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DEPARTMENT OF GRAIN SCIENCE AND INDUSTRY

Medicated Feed Additives for Swine

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Medicated feeds are instrumental in maintaining animal health and promoting growth and feed efficiency. However, it is important that medicated feeds be properly manufactured and withdrawal times be observed. If label instructions are not followed, animal health can be adversely affected and may result in illegal tissue residues.

The purpose of this bulletin is to explain the regulations regarding the use of medicated feed additives and to provide a list of approved drugs and drug combinations, use levels, and indications for use of medicated feed additives for swine.

Definitions

The regulations pertaining to the use of medicated feed additives are found in the Code of Federal Regulations (CFR), Title 21, Part 558. The Federal Food, Drug & Cosmetic Act provides the legal authority for these regulations. The following definitions are necessary in order to understand the regulations regarding the use of medicated feed additives:

Medicated feed — Any manufactured or mixed feed that contains drug ingredients intended to promote growth or feed efficiency or to cure, mitigate, prevent, or treat diseases of animals other than man.

Category I drug — Drugs that require no withdrawal period at their lowest use level for all approved species.

Category II drug — Drugs that require a withdrawal period at the lowest use level for at least one of the approved species.

Type A medicated article — The most concentrated form of a medicated feed additive. It usually consists of a drug source and a carrier ingredient. It can be used in the manufacturing of another Type A medicated article or a Type B or C medicated feed.

Type B medicated feed — A medicated feed containing an animal drug and a substantial amount of nutrients including vitamins, minerals, and other nutritional ingredients. Nutritional ingredients must make up at least 25 percent of the feed by weight. It can be diluted to manufacture other Type B medicated feeds or Type C medicated feeds.

Type C medicated feed — A medicated feed that is intended to be a complete feed. It can be fed as the sole ration, top-dressed, or free-choice. It is manufactured by diluting a Type A medicated article or a Type B or C medicated feed.

Veterinary Feed Directive (VFD) medicated feed —

Historically, all drugs for use in medicated feed were made available on an over-the-counter (OTC) basis. Recently, the Veterinary Feed Directive (VFD 1997) category was created by Congress. VFD drugs are available in Type A medicated feed articles, Type B medicated feed, and Type C medicated feed. The Food and Drug Administration's Center of Veterinary Medicine (CVM) determines whether a product is approved as a VFD drug or as an OTC drug (FDA Veterinarian 1997).

CVM policy is that all **new** antimicrobials for therapeutic use in feed will be approved as VFD drugs. VFD-medicated feed requires that a veterinarian, under a valid veterinarian-client relationship, examine and diagnose animal conditions and determine that the use of a VFD-medicated feed is necessary. The veterinarian then issues a VFD by filling out a form supplied by the drug sponsor. The producer then presents this form to the feed supplier who will manufacture and distribute the feed in accordance with the VFD. VFD feed can only be fed in a manner consistent with the FDA

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conditions of approval, and extralabel use is strictly prohibited. VFD feed may not be distributed without a signed VFD form. The veterinarian, producer, and company supplying the VFD feed must all retain copies of the signed VFD form.

Registered vs. Nonregistered Feed Mills

Any feed manufacturer that uses a Category II, Type A medicated feed article must be registered with the FDA as a drug establishment (FDA-2656) and must register annually (FDA-2656e). For each Category II, Type A medicated feed article (i.e., for each separate drug), a medicated feed application (FDA-1900) must be submitted to the FDA. You must be registered as a drug establishment and receive FDA approval for a particular drug before you can purchase a Category II, Type A medicated feed article containing that drug.

A nonregistered mill can use the following medicated article/feed(s):

- Category I, Type A medicated article
- Category I, Type B or C medicated feed
- Category II, Type B or C medicated feed

Any questions regarding the status of a medicated feed additive should be directed to Kansas State University's Grain Science and Industry Extension Office, the animal drug supplier, or the FDA.

