



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 1, 2022

Nate Gaubert
Spartan Chemical Company, Inc.
1110 Spartan Drive
Maumee, OH 43537

Subject: PRIA Label Amendment – Adding Emerging Viral Pathogen claim
Product Name: Steriphene II Brand Disinfectant Deodorant
EPA Registration Number: 5741-22
Application Date: 05/10/2021
Action Case Number: 00302082

Dear Mr. Gaubert:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Stacey Grigsby by phone at 703.305.6440, or via email at grigsby.stacey@epa.gov

Sincerely,

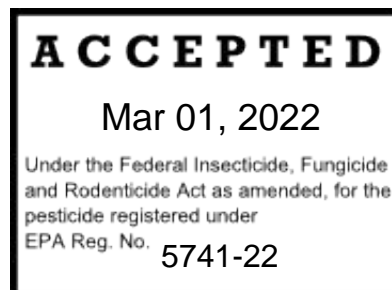
A handwritten signature in black ink, appearing to read "Marcel Howard". The signature is fluid and cursive, with the first name "Marcel" being more prominent than the last name "Howard".

Marcel Howard
Acting Product Manager 31
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: Accepted stamped label

Front Can Copy:

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



(Steriphene II Brand Disinfectant Deodorant) (Product Name)

(Spring Breeze Fragrance)

(Clean Fresh Fragrance)

(Citrus Fragrance)

Bactericidal / Tuberculocidal / Fungicidal* / Virucidal** /

Effective against Antibiotic-Resistant Bacteria***

ACTIVE INGREDIENTS:

Ethyl alcohol 64.000%

Ortho-Benzyl-para-chlorophenol 0.071%

Ortho-Phenylphenol 0.051%

INERT INGREDIENTS: 35.878%

TOTAL 100.000%

*This Product contains sodium nitrite

EPA Reg. No. 5741-22(-xxxx)

EPA Est. No. 33595-MO-2

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

For Hospital, Institutional and Industrial Use

NET CONTENTS: (15 oz./425 g.) (16 oz./454 g.) (XX oz./XXX g.)

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



WARNING: This product can expose you to Ortho-Phenylphenol, which is known to the State of California to cause cancer – www.p65warnings.ca.gov.

(Note to EPA: Bracketed information is denoted as: (optional text), [optional text]. The term “this product” used throughout this document may be replaced with the marketed product name. The term “x” is a place holder for numerical digits. Punctuation and plural/singular word forms may be adjusted to allow for grammatical correctness.

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

[Kills *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella enterica* and *Mycobacterium bovis*.
*Kills *Trichophyton interdigitale* (formerly *Trichophyton mentagrophytes*) (causes athlete's foot).
**Kills Hepatitis B Virus (HBV), Human Immunodeficiency Virus Type 1(AIDS Virus), Herpes Simplex Virus Type 2 (causes genital herpes), Human Coronavirus, H1N1 Influenza A Virus, and Norovirus 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 2009 H1N1 Pandemic (formerly called swine flu) are caused by Influenza A Virus H1N1. This product is a broad-spectrum hard surface disinfectant that has been shown to be effective against H1N1 Influenza A.
-This product has demonstrated effectiveness against H1N1 Influenza A Virus.
-Kills H1N1 Influenza A Virus]

Back Side Can Copy:

(This product) (Product name) is for use on hard, nonporous surfaces in (hospitals), (schools), (hotels), (office buildings), (industrial plants), (funeral homes), (laboratories), (prisons and jails), and (other) (medical), (commercial), (institutional or industrial facilities where a sanitary environment is important). Use on (bathroom and locker room fixtures), (tables), (countertops), (furniture), (doorknobs), (walls), (sinks), (telephones), (floors), (racks), (carts) and (wastebaskets).

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

[When used as directed, (Steriphene II Brand Disinfectant Deodorant) (This product) (Product Name) is effective against the following microorganisms at 5 minutes:

Bacteria:

Staphylococcus aureus, *Pseudomonas aeruginosa*, *Salmonella enterica*

***Fungi:**

Trichophyton interdigitale (formerly *Trichophyton mentagrophytes*) (causes athlete's foot).

