

Date of Approval: JUN 2 2006

FREEDOM OF INFORMATION SUMMARY

ANADA 200-305

ORIGINAL ABBERVIATED NEW ANIMAL DRUG APPLICATION

Oxytetracycline Hydrochloride Soluble Powder

Oxytetracycline hydrochloride

For the treatment of bacterial disease in chickens, turkeys, and swine

Sponsored by:

Vétoquinol N.-A., Inc.

2006-200-305

FOIS 1

Table of Contents

1.	GENERAL INFORMATION:.....	1
2.	TARGET ANIMAL SAFETY AND DRUG EFFECTIVNESS:.....	2
3.	HUMAN SAFETY:	3
4.	AGENCY CONCLUSIONS:.....	3
5.	ATTACHMENTS:	4

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-305
- b. Sponsor: Vétoquinol N.-A., Inc.
2000 chemin Georges
Lavaltrie (PQ), Canada J5T 3S5

Drug Labeler Code: 059320
- c. Established Name: Oxytetracycline hydrochloride
- d. Proprietary Name: Oxytetracycline hydrochloride soluble powder
- e. Dosage Form: Oral powder
- f. How Supplied: 280 g and 560 g packets and 2.27 kg pail
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 102.4 g or 204.8 g of oxytetracycline per packet, or 830.2 g of oxytetracycline per pail.
- i. Route of Administration: Oral in drinking water
- j. Species/Class: Chickens, turkeys, and swine
- k. Recommended Dosage: Chickens
For control of infectious synovitis caused by *Mycoplasma synoviae*, susceptible to oxytetracycline: 200-400 mg
For control of chronic respiratory disease (CRD) and air sac infections caused by *Mycoplasma gallisepticum* and *Escherichia coli* and fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline: 400-800 mg
Turkeys
For control of hexamitiasis caused by *Hexamita meleagridis*, susceptible to oxytetracycline: 200-400 mg
For control of infectious synovitis caused by *Mycoplasma synoviae*, susceptible to

oxytetracycline: 400 mg

- In growing turkeys, for control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis), susceptible to oxytetracycline: 25 mg/lb body weight

Swine

For control and treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*, bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline: 10 mg/lb body weight

In breeding swine, for Leptospirosis (reducing the incidence of abortion and shedding of leptospira) caused by *Leptospira pomona*, susceptible to oxytetracycline: 10 mg/lb body weight.

- l. Pharmacological Category: Antimicrobial
- m. Indications: For the treatment of bacterial diseases in chickens, turkeys, and swine.
- n. Pioneer Product: OXYTET Soluble (oxytetracycline hydrochloride); NADA 130-435; Alpharma, Inc.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guidance, revised October 09, 2002).

Based on the formulation characteristics of the generic product Vétoquinol N.-A., Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Oxytetracycline Hydrochloride Soluble Powder. The generic product is administered as an oral solution in drinking water, contains the same active ingredients in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, OXYTET Soluble (oxytetracycline hydrochloride), the subject of Alpharma, NADA 130-435, was approved on August 14, 1985.

3. HUMAN SAFETY:

- **Tolerances for Residues:**

The tolerances established for the pioneer product apply to the generic product. A tolerance of the following is established for tetracycline residues in the uncooked edible tissue of turkeys, chickens, and swine under 21 CFR 556.500:

- a) 2 parts per million (ppm) in muscle
- b) 6 ppm in liver
- c) 12 ppm in fat and kidney
- d) 0.3 ppm in milk

- **Withdrawal Times:**

Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

The withdrawal times are as follows:

- a) Turkeys: Do not use in birds producing eggs for human consumption. Withdraw 0 days prior to slaughter.
- b) Chickens: Do not use in birds producing eggs for human consumption. Withdraw 0 days prior to slaughter.
- c) Swine: Withdrawal time is 0 days prior to slaughter.

- **Regulatory Method for Residues:**

The analytical method for detection of residues in tissues is a microbiological test using *Bacillus cereus var mycoides* (ATCC 11778). This method is found on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

4. AGENCY CONCLUSIONS:

This ANADA filed under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that Oxytetracycline Hydrochloride Soluble Powder, when used under its proposed conditions of use, is safe and effective for its labeled indications.

