

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

10088-105

1/18/2006

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 18, 2006

Troy Munson
Regulatory Compliance Specialist
Athea Laboratories, Inc.
P.O. Box 240014
Milwaukee, WI 53224

Subject: C-Spray Disinfectant Deodorant
EPA Registration No. 10088-105
Application Date: October 24, 2005
EPA Received Date: October 25, 2005

Dear Mr. Munson:

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

Proposed Amendment

- Revised labeling

Conditions

Revise the label as follows:

1. Delete the statement "powerful hospital-type" from the dental facilities paragraph. The term is an implied heightened efficacy and comparisons are false and misleading. Refer to PR Notice 93-6 for further information.

General Comments

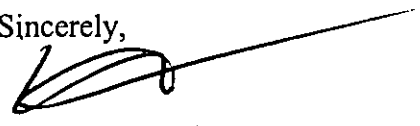
A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

CONCURRENCES

SYMBOL	7510C						
IRNAME							
DATE	1/18/06						

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

Sincerely,



Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510 C)

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

WARNING: Causes eye irritation. Do not get in eyes or on skin. Avoid breathing spray mist or vapors. Harmful if swallowed.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for further treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378.

For information on product, usage, etc., call 1-800-743-6417.

PHYSICAL OR CHEMICAL HAZARDS

FLAMMABLE. Keep away from heat, sparks, and flames. Do not use in the vicinity of pilot lights. Do not use on latex paint, polished wood furniture, or other materials that could be damaged by alcohol.

**DESINFECTANTE DESODORANTE
FEATURES, CLAIMS, AND USE**

FOR USE ON: Glass, porcelain, ceramic, metal, polyethylene, polypropylene, vinyl, polyester, ABS, Bakelite, rubber, enameled surfaces, and other hard, nonporous materials and surfaces not damaged by alcohol.

• READY-TO-USE, DOUBLE-ACTION PRODUCT •

Decontaminates surfaces two ways, leaving them thoroughly disinfected and deodorized.

DUAL-DEODORIZING ACTION: Fresh-scented to quickly suppress unpleasant odors from many sources as it destroys microorganisms that cause putrefactive odors.

HOSPITAL-TYPE DISINFECTING ACTION: Medical-level and broadspectrum antimicrobial activity destroys many organisms which threaten public health or create unpleasant odors and other undesirable effects. Reduces the hazard of cross-contamination from hard, inanimate surfaces in medical facilities.

Virucidal: Inactivates Human Immunodeficiency Virus Type 1 (HIV-1, a retrovirus that cause AIDS (Acquired Immune Deficiency Syndrome)); Herpes Simplex Types 1 & 2, Coxsackie viruses A2 and B3; Adenovirus Type 5; Influenza A2/Hong Kong; and Vaccinia on hard, inanimate surfaces.

Bactericidal: Kills Escherichia coli; Pseudomonas aeruginosa;

**C-SPRAY
DISINFECTANT • DEODORANT**

**KILLS HIV-1(AIDS VIRUS) AND HERPES SIMPLEX TYPES
1 & 2 VIRUSES ON PRECLEANED ENVIRONMENTAL
SURFACES/OBJECTS PREVIOUSLY SOILED WITH
BLOOD/BODY FLUIDS.**

**A READY-TO-USE MULTIPURPOSE HOSPITAL USE AND
BROAD-SPECTRUM DISINFECTANT • ANTIMICROBIAL •
DEODORIZER
FOR USE ON HARD, NONPOROUS, INANIMATE
SURFACES IN/ON INDUSTRIAL, INSTITUTIONAL,
COMMERCIAL, RESIDENTIAL, AND MEDICAL FACILITIES
AND VEHICLES.**

FOR USE IN MEAT AND POULTRY PLANTS.

**VIRUCIDAL • TUBERCULOCIDAL
FUNGICIDAL • BACTERICIDAL
PSEUDOMONACIDAL • STAPHYLOCOCIDAL
CONTROLS MOLD/MILDEW FUNGI
(Specific species/agents listed on side panel.)**

Active Ingredients:

2-Phenylphenol	0.249%
4-tert-Amylphenol	0.058%
Ethanol*	66.000%
Inert Ingredients:	33.693%
Total	100.000%

*Specially Denatured Alcohol

**KEEP OUT OF REACH OF CHILDREN
WARNING**

See side panel for additional precautionary statements

EPA REG. NO. 10088-105

EPA EST. NO. 10088-WI-1

AGGRAVATED
NEP CONTENTS
with COMMENTS 20 35 55 Gallons

EPA Letter Dated Manufactured By:

Athena Laboratories, Inc.

