K951123

APR 25 1995

510(k) Summary
Safe Medical Devices Act Summary

Cavicide® Surface Disinfectant/Decontaminant Cleaner

I. Preparation Date and Submitter's Contact Point

This 510(k) summary was prepared on February 10, 1995 and is submitted by:

Mr. Gregory F. Steil, Manager
Regulatory Affairs/Quality Control
Micro-Aseptic Products, Inc.
887 East Wilmette Road
Palatine, IL 60067
ph: 708-358-6303

II. Statement of Intended Use

Cavicide is a general purpose disinfectant intended for use in cleaning, decontaminating, and disinfecting equipment surfaces and non-critical instruments in hospitals, laboratories, and other critical care areas where environmental control of cross contamination is important.

III. Description and Overview of Cavicide Efficacy and Safety

Cavicide is a proprietary liquid formulation of isopropyl alcohol, quaternary ammonium salt/biodegradable detergents and sequestering agents used in spray-on and soak applications for the decontamination of instruments prior to terminal sterilization/ high-level procedures and disinfection of equipment surfaces used in medical, dental, ophthalmological, and other health care environments. It is a single container disinfectant with a clear, pale-straw color and a slight alcohol odor.

In standard AOAC or EPA laboratory tests, Cavicide has proved biocidal effectiveness against the following microorganisms:

Mycobacterium bovis BCG	Poliovirus 1 & 2
Pseudomonas aeruginosa	Coxsackie virus
Salmonella choleraesuis	*Candida albicans*
Staphylococcus aureus	*Aspergillus niger*
Human Immunodeficiency virus	*Trichophyton mentagrophytes*
Herpes simplex 1 & 2 viruses	Mold and Mildew organisms

Cavicide 510(k) Summary Continued

Laboratory tests as outlined in [Product Performance Criteria (Subdivision G Guidelines and DIS/TSS Efficacy Data Requirements)] were performed.

TB Studies

A Quantitative Suspension Test for Determining Tuberculocidal Activity of Micro-Aseptic Products' Liquid Disinfectant, Cavicide (10 minutes) Southern Research, June 19, 1991

Cavicide Hospital Disinfectant/Cleaner vs. Mycobacterium bovis BCG in a Rate of Kill Suspension Test (5 Minutes) MicroChem Laboratories, February 22, 1994

AOAC Tuberculocidal Test for Cavicide Against Mycobacterium bovis BCG with 5% soil load (10 minutes) Shaldra Biotest, September 21, 1985

AOAC Confirmative Tuberculocidal Activity of Cavicide Hospital Disinfectant/Cleaner (5 minutes) MicroChem laboratories, July 19, 1994

Bacteriocidal Studies

Bactericidal Activity of Cavicide Hospital Disinfectant/Cleaner in a Stainless Steel Cylinder Test and Suspension - MicroChem Laboratories, January 18, 1994

The Evaluation of the Efficacy of Micro-Aseptic Products, Inc. compound Cavicide against Pseudomonas aeruginosa. (10 minutes) Viromed Laboratories, November 9, 1993

Cavicide vs. Pseudomonas aeruginosa in the AOAC Germicidal Spray Products Test (2 minutes) MicroChem Laboratories, January 3, 1995

Cavicide vs. Staphylococcus aureus in the AOAC Germicidal Spray Products Test (2 minutes) MicroChem Laboratories, January 9, 1995

AOAC Use Dilution for Cavicide Against Salmonella choleraeraesuis, Staphylococcus aureus, Pseudononas aeruginosa with 5% soil load. (10 minutes) Shaldra Biotest, July 22, 1985

The Evaluation of the Efficacy of Micro-Aseptic Products, Inc. compound Cavicide Staphylococcus aureus. (10 minutes) Viromed Laboratories, May 24, 1993

Cavicide vs. Salmonella choleraesuis in the AOAC Germicidal Spray Products Test. (2 minutes) MicroChem Laboratories, January 18, 1995

The evaluation of the Efficacy of Micro-Aseptic Products, Inc. Compound Cavicide against Salmonella choleraesuis. (10 minutes) Viromed Laboratories, May 27, 1993

Fungicidal

AOAC Fungicidal Test using Trichophyton mentagrophytes with 5% soil (2 minutes) Shaldra Biotest, June 29, 1985

Cavicide Hospital Disinfectant/Cleaner vs. Aspergillus niger in a Stainless Steel Cylinder Use Dilution Test and in Suspension MicroChem Laboratories, April 21, 1994

Fungicidal Activity of Cavicide Hospital Disinfectant/Cleaner in a Stainless Steel Cylinder Use Dilution Test and in Suspension (Candida albicans, Trichophyton mentagrophytes) (10 minutes) MicroChem Laboratories, January 24, 1994

Virucidal

The effectiveness of Cavicide disinfectant to inactivate Coxsackie B5A virus, Polio virus I and II (2 minutes) Integrity Bioservices, Inc., December 19, 1989

Virucidal Efficacy of Micro-Aseptic Products, Inc.'s Cavicide against the Human Immunodeficiency Virus (2 minutes) Southern Research, July 14, 1992

Virucidal Efficacy of Cavicide Against Herpes Simplex Virus Type I (undiluted-immersion) (30 seconds) Gibraltar Biological Laboratories, Inc., July 6, 1984

Virucidal Efficacy of Cavicide Against Herpes Simplex Virus Type I (undiluted spray method) (30 seconds) Gibraltar Biological Laboratories, July 31, 1984

Virucidal Efficacy of Cavicide Against Herpes Simplex Virus Type II (undiluted-immersion) (30 seconds) Gibraltar Biological Laboratories, July 31, 1984

Virucidal Efficacy of Cavicide Against Herpes Simplex Virus Type II (undiluted spray method) (30 seconds) Gibraltar Biological Laboratories, July 31, 1984

Cavicide has not passed the AOAC Sporicidal test and is therefore not suited for use as a terminal disinfectant on semi-critical or critical instruments.

