

71847-6

05/21/2013

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

May 21, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Julia Ownbey
Medentech
c/o Manager, Regulatory Affairs
95 MacCorkle Ave, SW
S. Charleston, WV 25303

Subject: PRIA (D-473519)
Klorsept
EPA Registration No. 71847-6
Application Dated: October 19, 2012
Receipt Dated: December 31, 2012

Dear Ms. Ownbey:

This acknowledges the receipt of your Amendment application dated October 19, 2012 in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended is **acceptable**.

Submission and Proposed Changes

Amend the label and submit supporting efficacy data for disinfecting *Clostridium difficile* and its spores. In addition as a disinfectant against *Staphylococcus aureus*, *Salmonella enterica*, *Pseudomonas aeruginosa* for a ten minute contact time at 21°C, Swine Influenza Virus (H1N1) for a 10 minute contact time at 20°C in the presence of organic soil (5% serum). The original label was dated on November 19, 2012 (pin punch 12/31/12), was updated on May 14, 2013 (pin punch 03/14/13).

Comments and Conditions:

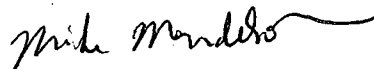
Based on the efficacy studies submitted (including amendment dated May 8, 2013) and the latest amended label dated May 14, 2013 (pin punch 05/14/13) is **acceptable**.

A stamped copy of the label is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

This amendment and a copy of this letter have been inserted in your file for future reference.

If you have any questions or comments concerning this letter, please contact David Liem at liem.david@epa.gov or call (703) 305-1284.

Sincerely,



Mike Mendelsohn
Acting Product Manager - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

Att: Accepted Stamp label

{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

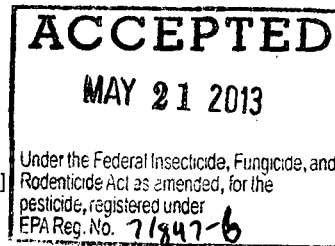
{Alternate product names:}
[Clearon Bleach Tablets]
[Klorsept Bleach Tablets]
[Agrisept]

[Effervescent Disinfectant Tablets for Hospitals and Institutional Use.]

{Healthcare Optional marketing statements. One or more statements may be combined.}
[For use in Cleaning and Disinfection in amusement parks, breweries, beverage and food processing plants,
[schools], [hospitals], [nursing homes], [child care centers], [daycares], [restaurants], [veterinary clinics], [zoos
and aquariums], [milk processing facilities], [dairy farms], [farms], [poultry premises] [poultry housing], [poultry
hatcheries], and [livestock quarters], [industrial facilities.] [kennels], [boarding facilities], [laboratories], [lab animal
facilities], [licensed care facilities].
[Easy],[Convenient], [accurate measurement]
[Helps infection control by quickly acting against a wide spectrum of micro-organisms.]
[Effective against clostridium difficile spores]
[Kill germs]
[Broad spectrum disinfectant.]

{Household Optional marketing statements. One or more statements may be combined.}
[For use in Cleaning and Disinfection in amusement parks, [schools], [hotels], [restaurants], [spas, hot tubs,]
[salons], [dairy farms], [farms], [office buildings], [industrial facilities.] [homes], [camp sites], [marine] and
[recreational vehicles], [R/V holding tanks].

[Disinfectant, Cleanser]
[Protects Against Odor]
[Eliminates and [&] Controls Odors]
[Controls Bacteria and Algae]
[Multi-purpose effervescent tablets]
[Disinfects and protects against odor]
[Disinfects]
[Convenient accurate measurement]
[Disinfects [precleaned, hard, nonporous surfaces] in 10 minutes.]
[Effective against, Staphylococcus aureus, Salmonella enterica
(formerly choleraesuis) [in 10 minutes]
[Kills 99.999% of bacteria]
[Value pack]
[Value size]
[Club pack]
[Club size]
[Scratch Free]
[Bleaches out tough stains]
[Disinfects]
[Disinfects while you clean]
[Kills Household Germs*] [* Staphylococcus aureus, Salmonella enterica, H1N1 Influenza]
[Kills Germs*][* Staphylococcus aureus, Salmonella enterica, H1N1 Influenza]
[Wipes out / Mops out most household germs including Staphylococcus aureus, Salmonella enterica, and
Pseudomonas aeruginosa.]
[For Laundry Use]
[Low temperature bleach]
[Deodorizer]
[Destainer]
[Stain Remover]
[Low temperature destainer]
[No splatter, no mess, completely splash-less!]
[No need to use liquid bleach again]
[Concentrated for whiter laundry and cleaner surfaces]
[1 tablet = 1 cup of liquid bleach]
[This product, a broad spectrum disinfectant, contains 48.21% of sodium dichloroisocyanurate per tablet. This is
equivalent to 29% of available chlorine.]
{Images: Washing machine, Floor, Sink, Stove, Toilet, Bathtub, Shower, Countertop}
[New!] {To be used for 6 months after the product is released to the market.}



Vertical column of small 'c' characters on the right side of the page.

[HEALTHCARE (marketing statements)
[This product] {or marketed product name} [is effective against the following micro-organisms on precleaned,

& 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, Clostridium difficile.

[This product] {or marketed product name} [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.]

[This product] {or marketed product name} [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.]

[GENERAL CLAIMS (marketing statements)

[This product] {or marketed product name} [is a disinfectant that disinfects pre-cleaned, hard, non porous, inanimate surfaces. This pre-cleaning may be accomplished with any cleaner solution including [This product] {or marketed product name}]

[This product] {or marketed product name} [provides effective cleaning strength that will not dull high gloss floors finishes with repeated use.]]

