

70799-9

12-11-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 11 2003

Julee Kasprisin
Regulatory Affairs
State Industrial Products
3100 Hamilton Avenue
Cleveland, OH 44114

Subject: **State Fix "Tera-O-Cide in a Can"**
EPA Registration Number 70799-9
Application Dated October 1, 2003
EPA Receive October 6, 2003

Dear Ms. Kasprisin:

The following amendment, submitted in connection with registration under section of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with comments:

Proposed Amendment:

- revise first aid statement PR Notice 2001-1

General Comment:

Based on the me-to product associated with this registration (reg. No.1839-84) the change in signal word to Warning is acceptable.

1. Revise the Precautionary Statement as follows:

"Causes substantial but temporary eye injury and skin irritation. Do not get in eyes on skin or on clothing. Wear protective eyewear, clothing and gloves. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse".

2. Revise the following phrase: "is also fungicidal against Pathogenic fungi (*Trichophyton* `Mentagrophytes) (when used as directed on *non-porous* hard surfaces found in the bathroom, shower stall....."

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Other Comments:

A stamped copy of the labeling accepted with conditions is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland on (703) 308-6224.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosure: Stamped Label

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. This product is not to be used as a terminal disinfectant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection. State FX "Terg-o-Cide in a Can" is designed for cleaning and disinfecting in hospitals, nursing homes, schools, offices, motels and hotels. When used as directed, it is formulated to disinfect inanimate hard surfaces (such as walls, sink tops, tables, chairs, telephones, bathrooms, shower stalls, bath tubs, hampers, cabinets and bed-springs).

In addition, State FX "Terg-o-Cide in a Can" deodorizes those areas generally hard to keep fresh smelling (such as garbage bins, basements, restrooms, and other areas which are prone to odors caused by micro-organisms). Contains no GFC's or other ozone depleting substances. Federal regulations prohibit GFC's propellants in aerosols. **DISINFECTING, DEODORIZATION AND CLEANING:** To disinfect hard nonporous surfaces proceed as indicated below:

- (1) Shake can before using. (2) Hold six to eight inches from surface to be sprayed. (3) Spray area until it is covered with white foam. Allow foam to penetrate and remain wet for 10 minutes. No scrubbing necessary. (4) Wipe off with a clean cloth, mop or sponge. State FX "Terg-o-Cide in a Can" should not leave grit or soap scum. For heavily soiled areas, remove gross soil before treatment.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING AGAINST HIV-1 (AIDS VIRUS) OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS: The product kills HIV-1 (AIDS Virus) in hospitals and other health care facilities in which there is an expected likelihood of soiling of inanimate surfaces with blood or body fluids, and in which the surfaces likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV-1 (AIDS Virus).

PERSONAL PROTECTION: Wear barrier protection such as latex gloves, gowns, or eye coverings when handling items soiled with blood or body fluids.

CLEANING PRECAUTIONS: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of State FX "Terg-o-Cide in a Can".

CONTACT TIME: Follow disinfecting instructions listed above. Allow the product to penetrate and remain wet for 10 minutes before wiping off.

World Headquarters
3100 Hamilton Ave.
Cleveland, OH 44114

To order call: 1-800-792-2458
www.statechemical.com



DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

When used as directed, State FX "Terg-o-Cide in a Can" demonstrates effective disinfection against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa, thus meeting the requirements for hospital use. It is an effective one-step cleaner/disinfectant in the presence of organic soil (5% blood serum).

State FX "Terg-o-Cide in a Can" is also highly effective against Pathogenic fungi (Trichophyton) when used as directed on hard surfaces found in the bathroom, shower stall, and locker room or other clean, hard, nonporous surfaces commonly contacted by bare feet.

State FX "Terg-o-Cide in a Can" is also virucidal against Herpes simplex Type 2 when used as directed on hard, non-porous, inanimate, environmental surfaces.

State FX "Terg-o-Cide in a Can" also kills HIV-1 (AIDS Virus) on pre-cleaned environmental surfaces / objects previously soiled with blood / body fluids.

MILDEWSTAT: To control mold and mildew on pre-cleaned, hard, nonporous surfaces (such as floor, walls, table tops) spray surfaces to be treated making sure to wet completely. Let air dry. Repeat application at weekly intervals or when mildew growth reappears.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING
KEEP OUT OF REACH OF CHILDREN. Causes moderate eye irritation and skin irritation. Do not get in eyes, on skin or on clothing. Harmful if swallowed. Avoid contact with food, remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor or going for treatment. If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center for treatment advice. If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center for treatment advice. If swallowed: Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTE TO PHARMACIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

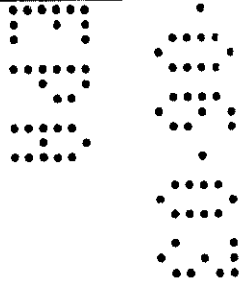
PRODUCT# 43671

ACCEPTED
with COMMENT
EPA Letter Date

DEC 11 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act, amended, for the pesticide registered under EPA Reg

707



STATE FIX

NET WT: 18 OZ. (1 lb. 2 oz.) 510g

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