

71847-2

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



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

July 29, 2008

Timothy H. Dickens, Ph.D.  
Scientific Coordination, Inc.  
4629 Cherry Valley Drive  
Rockville, MD 20853

Subject: Medentech Ltd.  
Klor-Kleen  
EPA Registration No. 71847-2  
Submission Dated: March 27, 2008  
Receipt Date: March 27, 2008

Dear Dr. Dickens:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with conditions.

The proposed label claims that this product, is an effective disinfectant and virucide against **Feline Calicivirus and Norovirus** at a one tablet of product per gallon of water dilution with a contact time of 10 minutes on hard, non-porous surfaces. These claims are acceptable as they are supported by the submitted data.

**Conditions**

1. The proposed label claims that the product is effective against "**Salmonella choleraesuis**." The ATCC has changed the nomenclature of this organism to "**Salmonella enterica**." The label must be revised to reflect the change and "Salmonella" must be italicized.
2. The proposed label claims that this product is effective against "**Clostridium difficile**." This claim was previously accepted, however at the time the product was evaluated against the vegetative form of the organism. The Agency changed that policy due to the potential public health risk. This claim must be removed until testing is conducted against "**C. diffilce spores**" using an Agency-approved testing method.

3. The ATCC numbers are not listed for any of the organisms on the proposed label. The ATCC numbers must be listed for all organisms appearing on the product label (see ATCC Letter, soon to be posted online). The applicant may choose to list ATCC numbers for the tested organisms in one of the following locations:

- a. On the Data Matrix, or
- b. On the master label (as optional text) with the listing of the organisms claimed, or
- c. As the final page of the master label (as optional text)

4. Revise the Ingredient Statement as follows:

<b>Active Ingredient:</b>	
Sodium Dichloroisocyanurate . . . . .	48.21%
<b>Other Ingredients.</b> . . . . .	<u>51.79%</u>
Total . . . . .	100.00%

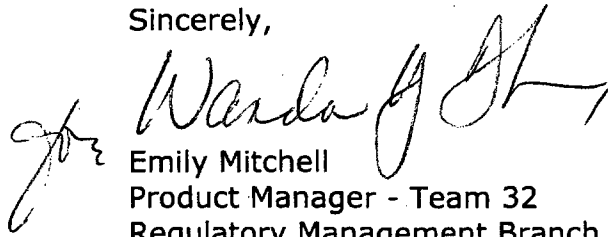
5. The statement "Amendment Final Label" has been removed from all the pages of the label. The final printed label will require changes to meet the conditions set forth in this letter.

**General Comments**

A stamped copy of the labeling accepted with conditions is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Wanda Henson at (703) 308-6345.

Sincerely,



Emily Mitchell  
 Product Manager - Team 32  
 Regulatory Management Branch II  
 Antimicrobials Division (7510P)

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# KLOR-KLEEN™

Effervescent Disinfectant Tablets for Hospitals and Institutional Use.

**ACTIVE INGREDIENT:**

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

**INERT INGREDIENTS:** ..... **51.79%**

**TOTAL** ..... **100.0%**

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER**  
See First Aid /Statement of Practical Treatment on back panel.

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

KLOR-KLEEN™ is effective against the following microorganisms on pre-cleaned, hard, nonporous, inanimate surfaces: *Salmonella*, ~~*Shigella*~~, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Staphylococcus epidermidis*, *Escherichia coli* O157:H7, *Staphylococcus aureus* - MRSA & GRSA, ~~*Clostridium difficile*~~, *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*

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

JUL 29 2008

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

71847-2

Manufactured by:

**Medentech Ltd.**

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

E.P.A. Reg. No. 71847-2

E.P.A. Est. No. 71847-IRL-001

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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.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage	

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## 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 (25°C/77°F) 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.

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

**PESTICIDE DISPOSAL** – Do not contaminate water, food or feed by storage or 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** – Do not reuse empty container. Rinse empty container thoroughly with water to dissolve all material before discarding. Securely wrap container in several layers of newspaper and discard in trash.