

PM 31

61178-4

12/9/97

1089

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 18 1998

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

ATTN: Robert Prince

SUBJECT: Public Places Towelette  
EPA Registration No. 61178-4  
Amendment Dated December 1, 1997

Dear Mr. Prince:

The justification provided to revise the certified limits are acceptable. The alternate Confidential Statement of Formula dated December 1, 1997, and the revised certified limits for the active ingredient are in compliance with PR Notice 91-2, and agrees with the label, and is acceptable.

The submitted alternate CSF dated December 1, 1997 supersedes all the other alternate CSF on file. If you have any further questions, please contact Ms Barbara Pringle at (703) 308-6236.

Sincerely,



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

CONCURRENCES

COL	7510W						
SURNAME	Pringle						
DATE	2-18-98						

Pm

209

FRONT PANEL

PUBLIC PLACES TOWELETTE  
Disinfectant Virucidal Wipe  
Cleans as it disinfects - Redefining Clean

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%

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.

PO Box 1281

West Caldwell, NJ 07006

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

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

DEC 9 1997

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 61178-4

BACK PANEL

PRECAUTIONARY STATEMENTS

Hazard to humans and domestic animals.

Avoid contact with eyes. In case of contact flush eyes with water. Get medical attention if irritation persists.

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 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 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.

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.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

DEC 9 1997

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 61178-4

**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. **FOR CALIFORNIA USE ONLY:** 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.**

**STORAGE AND DISPOSAL**

Empty towelette container and used towelette can be dispose in trash container.  
Do not reuse towelette.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
DEC 9 1997  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 61178-4

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

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

DEC 9 1997

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 61178-4

489

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*

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

DEC 9 1997

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 61178-4

- 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)

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

DEC 9 1997  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 61178-4

829

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) FOR CALIFORNIA USE ONLY: HBV contact time is 15 minutes
- 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

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

DEC 9 1997

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 61178-4



929

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.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
DEC 9 1997  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 61178-4