

46781-8

12-5-2001

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7504C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:
46781-8

Date of issuance:
DEC 5 2001

NOTICE OF PESTICIDE:
 Registration
 Reregistration

Term of Issuance:
DEC 5 2001

Name of Pesticide Product:
Caviwipes

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Metrex Research Corporation
1717 West Collins Avenue
Orange, CA 92667

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following label changes:

- a. Revise the EPA Registration Number to read, "EPA Reg. No. 46781-8".
- b. Place the appropriate EPA Establishment No. on the product labeling.

Signature of Approving Official:

Marshall Swindell, Product Manager 33,
RMBI, AD

Date:

DEC 5 2001

- c. Add a "First Aid" statement section directly below the "Precautionary Statements" section to read as follows:

IF IN EYES: Hold eyes open and revise 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: 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 by a poison control center or doctor.

IF ON SKIN OR CLOTHING: Take off contaminating clothing. rinse clothing skin immediately with plenty of water for 15 -20 minutes. Call a poison control center or doctor for treatment.

IF INHALED: 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.

- d. Revise the precautionary statements to include the following statements:

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.

3. Submit two copies of the revised final printed label for the record.

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 label is enclosed for your records.

Sincerely,



Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7505C)

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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)
- Herpes simplex virus types 1 and 2*
- Human Immunodeficiency Virus (HIV-1)*
- Canine parvovirus*

ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC 05 2001

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

46781-8

EPA Reg. No. 46781-1

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

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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.

ACCEPTED with COMMENT in EPA Letter Date
DEC. 05 2001
Under the Federal Insecticide, Fungicide, and Rodenticide Act, registered under EPA Reg. No. 467-81-8

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Precautionary Statements:

Harmful to Humans and Domestic Animals. Caution: Avoid contamination of food. Avoid contact with eyes. In case of eye contact, flush eyes with plenty of water for at least 15 minutes. If irritation persists, seek medical attention.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • 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 eye. • Call a poison control center or doctor for treatment advice.
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 further treatment 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. • Do not give anything by mouth to an unconscious person.
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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 in EPA Letter Dated:
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 amended, for the pesticide
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