

HFA-305

Date of Approval: JUL 25 2003

**FREEDOM OF INFORMATION SUMMARY**

**AN ORIGINAL ABBREVIATED NEW ANIMAL DRUG  
APPLICATION (ANADA)**

**ANADA 200-304**

**PRITOX™**  
(37.5% w/w Copper Naphthenate)

**Equine Antimicrobial**

As an aid in treating horses and ponies with thrush due to organisms susceptible to copper naphthenate.

**Sponsored by:**

**First Priority, Inc.  
1585 Todd Farm Drive  
Elgin, IL 60123**

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## FREEDOM OF INFORMATION SUMMARY

### 1. GENERAL INFORMATION:

- a. File Number: ANADA 200-304
- b. Sponsor: First Priority, Inc.  
1585 Todd Farm Drive  
Elgin, IL 60123
- Drug Labeler Code: 058829
- c. Established Name: Copper naphthenate solution
- d. Proprietary Name: Pritox™
- e. Dosage Form: Solution
- f. How Supplied: 8 oz (236 mL) & 16 oz (473 mL) cylinders
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 37.5 % w/w copper naphthenate
- i. Route of Administration: Topical
- j. Species/Class: Ponies & horses
- k. Recommended Dosage: Clean the hoof thoroughly, removing debris and necrotic material prior to application of Pritox™. Apply daily to affected hoofs until fully healed.
- l. Pharmacological Category: Antimicrobial
- m. Indications: As an aid in treating horses and ponies with thrush due to organisms susceptible to copper naphthenate.
- n. Pioneer Product: Kopertox™; copper naphthenate; NADA 012-991; Fort Dodge Animal Health

### 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 (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter), 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 is required to show that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. The requirements for the *in vivo* blood level bioequivalence study may be waived for certain generic products. Upon approval, an ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. ANADAs for drug products for food-producing animals will generally be required to include *in vivo* bioequivalence and tissue residue studies. If a waiver of the *in vivo* bioequivalence and/or tissue residue study is granted for a food animal product, then the withdrawal period established for the pioneer product will be assigned to the generic product. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, First Priority, Inc. was granted a waiver on August 16, 1999, from the requirement for an *in vivo* bioequivalence study for the generic product, Pritox™ (copper naphthenate). The generic and pioneer products contain the same active ingredient in the same concentration and are topical solutions for application to hoofs of horses and ponies as an aid in treating thrush due to organisms susceptible to copper naphthenate. The pioneer product Kopertox™ (copper naphthenate), the subject of Fort Dodge Animal Health (NADA 012-991), was approved on May 8, 1962.

### 3. HUMAN SAFETY:

This drug is indicated for use only in horses and ponies, which are non-food animals. Since this generic animal drug is not intended for food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this ANADA.

Human warning statements are provided on the product label as follows: **“KEEP OUT OF REACH OF CHILDREN AND PETS.” “CAUTION: Do not use on animals intended for food production.” “Not for use on horses intended for food.” “CAUTION: COMBUSTIBLE MIXTURE Use in a well-ventilated place. Avoid fire, flame, sparks or heaters. If swallowed, do not induce vomiting, call physician immediately Avoid breathing vapor. Avoid contact with skin and eyes.”**

### 4. AGENCY CONCLUSIONS:

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

### 5. ATTACHMENTS:

#### Pioneer Labeling for NADA 012-991:

Kopertox™ (37.5 % copper naphthenate in a suitable solvent)  
1 – Container Label 16 oz (473 mL); 1 – Container Label 8 oz (236 mL)

#### Generic Labeling for ANADA 200-304:

Pritox™ (37.5 % copper naphthenate in a suitable solvent)  
1 – Cylinder Label 16 oz (473 mL); 1 – Cylinder Label 8 oz (236 mL)

Back Panel

# KOPERTO<sup>X</sup>

Indicated in the treatment of  
thrush in horses and ponies

**CAUTION:** Do not use on animals which are raised  
for food production

**CAUTION: COMBUSTIBLE MIXTURE**

Use in a well-ventilated place. Avoid fire, flame, sparks  
or heaters

If swallowed, do not induce vomiting, call physician  
immediately. Avoid breathing vapor. Avoid contact  
with skin and eyes

Keep out of reach of children and pets

**GENERAL DIRECTIONS:** Clean the hoof thor-  
oughly removing debris and necrotic material prior  
to application of KOPERTO<sup>X</sup>. Apply daily to affect-  
ed hoofs with a narrow paint brush (about 1") until  
fully healed. **Caution:** Do not allow runoff of excess  
KOPERTO<sup>X</sup> onto hair since contact with KOPER-  
TO<sup>X</sup> may cause some hair loss. Do not contami-  
nate feed.

