

Subpart E—Safe Levels for Extralabel Use of Drugs in Animals and Drugs Prohibited From Extralabel Use in Animals

§ 530.40 Safe levels and availability of analytical methods.

(a) In accordance with § 530.22, the following safe levels for extralabel use of an approved animal drug or human drug have been established:

[Reserved]

(b) In accordance with § 530.22, the following analytical methods have been accepted by FDA:

[Reserved]

§ 530.41 Drugs prohibited for extralabel use in animals.

(a) The following drugs, families of drugs, and substances are prohibited for extralabel animal and human drug uses in food-producing animals.

- (1) Chloramphenicol;
- (2) Clenbuterol;
- (3) Diethylstilbestrol (DES);
- (4) Dimetridazole;
- (5) Iprnidazole;
- (6) Other nitroimidazoles;
- (7) Furazolidone (except for approved topical use);
- (8) Nitrofurazone (except for approved topical use);
- (9) Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine);
- (10) Fluoroquinolones; and
- (11) Glycopeptides.

(b) The following drugs, families of drugs, and substances are prohibited for extralabel animal and human drug uses in nonfood-producing animals:

[Reserved]

[62 FR 27947, May 22, 1997]

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

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- 556.20 2-Acetylamino-5-nitrothiazole.
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- 556.38 Amoxicillin.
- 556.40 Ampicillin.
- 556.50 Amprolium.
- 556.52 Apramycin.
- 556.60 Arsenic.
- 556.70 Bacitracin.
- 556.90 Buquinolate.
- 556.100 Carbadox.
- 556.110 Carbomycin.
- 556.113 Ceftiofur.
- 556.115 Cephapirin.
- 556.120 Chlorhexidine.
- 556.140 Chlorobutanol.
- 556.150 Chlortetracycline.
- 556.160 Clopidol.
- 556.163 Clorsulon.
- 556.165 Cloxacillin.
- 556.167 Colistimethate.
- 556.170 Decoquinatate.
- 556.175 Diclazuril.
- 556.180 Dichlorvos.
- 556.200 Dihydrostreptomycin.
- 556.220 3,5-Dinitrobenzamide.
- 556.225 Doramectin.
- 556.227 Eprinomectin.
- 556.228 Enrofloxacin.
- 556.230 Erythromycin.
- 556.240 Estradiol and related esters.
- 556.260 Ethopabate.
- 556.270 Ethylenediamine.
- 556.273 Famphur.
- 556.275 Fenbendazole.
- 556.277 Fenprostalene.
- 556.283 Florfenicol.
- 556.286 Flunixin meglumine.
- 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.
- 556.347 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 Nequinatate.
- 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.
556.594	Sarafloxacin.
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	Sulfaethoxypyridazine.
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.
556.750	Virginiamycin.
556.760	Zeranol.
556.770	Zoalene.

AUTHORITY: 21 U.S.C. 342, 360b, 371.

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 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-