JAN 18 2006 P.O. Box 240014
Milwaukee, WI 53224

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 10088-105

Salmonella choleraesuis; Salmonella schottmuelleri (paratyphoid B); Shigella dysenteriae; Staphylococcus aureus; and Streptococcus pyogenes.

Tuberculocidal: Mycobacterium tuberculosis (Tubercle bacilli) on surfaces that have been thoroughly cleaned prior to treatment. Effective in 10 minutes at 20°C(68°F).

Fungicidal: Kills Trichophyton mentagrophytes (athlete's foot fungi; formerly T. Interdigitale) in appropriate areas, such as shower room floors, locker room benches, and bath mats.

Controls Mold/Mildew: Completely inhibits growth of these fungi on cloth: Aspergillus niger and Penicillium variable(formerly P. glaucum).

Sanitizes: Reduces odor-causing microorganisms on nonporous surfaces.

DIRECTIONS FOR USE

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

This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

GENERAL: Thoroughly clean surface prior to application of this product. Do not get product on foods/drinks/feeds or surfaces that they may contact, protect during treatment by removing or covering them. Any contaminated food/drink/feed contact surfaces should be washed with a suitable cleaning product and rinsed with potable (drinking) water before using. Treat food/drink/feed processing areas only when the facility is not in operation.

TO KILL HIV-1 (Human Immunodeficiency virus Type 1, AIDS virus) ON PRECLEANED SURFACES in health care or other settings with inanimate environmental surfaces/objects associated with the potential for transmission of HIV-1 and likely to be soiled with blood/body fluids, follow these **ADDITIONAL SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS: PERSONAL PROTECTION** - Barrier protection items such as disposable latex gloves, gowns, masks, and eye coverings should be worn when handling items soiled with blood/body fluids. **CLEANING PROCEDURE** - Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of this product. **CONTACT TIME** - Leave surface wet for 10 minutes. **DISPOSAL OF INFECTIOUS MATERIALS** - Blood/body fluids and materials removed from or used to clean surfaces/objects should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

C-SPRAY DISINFECTANT DEODORANT (0167,02105)
EPA Reg. No. 10088-105

TO DISINFECT, CONTROL MILDEW, AND DEODORIZE PRE-CLEANED SURFACES: Hold spray opening about 6 to 8 inches (1/5 m) away from surface and spray until its thoroughly wetted. For proper disinfection, apply at approximately 20°C (68°F), then allow 10 minutes for it to act. For mildew control, repeat application when necessary.

IMPORTANT NOTICE!
RELABELING/REPACKAGING

It is illegal to distribute or sell a relabeled/repackaged pesticide without a prior, written contract with the basic registrant.

FEATURES, CLAIMS, AND USES
POWERFUL • PLEASANT

ELIMINATES ODORS BY ATTACKING THEM AT THEIR SOURCE.
FOR HOSPITAL USE AND BROAD-SPECTRUM
DISINFECTING/ANTIMICROBIAL ACTIVITY
ON HARD, NONPOROUS, INANIMATE SURFACES.

A ready-to-use, powerful, pleasant, hospital-type and broad-spectrum disinfectant that decontaminates and deodorizes surfaces after a 10 minute exposure time. Eliminates dilution errors, product contamination, and other problems common to products that require dilution and mixing.

VIROCIDAL* Inactivates these agents: Human Immunodeficiency virus Type 1 (HIV-1; a retrovirus that causes "AIDS" (Acquired Immune Deficiency Syndrome); Herpes simplex Type 1 (a herpesvirus that causes cold sores); Herpes simplex Type 2 (a herpesvirus that causes "genital herpes"); Coxsackie viruses A2 and B3 (picornaviruses; human enteroviruses); Adenovirus Type 5 (an adenovirus); Influenza A2/Hong Kong (a myxovirus); and Vaccinia (a poxvirus) on hard, inanimate surfaces.

