

PM 31 61178-1

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 26 1996

Microgen Inc.
PO Box 1281
West Caldwell, NJ 07006

Attention: Robert Prince, President

Subject: D-125
EPA Registration No. 61178-1
Your Amendment Dated July 24, 1991

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

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. Make the labeling changes as outlined in the attached enclosure "Efficacy Evaluation and Technical Management Section Efficacy Review - II" before you release the product for shipment.

NOTE: Even though the review comments were conducted on the 1991 label, the 1995 label was stamped with comments since this label reflects numerous amendments over the last 4 years. The integrity of those amendment changes will not be lost. Be aware that several of the label comments in the enclosure may no longer pertain to the 1995 label.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). A release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. Submit one copy of the final printed label for our files.

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

Sincerely,



Marion J. Johnson, Jr.
Product Manager 31

CONCURRENCES							
Microbial Program Branch							
Registration Division (7505C)							
SYMBOL							
SURNAME							
DATE							

2 8 5

CENTER PANEL

D-125

BROAD SPECTRUM

HOSPITAL SURFACE CLEANS AS IT
DISINFECTANT GERMICIDAL KILLS

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

ACTIVE INGREDIENTS:

n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride	2.25%
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	2.25%
INERT INGREDIENT	95.50%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENT

Microgen Inc.
PO BOX 1281
West Caldwell, NJ 07006

EPA Reg. No. 61178-1
EPA Est. No. 63907-R-01

NET CONTENTS:

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 26 1996

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

61178-1

3-9-5

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Under the Federal Insecticide,
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LEFT PANEL

PRECAUTIONARY STATEMENTS 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.

Directions for Use (Continued):

Virucidal: This product when used on environmental inanimate hard surfaces at 2 ounces per gal. of water for a 10 minute contact time (5% organic soil) is effective against Influenza A2-Asian, Herpes Simplex Type 1, Herpes Simplex Type 2, 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, and Polio Type 1 after 30 minute contact time (5% serum). HBV (Hepatitis B Virus) in 10 minutes. *KILLS HIV-1 ON PRECLEANED ENVIRONMENTAL SURFACE 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: NO 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, the following statements may be used:

Storage: Store in securely closed original container. Avoid storage at temperature extremes or in sunlight. Avoid shipping or storing below freezing. If product freezes, thaw at room temperature and shake gently to remix components. Store in area that will prevent cross contamination of other pesticides, fertilizer, food and feed.

Pesticide Disposal: Securely wrap original container in several layers of newspaper and discard in trash.

Container Disposal: Do not reuse container. Replace cap and discard container in trash.

BEST COPY AVAILABLE

RIGHT PANEL

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 in areas such as operating rooms, patient care rooms & facilities, recovery, anesthesia, E.R. radiology, X-ray cat labs, newborn nurseries, orthopedics, respiratory therapy, surgi-centers, labs, blood collection rooms, central supply, housekeeping & janitorial rooms, nursing homes, doctors offices & labs, dentists offices & labs, schools, food processing plants, salons and dairies, restaurants, bars, sick rooms, rest rooms, shower rooms, industries to disinfect inanimate hard surfaces such as walls, floors, sink tops, toilet bowls, tables, chairs, telephones, chairs, arms and bed frames, cabinets, bathtubs, and urnals.

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.

Bottle Use/Dilution: Remove outer cap. While holding bottle by the neck, twist off inner cap and discard. Replace outer cap loosely. Gently squeeze the lower chamber until the upper reservoir is filled to the desired level. Use at a dilution of 1:64 (2 ozs. per gallon of water or 16 ml per liter).

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 and 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.

INSTRUMENT & TOOLS: Thoroughly pre-clean. Completely immerse brushes, combs, scissors, clipper blades, razors, manicure and other shop tools for 10 minutes (or as required by local authorities). Change solution daily or when visibly dirty.

NOTE: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried and kept in a clean noncontaminated receptacle. Prolonged soaking may cause damage to metal instruments.

