

DM31

61178-1 6/30/98
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/11

JUN 30 1998

Microgen, Inc.
P.O. Box 1281
West Caldwell, NJ 07006

ATTN: Robert Prince, President

SUBJECT: D-125
EPA Registration No. 61178-1
Amendment Dated June 6, 1997

Dear Mr. Prince:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

Sincerely,



Velma Noble
Team Leader 31
Regulatory Management Branch I
Antimicrobial Division (7510W)

CONCURRENCES							
SYMBOL	7510W						
SURNAME	Noble						
DATE	6-30-98						

2/11

CENTER PANEL

D-125

BROAD SPECTRUM DISINFECTANT, HOSPITAL DISINFECTANT, CLEANS AS IT DISINFECTS, GERMICIDAL

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

ACTIVE INGREDIENTS:

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chloride . . .	2.25%
Alkyl (68% C ₁₂ , 32% C ₁₄) 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 STATEMENTS

NET CONTENTS: Varies

Microgen Inc.
PO Box 1281
West Caldwell, NJ 07006
EPA Reg. No. 61178-1, EPA Est. No. Varies

ALL INFORMATION
 ON THIS LABEL
 IS EPA Letter Dated
 JUN 30 1998 1998
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act
 61178-1

LEFT PANEL— NUMBER 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. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

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. If swallowed, drink egg whites, gelatin solution or if these are not available drink large quantities of water. Avoid alcohol. Call a physician immediately.

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

ENVIRONMENTAL HAZARDS

If container is 5 gallons or more, the following statement must be used:

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 into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

ACCEPTED
with COMMENTS
to RPA Letter Permit
JUN 30 1998
Director for Regional Administration
61178-1

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LEFT PANEL- NUMBER 2

STORAGE and DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Do not store on side. Avoid creasing or impacting of side walls.

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 an area that will prevent cross-contamination of other pesticides, fertilizer, food and feed.

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 of 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.

If container is 1 gallon or less, the following statement may be used: Securely wrap original container in several layers of newspaper and discard in trash.

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, remain clear of smoke.

If container is 1 gallon or less, the following statement may be used: Do not reuse container. Replace cap and discard container in trash.

ACCEPTED
 WITH COMMENTS
 by EPA Letter dated
 JUN 30 1998

Under the original instructions
 provided, the container was
 to be discarded in the container
 designated for EPA use. See
 611787

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RIGHT PANEL-NUMBER 1

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, ER, radiology, X-ray cat labs, newborn nurseries, orthopedics, respiratory therapy, surgi-centers, labs, blood collection rooms, central supply, housekeeping & janitorial rooms, nursing homes, doctor's offices & labs, dentists offices & labs (dental operatories), schools, salons, health clubs, spas, sick rooms, rest rooms, shower rooms, veterinary clinics, restaurants, bars, food processing plants, dairies, airplanes and 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. For heavily soiled areas, a pre-cleaning step is required. Apply solution with a cloth, mop, sponge or hand pump trigger sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes and then let air dry. Prepare a fresh solution for each use.

D-125 is effective in hard water up to 400 ppm hardness (calculated as CaCO₃) and in the presence of organic soil (5% blood serum).

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 preclean. Completely immerse brushes, combs, scissors, clipper blades, razors, tweezers, 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.

FUNGICIDE - At 2 ounces per gallon, D-125 is effective against the pathogenic fungus *Trichophyton mentagrophytes* in 5% organic soil. *Contact Time - 10 minutes*

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 ounces per gallon of water or 16 ml per liter).

ACCEPTED
WITH COMMENTS
By EPA Letter Request
JUN 30 1989

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this product is registered under EPA Reg. No. 61178-1

Product

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RIGHT PANEL CONTINUED

VIRUCIDAL*: When used on inanimate, hard, non-porous, environmental surfaces at 2 ounces per gallon of water for a 10 minute contact time (5% organic soil), except for Poliovirus type 1 (Chat strain): which requires a 30 minute contact time (5% organic soil).
FOR CALIFORNIA USE ONLY: HBV contact time is 15 minutes

***KILLS HBV AND HIV-1 ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in healthcare settings or other settings in which there is a likelihood of soiling 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 HBV (Hepatitis B Virus) or HIV-1 (AIDS virus).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HBV AND HIV-1 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, 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 and 10 minutes for HIV-1 and HBV, respectively. The 30-second contact time will not control other common types of viruses and bacteria. **FOR CALIFORNIA USE ONLY**: HBV contact time is 15 minutes

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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

ACCEPTED
with COMMENTS
to EPA Letter Request
JUN 30 1998
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61178-1