SAFE TO USE ON: Most glass, porcelain, ceramic, metal, painted enameled, plastic, rubber, and sealed leather, wood, concrete, and similar surfaces, including • Stainless steel • Aluminum • Iron & Steel • Chrome • Brass • Copper • Ceramic, Plastic & Quarry Tile • sealed Cement/Grouting • Cork • finished Woodwork • Leatherette • Polyethylene • Polypropylene • Polyurethane • Vinyl • Polyester • ABS • Bakelite • Acrylic • and other hard, non-porous materials and surfaces not damaged by alcohol.

EXCELLENT FOR DECONTAMINATING: Surfaces such as Toilet Seats • Urinals • Bathtubs • Shower Stalls • Bathroom Fixtures • Partitions • Walls, Baseboards, Floors, & Ceilings • Telephones • Bed Frames & Springs • Tiled Surfaces • Wash Basins & Sinks • Counter & Table Tops • Hoods • Exhaust Fans • Laminar Flow Cabinets & Hoods • Railings, Faucet Handles, Door Knobs & other Fixtures • Halls, Hallways, Stairs & Stairways • Elevators & Escalators • Light Switches & Fixtures • Plastic Upholstery • Seats & Benches • Lockers • Counters • Wheelchairs & Power Carts • Laundry, Linen, Dressing, Clean-Up, & Equipment Carts • Laundry Chutes & Hampers • Trash Compactors • Diaper Pails • Portable Toilets & Potties • Garbage & Refuse Containers • Pet Quarters •

Furniture • Chairs & Seating • Tables, Counters, & Desks • Cabinets, Closets & Lockers • Equipment & Machinery • Racks • Conveyors • Appliances • Medical Equipment & Furniture • many other similar public and residential surfaces which could harbor hazardous microorganisms.

TWO-WAY SURFACE DEODORIZING ACTION: Its fresh scent acts instantly and remains effective for long periods on unpleasant odors. Quickly counteracts "CHEMICAL" MALODORS such as garlic, onion, tobacco smoke, stale odors, musty smells, fish, gas, and urine; in kitchens, bathrooms, basements, and many other occasionally malodorous, unpleasant areas and situations. Kills many microorganisms that generate the "BIOLOGICAL" MALODORS associated with surgical dressings, ostomy pouches, malignant diseases, excised organs and tissue, fecal matter, burns, perspiration, garbage, and other decaying, putrefying organic matter.

IN DENTAL FACILITIES

This powerful hospital-type disinfectant/deodorizer helps decontaminate hard, nonporous surfaces on furniture, equipment, and other items in dental facilities, such as: patient's and operator's chairs, operator's light, working surfaces, bracket table, evacuator reservoir, tray racks and trays, x-ray control panel and button, viewers, waiting room furniture, bathroom fixtures, lab areas and equipment, railings and door knobs, and on other public surfaces which could harbor dangerous microorganisms. Use this product to disinfect and deodorize these and many other surfaces in dental areas.

OTHER CLAIMS

It kills the microorganisms listed, and helps to control odors caused by many biological putrefactive processes in: hospitals, doctor's offices, dentist's offices, nursing homes, ambulances, veterinary offices, animal hospitals, and other medical facilities, including those from surgical dressings, post-colostomy and post-ileostomy dressings and bags, ostomy pouches, malignant diseases, fecal matters, burns, perspiration, and other decaying tissue and organic matter. Also helps to control microorganisms and putrefactive odors in: food storage, processing, packaging, handling, and serving establishments & equipment; industrial and institutional facilities; plants and offices; zoos; pet boarding facilities; household pet quarters; homes; other commercial and residential facilities.

It is also a non-specific odor suppressant for space odor conditioning. Molecular deodorant attacks malodors at the source. Suppresses and eliminates odors by chemically neutralizing odor-producing materials. Does not cause anosmia.

CAN BE USED IN/ON SITES SUCH AS THE FOLLOWING (only under conditions where it will not contact foods/drinks/feeds, and where humans and animals would have only limited or incidental contact).

Processed or Manufactured Products-
Processed or manufactured nonfood plant and animal products(indoor): Textiles, fabrics, and fibers; fur and hair

products; and leather products.

Processing and handling equipment and machinery - other than food processing (Indoor).

Pets and Domestic Animals - their man-made premises.