ATTACHMENTS:

Facsimile labeling is attached as indicated below:

Generic animal drug labeling for ANADA 200-305

Oxytetracycline Hydrochloride Soluble Powder

280 g packet

560 g packet

2.27 kg pail

Pioneer animal drug labeling

OXYTET Soluble

25.6 g packet

102.4 g packet

512 g packet

648 g packet

Oxytetracycline

SOLUBLE POWDER

OXYTETRACYCLINE HCl ANTIBIOTIC

FOR USE IN DRINKING WATER ONLY

NOT FOR USE IN LIQUID TYPE B MEDICATED FEEDS

NDC 47015-002-01

This packet contains 102.4 g of oxytetracycline HCl and will make:
512 gallons (1936 L) containing 200 mg oxytetracycline HCl per gallon
128 gallons (484 L) containing 800 mg oxytetracycline HCl per gallon
This packet will treat 10,240 pounds of swine

ANADA 200-305, Approved by FDA
NET WEIGHT 9.87 oz (280 g)

KEEP OUT OF REACH OF CHILDREN

Restricted Drug. Use Only as Directed (CA).

DIRECTIONS FOR USE: Mix fresh solutions daily. Use as sole source of drinking water. Do not mix this product directly with milk or milk replacers. Administer one hour before or two hours after feeding milk or milk replacers. Consult a poultry diagnostic laboratory or poultry pathologist for diagnosis and advice on dosage for chickens and turkeys. As a generalization, 200 chickens will drink one gallon of water per day for each week of age. Turkeys will consume twice that amount. Administer up to 5 days to swine and 7 to 14 days for chickens and turkeys. **NOTE:** The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate, and the environmental temperatures and humidity, each of which affects water consumption. **CAUTION:** Use a sole source of oxytetracycline. Not to be used for more than 5 consecutive days in swine or 14 consecutive days in chickens and turkeys.

WARNING: Do not feed to birds producing eggs for human consumption. **LIVESTOCK REMEDY, NOT FOR HUMAN USE. HAZARDOUS REMEDY.**

RECOMMENDED PACKET STORAGE CONDITIONS : Store below 77°F (25°C).



Manufactured for:
Vétoquinol N.A. Inc.
2000, St. Georges,
Lavaltrie, QC, Canada J5T 3S5



Made in Canada

Disease	Treatment Level	Packs/gallon Stock
Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	200 - 400 mg	1/4 - 1/2 (70 - 140 g)
Control of chronic respiratory disease (CRD) and air sac infections caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> , susceptible to oxytetracycline.	400 - 800 mg	1/2 - 1 (140 - 280 g)
Control of fowl cholera caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline.	400 - 800 mg	1/2 - 1 (140 - 280 g)
Control of hexamitiasis caused by <i>Hexamita meleagridis</i> , susceptible to oxytetracycline.	200 - 400 mg	1/4 - 1/2 (70 - 140 g)
Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	400 mg	1/2 (140 g)
GROWING TURKEYS - Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis), susceptible to oxytetracycline.	25 mg/lb	Varies with age & water consumption
FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE - <i>Salmonella choleraesuis</i> , susceptible to oxytetracycline. Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Bacterial pneumonia</i> caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline. FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i> , susceptible to oxytetracycline.	10 mg/lb	Varies with age & water consumption

MIXING DIRECTIONS FOR WATER MEDICATION CHICKENS - TURKEYS - SWINE
Dosage and indications for use in water proportioners: - Add the following amount to one gallon of stock solution when water proportioner is set to meter at the rate of one ounce per gallon.

PANTONE 3135 C

PANTONE 354 CV

PANTONE 485 CV

BLACK

DOCUMENT INFORMATION
CLIENT: Vetoquinol
PRODUCT: Oxytetracycline 280g
DOCKET #:

SPOT COLOR



Colors on screen or printout may not be representative. Use color key for color specification. No trapping provided.

FONTS:

VERSION #: 1
DATE: July 11, 2005
APPROVED:

IMPORTANT: FINAL CLIENT APPROVAL
JOB WILL NOT PROCEED WITHOUT
CLIENT SIGNATURE.