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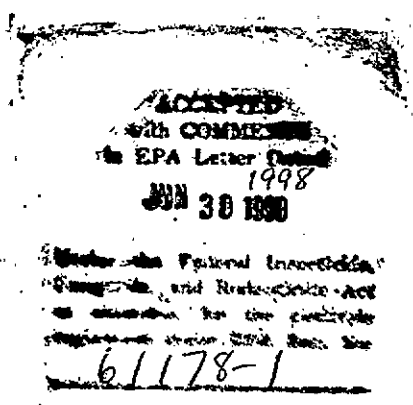
7/11

SANITIZATION - FOOD CONTACT SURFACES: 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 follow up with a potable water rinse prior to applying the sanitizing solution. To sanitize previously cleaned and rinsed hard, nonporous food contact surfaces such as food processing equipment, counter tops, drinking glasses and eating utensils in such areas as schools, institutions, industries, meat/poultry/food processing plants, dairies, bars and restaurants, use a mop, cloth or immerse item in a solution containing 4 ounces of D-125 per 7 gallons of water (200 ppm active solution) so as to wet surfaces thoroughly for 1 minute. Thoroughly drain the used solution from the surface or air dry. Fresh sanitizing solution should be prepared daily or more often if the solution becomes diluted or soiled. D-125 is an effective sanitizer when diluted in water up to 250 ppm hardness (CaCO₃).

SANITIZATION - NON-FOOD CONTACT SURFACES: 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, and industries, use a mop, cloth or immerse item in a solution containing 2 ounces per gallon so as to wet all surfaces thoroughly for 1 minute. Drain or air dry. Prepare a fresh solution daily or when solution gets visible dirty.

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 reappears.

DEODORIZER - D-125 deodorizes garbage storage areas, empty garbage bins and cans, toilet bowls and any other odor-causing areas. Use 2 ounces per gallon of water.



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ADDITIONAL SIDE PANEL OR BACK PANEL FOR D-125

CARPET [REDACTED]/SANITIZER AGAINST ODOR-CAUSING BACTERIA, FOR HOME, INSTITUTIONAL, INDUSTRIAL AND HOSPITAL USE

This product [REDACTED]/sanitizes the carpet by controlling/reducing the growth of odor-causing bacteria. It can be used in industrial and institutional areas such as homes, 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.

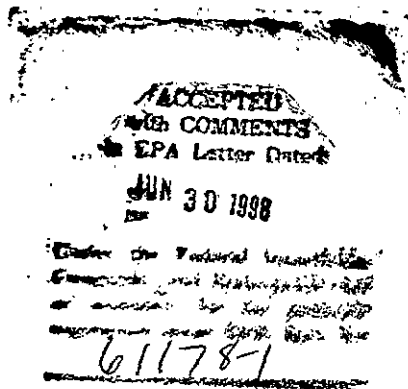
For use on washable synthetic fibers. Do not use on wool. Test color fastness of carpet before use. Apply diluted product to a small concealed spot, then rub with a clean white cloth. If color changes or transfers to cloth, a water-based product should not be used.

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 (DISINFECTANT, 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 disinfects/sanitizes laundry such as bedspreads, sheets, pillowcases, 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 it to 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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This product is effective against the following microorganisms:
Contact time is 10 minutes unless noted as below.

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 *Enterococcus faecalis*
- 8 *Micrococcus luteus*
- 9 *Staphylococcus aureus*
- 10 *Staphylococcus aureus* (Toxic shock)
- 11 *Staphylococcus epidermidis*
- 12 *Staphylococcus saprophyticus*
- 13 *Streptococcus haemolyticus*

Gram Negative Clinical Isolates

- 14 *Acinetobacter calcoaceticus* var. *anitratus*
- 15 *Acinetobacter calcoaceticus* var. *lwoffii*
- 16 *Bordetella bronchiseptica*
- 17 *Brevundimonas dimunita*
- 18 *Burkholderia cepacia*
- 19 *Enterobacter agglomerans*
- 20 *Enterobacter cloacae*
- 21 *Enterobacter gergoviae*
- 22 *Enterobacter liquefaciens*
- 23 *Escherichia coli* (Urinary)
- 24 *Escherichia coli* (Wound)
- 25 *Flavobacterium meningosepticum*
- 26 *Hafnia alvei*
- 27 *Klebsiella oxytoca*
- 28 *Klebsiella pneumoniae*
- 29 *Morganella morganii*
- 30 *Proteus mirabilis*
- 31 *Proteus vulgaris*
- 32 *Pseudomonas aeruginosa*
- 33 *Pseudomonas fluorescens*
- 34 *Pseudomonas pseudomallei*
- 35 *Pseudomonas putida*
- 36 *Pseudomonas stutzeri*
- 37 *Serratia marcescens*
- 38 *Sphingomonas paucimobilis*

Other Bacteria

- 39 *Actinobacillus pleuropneumoniae*
- 40 *Actinomyces pyogenes*
- 41 *Bacillus cereus*
- 42 *Brevibacterium ammoniagenes*
- 43 *Bordetella bronchiseptica*
- 44 *Burkholderia picketti*
- 45 *Campylobacter jejuni*