Fur and wool-bearing animals (indoor): Goats, sheep, minks, chinchillas, rabbits, foxes, and nutrais.

Animals for labor, display, riding, racing, lab uses, etc. (indoor): Dogs, horses, donkeys, and mules; guinea pigs; mice; rats; gerbils; hamsters; monkeys; cats; chickens and birds; wild rodents; zoo ruminants; zoo ungulates; zoo canines; zoo felines; zoo primates; zoo reptiles; zoo amphibians; zoo birds; zoo - others; aquarium fish.

Animals for pets, including their cages, bedding, nests, etc. (indoor): Dogs; cats; birds; rodents; lagomorphs; fish; amphibians; reptiles; primates; and other vertebrates.

Household -

Non-food areas and sites (indoor): Closets and storage areas; basements and cellars; bedrooms; attics; recreation rooms; living rooms; baseboards, window sills, etc.; plumbing fixtures; and sickrooms.

Household contents and space (indoor): Beds; rugs; bookcases; furs; fabrics; and blankets; play pens; and sickroom utensils.

Commercial and Industrial Uses -

Transportation Facilities (Indoor): Buses, trucks and trailers; containerized units; railroad cars; aircraft; ships/barges; autos and taxis; recreational vehicles; and shipping containers.

Food and feed processing plants (indoor): Inedible and nonprocessing areas of - Bakeries; bottlers; canneries; dairies; creameries, and milk processing plants; feed mills and feed stores; fresh fruit packing and processing; meat processing; poultry processing; wineries and wine cellars; flour mills, machinery, warehouses, bins, and elevators; egg processing; candy and confectionery plants; sugar processing, cane mills, etc.; cider mills; dry food products plants; tobacco processing; beverage processing; nut processing; cereal processing; seafood processing; vegetable oil processing; spice mills; vinegar processing; farinaceous processing (noodles, etc.); mushroom processing; dried fruit processing; pickle processing; ice plants; chocolate processing; and fruit juice processing.

Eating establishments - all (indoor): Non-food surfaces in/on - food handling areas; food serving and eating establishment nonfood areas; food storage and equipment (coolers, refrigerators, etc.)

Food marketing, storage, and distribution (Indoor): food contact surfaces in/on food dispensing and serving equipment; food stores, markets, and stands; meat and fish markets; food catering facilities; and food market and storage, and distribution equipment and utensils.

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Hospitals and related institutions and facilities (indoor): Critical premises (for example, burn wards), hospital patient premises (wards, emergency room, etc.); noncritical premises (labs, lounges, lobbies, storage); critical items (hypodermic needles, instruments, catheters, etc.); and noncritical items (such as bedpans, carpets, furniture, etc.).

Janitorial equipment (indoor).

Barber and beauty shop instruments and equipment (indoor).

Morgues, mortuaries, and funeral homes (indoor): Premises (embalming rooms, etc.); equipment (tables, etc.); instruments; and burial vaults and mausoleum.

Commercial, Institutional, and Industrial maintenance buildings and structures (indoor): Locker rooms and equipment; gyms, bowling alleys, and equipment; telephones and booths; shower rooms, mats, and equipment; cotton mill premises and equipment; auditoriums and stadiums; factories; rendering plants; loading docks and ramps; school buildings and equipment; and laundries.

Domestic and Human Use -

Fiber product protection (mildew-proofing) (indoor): Clothing; upholstery; ornamental fabrics (draperies, tapestries); ropes; and sail cloth.

Human articles and materials (indoor): Bedroom blankets; mattresses; clothing; face gear (such as goggles, face masks, etc.); headgear (such as helmets, headphones, etc.); mouthpieces for musical instruments, etc; brick, asbestos, etc.; wood surfaces; leather surfaces; fabric surfaces; and paper/paperboard surfaces.

Specialty uses (indoor): Non-food-contacting surfaces/materials in/on museum collections (presenting animal and plant specimens); military uses (not specified); quarantine uses (not specified); DHHS uses (not specified); underground cables; cuspidors, spittoons; diapers; laundry equipment (cans, chutes, tables, etc.); dust control products and equipment (mops, etc.); dry cleaning; carpets; and upholstery.

Bathrooms, toilet bowls and related sites (indoor): Bathroom premises; toilet bowls and urinals; toilet tanks; portable and chemical toilets; vehicular holding tanks; and diaper pails.

