

NOV 02 1993

Micro-Aseptic Products, Inc.
887 E. Willmette Road
Suite J
Palatine, IL 60067

Attn: Jack Wagner, President

Subject: Cavicide Disinfectant/Cleaner
EPA Registration No. 38526-1
Letter dated May 14, 1993

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you:

1. Make the following changes listed below before you release the product for shipment bearing the amended labeling:

a. Since your product is a disinfectant only, the following paragraph must be included on the label:

"This product is not to be used [as a 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."

b. Delete from the left panel "FAST ACTING".

c. Delete the following claims from the labeling until the company has obtained a 510(K) Pre-Market Clearance from the Food and Drug Administration (FDA)

2. FRONT PANEL

"Dental Disinfectant/Cleaner, Medical Disinfectant/Cleaner and Surgical Disinfectant/Cleaner"

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

(The above sentence can be retained if the word "Disinfectant" is replaced with the word "Decontaminant".)

3. LEFT PANEL

"For disinfecting medical equipment"

d. In the following sentence change "Safe for use..." to read "Safe ~~for~~ cleaning of ...".

"Safe for use on delicate medical/dental/surgical/ equipment/implements and instrumentation.

e. In the following paragraph, remove everything that is considered to be a critical or semi-critical medical item:

Cavicide will effectively disinfect when used as directed on such items as: infant incubators and bassinets, infant care cribs and warmers, oxygen hoods, anesthesia and respiratory therapy equipment, operating room tables and lights, physical therapy equipment, neck brace applicances and cervical collars, whirlpool tanks, hydro-therapy equipment and tanks, stretchers, mayo stands, bed railings, bathing units, bath tubs, shower stalls, diaper changing stations, baby cribs, hair cutting implements, surgical/dental/medical instruments, dental burs, dental handpieces, dental countertops dental chairs, units stools, light lense covers, curing lights, panoramic bite blocks, pliers, impresssion materials (hard rubber), condensation silicone and vinyl polysilicones), dentures and other inanimate surfaces".

4. Submit five (5) copies of final printed labeling before you release the product for shipment.

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5. Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

If you have any questions concerning this letter, please contact Martha Delaney at (703) 305-6982.

Sincerely,

John H. Lee
Product Manager 31
Antimicrobial Program Branch
Registration Division H7505C

Enclosure

(FRONT PANEL)

CAVICIDE®

HOSPITAL DISINFECTANT/CLEANER
SALON DISINFECTANT/CLEANER
VETERINARY DISINFECTANT/CLEANER
CLIPPER BLADE DISINFECTANT/CLEANER
DISINFECTANT/CLEANER
DENTAL DISINFECTANT/CLEANER
ONE-STEP DISINFECTANT/CLEANER
INSTITUTIONAL DISINFECTANT/CLEANER
MEDICAL DISINFECTANT/CLEANER
SURGICAL DISINFECTANT/CLEANER
SURFACE/INSTRUMENT DISINFECTANT/CLEANER
FOR PROFESSIONAL USE

4249
ACCEPTED
with COMMENTS
for EPA Letter Label

NOV 02 1993

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

38526-1

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 ~~XXXXXXXXXX~~

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 PER-
SISTS, SEEK MEDICAL ATTENTION.

NET CONTENTS: 1 GALLON (NET WEIGHT 8.45 LBS)

MICRO-ASEPTIC PRODUCTS, INC.

887 E. WILMETTE ROAD • PALATINE, IL 60067 USA

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

(LEFT PANEL)

CAVICIDE

- FAST ACTING
- 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 *
- 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, outpatient surgical centers, daycare centers, schools, ambulances, police and fire vehicles, jails, prisons, morgues, patient care areas, laboratories, food preparation areas, storage areas, health club facilities, and other critical care areas where environmental infection control and the control of cross contamination is important.

