

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



DEC 12 2001

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. Ronald T. Cook
Manager Regulatory Affairs
Spartan Chemical Company, Inc.
1110 Spartan Drive
Maumee, Ohio 43537

Subject: Label Amendment
Steriphene II Brand Company, Inc.
EPA Registration No. 5741-22
Your Application Dated June 25, 2001

Dear Mr. Cook:

The labeling referred to above, submitted in connection with registration under section 3 (c)(7)(A) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable.

- Add efficiency claim against Hepatitis B Virus (HBV)

Labeling:

1. The ingredient statement must total 100%
2. On the back side page 2 of 4, first paragraph, delete the statement "and others". All sites must be specified.

General Comments

The efficacy data (MRID #454433-01 and 02) submitted supports the product's effectiveness against Duck Hepatitis B Virus (DHBV), undiluted in the presence of an organic soil load (5% fetal bovine serum) at 20 ± 1°C (22C) for 10 minutes.

Submit three (3) copies of the final printed label bearing the label revisions sited above prior to releasing product for sale.

A stamped copy is enclosed for your records.

CONCURRENCES

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

If you have any questions concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely yours,



Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

Enclosure

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Mater Label for Steriphene II Brand Disinfectant

Spartan Chemical Company, Inc.

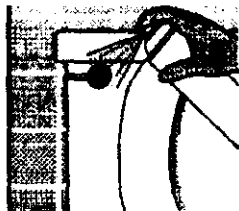
EPA Reg. No. 5741-22

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Submitted on : June 25, 2001

Front Can Copy:

(Graphic showing product being sprayed on flush handle of toilet)



Steriphene II Brand Disinfectant Deodorant

Spring Breeze Fragrance

Clean Fresh Fragrance

Bactericidal / Tuberculocidal / Fungicidal* / Virucidal**

Effective against Antibiotic-Resistant Bacteria***

For Hospital, Institutional and Industrial Use

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

[Kills Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella choleraesuis and Mycobacterium bovis.

*Kills Trichophyton mentagrophytes (causes athlete's foot).

**Kills Hepatitis B Virus (HBV), Human Immunodeficiency Virus Type 1(AIDS Virus), Herpes simplex Type 2 (causes genital herpes)and Influenza A/J305 on hard, nonporous inanimate surfaces.

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

ACTIVE INGREDIENTS:

Ethyl alcohol	64.000%
Ortho-Benzyl-para-chlorophenol	0.071%
Ortho-Phenylphenol	0.051%

INERT INGREDIENTS: 35.878%

contains sodium nitrite

ACCEPTED
with **COMMENTS**
in EPA Letter Dated:
DEC 12 2001

EPA Reg. No. 5741-22

EPA Est. No. 13891-IN-1

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No. **5741-22**

Keep Out of Reach of Children
WARNING:
See rear panel for additional precautions.

NET CONTENTS: 15 oz./425 g.

4 7 6

Mater Label for Steriphene II Brand Disinfectant

Spartan Chemical Company, Inc.

EPA Reg. No. 5741-22

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Submitted on : June 25, 2001

Back Side Can Copy:

Steriphene II Brand Disinfectant is recommended for use on hard, nonporous surfaces in hospitals, schools, hotels, office buildings, industrial plants and other medical, commercial, insitutional or industrial facilities where a sanitary environment is important.

Use on bathroom and locker room fixtures, tables, countertops, furniture, doorknobs, walls, wastebaskets and other hard, nonporous environmental surfaces.

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

[When used as directed, Steriphene II Brand Disinfectant is effective against the following pathogenic microorganisms:

Bacteria:

Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella choleraesuis, Mycobacterium bovis

***Fungi:**

Trichophyton mentagrophytes (causes athlete's foot).

****Viruses:**

Hepatitis B Virus (HBV), Human Immunodeficiency Virus Type 1(AIDS Virus), Herpes simplex Type 2 (causes genital herpes), Influenza A/J305 on hard, nonporous inanimate surfaces.

*****Antibiotic-Resistant Bacteria:**

Vancomycin-resistant Enterococcus faecalis (VRE),
Methicillin-resistant Staphylococcus aureus (MRSA)]

This product is not 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.

Clean all surfaces prior to disinfection.

Disinfection and Deodorization: Shake well. Hold can 6 to 8 inches from surface and apply in a uniform moist film. Treated surfaces should remain wet for 10 minutes. Allow to air dry or wipe off.

Tuberculocidal Activity: Steriphene II Brand Disinfectant is tuberculocidal under the above conditions in 10 minutes at 68°F (20°C).

ACCEPTED
with COMMENTS
in EPA Letter Dated:
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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended by the Fungicide
and Rodenticide Act

5741-22

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Mater Label for Steriphene II Brand Disinfectant

Spartan Chemical Company, Inc.

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Submitted on : June 25, 2001

*** 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:

1. **Personal Protection:** Clean up should be done wearing protective latex gloves, gowns, masks and eye protection.
2. **Cleaning Procedure:** Blood or body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant.
3. **Contact Time:** Leave surfaces wet for 10 minutes.
4. **Disposal of Infectious Material:** Contaminated cleaning materials, blood and other body fluids should be autoclaved and/or disposed of according to local regulations for infections waste disposal.

NOTE: Make sure valve opening is pointed in the direction of intended spray. Do not use on varnished wood or rayon fabrics. Steriphene II Brand Disinfectant Deodorant deodorizes at the source by killing the germs that cause malodors. This product is not intended for use as a general space spray air freshener.

PRECAUTIONARY STATEMENTS
 Hazards to Humans and Domestic Animals

WARNING: Causes substantial but temporary eye injury. Harmful if absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

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in EPA Letter Dated:
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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
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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.
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.	

PHYSICAL OR CHEMICAL HAZARDS

Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.

STORAGE AND DISPOSAL

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

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. (XXXX)

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