

5741-22

1/17/2002

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



JAN 17 2002

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: Final Labeling
Steriphene II Brand Disinfectant Deodorant
EPA Registration No. 5741-22
Your Letter Dated December 19, 2001

Dear Mr. Cook:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable.

Submit three (3) copies of your final printed label before you release the product for shipment bearing the amended label.

A stamped copy is enclosed for your records.

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

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Mater Label for Steriphene II Brand Disinfectant

Spartan Chemical Company, Inc.

EPA Reg. No. 5741-22

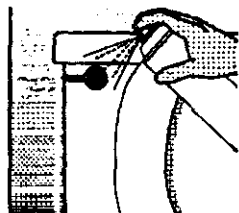
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(Steriphene II Label Corrected for 12-12-2001 EPA Comments)

2 7 5

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%

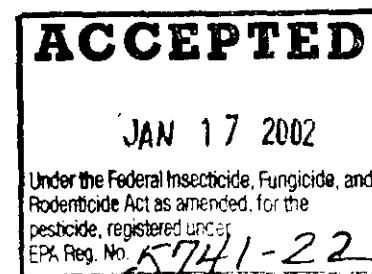
Ortho-Benzyl-para-chlorophenol 0.071%

Ortho-Phenylphenol 0.051%

INERT INGREDIENTS: 35.878%

TOTAL 100.000%

contains sodium nitrite



EPA Reg. No. 5741-22

EPA Est. No. 13891-IN-1

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

NET CONTENTS: 15 oz./425 g.

Mater Label for Steriphene II Brand Disinfectant

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(Steriphene II Label Corrected for 12-12-2001 EPA Comments)

3 7 5

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 and wastebaskets.

(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).

*** 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 infectious 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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Mater Label for Steriphene II Brand Disinfectant

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(Steriphene II Label Corrected for 12-12-2001 EPA Comments)

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)