Most on-farm feed manufacturers will be of the nonregistered type (i.e., not using a Category II,

Type A medicated article). However, nonregistered mills are still subject to federal regulations. The Federal Food, Drug & Cosmetic Act provides that a medicated feed will be considered adulterated if the methods or equipment used for its manufacturing, processing, packing, or holding is not in compliance with Good Manufacturing Practices (GMPs). GMPs for nonregistered feed mills are explained in more detail in the Kansas State University Extension Bulletin MF-2091, On-Farm Feed Manufacturers Quality Assurance Pocket Manual.

It is important to note that even though nonregistered mills may not be subject to regular inspections by the FDA (or an authorized FDA agency), they can be inspected for cause, such as when they manufacture or distribute adulterated feed products or food products that are found to contain illegal drug residues.

Drug Labeling Systems

The Animal Health Institute and the American Feed Industry Association have developed two symbols to appear on medicated feed additive labels to promote proper use: the "Eye Clock" and the "Double Arrows" universal warning symbols. See Figure 1. The Eye Clock serves as a reminder to read directions carefully regardless of whether the particular drug has a withdrawal time. Some drugs have special manufacturing precautions and other feeding limitations. For example, Carbadox (Mecadox®) should not be fed to swine weighing more than 75 pounds or mixed in feeds containing less than 15 percent protein. The Double Arrows warning symbol is designed to draw attention to precautions that must be observed if producers are to avoid violative residues in their products.

Withdrawal Times

The failure to follow label instructions and to observe withdrawal times are major causes of violative drug residues in animal products destined for human consumption. The presence of residues above the specified tolerances set forth in the Code of Federal Regulations Title 21 violate federal law against the sale of adulterated products. Violative tissue residues can lead to delays in marketing and condemnation of a shipment. They also can result in regulatory actions in accordance with the Federal Food, Drug & Cosmetic Act. Figure 2 illustrates how to calculate withdrawal times. Each withdrawal day is a full 24 hours starting with the last time an animal receives the drug. For example, if a drug has a 5-day withdrawal period and is discontinued at 9 a.m. on Friday, the end of the first withdrawal day will be 9 a.m. on Saturday. The fifth withdrawal day will end at 9 a.m. on Wednesday.

Figure 1. *"Eye Clock" and "Double Arrows"universal warning symbols*

Approved Drugs and Drug Combinations

Tables 1–3 provide information regarding the proper use of medicated feed additives for swine. (Title 21, CFR; 1995 Feed Additive Compendium)

- Table 1. Specific Applications of Approved Medicated Feed Additives for Swine.
- Table 2. Approved Medicated Feed Additive Use Levels for Swine.
- Table 3. Approved Medicated Feed Additive Combinations for Swine.

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Calculating the Amount of a Medicated Article/ Feed to add to the Mixer

The "Drug Use Levels" presented in the second table represent the intended concentration of the active ingredient or drug in the final feed, NOT the amount of Type A medicated article or Type B or C medicated feed to be added at the mixer. Refer to the manufacturer's directions to determine the amount of medicated article/feed needed to achieve the desired concentration. Most manufacturers provide a table showing the amount of their product that must be added to attain the desired drug use level. These values can be obtained by using Equation 1.

Equation 1.

$$\text{Amt. of product to add (lb.)} = \frac{\text{Drug Use Level (g/ton)} \times \text{Batch Size (ton)}}{\text{Concentration of the Drug Source (g/lb)}}$$

If the drug activity level (concentration of the drug source) is listed as a percent, it can be converted to grams per pound by multiplying the decimal equivalent of the percent drug activity level by 454. The decimal equivalent of a percent is obtained by moving the decimal two places to the left.

Some medicated feed additive directions require that an intermediate premix be made before incorporation into the final feed. To determine how much intermediate premix to add, refer to Equation 1, but use the concentration of the intermediate premix as the "concentration of the drug source."

