

1043-77

10-27-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 27 2010

Michael G. Sarli
Regulatory Affairs Manager
STERIS, Corp.
P.O. Box 147
St. Louis, MO 63166-0647

Subject: Powder Keg
EPA Registration No.: 1043-77
Amendments Dated: July 28, 2010
EPA Receipt Date: July 29, 2010

Dear Mr. Sarli,

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

- 1) Revise the Precautionary statements to include the following language:
"...Wash thoroughly with soap and water after handling and before eating, *drinking, chewing gum, using tobacco or using toilet.*
- 2) To provide clarity regarding how many packets are required for each use dilution, add the following statement to the beginning of the Directions for Use section. This statement must appear on every label:
"1:256 = 1 packet per gallon of water 1:128 = 2 packets per gallon of water"
- 3) Revise the second statement in the directions for use section to be in agreement with the precautionary statements by revising as follows: "DO NOT REMOVE PACKETS BEFORE USE. Handle only with *gloved* hands. Do not open packets."
- 4) Revise the forth section in the directions for use by deleting the repetitive language as follows: "...Prepare a *fresh solution daily* or more often if the..."

CONCURRENCES

SYMBOL	7510P							
SURNAME	S. Sarli							
DATE	10/27/10							

5) Revise the HIV language to include the following: "...Wear appropriate barrier protection such as latex gloves, gowns, masks, *and* eye coverings..." and "...HIV-1 virus is inactivated in 1 minute, use 10 minute contact time for disinfection of all *other* organisms on this label..."

6) Revise the Veterinary Clinic language to be in agreement with PR Notice 2000-5 as follows: "...Saturate all surfaces *with the disinfecting* solution for a period of..." deleting the word "recommended."

7) Revise the first section in the right column to be in agreement with PR Notice 2000-5 as follows: "...It is *for use in institutions* such as hospitals, nursing homes..." and "...It is *used for cleaning* and disinfecting of stainless steel..."

8) Since your product is marketed in water soluble packaging contained in a plastic pail, revise the container disposal language to read exactly as follows. The proposed rinsing instructions are not required. Revise to read: "*Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or dispose of pail in trash.*"

General Comments

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,




Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: Stamped accepted label
7510P:T.Lantz:10/27/10:1043-77 accepted label amend

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DANGER

DIRECTIONS FOR USE

DO NOT REMOVE PACKETS BEFORE USE. Handle only with  hands. Do not open packets; place directly into bucket.

Apply solution with a cloth, sponge, mop or brush using normal cleaning methods. Allow treated surfaces to soak for 10 minutes, then remove excess solution with a wrung out applicator. Preclean to remove gross filth. Prepare a fresh solution should be prepared at least daily or more often if the solution becomes diluted or soiled. Do not add other chemicals. Use only as directed.

FUNGICIDAL: For fungicidal activity in areas such as locker rooms, dressing rooms, showers and bath areas, and exercise facilities. Follow disinfection directions. Passes A.O.A.C. Fungicidal Test (Trichophyton mentagrophytes) 1:256 dilution, 10 minutes, in the presence of 5% organic soil (serum) at 20°C (1:128 in 400 ppm hard water).

***VIRUCIDAL:** Follow disinfection directions. Passes Virucidal Qualification Test [Influenza A₂ (Hong Kong), Herpes simplex Types 1 and 2, Vaccinia] 1:256 dilution. 10 minutes exposure time in the presence of organic soil (serum) at 20°C (1:128 in 400 ppm hard water). POWDER KEG is effective against Adenovirus Type 2 at 1:128 dilution (2 packets per gallon) in 400 ppm A.O.A.C. hard water in the presence of 5% organic soil (serum) in 10 minutes at 20°C.

harm water in the presence of a organic soil (primarily in the minutes to hours) kills HIV-1 (AIDS VIRUS) ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODILY 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 human immunodeficiency virus Type-1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks, and eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of Powder Keg.

Contact Time: While the HIV-1 virus is inactivated in 1 minute, use 10 minute contact time for disinfection of all organisms on this label.

Infectious Materials Disposal: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious disposal.

CONTROL OF MOLD AND MILDEW: Follow disinfectant directions.

FOR USE IN VETERINARY CLINICS: Remove all animals and feed from premise, vehicles, and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls chutes, and other facilities and fixtures occupied and traversed by animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with the ~~recommended~~ disinfecting solution for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent and rinse with potable water before reuse.

