

46781-6

09/18/2011

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SEP 18 2011

Ms. Wendy Urtel
Director of Regulatory Affairs for,
Metrex Research Corporation
1717 West Collins Avenue
Orange, CA 92867

Subject: Cavicide
EPA Registration Number 46781-6
Your Notification Dated August 18th, 2011
EPA Received Date August 19th, 2011

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act(FIFRA), as amended, to revise the labeling as per PR Notice 2007-4 by adding refillable container verbiage, is acceptable.

The notification has been part of the permanent record of this file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

A handwritten signature in black ink that reads "M. Swindell".

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510P)

Please read instructions on reverse before completing.

Form Approved. No. 2070-0060, Approval expires 2-28-95



United States Environmental Protection Agency Washington, DC 20460

Registration Amendment Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 46781 / 46781-6
2. EPA Product Manager M. Swindell
3. Proposed Classification None Restricted
4. Company/Product (Name) Metrex Research / Cavicide
5. Name and Address of Applicant (Include ZIP Code) Metrex Research 1717 West Collins Avenue Orange, CA 92867
6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name

Section - II

Amendment - Explain below. Resubmission in response to Agency letter dated. Notification - Explain below. Final printed labels in response to Agency letter dated. "Me Too" Application. Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.) LABEL NOTIFICATION to revise the label for Cavicide, EPA Reg. No. 46781-6, per PR-Notice 2007-4, by adding refillable container verbiage. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. Additionally, the Clostridium difficile claim has been deleted from the label and EPA Establishment Numbers for producers have been added to the label per previously approved CSF notifications. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In: Child-Resistant Packaging, Unit Packaging, Water Soluble Packaging, 2. Type of Container, 3. Location of Net Contents Information, 4. Size(s) Retail Container, 5. Location of Label Directions, 6. Manner in Which Label is Affixed to Product

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Name Wendy Garman, Title Director, Regulatory Affairs, Telephone No. 714-516-7602
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.
2. Signature Wendy Garman, 3. Title Director, Regulatory Affairs, 4. Typed Name Wendy Garman, 5. Date 8-18-11, 6. Date Application Received (Stamped)



SYBRON DENTAL SPECIALTIES

August 18, 2011

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room 5-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: **LABEL NOTIFICATION PER PR-NOTICE 2007-4**
Product: **Cavicide**, EPA Reg. No. 46781-6
Company: **Metrex Research Corporation**

Dear Sir or Madam:

Enclosed is a LABEL NOTIFICATION to revise the label for **Cavicide**, EPA Reg. No. 46781-6, per PR-Notice 2007-4, by adding refillable container verbiage.

The following documents are being submitted in support of this LABEL NOTIFICATION:

Two (2) copies of the Application for Pesticide Form 8570-1	Section 1
One (1) copy: Proposed Cavicide Label (Version 08-2011) With Changes Highlighted	Section 2

** Please treat the information contained in Sections 1-2 as proprietary and confidential as covered in the provisions of FIFRA Section 10.*

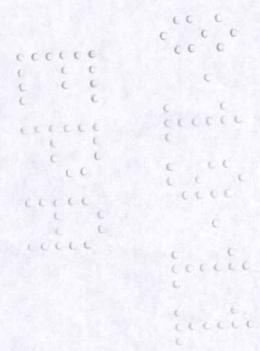
If you have any questions regarding this submission, please contact Orlando Tadeo, Jr. or me at any of the following numbers/addresses:

Phone Numbers: O. Tadeo, Jr. (714) 516-7419 or W. Garman (714) 516-7602
Fax Number: (714) 516-7488
Email addresses: orlando.tadeo@sybrondental.com or wendy.garman@sybrondental.com
Company Address: Metrex Research Corporation
1717 West Collins Avenue
Orange, CA 92867

Sincerely,

Wendy Garman
Director, Regulatory Affairs

Enclosures



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CAVICIDE

[Salon Disinfectant/Decontaminant Cleaner]
 [Barber Disinfectant/Decontaminant Cleaner]
 [Veterinary Disinfectant/Decontaminant Cleaner]
 [Clipper Blade Disinfectant/Decontaminant Cleaner]
 [Disinfectant/Decontaminant Cleaner]
 [Surface Disinfectant/Decontaminant Cleaner]
 [[Kitchen*** and Bath Solution] [for Hard, Non-porous Surfaces]]
 [Cleans, Deodorizes and Kills Common Household Germs]

[The descriptive terms below are to be used, as applicable, depending on the microorganisms listed in the Effective Against section.]