Store at controlled room temperature 15 C to 30 °C  
(59 to 86 F)

**NOTE:** KOPERTO<sup>X</sup> is easily removed from hands,  
clothing and surfaces with light grade fuel oil or any  
type of lighter fluid

**CONTAINS FOIL SEAL - REMOVE BEFORE USE**



LOT# 075452  
EXP. MAR. 04  
0754E  
90357

Front Panel

NDC 0856-9910-01

# KOPERTO<sup>X</sup>

**WATER-RESISTANT PROTECTION  
WITHOUT BANDAGING**



**RECOMMENDED**  
as an aid in treating horses and  
ponies with thrush due to organisms  
susceptible to copper naphthenate.

**Not for use on horses intended for food.**

**CAUTION: COMBUSTIBLE MIXTURE**

See caution statement on back panel.

|                          |             |
|--------------------------|-------------|
| <b>Active Ingredient</b> |             |
| Copper naphthenate       | --- 37.5%   |
| <b>Inert Ingredients</b> | ----- 62.5% |
| <b>Total</b>             | ----- 100%  |

**FOR EXTERNAL USE ONLY**

**236 mL (8 oz)**

NADA 12-991 Approved by FDA

**Fort Dodge Animal Health**  
Fort Dodge, Iowa 50501 USA

**NOTE:** This is a copy of the actual product container which was  
emptied and cut in half.

Front Panel

NDC 0856-9910-02

# KOPERTO<sup>7</sup>X™

**WATER-RESISTANT PROTECTION  
WITHOUT BANDAGING**



**RECOMMENDED**  
as an aid in treating horses and ponies  
with thrush due to organisms susceptible  
to copper naphthenate.

Not for use on horses intended for food.

**CAUTION: COMBUSTIBLE MIXTURE**

See caution statement on back panel.

|                    |             |
|--------------------|-------------|
| Active Ingredient  |             |
| Copper naphthenate | ----- 37.5% |
| Inert Ingredients  | ----- 62.5% |
| Total              | ----- 100%  |

**FOR EXTERNAL USE ONLY**

**473 mL (16 oz)**

NADA 12-991. Approved by FDA

Fort Dodge Animal Health  
Fort Dodge, Iowa 50501 USA

Back Panel

# KOPERTO<sup>7</sup>X

**Indicated in the treatment of  
thrush in horses and ponies**

**CAUTION:** Do not use on animals which are raised  
for food production.

**CAUTION: COMBUSTIBLE MIXTURE**

Use in a well-ventilated place. Avoid fire, flame,  
sparks or heaters.

If swallowed, do not induce vomiting, call physician  
immediately. Avoid breathing vapor. Avoid contact  
with skin and eyes.

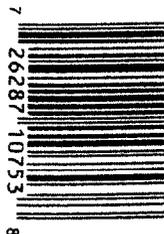
Keep out of reach of children and pets.

**GENERAL DIRECTIONS:** Clean the hoof thor-  
oughly removing debris and necrotic material prior  
to application of KOPERTO<sup>7</sup>X. Apply daily to affect-  
ed hoofs with a narrow paint brush (about 1") until  
fully healed. Caution: Do not allow runoff of  
excess KOPERTO<sup>7</sup>X onto hair since contact with  
KOPERTO<sup>7</sup>X may cause some hair loss. Do not  
contaminate feed.

Store at controlled room temperature 15°C to 30°C  
(59° to 86°F).

**NOTE:** KOPERTO<sup>7</sup>X is easily removed from hands,  
clothing and surfaces with light grade fuel oil or any  
type of lighter fluid.

