

46781-8

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: CaviWipes**  
EPA Registration No. 46781-8  
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.

Please note that the Agency has blacken out the "Clostridium difficile" claim on page 5 of 6 of the proposed label. This claim has been deleted from the label as per your request.

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 / 46781-8	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 / Caviwipes	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 <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container			
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) 714-513-7602
<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 (Stamped)
2. Signature <i>Wendy Garman</i>	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: **Caviwipes**, EPA Reg. No. 46781-8  
Company: **Metrex Research Corporation**

Dear Sir or Madam:

Enclosed is a LABEL NOTIFICATION to revise the label for **Caviwipes**, EPA Reg. No. 46781-8, 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:

Two (2) copies of the Application for Pesticide Form 8570-1	Section 1
One (1) copy: Current Caviwipes EPA Stamp Approved Label dated Jul 7, 2007	Section 2
One (1) copy: Proposed Caviwipes 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](mailto:orlando.tadeo@sybrondental.com) or [wendy.garman@sybrondental.com](mailto: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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# CAVIWIPES

[[Extra large] Disinfecting Towelettes]  
[Kitchen\*\* and Bath Wipes]  
[Kitchen\*\* and Bath Wipes 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 on the production label.]*

[TUBERCULOCIDAL] [[•] BACTERICIDAL] [[• VIRUCIDAL\*] [[• FUNGICIDAL]

[For Professional Use]  
[For Household Use]  
[For Professional and Household Use]

**ACTIVE INGREDIENTS:**

Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride.....	0.28%
Isopropanol .....	17.20%
<b>INERT INGREDIENTS†:</b> .....	<b>82.52%</b>
<b>TOTAL</b> .....	<b>100.00%</b>

† Does not include the weight of the dry [towelette] [[or] wipe].

## KEEP OUT OF REACH OF CHILDREN

## CAUTION

[See other panel for additional precautionary statements.]

EPA Reg. No. 46781-8  
EPA Est. No. 56952-WI-001 • [71979-SC-001] • **75272-WI-001** • **51435-WI-004**

Reorder No.

Net Contents: **#** **[[lbs.] [oz]]**  
# Pre-Saturated Towelette # x # in.

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

[For product or technical information, contact Metrex at **800-841-1428** or visit our web site at **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.



[CaviWipes Disinfecting Towelettes are non-woven disposable towelettes pre-saturated with CaviCide.]

CaviWipes are intended for use in [health care settings such as [hospitals,] [laboratories,] [clinics,] [dental offices,] [ophthalmic offices] [and veterinary facilities]] [, [and in] [kitchens\*\* and bathrooms]].

[CaviWipes are effective against the following microorganisms on hard, non-porous surfaces when used as directed:

- [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)\*]
- [Influenza A2 Virus\*]]

**DIRECTIONS FOR USE**

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

[CaviWipes Disinfecting Towelettes are non-woven disposable towelettes pre-saturated with CaviCide.]

CaviWipes are intended for use on hard, non-porous surfaces in [health care settings such as [hospitals,] [emergency medical settings,] [neonatal units,] [surgical centers,] [isolation areas,] [out-patient surgical centers (OPSC),] [laboratories,] [clinics,] [nursing homes,] [dental offices,] [ophthalmic offices,] [eye surgical centers,] [patient care areas,] [dialysis centers,] [donation centers (blood, plasma, semen, milk, aphaeresis),] [veterinary facilities,]] [[salon settings,] [emergency vehicles,] [correctional facilities,] [schools,] [health club facilities,] [tanning salons,] [kitchens\*\*,] [non-food contact surfaces in food preparation areas\*\*,] [bathrooms,] [daycare centers,] [police and fire vehicles,] [morgues,] [cadaver processing areas,] [funeral homes,] [laundry rooms,] [pet areas]] and other critical care areas where control of cross contamination between treated surfaces is required.

***[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".]***

CaviWipes will 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,] [diaper pails,] [high chairs,] [oxygen hoods,] [operating room tables and lights,] [laboratory equipment and surfaces,] [physical therapy (PT) equipment surfaces,] [spine back boards,] [ambulance equipment surfaces,] [slit lamps,] [eye glasses (do not use on contact lenses),] [hard, non-porous exterior surfaces of ultrasound transducers of 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,] [loupes,] [exterior surfaces of endodontic equipment, such as apex locators, pulp testers and motors,] [stools,]

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[Use A or B as applicable depending on the container type.]

