

) PM 31 8526-1  
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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NOV 6 1995

Micro-Aseptic Products, Inc.  
887 East Wilmette Road  
Palatine, IL 60067

Attn.: Gregory F. Steil

Subject: Cavicide  
EPA Registration No. 38526-1  
Submission Dated August 1, 1995

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act as amended to change your bactericidal contact time to two minutes is acceptable provided that you make the following labeling revisions:

a. The phrases "Active Ingredients" and "Inert Ingredients" must be of the same type size and type style.

b. Include the heading "Storage and Disposal" immediately above your storage and disposal instruction. Also revise your Container Disposal instructions to read as follows:

For Metal Containers:

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, (non-aerosol) or by other procedures approved by state and local authorities.

For Plastic Containers:

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

c. Center the front panel signal word and child hazard warning statement.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter please contact Marshall Swindell at 703-305-6908.

Sincerely yours,



Marion Johnson  
Product Manager 31  
Antimicrobial Programs Branch  
Registration Division (7505C)

(FRONT PANEL)

# CAVICIDE®

HOSPITAL DISINFECTANT/DECONTAMINANT CLEANER  
SALON/BARBER DISINFECTANT/DECONTAMINANT CLEANER  
VETERINARY DISINFECTANT/DECONTAMINANT CLEANER  
CLIPPER BLADE DISINFECTANT/DECONTAMINANT CLEANER  
DISINFECTANT/DECONTAMINANT CLEANER  
DENTAL DECONTAMINANT/CLEANER  
ONE-STEP DISINFECTANT/DECONTAMINANT CLEANER  
INSTITUTIONAL DISINFECTANT/DECONTAMINANT CLEANER  
MEDICAL DECONTAMINANT/CLEANER  
SURGICAL DECONTAMINANT/CLEANER  
SURFACE/INSTRUMENT DISINFECTANT/DECONTAMINANT CLEANER  
SURFACE DISINFECTANT/DECONTAMINANT CLEANER  
LABORATORY SURFACES DECONTAMINANT CLEANER  
SPRAY-ON SURFACE DECONTAMINANT DISINFECTANT

FOR PROFESSIONAL USE

IMMERSION SOLUTION • SURFACE CLEANER/DISINFECTANT • ULTRASONIC SOLUTION  
SONIC SOLUTION • SOAKING SOLUTION • PRESOAK SOLUTION • INSTRUMENT SOLUTION  
SURFACE SOLUTION • NON-POROUS SURFACE SOLUTION • CLEANER • DISINFECTANT

BACTERICIDAL • VIRUCIDAL • FUNGICIDAL • TUBERCULOCIDAL\*\* • PSEUDOMONICIDAL  
STAPHYLOCIDAL •

READY TO USE

CONTAINS BIODEGRADABLE DETERGENT

## ACTIVE INGREDIENTS:

Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride .....	0.25%
Isopropanol .....	15.30%
INERT INGREDIENTS .....	84.45%
TOTAL .....	100.00%

KEEP OUT OF REACH OF CHILDREN

## CAUTION

PRECAUTIONARY STATEMENTS: Harmful to Humans and Domestic Animals.

AVOID CONTAMINATION OF FOOD. MAY CAUSE EYE IRRITATION. AVOID DIRECT CONTACT WITH EYES. IN CASE OF DIRECT EYE CONTACT, IMMEDIATELY FLUSH EYES WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES. IF IRRITATION PERSISTS, SEEK MEDICAL ATTENTION.

NET CONTENTS: 1 U.S. GALLON / 3.785 Liters (NET WEIGHT 8.22 lbs / 3.73 kg)

MICRO-ASEPTIC PRODUCTS, INC.  
687 E. WILMETTE ROAD • PALATINE, IL 60067 USA

EPA REG. NO. 38526-1 EPA EST. NO. 39234-WV-001 REORDER NO: CO4-128

ACCEPTED  
with COMMENTS  
by EPA Letter Dated:

NOV 6 1995

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

38526-1

(LEFT PANEL)

# CAVICIDE

- NON STAINING
- NON CORROSIVE
- NON IRRITATING
- NO DILUTION
- READY TO USE
- NO TOXIC FUMES

## EFFECTIVE AGAINST:

- Staphylococcus aureus
- Pseudomonas aeruginosa
- Salmonella choleraesuis
- Mycobacterium tuberculosis var: bovis (BCG)\*\*
- Trichophyton mentagrophytes
- Aspergillus niger
- Herpes simplex virus type 1 and 2 \*
- Poliovirus type 1 and 2 \*
- Coxsackievirus \*
- Methicillin Resistant Staphylococcus aureus (MRSA)
- Vancomycin Resistant Enterococcus faecalis (VRE)
- Human Immunodeficiency Virus (HIV-1) (AIDS virus) \*
- Mold and Mildew

(\* on inanimate surfaces)

(\*\* in ten minutes at room temperature (20°C) )

**DIRECTIONS FOR USE:** It is a violation of U.S. Federal law to use this product in a manner inconsistent with its labeling.