Cavicide is essentially non-toxic in acute exposures to humans and animals: The oral LD_{50} is greater than 5.0 g/Kg body weight in rats, and the dermal LD_{50} is greater than 2.0 g/Kg in rabbits. Cavicide showed no dermal irritation in rabbits, but mild, reversible eye irritation was observed in unrinsed rabbit eyes 7 days after exposure.

Together, these results indicate that Cavicide is safe for use as a general purpose disinfectant with only routine safety precautions during use. Exposure to any Cavicide residues remaining after use are of no concern for adverse effects.

 1123

Toxicity and irritation data were obtained from the following studies.

- Final Report. Acute Oral Toxicity of Cavicide Disinfectant Cleaner in Sprague-Dawley Rats - American Standards Bioservices Corporation, May 23, 1986

- Cavicide Disinfectant Cleaner Primary Dermal Irritation in Rabbits. American Standards Bioservices Corporation, September 18, 1986

- Final Report. Acute Dermal Toxicity Study of Cavicide on New Zealand Albino Rabbits
  American Standards Bioservices Corporation, June 6, 1986

- Cavicide Disinfectant Cleaner Primary Eye Mucosa Irritation in Rabbits
  American Standards Bioservices Corporation, September 25, 1986

IV. Cavicide Substantial Equivalence

Cavicide is a general purpose disinfectant based on its being assigned an EPA registration number and on its demonstrated efficacy in the required standardized tests. Cavicide is equivalent to general purpose disinfectants that rely on a combination of active ingredients for their efficacy.

V. Conclusions

Results of safety and efficacy testing indicate that Cavicide is non-toxic to humans and animals in acute exposures and is effective in killing the microorganisms associated with infection and contamination of inanimate, hard surfaces. Cavicide is not intended for use as a terminal sterilant/high-level disinfectant for medical devices, although it may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization.

Gregory F. Steil, Manager, Regulatory Affairs
Micro-Aseptic Products, Inc.

February 15, 1995
Date

K951123 / A

SYBRON
DENTAL SPECIALTIES, INC.

August 28, 1996

Food and Drug Administration
Document Mail Center (HFZ 401)
1390 Piccard Drive
Rockville, MD 20850

Re: K951123
Cavicide Surface Disinfectant/Decontaminant Cleaner
Micro-Aseptic Products, Inc.
Date of Substantial Equivalence: April 25, 1995
New Contact Person

To Whom It May Concern:

This letter is to notify your office that as a result of the sale of assets of Micro-Aseptic Products, Inc. (887 E. Wilmette Road, Palatine, IL 60067) to Metrex Research Corporation (1717 W. Collins Avenue, Orange, CA 92867) that the new contact person for the above-referenced product, *Cavicide Surface Disinfectant/Decontaminant Cleaner*, K951123, will be:

Wendy A. Urtel
Metrex Research Corporation
Sybron Dental Specialties
1717 W. Collins Avenue
Orange, CA 92867

If you have any questions, please contact me at (714) 516-7425.

Sincerely,

Wendy A. Urtel
Regulatory Affairs Associate

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Anita Earl, RN
Director of Scientific Affairs
Micro-Aseptic Products, Incorporated
425 Creekside Drive
Palatine, Illinois 60067

JUL 31 1996

Re: K951123
Device Name: Cavicide® Surface Disinfectant/Decontaminant Cleaner
Dated: July 10, 1996
Received: July 15, 1996

Dear Ms. Earl:

We have reviewed the information dated July 10, 1996, regarding the 510(k) notification K951123 previously submitted for the device referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

Sincerely yours,

Timothy A. Ulatowski
Acting Division Director
Division of Dental, Infection Control, and General Hospital Devices
Office of Device Evaluation
Center for Devices and Radiological Health

JUL 31 1996

Ms. Anita Earl, RN
Director of Scientific Affairs
Micro-Aseptic Products, Incorporated
425 Creekside Drive
Palatine, Illinois 60067

Re: K951123
Device Name: Cavicide® Surface Disinfectant/Decontaminant Cleaner
Dated: July 10, 1996
Received: July 15, 1996

Dear Ms. Earl:

We have reviewed the information dated July 10, 1996, regarding the 510(k) notification K951123 previously submitted for the device referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

Sincerely yours,

Timothy A. Ulatowski
Acting Division Director
Division of Dental, Infection Control, and General Hospital Devices
Office of Device Evaluation
Center for Devices and Radiological Health

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-480	E. Marshall	7/24/96						
HFZ-480	L. Bailey	7/26/96						

bcc: HFZ-401 DMC
HFZ-480 DDIGD
D.O.
f/t:HFZ-480:ESM:RMD:7/23/96

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food And Drug Administration

Memorandum

Date: 7-15-96

From: Document Mail Center (HFZ-401)

Subject: Premarket Notification Number(s) K951123/A1

To: Division Director, HO/DDIG

The attached information has been received by the 510(k) Document Mail Center (DMC), on the above referenced 510(k) submission. Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below. Feel free to note any additional comments below.

Thank you for your cooperation.

__✓__ Information does not change status of the 510(k); no other action required by the DMC; please add to the image file. [THE DIVISION SHOULD PREPARE A CONFIRMATION LETTER - AN EXAMPLE IS AVAILABLE ON THE LAN (K25). THIS DOES NOT APPLY TRANSFER OF OWNERSHIP, PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS].

_____ Additional information requires a new 510(k), however the information submitted is incomplete. Notify the company to submit a new 510(k). [THE DIVISION SHOULD PREPARE THE K30 LETTER ON THE LAN.]

_____ Additional information requires a new 510(k); please process. [THIS INFORMATION WILL BE MADE INTO A NEW 510(K)].

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement or 510(k) statement).

COMMENTS: _____

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: Elaine S. Maychall

Date: 7/18/96

7/22/96

MEMORANDUM

DATE: July 18, 1996

FROM: Elaine Schalk Mayhall, Chemist, Infection Control Devices Branch, DDIGD, HFZ-480

SUBJECT: K951123/A1
MICRO-ASEPTIC PRODUCTS, INC. (by XTTRIUM LABS., INC. and REDU PRODUCTS, INC.)
CAVICIDE® SURFACE DISINFECTANT/DECONTAMINANT CLEANER

TO: The Record

The firm has submitted a revised EPA-stamped label for Cavicide® that expands the claims to include vancomycin resistant *Enterococcus faecalis* and methicillin resistant *Staphylococcus aureus*.

