

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 10 1989

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pm 31
61178-1

Microgen, Inc.
P.O. Box 1.
Fairfield, NJ - 07006

Attention: Bob Prince
President

Gentlemen:

Subject: D-125
EPA Registration No. 61178-1
Your Submission Dated March 30, 1989

The amendment referred to above, submitted in connection with registration under FIFRA, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
 - a. Revise Herpes simplex to read Herpes Simplex Type 1.
 - b. Under the heading "Contact time" (center panel) revise the statement 30 second contact time in presence of 10% blood serum to read: Leave surface wet for 30 seconds.
 - c. Include the reference asterisk two locations - Virucidal claim.
 - d. Delete the statement: Hospital Strength.
 - e. Move the Pseudo rabies claim to the virucidal section or include it under its own "Virucidal Activity" heading.

58320:I:V.G.:L-15:KENCO:10/03/89:11/15/89:CT:SW:VO:EK:CL

R:58321:V.G.:L-15:KENCO:10/06/89:11/20/89:CT:SW:VO:EK:CL

SYMBOL								
SURNAME								
DATE								

f. Delete the term: General Classification.

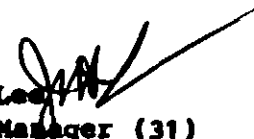
g. Revise HIV to HIV-1.

h. Refer to PR Notice 83-3 for acceptable Storage Disposal statements for your larger size containers.

2. 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.

Sincerely yours,


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

Enclosure

OCT 10 1989

RECEIVED
with COMMENTS
for EPA Letter Decide

Directions for Use
General Classification

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

D125 detergent disinfectant has been designed specifically for hospitals, nursing homes, schools, food processing plants and other institutions where housekeeping is of prime importance.

DISINFECTION To disinfect hard inanimate surfaces (such as walls, floors, table tops), add 2 ounces D125 detergent disinfectant per gallon of water. Apply solution with mop, cloth, or sponge, or mechanical sprayer so as to wet thoroughly. Allow to remain wet for 10 minutes and then let air dry. **KILLS HIV-1 ON THE GLASSER**
ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BOOD FLUIDS.

To disinfect toilet bowls, flush toilet, add 2 ounces D125 detergent disinfectant directly to the bowl water. Scrub the bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for 10 minutes and flush.

For heavily soiled areas, a pre-cleaning step is required and recommended. Prepare a fresh solution for each use.

MILDEWICIDE - To control mold and mildew on pre-cleaned, hard non-porous surfaces (such as floors, walls, table tops) add 2 ounces D125 per gallon of water. Apply solution with a cloth, mop, or sponge making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application at weekly intervals or when mildew growth reappears.

SANITIZATION - To sanitize previously cleaned and rinsed non-porous food contact surfaces, prepare 100ppm active quaternary D125 solution by adding 2 ounces D125 to 11 1/2 gallons of water.

To sanitize immobile items (such as tanks, chopping blocks, counter tops), flood the area with 100ppm D125 solution or apply with a cloth or sponge, making sure to wet all surfaces completely for at least 40 seconds. Let air dry. Prepare a fresh solution for each use.

To sanitize mobile items (such as drinking glasses, eating utensils), immerse in 100ppm D125 solution for at least 40 seconds making sure to immerse completely. Remove and let air dry. Prepare a fresh solution daily or more frequently as soil is apparent.

PRECAUTIONARY STATEMENTS
Hazard to Human and Domestic Animals
DANGER

Keep Out of Reach of Children. Causes severe eye and skin damage. Do not get in eyes, on skin or clothing. Harmful if swallowed. Wear goggles or face shield and rubber gloves when handling. Avoid contamination of food. Remove and wash contaminated clothing.

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash all contaminated clothing before reuse. If swallowed, drink milk, egg whites, gelatin solution or if these are not available drink large quantities of water. Call a physician.

NOTE TO PHYSICIAN

Probable adverse effects may contraindicate the use of gastric lavage. Resuscitate against circulatory shock, respiratory depression and convulsion may be needed.

D 125 DETERGENT DISINFECTANT
HOSPITAL STRENGTH

Cleaner	Disinfectant
Detergent	Phenoxide (against
Deodorizer	Pathogenic fungi)
Sanitizer	Virucide
Mildewstat	(on hard inanimate
	surfaces)

ACTIVE INGREDIENTS:
N-Alkyl (40% C₁₂, 20% C₁₄, 5% C₁₆, 5% C₁₈) dimethyl benzyl ammonium chloride.....2.25%
N-Alkyl (40% C₁₂, 20% C₁₄) dimethyl ethylbenzyl ammonium chloride.....2.25%
INERT INGREDIENTS.....95.50%

TOTAL 100.00%

EPA REG. NO. 61170-1

KEEP OUT OF REACH OF CHILDREN
DANGER

See side panels for additional precautionary and first aid statements

Microgen, Inc.
122 Fairfield Road
Post Office Box 1201
Fairfield, New Jersey 07006-1201

NET CONTENTS: 55 gal., 25 gal., 5 gal., 1 gal., 1/2 gal., 32 oz., and 16 oz. trigger; 29 oz. squeeze bottle

SPECIAL INSTRUCTIONS: For the use of antitubercular pesticides against HIV.

