

61178-2

10/22/2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 22 2003

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

Subject: Public Places
EPA Registration No. 61178-2
Amendment Date: July 21, 2003
EPA Receipt Date: July 24, 2003

Dear Mr. Prince,

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

- Update First Aid Statements per PR Notice 2001-1

Conditions

Revise the label as follows:

Page 1

1. According to data on file for this product, it is categorized as a III for acute dermal and primary eye irritation toxicity. Revise the "Precautionary Statements," as follows:

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.

2. Revise the "First Aid" statements to include the following: "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."

3. Add the heading, "To Disinfect/Clean/Deodorize:," to precede the 2nd paragraph of directions.

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4. Revise the 2nd Paragraph, by adding the statement, "For food contact surfaces such as tables and counters, rinse with potable water. Do not use on glasses, dishes, or utensils."
5. Revise the "Disposal" statement to read "**Storage and Disposal:** Store in area inaccessible to children and person unfamiliar with product use. Do not reuse empty container. Discard in trash."

Page 2

1. Under "Spray onto," revise the following site to read: "*exterior surfaces of refrigerators.*"

The Agency continues to classify this surface as food contact. We are particularly concerned about the use of this product in residential setting where we believe that the user will not conduct a potable water rinse on interior surfaces of refrigerators. If you desire that all surfaces of refrigerators be treated in a commercial setting and are willing to limit the use on these surfaces by homeowners, you should propose modified labeling to the Agency.

It is suggested that this label have separate surfaces and directions for use in commercial settings and residential settings. These directions would continue to indicate the necessity for a potable water rinse on food contact surfaces for commercial use and could include treatment of refrigerators. The residential directions would limit the product to use on exterior surfaces of refrigerators.

2. Under "For Use In," delete the site, "Veterinary Clinics," you must provide specific use directions as per DIS/TSS 18. If you would like to add this site to the label resubmit with appropriate use directions.

Page 3

1. Bold the HIV labeling that is capitalized.
2. Under "HIV Contact Time" revise the second sentence to read "*Use 10 minute contact time to mitigate other viruses, bacteria, and fungi listed on the label.*"
3. Under "Sanitization," delete "drain" from the last statement.
4. Delete "toilet bowls" from the deodorization claim. This product is marketed as a one step cleaner, deodorizer, and disinfectant, and toilet bowl disinfection is not approved
5. Since this product is effective against Trichophyton mentagrophytes, the following claim must be added to the label: "**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."

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Page 4

1. Capitalize the headings, "Carpet Sanitizer" and "Laundry Additive."
2. Delete the phrase, "Disinfectant Activity," under Laundry Additive heading and the term, "disinfect," from the instructions; data was never submitted or cited to support this claim.

Please Note: The Agency has decided "sanitizing" is a public health claim. Efficacy data was never submitted to support the sanitizing and residual self-sanitizing claims for carpet and laundry. Once 40 CFR Part 152 and Part 156 are published, you must either submit data to support the sanitizing claims or delete the uses from the label.

Page 5

1. Revise the "Storage and Disposal" Statements to reflect the following:

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

Bold the subheading, "Pesticide Disposal" and "Container Disposal."

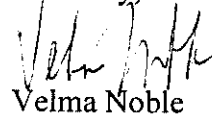
2. Delete the phrase, "Precautionary Statements (continued)."

General Comments

A stamped copy of the labeling accepted 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,



Velma Noble

Product Manager (31)

Regulatory Management Branch I

Antimicrobials Division (7510C)

CONCURRENCES

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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

ACTIVE INGREDIENTS

Alkyl (C14 60%,C16 30%,C12 5%,C18 5%) dimethyl benzyl ammonium chloride.....	0.07%
Alkyl (C12 68%,C14 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 toilet seats, telephones, door knobs and similar hard nonporous inanimate environmental surfaces in homes, restaurants, hotels, motels, gas stations, health clubs and spas. Controls cross contamination from treated inanimate environmental surfaces.

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. Wait 10 minutes, and wipe dry or air dry.
Refer to insert for complete organism contact times.

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals.
Avoid contact with eyes.

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

DISPOSAL Wrap empty container and dispose in trash container.

Microgen Inc.
33 Clinton Road Suite 102
West Caldwell, NJ 07006
EPA REG NO. 61178-2 EPA EST. NO. Varies

Public places label (07-21-2003) page 1 of 5

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 22 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 61178-2

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, Refrigerators
Countertops, 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
Schools, Offices
Laundromats
Camp Sites, RV's

FOR USE BY:

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

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:

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. The 30 second contact time will not control other common types of viruses, fungi and bacteria.

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.

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. Drain or 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, toilet bowls and any other odor-causing areas.

BACK OR SIDE PAGE INSERT

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/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 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. 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 the carpet is drying. Over-wetting can cause carpet to shrink. Manufacturer assumes no responsibility for over-wetting misuse.

**LAUNDRY ADDITIVE (RESIDUAL BACTERIOSTATIC, RESIDUAL SELF SANITIZING AND
DISINFECTANT 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 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.

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FOR USE ON 5 - 55 GALLON CONTAINERS OR REFILLS

PESTICIDE STORAGE

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

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

A 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 1 gallon or less, use this container disposal statement: Do not reuse empty container (bottle, can, bucket). Wrap container and put in trash.

PRECAUTIONARY STATEMENTS (continued)

ENVIRONMENTAL HAZARDS

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 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.

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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.*

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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)
- 88 *Enterococcus faecium* (Vancomycin Resistant)
- 89 *Staphylococcus aureus* (Methicillin, 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