

Food and Drug Administration, HHS

§ 556.1

556.275 Fenbendazole.
556.277 Fenprostalene.
556.283 Florfenicol.
556.286 Flunixin.
556.290 Furazolidone.
556.300 Gentamicin sulfate.
556.304 Gonadotropin.
556.308 Halofuginone hydrobromide.
556.310 Haloxon.
556.320 Hydrocortisone.
556.330 Hygromycin B.
556.344 Ivermectin.
556.346 Laidlomycin.
556.347 Lasalocid.
556.350 Levamisole hydrochloride.
556.360 Lincomycin.
556.375 Maduramicin ammonium.
556.380 Melengestrol acetate.
556.390 Methylparaben.
556.400 Methylprednisolone.
556.410 Metoserpate hydrochloride.
556.420 Monensin.
556.425 Morantel tartrate.
556.426 Moxidectin.
556.428 Narasin.
556.430 Neomycin.
556.440 Nequinat.
556.445 Nicarbazine.
556.460 Novobiocin.
556.470 Nystatin.
556.480 Oleandomycin.
556.490 Ormetoprim.
556.495 Oxfendazole.
556.500 Oxytetracycline.
556.510 Penicillin.
556.513 Piperazine.
556.515 Pirlimycin.
556.520 Prednisolone.
556.530 Prednisone.
556.540 Progesterone.
556.550 Propylparaben.
556.560 Pyrantel tartrate.
556.570 Ractopamine.
556.580 Robenidine hydrochloride.
556.590 Salicylic acid.
556.592 Salinomycin.
556.597 Semduramicin.
556.600 Spectinomycin.
556.610 Streptomycin.
556.620 Sulfabromomethazine sodium.
556.625 Sodium sulfachloropyrazine
monohydrate.
556.630 Sulfachlorpyridazine.
556.640 Sulfadimethoxine.
556.650 Sulfathoxypridazine.
556.660 Sulfamerazine.
556.670 Sulfamethazine.
556.680 Sulfanitran.
556.685 Sulfaquinoxaline.
556.690 Sulfathiazole.
556.700 Sulfomyxin.
556.710 Testosterone propionate.
556.720 Tetracycline.
556.730 Thiabendazole.
556.735 Tilmicosin.
556.738 Tiamulin.
556.739 Trenbolone.

556.740 Tylosin.
556.741 Tripelennamine.
556.745 Tulathromycin.
556.750 Virginiamycin.
556.760 Zeranol.
556.765 Zilpaterol.
556.770 Zoalene.

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SOURCE: 40 FR 13942, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 556.1 General considerations; tolerances for residues of new animal drugs in food.

(a) Tolerances established in this part are based upon residues of drugs in edible products of food-producing animals treated with such drugs. Consideration of an appropriate tolerance for a drug shall result in a conclusion either that:

(1) Finite residues will be present in the edible products—in which case a finite tolerance is required; or

(2) It is not possible to determine whether finite residues will be incurred but there is reasonable expectation that they may be present—in which case a tolerance for negligible residue is required; or

(3) The drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, has been shown to induce cancer in man or animal; however, such drug will not adversely affect the animals for which it is intended, and no residue of such drug will be found by prescribed methods of analysis in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal—in which case the accepted method of analysis shall be published or cited, if previously published and available elsewhere, in this part; or

(4) It may or may not be possible to determine whether finite residues will be incurred but there is no reasonable expectation that they may be present—in which case the establishment of a tolerance is not required; or

(5) The drug is such that it may be metabolized and/or assimilated in such form that any possible residue would

§ 556.20

be indistinguishable from normal tissue constituents—in which case the establishment of a tolerance is not required.

(b) No tolerance established pursuant to paragraph (a)(1) of this section will be set at any level higher than that reflected by the permitted use of the drug.

(c) Any tolerance required pursuant to this section will, in addition to the toxicological considerations, be conditioned on the availability of a practicable analytical method to determine the quantity of residue. Such method must be sensitive to and reliable at the established tolerance level or, in certain instances, may be sensitive at a higher level where such level is also deemed satisfactory and safe in light of the toxicity of the drug residue and of the unlikelihood of such residue's exceeding the tolerance.

Subpart B—Specific Tolerances for Residues of New Animal Drugs

§ 556.20 2-Acetylamino-5-nitrothiazole.

A tolerance of 0.1 part per million is established for negligible residues of 2-acetylamino-5-nitrothiazole in the edible tissues of turkeys.

§ 556.30 Aklomide.

Tolerances are established for combined residues of aklomide (2-chloro-4-nitrobenzamide) and its metabolite (4-amino-2-chlorobenzamide) in uncooked edible tissues of chickens as follows:

(a) 4.5 parts per million in liver and muscle.

(b) 3 parts per million in skin with fat.

§ 556.34 Albendazole.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of albendazole is 5 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*. A tolerance is established for albendazole 2-aminosulfone (marker residue) in liver (target tissue) of 0.2 part per million and in muscle of 0.05 part per million.

(2) *Sheep*. A tolerance is established for albendazole 2-aminosulfone (marker residue) in liver (target tissue) of 0.25

21 CFR Ch. I (4–1–07 Edition)

part per million and in muscle of 0.05 part per million.

[64 FR 1504, Jan. 11, 1999]

§ 556.36 Altrenogest.

(a) *Acceptable Daily Intake (ADI)*. The ADI for total residues of altrenogest is 0.04 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Swine*—(i) *Liver (the target tissue)*. The tolerance for altrenogest (the marker residue) is 4 parts per billion (ppb).

(ii) *Muscle*. The tolerance for altrenogest (the marker residue) is 1 ppb.

(2) [Reserved]

[68 FR 62007, Oct. 31, 2003]

§ 556.38 Amoxicillin.

A tolerance of 0.01 part per million is established for negligible residues of amoxicillin in milk and in the uncooked edible tissues of cattle.

[49 FR 45422, Nov. 16, 1984]

§ 556.40 Ampicillin.

A tolerance of 0.01 p/m is established for negligible residues of ampicillin in the uncooked edible tissues of swine and cattle and in milk.

§ 556.50 Amprolium.

Tolerances are established as follows for residues of amprolium (1-(4-amino-2-*n*-propyl-5-pyrimidinylmethyl)-2-picolinium chloride hydrochloride):

(a) In the edible tissues and in eggs of chickens and turkeys:

(1) 1 part per million in uncooked liver and kidney.

(2) 0.5 part per million in uncooked muscle tissue.

(3) In eggs:

(i) 8 parts per million in egg yolks.

(ii) 4 parts per million in whole eggs.

(b) In the edible tissues of calves:

(1) 2.0 parts per million in uncooked fat.

(2) 0.5 part per million in uncooked muscle tissue, liver, and kidney.

(c) In the edible tissues of pheasants:

(1) 1 part per million in uncooked liver.