DUCK & PARTNERS
1867, Industrial Boulevard,
Laval (Québec) H7S 1P5
Tel: 450 629-9599
wreyes@duckandpartners.com

Oxytetracycline

SOLUBLE POWDER

OXYTETRACYCLINE HCl ANTIBIOTIC

FOR USE IN DRINKING WATER ONLY

NOT FOR USE IN LIQUID TYPE B MEDICATED FEEDS

NDC 47015-002-02

This packet contains 204.8 g of oxytetracycline HCl and will make:
 1024 gallons (3872 L) containing 200 mg oxytetracycline HCl per gallon
 512 gallons (1936 L) containing 400 mg oxytetracycline HCl per gallon
 256 gallons (968 L) containing 800 mg oxytetracycline HCl per gallon
 This packet will treat 20,480 pounds of swine

ANADA 200-305, Approved by FDA
 NET WEIGHT 19.74 oz (560 g)

KEEP OUT OF REACH OF CHILDREN
 Restricted Drug. Use Only as Directed (CA).

DIRECTIONS FOR USE: Mix fresh solutions daily. Use as sole source of drinking water. Do not mix this product directly with milk or milk replacers. Administer one hour before or two hours after feeding milk or milk replacers. Consult a poultry diagnostic laboratory or poultry pathologist for diagnosis and advice on dosage for chickens and turkeys. As a generalization, 200 chickens will drink one gallon of water per day for each week of age. Turkeys will consume twice that amount. Administer up to 5 days to swine and 7 to 14 days for chickens and turkeys. NOTE: The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate, and the environmental temperatures and humidity, each of which affects water consumption. CAUTION: Use a sole source of oxytetracycline. Not to be used for more than 5 consecutive days in swine or 14 consecutive days in chickens and turkeys.

WARNING: Do not feed to birds producing eggs for human consumption. LIVESTOCK REMEDY. NOT FOR HUMAN USE. HAZARDOUS REMEDY.

RECOMMENDED PACKET STORAGE CONDITIONS : Store below 77°F (25°C).



Manufactured for:
 Vetoquinol N.A. Inc.
 2000, St. Georges,
 Lavalin, Q.C., Canada J5T 3S5



Made in Canada

Disease	Treatment Level	Packs/gallon Stock
Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	200 - 400 mg	1/4 - 1/2 (70 - 140 g)
Control of chronic respiratory disease (CRD) and air sac infections caused by <i>Mycoplasma gallisepticum</i> and <i>E. coli</i> , susceptible to oxytetracycline.	400 - 800 mg	1/2 - 1 (140 - 280 g)
Control of fowl cholera caused by <i>Fasteurella tularensis</i> , susceptible to oxytetracycline.	400 - 800 mg	1/2 - 1 (140 - 280 g)
Control of hexamitiasis caused by <i>Hexamita meleagridis</i> , susceptible to oxytetracycline.	200 - 400 mg	1/4 - 1/2 (70 - 140 g)
Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	400 mg	1/2 (140 g)
GROWING TURKEYS - Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronal enteritis), susceptible to oxytetracycline.	25 mg/lb	Varies with age & water consumption
FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE - Bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline.	10 mg/lb	Varies with age & water consumption
FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i> , susceptible to oxytetracycline.		

MIXING DIRECTIONS FOR WATER MEDICATION CHICKENS - TURKEYS - SWINE
 Dose and indications for use in water proportioners - Add the following amount to one gallon of stock solution when proportioner is set to meter at the rate of one ounce per gallon.

DOCUMENT INFORMATION
 CLIENT: Vetoquinol
 PRODUCT: Oxytetracycline560g
 DOCKET #:

SPOT COLOR
 PANTONE 3135
 PANTONE 485
 PANTONE 354
 BLACK

Colors on screen or printout may not be representative. Use color key for color specification. No trapping provided.

FONTS:

VERSION #: 1
 DATE: July 11, 2005
 APPROVED:

IMPORTANT: FINAL CLIENT APPROVAL
 JOB WILL NOT PROCEED WITHOUT
 CLIENT SIGNATURE.

DUCK & PARTNERS
 1867, Industrial Boulevard,
 Laval (Quebec) H7S 1P5
 Tel: 450-629-8699
 www.yes@duckandpartners.com

11 3/8"

1/8" 3 3/4" 1/8"

Oxytetracycline SOLUBLE POWDER

OXYTETRACYCLINE HCl ANTIBIOTIC

FOR USE IN DRINKING WATER ONLY
NOT FOR USE IN LIQUID TYPE B MEDICATED FEEDS

DIRECTIONS FOR USE: Mix fresh solutions daily. Use as sole source of drinking water. Do not mix this product directly with milk or milk replacers. Administer one hour before or two hours after feeding milk or milk replacers. Consult a poultry diagnostic laboratory or poultry pathologist for diagnosis and advice on dosage for chickens and turkeys. As a generalization, 200 chickens will drink one gallon of water per day for each week of age. Turkeys will consume twice that amount. Administer up to 5 days to swine and 7 to 14 days for chickens and turkeys. **NOTE:** The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate, and the environmental temperatures and humidity, each of which affects water consumption.