In addition, the firm noted a change of address.

These changes do not change the status of the 510(k). No action is necessary, but a letter will be sent to the firm confirming the receipt of the information and the decision.

Elaine S Mayhall

Elaine Schalk Mayhall, Ph.D.

MICRO ASEPTIC PRODUCTS, INC.

K951123/A1

July 10, 1996

Food and Drug Administration
Document Processing Desk
Office of Device Evaluation
Center for Devices and Radiological Health
9200 Corporate Blvd.
Rockville, MD 20850

RE: K951123 (AMENDED LABEL EPA APPROVED)
Trade Name: Cavicide® Surface Disinfectant/Decontaminant Cleaner
Regulatory Class: Unclassified
Product Code: LRJ

Dear Sir/Madam:

Please find enclosed a copy of the EPA approved Cavicide label dated November 6, 1995 for your records in order to be in compliance with PR Notice 94-4. This amended label provides additional claims for Vancomycin Resistant Enterococcus faecalis (VRE) and Methicillin Resistant Staphylococcus aureus (MRSA).

In addition, please note the change of address on record:

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

TO: Micro-Aseptic Products, Inc.
425 Creekside Drive
Palatine, IL 60067

If you have any questions concerning this letter, please call me at 847-358-6303.

Sincerely,
MICRO-ASEPTIC PRODUCTS, INC.

Anita Earl

Anita Earl, RN
Director of Scientific Affairs

AE/cpd

enclosure
fdaamend.doc

425 CREEKSIDE DRIVE • PALATINE, ILLINOIS 60067 USA • PH. (847) 358-6303 • FAX (847) 358-0634

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

NOV -6 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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.

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®

ACCEPTED
with COMMENTS
In EPA Letter Dated:
NOV 6 1995
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 38526-1

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.
887 E. WILMETTE ROAD • PALATINE, IL 60067 USA

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

(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.

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 operatory 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 sufaces, 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.

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 1ounce 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.

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide Registered under EPA Reg. 38536-7

NOV - 6 1998

ACCEPTED with COMMENTS In EPA Letter Dated

12

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 tuberculocidal 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 tuberculocidal 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
In EPA Letter Dated:
NOV 6 1995
Under the [illegible] Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 38526-1

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
In EPA Letter Dated:

NOV 6 1995

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide

38526-1

Revised 9/15/94

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 25 1995

Mr. Gregory F. Steil
Manager, Regulatory Affairs/Quality Control
Micro-Aseptic Products, Incorporated
887 East Wilmette Road
Palatine, Illinois 60067

Re: K951123
Trade Name: Cavicide® Surface Disinfectant/Decontaminant Cleaner
Regulatory Class: Unclassified
Product Code: LRJ
Dated: February 10, 1995
Received: February 24, 1995

Dear Mr. Steil:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Timothy A. Ulatowski
Acting Director
Pilot Division
Office of Device Evaluation
Center for Devices and
Radiological Health

2

ESM

510(K) ROUTE SLIP

510(k) NUMBER K951123 PANEL HO DIVISION DGRD BRANCH

TRADE NAME CAVICIDE SURFACE DISINFECTANT/DECONTAMINANT CLEANER

COMMON NAME

PRODUCT CODE ___

APPLICANT MICRO-ASEPTIC PRODUCTS, INC.
SHORT NAME MICRASEPPROD
CONTACT GREGORY F STEIL
DIVISION
ADDRESS 887 EAST WILMETTE ROAD
PALATINE, IL 60067
PHONE NO. (708) 358-6303 FAX NO. (708) 358-0634

MANUFACTURER XTTRIUM LABORATORIES, INC. REGISTRATION NO. 1410853
REDU PRODUCTS

DATE ON SUBMISSION 10-FEB-95 DATE DUE TO 510(K) STAFF 10-MAY-95

DATE RECEIVED IN ODE 24-FEB-95 DATE DECISION DUE 25-MAY-95

DECISION __ DECISION DATE _____

52

3

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date

From REVIEWER(S) - NAME(S) Elaine Schalk Mayhall

Subject 510(k) NOTIFICATION K951123

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

✓ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

_____ (C) Requires more data.

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☑

This 510(k) contains: (check appropriate box(es))

☑ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

_____ No Confidentiality

_____ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

LRJ 80 Unclassified

Additional Product Code(s) w/Panel (optional):

