

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1-17-97

Microgen, Inc.  
PO Box 1281  
West Caldwell, NJ 07006

Attention: Robert Prince  
President

Subject: D-125  
EPA Registration Number 61178-1  
Your Submission September 6, 1996

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to add additional organisms to the label is acceptable provided that you do the following:

On page 7 of the proposed label dated 9-6-96, under additional panel for subject amendment, the microorganisms Rhodococcus equi and Campylobacter jejuni should be repositioned and listed separately.

A stamped copy of your labeling is enclosed for your records. Submit one (1) copy of the final printed label prior to release of the product for shipment.

If you have any questions concerning this letter, please contact Velma Noble at (703) 305-7441.

Sincerely,



Marion J. Johnson, Jr.  
Product Manager (31)  
Antimicrobial Program Branch  
Registration Division (7505C)

## CONCURRENCES

SYMBOL								
SURNAME								
DATE								

CENTER PANEL

D-125

BROAD SPECTRUM DISINFECTANT  
HOSPITAL                      CLEANS AS IT  
DISINFECTANT                DISINFECTS  
GERMICIDAL

CLEANER • DISINFECTANT • DETERGENT • FUNGICIDE  
DEODORIZER • 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 INGREDIENTS.....	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 07005

EPA Reg. No. 61178-1                      NET CONTENTS: Varies  
EPA Est. No. 42186-MN-01

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

1-17-97

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticides  
registered under EPA Reg. No.  
61178-1

REC'D EPA/OPP/DPD1  
96 SEP 19 P2:54

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ACCEPTED  
with COMMENTS  
in EPA Letter 2-2-82

1-17-97

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended for the purpose  
registered under FIFRA law.

## LEFT PANEL

61128-1

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 on 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 hard, non-porous, inanimate environmental surfaces at 2 ounces per gal. of water for a 10 minute contact time (5% organic soil) is effective against Influenza A2-Asian, HBV (Hepatitis B Virus), Herpes Simplex Type 1, Herpes Simplex Type 2, Pseudorabies virus, and Vaccinia virus in 10 minutes. Kills human immunodeficiency virus Type 1 (HIV-1) (AIDS Virus) after 30 second contact time, and Polio Type 1 (Chat strain) after 30 minute contact time (5% serum).

\*KILLS HIV-1 AND HBV 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) or HBV.

#### SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 AND HBV OF 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, gown, 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 and 10 minutes for HIV-1 and HBV, respectively. The 30 second 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 rinsate 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 Containers:** 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.

# 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, audi-centers, labs, blood collection rooms, central supply, housekeeping & janitorial rooms, nursing homes, doctors offices & labs, dentists offices & labs (dental operatories), schools, salons, sick rooms, rest rooms, shower rooms, veterinary clinics, industries to disinfect inanimate hard, non-porous environmental surfaces such as walls, floors, sink tops, toilet bowls, tables, chairs, telephones, chair arms and bed frames, cabinets, bathtubs, and urinals.

Add two ounces D-125 per gallon of water. Remove gross filth or heavy soil. Apply solution with a mechanical sprayer so as to wet all surfaces 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 oz. 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.

D-125 is effective in the presence of organic soil (5% blood serum).

To disinfect toilet bowls, flush toilet and add 2 ounces D-125 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.

**BARBER AND BEAUTY SHOP INSTRUMENTS & 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). Fresh solution should be prepared daily or more often when the solution becomes diluted or soiled. After disinfection, wipe dry the product as appropriate.

**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, it 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 epidermis*
11. *Staphylococcus saprophyticus*
12. *Streptococcus hemolyticus*
13. *Streptococcus fecalis*
- Gram Negative Clinical Isolates
14. *Acinetobacter calcoaceticus* var. *anitratus*

15. *Acinetobacter calcoaceticus* var. *lwoffi*
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*
26. *Klebsiella aerogenes*
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 putrefaciens*
36. *Pseudomonas pseudomallei*
37. *Pseudomonas putida*
38. *Pseudomonas stutzeri*
39. *Serratia marcescens*
- Vinocel® Activity
40. Adeno Type 2
41. Cytomegalo
42. HBV (Hepatitis B Virus)
43. Herpes Simplex type 1
44. Herpes Simplex type 2
45. HIV-1 (AIDS Virus)
46. Influenza A2-Asian
47. Influenza B (Allan strain)
48. Influenza C (Taylor strain)
49. Measles Virus

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

**MILDEWSTAT** - To control mold and mildew on pre-cleaned, hard non-porous surfaces (such as floors, walls, table tops) add 2 ounces D-125 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 appears.