CAUTION: Use a sole source of oxytetracycline. Not to be used for more than 5 consecutive days in swine or 14 consecutive days in chickens and turkeys.

WARNING: Do not feed to birds producing eggs for human consumption. **LIVESTOCK REMEDY. NOT FOR HUMAN USE. HAZARDOUS REMEDY.**

RECOMMENDED PACKET STORAGE CONDITIONS:
Store below 77°F (25°C).

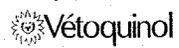
Manufactured by:
Vétoquinol N.-A. Inc.
2000, ch. Georges,
Lavaltrie, QC, Canada J5T 3S5

Made in Canada

Each pound contains 166 g of oxytetracycline hydrochloride activity
This pail contains 830.2 g of oxytetracycline HCl and will make:
4151 gallons (15713 L) containing 200 mg oxytetracycline HCl per gallon
2076 gallons (7858 L) containing 400 mg oxytetracycline HCl per gallon
1038 gallons (3929 L) containing 800 mg oxytetracycline HCl per gallon

ANADA 200-305, Approved by FDA
NET WEIGHT 5 lb (2.27 kg)

KEEP OUT OF REACH OF CHILDREN
Restricted Drug. Use Only as Directed (CA).



- PANTONE 3135 CVC
- PANTONE 354 CVC
- PANTONE 485 CVC
- BLACK

MIXING DIRECTIONS FOR WATER MEDICATION CHICKENS - TURKEYS - SWINE
Dosage and indications for use in water proportions: - Add the following amount to one gallon of stock solution when proportioner is set to meter at the rate of one ounce per gallon.

Disease	Treatment Level	Ounces per Gallon of Stock Solution
C Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	200 - 400 mg	2.5 - 4.9 (70 - 140 g)
C Control of chronic respiratory disease (CRD) and air sac infections caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> , susceptible to oxytetracycline.	400 - 800 mg	4.9 - 9.8 (140 - 280 g)
S Control of fowl cholera caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline.	400 - 800 mg	4.9 - 9.8 (140 - 280 g)
T Control of hexamitiasis caused by <i>Hexamita meleagridis</i> , susceptible to oxytetracycline.	200 - 400 mg	2.5 - 4.9 (70 - 140 g)
M Control of infectious synovitis caused by <i>Mycoplasma gonale</i> , susceptible to oxytetracycline.	400 mg	4.9 (140 g)
GROWING TURKEYS - Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronal enteritis), susceptible to oxytetracycline.	25 mg/lb body weight	Varies with age & water consumption
FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE - Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> , susceptible to oxytetracycline.	10 mg/lb body weight	Varies with age & water consumption
FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i> , susceptible to oxytetracycline.		

Exp: Lot:

DOCUMENT INFORMATION
CLIENT: Vétoquinol
PRODUCT: Oxytetracycline 5Lb
DOCKET #:

- SPOT COLOR**
- PANTONE 3135
 - PANTONE 485
 - PANTONE 354
 - BLACK

Colors on screen or printout may not be representative. Use color key for color specification. No trapping provided.

FORMATS:
VERSION #: 1
DATE: July 11, 2005
APPROVED:

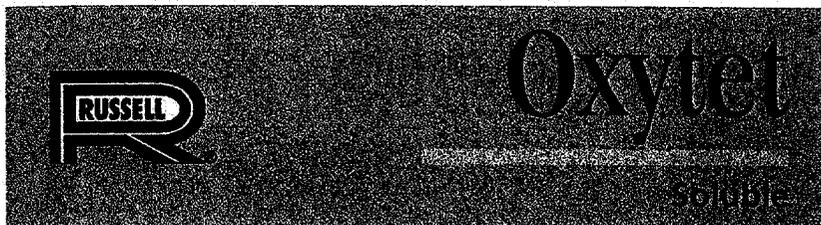
IMPORTANT: FINAL CLIENT APPROVAL JOB WILL NOT PROCEED WITHOUT CLIENT SIGNATURE.

