If pigs are infected with mature lungworms, coughing and vomiting may be observed soon after medicated feed is consumed. This reaction is due to the expulsion of worms from the lungs and will be over in several hours."

[40 FR 13959, Mar. 27, 1975, as amended at 43 FR 11176, Mar. 17, 1978; 43 FR 39351, Sept. 5, 1978; 43 FR 16013, Mar. 16, 1979; 51 FR 7398, Mar. 3, 1986]

§ 558.325 Lincomycin.

(a) *Approvals*. Type A articles and Type B feeds approved for sponsors in § 510.600(c) of this chapter for specific uses as in paragraph (c) of this section as follows:

(1) No. 000009: (i) 4 grams per pound as in paragraphs (c) (1) and (3) of this section.

(ii) 20 grams per pound as in paragraphs (c) (1) through (3) of this section.

(iii) 50 grams per pound as in paragraphs (c) (1) and (2) of this section.

(iv) 10 grams per pound as in paragraphs (c)(1) and (2) (i) through (iv) of this section.

(2)–(4) [Reserved]

(5) No. 043733 for 8 and 20 grams per pound as in paragraphs (c)(2) (i) through (iii) of this section.

(6)–(12) [Reserved]

(13) No. 017800 for 2.5 and 8 grams per pound as in paragraphs (c)(2) (i) through (iv) of this section.

(14)–(15) [Reserved]

(b) *Related tolerances in edible products*. See § 556.360 of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Broilers*:

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

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

(b) *Limitations*. As lincomycin hydrochloride monohydrate.

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

(a) *Indications for use*. For control of necrotic enteritis caused by *Clostridium* spp. or other susceptible organisms.

(b) *Limitations*. As lincomycin hydrochloride monohydrate.

(2) *Swine*—(i) *Amount per ton*. 40 grams.

(a) *Indications for use*. For control of swine dysentery.