**DEODORIZER:** D-125 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, D-125 is effective against pathogenic fungi. *Trichophyton mentagrophytes* in 5% organic soil.

This product is not to be used as a terminal sterilant/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.

REGISTERED  
WITH THE ENVIRONMENTAL  
PROTECTION AGENCY  
IN EPA Label Data.

1-17-97

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

61178-1

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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 300-500 sq. ft. per gallon.

For use on washable synthetic fibers. Do not use on wool. 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 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.

ADDED TO  
WITH COMMENTS  
in EPA Label Draft

1-17-97

x:\wp\microgen\labelupdate.125 (2/96), 4 of 4

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
61178-1

6/8

## ADDITIONAL PANEL

### SANITIZATION: NON FOOD CONTACT SURFACES ONLY

Remove all gross filth or heavy soil prior to applying sanitizing solution.

To sanitize walls, floors and other hard nonporous surfaces in such areas as schools, institutions, industries, use mop, cloth or immerse item within a solution containing 2 ounces per gallons so as to wet surfaces thoroughly for 1 minute. Drain or air dry. Prepare fresh solution daily or when solution gets visibly dirty.

THE FOLLOWING ORGANISMS WILL BE ADDED TO THEIR RESPECTIVE AREAS ON THE LABEL AT THE NEXT PRINTING OF THE LABEL.

Enterococcus faecalis (Vancomycin resistant)  
Listeria monocytogenes  
Staphylococcus aureus (Methicillin resistant)  
Salmonella typhi  
Staphylococcus capitis  
Streptococcus pyogenes  
Newcastle Disease virus  
Avian Influenza/Turkey/Wisconsin Virus  
Aspergillus niger  
Ulocladium sp.  
Penicillium oxalicum  
Penicillium spinalosum  
Influenza A/Brazil Virus

RECEIVED  
VETERINARY SERVICES  
in BIA Labor Branch

1-17-97

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

61178-1

ADDITIONAL PANEL

SANITIZATION: FOOD CONTACT SURFACES ONLY

Remove all gross food particles and heavy soil by preflush or prescrape or when necessary a presoak. Thoroughly wash the surfaces or objects with detergent/cleaner and followup with potable water rinse prior to applying sanitizing solution. To sanitize previously cleaned and rinsed hard nonporous food contact surfaces such as food processing equipment, counter tops, drinking glasses, eating utensils in such areas as schools, institutions, industries, meat/poultry/food processing plants, dairies, bars and restaurants use mop, cloth or immerse item within a solution containing 4 ounces per 7 gallons (200 ppm active solution) so as to wet surfaces thoroughly for 1 minute. Thoroughly drain the use solution from the surface or air dry. Fresh sanitizing solution should be prepared daily or more often if the solution becomes diluted or soiled. This product is an effective sanitizer when diluted in water up to 250 ppm hardness ( $\text{CaCO}_3$ )

THE FOLLOWING ORGANISMS WILL BE ADDED TO THEIR RESPECTIVE AREAS ON THE LABEL AT THE NEXT PRINTING OF THE LABEL.

Aspergillus candidus  
Penicillium chermesinum  
Porcine parvovirus

ENVIRONMENTAL HAZARDS (statement for containers of 5 gallons or more)

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

ACQUINNO  
W/8 6A. 6115  
In EPA Letter Dated:

1-17-97

Under the provisions of the Fungicide, and Insecticide Act as amended, for the product registered under EPA Reg. No. 61178-1

ADDITIONAL PANEL FOR SUBJECT AMENDMENT DATED 9-6-96

THE FOLLOWING ORGANISMS WILL BE ADDED TO THEIR RESPECTIVE AREAS ON THE LABEL AT THE NEXT PRINTING OF THE LABEL.

Bordetella bronchiseptica  
Streptococcus equi var. zooepidermicus  
Corynebacterium pseudotuberculosis  
Rhodococcus equi Campylobacter jejuni  
Yersinia enterocolitica  
Actinomyces pyogenes  
Pseudomonas pickettii  
Staphylococcus auricularis  
Staphylococcus simulans  
Staphylococcus hominis  
Escherichia coli strain 0157:H7  
Pasteurella haemolytica  
Escherichia vulneris  
Salmonella typhi

1-17-97  
with 10/1/97  
in EPA 1-17-97

Under the terms of the  
Regulatory and Enforcement Act  
no amount of the product  
registered under EPA Reg. No.

61178-1