DUCK & PARTNERS
1867, Industrial Boulevard,
Laval (Québec) H7S 1P5
Tel: 450 629-9599
wreyes@duckandpartners.com

MIXING DIRECTIONS FOR WATER MEDICATION CHICKENS — TURKEYS — SWINE

Dosage and Indications for use in water proportioners - Add the following amount to 1 gallon of stock solution when proportioner is set to meter at the rate of 1 oz per gallon.

	Disease	Treatment Level	Packs/Gallon Stock
CHICKENS	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	200 - 400 mg	1-2 (70-140 g)
	Control of chronic respiratory disease (CRD) and air sac infections caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> , susceptible to oxytetracycline.	400 - 800 mg	2-4 (140-280 g)
	Control of fowl cholera caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline.	400 - 800 mg	2-4 (140-280 g)
TURKEYS	Control of hexamitiasis caused by <i>Hexamita meleagridis</i> , susceptible to oxytetracycline.	200 - 400 mg	1-2 (70-140 g)
	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	400 mg	2 (140 g)
	GROWING TURKEYS — Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis), susceptible to oxytetracycline.	25 mg/lb body weight	Varies with age & water consumption
SWINE	FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE — Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> , susceptible to oxytetracycline. Bacterial pneumonia caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline. FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i> , susceptible to oxytetracycline.	10 mg/lb body weight	Varies with age & water consumption



**OXYTETRACYCLINE HCl
AN ANTIBIOTIC**

This packet contains 25.6 g of oxytetracycline HCl and will make:
 128 gallons (484 liters) containing 200 mg oxytetracycline HCl per gallon
 64 gallons (242 liters) containing 400 mg oxytetracycline HCl per gallon
 32 gallons (121 liters) containing 800 mg oxytetracycline HCl per gallon
 This packet will treat 2,560 lbs of swine

RECOMMENDED PACKET STORAGE CONDITIONS:

Store below 77° F (25° C)

See back panel for instructions

NADA #130-435, Approved by FDA



List #2202



Alpha Pharma Inc.
One Executive Drive, Fort Lee, New Jersey 07024

FDA AHF-049 0007

**For Use in Drinking Water Only
Not for Use in Liquid Type B
Medicated Feeds
Keep Out of Reach of Children**

**Net Weight
2.46 oz (70 g)**

Restricted Drug, Use Only as Directed (CA)

DIRECTIONS FOR USE: Mix fresh solutions daily. Use as sole source of drinking water. Do not mix this product directly with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers. Consult a poultry diagnostic laboratory or poultry pathologist for diagnosis and advice on dosage for chickens and turkeys. As a generalization, 200 chickens will drink 1 gallon of water per day for each week of age. Turkeys will consume twice that amount. Administer up to 5 days to swine and 7 to 14 days for chickens and turkeys. **NOTE:** The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate, and the environmental temperatures and humidity, each of which affects water consumption. **CAUTION:** Use as sole source of oxytetracycline. Not to be used for more than 5 consecutive days in swine or 14 consecutive days in chickens and turkeys.

**WARNING - Do not feed to birds producing eggs for human consumption.
LIVESTOCK REMEDY. NOT FOR HUMAN USE. HAZARDOUS REMEDY.**

Approximate Fold Lines

11 1/2"

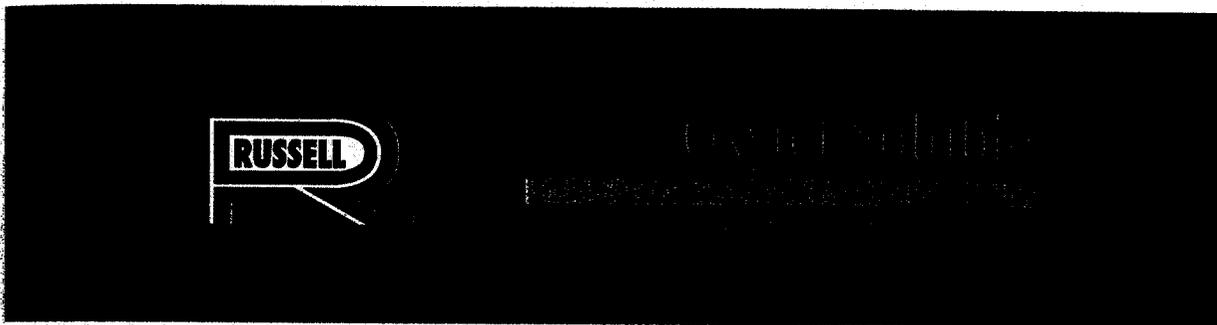
MIXING DIRECTIONS FOR WATER MEDICATION CHICKENS — TURKEYS — SWINE

Dosage and indications for use in water proportioners - Add the following amount to 1 gallon of stock solution when proportioner is set to meter at the rate of 1 oz per gallon.