_____

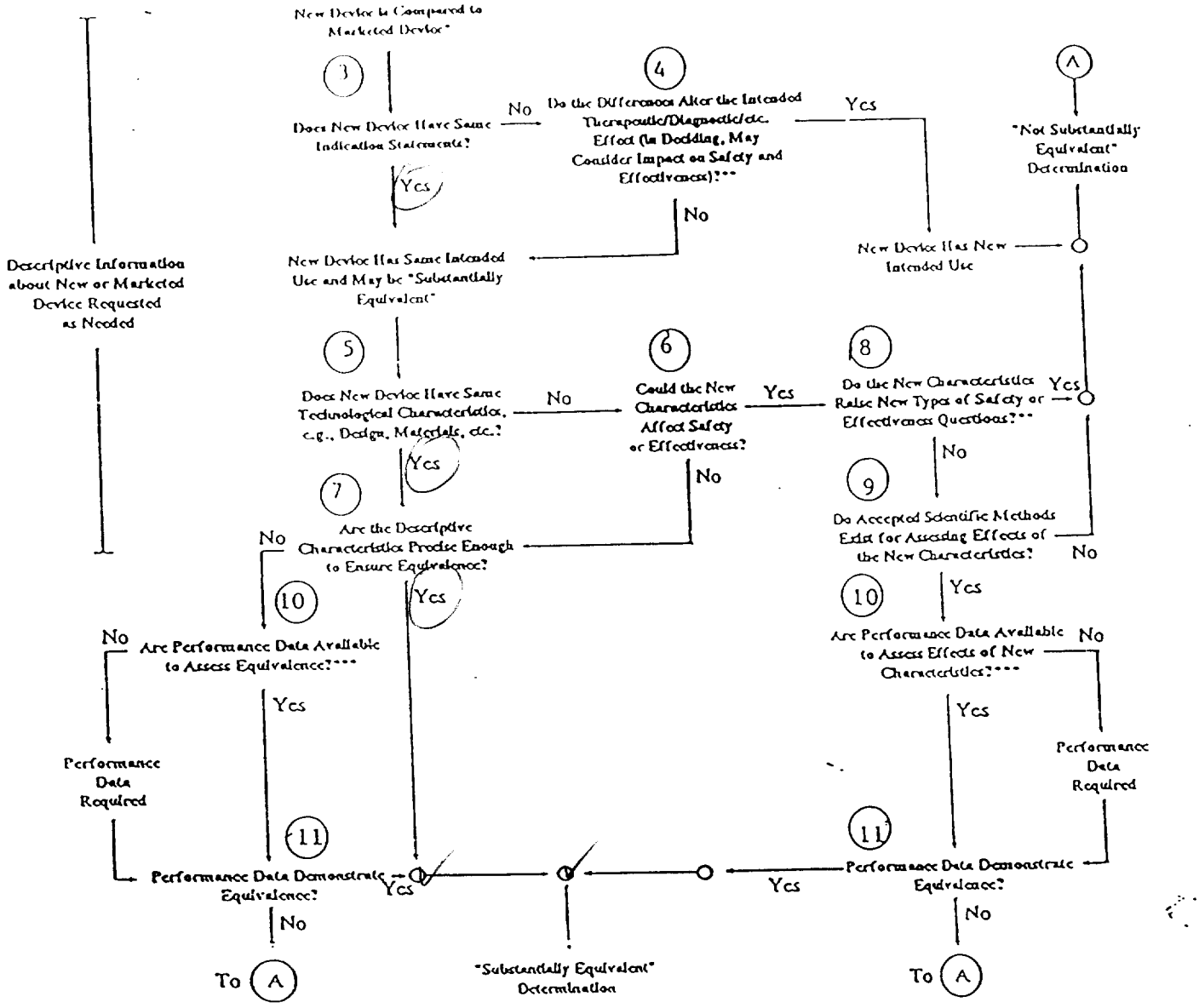
REVIEW: _____ (BRANCH CHIEF) FWC (BRANCH CODE) 4-18-95 (DATE)

FINAL REVIEW: _____ (DIVISION DIRECTOR) 4/21/95 (DATE)

*RULES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

510(k) Number: K951123

Reviewer: ELAINE SCHALK MAYHALL **Division/Branch:** Pilot/INCB

Manufacturer Name: XTTRIUM LABORATORIES, INC. AND REDU PRODUCTS FOR MICRO-ASEPTIC PRODUCTS, INC.

Trade Name: CAVICIDE SURFACE DISINFECTANT/DECONTAMINANT CLEANER

Common Name: GENERAL PURPOSE DISINFECTANT

Products To Which Compared: Preamendments (PRE 1976) liquid chemical germicides.

		YES	NO	
1.	IS PRODUCT A DEVICE?	X	___	IF NO STOP
2.	DEVICE SUBJECT TO 510(K)?	X	___	IF NO STOP
3.	SAME INDICATION STATEMENT?	X	___	IF YES GO TO 5
4.	DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?	___*	___	IF YES STOP > NE
5.	SAME TECHNOLOGICAL CHARACTERISTICS?	X	___	IF YES GO TO 7
6.	COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?	___*	___	IF YES GO TO 8
7.	DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	X	___	IF YES STOP SE IF NO GO TO 10
8.	NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?	___*	___	IF YES STOP > NSE
9.	ACCEPTED SCIENTIFIC METHODS EXIST?	___	___	IF NO STOP > NSE
10.	PERFORMANCE DATA AVAILABLE?	___	___	IF NO REQUEST DATA
11.	DATA DEMONSTRATE EQUIVALENCE?	___*	___	>

* "yes" responses to 4, 6, 8, and 11, and every "no" response requires an explanation (see last page).

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: Cavicide Surface Disinfectant/Decontaminant Cleaner is a liquid germicidal detergent for use in cleaning, decontaminating, and disinfecting noncritical instruments and inanimate, non-porous surfaces in health care facilities.

2. DEVICE DESCRIPTION: Cavicide is a liquid germicidal detergent containing quaternary ammonium compounds, isopropyl alcohol, and inert ingredients. This device has fulfilled EPA registration requirements and meets the criteria of the MOU dated June 4, 1993 between FDA and EPA for liquid chemical germicides as an intermediate level disinfectant.

Elaine Schalk Mayhall ESM 7/13/95

7

MEMORANDUM

DATE: April 11, 1995

FROM: Elaine Schalk Mayhall, Chemist, Infection Control Devices Branch, Pilot Division, HFZ-413

SUBJECT: K951123
MICRO-ASEPTIC PRODUCTS, INC. (by XTTRIUM LABS., INC. and REDU PRODUCTS, INC.)
CAVICIDE SURFACE DISINFECTANT/DECONTAMINANT CLEANER

TO: To the Record

This document was reviewed based on the October 1993 Document, Guidance on the Content and Format of Premarket Notification [510(K)] Submissions for General Purpose Disinfectants. The firm supplied data and information that were acceptable using the checklist (see attached) contained in the guidance document in accordance with the June 4, 1993 Memorandum of Understanding (MOU) between FDA and EPA for regulation of Liquid Chemical Germicides Intended for Use on Medical Devices.

RECOMMENDATION: Based on the checklist review criteria, I recommend a SUBSTANTIAL EQUIVALENCE determination for this device.