Refuse and solid waste (Indoor): Refuse and solid waste containers; refuse and solid waste transportation handling equipment; garbage dumps; household trash compactors; garbage disposal units and food disposals and incinerators.

Miscellaneous Indoor Uses -

Surface treatments (indoor): Non-food-contact surfaces including hard nonporous surfaces (painted, tile, plastic, metal, glass, etc.); hard porous surfaces (cement, plaster); camping equipment and gear; and grooming instruments (brushes, clippers, razors, etc.).

Laundry, cleaning, and dry cleaning (indoor).

NOTE: Below are special directions for use on a dental pouch; not for use on normal customer labels.

FOR DISINFECTING DENTAL HANDPIECES

NOTE: The disposal dental handpiece sleeve is not a substitute for sterilization. It is recommended only for disinfecting handpieces which cannot be sterilized by steam autoclave, unsaturated chemical vapor, dry heat, or ethylene oxide, due to physical limitations, incompatibility, or residue.

FOLLOW THESE STEPS!

1. Always wear gloves.
2. Flush handpiece thoroughly for 20 to 30 seconds. Remove the bur.
3. Clean handpiece thoroughly to remove saliva, blood, and other organic soil. Scrub handpiece with small brush and detergent under running water.
4. Blot handpiece dry with a clean paper towel. Water droplets clinging to the handpiece will dilute the disinfectant.
5. Grasp tabs at upper right corner of pouch and open to the line "open to here". This allows sufficient room to insert either a high or low speed handpiece.
6. Insert handpiece completely into sleeve between the disinfectant-soaked sponges.
7. Vigorously massage handpiece inside sleeve from top to bottom. Massaging action distributes disinfectant over entire handpiece surface and provides a beneficial scrubbing effect.
8. Leave handpiece inside sleeve for at least 10 minutes at approximately 20°C (68°F). Handpiece with sleeve may be suspended by tubing with open end of sleeve upward.
9. After 10 minute disinfection cycle, rinse handpiece in water, or wipe with an alcohol-saturated sponge to remove residual disinfectant.
10. Blot dry with a paper towel.
11. Lubricate handpiece according to manufacturer's directions.
12. Dispose of the used sleeve in the trash.

STORAGE AND DISPOSAL

GENERAL: Do not contaminate other materials (including water/food/feed) during transport, use, storage, and disposal. If damaged, leaking, or spilled, soak up and wrap any waste, then dispose of as below.

STORAGE: Keep unused sleeves in original carton in a cool, dry, locked area inaccessible to children and away from sources of ignition, heat, degradation, and contamination (including flames, sparks, hot surfaces, sunlight, and other chemicals).

DISPOSAL OF SLEEVE: Do not reuse sleeve; after use, discard in trash.

STORAGE AND DISPOSAL

GENERAL: Do not contaminate other materials including water/food/feed during transport, use, storage, and disposal. If damaged, leaking, or spilled, soak up and wrap any waste, then dispose of as below.

STORAGE: Keep in upright, tightly closed original container in a cool, dry, locked area inaccessible to children and away from sources of ignition, heat, degradation, and contamination including flames, sparks, hot surfaces, sunlight and other chemicals.

DISPOSAL: Do not reuse container. Rinse original container thoroughly, then securely wrap in several layers of newspaper and discard in trash.

Required disposal procedures for this product in containers over 1 gallon (3.78L) in size.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on-site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Rinsed plastic and paper reinforced plastic containers may also be disposed of by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

0167.102105

NET CONTENTS:

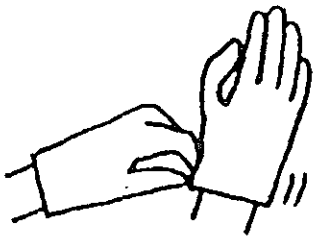
5 6 20 30 55
GALLONS

C-SPRAY DISINFECTANT DEODORANT (0167.102105)
EPA Reg. No. 10088-105

Page 3 of 4

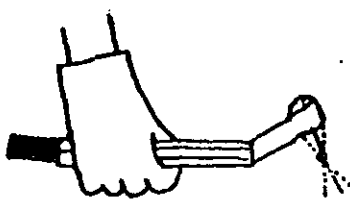
FOLLOW THESE STEPS!

