

July 30, 2003

Mr. Michael G. Sarli  
Steris Corp.  
P.O. Box 147  
St. Louis, MO 63166-0647

Subject: **AMERSE® 2**  
EPA Registration Number 1043-117  
Application Dated May 22, 2003

Dear Mr. Sarli:

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

**Proposed Amendment:**

- revised First Aid statement PR Notice 2001-1

**General Comments:**

1. Add the Signal Word "Danger" to the precautionary statement.
2. Revise the precautionary statement to read as follows:

"DANGER: Corrosive; causes eye and skin damage. Harmful if swallowed or absorbed through skin or inhaled . Do not get in eyes or on clothing. Wear goggle 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 or using tobacco. Remove contaminated clothing and wash before reuse.

**CONCURRENCES**

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Submit three (3) copies of your final printed labeling bearing the revised labeling. A copy of the label will be stamped and returned for your records.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Drusilla Copeland at (703) 308-6224.

Sincerely,

*Drusilla Copeland*  
for Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

Enclosure

**REDUCTION STATEMENTS:**

**HAZARD TO HUMANS AND DOMESTIC ANIMALS:** Corrosive, Causes eye and skin damage. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed.

**(For 5 gal. size and larger only) ENVIRONMENTAL HAZARD STATEMENT:** Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.  
**CLEANING AND DISINFECTING WASHABLE, HARD, NON-POROUS SURFACES:**  
 Add 1 fl. oz. (30 cc) to each measured gallon of water used. Always add this product to pre-measured water. Thoroughly mix solution until uniform. 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. Remove gross filth mechanically by sweeping before cleaning begins. Discard solution daily or when it becomes dirty and replace with a fresh solution. This is a complete product. Do not add other chemicals. If frozen, thaw and re-mix. Use only as directed.

**CLEANING AND DISINFECTING WASHABLE, HARD, NON-POROUS SURFACES:**  
 To make a one gallon (1:128) solution, loosen cap from dispensing chamber. Gently squeeze bottle to fill measuring chamber to the 1 fluid ounce line (30 cc.). Remove cap from the dispensing chamber. Pour measured product (concentrate) from the chamber into one gallon premeasured cold water. Apply solution with a cloth, sponge, mop, brush or from spray bottle using normal cleaning methods. Treated surfaces should remain wet for 10 minutes. Then remove excess solution with a wrung-out applicator. Remove gross filth mechanically by sweeping before cleaning begins. Discard solution daily or when it becomes dirty and replace with a fresh solution. This is a complete product. Do not add other chemicals. If frozen, thaw and re-mix. Use only as directed.

**SOLUTION TABLE FOR CONCENTRATE**

Water	1 Gallon	5 Gallons
Concentrate	1 fl. oz.	5 fl. oz.

**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 or 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.

**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.

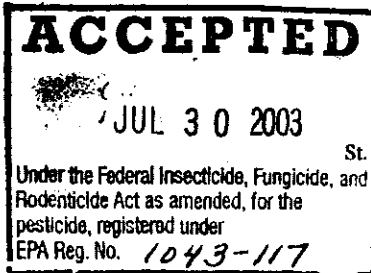
After cleaning, immerse articles and wet all surfaces thoroughly in a 1:128 solution for 10 minutes. Rinse and dry.

Not recommended for prolonged storage of instruments.

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.

EPA REG. NO. 1043-117 EPA Est. No. 1043-MO-2



**AMERSE® 2**

**ONE-STEP IN THE PRESENCE OF SERUM GERMICIDAL DETERGENT**

FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY

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%

**KEEP OUT OF REACH OF CHILDREN DANGER**

FIRST AID	
If inhaled	•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	•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	•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	•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.

**NET CONTENTS:**

STERIS Corporation  
 7501 Page Avenue  
 St. Louis, MO 63133 U.S.A.

**STORAGE AND DISPOSAL**

**PROHIBITIONS:** Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.  
**PESTICIDE DISPOSAL:** This germicide, its solutions or rinsings from empty containers, should be disposed of in a toilet or service sink served by a sanitary sewer, or in a landfill approved for pesticides.  
**CONTAINER DISPOSAL:** Triple rinse and deposit in a waste container for incineration or in a landfill approved for pesticide containers.  
**GENERAL:** Consult Federal, State, or Local disposal authorities for approved alternative procedures such as limited open burning.

This product represents a germicidal detergent system that is both research-developed and state of the art technology. It is effective in hard water and in the presence of serum. It has been formulated as a concentrate to clean, disinfect and deodorize simultaneously. Use this product for easy cleaning and disinfecting of all washable hard, non-porous environmental surfaces such as floors, walls, woodwork, bathroom fixtures, equipment and furniture. It may be used for cleaning and disinfecting chrome, stainless steel, other metal surfaces, porcelain, glass, tile, washable painted or varnished surfaces, as well as asphalt, linoleum, terrazzo or other combination type floors. This product is not for use in the neonatal (newborn) units in hospitals, specifically isolates and other infant contact surfaces. This germicidal detergent is intended for use in institutions such as hospitals and nursing homes, industrial plants, schools, medical and dental offices, pharmaceutical plants, veterinary clinics and other indoor areas where disinfection, cleaning and deodorizing are a necessity.

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.

**GERMICIDAL:** Passes A.O.A.C. Germicidal Use-Dilution Method (*S. aureus*, *S. choleraesuis*, *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
- Serratia 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 (EPA Proposed Method) (Influenza A<sub>2</sub> (Japan), Herpes Simplex Type 2, Vaccinia Virus, and Adenovirus Type 2, Avian Infectious Bronchitis, Avian Laryngotracheitis, Avian Newcastle Disease, and Porcine Pseudorabies), 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 an EPA-approved 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.

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

W/C