Elaine Schalk Mayhall /2 SM 4/13/95

8

3/30

K951123

H. **Checklist**

RECOMMENDED INFORMATION	YES	NO
COVER LETTER		
A. TRADE/PROPRIETARY NAME Cavicide	✓	
B. COMMON/USUAL NAME: GENERAL PURPOSE DISINFECTANT	NA	NA
C. CLASSIFICATION NAME: UNCLASSIFIED	NA	NA
D. ESTABLISHMENT REGISTRATION NUMBER LISTED (not essential at time of 510(k) submission) 5464-IL-1 39234-WV-001	✓	
E. PRODUCT CODE: LRJ	NA	NA
F. PANEL: 80	NA	NA
G. Manufacturing Sites 2 IL+WV	✓	
LABELING		
COPIES OF LABELS, LABELING, AND PROMOTIONAL LITERATURE WITH EPA STAMP AND LANGUAGE MEETING MOU REQUIREMENTS. Jan 17, 1995	✓	
EPA REGISTRATION		
A. NOTICE OF EPA REGISTRATION	✓	
B. EPA REGISTRATION NUMBER 38526-1	✓	
C. DATE OF EPA REGISTRATION	7/6/94	
SMDA STATEMENT		
A. SUMMARY OF SAFETY & EFFECTIVENESS, OR	✓	
B. STATEMENT OF SAFETY & EFFECTIVENESS		✓

No Truthful + Accuracy Stmt required since in before March 14.

Elaine Schalk Maghall

4/13/95

4

PILOT Evaluation Staff Checklist
for Premarket Notifications (510(k)s)

Device Trade Name: Carrie Surface disinfectant/decontaminant Cleaner	K#: 951123
Submitter Name: Micro Hygiene products, Inc	
Date Received: [illegible] 90 Day Due Date: [illegible]	

Review Tier (circle one): 1 2 3

Question	Yes	No
A. Is the product a device?	X	
B. Is the device exempt from 510(k)?		X
C. Expedited Review Status: Requested by sponsor,		X
or identified by PILOT Staff		
Granted by Pilot Staff?		
D. Has this device been the subject of a previous NSE decision?		X
If yes, does this new 510(k) address the NSE Issues(s), e.g., performance data?		
E. Has the sponsor been the subject of an integrity investigation?		X
If yes, has the ODE Integrity Officer given permission to proceed with the review?		

Administrative Reviewer Signature: Michael Thurnitz

Date: [illegible]

Supervisory Signature: _____

Date: _____

PILOT Evaluation Staff Screening Checklist
for Premarket Notifications [510(k)s]

Device Name: wipe surface disinfectant/decontaminant/cleaner	K#: 951123
Submitter Name: Micro-Kleen Products, Inc.	

Items to Include in the 510(k)	✓ if needed: Yes	✓ if needed: No	✓ if needed & MISSING
1. General information: a) trade name, b) common name, c) establishment registration # d) address of manufacturing sites, e) device class, f) panel, g) new device or modification, h) predicate device(s) identified, i) submitter's name and address	✓		-
2. SMDA requirements: 510(k) summary or statement (any Class device)	✓		
Class III Certification & Summary (if Class III)			
3. Proposed labeling: a) device and package labels, b) package insert, c) statement of intended use, d) advertisements or promotional materials	✓		
Description of device (or modification) including diagrams, engineering drawings, or photographs, and service manuals	✓		
Comparison Information (similarities and differences) to named legally marketed equivalent device(s) (comparison table of attributes recommended) should include: a) labeling, b) intended use, c) specifications, d) materials, e) performance (bench, animal, clinical) data (as needed), f) analysis of comparable safety and effectiveness	✓		
6. Biocompatibility data for all direct or indirect patient or user-contacting materials per Tripartite or ISO, OR, certification of identical material/formulation and method of sterilization to predicate			
7. Sterilization and expiration dating information: a) sterilization method, b) Sterility Assurance Level, c) type of packaging, d) pyrogen test method, e) EtO residues, f) radiation dose, g) validation method			
8. Software validation & verification per FDA guidance: a) hazard analysis, b) level of concern, c) development documentation, d) certification			
9. Additional data and information per device specific OGRD/PILOT Staff guidance			
10. Kit information			

Items with shaded "No" and checked "Yes" are necessary for ALL submissions.
Specific listed criteria in each item that are missing may be highlighted.
Any checks in the last (Needed & MISSING) column requires a resubmission.

ed

refuse to accept

	Yes Present Omission Justified	No Inadequate Omitted
I. Other (specify)	☐	☐

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 14, 1995

MICRO-ASEPTIC PRODUCTS, INC.
887 EAST WILMETTE ROAD
PALATINE, IL 60067
ATTN: GREGORY F. STEIL

510(k) Number: K951123
Received: 24-FEB-95
Product: CAVICIDE SURFACE DISINFECTANT/DEC ONTAMINANT CLEANER

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. Although the traditional timeframes for reviewing 510(k)s has been 90 days, it is now taking longer. These increasing response times have been caused by many factors, including a sharp increase in ODE's workload and increasingly complex device submissions. During 1992, we received about 1,500 more total submissions than we did the preceding year. We are troubled by these increases in response times and are making every effort to regain predictability in the timing of 510(k) reviews. Due to the increase in response times, CDRH has established a 510(k) Status Reporting System through which submitters may receive a status report on their 510(k) submissions(s) as follows:

- Beginning 90 days after ODE receives your 510(k) submission, you may begin requesting status information. Submit requests via fax (301-443-8818) or via mail to:
  510(k) Status Coordinator
  Division of Small Manufacturers Assistance (DSMA) (HFZ-220)
  Center for Devices and Radiological Health, FDA
  5600 Fishers Lane
  Rockville, Maryland 20857 USA
  Because of staff limitations, we cannot answer telephone status requests.

- 510(k) status requests should include:
  (1) submitter's name and mailing address;
  (2) requester's name, affiliation with the 510(k) submitter, mailing address, fax number (if applicable), telephone number, and signature; and

(3) 510(k) information, including product name, 510(k) number, date logged in by ODE (as identified in acknowledgment letter from ODE), and name of contact person identified on firm's 510(k) submission.

Enclosed is a suggested format that you may use to ensure that you include all of the required information.