1.



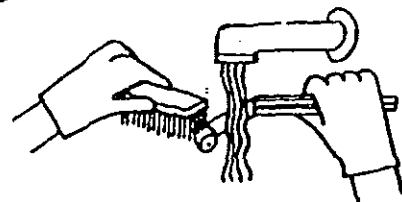
Always wear gloves.

2.



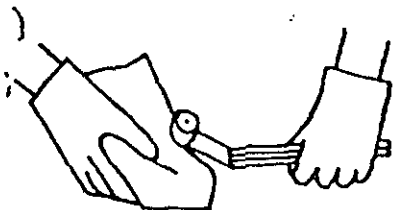
Flush handpiece thoroughly for 20-30 seconds. Remove the bur.

3.



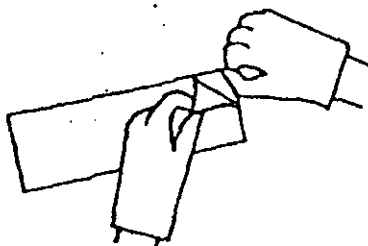
Clean handpiece thoroughly to remove saliva, blood, and other organic soil. Scrub handpiece with small brush and detergent under running water.

4.



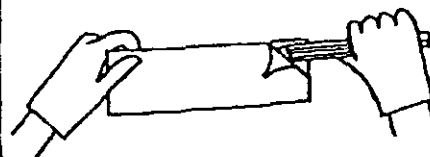
Blot handpiece dry with a clean paper towel. Water droplets clinging to the handpiece will dilute the disinfectant.

5.



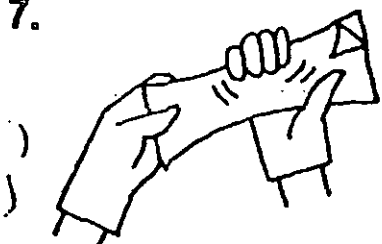
Grasp tabs at upper right corner of pouch and open to the line "open to here". This allows sufficient room to insert either a high or low speed handpiece.

6.



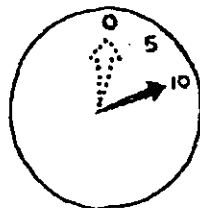
Insert handpiece completely into sleeve between the disinfectant soaked sponges.

7.



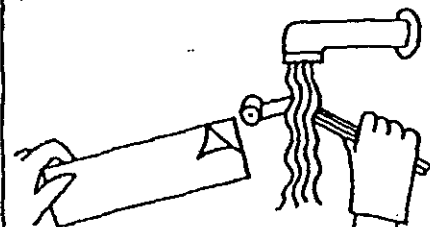
Vigorously massage handpiece inside sleeve from top to bottom. Massaging action distributes disinfectant over entire handpiece surface and provides beneficial scrubbing effect.

8.



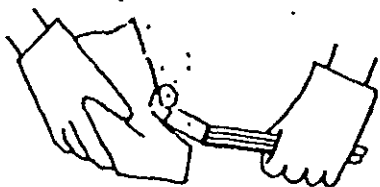
Leave handpiece inside sleeve for at least 10 minutes. Handpiece with sleeve may be suspended by tubing with open end of sleeve upward.

9.



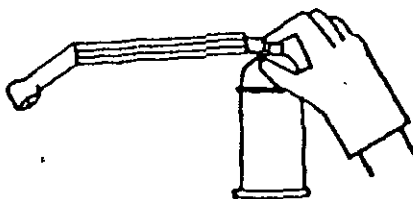
After 10 minute disinfection cycle, rinse handpiece in water, or wipe with an alcohol-saturated sponge to remove residual disinfectant.

10.



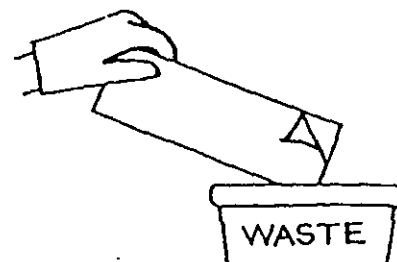
Blot dry with a paper towel.

11.



Lubricate handpiece according to manufacturer's directions.

12.



Dispose of the used sleeve in the trash.