

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 Towelette
EPA Registration No. 61178-4
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 2:

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. Revise the directions to state:

To Clean, Deodorize, and Disinfect: Preclean heavily soiled surfaces prior to disinfection. Thoroughly wet hard, nonporous surfaces so that it remains wet for 10 minutes. Allow to air dry. For food contact surfaces such as tables and counters, rinse

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with potable water. Do not use on glasses, dishes, or utensils.

- 4. Under "Sanitization," delete "drain" from the last statement.
- 5. 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
- 6. 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."

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. Revise the "Storage and Disposal" statements to read "*Store in area inaccessible to children and person unfamiliar with product use. Do not reuse towelette(s). Discard used towelette(s) and empty container in trash.*"

Page 4

- 1. Under "Wipe Onto" revise the site, refrigerators" to read "*Refrigerator exteriors.*"

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 "veterinary clinics" because a towelette is not an appropriate formulation to be used for veterinary clinic disinfection. DIS/TSS 18 label directions are required for this use.

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Page 5

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

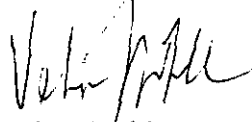
Bold the subheading, "Pesticide Disposal" and "Container Disposal."

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)

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HIGHLIGHTED COPY

FRONT PANEL

PUBLIC PLACES TOWELETTE

Disinfectant Virucidal Wipe - Cleans as it disinfects - Redefining Clean
Cleans and Disinfects
Kills germs found on phones- Cell phone cleaner and disinfectant
Will not damage-harm-discolor phones

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%
	100.00%

NOTE: Inert ingredients do not include the towelette

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for additional precautionary statements.
Net Contents: one towelette per foil wrap
6-12-24 per pak
50-100-150 per dispenser

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

EPA REG NO. 61178-4 EPA EST. NO.

**ACCEPTED
with COMMENTS
in EPA Letter Dated:
OCT 22 2003**

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

61178-4

BACK PANEL - 01

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.

DIRECTIONS FOR USE

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

TYPES OF TOWELETTE DISPENSERS

TOWELETTE: Open foil wrap, discard foil, unfold wipe.

TRAVEL PAK: Pull out wipes as needed and reseal container.

DISPENSER: To start feed, flip open cap, remove foil seal, pull towelette from center, break off at perforation and close container.

A one-step disinfectant 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.

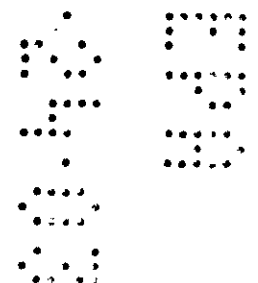
Preclean all heavily soiled surfaces prior to using the towelette. To clean, deodorize, and disinfect wipe to thoroughly wet surface. Wait 10 minutes, and let air dry. Refer to insert for complete organism contact times.

Open, unfold wipe and remove gross filth. Use a second towelette to thoroughly wet surface. The organisms are killed by exposure to the liquid in the towelette. Organisms are removed from the surface by thoroughly wiping on the surface with the towelette. Any remaining organisms are killed by the liquid deposited on the surface from the towelette.

FOR MOLD/MILDEW CONTROL - wipe surface until thoroughly wet. Allow surface to remain wet for 5 minutes. Air Dry. Repeat as needed or when mold/mildew reappears.

SANITIZATION - NON-FOOD CONTACT SURFACES: Remove all gross filth or heavy soil prior to using towelette. To sanitize hard, nonporous surfaces in such areas as schools, institutions, and industries, wipe surface until thoroughly wet. Allow surface to remain wet for 1 minute. Drain or air dry.

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



BACK PANEL - 02

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 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.

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.

STORAGE AND DISPOSAL

Empty towelette container and used towelette can be dispose in trash container.

Do not reuse towelette.

BACK PANEL - 03

Keep your cell phone clean and free of germs.
Premoistened wipe removes soil and germs.

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

WIPE ONTO:

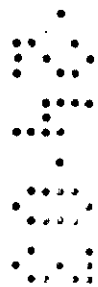
- Toilet Seats
- Telephones, Furniture
- Door Knobs, Light Switches
- Bathroom Fixtures, Sinks
- Bathtubs, Shower Stalls
- Stoves, Refrigerators
- Counters, Tables

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

FOR USE BY:

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



FOR USE ON MULTIPLE TOWELETTE BOX CONTAINERS**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 EPA Regional Office for guidance.

CONTAINER DISPOSAL

Plastic Containers. 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.

Outer Paper or Box Containers: Dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

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*
- 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

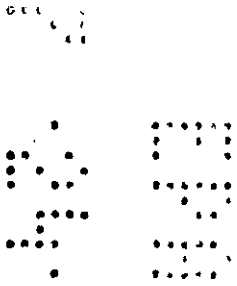
- 39 *Actinobacillus pleuropneumoniae*
- 40 *Actinomyces pyogenes*
- 41 *Bacillus cereus*
- 42 *Brevibacterium ammoniagenes*
- 43 *Bordetella bronchiseptica*
- 44 *Burkholderia picketti*
- 45 *Campylobacter jejuni*
- 46 *Chryseomonas luteola*
- 47 *Corynebacterium ammoniagenes*
- 48 *Corynebacterium 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*
- 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)
- 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

