

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Mr. Ronald Cook
Spartan Chemical Company
1110 Spartan Drive
Maumee, OH 43537

DEC 20 2001

Subject: CDC-10
EPA Registration No. 5741-21
Application Date: June 18, 2001
EPA Receipt Date: June 25, 2001

Dear Mr. Cook:

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below:

- Addition of HBV Claim
- Update Precautionary and First Aid Statements

Conditions

Revise the label as follows:

1. On page 1 and 2, the use of the triple asterisks for listing the antibiotic resistant bacteria is not necessary. However, you need include *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Salmonella choleraesuis* in the list of bacteria, this product mitigates. Also, the brackets around the organism section must be deleted because this text is not optional.
2. On page 1 and 2, Revise the "kills athletes foot fungi" claim to state "Kills *Trichophyton mentagrophytes*, the fungus that causes Athlete's Foot when used on hard non-porous surfaces such as shower room floors, bath mats, locker room benches."
3. One page 2, the use sites other commercial, industrial, or institutional facility is too broad. You need to cite specific use sites; for example, restaurants, bars,

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

cafeterias, food processing plants, offices, bus stations, manufacturing sites/facilities, food processing plants.

- 4. On page 3, revise the statement, "for five minute presence of organic soil" to read "for five minute disinfectant activity against the listed bacteria and viruses* in the presence of 5% organic soil:".
- 5. On page 3, Since this product can be used in "other commercial or industrial facility" which includes restaurants, institutional kitchens, food processing plants, you need to add the following directions under "five minute disinfectant action":

Before using this product in food processing areas, all food products and packaging materials must be removed from the room or carefully protected. After use, all food contact surfaces must be thoroughly rinse with potable water before reuse. Do not use this product to disinfect or clean utensils, glasses, dishes, or cookware.

- 6. On page 5, Under containers larger than one gallon, storage instructions must be developed with the appropriate heading for all pesticide products according to PR Notice 83-3. You may use the instructions under the one gallon or smaller storage/disposal section.

Acceptable Data

Data Requirement	Means of Support	Status
Virucidal Effectiveness Test Using Duck Hepatitis B Virus	Submitted study, MRID 454435-01	Acceptable
Confirmatory Virucidal Test using Duck Hepatitis B Virus	Submitted study, MRID 454435-02	Acceptable

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

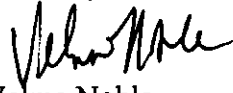
Submit and/or cite all data required for registration/reregistration of you product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not compiled 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.

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If you should 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)

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Front Copy

**CDC-10
Clinging Disinfectant Cleaner**

Foaming Clinging Action Kills Many Germs in Five Minutes!

Staphylocidal/ Pseudomonocidal/ Salmonellacidal/ Fungicidal*/ Virucidal**
Effective Against Antibiotic-Resistant Bacteria***

*Kills athlete's foot fungi, *Trichophyton mentagrophytes*.

**Kills Hepatitis B Virus (HBV), HIV-1 (AIDS Virus), Kills Herpes Simplex Type 2 and Influenza A₃/Hong Kong viruses on hard nonporous inanimate surfaces.

***Kills Methicillin-resistant Staphylococcus aureus (MRSA) and Vancomycin-resistant Enterococcus faecalis (VRE).

ACTIVE INGREDIENTS:	
Alkyl (C ₁₄ -50%, C ₁₂ -40%, C ₁₆ -10%)	
dimethyl benzyl ammonium chlorides.....	0.24%
octyl decyl dimethyl ammonium chloride.....	0.18%
dioctyl dimethyl ammonium chloride.....	0.09%
didecyl dimethyl ammonium chloride.....	0.09%
INERT INGREDIENTS:	99.40%

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

E.P.A. Reg. No. 5741-21 E.P.A. Est. No. 5741-OH-1

DEC 20 2001
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. **5741-21**

**KEEP OUT OF REACH OF CHILDREN
DANGER**
See directional panel for additional precautionary statements.

FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY

NET CONTENTS: 5 U.S. Gallons/18.95 Liters

NET CONTENTS: 1 U.S. Gallon/3.79 Liters

NET CONTENTS: 1 Quart/0.946 Liters

Label for CDC-10

EPA Reg. No. 5741-21

Spartan Chemical Company, Inc.

