



46781-8

07-27-2007

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

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JUL 27 2007

Ms. Wendy Urtel  
Manager for Regulatory Affairs for,  
Metrex Research Corporation  
1717 W Collins Avenue  
Orange, CA 92867

Mail to: Wendy Urtel  
Sybron Dental Specialties  
100 Bayview Circle, Suite 6000  
Newport, CA 92660-8915

Subject: Caviwipes  
EPA Registration Number 46781-8  
Your Amendment Dated July 27, 2007

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, to incorporate labeling changes requested in the Agency's February 15, 2007 letter is acceptable.

The Agency re-iterates below that the following claims included in the February 15, 2007 acceptance letter are still acceptable:

The submitted confirmatory efficacy study, (MRID# 469453-01), supports the use of the product Caviwipes as a disinfectant towelette against *M. Bovis*, at the ready to use preparation for a contact time of 3 minutes in the presence of organic soil for hard, non-porous surfaces.

The submitted efficacy study, (MRID# 469453-02), supports the use of the product, Caviwipes as a disinfectant towelette against *C. difficile* (vegetative cells) for a contact time of 2 minutes in the presence of organic soil on hard, non-porous surfaces.

The submitted efficacy study, (MRID# 469453-03), supports the use of product, Caviwipes as a disinfectant towelette against *Staphylococcus aureus* (VISA) for a contact time of 2 minutes in the presence of organic soil on hard, non-porous surfaces.

The submitted efficacy study, (MRID# 469453-04), supports the use of product, Caviwipes, as a disinfectant against Bovine Viral Diarrhea Virus (BVDV) (Surrogate for Human Hepatitis C Virus) for a contact time of 1 minute on hard non-porous surfaces.

The submitted efficacy study, (MRID# 469453-05), supports the use of the product, Caviwipes, as a disinfectant against Influenza A2 virus for a contact time of 30 seconds on hard, non-porous surfaces in the presence of organic soil.

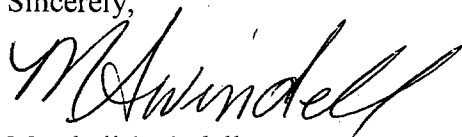
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The submitted efficacy study, (MRID# 469453-06), supports the use of the product, Caviwipes, as a disinfectant with virucidal claims against Duck Hepatitis B virus (Surrogate for Hepatitis B) for a contact time of 2 minutes on hard, non-porous surfaces in the presence of organic soil.

The proposed label claims are acceptable regarding the use of Caviwipes as a virucide against Hepatitis C Virus, Influenza A2 Virus, and Hepatitis B virus on hard, non-porous surfaces for a contact time of 2 minutes in the presence of organic soil. Special instructions were extended to Hepatitis B (HBV) and Hepatitis C (HCV) for bloodborne pathogens.

The proposed label was modified to reduce contact time for ultrasound transducer disinfection from 5 to 3 minutes. These claims are acceptable; as supported by the acceptance contact time of  $\leq$  3 minutes for effectiveness against all organisms claimed.

Sincerely,



Marshall Swindell  
Product Manager 33  
Regulatory Management Branch I  
Antimicrobial Division (7510P)

# CAVIWIPES

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[[Extra large] Disinfecting Towelettes]  
[Kitchen\*\* and Bath Wipes]  
[Kitchen\*\* and Bath Wipes for Hard, Non-Porous Surfaces]  
[Cleans, Deodorizes and Kills Common Household Germs]

*[The descriptive terms below are to be used, as applicable, depending on the microorganisms listed on the production label.]*

[TUBERCULOCIDAL] [[•] BACTERICIDAL] [[• VIRUCIDAL\*] [[• FUNGICIDAL]

[For Professional Use]  
[For Household Use]  
[For Professional and Household Use]

### ACTIVE INGREDIENTS:

Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride .....0.28%  
Isopropanol..... 17.20%

**INERT INGREDIENTS†:** ..... **82.52%**

**TOTAL**..... **100.00%**

† Does not include the weight of the dry [towelette] [[or] wipe].

**KEEP OUT OF REACH OF CHILDREN**

## CAUTION

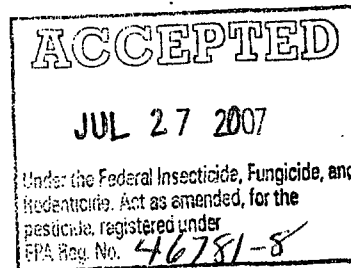
[See other panel for additional precautionary statements.]

EPA Reg. No. 46781-8  
EPA Est. No. 56952-WI-001 • [71979-SC-001]

Reorder No.

