



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 15 2005

Mr. Robert Prince
Microgen Inc.
33 Clinton Rd. Ste. 102
West Caldwell, NJ 07006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: Public Places
EPA Registration No. 61178-2
Amendment Date: May 18, 2005
EPA Receipt Date: May 18, 2005

Dear Mr. Prince,

The amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

- Response to Agency letter dated October 12, 2004

Conditions

Revise the label as follows:

1. Bold the headings, "**Precautionary Statements**" and "**First Aid.**"
2. Revise the "Fungicidal" directions by stating "*Spray solution making sure to wet all surfaces completely. Wait 10 minutes, then remove excess liquid or allow to air dry.*"
3. Revise the "Deodorizer" directions by stating "*Spray solution making sure to wet all surfaces completely. Allow to air dry.*"
4. The additional use, "Food Processing Areas," must have specific use directions. Add the following:

Disinfection of Food Processing Areas: Before use in food processing areas, all food products and packaging materials must be removed from the room or carefully protected. Spray solution making sure to wet all surfaces completely. Wait 10 minutes, then remove excess liquid or allow to air dry.
5. Under "Special Instructions for Cleaning/Sanitizing Carpet Against Odor Causing

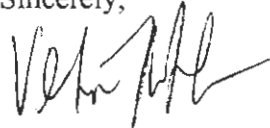
Bacteria,” state “*Do not mix this product with other cleaning products. After using this product, set the carpet pile in one direction with a stiff brush. Protect the carpet from furniture legs and bases while drying by placing aluminum foil under them. Do not over wet because it can cause carpet shrinkage.*”

General Comments

A stamped copy of the accepted labeling with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

If you have any questions or comments regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

A handwritten signature in black ink, appearing to read 'Velma Noble', with a stylized flourish at the end.

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosure: Stamped Label

BOTTLE:FRONT PANEL

PUBLIC PLACES

Virucidal Disinfectant spray, Cleans as it disinfects, Redefining Clean
Ready to Use, Ready to Use Spray, Ready to Use Solution
Contains Public Places Brand Hospital Disinfectant Formula Exclusively from Microgen, Inc
Disinfectant, Cleaner, Fungicide, Mildewstat, Virucide*, Germicide, Deodorizer

ACTIVE INGREDIENTS

Alkyl (C ₁₄ 60%,C ₁₆ 30%,C ₁₂ 5%,C ₁₈ 5%) dimethyl benzyl ammonium chloride.....	0.07%
Alkyl (C ₁₂ 68%,C ₁₄ 32%) dimethyl ethylbenzyl ammonium chloride.....	0.07%
INERT INGREDIENTS	99.86%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for additional precautionary statements.
Net Contents: 1-32 ounces

BOTTLE:BACK PANEL

DIRECTIONS FOR USE

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

A one-step disinfectant spray that works in the presence of 5% organic load. For use on tables, counters, toilet seats, telephones, door knobs and similar hard nonporous inanimate environmental surfaces in hospitals, food processing areas, homes, restaurants, hotels, motels, gas stations, health clubs and spas. Controls cross contamination from treated inanimate environmental surfaces.

TO DISINFECT/ CLEAN/ DEODORIZE:

Preclean all heavily soiled surfaces prior product application. To clean, deodorize, and disinfect hold dispenser 10 inches from the surface, press atomizer with quick short strokes, spraying evenly until surface is thoroughly wet. OR To clean, deodorize, and disinfect apply product with a cloth, sponge or other suitable applicator until surface is thoroughly wet. Wait 10 minutes, and wipe dry or air dry. For food contact surfaces such as tables and counters, rinse with potable water. Do not use on glasses, dishes or utensils. Refer to insert for complete organism contact times.

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals.

Caution. Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or tobacco. Remove contaminated clothing and wash before reuse.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

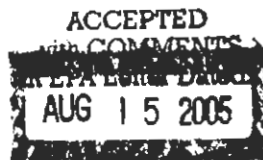
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional medical advice, call the following emergency phone number: 000-000-0000.

(For containers 1 gallon or less)

STORAGE AND DISPOSAL

Store in area inaccessible to children and person unfamiliar with product use. Do not reuse empty container. Discard in trash.