PRODUCT MADE IN USA

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 27 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 10

EPA Reg. No. 1043-77

EPA Est. No. 46275-II.-2

Active Ingredients:

Octyl Decyl Dimethyl Ammonium Chloride	3.25%
Dioctyl Dimethyl Ammonium Chloride	1.63%
Didecyl Dimethyl Ammonium Chloride	1.63%
n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
Dimethyl Benzyl Ammonium Chloride	3.16%
n-Alkyl (68% C ₁₂ , 32% C ₁₄)	
Dimethyl Ethyl Benzyl Ammonium Chloride	3.16%
Inert Ingredients	87.17%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

See side panel for additional precautionary statements.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> •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 the eye. •Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> •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.
If swallowed	<ul style="list-style-type: none"> •Call 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 to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none"> •Move person to fresh air. •If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. •Call a poison control center or doctor for further treatment advice.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

Net Weight:

STERIS

7501 Page Ave..
St. Louis, MO 63110

POWDER KEG is a concentrated, powdered, hard-water effective, phosphate-free germicidal detergent which is packaged in handy premeasured ½ ounce soluble packets. The use-solution made by dissolving one packet per gallon of warm water (70° - 80°F) simultaneously cleans and deodorizes while disinfecting.

It is designed for cleaning and disinfecting of washable, non-porous hard surfaces such as floors and walls. It is ~~designed~~ for use ~~only~~ in institutions such as hospitals, nursing homes, industrial plants, medical and dental offices, veterinary clinics, and other public areas. It ~~may~~ be used for the cleaning and disinfecting of stainless steel, chrome, glass, glazed porcelain, glazed-tile, terrazzo and resilient vinyl, linoleum, asphalt or rubber flooring as well as washable painted and varnished surfaces.

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 blood stream 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.

GERMICIDAL: Passes A.O.A.C. Germicidal Use Dilution Method (*Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*) 10 minutes, in the presence of 5% organic soil (serum) at 20°C, 1:256 dilution, (1:128 in 400 ppm hard water).

BROAD SPECTRUM DATA: In addition, the following organisms pass the A.O.A.C. Use Dilution Test, 10 minutes, in the presence of 5% organic soil (serum) at 20°C, 1:256 dilution (1:128 in 400 ppm hard water).

<i>Acinetobacter calcoaceticus</i> , ATCC 19066	<i>Salmonella typhimurium</i> , ATCC 14028
<i>Candida albicans</i> , Clinical isolate	<i>Serratia marcescens</i> , ATCC 8100
<i>Clididia parapsilosis</i> , Clinical isolate	<i>Shigella flexneri</i> , ATCC 12022
<i>Citrobacter freundii</i> , ATCC 8090	<i>Shigella sonnei</i> , ATCC 25931
<i>Enterobacter aerogenes</i> , ATCC 13048	<i>Staphylococcus aureus</i> , ATCC 25923
<i>Enterobacter cloacae</i> , ATCC 23355	<i>Staphylococcus aureus</i> , (MRSA), Multiple (Methicillin)-Resistant Clinical Isolate
<i>Escherichia coli</i> , ATCC 25922	<i>Staphylococcus epidermidis</i> , ATCC 12228
<i>Klebsiella pneumoniae</i> , ATCC 13883	<i>Streptococcus faecalis</i> , ATCC 19433
<i>Proteus mirabilis</i> , Clinical Isolate	<i>Streptococcus pyogenes</i> , ATCC 19615
<i>Proteus vulgaris</i> , ATCC 13315	
<i>Pseudomonas aeruginosa</i> , ATCC 27853	

When tested by the AOAC Dilution Method, the HIV-1 (AIDS) virus, with added 10% organic soil (serum), was completely inactivated by a 1:256 (1 packet per 1 gallon) solution in 60 seconds at 20°-25°C. Although efficacy at 1 minute contact time has been shown to be adequate against the HIV-1, this contact time is not sufficient for other organisms. Use a 10 minute contact time for disinfection against all of the organisms claimed.

ODOR-COUNTERACTANT: POWDER KEG attacks the odors in three ways by killing odor-causing bacteria, chemically neutralizing odor residues, and with fine detergent cleaning ingredients.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Do not store on side. Avoid creasing or impacting of side container walls. **Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA regional office for guidance.

Container Disposal: Nonrefillable container. Do not reuse or refill this container.

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DRAFT 07/28/10

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