WARNING: SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV ON SURFACE/OBJECTS SOILED WITH BLOOD/BOOD FLUIDS; FOLLOWING:

GENERAL INSTRUCTIONS: When handling items soiled with blood or body fluids specific barrier protection must be worn, such as disposable latex gloves, gowns, masks or eye coverings.

CLEANING PRECAUTIONS: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant.

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

CONTACT TIME: 30 second contact time in the presence of 100 blood serum, this contact time will not control other common types of viruses and bacteria.

The only use patterns considered acceptable in conjunction with HIV efficacy claims are those that involve health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV

D125 is a phosphate free concept which provides effective cleaning specifically for hospitals, nursing homes, schools, food processing plants and other institutions where housekeeping is of prime importance in controlling contamination.

D125 when diluted at the rate of 2 ounces per gallon of water is an effective disinfectant against bacteria and fungi. It is used on all types of hard surfaces such as walls, floors, tables, chairs, telephones and such as operating rooms, patient rooms, etc. The product is designed to provide disinfection.

In addition, D125 deodorizes the hard to keep fresh smelling, empty garbage bins and cans, to keep them from odors caused by them.

DISINFECTION - At 2 ounces per gallon of water, D125 is an effective disinfectant against *Pseudomonas aeruginosa* ATCC 27812, *Escherichia coli*, *Staphylococcus aureus*, *Salmonella schottmulleri*, *Salmonella choleraesuis*, *Streptococcus salivarius*.

Disinfects Additional 38
At this level the product is also active against *Trichophyton* spp.

Virucidal Activity: The product is an effective virucidal activity against *Pseudomonas aeruginosa* ATCC 27812, *Escherichia coli*, *Staphylococcus aureus*, *Salmonella schottmulleri*, *Salmonella choleraesuis*, *Streptococcus salivarius*, *Adenovirus* type 12, *Poliovirus* type 1, *Rotavirus* type 1, *Herpesvirus* type 1, *Measles virus* (representative of all measles viruses), *Human immunodeficiency virus* (HIV) after 30 second contact time. This contact time is sufficient to control types of viruses and bacteria.

Efficacy tests have demonstrated that D125 is effective against *Herpesvirus* type 1, *Measles virus* (representative of all measles viruses), *Human immunodeficiency virus* (HIV) after 30 second contact time.

Mold and Mildewstat - D125 prevents the growth of mold and mildew on hard surfaces.

SANITIZATION - When used for sanitization of food contact surfaces, D125 is effective against *Escherichia coli*, *Staphylococcus aureus*, *Salmonella schottmulleri*, *Salmonella choleraesuis*, *Streptococcus salivarius*, *Adenovirus* type 12, *Poliovirus* type 1, *Rotavirus* type 1, *Herpesvirus* type 1, *Measles virus* (representative of all measles viruses), *Human immunodeficiency virus* (HIV) after 30 second contact time.

STORAGE AND DISPOSAL
DO NOT CONTAMINATE
DO NOT REUSE
DO NOT REUSE

Registration Number - Pesticide Registration Number must be applicable (federal, state and local).

Consult Microgen - Dispose of or by incineration, or, if all other methods fail, by burning. If all other methods fail, by burning.

General (Consult Federal, State or approved alternative procedures).

1. Aspergillus niger isolate AIDS (C-1)* (lung)
2. Cryptococcus neoformans isolate AIDS (C-2) (lung)
3. Candida albicans isolate AIDS (C-3)* Sputum
4. Staphylococcus aureus isolate AIDS (C-4) (80/81)* (sepsis)
5. Streptococcus pneumoniae isolate AIDS (C-5)* (lung)
6. Pseudomonas aeruginosa isolate AIDS (C-6)* (ankle lesion ulcer)

Gram Positive Cocci

7. Streptococcus agalactiae hemolyticus*
8. Enterococcus faecalis*
9. Staphylococcus epidermidis septicemia (Drug resistant)*
10. Staphylococcus saprophyticus
11. Staphylococcus aureus (toxic shock, penicillin resistant) strain 750
12. Micrococcus luteus

Gram Negative Rods

13. Klebsiella oxytoca (Drug resistant)* (wound)
14. Enterobacter agglomerans (Drug resistant)* (abscess)
15. Enterobacter liquefaciens*
16. Morganella morganii (Drug resistant)*
17. Proteus mirabilis (drug resistant)*
18. Escherichia coli (Drug resistant)* wound
19. Klebsiella pneumoniae (Drug resistant)*
20. Proteus vulgaris*
21. Acinetobacter anitratus*
22. Escherichia coli* (urine)
23. Pseudomonas aeruginosa (Drug resistant) (Burn sepsis)*
24. Hafnia alvei (lesion)*
25. Enterobacter cloacae (urine)*
26. Pseudomonas cepacia (CDC PVP-I resistant)
27. Acinetobacter lwoffii
28. Bordetella bronchiseptica
29. Pseudomonas paucimobilis
30. Pseudomonas pseudomallei (Viet Nam)
31. Pseudomonas putida
32. Flavobacterium menigosepticum
33. Pseudomonas fluorescens
34. Pseudomonas stutzeri
35. Pseudomonas dimunita
36. Serratia marcescens (cyst)* (Sulfa-resistant)
37. Enterobacter gergoviae
38. Psuedorabies NOTE. 30 Second Contact Time. Non-Human Pathogenic Virus
No Data Submitted.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 10 1989

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* Recent Clinical Isolates

jiList#1