



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue, NW
Washington, D.C. 20004

EPA Reg. Number:

Date of Issuance:

71847-2

APR 20 2004

Term of Issuance:

Conditional

Name of Pesticide Product:

Klor Kleen™

NOTICE OF PESTICIDE:

Reregistration
 Registration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Medentech, Ltd.
Scientific Coordination, Inc.
4629 Cherry Valley Drive
Rockville, MD 20853

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following label changes:

- a. Revise the EPA Registration Number to read, "EPA Reg. No. 71847-2."
- b. In the "Ingredient" statement delete the "s" on Active Ingredients.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

Date:

Emily H. Mitchell
Emily H. Mitchell, Acting Product Manager

04/20/04

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KLOR-KLEEN™

Effervescent Disinfectant Tablets for Hospitals and Institutional Use.

ACTIVE INGREDIENTS:

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*,

**ACCEPTED
with COMMENTS
EPA Letter Dated:**

APR 20 2004

Manufactured by:

Medentech Ltd.

Whitemill Industrial Estate, Clonard Road,
Wexford, Ireland

Tel: 353 53 60040 Fax: 353 53 41271

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

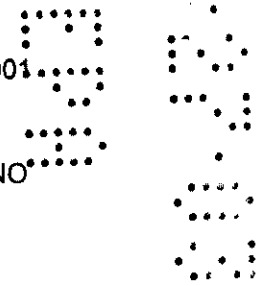
71847-2

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

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	
If inhaled	<ul style="list-style-type: none"> • 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 centre or doctor for further treatment advice
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing • Rinse skin immediately with plenty of water for 15 – 20 minutes. • Call a poison control centre or doctor for treatment advice
If in eyes	<ul style="list-style-type: none"> • 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 centre or doctor for treatment advice
If swallowed	<ul style="list-style-type: none"> • 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 centre or doctor. • Do not give anything by mouth to an unconscious person
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	

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/Litre) 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.

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.