



Mary-Ann Warmerdam
Director

Arnold Schwarzenegger
Governor

September 7, 2005

ID #212645

Mr. Robert Prince
Microgen, Inc.
33 Clinton Road, Suite 102
West Caldwell, New Jersey 07006

Dear Mr. Prince:

D125, EPA Reg. No. 61178-1-AA;
LABEL AMENDMENT TO ADD CLAIMS TO CONTROL MOLD AND
MILDEW, VIRUCIDAL CLAIMS AGAINST CANINE CORONAVIRUS
FUNGICIDAL CLAIMS AGAINST *TRICHOPHYTON MENTAGROPHYTES*
AND BACTERICIDAL CLAIMS AGAINST *ESCHERICHIA COLI*,
KLEBSIELLA OXYTOCA, *ENTEROCOCCUS HIRAE* AND OTHER
ORGANISMS TO THE LIST OF ORGANISMS CONTROLLED

The above-amended label was registered effective September 7, 2005.

This registration action is based on compliance with provisions of California laws and regulations pertaining to pesticide registration. It is on file as the "latest" registered label.

A stamped, accepted copy of the amended label is enclosed.

Sincerely,

Andrew Yokoyama
Senior Pesticide Use Specialist
Pesticide Registration Branch
(916) 324-3914
e-mail: ayokoyama@cdpr.ca.gov

Enclosures



CENTER PANEL

D-125

BROAD SPECTRUM DISINFECTANT, HOSPITAL DISINFECTANT, ANTIMICROBIAL, BROAD SPECTRUM CLEANER & DISINFECTANT, GERMICIDAL, GERMICIDE, GERMICIDAL CLEANER, CLEANS AS IT DISINFECTS, ANTIBACTERIAL, BACTERICIDE, HIV & HBV & HCV VIRUCIDE*, KILLS COMMON HOUSEHOLD GERMS, REDEFINING CLEAN

HOSPITAL VIRUCIDAL* DISINFECTANT, CONCENTRATED DISINFECTANT CLEANER, CONCENTRATED FORMULA

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	2.37%
Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chloride	2.37%
INERT INGREDIENTS	95.26%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

NET CONTENTS: Varies

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

EPA Reg. No. 61178-1
EPA Est. No. Varies

RECEIVED

JUN 08 2005

MASTER LABEL ACCEPTABLE
 NOT FOR DISTRIBUTION BY
 STATE OF CALIFORNIA
 DEPARTMENT OF PESTICIDE REGULATION
 PESTICIDE REGISTRATION
 Date 9/7/05 Reviewer YOKOYAMA
 Reg. No. 61178-1-AA

PEST/REGISTRATION

ID# _____

Contains **DISNFX-125** Brand Hospital Disinfectant Formula Exclusively from **MICROGEN, INC**

LEFT PANEL- NUMBER 1

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. KEEP OUT OF REACH OF CHILDREN. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. Wear protective eyewear (goggles, face shield or safety glasses). Wear protective clothing and rubber gloves. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT – FIRST AID

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.

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 SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

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.

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

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 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.

LEFT PANEL- NUMBER 2

STORAGE and DISPOSAL

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

STORAGE

Do not store on side. Avoid creasing or impacting of side walls. Store securely in 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. Use locked storage in an area that will prevent cross-contamination of other pesticides, fertilizer, food and feed. Store in locked area inaccessible to children.

If container is 1 gallon or less, the above storage statements may be used.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or 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 above pesticide disposal statements may be used.

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.

If container is 1 gallon or less, the following statement may be used: Do not reuse empty container. Replace cap and discard container in trash. Securely wrap original container in several layers of newspaper and discard in trash.

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.

To be used in hospitals in the following areas as a disinfectant: 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).

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.