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

[Packed For:] Metrex Research Corporation  
[Distributed By:] 28210 Wick Road  
[Sold By:] Romulus, Michigan 48174



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

### THE INFORMATION IN THIS BOX IS NOT PART OF THE LABELING

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**PRECAUTIONARY STATEMENTS**  
**Hazards to Humans and Domestic Animals**

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**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. [See other panel for additional precautionary statements.]

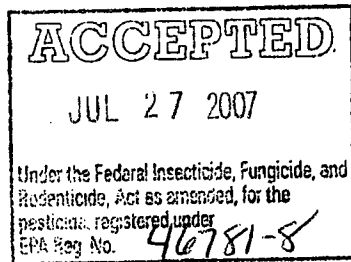
**FIRST AID**

**If 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.

**If 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 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.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.



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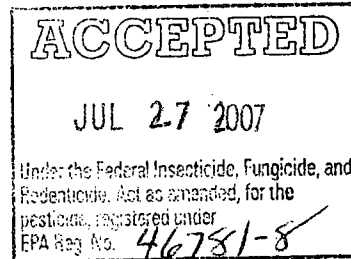
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[CaviWipes Disinfecting Towelettes are non-woven disposable towelettes pre-saturated with CaviCide.]

CaviWipes are intended for use in [health care settings such as [hospitals,] [laboratories,] [clinics,] [dental offices,] [ophthalmic offices] [and veterinary facilities]] [, [and in] [kitchens\*\* and bathrooms]].

[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]
- [Clostridium difficile (vegetative cells only)]
- [Trichophyton mentagrophytes]
- [Methicillin Resistant Staphylococcus aureus (MRSA)]
- [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\*]]



**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,] [isolation areas,] [out-patient surgical centers (OPSC),] [laboratories,] [clinics,] [nursing homes,] [dental offices,] [ophthalmic offices,] [eye surgical centers,] [patient care areas,] [dialysis centers,] [donation centers (blood, plasma, semen, milk, aphaeresis),] [veterinary facilities,]] [[salon settings,] [emergency vehicles,] [correctional facilities,] [schools,] [health club facilities,] [tanning salons,] [kitchens\*\*,] [non-food contact surfaces in food preparation areas\*\*,] [bathrooms,] [daycare centers,] [police and fire vehicles,] [morgues,] [cadaver processing areas,] [funeral homes,] [laundry rooms,] [pet areas]] and other critical care areas where control of cross contamination between treated surfaces is required.

*[Listing of at least one of the following equipment/instruments/hard, non-porous surfaces on production labels is required. The last equipment/instruments/hard, non-porous surface listed will be preceded with the word "and".]*

CaviWipes 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,] [diaper pails,] [high chairs,] [oxygen hoods,] [operating room tables and lights,] [laboratory equipment and surfaces,] [physical therapy (PT) equipment surfaces,] [spine back boards,] [ambulance equipment surfaces,] [slit lamps,] [eye glasses (do not use on contact lenses),] [hard, non-porous exterior surfaces of ultrasound transducers or probes,] [exam tables,] [gurneys,] [IV poles,] [dental unit instrument trays,] [operatory light switches,] [exterior surfaces of amalgamators and dental curing lights,] [exterior surfaces of anesthesia machines and respiratory therapy equipment,] [SilkPeel™ with DermallInfusion™,] [workstations,] [dental countertops,] [dental chairs,] [loupes,] [exterior surfaces of endodontic equipment, such as apex locators, pulp testers and motors,] [stools,] [nail/hair care implements,] [tanning beds,] [hair dryers,] [hair clippers,] [shears,] [razors,] [hair cutting implements,] [clipper blades,] [salon surfaces,] [scissors,] [combs,] [brushes,] [manicure implements,] [washable nail files,]

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[non-food contact surfaces\*\*,] [exterior surfaces of refrigerator units\*\*,] [exterior surfaces of appliances such as refrigerators, microwaves, food processors and stoves\*\*,] [vanity tops\*\*,] [tiles\*\*,] [floors,] [walls,] [handrails,] [door knobs,] [bed railings,] [tables,] [chairs,] [faucets,] [bathroom fixtures,] [exterior toilet surfaces,] [garbage cans,] [computers,] [keyboards,] [carts,] [baskets,] [grocery 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. **DO NOT USE AS A BABY WIPE. [Not For Use On Skin]**

**ACCEPTED**  
JUL 27 2007

Under the Federal Insecticide, Fungicide, and  
Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. 46781-8

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[Use A or B as applicable depending on the container type.]

