

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 08 1990

10F5
PM 31
61178-1

Microgen, Inc.
P.O. Box 1281
Fairfield, NJ 07006

Attention: Bob Prince
President

Gentlemen:

Subject: D-125
EPA Registration No. 61178-1
Your Submission Dated December 12, 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. Within the Instruments/Tools section
 - Add: Thoroughly preclean
 - Revise: Change solution weekly to: Change solution daily or when visibly dirty.
 - b. Include the reference asterisk for all the virucidal claims (3 locations).
 - c. Herpes Simplex Type 2 has been deleted as per phone conversation. No Data as yet to be submitted.
 - d. Clearly indicate that Polio Type I is a 30 minute contact time.

59566:I:V.G.:Lee:L-3:KENC0:2/5/90:3/5/90:dg:sw:vo:ek:dg

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

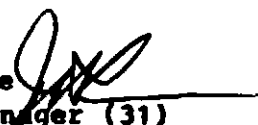
-2-

- e. Clearly indicate that left panel virucidal claim is a continuation of the Directions for Use (right panel). 20FS
- f. Revise Mold to read: Fungi.
- g. Sanitization section - Add the necessity of removal of gross food particles and soil prior to cleaning.
- h. Revise the HIV-1 claim (1st paragraph) to read: precleaned environmental surfaces. Refer to FR.

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

5073

ACCEPTED
with COMMENTS
in EPA Register

FEB 08 1990

FRONT PANEL

61178-1

D-125

HOSPITAL SURFACE DISINFECTANT

B R O A D S P E C T R U M

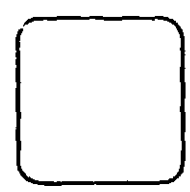
CLEANS AS IT
KILLS

**CLEANER • DISINFECTANT • DETERGENT • FUNGICIDE • DEODORIZER
SANITIZER • VIRUCIDE • MILDEWSTAT**

ACTIVE INGREDIENTS:

Alkyl (60%C14, 30%C16, 5%C12, 5%C18)
benzyl ammonium chloride2.25%
n-Alkyl (68%C12, 32%C14)
dimethyl ethylbenzyl ammonium chloride2.25%
Inert ingredient95.50%

TOTAL.....100.00%



MICROGEN, INC.
122 Fairfield Road
P.O. Box 1251
West Caldwell, N.J. 07006-1281

EPA Reg. No. 61178-1
EPA Est. No. 42186-MN-01

NET CONTENTS: 55 gal.,
35 gal., 5 gal., 1 gal., 1/2 gal.,
32 oz., and 16 oz. trigger,
20 oz. squeeze bottle

**KEEP OUT OF REACH OF CHILDREN
DANGER**

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Right Panel

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61128-1

dairies
restaurants
bars

Cabinets
bath tubs
shower rooms
urinals

DIRECTIONS FOR USE

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

DISINFECTION:

To be used in hospitals, nursing homes, schools, food processing plants, salons and industries to disinfect inanimate hard surfaces such as walls, floors, sink tops, toilet bowls, tables, chairs, telephones, chair arms and bed frames in areas such as operating rooms, patient care facilities and restrooms.

Add two ounces D125 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.

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

D125 is effective in the presence of organic soil (5% blood serum).

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

At 2 ounces per gallon, it is effective against the following:

INSTRUMENTS & TOOLS: Completely immerse brushes, combs, scissors, clipper blades, razors, manicure and other shop tools for 10 minutes (or as required by local authorities). Change solution weekly or when dry.

Isolates From AIDS Patients

1. Aspergillus niger
2. Candida albicans
3. Cryptococcus neoformans
4. Pseudomonas aeruginosa
5. Staphylococcus aureus
6. Streptococcus pneumoniae
- Gram Positive Clinical Isolates
7. Micrococcus luteus
8. Staphylococcus aureus
9. Staphylococcus aureus (toxic shock)
10. Staphylococcus epidermidis
11. Staphylococcus saprophyticus
12. Staphylococcus epidermidis hemolyticus
13. Streptococcus faecalis
- Gram Negative Clinical Isolates
14. Acinetobacter baumannii var. anitabae
15. Acinetobacter baumannii var. lwoffii
16. Bordetella pertussis
17. Enterobacter agglomerans