	Disease	Treatment Level	Packs/gallon Stock
C H I C K E N S	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	200 - 400 mg	¼-½ (70-140 g)
	Control of chronic respiratory disease (CRD) and air sac infections caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> , susceptible to oxytetracycline.	400 - 800 mg	½-1 (140-280 g)
	Control of fowl cholera caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline.	400 - 800 mg	½-1 (140-280 g)
T U R K E Y S	Control of hexamitiasis caused by <i>Hexamita meleagridis</i> , susceptible to oxytetracycline.	200 - 400 mg	¼-½ (70-140 g)
	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	400 mg	½ (140 g)
	GROWING TURKEYS — Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis), susceptible to oxytetracycline.	25 mg/lb body weight	Varies with age & water consumption
S W I N E	FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE — Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> , susceptible to oxytetracycline. Bacterial pneumonia caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline. FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i> , susceptible to oxytetracycline.	10 mg/lb body weight	Varies with age & water consumption



List # 2201



This packet contains 102.4 g of oxytetracycline HCl and will make:
 512 gallons (1936 liters) containing 200 mg oxytetracycline HCl per gallon
 128 gallons (484 liters) containing 800 mg oxytetracycline HCl per gallon

This packet will treat 10,240 lbs of swine

RECOMMENDED PACKET STORAGE CONDITIONS:

Store below 77° F (25° C)

NADA #130-435, Approved by FDA

Not for Use in Liquid Feed Supplements For Use in Drinking Water Only Keep Out of Reach of Children

Net Weight 9.87 oz (280 g)



Alpharma Inc.
 One Executive Drive, Fort Lee, New Jersey 07024

AHF-031A 0002

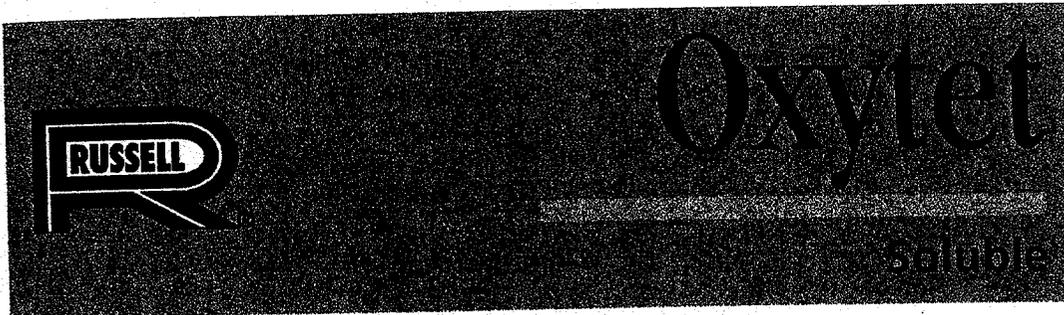
DIRECTIONS FOR USE: Mix fresh solutions daily. Use as sole source of drinking water. Do not mix this product directly with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers. Consult a poultry diagnostic laboratory or poultry pathologist for diagnosis and advice on dosage for chickens and turkeys. As a generalization, 200 chickens will drink 1 gallon of water per day for each week of age. Turkeys will consume twice that amount. Administer up to 5 days to swine and 7 to 14 days for chickens and turkeys. **NOTE:** The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate, and the environmental temperatures and humidity, each of which affects water consumption. **CAUTION:** Use as sole source of oxytetracycline. Not to be used for more than 5 consecutive days in swine or 14 consecutive days in chickens and turkeys.

WARNING - Do not feed to birds producing eggs for human consumption. Discontinue treatment of swine 13 days prior to slaughter. LIVESTOCK REMEDY. NOT FOR HUMAN CONSUMPTION. HAZARDOUS REMEDY.

MIXING DIRECTIONS FOR WATER MEDICATION CHICKENS — TURKEYS — SWINE

Dosage and indications for use in water proportioners - Add 1 pack to the following amount of water to make a stock solution for use in a proportioner set to meter at the rate of one ounce per gallon.

