

71847-6

2/27/2012

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U.S. ENVIRONMENTAL PROTECTION  
AGENCY

Office of Pesticide Programs  
Antimicrobials Division (7510-P)  
1200 Pennsylvania Avenue N.W.  
Washington, D.C. 20460

NOTICE OF PESTICIDE:

Registration  
 Reregistration

(under FIFRA, as amended)

EPA Reg.

Number:

71847-6

Date of

Issuance:

Feb. 27, 2012

Term of Issuance: Unconditional

Name of Pesticide Product:

**Klorsept**

Name and Address of Registrant (include ZIP Code):

Medentech Ltd.  
c/o Clearon Corporation  
95 Maccorkle Ave., S.W.  
Charleston, WV. 25303

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 (OPP Decision No. D-457302) is unconditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration 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 re-registration of your product under FIFRA section 4.
2. Change EPA File Symbol 71847-A to EPA Registration Number 71847-6.
3. Delete the DIS/TSS references, an editing error, on page 3.

Submit two copies of the finished final printed label prior to releasing this product for sale.

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 unconditionally approved label is enclosed for your records.

Signature of Approving Official:

Monisha Harris  
Product Manager 32  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Date:

February 27, 2012



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{All text in brackets [xxx] is optional and may or may not be intended on a final label}  
{All text in braces {xxx} is administrative and will not appear on a final label}

# KLORSEPT

{Optional marketing statements. One or more statements may be used}

Effervescent Disinfectant Tablets for Hospitals and Institutional Use.

[KLORSEPT is effective against the following micro-organisms on pre-cleaned, hard, nonporous, inanimate surfaces: *Salmonella enterica*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Staphylococcus epidermidis*, *Escherichia coli O157:H7*, *Staphylococcus aureus* – MRSA & GRSA, *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*].

[KLORSEPT is designed to provide effective cleaning, 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.]

[KLORSEPT 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.]

[KLORSEPT is a disinfectant and cleaner that disinfects and cleans pre-cleaned, hard, non porous, inanimate surfaces. This pre-cleaning may be accomplished with any cleaner solution including KLORSEPT.]

[KLORSEPT provides effective cleaning strength that will not dull high gloss floors finishes with repeated use.]

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

ACCP

FEB 27 2012

**ACTIVE INGREDIENT:**

Sodium dichloro-s-triazinetrione ...48.21%

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

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

71847-6

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

**First Aid**

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.

IF INHALED:

- Move person to Fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably 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.

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.



3044

**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, and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

**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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

**PREPARATION OF USE SOLUTION:**

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

KLOORSEPT is a Hospital Use Disinfectant at 1 tablet per gallon.

**Disinfection\*/Virucidal Directions:**

Apply use solution to pre-cleaned, hard, non-porous, 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.

\*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, and eye coverings.

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

**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, KLOORSEPT 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.

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION IN ANIMAL HOUSING FACILITIES:**

1. Remove all animals and feed from premises, vehicles, and enclosures.
2. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.

71847-6



- 3. Empty all troughs, racks, and other feeding and watering appliances.
- 4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5. Saturate all surfaces with 937 ppm available chlorine disinfecting solution for a period of 10 minutes
- 6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
- 7. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried.
- 8. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse. ~~DIS/TSS-18 17 Jan. 80-DIS/TSS-18~~

*delete*

**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 40°C/104°F.

**PESTICIDE DISPOSAL:** Pesticide may be acutely hazardous. Wastes resulting from the use of this product must be disposed of on-site, or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or puncture and dispose of in a sanitary landfill.

Manufactured by:

**Medentech Ltd.**  
 Whitemill Industrial Estate  
 Clonard Road, Wexford, Ireland  
 Tel: 353 53 60040; Fax: 353 53 41272

EPA. Reg. No. 71847-  
 EPA. Est. No. 71847-IRL-001

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BATCH NO \_\_\_\_\_

ACCEPTED  
 FEB 27 2012

71847-6