In addition, this product may be used as a disinfectant in Mortuaries, Cosmetic Manufacturing Facilities, Medical Device Manufacturing Facilities, Biotechnology Firms, Shipping Terminals, Police Stations, Bus Stations, Train Stations, Laundromats, Trucks, Photocopier Centers, Exercise Rooms, Museums, Art Galleries, Bicycle Shops, Computer Manufacturing Sites, Post Offices, Performance/Theater Centers, Banks, Libraries, Recycling Centers, Toy Factories, Gift Shops, Tatoo Parlors, Gyms, Gymnasiums, Tanning Spas, Massage/Facial Salons, Hair/Nail Salons, Video Centers, Public Transportation, Physician Offices, EMS & Fire Facilities, Pharmaceutical Manufacturing Facilities, Auto Repair Centers, Cruise Lines, Airlines Terminals, Log Cabins, Coffee Shops, Department Stores, Retail Stores, Bagel Stores, Court Houses, Municipal Government Buildings, Colleges, Universities, Community Colleges, Campgrounds, Travel Rest Areas, Recreational Facilities, Sports Arenas, Donut Shops, Boats/Ships, Hotels/Motels, Dormitories, Movie Houses, Pizza Parlors, Lifecare Retirement Communities, Hospices, Book Stores, Convenient Stores, Liquor Stores, Day Care Centers, Acute Care Institutions, Alternate Care Institutions, Home Health Care Institutions, Food Establishments, Shopping Malls, Churches, Picnic Facilities, Schools, Barber/Beauty Shops, Salons, Health Clubs, Spas, Sick Rooms, Rest Rooms, Shower Rooms, Shower Stalls, Bathrooms, Veterinary Clinics, Restaurants, Cafeterias, Bars, Meat/Poultry/Food Processing Plants, Meat/Poultry Producing Establishments, Dairies, Farms, Poultry Houses, Swine Farms, Dog/Cat Animal Kennels, Airplanes, Industries and Homes.

This product can be used to disinfect the following inanimate, hard, non-porous nonfood environmental surfaces: walls, floors, sink tops, toilet bowls, table tops, counters, countertops, barber shop instruments and tools, appliances, tables, chairs, benches, telephones, chair arms, bed frames, cabinets, bathtubs, and urinals.

Meat/Poultry/Food Processing plants: Do not use on food contact/processing surfaces or before using this product, food products and packaging materials must be removed from the room or carefully protected. After use, all food contact surfaces in the area must be thoroughly rinsed with potable water. This product may be used in inedible product processing areas, nonprocessing areas and/or exterior areas without a rinse.

Restaurants, Cafeterias, Bars: Use a potable rinse on the following specific food contact surfaces: counters, tables, picnic tables, appliances and/or stovetops. This product should not be used to disinfect or clean utensils, glassware, dishes and cookware.

RIGHT PANEL-NUMBER 2

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).

BACTERICIDAL STABILITY OF USE-DILUTION:

Tests confirm that this product, when diluted in 400 ppm hard water and in the presence of 5% soil load, remains effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis* for up to 64 days when stored in a sealed container at room temperature.

If the use-dilution product becomes visibly dirty or contaminated, the use-dilution must be discarded and a fresh product prepared. Always use clean, properly labeled dry containers when diluting the product. Bactericidal stability of the use-dilution does not apply to open containers such as buckets or pails. Use-dilution product in open containers must be prepared daily or more often if the solution becomes visibly dirty or diluted or contaminated.

DISINFECTION:

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, hand pump trigger sprayer or other mechanical sprayer devices such that all surfaces remain wet for 10 minutes. Let air dry. Prepare a fresh solution for each use. D-125 is effective in hard water up to 300 ppm hardness (calculated as CaCO_3) and in the presence of organic soil (5% blood serum).

This product, in the presence of a 98 % organic soil load, diluted 1:64 (2 ounces per gallon) in 791 ppm Hard Water, demonstrated efficacy within 10 minutes against the following organisms:

Staphylococcus aureus, *Salmonella choleraesuis*. Note that the organisms referenced in the above statement are not associated with blood spills. For blood spills, the surface must be thoroughly cleaned before applying the disinfectant.

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.

DISINFECTION OF BARBER AND BEAUTY SHOP INSTRUMENTS & TOOLS: Thoroughly pre-clean. Completely immerse brushes, combs, scissors, clipper blades, razors, tweezers, manicure and other shop tools for 10 minutes (or longer 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.

RIGHT PANEL-NUMBER 3

FOR VETERINARY, DOG/CAT ANIMAL KENNEL, FARM PREMISE, SWINE FARM, DAIRY DISINFECTANT USE

- 1.Remove all animals and feed from premise, vehicles, and enclosures.
- 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.Immerse 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.

FOR POULTRY HOUSE DISINFECTANT USE

- 1.Remove all poultry and feeds from premises, trucks, coops and crates.
- 2.Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 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.Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set or dried.
- 7.Thoroughly scrub all treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

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 - Thoroughly clean surfaces prior to treatment. 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.

CLEANING AND DEODORIZATION - D-125 deodorizes garbage storage areas, empty garbage bins and cans, toilet bowls and any other odor-causing areas. Mix 2 ounces per gallon of water and apply solution to surfaces. Be sure to thoroughly wet surfaces, allow to air dry.