At 2 ounces per gallon, 4 is effective against the following

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. Streptococcus agalactiae hemolyticus
13. Streptococcus lactalis
- Gram Negative Clinical Isolates
14. Acinetobacter calcoaceticus var. anitratus

15. Acinetobacter calcoaceticus var. wolfei
16. Bordetella bronchiseptica
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 dimorpha
34. Pseudomonas fluorescens
35. Pseudomonas paucimobis
36. Pseudomonas pseudomallei
37. Pseudomonas putida
38. Pseudomonas stutzeri
39. Serratia marcescens
- Viricidal Activity
40. Adeno Type 2
41. Cytomegalovirus
42. Herpes Simplex type 1
43. Herpes Simplex type 2
44. HIV-1 (AIDS Virus)
45. Influenza A2-A/San
46. Influenza B
47. Influenza C
48. Measles Virus

HBV (Hepatitis B Virus)

49. Parainfluenza type 1
50. Polio Type 1
51. Pseudorabies
52. T1 bacteriophage
53. T4 bacteriophage
54. Vaccinia
- Other Organisms
55. Brucella abortus
56. Enterobacter aerogenes
57. Escherichia coli
58. Pseudomonas aeruginosa
59. Salmonella choleraesuis
60. Salmonella schottmulleri
61. Shigella dysenteriae
62. Streptococcus salivarius
- Fungi
63. Trichophyton mentagrophytes

SANITIZATION — Remove gross food particles and soil by preflush or scrape. To sanitize previously cleaned and rinsed hard non-porous food contact surfaces (such as meat/poultry processing plants), 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 or thoroughly drain the used solution from the surface. 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 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 26 1996

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

61128.1

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ADDITIONAL SIDE PANEL OR BACK PANEL FOR D-125

CARPET SANITIZER AGAINST ODOR CAUSING BACTERIA FOR INSTITUTIONAL AND INDUSTRIAL USE

This product sanitizes the carpet by controlling/reducing the growth of odor causing bacteria. It can be used in industrial and institutional areas such as motels, hotel chains, nursing homes and hospitals.

Vacuum carpet thoroughly prior to application. Mix 1 ounce of product per gallon of water. Follow the Injection and/or Extraction procedures as specified for any conventional steam cleaning equipment you are using. For rotary floor machines, mix 2 ounces per gallon of water and spray on carpet at a rate of 200-300 sq. ft. per gallon.

For use on washable synthetic fibers. Do not use on wool. Do not use on stain resistant carpets. Test color fastness of carpet before use. Apply diluted product to a small concealed spot, then rub with a clean white cloth. If color changes or transfers to cloth, a water base product should not be used.

After using the product, set carpet pile in one direction with a stiff brush. Place aluminum foil under the legs of furniture while carpet is drying. Over-wetting can cause carpet to shrink. Manufacturer assumes no responsibility for over-wetting to misuse.

LAUNDRY ADDITIVE (RESIDUAL BACTERIOSTATIC AND RESIDUAL SELF SANITIZING ACTIVITY UNDER CONDITIONS OF HIGH RELATIVE HUMIDITY OR WET CONTAMINATION) AGAINST ODOR CAUSING BACTERIA FOR INSTITUTIONAL, INDUSTRIAL AND HOSPITAL USE

This product sanitizes laundry such as bed spreads, sheets, pillow cases, diapers, towels, and other wet linens by controlling and/or reducing the growth of odor causing bacteria. It can be used in industrial and institutional areas such as motels, hotel chains, nursing homes and hospitals. This product is used as an addition to the final rinse cycle.

Add 8 fluid ounces of this product per 100 lbs of dry laundry to the final rinse cycle water (200 ppm).

If the product is to be diluted prior to adding in the final rinse cycle, use 1 ounce per gallon of water and then add to the washwheel in the final rinse cycle.

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in EPA Letter Dated:**

JAN 26 1996

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