ACCEPTED
with COMMENTS
by EPA Letter Dated

NOV 02 1993

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

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Safe for use on delicate medical/dental/surgical/salon/environmental/equipment/implants and instrumentation. Cavicide will effectively clean and disinfect, when used as directed, such items as: infant incubators and bassinets, infant care cribs and warmers, oxygen hoods, anesthesia and respiratory therapy equipment, operating room tables and lights, laboratory equipment and surfaces, physical therapy equipment, neck brace appliances and cervical collars, whirlpool tanks, hydro-therapy equipment and tanks, stretchers, mayo stands, counter tops, toilets, sinks, refrigerator units, floors, walls, handrails, door knobs, bed railings, bathing units, bath tubs, shower stalls, cabinets, shampoo bowls, manicure tables, chairs, workstations, 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, surgical/dental/medical instruments, dental burs, dental handpieces, dental countertops, dental chairs, unit stools, light lense covers, curing lights, Panoramic bite blocks, pliers, impression materials (hard rubber, condensation silicone and vinyl polysilicones), dentures and other inanimate surfaces, including those made of plastics (such as: polycarbonate, polyvinylchloride, polypropylene and polystyrene), non-porous vinyl and upholstery, stainless steel, painted surfaces, plexiglas, glass, and other hard non-porous surfaces.

ACCEPTED
with COMMENTS
EPA Letter Dated:

APPLICATIONS:

NOV 02 1993

SURFACES: (Where appropriate, follow Universal Precautions.)

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

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.

For disinfecting medical equipment and other surfaces:

- Spray/apply Cavicide to directly surface, thoroughly wetting area to be disinfected. (Visibly soiled surfaces should be first 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).

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7 of 9

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

For use as pre-soak/pre-cleaning solution:

- Fill appropriate size container with a sufficient amount of Cavicide so as to allow for complete submersion of instruments/objects. Place objects into Cavicide solution, cover and allow to soak prior to transporting and/or cleaning. Rinse thoroughly. Change solution daily or more often as needed if the solution becomes diluted or visibly soiled.

For use as an instrument pre-clean/pre-transport spray:

- Place instruments onto or into a suitable container. Without handling instruments, thoroughly spray Cavicide solution onto instruments so as to thoroughly wet all exposed surfaces. Cover instruments and transport to appropriate cleaning area. Rinse instruments prior to routine cleaning process.

For use as an instrument ultrasonic cleaning solution:

- Thoroughly rinse objects under running water to remove visible gross debris. Add 1 part Cavicide to 3 parts water in ultrasonic unit, immerse instruments into mixed solution and activate ultrasonic unit for 10 minutes or longer if necessary. Remove objects and rinse thoroughly. Change solution as needed.

For use as a manual cleaner:

- Rinse dirty objects under running tap water to remove visible gross debris. Place pre-rinsed objects into a solution of 1 part Cavicide to 3 parts ordinary tap water. Scrub objects using a stiff bristle brush. (Objects should be submerged as scrubbed.) Rinse thoroughly. Change solution as needed.

For use on hair clippers, shears, barber implements:

- While the 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.

For cleaning salon implements:

- First, spray object using a pump spray bottle of Cavicide. Scrub/wipe away visible debris using a soft bristle brush or soft cloth. Immerse implements into an undiluted solution of Cavicide 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.

ACCEPTED
with COMMENTS
In EPA Letter Dated

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the purpose of
registration under FIFRA Reg. 156

38526-1
MAY 11 93 06:45PM NRT WORKS DESIGN STUDIO 22-091555

1029

INSTRUMENT/IMPLEMENT/SMALL OBJECT DISINFECTION INSTRUCTIONS:

(Where appropriate, follow Universal Precautions)

For disinfection of pre-cleaned instruments/objects:

- Instruments/objects must be thoroughly pre-cleaned to remove excess organic debris, rinsed and then rough dried. (Clean and rinse the lumens of hollow instruments before filling with solution or before immersion.) Immerse instruments/objects into Cavicide solution and allow to remain submerged for 10 minutes at room temperature (20°C) for tuberculocidal kill. 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.

For disinfection of pre-cleaned instruments/objects in ultrasonic units:

- Instruments/objects must be thoroughly pre-cleaned to remove excess organic debris, rinsed and rough dried. (Clean and rinse the lumens of hollow instruments before filling with solution or before immersion.) Immerse pre-cleaned instruments/objects into undiluted Cavicide solution and activate ultrasonic unit for 10 minutes. 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.

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with COMMENTS
in EPA letter Dated

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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.

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the purpose
registered under EPL 10-1-10

CAVICIDE EFFECTIVELY KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACE 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).

3852.6-1

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.

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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.

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with COMMENTS
In EEA letter Dated

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38526-1

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