

PM 32 1043-36

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Calgon Vestal Laboratories
Division of Calgon Corporation
P.O. Box 147
St. Louis, MO 63166

8 MAY 1994

Attn: Michael Ebers

Subject: Amerse
EPA Registration No. 1043-36
Your Labeling Amendment of October 18, 1993

The proposed labeling amendment involving revisions to the text for restrictions on the use of the product in the disinfection or sterilization of semi-critical or critical medical devices; in accordance with the joint FDA/EPA Memorandum of Understanding (MOU), has been reviewed. Please note the following.

-The labeling referred to above, submitted on connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. A stamped copy is enclosed for your records. Submit five copies of the finished, printed labeling, which include this comment before releasing the product for shipment.

1. In the second paragraph on page 2 of the label concerning the medical device restrictions, revise the first sentence to read: "This product is not to be used as a terminal sterilant/high level disinfectant that (1) is introduced directly..."

If you should have any questions concerning this letter, you may call Robert Travaglini on (703) 305-6909.

Sincerely,

Ruth G. Douglas
Product Manager (32)
Antimicrobial Program Branch
Registration Division (7505C)

CONCURRENCES

SYMBOL	12502C						
SURNAME	Travaglini						
DATE	18 MAY 94						

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amerse®

Hospital Instrument Germicide

EPA Reg. No. 1043-36

EPA Est. No. 1043-MO-1

Germicide · Tuberculocide · Fungicide

FOR INTERIM INSTRUMENT DECONTAMINATION/DISINFECTION
PRIOR TO TERMINAL CLEANING AND STERILIZATION OF SURGICAL
INSTRUMENTS AND APPARATUS

Active Ingredients:

o-Benzyl-p-chlorophenol	5.25%
o-Phenylphenol	1.00%
Inert Ingredients	93.75%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

STATEMENT OF PRACTICAL TREATMENT

In case of eye contact, flush with water for 15 minutes. Get prompt medical attention. For skin contact, flush with water. See back panel for additional precautionary statements and directions for use.

CONTENTS: 64 FL. OZ. (½ U.S. GALLON) (1.89 LITERS)

ACCEPTED
with COMMENTS
in EPA Letter Dated

18 MAY 1994

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

1043-36

BEST AVAILABLE COPY

324

Amerse Instrument Germicide is a concentrated disinfectant to be used at a 1:32 dilution with water for cold decontamination/disinfection of pre-cleaned equipment, thermometers, surgical and dental instruments. Recommended for use in hospitals and dental offices or other facilities requiring decontamination/disinfection of instruments and equipment.

This product is not to be used as a final disinfection step 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. These surfaces should be sterilized or high-level disinfected as appropriate in separate subsequent steps.

The 1:32 dilution kills pathogenic bacteria and fungi such as *S. aureus*, *S. choleraesuis*, *Ps. aeruginosa*, *M. tuberculosis* (effective in 10 minutes at 20°C), and *C. albicans*. Amerse is virucidal against Influenza A₂ (Hong Kong), Herpes simplex 1 and 2, Type 2 Adenovirus and Vaccinia on hard, inanimate, surfaces in 10 minutes at 20°C.

Minimum Use-Dilution Confirmation (A.O.A.C.-10 Min.-20°C) *S. choleraesuis*-1:32, *S. aureus*-1:32, *Ps. aeruginosa*-1:32.

A 1:32 dilution is effective against *M. tuberculosis* on hard, inanimate surfaces in 10 minutes at 20°C. Remove heavy soil or gross filth and thoroughly clean surfaces.

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 burial in a landfill approved for pesticide containers.

General: Consult federal, state or local disposal authorities for approved alternative procedures such as limited open burning.

Calgon Vestal Laboratories
Division of Calgon Corporation
Subsidiary of MERCK & Co., Inc.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

6401-12C(592)

18 MAY 1994
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.

1013-76

PRODUCT MADE IN USA

BEST AVAILABLE COPY

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Precautionary Statements

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid prolonged skin contact and avoid splashing in eyes. Wash eyes with large amounts of flowing water if exposed.

DIRECTIONS FOR USE

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

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.

Use a 1:32 dilution with water for cold disinfection of pre-cleaned equipment. The removal of heavy soils and the cleaning of all surfaces prior to application of this product is required.

DILUTION TABLE

QUANTITY OF AMERSE INSTRUMENT GERMICIDE TO MAKE A 1:32 AQUEOUS USE-DILUTION				
Water	1 Pint	1 Quart	½ Gallon	1 Gallon
AMERSE	(1 stroke) ½ fl. oz.	(2 strokes) 1 fl. oz.	(4 strokes) 2 fl. oz.	(8 strokes) 4 fl. oz.

To remove residue of previous disinfectant, thoroughly clean and rinse instruments, trays or containers prior to first use of this product. Prepare a new solution daily or when solution turns cloudy or dirty for disinfecting pre-cleaned items.

FOR COLD INSTRUMENT DISINFECTION - After cleaning, immerse articles and wet all surfaces thoroughly in a 1:32 solution for 10 minutes. Rinse and dry.

FOR METAL INSTRUMENT STORAGE - A 1:32 solution is non-corrosive and does not rust, dull or otherwise stain or attack quality instruments such as carbide dental burs. The solution may be used for prolonged storage of all but lens instruments, plastic or rubber items. This is a complete product. Do not add other chemicals. Use only as directed. If frozen, thaw and remix before use.

ACCEPTED
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in EPA Letter Dated:

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1043-36