- Within three working days after DSMA receives a submitter's status request, DSMA will send the submitter a fax or letter that includes:
  (1) the branch to which the 510(k) has been assigned;
  (2) the last action, and date of that action, that CDRH has taken regarding the 510(k), e.g., logging in an amendment, preparing a decision letter; and
  (3) the position of the 510(k) in the reviewer's queue.

We request that 510(k) submitters make status inquiries no more than every four weeks. We do not have the resources to respond more frequently.

The SMDA also requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages 510(k) submitters to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. **Since the law requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.**

Additionally, the new legislation also requires any person who asserts that their device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The

description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

As of March 9, 1993, FDA has implemented the Good Manufacturing Practice(GMP) Pre-Clearance Inspection Program for all class III devices that are being reviewed under the premarket notification program. A letter of substantial equivalence cannot be sent until the finished device manufacturing site(s) and sterilization sites(s) as appropriate, have been identified and FDA has determined that the manufacturer(s) is in compliance with the GMP regulation (21 CFR Part 820).

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/ Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

15

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

PREMARKET NOTIFICATION (510(k)) STATUS REQUEST

TO: 510(k) Status Coordinator
Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health, FDA
5600 Fishers Lane
Rockville, MD 20857
USA
Fax Number: (301) 443-8818

Please provide the status of the 510(k) identified below. Please send the information to the requester identified in section B by (check one):

____ fax
____ mail

A. Sponsor Information:

1. Name of 510(k) sponsor: _____

2. Sponsor's mailing address: _____

_____

_____

B. Requester information:

1. Request name: _____

equester affiliation with sponsor: _____

3. Requester mailing address: _____

_____

_____

4. Request fax number (if applicable): _____

5. Requester telephone number: _____

C. 510(k) information:

1. Product name: _____

2. 510(k) number: _____

3. Date logged in by Office of Device Evaluation (ODE) (as identified in acknowledgment letter from ODE): _____

Name of contact person identified on firm's 510(k) submission: _____

I certify that the above information is accurate and truthful to the of my knowledge.

_____
Requester signature

(Rev:2)

MICRO ASEPTIC PRODUCTS, INC.

HO K951123

ORIGINAL

February 10, 1995

Food and Drug Administration
Document Mail Center: HFZ-401
1390 Piccard Drive
Rockville, MD 20850

510(k) Notification for Cavicide® Surface Disinfectant/Decontaminant Cleaner

Dear Reviewer:

Micro-Aseptic Products, Inc., in compliance with 21 CFR § 807.81, is pleased to submit the Premarket Notification [510(k)] for our general purpose disinfectant Cavicide® Surface Disinfectant/Decontamination Cleaner currently manufactured and sold under Environmental Protection Agency Registration Number **38526-1**. The Product is "Unclassified" with Product Code **LRJ** and Review Panel **80**. Throughout this 510(k), Cavicide will be used, rather than Cavicide®, as it appears on the product label.

The two manufacturing sites for Cavicide are:

(b) (4)

Our 510(k) submission includes this cover letter and three attachments:

- Attachment I contains our most current stamped master label baring the changes as directed by PR Notice 94-4 and FDA/EPA Memorandum of Understanding, a copy of the Cavicide bottle label and promotional literature.

- Attachment II contains the dated EPA Certification of Registration for Cavicide.

887 EAST WILMETTE ROAD • PALATINE, ILLINOIS 60067 USA • PH. (708) 358-6303 • FAX (708) 358-0634

18

- Attachment III contains the Safe Medical Devices Act Statement.

Questions or requests for additional information may be directed to the following:

Mr. Gregory F. Steil, Manager
Regulatory Affairs/Quality Control
Micro-Aseptic Products, Inc.
887 East Wilmette Road
Palatine, IL 60067

Telephone: 800-536-4129

Thank you for your attention to our Premarket Notification [510(k)] submission.

Sincerely,
Micro-Aseptic Products, Inc.

Gregory F. Steil, Manager
Regulatory Affairs/Quality Control

ATTACHMENT I

Cavicide Label and Promotional Literature

Cavicide 510(k)

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

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

JAN 17 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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

Attention: Jack Wagner
President

Subject: Cavacide®
EPA Registration No. 38526-1
MOU Compliance Amendment dated October 7, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable.

The labeling submitted in compliance with PR Notice 94-4 is acceptable. A stamped copy is enclosed for your records.

If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 305-6141.

Sincerely yours,

Walter C. Francis

Walter C. Francis
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

(FRONT PANEL)

CAVICIDE®

OSPITAL 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.
887 E. WILMETTE ROAD • PALATINE, IL 60067 USA

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

23

(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 *
- 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, prisioner 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.

24

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 eqiupment 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 operatory 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 sufaces, 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.

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 1ounce 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.

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 tuberculocidal 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 tuberculocidal 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.

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

Revised 9/15/94

cavicide®

• Non Staining • Non Corrosive • Non Irritating
• No Dilution • Ready to Use • No Toxic Fumes

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

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, out-patient surgical centers, ambulances, patient care areas, laboratories, and other critical care areas where environmental control of cross contamination is important.
Safe for cleaning/decontamination of equipment and instrumentation. Cavicide will clean and disinfect such items as: infant care equipment surfaces, anesthesia machines and respiratory therapy equipment surfaces, operating room tables and lights, laboratory surfaces, dental operatory surfaces, light lense covers, 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.

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

For disinfecting non-critical devices/medical equipment and other surfaces:
• 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. 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. Discard dirty towel.

INSTRUMENTS: (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 disinfection process. Change solution as needed when it 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 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.)*

cav

SURFACE DISINFECT

BACTERICIDAL • VIRU

READY TO USE - CON

ACTIVE INGREDIENTS
Diisobutylphenoxyethox
benzyl ammonium chlo
Isopropanol.....
INERT INGREDIENTS
TOTAL.....

