

46781-8

05/10/2011

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



Office of Pesticide Programs

Metrex Research Corporation  
1717 West Collins Avenue  
Orange, CA 92867

MAY 10 2011

Attention: Wendy Garman, Manager  
Regulatory Affairs

**Subject: Caviwipes**  
EPA Registration No. 46781-8  
Notification Dated April 25, 2011

This will acknowledge receipt of your notification, submitted under the provisions of FIFRA Section 3(c)(9)

**Proposed Notification**

- Alternate Brand Name: "MetriWipes"

**General Comments**

Based on a review of the submitted material, the following comments apply.

The Notification dated April 25, 2011 is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

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

Sincerely,

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

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

 <p>United States <b>Environmental Protection Agency</b> Washington, DC 20460</p>	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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**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 / Caviwipes	PM# 33	
5. Name and Address of Applicant (Include ZIP Code)  Metrex Research 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.)  
 LABEL NOTIFICATION for an alternate brand name of the Metrex Research product, CaviWipes, EPA Reg. No. 46781-8. The alternate brand name is MetriWipes.  
 This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Section 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, 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 <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	2. Type of Container <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	If "Yes" Package wgt    No. per container	

3. Location of Net Contents Information  
 Label     Container

4. Size(s) Retail Container

5. Location of Label Directions  
 On Label  
 On Labeling accompanying product

6. Manner in Which Label is Affixed to Product  
 Lithograph  
 Paper glued  
 Stenciled     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) 714-516-7602
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**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 	3. Title Director, Regulatory Affairs	6. Date Application Received  (Stamped)
4. Typed Name Wendy Garman	5. Date 4-27-11	



SYBRON DENTAL SPECIALTIES

April 25, 2011

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

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Re: NOTIFICATION OF AN ALTERNATE BRAND NAME FOR CAVIWIPES, EPA REG. NO. 46781-8,  
per PR-NOTICE 98-10  
Alternate Brand Name: MetriWipes, EPA Reg. No. 46781-8  
Company: Metrex Research

Dear Sir or Madam:

Enclosed is a NOTIFICATION for an alternate brand name for the Metrex Research product,  
CaviWipes, EPA Reg. No. 46781-8. **The alternate brand name is MetriWipes.**

Also enclosed is a copy of the MetriWipes label.

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) 516-7472  
Email addresses: orlando.tadeo@sybrondental.com or wendy.garman@sybrondental.com  
Company Address: Metrex Research  
1717 West Collins Avenue  
Orange, CA 92867

Sincerely,

Orlando Tadeo, Jr.  
Manager, Regulatory Affairs

Enclosures

**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 MetriWipes towelette can be used for this purpose.

**Contact Time:** Thoroughly wet surface with a new MetriWipes 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 must be autoclaved and disposed of in accordance with Federal, State and local regulations for infectious materials disposal.

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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization/high-level disinfection.

**PRECAUTIONARY STATEMENTS**

**Hazards to Humans and Domestic Animals**

**CAUTION**

Harmful if absorbed through the 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 re-use.

**FIRST AID**

**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. Call a poison control center or doctor for further advice.

**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.

**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.

For product or technical information, contact Metrex at 800-841-1428 or visit our web site at [www.metrex.com](http://www.metrex.com).

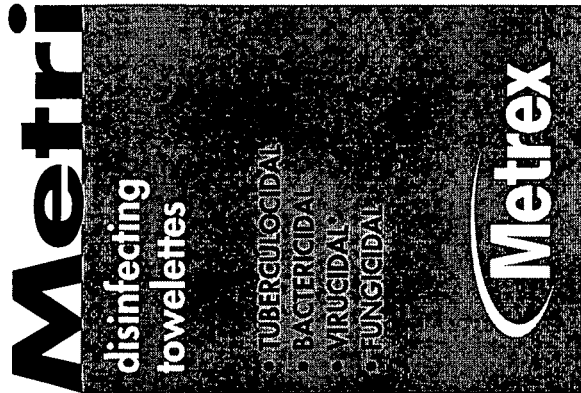
Packed For:

METREX RESEARCH  
28210 Wick Road  
Romulus, MI 48174

MADE IN USA

REORDER No. XX-XXX

70-xxxx-1  
xxxxxx-xx



Net Contents: X lb. X oz.  
120 Pre-Saturated Towelettes (7" x 9")

# MetriWipes®

MetriWipes Disinfecting Towelettes are non-woven disposable towelettes pre-saturated with CaviCide®. MetriWipes are intended for use in health care settings such as hospitals, dental offices, laboratories, clinics, ophthalmic offices, veterinary facilities and in kitchens\*\* and bathrooms. MetriWipes 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 enterica*
- *Trichophyton mentagrophytes*
- Methicillin Resistant *Staphylococcus faecalis* (VRE)
- 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\*



**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

See other panel for additional precautionary statements.

EPA Reg. No. 46781-8  
EPA Est. No. 56952-WH-001

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

† Does not include the weight of the dry towelette.

**DO NOT USE AS A BABY WIFE. Not For Use On Skin.**

**DIRECTIONS FOR USE**

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

**MetriWipes** Disinfecting Towellettes are non-woven disposable towellettes pre-saturated with Cavicide®. **MetriWipes** 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, nursing homes, dental offices, ophthalmic offices, eye surgical centers, patient care areas, dialysis centers, donation centers (blood, plasma, semen, milk, ophaeresis), veterinary facilities, salon settings, emergency vehicles, correctional facilities, schools, health club facilities, tanning salons, kitchens\*, non-food contact surfaces in food preparation areas\*\*, bathrooms, day care centers, police and fire vehicles, cadaver processing areas, laundry rooms, and other critical care areas where control of cross contamination between treated surfaces is required.

**MetriWipes** 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, oxygen hoods, operating room tables and lights, laboratory equipment and surfaces, physical therapy equipment surfaces, ambulance equipment surfaces, slit lamps, hard, non-porous exterior surfaces of ultrasound transducers or probes, exam tables, gurneys, IV poles, dental unit instrument trays, operating light switches, exterior surfaces of amalgamators and dental curing lights, exterior surfaces of anesthesia machines and respiratory therapy equipment, Siphpeet™ with Dermalinuson™ workstations, dental countertops, lounges, exterior surfaces of endodontic equipment, such as apex locators, pulp testers and motors, stools, nailhair care implements, tanning beds, salon surfaces, non-food contact surfaces\*\*, exterior surfaces of refrigerator units\*, exterior surfaces of appliances such as refrigerators, microwaves, food processors and toasters\*, vanity tops\*, floors, walls, handrails, door knobs, bed railings, tables, chairs, bathroom fixtures, exterior toilet surfaces, garbage cans, keyboards, 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.

**Kitchen\* and Bath Wipes for Hard, Non-Porous Surfaces  
Cleans, Deodorizes and Kills Common Household Germs**

**Dispenser Directions:**

To start feed, remove cover and discard seal. From center of towellette roll, pull up a towellette 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 towellette and tear off at a 90° angle. Remaining towellettes feed automatically, ready for next use. When not in use, keep center cap closed to prevent solution loss.

**Cleaning Instructions:**

Use one **MetriWipes** towellette to completely pre-clean surface of all gross debris. For use as a virucide\*, including HIV-1, HBV and HCV applications and effectiveness against Methicillin Resistant, *Staphylococcus aureus* (MRSA), Vancomycin Resistant, *Enterococcus faecalis* (VRE) and *Staphylococcus aureus* with reduced susceptibility to vancomycin.

Use a second **MetriWipes** towellette 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 (68°-72° C).

**For use as a disinfectant:**

Use a second **MetriWipes** towellette 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 (68°-72° C) for Tuberculocidal activity and effectiveness against *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Trichophyton mentagrophytes* and *Salmonella enterica*.

**To disinfect external surfaces of ultrasound transducers:**

Pre-clean ultrasound gel from external transducer to be disinfected. Then thoroughly wet the probe with a **MetriWipes** towellette. Repeated use of the product may be required to ensure that the surface remains visibly wet for 3 minutes at 20 °C.

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

**MetriWipes** effectively kills Human Immunodeficiency Virus Type 1 (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) on pre-cleaned 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 surface/objects can be associated with the potential for transmission of HIV, HBV and HCV.