## DESCRIPTION:

Cavicide is a multi-purpose, broad spectrum, ready to use, highly effective cleaner and disinfectant for use on the surfaces of inanimate objects. It is especially useful in hospital operating rooms, emergency departments, isolation areas, neonatal units, dental operatories, surgical suites, animal care facilities, beauty salons, salon settings, manicure salons, skin care salons, barber shops, bathrooms, tanning salons, out-patient surgical centers, daycare centers, schools, ambulances, police and fire vehicles, prisoner detention facilities, jails, prisons, morgues, cadaver processing areas, funeral homes, cadaver cavities, patient care areas, laboratories, food preparation areas, storage areas, health club facilities, and other critical care areas where environmental control of cross contamination is important.

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ACCEPTED  
WITH COMMENTS  
by EPA Region 9

NOV 6 1995

This product is a disinfectant,  
Fungicide, and Antifungal and  
is intended for the purposes  
registered under EPA Reg. No.  
38526-1

Safe for cleaning/decontamination of delicate medical/dental/surgical/salon/barber/veterinary/environmental/equipment/implements and instrumentation. Cavicide will effectively clean and disinfect, when used as directed, such items as: infant incubators and bassinets, infant care cribs and warmers, infant/child care equipment surfaces, oxygen hoods, anesthesia machines and respiratory therapy equipment surfaces, operating room tables and lights, laboratory equipment and surfaces, physical therapy (PT) equipment surfaces, neck brace appliances and cervical collars, whirlpool tanks, hydrotherapy equipment and tanks/hot tubs, stretchers, spine/back boards, ambulance equipment surfaces, jacuzzis, mayo stands, countertops, toilets, sinks, refrigerator units, floors, walls, handrails, door knobs, bed railings, bathing units, bath tubs, shower stalls, cabinets, shampoo bowls, manicure tables, chairs, workstations, nail/hair care implements, tanning beds, hair dryers, telephones, diaper changing stations, baby cribs, hair clippers, shears, razors, hair cutting implements, clipper blades, salon surfaces, scissors, combs, brushes, manicure implements, washable nail files, hair rollers, animal cages, veterinary care surfaces, dental operator surfaces, dental countertops, dental chairs, unit stools, light lense covers, curing lights, and other inanimate surfaces, including those made of plastics (such as: polycarbonate, polyvinylchloride, polypropylene and polystyrene), weight lifting surfaces, non-porous vinyl and upholstery, stainless steel, painted surfaces, plexiglas, glass, and other hard non-porous surfaces.

#### APPLICATIONS:

**SURFACES:** (Where appropriate, follow Universal Precautions.)

**For disinfecting non-critical devices/medical equipment and other surfaces:**

- Spray/apply Cavicide directly to surface, thoroughly wetting area to be disinfected. (\*\*\*\* Visibly soiled surfaces should be pre-cleaned.) Allow surface to remain wet for 2 minutes. ( **FOR TUBERCULOCIDAL ACTIVITY:** Allow surface to remain wet for 10 minutes at room temperature (20°C).) Follow by wiping surface with a fresh, clean, paper or cloth towel; or rinse and either allow surface to air dry or wipe rinsed surface dry using a fresh, clean, paper or cloth towel. Discard towel.

- Cavicide completely inactivates the HIV-1 (AIDS virus) on hard, non-porous surfaces in the presence of a moderate amount of organic soil (5% blood serum) with a contact time of 2 minutes at room temperature (20-25°C).

**\*\*\*\* For pre-cleaning visibly soiled medical equipment and other surfaces prior to disinfection:**

- Apply Cavicide directly to surface. Allow to remain wet for about 30 seconds. Wipe surface clean using a clean paper or cloth towel or rinse surface and either wipe dry or allow to air dry. Discard dirty towel.

ACCEPTED  
NOV 0 1992  
Under the Federal Insecticide, Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
38526-7

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**INSTRUMENT/IMPLEMENT CLEANING INSTRUCTIONS:** (Where appropriate, follow Universal Precautions.)

**For use as immersion pre-cleaning instrument decontaminant solution:**

- Fill appropriate size container with a sufficient amount of undiluted Cavicide so as to allow for complete submersion of instruments/objects. Place objects into Cavicide solution, cover and allow to soak for 10 minutes. Remove and rinse. Follow with appropriate cleaning and disinfection process. Change solution as needed when the solution becomes diluted or visibly soiled. (**Critical and semi-critical devices must be followed by appropriate terminal sterilization/high level disinfection process.**)

**For use as instrument pre-transport/pre-clean decontamination spray:**

- Place instruments onto or into a suitable container. Thoroughly spray Cavicide solution onto instruments so as to thoroughly drench all surfaces. Cover instruments and transport to appropriate cleaning area. Rinse instruments, follow with appropriate cleaning and disinfection process. (**Critical and semi-critical devices must be followed by appropriate terminal sterilization/high level disinfection process.**)

