

FEB 06 1988

Sporicidin International  
12000 Old Georgetown Road  
Rockville, MD 20852

Attention: Dr. Curtis Lynch  
Vice President

Gentlemen:

Subject: Permacide Brand Ristex Germicidal/Disinfectant Spray  
EPA Registration No. 8383-4  
Your Amendment Application Dated March 14, 1988

The submitted data are acceptable to support effectiveness of the product as a virucide against HIV-1 (AIDS virus) when used as an undiluted pressurized spray on hard, nonporous surfaces in the presence of a moderate amount of organic soil (5% blood serum) at a contact time of 1 minute or 10 minutes at room temperature (20 to 25 °C).

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of 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. The contact time of 1 minute employed for efficacy testing against HIV-1 does not correlate with the contact time of 10 minutes supported in previously accepted efficacy data for disinfection and the last accepted labeling for this product. Therefore, if a claim for shorter contact time is made for HIV-1, a statement similar to the following will be required "Although efficacy at a 1 minute contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms. Use a 10-minute contact time for disinfection against all of the organisms claimed."
  - b. The label reference to "AIDS/HIV-1 virus" must be revised to read "HIV-1 (AIDS virus)."

57151:I:Douglas:LK-7:KENC0:12/23/88:1/4/89:SG:VO:DD

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

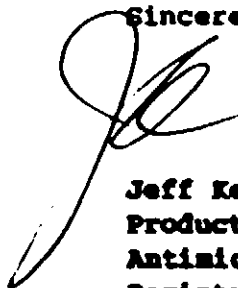
- 1/3
- c. The labeling requirements for antimicrobial pesticides used on hard surfaces against HIV-1 (AIDS virus) are indicated on the enclosure. It is important to note that featured statements/phrases, emphasized/enlarged lettering, special graphics, or any product name that employs the term "AIDS" are not acceptable, as indicated in item 2. Special instructions for this use pattern must be provided in the format indicated in item 4 of this enclosure.
  - d. Refer to our letter dated April 19, 1988 for additional labeling requirements.
  - e. Refer to our letter dated November 16, 1988 for EPA Registration No. 8383-3 regarding the correct format for the ingredient statement and revise this label accordingly.
2. Submit five (5) copies of your final printed labeling before you release the product for shipment.

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

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

If you have any questions in this regard, please contact Ms. Ruth Douglas at (703) 557-3842.

Sincerely yours,



Jeff Kempter  
Product Manager (32)  
Antimicrobial Program Branch  
Registration Division (TS-767C)

Enclosures

1A-011

FORM 209

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**Continuous  
RESIDUAL ACTIVITY  
for Over 6 Months\***

**PERMUCIDE BRAND RISTEX  
GERMICIDAL/DISINFECTANT SPRAY**

**BACTERICIDAL • TUBERCULOCIDAL  
• VIRUCIDAL • FUNGICIDAL  
• PREVENTS MOLD AND MILDEW  
• ELIMINATES ODORS**

**FOR  
CONTAMINATION  
CONTROL**

Active Ingredients  
17.0% (w/v) 4.4  
Inert Ingredients

Phenol 4.1% Sodium  
Ethoxide 4.4%  
80.350

EXCEPTED  
WITH COMMENTS  
in 10/1/1989

FEB 06 1989

8393-4

**WARNING  
KEEP OUT OF REACH  
OF CHILDREN**

Net Wt 22 oz

See additional instructions on back panel

**AN EXCELLENT DISINFECTANT  
AND ACTIVE DEODORANT FOR  
MEDICAL, DENTAL AND VETEH-  
NARY AREAS IN HOSPITALS,  
CLINICS AND OFFICES as well as  
nursing homes, ambulances, hotels,  
schools, buses and health spas**

**Action:**

- 1 Reduces the hazards of cross-contamination on multiple environmental surfaces
- 2 Prevents mold and mildew
- 3 Eliminates odor-causing organisms and prevents their return for over 6 months
- 4 Kills Adenovirus Foot fungi on bathroom, shower and pool surfaces
- 5 Non-staining
- 6 Disinfects hard non porous surfaces & penetrates cracks
- 7 Contains no harmful abrasives
- 8 Non-flammable

PERMUCIDE BRAND RISTEX is germicidal when used as directed for disinfection but differs in composition from other PERMUCIDE BRAND PRODUCTS

**Directions:** It is a violation of U.S. Federal Law to use this product in a manner inconsistent with its labeling. Shake well before using.

**To Pre-clean Surface:** Spray until wet. Dry with tissue, paper towel or cloth.

**To Disinfect:** Hold spray nozzle 6" to 8" from pre-cleaned surface. Spray for 4 seconds or until surface is covered with mist. Allow 10 minute contact time. **NOTE:** (AIDS)/HIV-1 Virus is killed in 1 minute.

**To Prevent Mold and Mildew:** Repeat application weekly or sooner if new growth appears.

**To Eliminate Odors:** Spray 2-4 seconds toward center of room.

**Storage and Disposal:** Store at room temperature. Discard empty container in regular trash collection.

EPA Reg No 87614  
EPA (EIN No 3621) M002

PASSES THE  
CAPACITY STAND-  
TAL AND INS  
SPRAY DISINF-  
spray provides  
case and odor-ca  
as Staphylococ  
coccus solivora  
pyogenes, Salmon  
typhimurium, aeru  
cuis, pneumo  
influenzae A, (Ja  
ococcus, P. flu  
groupylos (A) (A)  
mycobacterium L  
acid and mildew

Acts quickly on  
patient rooms, of  
thirty rooms, de  
rooms. Safe for  
furniture floors,  
dies under sinks,  
cans, linen ham  
lyon switches,  
chairs, walkers,  
and musty enclo  
areas. Reduces  
contamination

**A DEODORANT**  
Residual active  
static long-staic  
organisms for ori  
man-made surface  
surfaces. It is an  
fungicidal and fun  
rics, plastics, lak  
metal, porcelain

**WARNING:** Avoid  
sprayed directly  
directly flush with  
with a physician

**CONTENTS U**  
Do not use near  
Do not puncture  
Exposure to fumes  
may cause dizziness

**Spoil**  
INTL  
4000 Massachusetts  
Washington