**KEEP OUT OF REACH OF CHILDREN
DANGER**

ACTIVE INGREDIENT:

Sodium dichloro-s-triazinetrione.....48.21%

OTHER INGREDIENTS:51.79%

TOTAL:100.00%

Refer to dilution chart for Available Chlorine concentrations.

FIRST AID	
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 center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none"> • Call a 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	<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 center 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 center or doctor for treatment advice.
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p> <p>YOU MAY ALSO CONTACT [1-800-420-9236] FOR EMERGENCY MEDICAL TREATMENT INFORMATION.</p>	
<p>NOTE TO PHYSICIAN</p> <p>Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

**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 chemical-resistant 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 and wash contaminated clothing before reuse.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label and use strictly in accordance with precautionary statements and directions.

{Number 1 alternate disinfection application.}

[HEALTHCARE DISINFECTION]

[This product {marketed product name} is a Hospital Use Disinfectant at 479ppm, 958ppm or 1988ppm available chlorine disinfectant solution.]

[Notice to User: 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 blood stream 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.]

[GENERAL DISINFECTION]

Add 1 tablet to 1 gallon of water {optional statement to be used only for 6.55g tablet}. [Prepare a 479ppm solution {(refer to Dilution Chart)}. Clean surface then apply solution with mop, cloth, sponge, brush, foaming equipment or coarse trigger sprayer. Allow surface to remain wet for 10 minutes. Wipe with a brush, sponge or cloth and allow to air dry. Prepare a fresh solution daily or when it becomes soiled or diluted. All treated equipment that will contact food, feed, or drinking water must be rinsed with potable water before reuse.]

{Number 2 alternate disinfection application.}

[DISINFECTION FOR SURFACES CONTAMINATED WITH HIV] [AND] [OTHER VIRUSES] [AND] [ANIMAL HOUSING FACILITIES]

[PREPARATION OF USE SOLUTION:

Add 2 tablets to 1 gallon of water (77°F/25°C) to obtain a concentration of 958ppm (mg/L) of available chlorine {optional statement to be used only for 6.55g tablet}. Prepare a 958ppm solution {(refer to Dilution Chart)}. This solution must be freshly prepared. Use within day. Keep in a properly labeled container to protect against contamination. Unused solution must be discarded.]

{Number 3 alternate disinfection application.}

[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, and 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 {marketed product name}. This pre-cleaning may be accomplished with any cleaning solution including {marketed product name}.

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.]

{Number 4 alternate disinfection application.}

[ANIMAL PATHOGENS:

When used at 958ppm solution, applied as outlined under Disinfection/Virucidal Directions, {marketed product

name} is effective against the following animal pathogens: *Feline Calicivirus, Norovirus, Canine Distemper virus, Infectious Canine hepatitis, Teschen/Talfan disease, Avian influenza, Porcine parvovirus, Runtig & Stunting 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.
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 958 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.]

{Number 5 alternate disinfection application.}

[DISINFECTION FOR SURFACES CONTAMINATED WITH CLOSTRIDIUM DIFICILE]

[Add 4 tablets to 1 gallon of water {optional statement to be used only for 6.55g tablet}.] [Prepare a 1988ppm solution {(refer to Dilution Chart)}. Clean surface then apply solution with mop, cloth, sponge, brush, foaming equipment or coarse trigger sprayer. Allow surface to remain wet for 10 minutes. Wipe with a brush, sponge or cloth and allow to air dry. Prepare a fresh solution daily or when it becomes soiled or diluted. All treated equipment that will contact food, feed, or drinking water must be rinsed with potable water before reuse.]

{Number 6 alternate disinfection application.}

[HOUSEHOLD DISINFECTION]

[Disinfects floors, walls and other hard nonporous surfaces including walls, floors, tables, chairs, countertops, bathroom fixtures, sinks, shelves, racks, carts, refrigerators, coolers, glazed tile, linoleum, vinyl, glazed porcelain plastic (such as polypropylene and polyethylene), stainless steel, or glass.]

[Where to Use]

[This product {or marketed product name} is [are] a concentrated multi-purpose bleach tablet that can be used everyday around the house to remove stains, clean and deodorize. Use it [them] in washing machines, toilets, on floors, on tiles, in bathtubs, in showers, in kitchen sinks and garbage cans [and laundry washers {washing machines}].]

[How to Use]

[Toilets: To clean and deodorize, add 1 TABLET into the toilet bowl. The tablet will fizz and dissolve, then use brush to clean. Flush toilet before use. {Toilet application to be used only for 5g tablet}.]

[Laundry: For white and colorfast bleaching. HE Machines: Regular Load: add 1 TABLET to detergent dispenser. Close dispenser and start wash cycle. Standard Machines: Regular Load: Begin filling the washer with water. Add 1 TABLET into the water. Allow to dissolve for 1-2 minutes. Place clothes in washer and start wash cycle. For extra whitening power use 2 TABLETS per regular load.

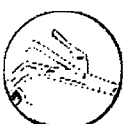
For extra large loads or heavily soiled clothing use 3 TABLETS.

Deodorizing Washers: Once weekly or as needed run the washer on a cold wash program with no laundry and 2 tablets in detergent dispenser or washer. {Laundry application to be used only for 5g tablet}.]

[Floors, Tiles, Bathtubs, Showers, Kitchen Sinks, Garbage Cans: To clean, deodorize and remove mildew stains add 1 TABLET to 1 gallon of water. For heavily soiled areas use 2 TABLETS. Mop or wipe with bleach solution. Allow solution to contact surface for 5-10 minutes. Rinse well and air dry. Use gloves for prolonged use.]

{Application to be used only for 5g tablet}.]

ICONS USED FOR KLORSEPT
MASTER LABEL (71847-6)



Braille characters consisting of groups of six dots, arranged in a grid-like pattern.