

46781-6

1/14/2010

1/10

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



Office of Pesticide Programs

Metrex Research Corporation  
1717 West Collins Avenue  
Orange, CA 92867

JAN 14 2010

Attention: Wendy Garman, Manager  
Regulatory Affairs

**Subject: Cavicide**  
EPA Registration No. 46781-6  
Notification Dated December 14, 2009

This will acknowledge receipt of your notification, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

**Proposed Notification**

Label change per PR Notice 2007-4

**General Comments**

The Notification dated December 14, 2009 is in compliance with PR Notice 98-10 and is acceptable. The information has been added to your file.

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

Sincerely

Marshall Swindell  
Product Manager (33)  
Regulatory Management Branch 1  
Antimicrobials Division (7510P)



United States  
**Environmental Protection Agency**  
 Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	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 <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Metrex Research Corporation / Cavicide	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Metrex Research Corporation 1717 West Collins Avenue Orange, CA 92867 <input type="checkbox"/> Check if this is a new address	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**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Notification of label change per PR Notice 2007-4. 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:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
					<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					<input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

**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. (Include Area Code) 714-516-7902
<b>Certification</b> 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.		6. Date Application Received (Stamp & Sign)
2. Signature 	3. Title Director, Regulatory Affairs	
4. Typed Name Wendy Garman	5. Date 12-14-09	



SYBRON DENTAL SPECIALTIES

December 14, 2009

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-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. 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.

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

Table with 2 columns: Document Description and Section. Row 1: Two (2) copies of the Application for Pesticide Form 8570-1, Section 1. Row 2: One (1) copy: Current Cavicide EPA Stamp Approved Label dated Nov 20, 2006, Section 2. Row 3: One (1) copy: Proposed Cavicide Label (Version 12-1-2009) With Changes Highlighted, Section 3.

\* Please treat the information contained in Sections 1-3 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,

Handwritten signature of Wendy Garman

Wendy Garman
Director, Regulatory Affairs

Enclosures

2/12

# CAVICIDE

2/10

[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 Corporation  
 [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](http://www.metrex.com).]

**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.



**EFFECTIVE AGAINST**

- [Mycobacterium tuberculosis var: bovis (BCG)\*\*]
- [Staphylococcus aureus]
- [Pseudomonas aeruginosa]
- [Salmonella choleraesuis]
- [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 choleraesuis*.

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 DEVICES<sup>1</sup>, 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).

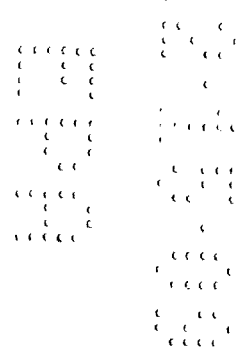
**FOR USE AS A DISINFECTANT ON PRECLEANED NON-CRITICAL MEDICAL DEVICES<sup>1</sup>, INSTRUMENTS AND IMPLEMENTS:**

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 choleraesuis*.

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

<sup>1</sup> 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.



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