Examples

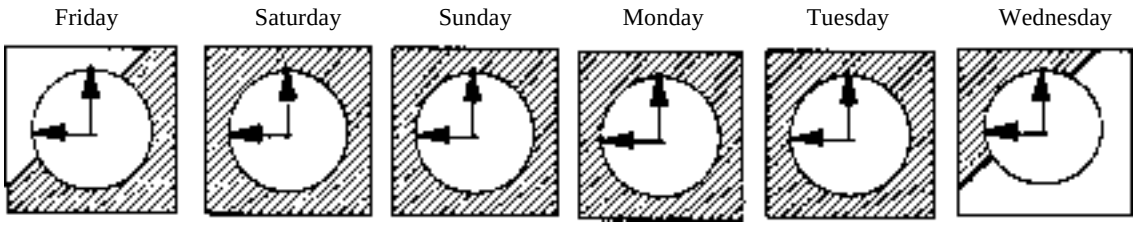
1) Assume that the table specifies that the desired drug use level is 200 g/ton. The drug concentration in the medicated feed additive is 75 g/lb and 2 tons of complete feed will be manufactured. Use Equation 1 to show that 5.3 lbs. of medicated feed additive should be added to the mixer.

$$\text{Amt. to add (lb.)} = \frac{200 \times 2}{75} = 5.3$$

2) Assume that the table specifies that the desired drug use level is 150 g/ton. If the drug concentration in the medicated feed additive is 11 percent and 3 tons of complete feed will be manufactured, use Equation 1 to show that 9.0 lbs of medicated feed additive should be added to the mixer.

$$\text{Amt. to add (lb.)} = \frac{150 \times 3}{454 \times .11} = 9.0$$

Figure 2. *Calculating Wthdrawal Times*[1]



[1]CVMM–16. *Drug Use Guide: Swine*

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Table 1. *Specific Applications of Approved Medicated Feed Additives for Swine*

Growth Promotion & Feed Efficiency
- Arsanilic Acid
- Bacitracin Methylene Disalicylate
- Bacitracin Zinc
- Bambermycins
- Carbadox
- Chlortetracycline
- Lincomycin
- Oxytetracycline
- Penicillin
- Roxarsone
- Tiamulin
- Tylosin
- Tylosin/Sulfamethazine
- Virginiamycin

Atrophic Rhinitis
- Tylosin
- Tylosin/Sulfamethazine

Bacterial Swine Enteritis (Scours)
- Apramycin
- Carbadox
- Chlortetracycline
- Oxytetracycline

Cervical Abscesses
- Chlortetracycline

Colibacillosis
- Apramycin

Clostridial enteritis
- Bacitracin Methylene Disalicylate

Dysentery
- Arsanilic Acid
- Bacitracin Methylene
- Carbadox
- Lincomycin
- Roxarsone
- Tiamulin
- Virginiamycin

Dysentery, Vibrionic
- Carbadox
- Oxytetracycline
- Tylosin
- Tylosin/Sulfamethazine

Fly Control
- Rabon

Leptospirosis
- Chlortetracycline
- Oxytetracycline

Mange Mites
- Ivermectin

Mycoplasma Pneumonia
- Lincomycin

Necrotic Enteritis
- Carbadox
- Lincomycin
- Oxytetracycline
- Virginiamycin

Stress
- Chlortetracycline

Worms

Kidney Worms
- Fenbendazole
- Ivermectin
- Levamisole Hydrochloride

Large Roundworms
- Dichlorvos
- Fenbendazole
- Hygromycin B
- Ivermectin
- Levamisole Hydrochloride
- Piperazine
- Pyrantel Tartrate

Lungworms
- Fenbendazole
- Ivermectin
- Levamisole Hydrochloride

Nodular Worms
- Dichlorvos
- Hygromycin B
- Levamisole Hydrochloride
- Piperazine
- Pyrantel Tartrate

