

61178-5

5-20-2003

1/11

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 20 2003

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

Subject: CCX-151
EPA Registration No. 61178-5
Amendment Date: November 21, 2002
EPA Receipt Date:

Dear Mr. Prince,

The following amendment submitted in connection with registration under FIFRA 3(c)(7)(A), as amended, is acceptable with the conditions listed below.

- Response to Agency letter dated February 13, 2002

Conditions

Revise the label as follows:

The claim, "This product in the presence of 98% soil load, diluted 1:365 (0.35 oz. per gallon) in 500 ppm hard water demonstrate efficacy within 5 minutes against *S. aureus* and *S. choleraesuis*," must be deleted from the label. The above claim deviates from the standard practices, procedures, and guidelines established by the Center of Disease Control and hospitals for handling blood spills. Also, the organisms tested are vegetative bacteria that are not bloodborne pathogens commonly associated with blood spills. Therefore, the use of this product to disinfect a blood spill will be inappropriate.

You should note that the Agency inadvertently accepted the 98% soil load claim on EPA Registration No. 61178-1, D-125, label dated , and a letter with a new stamped label has been sent to rectify the error.

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.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

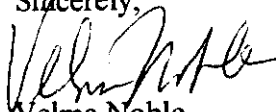
2/11

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

Sincerely,



Velma Noble

Product Manager (31)

Regulatory Management Branch I

Antimicrobials Division (7510C)

3/11

CENTER PANEL

CCX-151

BROAD SPECTRUM DISINFECTANT, HOSPITAL DISINFECTANT, CLEANS AS IT DISINFECTS, GERMICIDAL

CLEANER, DISINFECTANT, SANITIZER, DETERGENT, DEODORIZER, VIRUCIDE*

ACTIVE INGREDIENTS:

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chloride	13.238%
Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chloride	13.238%
INERT INGREDIENTS	73.524%
TOTAL	100.000%

KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

NET CONTENTS: 1 quart, 2 quarts, 1 gallon, 2 gallons, 5 gallons, 15 gallons, 55 gallons

Microgen Inc.
33 Clinton Road Suite 102
West Caldwell, NJ 07006
EPA Reg. No. 61178-5
EPA Est. No. (to be assigned)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 20 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 61178-5

Contains **CCX-151** Brand Hospital Disinfectant Formula Exclusively from **MICROGEN, INC**

4/11

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. Harmful if absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear protective clothing and rubber gloves. Wash thoroughly with soap and water after handling. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. 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.

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.

5/11

LEFT PANEL- NUMBER 2

STORAGE and DISPOSAL

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

PESTICIDE STORAGE Do not store on side. Avoid creasing or impacting of side walls. Store in locked area inaccessible to children.

If container is 1 gallon or less, the following statements may be used: Storage: Store in securely 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.

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.

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:

PESTICIDE DISPOSAL AND CONTAINER DISPOSAL

Securely wrap original container in several layers of newspaper and discard in trash. Do not reuse empty container.

6/11

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.

This product is for use in hospitals in the following areas: 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. In addition this product may be used in nursing homes, doctor's offices & labs, dentists offices & labs (dental operatories), schools, salons, health clubs, spas, sick rooms, rest rooms, shower rooms, veterinary clinics, restaurants, bars, food processing plants, dairies, airplanes on the following inanimate, hard, non-porous environmental non-food contact surfaces such as walls, floors, sink tops, exterior of toilet bowls, tables, chairs, telephones, chair arms and bed frames, cabinets, bathtubs, and exterior of urinals.

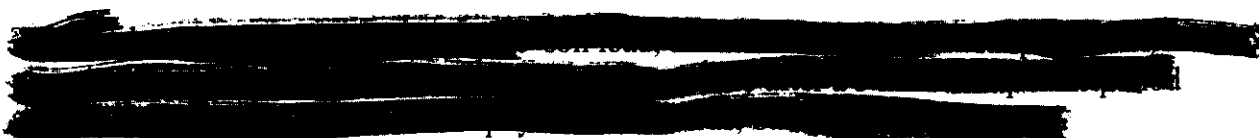
This product may also be used as a deodorizer in garbage storage areas, empty garbage bins and cans, exterior and/or interior of toilet bowls and any other odor-causing areas.

FOR VETERINARY AND DAIRY 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.

NOTE: For food processing plants and dairies, this product as a disinfectant may only be used in inedible product processing areas, nonprocessing areas and/or exterior areas.

Product is effective in hard water up to 300 ppm hardness (calculated as CaCO_3) and in the presence of organic soil (5% blood serum).



7/11

RIGHT PANEL - NUMBER 2.

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.

DISINFECTION:

Add 0.35 ounces per gallon of water (1:365 dilution). Remove gross filth or heavy soil. For heavily soiled areas, a pre-cleaning step is required. Apply solution with a cloth, mop, sponge or hand pump trigger sprayer such that all surfaces remain wet for 10 minutes. For sprayer applications, use a coarse spray device. Spray 6 to 8 inches from the surface. Rub with brush, sponge or cloth. Do not breath spray mist. Let air dry. Prepare a fresh solution for each use.

DISINFECTION OF BARBER AND BEAUTY SHOP INSTRUMENTS & TOOLS:

Thoroughly preclean. 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 instrument or tool 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.

SANITIZATION - NON-FOOD CONTACT SURFACES: Remove all gross filth or heavy soil prior to applying sanitizing solution. Where a sanitizer is required, this product can be used in the same sites and surfaces as indicated in this label. Use a mop, cloth or immerse item in a solution containing 0.35 ounces per gallon (1:365 dilution) so as to wet all surfaces thoroughly for 1 minute. Drain or air dry. Prepare a fresh solution at least daily or when solution is visibly diluted or soiled.