[Bactericidal] [[*]Virucidal*] [[*] Fungicidal] [[*] Tuberculocidal**]

[Ready-To-Use]
 [For Professional Use]
 [For Household Use]

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

[See other panel for additional precautionary statements.]

EPA Reg. No. 46781-6
 EPA Est. No. 46781-MI-1 [* 000312-WI-003] [* 000312-WI-001] [* 51435-WI-004]

Reorder No. x-x

Net Contents: x [[Gallon] [gal]] [[Ounce] [oz]] / x [[Liter] [L]] [[Milliliters] [mL]] (Net Weight x lbs. / x kg.)

[Manufactured By:] Metrex Research
 [Packed For:] 28210 Wick Road
 [Distributed By:] Romulus, MI 48174
 [Sold By:]

[For product or technical information, contact Metrex at **800-841-1428** or visit our website at www.metrex.com.]

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

THE INFORMATION IN THIS BOX IS NOT PART OF THE LABELING
 Statements in brackets, [], are optional or instructional. Italicized words in brackets are not included on production labels. Sequence of statements is optional unless specified in 40 CFR 156.10. Capitalizing, pluralizing, singularizing, bolding, italicizing and abbreviating are variable unless specified in 40 CFR. Lists of uses and use sites may be used partially or in their entirety.

CAUTION

Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse. [See other panel for additional precautionary statements.]

Physical or Chemical Hazards: Combustible. Do not use or store near heat or open flame.

[The following Environmental Hazards statement is to be included only on labeling of containers that are 5 gallons and larger.]

Environmental Hazards: This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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

For Chemical Emergency ONLY (spill, leak, fire, exposure or accident), call CHEMTREC at 1-800-424-9300. For ALL other inquiries about this product, call Metrex Customer Service at 1-800-841-1428, Monday through Friday, between 6 a.m. and 4 p.m. Pacific Time.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

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EFFECTIVE AGAINST

- [Mycobacterium tuberculosis var: bovis (BCG)**]
- [Staphylococcus aureus]
- [Pseudomonas aeruginosa]
- [Salmonella enterica]
- [Trichophyton mentagrophytes]
- [Methicillin Resistant Staphylococcus aureus (MRSA)]
- [Vancomycin Resistant Enterococcus faecalis (VRE)]
- [Staphylococcus aureus with reduced susceptibility to vancomycin]
- [Hepatitis B Virus (HBV)*]
- [Hepatitis C Virus (HCV)*]
- [Herpes Simplex Virus Types 1 and 2*]
- [Human Immunodeficiency Virus (HIV-1)*]
- [Human Coronavirus (not associated with Severe Acute Respiratory Syndrome or SARS)*]
- [Influenza A2 Virus*]

DESCRIPTION

CaviCide is a multi-purpose disinfectant/decontaminant cleaner for use on hard, non-porous inanimate surfaces.

It is useful in [health care settings such as [hospitals,] [hospital operating rooms,] [emergency departments,] [emergency medical settings,] [surgical centers,] [surgical suites,] [out-patient surgical centers (OPSC),] [isolation areas,] [neonatal units,] [laboratories,] [clinics,] [patient care areas,] [nursing homes,] [ophthalmic offices,] [ophthalmic and optometric facilities,] [eye surgical centers,] [patient care areas,] [dialysis centers,] [donation centers (blood, plasma, semen, milk, aphaeresis),] [dental offices,] [dental operatories,] [animal care facilities,] [veterinary facilities,]]

[[beauty salons,] [salon settings,] [manicure salons,] [skin care salons,] [barber shops,] [tanning salons,] [emergency vehicles,] [ambulances,] [police and fire vehicles,] [schools,] [health club facilities,] [kitchens***,] [food preparation areas***,] [bathrooms,] [daycare centers,] [correctional facilities,] [prisoner detention facilities,] [jails,] [prisons,] [morgues,] [cadaver processing areas,] [funeral homes,] [laundry rooms,] [pet areas]] and other critical care areas where control of cross contamination between treated surfaces is important.

[Listing of at least one of the following equipment/instruments/hard, non-porous surfaces on production labels is required. The last equipment/instruments/hard, non-porous surface listed will be preceded with the word "and".]

