

5741-22

05/19/2010

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

MAY 19 2010

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

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

Subject: Steriphene II Brand Disinfectant Deodorant  
EPA Registration Number: 5741-22  
Application Date: February 3, 2010  
Receipt Date: February 18, 2010

Dear Mr. Cook:

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with conditions.

**Proposed Amendment**

- Update Storage and Disposal statements to conform to PR 2007-4
- Add Pandemic 2009 H1N1 Influenza A Claims

**Conditions**

Revise your label as follows:

- 1.) The nomenclature for Salmonella choleraesuis must be updated to read "*Salmonella enterica*" on pages 1 and 3.
- 2.) The 1<sup>st</sup> statement under "Back Side Can Copy" on page 3 must be brought into compliance with PR Notice 2000-5, Mandatory Labeling, by deleting the term, recommended.
- 3.) Revise the claim under "Note to EPA" by deleting the term, pathogenic.
- 4.) The 2<sup>nd</sup> statement under "Disinfection/Deodorization" directions on page 3 must be revised to be in compliance with PR notice 2000-5, Mandatory Labeling, by deleting the term, should, and stating "must."
- 5.) The "Personal Protection" statement under the HIV directions on page 4 must be in compliance with PR Notice 2000-5, Mandatory Labeling, by deleting the term, should, and stating "must."
- 6.) Revise the "User Safety Recommendations" heading on page 4 to be in compliance with PR Notice 2000-5, Mandatory Labeling, by stating "User Safety Requirements."

**CONCURRENCES**

SYMBOL	SURNAME	DATE						

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

7.) The "First Aid" statements must be reorganized so that the most severe routes of exposure, as demonstrated by the toxicity classification, are listed first. Therefore, reorganize the section as follows:

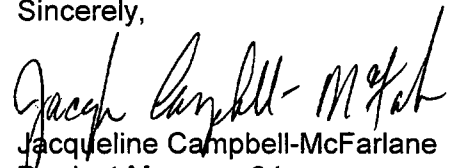
- If in eyes:
- If on skin or clothing:
- If swallowed:
- If inhaled:

**General Comments**

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

If you have further questions concerning this letter, then please contact me by telephone at (703) 308-6416 or by e-mail at [campbell-mcfarlane.jacqueline@epa.gov](mailto:campbell-mcfarlane.jacqueline@epa.gov) or Killian Swift by telephone at (703) 308-6346 email address at [swift.killian@epa.gov](mailto:swift.killian@epa.gov). When you are submitting information or data in response to this letter, send a copy of this letter to accompany the submission in order to facilitate processing.

Sincerely,



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

Enclosure: Stamped label with conditions

**CONCURRENCES**

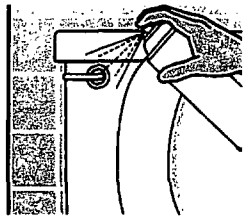
SYMBOL							
SURNAME							
DATE							

**Master Label for Steriphene II Brand Disinfectant**  
Spartan Chemical Company, Inc.  
EPA Reg. No. 5741-22  
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**Front Can Copy:**

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



ACCEPTED  
ACCEPTED  
with COMMENTS  
EPA Letter Dated:  
**MAY 19 2010**

**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) ]

(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 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]~~

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

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**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: 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 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.

**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.

**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).

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**\* 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: 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)

**User Safety Recommendations**

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.

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<b>FIRST AID</b>	
<b>If Swallowed:</b>	-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 by a Poison Control Center or doctor. -Do not give anything by mouth to an unconscious person.
<b>If on skin or clothing:</b>	-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.
<b>If in eyes:</b>	-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.
<b>24 HOUR MEDICAL EMERGENCY NUMBER: 888- 314-6171</b>	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
<b>NOTE TO PHYSICIAN</b>	
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.

**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](http://www.spartanchemical.com)

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

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