ACCEPTED
WITH COMMENTS
to EPA Letter Report

JUN 30 1998

Office of Federal Insecticide,
Fungicide and Rodenticide Act
is required by the pesticide
law to file EPA Form 611-7B-1

8710

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- 46 *Chryseomonas luteola*
- 47 *Corynebacterium pseudotuberculosis*
- 48 *Enterobacter aerogenes*
- 49 *Escherichia coli*
- 50 *Escherichia coli* strain O157:H7
- 51 *Escherichia vulneris*
- 52 *Listeria monocytogenes*
- 53 *Pasteurella haemolytica*
- 54 *Pseudomonas aeruginosa*
- 55 *Rhodococcus equi*
- 56 *Salmonella choleraesuis*
- 57 *Salmonella schottmuelleri*
- 58 *Salmonella typhi*
- 59 *Shigella dysenteriae*
- 60 *Staphylococcus auricularis*
- 61 *Staphylococcus capitis*
- 62 *Staphylococcus hominis*
- 63 *Staphylococcus simulans*
- 64 *Stenotrophomonas maltophilia*
- 65 *Streptococcus equi* var. *equi*
- 66 *Streptococcus equi* var. *zooepidermicus*
- 67 *Streptococcus pyogenes*
- 68 *Streptococcus salivarius*
- 69 *Yersinia enterocolitica*

ACCEPTED
with COMMENTS
EPA Letter Dated:
JUN 30 1998
Gene in Federal Insecticide,
Fungicide, and Rodenticide Act
is exempted for the pesticide
application under FIFRA Sec. 24c
61178-1

Pathogenic Fungi

- 70 *Trichophyton mentagrophytes*

Environmental Fungi

- 71 *Aspergillus candidus*
- 72 *Aspergillus niger*
- 73 *Penicillium chermesinum*
- 74 *Penicillium oxalicum*
- 75 *Penicillium spinulosum*
- 76 *Ulocladium sp.*

Antibiotic Resistant Gram Negative Rods

- 77 *Pseudomonas aeruginosa* (Sulfa, Cefatoxime, Nitrofurantoin, Tetracycline, Amikacin, Ampicillin, Cephalothin and Bactine Resistant)
- 78 *Escherichia coli* (Sulfa, Tetracycline, Ampicillin and Penicillin Resistant)
- 79 *Klebsiella oxytoca* (Sulfanilimide and Tetracycline Resistant)
- 80 *Klebsiella pneumoniae* type 1 (Cephalothin, Ampicillin, Sulfa and Tetracycline Resistant)
- 81 *Morganella morganii* (Penicillin and Tetracycline Resistant)
- 82 *Enterobacter agglomerans* (Ampicillin and Sulfanilimide Resistant)

Antibiotic Resistant Gram Positive Rods

- 83 *Enterococcus faecalis* (Vancomycin Resistant)
- 84 *Staphylococcus aureus* (Methicillin, Penicillin G, Ampicillin, Cefaeolin, Cefatoxime, Chloramphenicol, Ciprofloxacin, Clindimycin, Erythromycin, Oxacillin, Rifampin and Tetracycline Resistant)
- 85 *Staphylococcus epidermidis* (Drug Resistant)

Human Viruses

- 86 Adenovirus type 2
- 87 Cytomegalovirus
- 88 HBV (Hepatitis B Virus) FOR CALIFORNIA USE ONLY: HBV contact

11/11

- time is 15 minutes
- 89 Herpes Simplex type 1 Virus
- 90 Herpes Simplex type 2 Virus
- 91 HIV-1 (AIDS Virus)
- 92 Influenza A/Brazil Virus
- 93 Influenza A/Victoria (H3N2) Virus
- 94 Influenza A2-Asian Virus
- 95 Influenza B Virus (Allen strain)
- 96 Influenza C Virus (Taylor strain)
- 97 Measles Virus
- 98 Parainfluenza type 1
- 99 Poliovirus type 1 (Chat strain) 30 minutes contact time
- 100 Vaccinia Virus
- Non-Human Viruses**
- 101 Avian Influenza/Turkey/Wisconsin Virus
- 102 Canine Herpesvirus
- 103 Duck Hepatitis B Virus
- 104 Equine Herpesvirus
- 105 Equine Influenza
- 106 Feline Calicivirus
- 107 Feline Infectious Peritonitis
- 108 Infectious Bovine Rhinotracheitis (IBR)
- 109 Newcastle Disease Virus
- 110 Porcine Parvovirus
- 111 Pseudorabies Virus
- 112 Transmissible Gastroenteritis (TGE)
- 113 T1 bacteriophage
- 114 T4 bacteriophage

ACCEPTED
 with COMMENTS
 to EPA Letter Dated
 JUN 30 1988
 Date of Review Meeting
 Panel and Recommendations
 as shown on the sample
 application cover sheet for
 61178-1