- CaviCide will effectively clean and disinfect, when used as directed, such items as [interior and exterior surfaces of infant incubators, bassinets, cribs and warmers,] [infant/child care equipment surfaces,] [diaper changing stations,] [baby cribs,] [diaper pails,] [toys,] [high chairs,]
- [oxygen hoods,] [operating room tables and lights,] [laboratory equipment and surfaces,] [physical therapy (PT) equipment surfaces,] [stretchers,] [spine back boards,] [ambulance equipment surfaces,] [slit lamps,] [eye glasses (do not use on contact lenses),] [loupes,] [hard, non-porous exterior surfaces of ultrasound transducers or probes,] [exam tables,] [gurneys,] [IV poles,] [dental unit instrument trays,] [operator light switches,] [exterior surfaces of amalgamators and dental curing lights,] [exterior surfaces of anesthesia machines and respiratory therapy equipment,] [SilkPeel™ with DermalInfusion™,] [workstations,] [dental countertops,] [dental chairs,] [exterior surfaces of dental operatories,] [exterior surfaces of endodontic equipment, such as apex locators, pulp testers and motors,] [stools,]
- [animal cages,] [veterinary care surfaces,] [nail/hair care implements,] [tanning beds,] [hair dryers,] [hair clippers,] [shears,] [razors,] [hair cutting implements,] [clipper blades,] [salon surfaces,] [scissors,] [combs,] [brushes,] [manicure tables,] [manicure implements,] [washable nail files,] [hair rollers,]

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[non-food contact surfaces,] [exterior surfaces of refrigerator units***,] [exterior surfaces of appliances such as refrigerators, microwaves, food processors and stoves***,] [sinks***,] [counter tops***,] [vanity tops***,] [tiles***,] [floors,] [walls,] [handrails,] [door knobs,] [bed railings,] [tables,] [chairs,] [faucets,] [bathroom fixtures,] [exterior toilet surfaces,] [bathing units,] [bathtubs] [shower stalls,] [cabinets,] [shampoo bowls,] [garbage cans,] [computers,] [keyboards,] [carts,] [baskets,] [grocery carts,] [shopping carts,] [weight-lifting surfaces,] [drained whirlpool tank surfaces,] [cabinets,] [lights,] [telephones,] which are made of plastic (i.e., polycarbonate, polypropylene, polyvinylchloride, polystyrene), and use sites listed on this label consisting of non-porous vinyl, stainless steel, painted surfaces, Plexiglas®, Formica® and glass.

DIRECTIONS FOR USE

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

FOR PRECLEANING NON-INSTRUMENT SURFACES PRIOR TO DISINFECTION:

Remove gross filth and heavy soil loads. Spray CaviCide directly onto surface. Allow to remain visibly wet for 30 seconds. Wipe surface using a towel.

FOR PRECLEANING INSTRUMENTS PRIOR TO DISINFECTION:

Remove gross filth and heavy soil loads.

[Listing of at least one of the following precleaning instructions, A – F, is required.]

[A]

[For use as a precleaning decontaminant immersion solution: Place instruments in a container with a sufficient amount of CaviCide so as to allow for complete submersion, cover and immerse for 10 minutes at room temperature (69°F/20°C). Remove and rinse instruments. Follow with appropriate cleaning and disinfection process. Discard solution after each use.]

[B]

[For use as a precleaning decontaminant spray: Place instruments in a container. Spray CaviCide so as to thoroughly drench all instrument surfaces and allow to remain visibly wet for 30 seconds. Remove and rinse instruments. Follow with appropriate cleaning and disinfection process.]

[C]

[For use as an ultrasonic precleaning solution: Thoroughly rinse instruments under running water to remove visible gross debris. Add 1 ounce CaviCide per liter of water to ultrasonic unit. Immerse instruments in solution and activate ultrasonic unit for 5 minutes or longer, if necessary. Remove and rinse instruments. Follow with appropriate cleaning and disinfection process. Discard solution after each use.]

[D]

[For use as a manual precleaner: Thoroughly rinse instruments under running water to remove visible gross debris. Place instruments in a container with 1 ounce CaviCide per liter of water. Scrub instruments while submerged for 30 seconds using a stiff bristle brush until visibly clean. Remove and rinse instruments. Follow with appropriate cleaning and disinfection process. Discard solution after each use.]

[E]

[For precleaning hair clippers and electric shears: While clipper/electric shear is running, hold it in the downward position and spray CaviCide to thoroughly wet the blades. Allow to remain wet for 30 seconds. Avoid spraying on the clipper case or dripping into the clipper housing. Rinse clipper/electric shear and follow with appropriate cleaning/lubricating and disinfection process.]

