

71847-2

11/29/2005

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 29 2005

Ms. Berma L. Johnson  
Medentech, Ltd.  
P.O. Box 270  
Indianapolis, IN 46206

Subject: Klor Kleen™  
EPA Registration Number 71847-2  
Application Date: 8/11/05  
Receipt Date: 8/19/05

Dear Ms. Johnson:

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

- To add *Enterococcus faecalis*, Vancomycin Resistant, and *Trichophyton mentagrophytes* claims to your label

**Conditions**

Revise the label as follows:

- The proposed label lists floors as the only example of surfaces, objects, or items on which the product may be used. You may expand the list of use surfaces.
- There were no data submitted to support animal pathogens. Until acceptable efficacy data is received by the Agency, all references to the animal pathogens listed on the label must be deleted.
- Make the following changes:
  - On page 1, change "Escherichia coli 0157.H7" to read *Escherichia coli* O157:H7" (i.e, change the zero preceding 157 to the capital letter "O").
  - In the "If haled" section, change "gresh air" to read "fresh air".
  - In the "If haled" section, remove the semicolon between "911" and "or an ambulance."

CONCURRENCES

SYMBOL	75100	75100					
SURNAME		Estrella					
DATE	11/29/05	11/28/05					

- In the "Disinfection/Virucidal Directions" section, change "too remain wet" to read "to remain wet".
- In the "Disinfection/Virucidal Directions" section, add a description of how the use solution is to be applied to surfaces (e.g., "by sponge, mop, or spray"), and follow this description with a statement such as "to wet all surfaces thoroughly."
- In the "Disinfection/Virucidal Directions" section, delete "For heavily soiled areas, a preliminary cleaning is required." This sentence is not necessary, as all surfaces must be pre-cleaned prior to disinfecting.
- In the "Disinfection/Virucidal Directions" section, delete "Add 1 tablet per gallon of water to disinfect hard, non-porous surfaces. Treated surfaces must remain wet for 10 minutes." This text is repetitive and does not specify that surfaces should be pre-cleaned before disinfecting.

**General Comments**

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies 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 Delores Williams at (703) 308-6372.

Sincerely,

Emily H. Mitchell  
Product Manager 32  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

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# KLOR-KLEEN™

Effervescent Disinfectant Tablets for Hospitals and Institutional Use.

<b>ACTIVE INGREDIENT:</b>	
Sodium Dichloroisocyanurate .....	48.21%
<b>INERT INGREDIENTS:</b> .....	<u>51.79%</u>
<b>TOTAL</b> .....	100.00%

<p><b>KEEP OUT OF REACH OF CHILDREN</b></p> <p><b>DANGER</b></p> <p>See First Aid / Statement of Practical Treatment on back panel</p>
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ACCEPTED  
with COMMENTS  
EPA Letter Dated:

NOV 29 2005

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

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

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**KLOR-KLEEN** is effective against the following micro-organisms on precleaned, hard, nonporous, inanimate surfaces: *Salmonella choleraesuis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Staphylococcus epidermidis*, *Escherichia coli* 0157: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*, *Enterococcus faecalis* Vancomycin Resistant, *Trichophyton mentagrophytes*

Manufactured by:

**Medentech Ltd.**

Whitemill Industrial Estate, Clonard Road  
Wexford, Ireland

Tel: 353 53 60040 Fax: 353 53 41272

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 pre-cleaned, 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 pre-cleaned, 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

- IF INHALED:**
- Move person to fresh air.
  - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
  - Call a poison control center or doctor for treatment advice.

- IF ON SKIN OR CLOTHING:**
- 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.

- 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 eye.
  - Call a poison control center or doctor for treatment advice.

- IF SWALLOWED:**
- Call 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 the poison control center or doctor.
  - Do not give anything by mouth to an unconscious person.

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 937 ppm (mg/Litre) of available chlorine. This solution should be freshly prepared. Use within day. Keep in a properly labeled 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, non-porous, inanimate surfaces. Allow to remain wet for 10 minutes, then remove product by wiping with brush, sponge, or cloth. For heavily soiled areas, a preliminary cleaning is required. 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.

Add 1 tablet per gallon of water to disinfect hard, non-porous surfaces. Treated surfaces must remain wet for 10 minutes. 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:

[REDACTED SECTION]

### 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

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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.