KEEP OUT

PRECAUTIONARY STATEM
AVOID CONTAMINATION OF FO
CONTACT WITH EYES. IN CAS
EYES WITH PLENTY OF WA
PERSISTS

MICRO SEPTIC PRODUC
U S

Net Contents
1 U.S. Gallon / 3.785 Liters
(Net Weight 8.22 lbs. / 3.73 kg.)

vicide®

ANT / DECONTAMINANT CLEANER

IDAL* • FUNGICIDAL • TUBERCULOCIDAL**

TAINS BIODEGRADABLE DETERGENT

:

yethyl dimethyl

de.....0.25%

.....15.30%

.....84.45%

.....100.00%

OF REACH OF CHILDREN

CAUTION

IENTS: Harmful to Humans and Domestic Animals.
OOD. MAY CAUSE EYE IRRITATION. AVOID DIRECT
E OF DIRECT EYE CONTACT, IMMEDIATELY FLUSH
TER FOR AT LEAST 15 MINUTES. IF IRRITATION
, SEEK MEDICAL ATTENTION.

TS, INC.
A

BARCODE

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, immerse instruments/objects into mixed solution and activate 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 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 disinfection of *non-critical*, pre-cleaned instruments/objects:**

• Instruments/devices 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 tuberculocidal 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.

CAVICIDE EFFECTIVELY KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS IN HEALTHCARE 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 container and place into ordinary trash receptacle.

Manufactured For: Micro-Aseptic Products, Inc. • 887 E. Wilmette Rd. • Palatine, IL 60067 USA R9409

30

Note: We have submitted a one gallon bottle label, the text for our other container types and sizes is not different from the required information on this label. Final printed labels of all sizes will be made available upon request.

Signed: _____

Gregory F. Steil, R.S.
Manager of Regulatory Affairs

READY TO USE!

cavicide®

** Virucidal • Bactericidal • Fungicidal • Tuberculocidal

EPA REG. NO. 38526-1

New Use;

INSTRUMENT DECONTAMINANT SOLUTION**

Helps provide fast, effective instrument decontamination prior to terminal sterilization / high level disinfection.

- Reduces bioburden on instruments prior to the handling, packaging, and terminal sterilization/high level disinfection process.
- Helps prevent protein matter, blood and other organic debris from coagulating on instrument surfaces and in cracks and crevices.
- Either spray undiluted solution directly onto untouched instrument surfaces or immerse dirty instruments into undiluted **Cavicide**® solution.
- Free rinsing, **Cavicide**® leaves no unwanted residue.
- **Cavicide**® is available as: 8 ounce liquid spray, 24 ounce liquid spray, 1 gallon liquid pour bottle, and 5 gallon liquid container w/spigot.

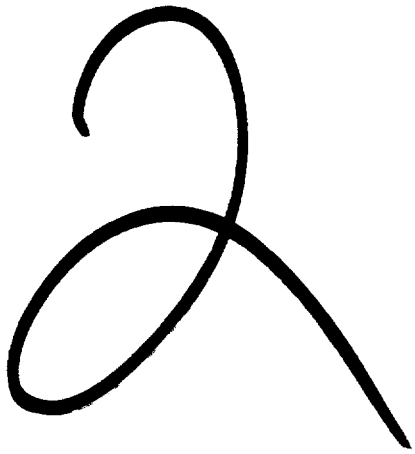
** FOLLOW LABEL INSTRUCTIONS.

Distributed By:

Manufactured By:

MICRO SEPTIC PRODUCTS, INC.
PROVIDING ANTIMICROBIAL PRODUCTS FOR THE HEALTH CARE INDUSTRY
PALATINE, ILLINOIS 60067 USA

For information, call TOLL FREE - 1-800-536-4129



ATTACHMENT II

EPA Registration Information

Cavicide 510(k)

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

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

JUL 6 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

TO WHOM IT MAY CONCERN:

I, Marshall Swindell, Acting Product Manager 31, Antimicrobial Program Branch, Registration Division, Office of Pesticide Programs, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, do hereby certify that the pesticide product listed below is currently registered with this Agency under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, that the labeling attached are true, correct, and compared copy of the correspondence of record, and that the products may be sold and marketed in the United States of America for the uses indicated on the label.

The product registrations listed below have been issued to:

Name and Adress of Company

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

EPA Registration No.	Name of Product
38526-1	CAVICIDE

IN WITNESS WHEREOF
I have hereunto set my hand and affixed the seal of the U.S. Environmental Protection Agency this (6th) of (July) A.D. 1994

Marshall Swindell

Marshall Swindell
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

3

ATTACHMENT III

Safe Medical Devices Act Summary

Cavicide 510(k) Summary

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

510(k) Summary
Safe Medical Devices Act Summary

Cavicide® Surface Disinfectant/Decontaminant Cleaner

I. Preparation Date and Submitter's Contact Point

This 510(k) summary was prepared on February 10, 1995 and is submitted by:

Mr. Gregory F. Steil, Manager
Regulatory Affairs/Quality Control
Micro-Aseptic Products, Inc.
887 East Wilmette Road
Palatine, IL 60067
ph: 708-358-6303

II. Statement of Intended Use

Cavicide is a general purpose disinfectant intended for use in cleaning, decontaminating, and disinfecting equipment surfaces and non-critical instruments in hospitals, laboratories, and other critical care areas where environmental control of cross contamination is important.

III. Description and Overview of Cavicide Efficacy and Safety

Cavicide is a proprietary liquid formulation of isopropyl alcohol, quaternary ammonium salt/biodegradable detergents and sequestering agents used in spray-on and soak applications for the decontamination of instruments prior to terminal sterilization/ high-level procedures and disinfection of equipment surfaces used in medical, dental, ophthalmological, and other health care environments. It is a single container disinfectant with a clear, pale-straw color and a slight alcohol odor.

In standard AOAC or EPA laboratory tests, Cavicide has proved biocidal effectiveness against the following microorganisms:

Mycobacterium bovis BCG	Poliovirus 1 & 2
Pseudomonas aeruginosa	Coxsackie virus
Salmonella choleraesuis	*Candida albicans*
Staphylococcus aureus	*Aspergillus niger*
Human Immunodeficiency virus	*Trichophyton mentagrophytes*
Herpes simplex 1 & 2 viruses	Mold and Mildew organisms

Laboratory tests as outlined in [Product Performance Criteria (Subdivision G Guidelines and DIS/TSS Efficacy Data Requirements)] were performed.

