

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number: 61178-5

Date of Issuance: NOV 09 1999

NOTICE OF PESTICIDE:
[X] Registration
Reregistration

Term of Issuance:
CONDITIONAL

Name of Pesticide Product:
CCX-151

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

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

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Add the phrase EPA Registration Number "EPA Reg. No. 61178-5".

Signature of Approving Official:

Handwritten signature of Velma Noble

Velma Noble
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Date:

NOV 09 1999

EPA Form 8570-6

CONCURRENCES

Table with columns for SYMBOL, SURNAMES, and DATE. Handwritten entries include 7510C, S. Leath, and 11/8/99.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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EPA Reg. No. 61178-5

3. On the center panel, place the word "Poison" on a separate line. Note that the label on the final product must list the exact contents of that package. It has been noted that your submitted label does not include an EPA Establishment Number. Be advised that the EPA Establishment Number must appear on the product label or on the immediate container of the product.

- 4. On the left panel number 2 make the following revisions.
 - 1) The last sentence of the Pesticide Storage statement for containers of 1 gallon or less must begin as follows: "Use locked storage in an area that will..."
 - 2) The last line of the Container Disposal statement for packages larger than 1 gallon must state "If burned, stay out of smoke."
 - 3) The Container Disposal statement for containers one gallon and smaller must include the statement "Do not reuse empty container."

- 5. On the right panel number 1 make the following revisions.
 - 1) Delete the phrase "General Statement". Begin this section as follows: "This product is for use in hospitals in the following areas: operating rooms, patient care rooms & facilities... janitorial rooms." The next statement must begin "In addition this product may be used in nursing homes, doctor's offices...dairies and airplanes." deleting the site "institutions" which is too broad. This section must conclude as follows: "...airplanes on the following inanimate hard, non-porous environmental non-food..."
 - 2) Then include the following statement in this section: "This product may also be used as a deodorizer in garbage storage areas, empty garbage bins, toilet bowls and other odor-causing areas."

6. Delete the "NOTE: For veterinary clinics..." and replace this with the following as per DIS/TSS-18:

"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.

		CONCURRENCES			
SYMBOL	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.			
SURNAME					
DATE					

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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7. Revise your label such that the section beginning: "This product is not to be used as a terminal sterilant/high-level disinfectant on any..." and ending "...prior to sterilization or high-level disinfection." is placed immediately before the directions for use of this product as a disinfectant.

8. Make the following revisions to the directions for disinfection.

- 1) Delete the sentence: "Refer to the General Statement section for use sites and surfaces to be treated."
- 2) Replace the phrase "so as to wet all surfaces thoroughly." with "such that all surfaces remain wet for 10 minutes."
- 3) Delete the phrase "Allow to remain wet for 10 minutes" and change that sentence to read "Let air dry."

9. On the right panel continued make the following revisions:

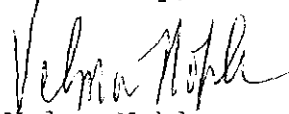
- 1) Change the phrase "or as required by local authorities" to read "or longer as required by local authorities".
- 2) In the section on sanitization delete the phrase "the General Statement section of".
- 3) Revise the subheading "Deodorization" to read "Cleaning and Deodorization". Include "Apply and wipe." as the last statement of this section.
- 4) Delete the subheadings "Cleaner" and "Detergent" including the associated directions for each.
- 5) In the section on the use of this product as a fungicide, delete the phrase "the General Statement section of".

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

A stamped copy of the label is enclosed for your records. Submit one (1) copy of the final printed label prior to the release of the product for shipment.

If you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510C)

CONCURRENCES							
SYMBOL	Enclosure (stamped label)						
SURNAME	7510C:T.Lantz:11/8/99:61178-5						
DATE							

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 - POISON



In Red (with arrow pointing to the skull and crossbones symbol)

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

NET CONTENTS: Varies

Microgen Inc.
PO Box 1281
West Caldwell, NJ 07006
EPA Reg. No. 61178-

EPA Est. No. Varies

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

NOV 9 1999

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

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LEFT PANEL- NUMBER 1

ACCEPTED
with COMMENTS
in EPA Letter Dated:

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

NOV 9 1999
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
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DANGER

KEEP OUT OF REACH OF CHILDREN: Fatal if inhaled. Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Wear goggles or face shield, protective clothing and rubber gloves. For handling activities, wear one of the following NIOSH-approved respirators: (1) A non-powered cartridge respirator equipped with an N-, R-, or P-series air-purifying filter (NIOSH prefix TC-84A), or (2) a powered cartridge respirator equipped with a high efficiency particulate air (HEPA) filter (MSHA/NIOSH approval number prefix TC-21C). 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:

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting. Do not give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or if these are not available drink large quantities of water. Avoid alcohol.

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

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

ENVIRONMENTAL HAZARDS

If 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 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.

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. Store 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, remain clear 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 9 1993

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

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.

GENERAL STATEMENT:

To be used in hospitals in areas such as 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), schools, salons, health clubs, spas, sick rooms, rest rooms, shower rooms, veterinary clinics, restaurants, bars, food processing plants, dairies, airplanes and industries to disinfect inanimate, hard, non-porous environmental nonfood contact surfaces such as walls, floors, sink tops, toilet bowls, tables, chairs, telephones, chair arms and bed frames, cabinets, bathtubs, and urinals.

NOTE: For veterinary clinics and dairies, animals should be removed from the areas being treated.

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.

DISINFECTION:

Refer to the General Statement section for use sites and surfaces to be treated. 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 so as to wet all surfaces thoroughly. For sprayer applications, use a course spray device. Spray 6 to 8 inches from the surface. Rub with brush, sponge or cloth. Do not breath spray mist. Allow to remain wet for 10 minutes and then let air dry. Prepare a fresh solution for each use.

Product is effective in hard water up to 300 ppm hardness (calculated as CaCO₃) and in the presence of organic soil (5% blood serum).

ACCEPTED
with COMMENTS
in EPA Letter Dated:

June 9

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

RIGHT PANEL CONTINUED.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 9 1991

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
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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 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 used in the same sites and surfaces as indicated in the General Statement section of 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.

DEODORIZER - Product deodorizes garbage storage areas, empty garbage bins and cans, toilet bowls and any other odor-causing areas. Use 0.35 ounces per gallon of water(1:365 dilution).

CLEANER: Where cleaning is required, this product can be used in the same sites and surfaces as indicated in the General Statement section of this label. The dilution and application and contact time is the same as the disinfection section.

DETERGENT: Where a detergent is required, this product can be used in the same sites and surfaces as indicated in the General Statement section of this label. The dilution and application and contact time is the same as the disinfection section.

FUNGICIDE: Where a fungicide is required, this product can be used in the same sites and surfaces as indicated in the General Statement section of this label. The dilution and application and contact time is the same as the disinfection section.

RIGHT PANEL CONTINUED

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).

FOR CALIFORNIA USE ONLY: HBV contact time is 15 minutes

***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.
FOR CALIFORNIA USE ONLY: HBV 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.

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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 dimunita*
- 33 *Pseudomonas fluorescens*
- 34 *Sphingomonas paucimobilis*
- 35 *Pseudomonas pseudomallei*
- 36 *Pseudomonas putida*
- 37 *Pseudomonas stutzeri*
- 38 *Serratia marcescens*

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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 picketti*
- 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)
- 68 *Staphylococcus aureus* (Methicillin Resistant)

Human Viruses

- 69 Cytomegalovirus
- 70 HBV (Hepatitis B Virus) FOR CALIFORNIA USE ONLY: HBV contact time is 15 minutes
- 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)
- 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

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- 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

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