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Back Side Copy

CDC-10 is a ready-to-use clinging foam formulation designed for cleaning and disinfecting of walls, partitions, shower stalls, door knobs and other similar hard non-porous surfaces.

CDC-10 is recommended for use in hospitals, schools, hotels or other commercial, industrial or institutional facility where a clean and sanitary environment is important.

(NOTE TO EPA -The following bracketed text is optional)

[Staphylocidal/ Pseudomonocidal/ Salmonellacidal

*Kills athlete's foot fungi, *Trichophyton mentagrophytes*.

**Kills Hepatitis B Virus (HBV), HIV-1 (AIDS Virus), Kills Herpes Simplex Type 2 and Influenza A₃/Hong Kong viruses on hard nonporous inanimate surfaces.

***Kills Methicillin-resistant Staphylococcus aureus (MRSA) and Vancomycin-resistant Enterococcus faecalis (VRE).]

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.

Directions for Use

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

Five-Minute Disinfection Action

For five-minute disinfectant activity against the listed ***bacteria and **viruses in the presence of organic soil:

1. Spray area with undiluted CDC-10 until surface is covered with foam.
2. Allow the product to wet surface for five minutes.
3. Wipe off with a clean damp cloth or sponge. On chrome, stainless steel or glass, rinse with water.

Preliminary cleaning is required for heavily soiled areas.

For *Fungicidal Activity

1. Spray pre-cleaned surface with undiluted CDC-10.
2. Allow product to wet surface for five minutes.
3. Wipe off with a clean damp cloth or sponge.

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CDC-10 retains its disinfectant activity even when diluted!

1:10 Bactericidal Activity

1. Apply CDC-10 at 13 oz. per gallon of water (1:10) with a foam gun, mop or cloth.
2. Scrub and allow product to wet surface for 10 minutes.
3. Rinse thoroughly with water.

Preliminary cleaning is required for heavily soiled surfaces.

****KILLS HBV AND HIV 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 Hepatitis B Virus (HBV) and human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HBV AND HIV-1 ON SURFACES OR OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

PERSONAL PROTECTION: Exposure to blood or body fluids should be avoided by use of barrier protection such as latex or other impervious gloves. Face shields and impervious gowns should also be worn if splashing of blood or body fluids may occur.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant.

CONTACT TIME: Leave surfaces wet for 5 minutes.

DISPOSAL OF INFECTIOUS MATERIAL: Contaminated cleaning materials, blood and other body fluids should be autoclaved and/or disposed of according to local regulations for infectious waste disposal.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

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

(NOTE TO EPA -The following text will be used on five gallon pails and larger containers only)

ENVIRONMENTAL HAZARDS

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 to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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.
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 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.
24 HOUR MEDICAL EMERGENCY NUMBER: 888- 314-6171	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may counter indicate the use of gastric lavage.	

(NOTE TO EPA -The following text will be used on one gallon and smaller containers only)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.
Pesticide Storage: Store in original container in a cool, dry place.
Container Disposal: Securely wrap original container in several layers of newspaper and discard in trash.

Label for CDC-10

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(NOTE TO EPA -The following text will be used on five gallon pails and larger containers only)

STORAGE AND DISPOSAL

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

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 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: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.

SPARTAN CHEMICAL COMPANY, INC. 1110 Spartan Drive, Maumee, Ohio 43537

Questions? 800-537-8990/ www.spartanchemical.com

(NOTE TO EPA: The following is an optional phrase)

Fax On Demand Material Safety Data Sheet: 888-383-4666, No. (XXXXX)