TB Studies

A Quantitative Suspension Test for Determining Tuberculocidal Activity of Micro-Aseptic Products' Liquid Disinfectant, Cavicide (10 minutes) Southern Research, June 19, 1991

Cavicide Hospital Disinfectant/Cleaner vs. Mycobacterium bovis BCG in a Rate of Kill Suspension Test (5 Minutes) MicroChem Laboratories, February 22, 1994

AOAC Tuberculocidal Test for Cavicide Against Mycobacterium bovis BCG with 5% soil load (10 minutes) Shaldra Biotest, September 21, 1985

AOAC Confirmative Tuberculocidal Activity of Cavicide Hospital Disinfectant/Cleaner (5 minutes) MicroChem laboratories, July 19, 1994

Bacteriocidal Studies

Bactericidal Activity of Cavicide Hospital Disinfectant/Cleaner in a Stainless Steel Cylinder Test and Suspension - MicroChem Laboratories, January 18, 1994

The Evaluation of the Efficacy of Micro-Aseptic Products, Inc. compound Cavicide against Pseudomonas aeruginosa. (10 minutes) Viromed Laboratories, November 9, 1993

Cavicide vs. Pseudomonas aeruginosa in the AOAC Germicidal Spray Products Test (2 minutes) MicroChem Laboratories, January 3, 1995

Cavicide vs. Staphylococcus aureus in the AOAC Germicidal Spray Products Test (2 minutes) MicroChem Laboratories, January 9, 1995

AOAC Use Dilution for Cavicide Against Salmonella choleraeraesuis, Staphylococcus aureus, Pseudononas aeruginosa with 5% soil load. (10 minutes) Shaldra Biotest, July 22, 1985

The Evaluation of the Efficacy of Micro-Aseptic Products, Inc. compound Cavicide Staphylococcus aureus. (10 minutes) Viromed Laboratories, May 24, 1993

Cavicide vs. Salmonella choleraesuis in the AOAC Germicidal Spray Products Test. (2 minutes) MicroChem Laboratories, January 18, 1995

The evaluation of the Efficacy of Micro-Aseptic Products, Inc. Compound Cavicide against Salmonella choleraesuis. (10 minutes) Viromed Laboratories, May 27, 1993

29

Fungicidal

AOAC Fungicidal Test using Trichophyton mentagrophytes with 5% soil (2 minutes) Shaldra Biotest, June 29, 1985

Cavicide Hospital Disinfectant/Cleaner vs. Aspergillus niger in a Stainless Steel Cylinder Use Dilution Test and in Suspension MicroChem Laboratories, April 21, 1994

Fungicidal Activity of Cavicide Hospital Disinfectant/Cleaner in a Stainless Steel Cylinder Use Dilution Test and in Suspension (Candida albicans, Trichophyton mentagrophytes) (10 minutes) MicroChem Laboratories, January 24, 1994

Virucidal

The effectiveness of Cavicide disinfectant to inactivate Coxsackie B5A virus, Polio virus I and II (2 minutes) Integrity Bioservices, Inc., December 19, 1989

Virucidal Efficacy of Micro-Aseptic Products, Inc.'s Cavicide against the Human Immunodeficiency Virus (2 minutes) Southern Research, July 14, 1992

Virucidal Efficacy of Cavicide Against Herpes Simplex Virus Type I (undiluted-immersion) (30 seconds) Gibraltar Biological Laboratories, Inc., July 6, 1984

Virucidal Efficacy of Cavicide Against Herpes Simplex Virus Type I (undiluted spray method) (30 seconds) Gibraltar Biological Laboratories, July 31, 1984

Virucidal Efficacy of Cavicide Against Herpes Simplex Virus Type II (undiluted-immersion) (30 seconds) Gibraltar Biological Laboratories, July 31, 1984

Virucidal Efficacy of Cavicide Against Herpes Simplex Virus Type II (undiluted spray method) (30 seconds) Gibraltar Biological Laboratories, July 31, 1984

Cavicide has not passed the AOAC Sporicidal test and is therefore not suited for use as a terminal disinfectant on semi-critical or critical instruments.

Cavicide is essentially non-toxic in acute exposures to humans and animals: The oral LD_{50} is greater than 5.0 g/Kg body weight in rats, and the dermal LD_{50} is greater than 2.0 g/Kg in rabbits. Cavicide showed no dermal irritation in rabbits, but mild, reversible eye irritation was observed in unrinsed rabbit eyes 7 days after exposure.

Together, these results indicate that Cavicide is safe for use as a general purpose disinfectant with only routine safety precautions during use. Exposure to any Cavicide residues remaining after use are of no concern for adverse effects.

40

Toxicity and irritation data were obtained from the following studies.

- Final Report. Acute Oral Toxicity of Cavicide Disinfectant Cleaner in Sprague-Dawley Rats - American Standards Bioservices Corporation, May 23, 1986

- Cavicide Disinfectant Cleaner Primary Dermal Irritation in Rabbits.
  American Standards Bioservices Corporation, September 18, 1986

- Final Report. Acute Dermal Toxicity Study of Cavicide on New Zealand Albino Rabbits
  American Standards Bioservices Corporation, June 6, 1986

- Cavicide Disinfectant Cleaner Primary Eye Mucosa Irritation in Rabbits
  American Standards Bioservices Corporation, September 25, 1986

IV. Cavicide Substantial Equivalence

Cavicide is a general purpose disinfectant based on its being assigned an EPA registration number and on its demonstrated efficacy in the required standardized tests. Cavicide is equivalent to general purpose disinfectants that rely on a combination of active ingredients for their efficacy.

V. Conclusions

Results of safety and efficacy testing indicate that Cavicide is non-toxic to humans and animals in acute exposures and is effective in killing the microorganisms associated with infection and contamination of inanimate, hard surfaces. Cavicide is not intended for use as a terminal sterilant/high-level disinfectant for medical devices, although it may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization.

Gregory F. Steil, Manager, Regulatory Affairs
Micro-Aseptic Products, Inc.

February 15, 1995
Date