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**[A - canister]**

**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 Instructions:**

Use one **CaviWipes** towelette to completely preclean surface of all gross debris.

**For use as a virucide\***, including HIV-1, HBV and HCV applications and effectiveness against ***Clostridium difficile*** (vegetative cells only), **Methicillin Resistant *Staphylococcus aureus*** (MRSA), **Vancomycin Resistant *Enterococcus faecalis*** (VRE) and ***Staphylococcus aureus*** with reduced susceptibility to vancomycin:

Use a second CaviWipes towelette 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 (69°F/20°C).

**For use as a disinfectant:**

Use a second CaviWipes towelette 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 (69°F/20°C) for Tuberculocidal\*\* activity and effectiveness against *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Trichophyton mentagrophytes* and *Salmonella choleraesuis*.

**[B - packet]**

**Packet Directions:**

Open packet, remove towelette and unfold.

**Cleaning Instructions:**

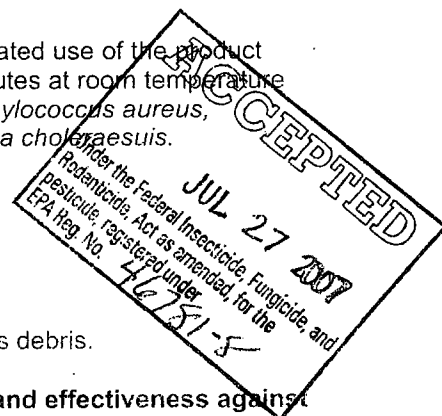
Use one **CaviWipes** towelette to completely preclean surface of all gross debris.

**For use as a virucide\***, including HIV-1, HBV and HCV applications and effectiveness against ***Clostridium difficile*** (vegetative cells only), **Methicillin Resistant *Staphylococcus aureus*** (MRSA), **Vancomycin Resistant *Enterococcus faecalis*** (VRE) and ***Staphylococcus aureus*** with reduced susceptibility to vancomycin:

Use a second CaviWipes towelette 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 (69°F/20°C).

**For use as a disinfectant:**

Use a second CaviWipes towelette 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 (69°F/20°C) for Tuberculocidal\*\* activity and effectiveness against *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Trichophyton mentagrophytes* and *Salmonella choleraesuis*.



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[The following direction is to be included when hard, non-porous exterior surfaces of ultrasound transducers or probes is listed as a use site.]

[To disinfect external surfaces of ultrasound transducers: Pre-clean ultrasound gel from external transducer to be disinfected [by using a clean wash cloth]. Then thoroughly wet the probe with a Caviwipes towelette and allow the precleaned surface. Repeated use of the product may be required to ensure that the surface remains visibly wet for 3 minutes at 20°C.]

[The following statement is to be included on production labels when food contact surfaces are listed.]

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

[The following HIV / HBV / HCV instructions are to be included on production labels when claims against HIV or HBV or HCV are listed.]

**CaviWipes** effectively kills [Human Immunodeficiency Virus Type 1 (HIV),] [Hepatitis B Virus (HBV),] [[and] Hepatitis C Virus (HCV)] 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 [HIV,] [HBV,] [[and] [HCV].

**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 **CaviWipes** towelette can be used for this purpose.

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

[The following paragraph will be included in its entirety when the production label references health care use.]

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.

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ACCEPTED  
JUL 27 2007  
Under the Federal Insecticide, Fungicide, and  
Rodenticide Act as amended, for the  
pesticide, registered under  
Reg. No. 44651-5



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[Use A or B as applicable depending on the container type.]

[A - canister]

**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.

[B - packet]

**STORAGE AND DISPOSAL**

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

[The following statements are optional verbiage to be used for marketing purposes and may appear on the product label and/or in promotional materials for CaviWipes, EPA Reg. No. 46781-8.]

[New Claims and 40% Faster Kill]

[New Claims and Faster Contact Times]

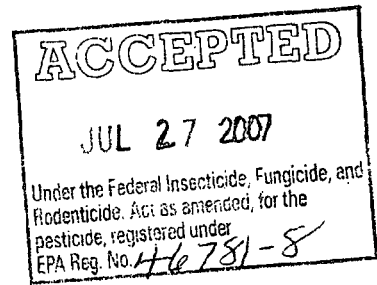
[New Kill Claims *[must specify what claims are new]*]

[New Claims - Kills TB in 3 Minutes]

[New Claims - Kills TB 40% Faster]

[New - Saves Time - It's 40% Faster]

[New - Kills TB in 3 Minutes]



[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.]



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