

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 15 2002

Metrex Research Corporation
1717 West Collins Avenue
Orange, CA 92867

Attention: Wendy Urtel, Manager
Regulatory Affairs

Subject: CaviWipes
EPA Registration No. 46781-8
Amendment Dated January 28, 2002

The amendment, submitted in connection with registration under the FIFRA sec. 3(e)(7)(A), to add a claim against Hepatitis B Virus (HBV) to the label, is acceptable, provided that you:

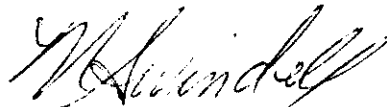
1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec.3(c)(5) and sec. 4 when the Agency requires all registrants of similar products to submit such data.
2. Submit two (2) copies of final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the revised draft label is enclosed for your records.

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
Antimicrobial Division 7510C

Enclosure

CONCURRENCES

SYMBOL	SURNAME	DATE						

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*

ACCEPTED
with **COMMENTS**
in EPA Letter Dated:
MAR 15 2002

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

46781-8

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 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).

Special Instructions for Cleaning and Decontamination Against HIV-1 (Human Immunodeficiency Virus) 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 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.

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.

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116701-0

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.

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**.

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