18. Enterobacter cloacae
19. Enterobacter gergoviae
20. Enterobacter liquefaciens
21. Enterococcus faecalis
22. Escherichia coli (Urinary)
23. Escherichia coli (Wound)
24. Flavobacterium meningosepticum
25. Haemophilus influenzae
26. Klebsiella oxytoca
27. Klebsiella pneumoniae
28. Morganella morganii
29. Proteus mirabilis
30. Proteus vulgaris
31. Pseudomonas aeruginosa
32. Pseudomonas cepacia
33. Pseudomonas diminuta
34. Pseudomonas fluorescens
35. Pseudomonas putida
36. Pseudomonas pseudomallei
37. Pseudomonas putida

38. Pseudomonas stutzeri
39. Serratia marcescens
- Virucidal Activity +
40. Adeno Type 2
41. Herpes Simplex type 1
42. Influenza A2-Asian
43. HIV-1 (Aids Virus)
44. Pseudorabies
45. Vaccinia
- Other Organisms
46. Brevibacterium ammoniagenes
47. Enterobacter aerogenes
48. Escherichia coli
49. Pseudomonas aeruginosa
50. Salmonella choleraesuis
51. Salmonella enteritidis
52. Salmonella enteritidis
53. Shigella dysenteriae
54. Streptococcus salivarius
- Mold
55. Trichophyton mentagrophytes

SANITIZATION - To sanitize previously cleaned and rinsed non-porous food contact surfaces, prepare 200ppm active solution by adding 4 ounces D125 to 7 gallons of water.

To sanitize immobile items (such as tanks, chopping blocks, counter tops), apply with a cloth or sponge, making sure to wet all surfaces thoroughly for at least 60 seconds.

To sanitize mobile items (such as drinking glasses, eating utensils), completely immerse for at least 60 seconds. Let air dry. Prepare a fresh solution daily or more frequently if soil is apparent.

D125 is an effective sanitizer when diluted in water up to 250 ppm hardness (CaCO₃).

MILDEWSTAT - 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.

DEODORIZER - D125 deodorizes garbage storage areas, empty garbage bins and cans, toilet bowls and any other odor causing areas. Use 2 oz. per gallon of water.

FUNGICIDE - At 2 oz. per gallon, D125 is effective against pathogenic fungi, Trichophyton mentagrophytes, in 5% organic soil.

Influenza C
Influenza B
Parainfluenza Type 1
Measles Virus
Polio Type 1

Left Panel

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6/178-1

**Precautionary Statement
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER**

KEEP OUT OF REACH OF CHILDREN: Corrosive. Causes severe eye and skin damage. Do not get in eyes, on skin or clothes. 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 eye contacts, call a physician. Remove and wash all contaminated clothing before reuse. If swallowed, drink egg whites, gelatin solution or if these are not available drink large quantities of water. Call a physician.

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

Virucidal: This product when used on environmental inanimate hard surfaces at 2 ounces per gallon of water for a 10 minute contact time (5% organic soil) is effective against Influenza A2 - Asian, Herpes Simplex Type 1, Pseudorabies virus, and Vaccinia virus. kills human immunodeficiency virus Type 1 (HIV-1) (AIDS Virus) after 30 second contact time in the presence of 10% Blood serum.

***KILLS HIV-1 ON ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in 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 the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type (HIV-1) (AIDS virus).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 FOUND ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

PERSONAL PROTECTION: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, or eye coverings.

CLEANING PROCEDURE: 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: Leave surfaces wet for 30 seconds. This contact time will not control other common types of viruses and bacteria.

STORAGE and DISPOSAL

—Do not contaminate water, food, or feed by storage disposal.

—Do not store on side.

—Avoid creasing or impacting of side walls.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray or mixture of residue is a violation of federal law. If these wastes cannot be disposed according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Triple rinse (or equivalent), then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay clear from smoke.

Metal Container: Triple rinse (or equivalent), then offer for recycling or reconditioning, or dispose of in a sanitary landfill or by other procedures approved by state and local authorities. (If container is 1 gallon or less, use this container disposal statement.)

Do not reuse empty container (bottle, can, bucket). Wrap container and put in trash.