**For use as instrument/object ultrasonic cleaning solution:**

- Thoroughly pre-rinse instruments/objects under running water to remove visible gross debris. Using 1 ounce Cavicide per liter of water in ultrasonic unit, immerse instruments/objects into mixed solution and activate ultrasonic unit for 5 minutes or longer if necessary. Remove instruments/objects and rinse thoroughly. Change solution as needed. Follow with appropriate disinfection process. (**Critical and semi-critical devices must be followed by appropriate terminal sterilization/high level disinfection process.**)

**For use as manual instrument/object cleaner:**

- Thoroughly pre-rinse dirty instruments/objects under running tap water to remove visible gross debris. Place pre-rinsed instruments/objects into a solution of 1 ounce Cavicide per liter of ordinary tap water. Scrub objects using a stiff bristle brush until visibly clean. (Objects should be submerged as scrubbed.) Rinse instruments/objects thoroughly. Change solution as needed. Follow with appropriate disinfection process. (**Critical and semi-critical devices must be followed by appropriate terminal sterilization/high level disinfection process.**)

**For use on hair clippers, electric shears:**

- While clipper is running, hold it in the downward position and spray undiluted Cavicide directly onto the blades two or three times so as to thoroughly wet the blades, (Avoid getting the spray on the clipper case or allowing it to run into the inside of the clipper housing.) Allow to remain wet for 2 minutes before wiping dry with a clean, soft cloth. Lubricate as per clipper manufacturer's instructions.

NOV 6 1995  
ACCEPTED  
WITH COMMENTS  
in EPA Letter Data:  
38526-1  
EPA Reg. No.

**For cleaning salon implements, shears and barber implements:**

- First, spray object so as to thoroughly wet with undiluted Cavicide solution. Scrub/wipe away visible debris using a soft bristle brush or soft cloth. Immerse pre-cleaned implements into an undiluted solution of Cavicide for 2 minutes. For tuberculo-cidal activity, allow to soak for 10 minutes at room temperature (69°F). Remove and wipe dry. No rinsing is necessary. Change solution weekly or more often if solution becomes visibly soiled.

**INSTRUMENT / IMPLEMENT / SMALL OBJECT / DEVICE DISINFECTION**

**INSTRUCTIONS:** (Where appropriate, follow Universal Precautions)

**\*\*\* For disinfection of *non-critical*, pre-cleaned instruments/devices:**

- Instruments/device must be thoroughly pre-cleaned to remove excess organic debris, rinsed and then rough dried. (Clean and rinse the lumens of hollow instruments/devices before filling with solution or before immersion.) Using either a soaking tray or ultrasonic unit, immerse instruments/devices into undiluted Cavicide solution and allow to remain submerged for 2 minutes. For tuberculo-cidal activity, allow 10 minutes at room temperature (20°C). Remove and rinse or wipe dry prior to use. Change solution daily or more often as needed if the solution becomes diluted or visibly soiled.

**( Critical and semi-critical devices must be followed by appropriate terminal sterilization/high level disinfection process. )**

*\*\*\* 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.) contact 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 / high level disinfection.*

**MOLD AND MILDEW:** To control mold and mildew on clean, hard surfaces, apply so as to wet entire surface thoroughly with Cavicide. Allow to air dry after application. Repeat application in seven days or as necessary to maintain control.

ACCEPTED  
with COMMENTS  
by EPA Letter Dated:

NOV 6

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended for the pesticide  
registered under EPA Reg. No.  
38526-1

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**CAVICIDE EFFECTIVELY KILLS HIV ON PRECLEANED 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/BODY FLUIDS, AND IN WHICH THE SURFACES/OBJECTS 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 FLUID:**

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

**Cleaning Procedure:** Blood and other bodily fluids must be thoroughly cleaned from surfaces and objects before disinfection with Cavicide.

**Contact Time:** While the HIV-1 virus is inactivated in 2 minutes, use the recommended contact time for the disinfection of other organisms listed on this label.

**Infectious Materials Disposal:** Cleaning materials used that may contain blood or other bodily fluids should be autoclaved and/or disposed of in accordance with local regulations for infectious materials disposal.

For product information, please contact our technical service department at 1-800-536-4129 (TOLL FREE).

**STORAGE:** Store in a cool place.

**PESTICIDE DISPOSAL:** Dilute with water. Dispose of in ordinary sanitary sewer.

**CONTAINER DISPOSAL:** Do not reuse empty container. Wrap empty container and place into ordinary trash receptacle.

Cavicide spray bottles are refillable.

Manufactured For:

Micro-Aseptic Products, Inc. • 887 E. Wilmette Rd. • Palatine, IL 60067 USA

ACCEPTED  
WITH COMMENTS  
by EPA Letter Dated:

Revised 9/15/94

NOV 6

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

38526-1

**BEST COPY AVAILABLE**