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[F]

[For precleaning salon implements and shears: Spray with CaviCide to thoroughly wet the implement/shear. Allow to remain wet for 30 seconds. Wipe away visible debris using a soft bristle brush or cloth. Rinse implement/shear and follow with appropriate cleaning/lubricating and disinfection process.]

FOR USE AS A VIRUCIDE* ON NON-INSTRUMENT SURFACES, INCLUDING HIV-1, HBV AND HCV APPLICATIONS:

Spray CaviCide directly onto precleaned surface, thoroughly wetting area to be treated. Allow surface to remain visibly wet for 2 minutes at room temperature (69°F/20°C).

FOR USE AS A DISINFECTANT ON NON-INSTRUMENT SURFACES:

Spray CaviCide directly onto precleaned surface, thoroughly wetting area to be disinfected. Allow surface to remain visibly wet for 3 minutes at room temperature (69°F/20°C) for Tuberculocidal** activity and effectiveness against *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Trichophyton mentagrophytes* and *Salmonella enterica*.

Wipe surface using a towel or allow to air dry.

[The following statement is to be included on production labels when food contact areas or surfaces are listed.]

[***A thorough rinse with potable water is required for surfaces in direct contact with food.]

FOR USE AS A VIRUCIDE* ON PRECLEANED NON-CRITICAL MEDICAL DEVICES¹, INSTRUMENTS AND IMPLEMENTS INCLUDING HIV-1, HBV AND HCV APPLICATIONS:

Instruments must be thoroughly cleaned to remove excess organic debris, rinsed and dried. Thoroughly clean and rinse lumens of hollow instruments. Using either a tray or an ultrasonic unit, immerse instruments in CaviCide for 2 minutes at room temperature (69°F/20°C).

FOR USE AS A DISINFECTANT ON PRECLEANED NON-CRITICAL MEDICAL DEVICES¹, INSTRUMENTS AND IMPLEMENTS:

Instruments must be thoroughly cleaned to remove excess organic debris, rinsed and dried. Thoroughly clean and rinse lumens of hollow instruments. Using either a tray or an ultrasonic unit, immerse instruments in CaviCide for 3 minutes at room temperature (69°F/20°C) for Tuberculocidal** activity and effectiveness against *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Trichophyton mentagrophytes* and *Salmonella enterica*.

Remove and rinse instruments. Wipe dry prior to use. Discard solution after each use.

¹ Non-critical medical devices are items that come in contact only with intact skin.

Note: Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.

[The following instruction is to be included when hard, non-porous exterior surfaces of ultrasound transducers or probes is listed as a use site.]

[To disinfect external surfaces of ultrasound transducers: Pre-clean ultrasound gel from external transducer to be disinfected [by using a clean wash cloth]. Spray CaviCide directly onto precleaned surface, thoroughly wetting area to be disinfected. Allow surface to remain visibly wet for 3 minutes at 69°F/20°C.

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[The following HIV / HBV / HCV instructions are to be included on production labels when claims against HIV, HBV or HCV are listed.]

CAVICIDE EFFECTIVELY KILLS [HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV),] [HEPATITIS B VIRUS (HBV),] [[AND] HEPATITIS C VIRUS (HCV)] 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 WITH BLOOD/BODY FLUIDS, AND IN WHICH THE SURFACES/OBJECTS CAN BE ASSOCIATED WITH THE POTENTIAL FOR TRANSMISSION OF [HIV-1,] [HBV,] [[AND] [HCV].

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST [HIV-1,] [HBV,] [[AND] HCV] OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUID:

Personal Protection: Wear appropriate barrier protection such as protective gloves, gowns, masks and eye coverings.

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

Contact Time: A contact time of 2 minutes is required for HIV-1, HBV and HCV. This contact time will not be sufficient for some of the organisms listed on the label. Refer to label for contact times against other organisms.

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

[The following paragraph will be included in its entirety when the production label references health care use.]

[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.]

[The following section applies to NON-REFILLABLE containers only]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in a cool place.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of according to applicable Federal, State, or local procedures.

Container Disposal: Nonrefillable container. Do not reuse or refill this container.

[Choose one of the following recycling statements.]

[a]

[Offer for recycling, if available.]

[b]

[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.]

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[The following section applies to REFILLABLE containers only]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in a cool place.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of according to applicable Federal, State, or local procedures.

Container Disposal: Refillable container. Refill this container with Cavicide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. A 50 gallon rinse with DI water is required to clean a 350 gallon tote. Cleaning before refilling is the responsibility of the refiller.

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