RIGHT PANEL-NUMBER 4

FUNGICIDE - At 2 ounces per gallon, D-125 is effective against the pathogenic fungus *Trichophyton mentagrophytes* in 5% organic soil load. **Contact time - 10 minutes.** Surfaces where this fungus is found: shower areas & stalls, bathroom floors, bathroom benches.

This product, in the presence of a ~100 % organic soil load, diluted 1:64 (2 ounces per gallon) in 395 ppm Hard Water, demonstrated efficacy within 10 minutes against the following pathogenic fungus: *Trichophyton mentagrophytes*. Note that the organism referenced in the above statement is not associated with blood spills. For blood spills, the surface must be thoroughly cleaned before applying this product.

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) and HIV-1 which requires only a 30 second contact time.

This product, in the presence of a 98 % organic soil load, diluted 1:64 (2 ounces per gallon) in 400 ppm Hard Water, demonstrated efficacy within 10 minutes against the following virus: Human Coronavirus. Note that the organism referenced in the above statement is not associated with blood spills. For blood spills, the surface must be thoroughly cleaned before applying this product.

***KILLS HCV, HBV AND HIV-1 ON PRE-CLEANED 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 HCV (Hepatitis C Virus), HBV (Hepatitis B Virus) or HIV-1 (AIDS virus).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HCV, 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 for HIV-1 and 10 minutes for HCV and HBV. The contact time for the viruses, fungi and bacteria listed on this label is 10 minutes except for Polio virus Type 1 (Chat strain) which is 30 minutes.

MICROORGANISM LIST 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 diminuta*
- 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 *Bordetella bronchiseptica*
- 42 *Burkholderia pickettii*
- 43 *Campylobacter jejuni*
- 44 *Corynebacterium pseudotuberculosis*
- 45 *Enterobacter aerogenes*
- 46 *Enterococcus faecalis*
- 47 *Enterococcus faecium*
- 48 *Enterococcus hirae*
- 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 schottmulleri*
- 58 *Salmonella typhi*
- 59 *Staphylococcus aureus*
- 60 *Staphylococcus auricularis*
- 61 *Staphylococcus capitis*
- 62 *Staphylococcus hominis*
- 63 *Staphylococcus simulans*
- 64 *Streptococcus equi* var. *equi*
- 65 *Streptococcus equi* var. *zooepidermicus*
- 66 *Streptococcus pyogenes*
- 67 *Streptococcus salivarius*
- 68 *Yersinia enterocolitica*

Pathogenic Fungi

- 69 *Trichophyton mentagrophytes*

Environmental Fungi

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

Antibiotic Resistant Gram Negative Bacteria

- 76 Enterobacteriaceae with extended beta-lactamase resistance (Ampicillin and Piperacillin Resistant)
- 77 *Escherichia coli* (Ampicillin, Tetracycline)
- 78 *Klebsiella oxytoca* (Ampicillin)
- 79 *Klebsiella pneumoniae* type 1 (Ampicillin, Tetracycline)

Antibiotic Resistant Gram Positive Bacteria

- 80 *Enterococcus faecalis* (Vancomycin Resistant-VRE)
- 81 *Enterococcus faecium* (Vancomycin Resistant-VRE)
- 82 *Staphylococcus aureus* (Methicillin-MRSA, Penicillin, Ampicillin, Erythromycin, Oxacillin, Tetracycline Resistant)
- 83 *Staphylococcus epidermidis* (Ampicillin)

Human Viruses

- 84 Cytomegalovirus
- 85 HBV (Hepatitis B Virus)
- 86 HCV (Hepatitis C Virus)
- 87 Herpes Simplex type 2 Virus
- 88 HIV-1 (AIDS Virus)
- 89 Human Coronavirus
- 90 Influenza A/Brazil Virus
- 91 Influenza B Virus (Alien strain)
- 92 Influenza C Virus (Taylor strain)
- 93 Measles Virus
- 94 Parainfluenza type 1
- 95 Poliovirus type 1 (Chat strain) 30 minutes contact time
- 96 Respiratory Syncytial Virus
- 97 Rotavirus

Non-Human Viruses

- 98 Avian Influenza/Turkey/Wisconsin Virus
- 99 Canine Coronavirus
- 100 Equine Influenza
- 101 Feline Calicivirus
- 102 Infectious Bovine Rhinotracheitis (IBR)
- 103 Newcastle Disease Virus
- 104 Porcine Parvovirus
- 105 Pseudorabies Virus
- 106 Transmissible Gastroenteritis (TGE)
- 107 T1 bacteriophage
- 108 T4 bacteriophage
- 109 Bovine Viral Diarrhea Virus (BVDV)