Small Stomach Worms
- Fenbendazole

Thick Stomach Worms
- Dichlorvos

Threadworms
- Levamisole Hydrochloride

Whipworms
- Dichlorvos
- Fenbendazole
- Hygromycin B

Table 2. *Approved Medicated Feed Additive Use Levels for Swine*

Drug	Drug Use Level	Indications for Use	Withdrawal Time (days)
Apramycin	150 g/ton	For control of porcine Colibacillosis (weanling pig scours) caused by susceptible strains of Escherichia coli.	28
Arsanilic Acid	45–90 g/ton	For increased rate of weight gain and improved feed efficiency in growing swine.	5
Bacitracin Methylene Disalicyate	10–30 g/ton	Growing/Finishing Swine: For increased rate of weight gain and improved feed efficiency.	None
	250 g/ton	Growing/Finishing Swine: For control of swine dysentery associated with Treponema hyodysenteriae on premises with a history of swine dysentery, but where signs of the disease have not yet occurred, or following an approved treatment of the disease condition.	None
	250 g/ton	Pregnant Sows: For control of clostridial enteritis caused by Clostridium perfingens in suckling piglets.	None

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Drug	Drug Use Level	Indications for Use	Withdrawal Time (days)
Bacitracin Zinc	10–50 g/ton	Growing/Finishing Swine: Increased rate of weight gain and improved feed efficiency.	None
	20 g/ton	Growing/Finishing Swine: Increased rate of weight gain.	None
	20–40 g/ton	Growing/Finishing Swine: Improved feed efficiency.	None
Bambermycins	2 g/ton	For increased rate of weight gain and improved feed efficiency. Feed continuously as sole ration.	None
	2–4 g/ton	For increased rate of weight gain. Feed continuously as sole ration.	None
Carbadox	10–25 g/ton	For increase in rate of weight gain and improvement of feed efficiency.	42
	50 g/ton	For control of swine dysentery (Vibrionic dysentery, bloody scours, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by Salmonella choleraesuis); increased rate of weight gain and improved feed efficiency.	42
Chlortetracycline	10–50 g/ton	Promote growth and improve feed efficiency.	None
	50-100g/ton	Reduces the incidence of cervical lymphadenitis (jowl abscesses) caused by group Escherichia streptococci susceptible to Chlortetracycline.	None
	400g/ton	(breeding) Leptospirosis caused by Leptospira pomona susceptible to Chlortetracycline.	None
	10mg/lb body weight/day	Treatment of bacterial enteritis caused by Escherichia coli and Salmonella choleraesuis and bacterial pneumonia caused by Pasteurella multocida susceptible to Chlortetracycline.	None
Chlortetracycline and Sulfamethazine and Procaine Penicillin	100g/ton 100g/ton 50g/ton	Administration in a type C feed for reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonella or necrotic enteritis caused by Salmonella choleraesuis and Vibrotic dysentery) prevention. Of these diseases during times of stress; maintenance of weight gains in the presence of atrophic rhinitis; growth motion and increased feed efficiency in swine weighing up to 75 lbs.	15
Chlortetracycline and Sulfathiazole and Procaine Penicillin	100g/ton 100g/ton 50g/ton	For increased rate of weight gain and improved feed efficiency in animals up to six weeks post-weaning. For increased rate of weight gain in animals from 6-16 weeks post -weaning. Maintenance of weight gains in the presence of atrophic rhinitis; reduction of the incidence of cervical absecesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by Salmonella choleraesuis and vibrotic dysentery)	7
Dichlorvos	348g/ton	Boars/Gilts/Sows: For the removal and control of manure, immature and or fourth stage larvae of the whipworm, nodular worm, large roundworm and the thick stomach worm occurring in the gastrointestinal tracts.	None
	479g/ton	Boars/Gilts/Sows: For the removal and control of manure, immature and or fourth stage larvae of the whipworm, nodular worm, large roundworm and the thick stomach worm occurring in the gastrointestinal tracts.	None
	334-500g/ton	Sows/Gilts: An aid in improving litter production efficiency by increasing pigs born alive, birth weights, survival to market and rate of weight gain. Treatment also removes and controls mature, immature, or fourth-stage larvae of the whipworm, nodular worm, large roundworm and the thick stomach worm occurring in the gastrointestinal tracts.	None

