

71847-2

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

FEB - 4 2009

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Timothy H. Dickens, Agent for Medentech Ltd.  
Scientific Coordination, Inc.  
4629 Cherry Valley Drive  
Rockville, MD. 20853

Subject: Label Amendment Nov. 11, 2008  
Product Name: KLOR-KLEEN  
EPA File Symbol: 71847-2

Dear Mr. Dickens:

The Agency has reviewed your submission in accordance with continuing registration under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended, and determined the action acceptable. In summary, you have added the ATCC numbers to the corresponding organism as optional language.

A copy of your accepted label is enclosed. If you have any questions about this letter, contact Tom Luminello at 703-308-8075 or by e-mail [luminello.tom@epa.gov](mailto:luminello.tom@epa.gov) during the hours of 8:00 am to 4:00 pm EST.

Sincerely,

A handwritten signature in cursive script that reads "Emily H. Mitchell".

Emily H. Mitchell, Product Manager 32  
Regulatory Branch II  
Antimicrobial Division

# KLOR-KLEEN™

**Effervescent Disinfectant Tablets for Hospitals and Institutional Use.**

**KLOR-KLEEN™** is effective against the following microorganisms on precleaned, hard, nonporous, inanimate surfaces: *Salmonella enterica*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Staphylococcus epidermidis*, *Escherichia coli* O157:H7, *Staphylococcus aureus* - MRSA & GRSA, *Mycobacterium bovis* – BCG, *Poliovirus* type 1, *Herpes simplex virus* type 1, *Hepatitis A virus*, *Human Immunodeficiency Virus* Type 1 (associated with AIDS) or (AIDS Virus), *Canine Parvovirus*, *Newcastle Disease virus*, *Pseudorabies*, *Canine Distemper Virus*, *Feline Calicivirus*, *Norovirus*, *Enterococcus faecalis* *Vancomycin Resistant*, *Trichophyton mentagrophytes*.

**ACTIVE INGREDIENT:**

Sodium Dichloroisocyanurate ..... **48.21%**

**OTHER INGREDIENTS:** ..... **51.79%**

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

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER**  
See First Aid on back panel

**Each tablet will produce a 937 ppm disinfectant solution  
when dissolved in one gallon of water.**

[ ] indicates optional text

**ACCEPTED**  
FEB - 4 2009  
Under the Federal Insecticide, Fungicide, and  
Rodenticide Act as amended, for the  
pesticide, registered under  
EPA Reg. No. 71847-2

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**KLOR-KLEEN™** is designed to provide effective cleaning, deodorizing and disinfection in areas where it is of prime importance in controlling the hazard of cross contamination on treated precleaned, hard, nonporous, inanimate surfaces.

**KLOR-KLEEN™** is for use in:

- Hospitals, nursing homes, medical and dental offices and clinics, operating rooms, isolation wards, and medical research facilities.
- Day care centers and nurseries.
- Veterinary clinics, animal life science laboratories, kennels, breeding and grooming establishments, pet animal quarters, zoos, pet shops, and other animal care facilities.

**KLOR-KLEEN™** is a disinfectant and cleaner that disinfects, cleans, and deodorizes precleaned, hard, nonporous, inanimate surfaces. This pre-cleaning may be accomplished with any cleaner solution including Klor-Kleen

**KLOR-KLEEN™** provides effective cleaning strength that will not dull high gloss floor finishes with repeated use.

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**Danger:** Corrosive. Causes irreversible eye damage. Harmful if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin or clothing. Avoid breathing dust. Wear rubber gloves and safety glasses or face shield when making up solution. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

FIRST AID	
<b>If inhaled</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for treatment advice</li> </ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing</li> <li>• Rinse skin immediately with plenty of water for 15 – 20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice</li> </ul>
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice</li> </ul>
<b>If swallowed</b>	<ul style="list-style-type: none"> <li>• Call poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person</li> </ul>
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
<b>NOTE TO PHYSICIAN</b>	
Probable mucosal damage may contraindicate the use of gastric lavage	

**ACCEPTED**

**FEB - 4 2009**

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this pesticide is registered under EPA Reg. No. 71847-2

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

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 or high level disinfection.

### PREPARATION OF USE SOLUTION:

Add 1 KLOR-KLEEN™ tablet to 1 gallon of water (77°F/25°C) to obtain a concentration of 937ppm (mg/Liter) of available chlorine. This solution should be freshly prepared. Use within day. Keep in a properly labelled container to protect against contamination. Unused solution should be discarded.

KLOR-KLEEN™ is a Hospital Use Disinfectant at 1 tablet per gallon.

### Disinfection/\*Virucidal Directions:

Apply use solution to precleaned, hard, nonporous, inanimate surfaces with brush, spray device, sponge, cloth or mop to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove product by wiping with brush, sponge, or cloth. For sprayer applications use a coarse spray device. Spray 6-8 inches from surface, rub with brush, sponge, or cloth. Do not breathe spray mist.

Before using this product, food products and packaging materials must be removed from the room or carefully protected. After use, all surfaces in the area must be thoroughly rinsed with potable water.

Prepare a fresh solution daily or when use dilution becomes diluted or soiled.

Effective as a tuberculocide in 10 minutes at 20°C against *Mycobacterium bovis* - BCG

**\* Kills HIV-1 on PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

### SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

**PERSONAL PROTECTION:** Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, or eye coverings.

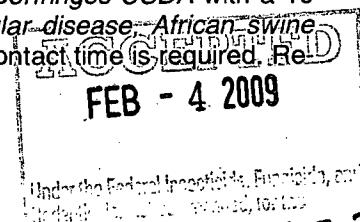
**CLEANING PROCEDURE:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of KLOR-KLEEN™. This pre-cleaning may be accomplished with any cleaning solution including KLOR-KLEEN™.