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**[A - canister]**

**Dispenser Directions:**

To start feed, remove cover and discard seal. From center of towelette roll, pull up a towelette corner, twist it into a point and thread it through the hole in the container cover. Pull through about one inch. Replace cover. Pull out first towelette and tear off at a 90° angle. Remaining towelettes feed automatically, ready for next use. When not in use, keep center cap closed to prevent solution loss.

**Cleaning Instructions:**

Use one **CaviWipes** towelette to completely preclean surface of all gross debris.

**For use as a virucide\***, including HIV-1, HBV and HCV applications and effectiveness against ~~Clostridium difficile (vegetative cells only)~~, **Methicillin Resistant *Staphylococcus aureus* (MRSA), Vancomycin Resistant *Enterococcus faecalis* (VRE) and *Staphylococcus aureus* with reduced susceptibility to vancomycin:**

Use a second CaviWipes towelette to thoroughly wet the surface. Repeated use of the product may be required to ensure that the surface remains visibly wet for 2 minutes at room temperature (69°F/20°C).

**For use as a disinfectant:**

Use a second CaviWipes towelette to thoroughly wet the surface. Repeated use of the product may be required to ensure that the surface remains 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*.

**[B - packet]**

**Packet Directions:**

Open packet, remove towelette and unfold.

**Cleaning Instructions:**

Use one **CaviWipes** towelette to completely preclean surface of all gross debris.

**For use as a virucide\***, including HIV-1, HBV and HCV applications and effectiveness against *Clostridium difficile* (vegetative cells only), **Methicillin Resistant *Staphylococcus aureus* (MRSA), Vancomycin Resistant *Enterococcus faecalis* (VRE) and *Staphylococcus aureus* with reduced susceptibility to vancomycin:**

Use a second CaviWipes towelette to thoroughly wet the surface. Repeated use of the product may be required to ensure that the surface remains visibly wet for 2 minutes at room temperature (69°F/20°C).

**For use as a disinfectant:**

Use a second CaviWipes towelette to thoroughly wet the surface. Repeated use of the product may be required to ensure that the surface remains 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*.

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**[The following direction 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]. Then thoroughly wet the probe with a Caviwipes towelette and allow the precleaned surface. Repeated use of the product may be required to ensure that the surface remains visibly wet for 3 minutes at 20°C.]

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

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

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

**CaviWipes** 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,] [HBV,] [[and] [HCV].

**Special Instructions for Cleaning and Decontamination Against [HIV-1,] [HBV,] [[and] HCV] of Surfaces or Objects Soiled With Blood or Body Fluids:**

**Personal Protection:** When using this disinfecting towelette, wear appropriate barrier protection such as disposable protective gloves, protective gown, face mask and eye covering.

**Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfecting towelette. A **CaviWipes** towelette can be used for this purpose.

**Contact Time:** Thoroughly wet surface with a new **CaviWipes** towelette. Repeated use of the product may be required to ensure that the surface remains visibly wet for 2 minutes. 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.

**Disposal Of Infectious Materials:** Cleaning materials used that may contain blood or other body fluids should be autoclaved and disposed of in accordance with Federal, State and 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.

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[Use A or B as applicable depending on the container type.]

[A - canister]

**STORAGE AND DISPOSAL**

**Towelette** - Do not reuse towelette. Dispose of used towelette in trash.

**Dispenser** - Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. [Wrap container and discard in trash.]

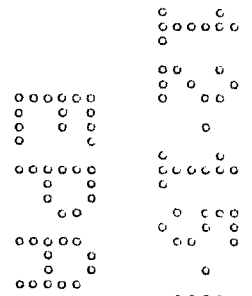
[B - packet]

**STORAGE AND DISPOSAL**

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

**Towelette** - Do not reuse towelette. Dispose of used towelette and empty packet in trash.

The following graphics are optional for canister containers only. They will be affixed to the label/canister so that it does not interfere with any label text. Due to size constraints, they will not appear on individually wrapped packets.



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