****Viruses:** Human Immunodeficiency Virus Type 1(AIDS Virus), Herpes Simplex Virus Type 2 (causes genital herpes), Human Coronavirus, H1N1 Influenza A Virus, and Norovirus on hard, nonporous inanimate surfaces.

(When used as directed,) (Steriphene II Brand Disinfectant) (This product) is effective against the following microorganisms at 10 minutes:

Bacteria: *Mycobacterium bovis*

Viruses: Hepatitis B Virus (HBV)

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

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

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. 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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

Disinfection and Deodorization: Clean all surfaces prior to disinfection. Shake well. Hold can 6 to 8 inches from surface and apply in a uniform moist film. Treated surfaces must remain visibly wet for 5 minutes. For *Mycobacterium bovis* (TB), Hepatitis B Virus (HBV), and antibiotic resistant bacteria, treated surfaces must remain visibly wet for **10 minutes**. Allow to air dry or wipe off.

5 Minute Contact Time:

Bacteria: *Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708)

Fungi: *Trichophyton interdigitale* (formerly *Trichophyton mentagrophytes*) (ATCC 9533)

Viruses: Human Immunodeficiency Virus Type 1 (AIDS Virus) (Strain IIIB (B), ZeptoMetrix), Herpes Simplex Virus Type 2 (causes genital herpes) (ATCC VR-734), Human Coronavirus (ATCC VR-740, Strain 229E), H1N1 Influenza A Virus (A/PR/8/34, Charles River Laboratories) and Norovirus (Feline Calicivirus as surrogate, ATCC VR-782) on hard, nonporous inanimate surfaces.

10 Minute Contact Time:

Bacteria: *Mycobacterium bovis* (TB) (Organon Teknika Corp.)

Viruses: Hepatitis B Virus (HBV) (Duck Hepatitis B virus as surrogate) (HepadnaVirus Testing, Grimand strain)

*****Antibiotic Resistant Bacteria:** Vancomycin-Resistant *Enterococcus faecalis* (VRE) (ATCC 51299), Methicillin-Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592)

Tuberculocidal Activity: (Steriphene II Brand Disinfectant Deodorant) (Product name) (This product) 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 5 minutes for HIV-1. Leave Surfaces wet for 10 minutes for HBV.

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.

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.

EMERGING VIRAL PATHOGENS:

Product Name – or - this product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.

Product Name – or - this product meets the criteria to makes claims against certain emerging viral pathogens from the following viral category:

- Enveloped virus
- Large, non-enveloped virus

For an emerging viral pathogen that is a/an:	...follow the direction for use for the following organisms on the label:
Enveloped virus	Norovirus (Feline Calicivirus)
Large, non-enveloped virus	Norovirus (Feline Calicivirus)

Steriphene II [**product name**] has demonstrated effectiveness against viruses similar to [**name of emerging virus**] on hard non-porous surfaces. Therefore this product [**product name**] can be used against [**name of emerging virus**] when used in accordance with the directions for use against Norovirus (Feline Calicivirus) on hard, non-porous surfaces. Refer to the [**CDC or OIE**] website at [**website address**] for additional information.

[**Name of illness/outbreak**] is caused by [**name of emerging virus**]. [**Product name**] kills similar viruses and therefore can be used against [**name of emerging virus**] when used in accordance with the directions for use against [**name of supporting virus**] on hard, porous/non-porous surfaces. Refer to the [**CDC or OIE**] website at [**website address**] for additional information.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: PRECAUCIÓN: Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

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.

FIRST AID

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.

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.

(Sold by:) (SPARTAN CHEMICAL COMPANY, INC. 1110 Spartan Drive, Maumee, Ohio 43537)

(Company Name, address)

Questions? (800-537-8990/ www.spartanchemical.com) (Company Phone/website)