

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Metrex Research Corporation
1717 West Collins Avenue
Orange, CA 9267

SEP 25 2002

Attention: Ms. Wendy Urtel

Subject: Caviwipes
EPA Registration No. 46781-8
Amendment Application Date: August 28, 2002
EPA Received Date: August 30, 2002

This will acknowledge receipt of your notification, Per the State of California request that the current label be revised to make the instruction for use against HBV to be similar to the instructions for use against HIV.", submitted under the provisions of FIFRA section 3 (c) 9. Based on a review of the material, the following comment apply.

This application is acceptable and has been made a part of the records for this file. This information has been made a part of your file.

If you have any questions or comments concerning this letter, please contact me at 703-308-6341 or Portia Jenkins at (703) 308-6230.

Sincerely yours,

for Portia M. Jenkins

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

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

286

EPA	United States Environmental Protection Agency Washington, DC 20460	<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 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 TO REVISE THE CAVIWIPES, EPA REG. NO. 46781-8, LABEL PER PR-NOTICE 98-10 AND PER RECOMMENDATION FROM THE CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION (CA DPR). During the California state pesticide registration review of Caviwipes, a labeling issue was raised concerning Hepatitis B Virus and the current US EPA labeling policy. The CA DPR requested that the current label be revised to make the instructions for use against HBV to be similar to the instructions for use against HIV. See additional page.

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 If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt No. per container	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) _____
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* Certification must be submitted

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"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		

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) 714-513-7425
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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.	6. Date Application Received (Stamped)
2. Signature 	3. Title Manager, Regulatory Affairs
4. Typed Name Wendy Urtel	5. Date 8-28-02

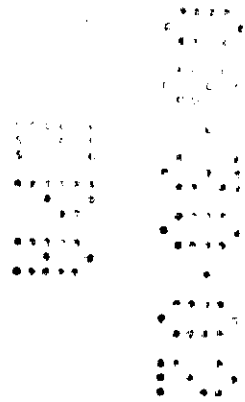
**APPLICATION FOR PESTICIDE
NOTIFICATION TO REVISE THE LABEL PER CALIFORNIA
DEPARTMENT OF PESTICIDE REGULATION (CA DPR) RECOMMENDATION**

Product Name: Caviwipes, EPA Reg. No. 46781-8

The California Department of Pesticide Regulation requested that the current label be revised to make the instructions for use against HBV to be similar to the instructions for use against HIV.

Section II – Additional Page

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.



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CAVIWIPES™

DISINFECTING TOWELETTES

TUBERCULOCIDAL • BACTERICIDAL • VIRUCIDAL* • FUNGICIDAL

ACTIVE INGREDIENTS:

Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride	0.23%
Isopropanol	14.30%
INERT INGREDIENTS	85.47%
TOTAL	100.00%

CAUTION

KEEP OUT OF REACH OF CHILDREN
 See back panel for additional precautionary statements.

CaviWipes Disinfecting Towelettes are non-woven disposable towelettes pre-saturated with **Cavicide Surface Disinfectant/Decontaminant Cleaner**. *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:

- 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

REORDER No. 00-0000

Net Contents: 160 Pre-Saturated Towelettes 6 x 6.75 in.

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

DIRECTIONS FOR USE

It is a violation of U.S. 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 Surface Disinfectant/Decontaminant Cleaner*. *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, stainless steel, glass, Plexiglas®, plastics (i.e., polycarbonate, polypropylene, polyvinylchloride, polystyrene) and other hard, non-porous, inanimate surfaces. **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 wet for 3 minutes at 20°C. For tuberculocidal disinfection, allow the surface to remain 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) of Surfaces or Objects Soiled With Blood or Body Fluids:
and HBV

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 air dry. Although efficacy at a 2 minute contact time has been shown to be adequate against HIV-1 (AIDS Virus), use the recommended contact time for the disinfection of other organisms listed on this label. and 3 minutes for HBV.

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

Storage and Disposal Instructions:

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.