**CONTAINS FOIL SEAL - REMOVE BEFORE USE**



LOT# 075449  
EXP JAN 04  
0755F  
90097

**NOTE:** This is a copy of the actual product container which was  
emptied and cut in half.

**PRITOX™** is indicated in the treatment of thrush in horses and ponies.

**GENERAL DIRECTIONS:** Clean the hoof thoroughly, removing debris and necrotic material prior to application of PRITOX™. Apply daily to affected hoofs with a narrow paint brush (about 1") until fully healed. Caution: Do not allow runoff of excess PRITOX™ onto hair since contact with PRITOX™ may cause some hair loss. Do not contaminate feed.

**NOTE:** PRITOX™ is easily removed from hands, clothing and surfaces with light grade fuel oil or any type of lighter fluid.

**CONTAINS FOIL SEAL-REMOVE BEFORE USE.**

**SHAKE WELL BEFORE USE.**

TAKE TIME  OBSERVE LABEL DIRECTIONS  
Iss. 06-01

NDC# 58829-289-08

Priority Care 

**PRITOX™**

**Water-Resistant Protection Without Bandaging**

Recommended as an aid in treating horses and ponies with thrush due to organisms susceptible to copper naphthenate.

Not for use on horses intended for food.

**FOR EXTERNAL USE ONLY**  
**CAUTION: COMBUSTIBLE MIXTURE**

ANADA 200-304, Approved by FDA

Net Contents: 8 oz. (236 mL)

**Active Ingredient**

Copper Naphthenate.....37.5% w/w  
Inert Ingredients.....62.5% w/w  
Total.....100.0%

**CAUTION:** Do not use on animals which are raised for food production.

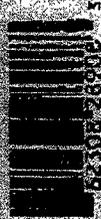
**CAUTION: COMBUSTIBLE MIXTURE**  
Use in a well-ventilated place. Avoid fire, flame, sparks or heaters.

If swallowed, do not induce vomiting, call physician immediately. Avoid breathing vapor. Avoid contact with skin and eyes.

**KEEP OUT OF REACH OF CHILDREN AND PETS.**

Store at controlled room temperature 15° to 30°C (59° to 86°F).

Lot No. Exp. Date



Reorder No: TP280PCARE

NDC# 58829-289-16

Priority Care 

**PRITOX™** is indicated in the treatment of thrush in horses and ponies.

**GENERAL DIRECTIONS:** Clean the hoof thoroughly, removing debris and necrotic material prior to application of PRITOX™. Apply daily to affected hoofs with a narrow paint brush (about 1") until fully healed. Caution: Do not allow runoff of excess PRITOX™ onto hair since contact with PRITOX™ may cause some hair loss. Do not contaminate feed.

**NOTE:** PRITOX™ is easily removed from hands, clothing and surfaces with light grade fuel oil or any type of lighter fluid.

**CONTAINS FOIL SEAL- REMOVE BEFORE USE.**

**SHAKE WELL BEFORE USE.**

TAKE TIME



OBSERVE LABEL DIRECTIONS

Iss 06-01

**PRITOX™**

**Water-Resistant Protection Without Bandaging**

**Recommended as an aid in treating horses and ponies with thrush due to organisms susceptible to copper naphthenate.**

**Not for use on horses intended for food.**

**FOR EXTERNAL USE ONLY**

**CAUTION: COMBUSTIBLE MIXTURE**

ANADA 208-304. Approved by FDA

**Net Contents: 16 fl. oz. (473 mL)**

**Active ingredient**  
Copper Naphthenate.....37.5% w/w  
**Inert ingredients**.....62.5% w/w  
Total.....100.0%

**CAUTION:** Do not use on animals which are raised for food production.

**CAUTION: COMBUSTIBLE MIXTURE**

Use in a well-ventilated place. Avoid fire, flame, sparks or heaters.

If swallowed, do not induce vomiting, call physician immediately. Avoid breathing vapor. Avoid contact with skin and eyes.

**KEEP OUT OF REACH OF CHILDREN AND PETS.**

Store at controlled room temperature 15° to 30° C (59° to 86° F).



Lot No. Exp. Date

Reorder No. TP281PCARE