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Drug	Drug Use Level	Indications for Use	Withdrawal Time (days)
Fenbendazole	9mg/kg of bodyweight divided over a period of 3-12 days	For the removal of adult-stage lungworms, adult and larvae stage large roundworms, adult-stage nodular worms, small stomach worms, adult and larvae whipworms, adult and larvae kidney worm.	None
Hygromycin B	12g/ton	Control of infestation of large roundworms, nodular worms, and whipworms.(weaned/growing/ finishing pigs)	15
Ivermectin	1.8 g/ton for 7 days	For the treatment and control of gastrointestinal roundworms, kidney worms, lungworms, lice, and mange mites. (adult and breeding)	5
	1.8-11.8 g/ton for 7 days	For the treatment and control of gastrointestinal roundworms, kidney worms, lungworms, lice, and mange mites.	5
Levamisole Hydrochloride	0.36g/lb	Treatment of the following nematode infections: large roundworm, nodular worms, lungworms, intestinal threadworms, and swine kidney worms.	3
Lincomycin	20g/ton	For increased rate of weight gain in growing -finishing swine.	None
	100 g/ton	For treatment of swine dysentery. Feed as sole ration for (continued) 3 weeks or until signs of disease disappear.	None
	200 g/ton	For reduction in the severity of swine mycoplasmal pneumonia caused by Mycoplasma hypopneumoniae. Feed as sole ration for 3 weeks.	None
Oxytetracycline	10-50 g/ton of bodyweight daily	To increase rate of weight gain and improve feed efficiency.	5
	10mg/lb.	Feed continuously for 7-14 days. As treatment of bacterial enteritis caused by Escherichia coli and Salmonella choleraesuis susceptible to Oxytetracycline and control of bacterial pneumonia caused by Pasteurella multocida susceptible to Oxytetracycline.	5
	10mg/lb of bodyweight daily (breeding swine)	Prevention and treatment of Leptospirosis caused by Leptospira ponoma susceptible to Oxytetracycline.	5
Penicillin	10-50 g/ton	Aid in stimulating growth and improving feed efficiency.	None
Piperazine	50 mg/lb bodyweight	Removal of large roundworms and nodular worms	21
Pyrantel Tartrate	96 g/ton	Aid in the prevention of migration and establishment of large roundworm infections; aid in the prevention of establishment of nodular worm infections.	1
	96 g/ton	For the removal and control of large roundworm infections. Feed for 3 days as sole ration.	1
	800 g/ton	For the removal and control of large roundworm and nodular worm infections. Feed as a single therapeutic treatment.	1
Rabon	.00011lb/100ib bodyweight/day	Control of fecal flies in manure of treated swine. Prevents development of house flies in the manure of treated swine.	None
Roxarsone	22.7-34.1 g/ton	Growing/Finishing: For increased rate of weight gain and improved feed efficiency.	5
	181.5 g/ton	For treatment of swine dysentery. Feed for no more than 6 consecutive days.	5

