

APR 17 1998

Metrex Research Corporation
1717 West Collins Avenue
Orange, CA 92867

Attention: Wendy A. Urtel
Regulatory Affairs Specialist

Subject: Cavicide
EPA Registration No. 46781-6
Amendment Dated February 20, 1998

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to add a claim against Canine parvovirus, and to revise the product description to include references for use in opthalmic/optometric facilities, is acceptable, provided that you:

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

A. Delete the uses "coated and non-coated eye and safety glasses" and "air masks".

B. Delete the use "tonometers".

2. Submit two (2) copies of final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,

Marshall Swindell
Marshall Swindell

Product Manager (33)
Regulatory Management Branch 1
Antimicrobial Division (7510W)

CONCURRENCES

SYMBOL	Enclosure							
SURNAME								
DATE								

CAVICIDE®

2/6

HOSPITAL DISINFECTANT/DECONTAMINANT CLEANER
SALON DISINFECTANT/DECONTAMINANT CLEANER
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 DISINFECTANT/ DECONTAMINANT CLEANER
INSTRUMENT DISINFECTANT/ DECONTAMINANT CLEANER
LABORATORY SURFACES DECONTAMINANT/CLEANER
SPRAY-ON SURFACE DECONTAMINANT/CLEANER

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.
46781-6

BACTERICIDAL • VIRUCIDAL* • FUNGICIDAL • TUBERCULOCIDAL** •
PSEUDOMONACIDAL

READY TO USE

CONTAINS BIODEGRADABLE DETERGENT

FOR PROFESSIONAL USE ONLY.

ACTIVE INGREDIENTS:

Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride.....	0.28%
Isopropanol.....	17.20%
INERT INGREDIENTS	82.52%
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.

EPA REG. NO. 46781-6

EPA EST. NO. 46781-CO-1

REORDER NO: 00-0000

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

MANUFACTURED BY: Metrex Research Corporation
10270 South Dransfeldt Road
Parker, CO 80134

EFFECTIVE AGAINST:

- Staphylococcus aureus
- Pseudomonas aeruginosa
- Salmonella choleraesuis
- Mycobacterium tuberculosis var: bovis (BCG)**
- Trichophyton mentagrophytes
- Adenovirus type 8
- Herpes simplex virus types 1 and 2*
- Poliovirus types 1 and 2*
- Coxsackievirus*
- Methicillin Resistant Staphylococcus aureus (MRSA)
- Vancomycin Resistant Enterococcus faecalis (VRE)
- Human Immunodeficiency Virus (HIV-1)*
- Canine parvovirus** > ADDITION

(*On inanimate surfaces.)

(**In 10 minutes at room temperature - 20°C).

34
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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, ophthalmic and optometric facilities, > ADDITION eye surgical centers, 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, patient care areas, laboratories, non-food contact surfaces in 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/ optical/ 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, drained whirlpool tank surfaces, stretchers, spine back boards, ambulance equipment surfaces, slit lamps, external lenses for vision correction*, > ADDITION countertops, exterior toilet surfaces, sinks, refrigerator units, floors, walls, handrails, door knobs, bed railings, bathing units, bathtubs, shower stalls, cabinets, shampoo bowls, manicure tables, chairs, workstations, nail/ hair care implements, tanning beds, hair dryers, telephones, diaper changing stations, baby cribs, hair clippers, shears, razors, hair cutting implements, clipper blades, salon surfaces, scissors, combs, brushes, manicure implements, washable nail files, hair rollers, animal cages, veterinary care surfaces, dental operator surfaces, dental countertops, dental chairs, unit stools, light lens covers, curing lights, and other inanimate surfaces, including those made of plastics (such as: polycarbonate, polyvinylchloride, polypropylene and polystyrene), weight lifting surfaces, non-porous vinyl and upholstery, stainless steel, painted surfaces, Plexiglas®, glass, and other hard non-porous surfaces.

*Not for use on contact lenses. > ADDITION

APPLICATIONS:

SURFACES: (Where appropriate, follow Universal Precautions.)

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For disinfecting non-critical devices/medical equipment and surfaces: Allow surface to remain wet for 3 minutes at room temperature (69°F/20°C). ******(For Tuberculocidal Activity: allow 10 minutes at room temperature. For inactivation of Adenovirus type 8: allow 20 minutes at room temperature.) Follow by wiping surface using a clean paper or cloth towel; or rinse and either allow surface to air dry or wipe rinsed surface dry using a clean paper or cloth towel. Discard towel.

For precleaning medical equipment and other surfaces prior to disinfection:

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

INSTRUMENTS: (Where appropriate, follow Universal Precautions.)

For use as an immersion precleaning instrument decontaminant solution:

- Fill appropriate size container with a sufficient amount of undiluted Cavicide as to allow for complete submersion of instruments. Place instruments 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 an instrument preclean 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.)**

For use as an instrument ultrasonic cleaning solution:

- Thoroughly pre-rinse instruments under running water to remove visible gross debris. Using 1 ounce Cavicide per liter of water in ultrasonic unit, immerse instruments into mixed solution and activate ultrasonic unit for 5 minutes or longer if necessary. Remove instruments into 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 a manual instrument cleaner:

- Thoroughly pre-rinse dirty instruments under running tap water to remove visible gross debris. Place pre-rinsed instruments into a solution of 1 ounce Cavicide per liter of water. Scrub instruments using a stiff bristle brush until visibly clean. (Instruments should be submerged as scrubbed.) Rinse instruments 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 3 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 cloth. Immerse precleaned implements into an undiluted solution of Cavicide for 3 minutes. For tuberculocidal activity, allow to soak for 10 minutes at room temperature (69°F/20°C). Remove and wipe dry. No rinsing necessary. Change solution weekly or more often if solution becomes visibly soiled.

For disinfection of NON-CRITICAL, precleaned instruments:

- Instruments must be thoroughly precleaned to remove excess organic debris, rinsed and then rough dried. (Clean and rinse lumens of hollow instruments before filling with solution or before immersion.) Using either a soaking tray or ultrasonic unit, immerse instruments into undiluted Cavicide solution and allow to remain submerged for 3 minutes. For tuberculocidal activity, allow 10 minutes at room temperature (69°F/20°C). For inactivation of Adenovirus type 8, allow 20 minutes at room temperature. 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) 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/high-level disinfection.

CAVICIDE EFFECTIVELY KILLS HIV ON PRECLEANED 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 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).

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SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY 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.

46/4
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.

STORAGE: Store in a cool place.

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

CONTAINER DISPOSAL: Triple rinse. 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, keep out of smoke.

For product information, please contact our Customer Service Department at 1-800-841-1428.

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