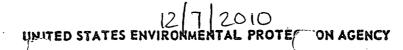
5741-22





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC - 7 2010

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Subject:

Steriphene II Brand Disinfectant Deodorant EPA Registration Number: 5741-22 Application Date: August 30, 2010 Receipt Date: September 8, 2010

Dear Mr. Cook:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable

#### **Proposed Amendment:**

Label revision per Agency letter dated May 19, 2010.

**General Comments:** 

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

Should you have questions concerning this letter, please contact me by telephone at 703-308-6416 or by email at <u>campbell-mcfarlane.jacquelline@epa.gov</u> or Killian Swift by telephone at 703-308-6346 or by email at <u>swift.killian@epa.gov</u>. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Jacqueline Campbell-McFarlane Product Manager 34 Regulatory Management Branch II Antimicrobials Division (7510P)

	Enclosure: EPA	stamped label	 CONCURRENC	ES		
SYMBOL	M					
SURNAME						
DATE	N			·		

EPA Form 1320-1A (1/90)

OFFICIAL FILE COPY

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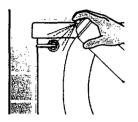
Submitted 8/30/2010

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## Front Can Copy:

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



ACCEPTED with COMMENTS EPA Letter Dated: DEC - 7 2010

Under the Federal Insecticide, Fungicide, and Rodenticide, Act as

aniended, for the pesticide, registered under EPA Reg. No. 5741-22

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 enterica 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) ]

(NOTE TO EPA: -The use of the following bracketed phrases are optional:)

[-Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza A/J305 and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

-This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.

-This product has demonstrated effectiveness against influenza A/J305 and is expected to

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inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).

-Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).

-Kills Pandemic 2009 H1N1 influenza A virus]

## **ACTIVE INGREDIENTS:**

Ethyl alcohol	64.000%
Ortho-Benzyl-para-chlorophenol	0.071%
Ortho-Phenylphenol	0.051%
INERT INGREDIENTS:	<u>35.878%</u>
TOTAL	100.000%
contains sodium nitrite	

EPA Reg. No. 5741-22

EPA Est. No. 13891-IN-1

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

NET CONTENTS: 15 oz./425 g.

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## Back Side Can Copy:

Steriphene II Brand Disinfectant is 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 microorganisms:

### **Bacteria:**

. .

Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella enterica, 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.

# **General Precautions and Restrictions**

Do not apply this product in a way that will contact workers or other persons. Only protected handlers may be in the area during application. Following application as a spray, do not enter or allow others to enter the treated area until the sprays have dried.

# **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.

## Master Label for Steriphene II Brand Disinfectant Spartan Chemical Company, Inc. EPA Reg. No. 5741-22

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**Disinfection and Deodorization:** Shake well. Hold can 6 to 8 inches from surface and apply in a uniform moist film. Treated surfaces must 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 must 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 must 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: AVISO: Causes substantial but temporary eye injury. Harmful if absorbed through the skin. Do not get in eyes or on clothing. Avoid contact with skin. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

### Applicators and other handlers must wear:

-long sleeved shirt and long pants.

-socks and shoes,

-goggles or face shield, and

-chemical resistant gloves (such as rubber or waterproof)

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#### **User Safety Requirements**

Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users must remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users must remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

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.			
lf Swallowed:	<ul> <li>-Call a Poison Control Center or doctor immediately for treatment advice.</li> <li>-Have person sip a glass of water if able to swallow.</li> <li>-Do not induce vomiting unless told by a Poison Control Center or doctor.</li> <li>-Do not give anything by mouth to an unconscious person.</li> </ul>			

### 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 contraindicate the use of gastric lavage.

# 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.

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### **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage and disposal. **Pesticide Storage:** Store in original container in areas inaccessible to small children. **Pesticide Disposal:** Non-refillable container. Do not reuse empty container. Replace cap and discard in trash or offer for recycle, if available. Do not incinerate or puncture.

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)