

32867-2

PM 31

1989

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 14 1989

TEF Medical
2450 Meadowbrook Parkway
Duluth, GA 30136

Attention: Karenann J. Brozowski

Gentlemen:

Subject: Urolocide
EPA Registration No. 32867-2
Your Application Dated May 10, 1989
EPA received Date June 1, 1989

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling.
 - a. Box Label

Revise "See packet label for first aid and additional precautions" to read "See packet label for additional precautionary statements."
 - b. Packet Label

Revise "First Aid" to "Statement of Practical Treatment."
 - c. Delete the word "milk."
 - d. On the back label, over the word "DANGER," include a precautionary statement to read:

Precautionary Statement
Hazards to Humans and Domestic Animals

56892: I: DeLaney: LL-13: KENCO: 09/13/89: 10/26/89: aw: VO: EK: CL

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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e. Revise the "Instructions For Use" heading to read

Directions For Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

- 2. Submit five (5) copies of your final printed labeling before you release the product for shipment. Also, submit five (5) copies of your brochures to comply with the label changes outlined above.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martna DeLaney at (703) 557-6982.

Sincerely yours,

John H. Lee
 Product Manager (31)
 Antimicrobial Program Branch
 Registration Division (H7505C)

nclosure

BOX LABEL

T.F.X. Medical Urolocide®

Untinted CRYSTALS
For making untinted solutions

ACTIVE INGREDIENT
Benzyl (Dodecylcarbonylmethyl)
Dimethylammonium Chloride 100%

GERMICIDE

Keep out of reach of children!

DANGER

SEE PACKET LABEL
FOR FIRST AID AND
ADDITIONAL
PRECAUTIONS

Brochure with additional
information available on
request

REORDER NO
3771-00

STORAGE AND
DISPOSAL:

Store in a cool, dry place,
away from excessive
heat. Wrap empty packet
and put in trash

Made in USA for:

T.F.X. Medical,
2450 Meadowbrook Parkway, Duluth, Ga. 30136, USA
Toll Free: (800) 241 1926, (800) 325 8228.

EPA Reg No. 32867-2
EPA Est No. 34848-R-01

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 14 1989

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

32867-2

T.F.X. Medical Urolocide®

12 Packets

Net Wt 3.8 gm (0.13 oz) EACH

REORDER NO
3771-00

PACKET LABEL

FRONT

TFX Medical Urolocide®

Untinted CRYSTALS
For making untinted solutions

ACTIVE INGREDIENT
Benzyl (Dodecylcarbonylmethyl)
Dimethylammonium Chloride 100%

GERMICIDE

Keep out of Reach of Children!

DANGER

FIRST AID:

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For the eyes, call a physician. Remove and wash contaminated clothing before reuse.

If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution or if these are not available, drink large quantities of water. Call a physician immediately.

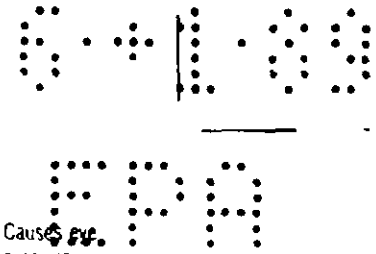
Made in USA for
TFX Medical,
2450 Meadowbrook Parkway,
Duluth, Ga. 30136, USA.
Toll Free (800) 241 1926
(800) 325 8228

EPA Reg. No. 32867-2
EPA Est. No. 34848-IL-01

SEE BACK FOR FIRST AID,
ADDITIONAL PRECAUTIONS
AND INSTRUCTIONS FOR
USE

Net Wt. 3.8 gm (0.13 oz)

BACK



DANGER:

Keep out of reach of children. Corrosive. Causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing. Protect eyes and skin when handling. Harmful if swallowed. Avoid contamination of food.

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

Instructions for use:

To make a 1:1000 aqueous solution, dissolve 3.8 gm of Crystal UROLOCIDE in one gallon of distilled water. The Crystals will readily dissolve in either hot or cold water with brisk stirring.

For the disinfection of instruments that do not withstand heat sterilization, immersion for a period of 30 minutes in 1:1000 aqueous solution of UROLOCIDE is recommended.

Prior to immersion, all surfaces of the instrument should be washed and cleaned with soap or detergent and thoroughly rinsed with water. (A film of soap or detergent on the instrument may neutralize the antibacterial effect of urolocide.)

STORAGE AND DISPOSAL:

Store in a cool, dry place, away from excessive heat. Wrap empty packet and put in trash.

REORDER NO
3771-00

TEAR HERE TO OPEN

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 14 1989

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
has been registered for the pesticide
category under EPA Reg. No.

32867-2

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