**DISPOSAL OF INFECTIOUS MATERIALS:** Blood and other body fluids should be autoclaved and disposed of according to Federal, state and local regulations for infectious waste disposal.

**CONTACT TIME:** Leave surfaces wet for 10 minutes.

### ANIMAL PATHOGENS:

When used at one tablet per gallon of water, applied as outlined under Disinfection/Virucidal Directions, Klor-Kleen is effective against the following animal pathogens: *Feline Calicivirus*, *Norovirus*, *Canine Distemper virus*, *Infectious Canine hepatitis*, *Teschen/Talfan disease*, *Avian influenza*, *Porcine parvovirus*, *Runting & Stunging virus (tenosynovitis)*, *Actinobacillus pleuropneumoniae*, *Bordetella bronchiseptica (rhinitis)*, *Brachyspira (Treponema/Serpuline) hyodysenteriae (swine dysentery)*, *Gumboro disease*, *Streptococcus uberis*, *Streptococcus dysgalactiae*, and *Clostridium perfringens* USDA with a 10 minute contact time. For *Transmissible gastroenteritis (TGE)*, *Swine Vesicular disease - African swine fever*, *Hog cholera/Classical swine fever*, and *Avipox (fowl pox)*, a 30 minute contact time is required. Re-apply product as necessary to ensure surface remains wet.



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### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

**Pesticide Storage:** Store in a cool, dry, well-ventilated area. Do not store at temperatures above 104°F (40°C).

**Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on-site, in a toilet, or service sink served by a sanitary sewer or an approved waste disposal facility for pesticides.

**Container Disposal, If empty:** Do not reuse or refill empty container. Rinse empty container thoroughly with water to dissolve all material before discarding. Offer for recycling, if available or securely wrap container in several layers of newspaper and discard in trash.

**Container Disposal, If partly filled:** Call your local solid waste agency [or toll free number or website which meets the criteria in paragraph II.E.] for disposal instructions. Never place unused product down any indoor or outdoor drain.

Manufactured by:

**Medentech Ltd.**

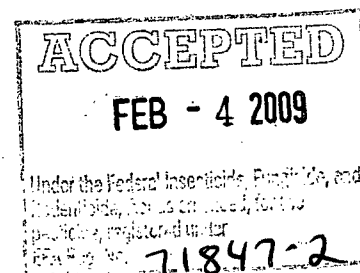
Whitemill Industrial Estate, Clonard Road  
Wexford, Ireland  
Tel: 353 53 60040 Fax: 353 53 41271

EPA Reg. No. 71847-2

EPA Est. No. 71847-IRL-001

NET CONTENTS:

BATCH NO:



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**[Klor-Kleen Claimed Pathogen/Organisms based on submitted data:** *Salmonella enterica* (ATCC 10708), *Staphylococcus aureus*, (ATCC 6538), *Pseudomonas aeruginosa*, (ATCC 15442), *Klebsiella pneumoniae*, (ATCC 4352), *Staphylococcus epidermidis*, (ATCC 51624), *Escherichia coli* O157:H7, (ATCC 35150), *Staphylococcus aureus - MRSA & GRSA*, (ATCC 33592), *Mycobacterium bovis* – BCG, (ATCC 19015), *Poliovirus* type 1, (ATCC VR-1000), *Herpes simplex virus* type 1, (ATCC VR-733), *Hepatitis A virus*, (ATCC VR –1541), *Human Immunodeficiency Virus* Type 1 (associated with AIDS) or (AIDS Virus), (ATCC VRMC-39), *Canine Parvovirus*, (ATCC VR-2017), *Newcastle Disease virus*, (ATCC VR-108), *Pseudorabies*, (ATCC VR-135), *Canine Distemper Virus*, (ATCC VR-128), *Feline Calicivirus*, (ATCC VR-652), *Norovirus*<sup>1</sup> (Claim based on Feline Calicivirus tested as surrogate.), *Enterococcus faecalis* Vancomycin Resistant, (ATCC 51299), *Trichophyton mentagrophytes*, (ATCC 9533)]

**[Klor-Kleen Claimed Animal Pathogen/Organisms added by Notification<sup>2</sup>:** *Infectious Canine hepatitis*, (ATCC VR-293), *Teschen/Talfan disease*, (ATCC VR-669), *Avian influenza*, (ATCC VR-1608), *Porcine parvovirus*, (ATCC VR-742), *Runting virus*, (ATCC VR-2449), *Stunging [Stunting] virus (tenosynovitis)*, (ATCC VR-21), *Actinobacillus pleuropneumoniae*, (ATCC 27088), *Bordetella bronchiseptica (rhinitis)*, (ATCC 19), *Brachyspira (Treponema/Serpuline) hyodysenteriae (swine dysentery)*, (ATCC 27164<sup>T</sup>), *Gumboro disease*, (ATCC VR-478), *Streptococcus uberis*, (ATCC 9927), *Streptococcus dysgalactiae*, (ATCC 6644), *Clostridium perfringens (perfringens) USDA*, (ATCC 3624), *Transmissible (Transmissible) gastroenteritis (TGE)*, (ATCC VR-743), *Swine Vesicular disease*, (ATCC VR-158), *African swine fever*<sup>1</sup> (ASFV) vectored by *Ornithodoros moubata porcinus*, *Hog cholera/Classical swine fever*<sup>1</sup>, *Avipox (fowl pox)*<sup>1</sup>]

[<sup>1</sup>ATCC Number not identified or not found in the ATCC.org website database.]

[<sup>2</sup> Because the actual data was not available since the names were added by notification, the animal pathogen ATCC numbers in this paragraph represent the type species (lowest ATCC number) taken from the ATCC.org website database.]