	Disease	Treatment Level	Gallons/Stock Pack
C H I C K E N S	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	200 - 400 mg	20-10
	Control of chronic respiratory disease (CRD) and air sac infections caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> , susceptible to oxytetracycline.	400 - 800 mg	10-5
	Control of fowl cholera caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline.	400 - 800 mg	10-5
T U R K E Y S	Control of hexamitiasis caused by <i>Hexamita meleagridis</i> , susceptible to oxytetracycline.	200 - 400 mg	20-10
	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	400 mg	10
	GROWING TURKEYS — Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis), susceptible to oxytetracycline.	25 mg/lb body weight	Varies with age & water consumption
S W I N E	FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE — Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> , susceptible to oxytetracycline. Bacterial pneumonia caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline. FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i> , susceptible to oxytetracycline.	10 mg/lb body weight	Varies with age & water consumption



OXYTETRACYCLINE HCl

AN ANTIBIOTIC

This packet contains 512 grams of oxytetracycline HCl and will make:

2560 gallons (9690 L) containing 200 mg oxytetracycline HCl per gallon

1280 gallons (4845 L) containing 400 mg oxytetracycline HCl per gallon

640 gallons (2422 L) containing 800 mg oxytetracycline HCl per gallon

This packet will treat 51,200 lbs of swine

RECOMMENDED PACKET STORAGE CONDITIONS:

Store below 77° F (25° C)

See back panel for instructions

NADA #130-435, Approved by FDA

**For Use in Drinking Water Only
Not for Use in Liquid Type B Medicated Feeds
Keep Out of Reach of Children**

**Net Weight
3.09 lbs (1400 g)**

Restricted Drug, Use Only as Directed (CA)

Take Time



Observe Label Directions

List #2205



Alpharma Inc.
One Executive Drive, Fort Lee, New Jersey 07024

FDA AHF-039 0007

DIRECTIONS FOR USE: Mix fresh solutions daily. Use as sole source of drinking water. Do not mix this product directly with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers. Consult a poultry diagnostic laboratory or poultry pathologist for diagnosis and advice on dosage for chickens and turkeys. As a generalization, 200 chickens will drink 1 gallon of water per day for each week of age. Turkeys will consume twice that amount. Administer up to 5 days to swine and 7 to 14 days for chickens and turkeys. **NOTE:** The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate, and the environmental temperatures and humidity, each of which affects water consumption. **CAUTION:** Use as sole source of oxytetracycline. Not to be used for more than 5 consecutive days in swine or 14 consecutive days in chickens and turkeys.

WARNING - Do not feed to birds producing eggs for human consumption. LIVESTOCK REMEDY. NOT FOR HUMAN USE. HAZARDOUS REMEDY.



TETRAVET-CA

(OXYTETRACYCLINE HCl) • AN ANTIBIOTIC

FOR USE IN DRINKING WATER ONLY • NOT FOR USE IN LIQUID FEED SUPPLEMENTS

This packet contains 648 grams of oxytetracycline HCl

This packet will treat 64,800 pounds of swine

NET WT. 3.91 LBS. (1772 GRAMS) • KEEP OUT OF REACH OF CHILDREN

NADA #130-435. APPROVED BY FDA

MIXING DIRECTIONS FOR WATER MEDICATION

	Disease	Treatment Level
S W I N E	FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE -- Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> , susceptible to oxytetracycline. Bacterial pneumonia caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline. FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i> , susceptible to oxytetracycline.	10 mg/lb. body weight

DIRECTIONS FOR USE

Mix fresh solutions daily. Use as sole source of drinking water. Do not mix this product directly with milk or milk replacers. Administer one hour before or two hours after feeding milk or milk replacers. Administer up to 5 days to swine. **Note:** The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate, and the environmental temperatures and humidity, each of which affects water consumption.

- CAUTION -

Use as sole source of oxytetracycline. Not to be used for more than 5 consecutive days in swine.

LIVESTOCK REMEDY. NOT FOR HUMAN CONSUMPTION. HAZARDOUS REMEDY.

RECOMMENDED PACKET
STORAGE CONDITIONS:
Store below 77° F (25° C).



OBSERVE LABEL DIRECTIONS

Consult Material Safety
Data Sheet Prior to Use.

LIST #2203

Alpharma Inc., One Executive Drive, Fort Lee, New Jersey 07024