CLEANING AND DEODORIZATION - Product deodorizes garbage storage areas, empty garbage bins and cans, exterior and/or interior of toilet bowls and any other odor-causing areas. Use 0.35 ounces per gallon of water(1:365 dilution). Apply and wipe.

FUNGICIDE: Where a fungicide is required, this product can be used in the same sites and surfaces as indicated in this label. The dilution and application and contact time is the same as the disinfection section. List of specific sites for where a fungicide is necessary: shower areas, shower stalls, bathroom floors, bathroom benches.

8/11

RIGHT PANEL - NUMBER 3.

VIRUCIDAL*: When used on inanimate, hard, non-porous, environmental surfaces at 0.35 ounces per gallon of water (1:365 dilution) 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).

***KILLS HBV AND HIV-1 ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in healthcare settings or other settings in which there is a likelihood of soiling 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 HBV (Hepatitis B Virus) or Human Immunodeficiency Virus Type 1 HIV-1 (AIDS virus).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST 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 surface wet for 30 seconds for HIV-1 and 10 minutes for HBV. The 30-second contact time will not control other common types of viruses and bacteria.

9/11

At 0.35 ounces per gallon (1:365 dilution) and according to directions contained on this label, this product is effective against the following micro-organisms:

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 *Micrococcus luteus*
- 8 *Staphylococcus aureus*
- 9 *Staphylococcus aureus* (Toxic shock)
- 10 *Staphylococcus epidermidis*
- 11 *Staphylococcus saprophyticus*
- 12 *Streptococcus haemolyticus*
- 13 *Enterococcus faecalis*

Gram Negative Clinical Isolates

- 14 *Acinetobacter calcoaceticus* var. *anitratus*
- 15 *Acinetobacter calcoaceticus* var. *lwoffii*
- 16 *Bordetella bronchiseptica*
- 17 *Enterobacter agglomerans*
- 18 *Enterobacter cloacae*
- 19 *Enterobacter gergoviae*
- 20 *Enterobacter liquefaciens*
- 21 *Escherichia coli* (Urinary)
- 22 *Escherichia coli* (Wound)
- 23 *Flavobacterium meningosepticum*
- 24 *Hafnia alvei*
- 25 *Klebsiella oxytoca*
- 26 *Klebsiella pneumoniae*
- 27 *Morganella morganii*
- 28 *Proteus mirabilis*
- 29 *Proteus vulgaris*
- 30 *Pseudomonas aeruginosa*
- 31 *Burkholderia cepacia*
- 32 *Brevundimonas diminuta*
- 33 *Pseudomonas fluorescens*
- 34 *Sphingomonas paucimobilis*
- 35 *Pseudomonas pseudomallei*
- 36 *Pseudomonas putida*
- 37 *Pseudomonas stutzeri*
- 38 *Serratia marcescens*

10/11

Other Bacteria

- 39 *Actinobacillus pleuropneumoniae*
- 40 *Actinomyces pyogenes*
- 41 *Bordetella bronchiseptica*
- 42 *Campylobacter jejuni*
- 43 *Corynebacterium pseudotuberculosis*
- 44 *Escherichia coli* strain O157:H7
- 45 *Escherichia vulneris*
- 46 *Listeria monocytogenes*
- 47 *Pasteurella haemolyticus*
- 48 *Pseudomonas aeruginosa*
- 49 *Burkholderia pickettii*
- 50 *Rhodococcus equi*
- 51 *Salmonella choleraesuis*
- 52 *Salmonella typhi*
- 53 *Staphylococcus auricularis*
- 54 *Staphylococcus capitis*
- 55 *Staphylococcus hominis*
- 56 *Staphylococcus simulans*
- 57 *Streptococcus equi* var. *equi*
- 58 *Streptococcus equi* var. *zooepidermicus*
- 59 *Streptococcus pyogenes*
- 60 *Yersinia enterocolitica*

Environmental Fungi

- 61 *Aspergillus candidus*
- 62 *Aspergillus niger*
- 63 *Penicillium chermesinum*
- 64 *Penicillium oxalicum*
- 65 *Penicillium spinulosum*
- 66 *Ulocladium sp.*

Antibiotic Resistant Bacteria

- 67 *Enterococcus faecalis* (Vancomycin Resistant-VRE)
- 68 *Staphylococcus aureus* (Methicillin Resistant-MRSA)

Human Viruses

- 69 Cytomegalovirus
- 70 HBV (Hepatitis B Virus)
- 71 Herpes Simplex type 2 Virus
- 72 HIV-1 (AIDS Virus)
- 73 Influenza A/Brazil Virus
- 74 Influenza B Virus (Allen strain)
- 75 Influenza C Virus (Taylor strain)

11/11

- 76 Measles Virus
- 77 Parainfluenza type 1
- 78 Poliovirus type 1 (Chat strain) 30 minutes contact time

Non-Human Viruses

- 79 Avian Influenza/Turkey/Wisconsin Virus
- 80 Equine Influenza
- 81 Feline Calicivirus
- 82 Infectious Bovine Rhinotracheitis (IBR)
- 83 Newcastle Disease Virus
- 84 Porcine Parvovirus
- 85 Pseudorabies Virus
- 86 Transmissible Gastroenteritis (TGE)
- 87 T1 bacteriophage
- 88 T4 bacteriophage