

46781-8

4-13-2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 13 2004

Wendy Urtel
Metrex Research Corporation
1717 West Collins Avenue
Orange, CA 92867

**Subject: Caviwipes
EPA Reg. No. 46781-8
Notification Dated 3/26/04**

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to add the graphic which includes the statement "This is not a baby wipe", in three languages, and which provides a final printed label with the changes required in the EPA letter dated 12/16/03, is acceptable.

This notification has been made part of the permanent record for this product.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,

Marshall Swindell,
Product Manager Team 33,
Regulatory Management Branch I
Antimicrobials Division (7510C)

CONCURRENCES

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 46781 / 46781-8	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 the addition of an optional graphic to the Caviwipes label, EPA Reg. No. 46781-8, per PR-Notice 98-10. The graphic, which includes the statement "THIS IS NOT A BABY WIPE", is intended to be affixed to the label/canister so that it does not interfere with any label text. 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 A 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	If "Yes" Unit Packaging wgt. No. per container		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package 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 Urtel	Title Manager, Regulatory Affairs	Telephone No. (Include Area Code) 714-516-7425
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.		6. Date Application Received (Stamped)
2. Signature 	3. Title Manager, Regulatory Affairs	
4. Typed Name Wendy Urtel	5. Date 3-26-04	



March 26, 2004

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
US EPA
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Re: NOTIFICATION OF THE ADDITION OF AN OPTIONAL GRAPHIC PER
PR-NOTICE 98-10
Product: Caviwipes, EPA Reg. No. 46781-8
Company: Metrex Research Corporation

Dear Sir or Madam:

Enclosed is a NOTIFICATION of the addition of an optional graphic to the Caviwipes label, EPA Reg. No. 46781-8, per PR-Notice 98-10. The graphic, which includes the statement "THIS IS NOT A BABY WIPE", is intended to be affixed to the label/canister so that it does not cover or interfere with any label text.

The following documents are being submitted in support of this notification:

- Two (2) copies of the Application for Pesticide Form (Section 1)*
- One (1) copy of the current Caviwipes stamp approved label, dated 12-16-2003 (Section 2)*
- One (1) copy of the proposed Caviwipes label 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. Urtel (714) 516-7425
Fax Number:	(714) 516-7488
Email addresses:	tadeoo@sybrondental.com or urtelw@sybrondental.com
Company Address:	Metrex Research Corporation 1717 West Collins Avenue Orange, CA 92867

Sincerely,

Wendy Urtel
Manager, Regulatory Affairs

Enclosures

CAVIWIPES

[Front Panel – The following verbiage will only appear on canister containers.]

DISINFECTING TOWELETTES

[Front Panel – The following verbiage will only appear on individually wrapped packets.]

DISINFECTING TOWELETTE

TUBERCULOCIDAL • BACTERICIDAL • VIRUCIDAL* • FUNGICIDAL

ACTIVE INGREDIENTS:

Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride	0.233%
Isopropanol.....	14.300%
INERT INGREDIENTS	85.467%
TOTAL	100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for additional precautionary statements.

[Front Panel – The following verbiage will only appear on canister containers.]

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

[Front Panel – The following verbiage will only appear on individually wrapped packets.]

CaviWipes Disinfecting Towelette is a non-woven disposable towelette pre-saturated with **CaviCide**. *CaviWipes* is intended for use in health care settings such as hospitals, laboratories, clinics, dental offices, ophthalmic offices and veterinary facilities. *CaviWipes* is 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)
- Hepatitis B Virus (HBV)*
- Herpes simplex virus types 1 and 2*
- Human Immunodeficiency Virus (HIV-1)*
- Canine parvovirus*

EPA Reg. No. 46781-8

EPA Est. No. 9480-NY-001

EPA Est. No. 56952-WI-001

EPA Est. No. 71979-SC-001

REORDER No.

Net Contents: # Pre-Saturated Towelettes # x # in.

Packed For: Metrex Research Corporation
28210 Wick Road
Romulus, Michigan 48174

[Side Panel – The following verbiage will only appear on canister containers.]

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, laboratories, clinics, nursing homes, dental offices, ophthalmic offices, veterinary facilities, salon settings, emergency vehicles, correctional facilities, schools, health club facilities, non-food contact surfaces and other critical care areas where control of cross contamination is required.

CaviWipes will clean and disinfect, when used as directed, such items as tables, chairs, counter tops, carts, baskets, cabinets, lights, telephones which are made of stainless steel, glass, Plexiglas®, and plastics (i.e., polycarbonate, polypropylene, polyvinylchloride, polystyrene).

DO NOT USE AS A BABY WIPE.

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 and Disinfection Instructions:

Use one *CaviWipes* towelette to completely preclean surface of all gross debris. To disinfect the precleaned surface, use a second *CaviWipes* towelette to thoroughly wet the surface and allow to remain visibly wet for 3 minutes at 20°C. For tuberculocidal disinfection, allow the surface to remain visibly wet for 5 minutes at 20°C.

CaviWipes Disinfecting Towelette is a non-woven disposable towelette pre-saturated with *CaviCide*. *CaviWipes* is intended for use on hard non-porous surfaces in health care settings such as hospitals, emergency medical settings, neonatal units, surgical centers, laboratories, clinics, nursing homes, dental offices, ophthalmic offices, veterinary facilities, salon settings, emergency vehicles, correctional facilities, schools, health club facilities, non-food contact surfaces and other critical care areas where control of cross contamination is required. *CaviWipes* will clean and disinfect, when used as directed, such items as tables, chairs, counter tops, carts, baskets, cabinets, lights, telephones which are made of stainless steel, glass, Plexiglas®, and plastics (i.e., polycarbonate, polypropylene, polyvinylchloride, polystyrene). **DO NOT USE AS A BABY WIPE.**

Packet Directions:

Open packet, remove towelette and unfold.

Cleaning and Disinfection Instructions:

Use one *CaviWipes* towelette to completely preclean surface of all gross debris. To disinfect the precleaned surface, open and use a second *CaviWipes* towelette to thoroughly wet the surface and allow to remain visibly wet for 3 minutes at 20°C. For tuberculocidal disinfection, allow the surface to remain visibly wet for 5 minutes at 20°C.

CaviWipes effectively kills HIV and HBV 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 Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis B Virus (HBV).

Special Instructions for Cleaning and Decontamination Against HIV-1 (Human Immunodeficiency Virus) and HBV 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. Allow to remain visibly wet for 3 minutes.

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.

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 reuse.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eyes 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.
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment.
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
<p>For emergency information on product, call Metrex at 1-800-841-1428, Monday through Friday, between 6 a.m. and 4 p.m. Pacific Time. After 4 p.m., call Chemtrec 24-Hour Emergency Service at 1-800-424-9300.</p>	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	

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.

[Side Panel – The following verbiage will only appear on canister containers.]

STORAGE AND DISPOSAL:

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

Dispenser - Do not reuse empty container. Wrap container and discard in trash.

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

[Side Panel – The following verbiage will only appear on individually wrapped packets.]

STORAGE AND DISPOSAL:

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

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

[The following graphic is optional for canister containers only. It will be affixed to the label/canister so that it does not interfere with any label text. Due to size constraints, it will not appear on individually wrapped packets.]