Microgen Inc.
33 Clinton Road Suite 102
West Caldwell, NJ 07006



EPA REG NO. 61178-2
EPA EST. NO. Varies

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

CARD- FRONT PANEL

For pocket, purse, or institutional use
For travel or work

SPRAY ONTO:

Toilet Seats
Telephones, Furniture
Door Knobs, Light Switches
Bathroom Fixtures, Sinks
Bathtubs, Shower Stalls
Stoves, Exterior Surfaces of Refrigerators
Interior Surfaces of Commercial Refrigerators**
Counters, Tables

FOR USE IN:

Public Restrooms
Airplanes
Hotels, Motels
Day Care Centers/Nursing Homes
Highway Service Areas/Gas Stations
Hospitals/Doctors-Dentist Offices & Labs/Clinics & Sickrooms
Veterinary Clinics
Health Clubs/Spas/Gyms
Restaurants/Bars/Fast Food Chains
Homes, Offices
Laundromats
Camp Sites, RV's
Industries/Institutions
Food Processing Areas

FOR USE BY:

Vacationers
Business Travelers
Truckers
Doctors, Nurses
Paramedics
CPR Instructors
Firefighters, Police

**Note to users in commercial settings: Interior surfaces of refrigerators are classified by the USEPA as a food contact surface and require the user to conduct a potable water rinse on the interior surfaces of the refrigerator after the interior surfaces are treated with this product.

SIDE PANEL

***KILLS HIV-1 AND HBV ON PRECLEANED 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 1 (HIV-1) (associated with AIDS) or Hepatitis B Virus (HBV).

SPECIAL INSTRUCTIONS FOR CLEANING & DECONTAMINATION AGAINST HIV-1 AND HBV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:(bolded as per EPA ltr)

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 10 minutes and 30 seconds for HBV and HIV-1, respectively. Use 10 minute contact time to mitigate other viruses, bacteria and fungi listed on the label and/or on the insert unless noted for specific organisms which require longer contact time.

Note: For hospital/medical areas, one of the following statements must be retained

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.

OR

This product is not for use on medical device surfaces.

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, spray this solution so as to wet all surfaces thoroughly for 1 minute. Air dry.

MILDEWSTAT: To control mold and mildew on pre-cleaned, hard, non-porous surfaces (such as floors, walls, table tops). Spray solution making sure to wet all surfaces completely. Let air dry. Repeat application at weekly intervals or when mildew growth reappears.

DEODORIZER: This product deodorizes garbage storage areas, empty garbage bins and cans, exterior surfaces of toilet bowls and any other odor-causing areas.

FUNGICIDAL: Kills Trichophyton mentagrophytes, agent causes Athlete's Foot Fungus, on hard nonporous surfaces in areas such as locker rooms, exercise facilities and bath and shower areas.

FOR VETERINARY CLINICS DISINFECTANT USE

1. Remove all animals and feed from premises, cars, boats, trucks and other equipment.
2. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Treat all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried.
8. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

BACK OR SIDE PAGE/PANEL OR INSERT NO. 01

NOTE: INSTRUCTIONS FOR USE ON LARGER SIZE CONTAINERS SUCH AS ONE QUART, ONE GALLON OR BULK WHICH ARE NOT SOLD WITH A HAND PUMP TRIGGER DEVICE

CARPET TREATMENT AGAINST ODOR CAUSING BACTERIA FOR INSTITUTIONAL AND INDUSTRIAL USE

This product treats 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 quart (32 ounces) 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 quarts (64 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. 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 the carpet is drying. Over-wetting can cause carpet to shrink. Manufacturer assumes no responsibility for over-wetting misuse.

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

This product treats 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 2 gallons 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 quart per gallon of water and then add to the washwheel in the final rinse cycle.

NOTE: INSTRUCTIONS FOR USE ON LARGER SIZE CONTAINERS SUCH AS ONE QUART, ONE GALLON, FIVE GALLONS OR BULK WHICH MAY OR MAY NOT BE SOLD WITH A HAND PUMP TRIGGER DEVICE

WATER DAMAGE RESTORATION :

Sanitizer against odor-causing bacteria and fungi for home, institutional, industrial, and hospital use.

This product is particularly suitable for use in water damage restoration situations to sanitize against odor causing bacteria on the following porous and semi-porous materials: carpets, carpet cushion, sub floors, drywall, trim, and frame lumber, tackless strip and paneling. Use as supplied, saturate affected materials with enough product to remain wet for at least 10 minutes. Use proper ventilation.

Carpets, carpet cushions and other porous materials such as sub floors, drywall, trim and frame lumber, tackless strip and paneling: For water damage from a clean water source, extract excess water. Test hidden area for color fastness. Apply product as supplied. Remove gross filth or heavy soil. Apply directly with a sprayer using a coarse spray tip, to fully saturate affected materials. Roll, brush or agitate into materials and allow the materials to remain damp for 10 minutes. Follow with a thorough extraction. Dry rapidly and thoroughly.

