

1043-117

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 13 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Michael G. Sarli
Manager Regulatory Affairs
STERIS Corporation
P.O. Box 147
St. Louis, MO 63166-0147

Subject: Amerse® 2
EPA Registration No.: 1043-117
Application Date: 04/15/2011
Receipt Date: 04/18/11

Dear Mr. Michael G. Sarli:

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

Proposed Amendment

- Formula Change

Conditions

Revise the label as follows:

1. Revise the first line in the Pesticide Disposal in the Storage and Disposal section to read:

“Pesticide wastes are acutely hazardous.”

General Comments

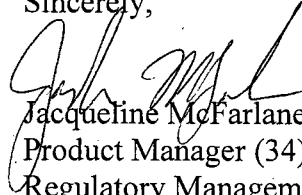
The Confidential Statements of Formulas for the basic and alternate formulation dated March 14 of 2011 are acceptable. They are in compliance with PR Notice 91-2 and in agreement with the label.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Jaclyn Carl by telephone at (703) 347-0213 or by e-mail at carl.jaclyn@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

Sincerely,



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

CONCURRENCES

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SURNAME								
DATE								

One-Step Germicidal Detergent

For Industrial and Institutional Use

Germicide Fungicide Virucide* Tuberculocide
 Deodorizer Cleaner Detergent

Active Ingredients

o-phenylphenol.....9.09%
 p-tertiary amyphenol.....7.66%

Inert Ingredients..... 83.25%
 Total 100.00%

ACCEPTED
 with COMMENTS
 EPA Letter Dated:

JUN 13 2011

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

1043-117

KEEP OUT OF REACH OF CHILDREN
DANGER

FIRST AID	
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.
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 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 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.
HOTLINE NUMBER	
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.	

See side panel for additional precautionary statements.

STERIS Corporation
 7501 Page Avenue
 St. Louis, MO 63133 U.S.A.
 800-548-4873
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4
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PRECAUTIONARY STATEMENTS
H. HARMFUL TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Wear goggles or face shield (safety glasses), protective clothing and chemical resistant rubber gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco, chewing gum or using the toilet. Remove contaminated clothing and wash before reuse.

GERMICIDAL: Passes A.O.A.C. Germicidal Use-Dilution Method (*S. aureus*, *S. enterica*, *Ps. aeruginosa*) when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

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

Acinetobacter calcoaceticus, ATCC 19606
Candida albicans, Clinical Isolate
Candida parapsilosis, Clinical Isolate
Citrobacter freundii, ATCC 8090
Enterobacter aerogenes, ATCC 13048
Enterobacter cloacae, ATCC 23355
Escherichia coli, ATCC 25922
Klebsiella pneumoniae, ATCC 13883
Staphylococcus aureus, (MRSA),
Multiply (Methicillin)-Resistant
Clinical Isolate
Proteus mirabilis, Clinical Isolate

Proteus vulgaris, ATCC 13315
Pseudomonas aeruginosa, ATCC 27853
Pseudomonas cepacia, ATCC 25416
Salmonella typhi, ATCC 6539
Salmonella typhimurium, ATCC 14028
Serratia marcescens, ATCC 8100
Shigella flexneri, ATCC 12022
Shigella sonnei, ATCC 25931
Staphylococcus aureus, ATCC 25923
Staphylococcus epidermidis, ATCC 12228
Streptococcus faecalis, ATCC 19433
Streptococcus pyogenes, ATCC 19615

Amerse 2 is effective in 3 minutes at 20°C against *Pseudomonas aeruginosa* ATCC 13388, according to the A.O.A.C. Use Dilution Test when diluted with 400 ppm hard water to make a 1:64 (2 ounces per gallon) solution, in the presence of 5% added organic soil (serum).

FUNGICIDAL: Passes A.O.A.C. Fungicidal Test (*T. mentagrophytes*) when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

TUBERCULOCIDAL: Passes A.O.A.C. Tuberculocidal Test (*Mycobacterium tuberculosis*, var. *bovis*) when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

***VIRUCIDAL:** Passes Virucidal Assay [Influenza A₂ (Japan) virus, Herpes Simplex Type 2 virus, Vaccinia virus, Adenovirus Type 2, Avian Infectious Bronchitis virus, Avian Laryngotracheitis virus, Avian Newcastle Disease virus, and Porcine Pseudorabies virus], when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 1 gallon) solution in the presence of 5% organic soil (serum) in 10 minutes at 20°C.

When tested by a Dilution Method, the HIV-1(AIDS) virus, with added 10% organic soil (serum), was completely inactivated by a 1:128 (1 ounce per 1 gallon) solution in 400 ppm A.O.A.C. hard water in 60 seconds at 20-25°C. Although efficacy at 1 minute contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms. Use a 10-minute contact time for disinfection against all of the organisms claimed.

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.

or

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

ODOR CONTROL: It eliminates many odors by killing odor-causing bacteria while simultaneously chemically neutralizing their odors and leaving a pleasant fragrance.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

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For Interim Instrument Decontamination prior to Terminal Cleaning and Sterilization of Surgical Instruments and Apparatus: The removal of heavy soils and the cleaning of all surfaces prior to application of this product is required. All instruments and devices must be thoroughly cleaned to remove excess organic debris, rinsed and then rough dried before immersion. Clean and rinse the lumens of hollow instruments before filling with solution. After cleaning, immerse articles and wet all surfaces thoroughly in 1:128 solution for 10 minutes. Rinse and dry. Do not store instruments in the solution. Avoid splashing and cover, where possible, when transporting soiled instruments. Prepare a new solution daily or when solution becomes dirty for decontaminating pre-cleaned items.

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.

KILLS 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 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 a 1:128 use-solution (1 ounce per 1 gallon). Prepare and apply solution as directed in paragraph above.

Contact Time: While the HIV-1 virus is inactivated in 1 minute, use a 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.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in a cool dry area. Always store pesticides in the original container. Store away from food, pet food, feed, seed, fertilizers, and veterinary supplies.

PESTICIDE DISPOSAL: Pesticide wastes ^{are always} may be hazardous. Improper disposal of excess pesticide, spray 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.

(For foil packets)

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(For containers ≤ 5 gallons)

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

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