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Drug	Drug Use Level	Indications for Use	Withdrawal Time (days)
Tiamulin hydrogen fumerate	10 g/ton	Increased rate of weight gain and improved feed efficiency.	None
	35 g/ton	Control of swine dysentery associated with Treponema hyodysenteriae susceptible to Tiamulin.	2
	200 g/ton	For treatment of swine dysentery associated with Serpulina hyodysenteriae. Feed for 2 weeks then follow with 35 g/ton to prevent reinfection.	7
Tilmicosin	181-363 g/ton	For the control of swine respiratory disease associated with Actinobacillus pleuropneumoniae and Pasteurella multocida.	7
Tylosin	10-100 g/ton	Prevention of swine dysentery	None
Tylosin	40–100 g/ton	Prevention of swine dysentery (Vibrionic). after treatment of swine dysentery (Vibrionic) after treatment with tylosin in drinking water.	None
	100 g/ton	Maintaining weight gains and feed efficiency in presence of atrophic rhinitis.	None
	100 g/ton 21 days as sole ration	Prevention and or control of porcine proliferative enteropathies associated with Lawsonia intracellularis.	None
	10-20 g/ton	(Finisher) For increased rate of weight gain and improved efficiency.	None
	20-40 g/ton	(Grower) For increased rate of weight gain and improved efficiency.	None
	20-100 g/ton	(Starter and pre-starter feeds) For increased rate of weight gain and improved efficiency.	None
Tylosin/ Sulfamethazine	100g/ton	Maintaining weight gains and feed efficincy in the presence of atrophic rhinitis; lowering the incidence and severity of Brodetella bronchiseptica rhinitis; prevention of swine dysentery (Vibrionic); control of swine pneumonia caused by bacterial pathogens (Pasteurella multocida or Actinomyces pyogenes)	15
Virginiamycin	10 g/ton by 5 g/ton to 10 g/ton from weaning up to 120 pounds.	For increased rate of weight gain and improved feed efficiency, followed market weight for increased rate of weight gain and improved feed efficiency. For continuous use from weaning to market weight.	None
	10 g/ton followed by 5g/ton	10 g/ton followed by 5-10g/ton from weaning up to 20 pounds for increased rate of weight gain and improved feed efficiency, followed by 5–10 g/ton to market weight for increased rate of weight gain and improved feed efficiency. For continuous use from weaning to market weight.	None
	25 g/ton	As an aid in the control of swine dysentery in swine up to 120 pounds. For use in animals or on premises with a history of swine dysentery, but where symptoms have not yet occurred.	None
	100 g/ton followed by 50 g/ton	Feed for 2 weeks at 100 g/ton. Thereafter feed at 50 g/ton for treatment and control of swine dysentery up to 120 pounds.	None
	100 g/ton	For treatment of swine dysentery for 2 weeks in nonbreeding swine more than 120 pounds.	None

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Table 3 shows the approved drug combinations for swine. Unless otherwise designated, all use levels of the individual drugs are allowable. Any limitation or withdrawal period that pertains to an individual drug also pertains to the combination. If both drugs require a withdrawal period, the longer period must be observed. For example, if a feed has a combination of Arsanilic Acid and Bacitracin Zinc, it requires a five-day withdrawal period even though Bacitracin Zinc does not require a withdrawal period.

Note that only the drugs listed in bold and light print may be combined (e.g., Roxarsone and Chlortetracycline, but not Chlortetracycline and Bacitracin Zinc).

Table 3. *Approved Medicated Feed Additive Combinations for Swine*

Arsanilic Acid
Bacitracin Zinc
Chlorteracycline
Penicillin
Bacitracin Methylene Disalicylate
Arsanilic Acid
Chlortetracycline
Roxarsone

Bacitracin Zinc
Arsanilic Acid
Hygromycin B

Carbadox
Pyrantel Tartrate (96 g/ton)[2]

Chlortetracycline
Hygromycin B
Roxarsone

Fenbendazole
Lincomycin[1]

Hygromycin B
Chlortetracycline (100–200 g/ton)
Tylosin (10–100 g/ton)
Ivermectin
Lincomycin

Lincomycin
Pyrantel Tartrate
Fenbendazole
Ivermectin
Oxytetracycline
Arsanilic Acid
Roxarsone

Pyrantel Tartrate[2]
Carbadox (50 g/ton)
Tylosin
Lincomycin

Roxarsone
Bacitracin Methylene Disalicylate
Penicillin
Chlortetracycline
Tiamulin hydrogen fumerate
Chlortetracycline

Tylosin
Hygromycin B
Pyrantel Tartrate

[1]To be used as an anthelmintic in addition to the indicated use in Table 2.
[2]Pyrantel Tartrate at 96 g/ton ONLY.

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