

71847-2

5/11/2011

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

MAY 11 2011

Ms. Berma Johnson
Agent for Medentech
P.O. Box 270
Indianapolis, IN 46206

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: Klor-Kleen
EPA Registration No.: 71847-2
Notification Date: 04/18/2011
EPA Receipt Date: 04/25/2011

Dear Ms. Berma Johnson,

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

Proposed Notification

- Update of Container Disposal statements

General Comments

Based on a review of the submitted materials, your notification for the updated Container Disposal statements is acceptable and has been made a part of the records on file.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6345 or by e-mail at henson.wanda@epa.gov or Jaclyn Carl by telephone at (703) 347-0213 or by e-mail at carl.jaclyn@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to be "Wanda Henson".

Wanda Henson
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 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 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 Berma L. Johnson, Brulin & Company, Inc. P.O. Box 270, Indianapolis, IN 46206 <input 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 dated _____	<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 of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that if the amended label is not consistent with the requirements of 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156, 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:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging - wgt. No. per container	If "Yes" Package wgt No. per container

3. Location of Net Contents Information
 Label Container

4. Size(s) Retail Container

5. Location of Label Directions
 On Label
 On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
 Lithograph
 Paper glued
 Stenciled Other _____

Section - IV

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

Name Berma L. Johnson	Title Agent for Medentech	Telephone No. (Include Area Code) 317 923-3211
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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 	3. Title Agent for Medentech	6. Date Application Received (Stamped)
4. Typed Name Berma L. Johnson	5. Date 18 April 2011	

KLOR-KLEEN™

Effervescent Disinfectant Tablets for Hospitals and Institutional Use.

KLOR-KLEEN is effective against the following micro-organisms on precleaned, hard, nonporous, inanimate surfaces: *Salmonella enterica*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Staphylococcus epidermidis*, *Escherichia coli* O157:H7, *Staphylococcus aureus* – MRSA & GRSA, *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*

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

<p>KEEP OUT OF REACH OF CHILDREN</p> <p>DANGER</p> <p>See First Aid / Statement of Practical Treatment on back panel</p>
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Each tablet will produce a 937 ppm disinfectant solution when dissolved in one gallon of water.

NOTIFICATION
 Date Reviewed: 5/11/2011
 Reviewed By: WTP/na

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

NET CONTENTS

BATCH NO

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.

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 (77°F/25°C) 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 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, 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.

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 (tenoysynovitis)*, *Actinobacillus pleuropneumoniae*, *Bordetella bronchiseptica (rhinitis)*, *Brachyspira (Treponema/Serpuline) hyodysenteriae (swine dysentery)*, *Gumboro disease*, *Streptococcus uberis*, *Streptococcus dysgalactiae*, and *Clostridium perfringes* 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.

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 – 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.

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CONTAINER DISPOSAL – Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling, if available, or puncture and dispose in a sanitary landfill, or by other procedures approved by state and local authorities.

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