Special Instructions for Cleaning/Sanitizing Carpet Against Odor Causing Bacteria:

This product may be used in industrial and institutional areas such as homes, motels and hotels, nursing homes, schools and hospitals. For use on wet cleanable synthetic fibers, do not use on wool. Vacuum carpet thoroughly prior to cleaning. Test fabric for color fastness. For portable extraction units: Use product as supplied without dilution. Follow the cleaning procedures specified by the manufacturer of the cleaning equipment.

FOR USE ON 5 - 55 GALLON CONTAINERS OR REFILLS

(For containers greater than 1 gallon)

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store in area inaccessible to children or persons unfamiliar with product uses. Do not store on side.

Avoid creasing or impacting 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 of by use 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 out of 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 5 gallons or more, the following statement must be used:

ENVIRONMENTAL HAZARDS

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.

INSERT

This product is effective against the following microorganisms:
Contact time is 10 minutes unless noted as below.

Isolates From AIDS Patients

- 1 *Aspergillus niger* (FOR CALIFORNIA USE ONLY: Contact Time is 20 Minutes)
- 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*
- 46 *Chryseomonas luteola*
- 47 *Corynebacterium ammoniagenes*
- 48 *Corynebacterium pseudotuberculosis*
- 49 *Enterobacter aerogenes*
- 50 *Escherichia coli*
- 51 *Escherichia coli* strain O157:H7
- 52 *Escherichia vulneris*
- 53 *Legionella pneumophila*
- 54 *Listeria monocytogenes*
- 55 *Neisseria gonorrhoeae*
- 56 *Pasteurella haemolytica*
- 57 *Pseudomonas aeruginosa*
- 58 *Rhodococcus equi*
- 59 *Salmonella choleraesuis*
- 60 *Salmonella schottmuelleri*
- 61 *Salmonella typhi*
- 62 *Shigella dysenteriae*
- 63 *Staphylococcus auricularis*
- 64 *Staphylococcus capitis*
- 65 *Staphylococcus hominis*
- 66 *Staphylococcus simulans*
- 67 *Stenotrophomonas maltophilia*
- 68 *Streptococcus equi* var. *equi*
- 69 *Streptococcus equi* var. *zooepidermicus*
- 70 *Streptococcus pyogenes*
- 71 *Streptococcus salivarius*
- 72 *Treponema pallidum* (ATCC # 27087)
- 73 *Yersinia enterocolitica*

Pathogenic Fungi

- 74 *Trichophyton mentagrophytes*

Environmental Fungi

- 75 *Aspergillus candidus*
- 76 *Aspergillus niger* (FOR CALIFORNIA USE ONLY: Contact Time is 20 Minutes)
- 77 *Penicillium chermesinum*
- 78 *Penicillium oxalicum*
- 79 *Penicillium spinulosum*
- 80 *Ulocladium* sp.

Antibiotic Resistant Gram Negative Rods

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

Antibiotic Resistant Gram Positive Rods

- 87 *Enterococcus faecalis* (Vancomycin Resistant-VRE)
- 88 *Enterococcus faecium* (Vancomycin Resistant-VRE)
- 89 *Staphylococcus aureus* (Methicillin-MRSA, Penicillin G, Ampicillin, Cefaeolin, Cefatoxime, Chloramphenicol, Ciprofloxacin, Clindimycin, Erythromycin, Oxacillin, Rifampin and Tetracycline Resistant)
- 90 *Staphylococcus epidermidis* (Drug Resistant)

Human Viruses

- 91 Adenovirus type 2
- 92 Cytomegalovirus
- 93 Echovirus II (30 minute contact time)
- 94 HBV (Hepatitis B Virus)

- 95 Herpes Simplex type 1 Virus
- 96 Herpes Simplex type 2 Virus
- 97 HIV-1 (AIDS Virus)
- 98 Influenza A/Brazil Virus
- 99 Influenza A/Victoria (H3N2) Virus
- 100 Influenza A2-Asian Virus
- 101 Influenza B Virus (Allen strain)
- 102 Influenza C Virus (Taylor strain)
- 103 Measles Virus
- 104 Parainfluenza type 1
- 105 Poliovirus type 1 (Chat strain) 30 minutes contact time
- 106 Vaccinia Virus

Non-Human Viruses

- 107 Avian Influenza/Turkey/Wisconsin Virus
- 108 Canine Herpesvirus
- 109 Duck Hepatitis B Virus
- 110 Equine Herpesvirus
- 111 Equine Influenza
- 112 Feline Calicivirus
- 113 Feline Infectious Peritonitis
- 114 Infectious Bovine Rhinotracheitis (IBR)
- 115 Newcastle Disease Virus
- 116 Porcine Parvovirus
- 117 Pseudorabies Virus
- 118 Transmissible Gastroenteritis (TGE)
- 119 T1 bacteriophage
- 120 T4 bacteriophage