

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

December 30, 2004

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

Subject: KLOR-KLEEN  
EPA Registration No. 71847-2  
Application Date: December 1, 2004  
Receipt Date: December 3, 2004

Dear Mr. Dickens:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

**Proposed Notification**

- addition of animal pathogens to label

**General Comments**

Based on a review of the material submitted, the following comments apply:

- 1) The notification application is acceptable and a copy has been inserted in your file for future reference.
- 2) It is not Agency policy to stamp labels for changes submitted by notification. In order to obtain a stamped label, you must submit these changes as an Application for Amended Registration.

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

Sincerely,

Wanda Y. Mitchell  
Product Reviewer (32)  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

**CONCURRENCES**

SYMBOL	7510C	7510C						
SURNAME	E. Berg							
DATE	12/30/04							

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**Scientific Coordination, Inc.**

*Helping Technology Transfer*

4629 Cherry Valley Drive

Rockville, MD 20853

December 1, 2004

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
1801 South Bell St.  
Arlington, VA 22202-4501

Subject: KLOR-KLEEN™  
EPA Reg. No. 71847-2  
NOTIFICATION

Dear Sir or Madam:

By notification, our Client, Medentech Ltd. is adding animal pathogens to their label in accordance with Section II.B of PR Notice 98-10. Further, our Client does not believe that efficacy data is required as the proposed microorganisms listed on the enclosed draft label are solely pathogenic to animals (DIS/TSS-16).

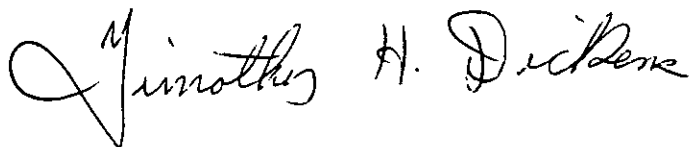
Enclosed, please find the following:

- 1. Application for Pesticide (Other), EPA Form 8570-1
- 2. One copy of a draft label as a reference illustrating all label revisions.
- 3. Two copies of the final label.

We would appreciate receiving a copy of the label stamped approved –notification.

If you have any questions or comments regarding this submission, please do not hesitate to contact me at (301) 570-4390 or by e-mail at dickensth@aol.com.

Sincerely,



Timothy H. Dickens, Ph.D.

Registered Agent

Encl./as listed

**NOTIFICATION**

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95 3/7



United States  
**Environmental Protection Agency**  
 - Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 71847 - 2	2. EPA Product Manager Emily H. Mitchell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Klor-Kleen™	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Medentech Ltd., c/o Scientific Coordination, Inc. 4629 Cherry Valley Drive Rockville, MD 20853 <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

**Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter July 18, 2003	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)  
 "Notification to add animal pathogens in accordance with Section II.B of PR Notice 98-10." "This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted		If "Yes" Unit Packaging wgt. 3.7 kg	No. per container 300 tabs	Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 4 Liter Capacity		5. Location of Label Directions <input checked="" type="checkbox"/> On Labeling Accompanying Product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Timothy H. Dickens, Ph.D.	Title Registered Agent	Telephone No. (Include Area Code) (301) 570 4390
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**Certification**  
 I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature <i>Timothy H. Dickens</i>	3. Title Registered Agent	6. Date Application Received  (Stamped)
4. Typed Name Timothy H. Dickens, Ph.D.	5. Date December 01, 2004	

# 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 937ppm disinfectant solution  
when dissolved in one gallon of water.**

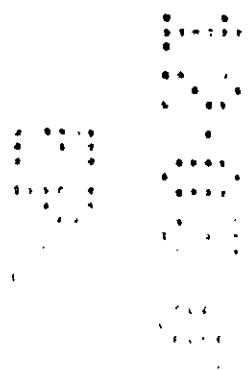
**KLOR-KLEEN™** is effective against the following microorganisms on precleaned, hard, nonporous, inanimate surfaces: *Salmonella choleraesuis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Staphylococcus epidermidis*, *Escherichia coli* O157:H7, *Staphylococcus aureus* - 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*,

Underlined denotes new verbiage.

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

NET CONTENTS

BATCH NO

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**KLOR-KLEEN™** is designed to provide effective cleaning, deodorizing and disinfection in areas where it is of prime importance to control 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 further 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>
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-xxx-xxx for emergency medical treatment information.	
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. 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:

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: *Infectious Canine hepatitis, Gumboro disease, Transmissible gastroenteritis (TGE), Swine Vesicular disease, Teschen/Talfan disease, African swine fever, Avian influenza, Porcine parvovirus, Hog cholera/Classical swine fever, Avipox (fowl pox), Runtig & Stunting virus (tenosynovitis), Actinobacillus pleuropneumonia, Bordetella bronchiseptica (rhinitis), Brachispira (Treponema/Serpulina) hyodysenteriae (swine dysentery), Streptococcus uberis, Streptococcus dysgalactiae, Clostridium perfringens USDA.*

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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.