

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 8, 2015

J. Michael Kelley, Ph.D. Authorized Agent Medentech Ltd. Whitemill Industrial Estate Clonard Road, Wexford Ireland

Subject: Notification per PRN 98-10 – To change "visibly clean" to "pre-cleaned" Product Name: Klorsept EPA Registration Number: 71847-6 Application Date: February 9, 2015 Decision Number: 502433

Dear Dr. Kelley:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, you may contact Wanda Henson at (703) 308-6345 or via email at <u>henson.wanda@epa.gov</u>.

Sincerely,

for Warda

Demson Fuller, Product Manager 32 Regulatory Management Branch II Antimicrobials Division (7510P) Office of Pesticide Programs

{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:} [Klorsept Bleach Tablets] [Agrisept] [Aquatabs Food Service Tablets] [EZ Bleach Disinfectant Tablets] [Septrivet] NOTIFICATION

### 71847-6

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

04/08/2015

{Healthcare} {Institutional} {Industrial} {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], [egg processing plants], [schools], [hospitals], [nursing homes], [child care centers], [daycares], [restaurants], [stores], [shops], [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], [institutions], [catering], [vending machines], [kitchens], [[Intensive Care Unit] [ICU] operating rooms], [dental facilities], [gyms], [health clubs], [restrooms], [and] [commercial laundries].] [Easv]. [Convenient]. [Accurate Measurement] [Helps infection control by quickly acting against a wide spectrum of micro-organisms] [Effective against clostridium difficile spores] [in 4 minutes] [Effective against [hepatitis A] [and] [hepatitis B]] [Kill germs] [Broad spectrum disinfectant] [Strong] [Simple] [Small] [Stable] [Surface Friendly] [Smells Better [than bleach]] [Simple to use] [Small in size] [Stable in solution (as compared to bleach)] [Surface Friendly] [Bleach alternative in effervescent tablet form] [Effective against a broad range of microorganisms] [Single dose tablet delivers accurate strength solution every time, eliminating "measure and pour" guesswork] [Kills C.diff [clostridium difficile spores] in 4 minutes!] [Convenient tablet form that can be used to be used with [dry wipes] [Can be applied [spray] [mop] [wipe], [cloth], [sponge], [ brush], [foaming equipment], [or] [coarse trigger sprayer].] {Household Optional marketing statements. One or more statements may be combined.} [For use in Cleaning and Disinfection in [amusement parks], [schools], [hotels], [restaurants], [pools], [spas], [hot tubs], [salons], [dairy farms], [farms], [office buildings], [industrial facilities], [homes], [camp sites], [pet areas], [kennels], [marine] [and] [recreational vehicles], [R/V holding tanks], [wells], [kitchen], [bath], [floors], [toilets], [laundry], [washing machines], [shower], [garbage cans] [trash cans], [sinks], [disposals], [tubs], [outdoor uses\* include driveway, fences, decks, patio, garage, siding, and patio furniture] [\*DO NOT use directly in pressure washers mix in garden sprayer]] [Disinfectant] [and] [Cleanser] [Sanitizer] [Protects Against Odor] [Eliminates [and] [&] Controls Odors] [Controls Bacteria and Algae] [Multi-purpose effervescent tablets] [Disinfects and protects against odor] [Convenient accurate measurement] [Disinfects [visibly cleaned], [visibly clean] [hard], [nonporous] surfaces in 10 minutes] [Disinfects] [and] [Deodorizes] [your] [washing machine tank] [all washers]

[Disinfects and deodorizes your dishwasher]

[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] [Cleans] [Disinfects while you clean] [Kills Household Germs\*] [\* Staphylococcus aureus, Salmonella enterica, H1N1 Influenza] [Kills Germs\*][\* Staphylococcus aureus, Salmonella enterica, H1N1 Influenza] [Kills 99.999% of Germs\*] [\* Staphylococcus aureus, Salmonella enterica, H1N1 Influenza] [Kills colds and flu\*][\*respiratory syncytial virus and H1N1 Influenza] [Kills 99.9% of viruses and bacteria] [Kills 99.9% of odor causing bacteria] [Wipes out / Mops out most household germs including] [Staphylococcus aureus], [Salmonella enterica], [and] [Pseudomonas aeruginosa] [Cold and Flu viruses\*] [\*respiratory syncytial virus and H1N1 Influenza] [Sustainable] [Less packaging to throw away] [Compact - storage takes up less shelf space] [Never carry around or spill heavy bleach bottles again] [Convenient, multipurpose cleaning - inside and outside your home] [Longer shelf life than liquid bleach] [New technology] [For Laundry Use] [Pet areas] [Low temperature bleach] [For both hot and cold water] [Deodorizer] [Destainer] [Unique fizzy formula] [-] [Unique fizzing tablet dissolves fast and completely] [[Powerful] [Convenient] [Easy to use] Bleach in a convenient tablet form with no mess] [Use anywhere you would use liquid bleach] [Chlorine Bleach in tablet form with no mess] [100% USA made active ingredients][The Clearon fizz] [100% US manufactured active ingredient] [Stain Remover] [Low temperature destainer] [Exclusive Effervescent Formula] [No splatter or spills to ruin your clothes] [Easy-no splatter] [No mess] [Splash-less, no mess] [No need to use liquid bleach again] [Nothing cleans like bleach] [Concentrated for whiter laundry and cleaner surfaces] [For whiter laundry] [1 tablet = 1 cup of liquid bleach] [1 tablet =  $\frac{1}{2}$  cup of concentrated bleach] [1 bottle of bleach tabs = 2 [gallon] [bottles] of [liquid] bleach] [Just 1 tablet for all your laundry and cleaning needs] [Neutral pH] [Removes Mold and Mildew stains] ] [inside & outside your house] [Cleans mold & mildew [in bathrooms] [off of outdoor furniture] [Dissolves in 2 minutes] [Exclusive Effervescent Formula] [Reinvigorate] [Freshen] [your spa] [1 Bottle for all your household needs] [Multipurpose tablet] [10+ Uses] [One tablet per load of laundry] [Less than 20¢ per load] [\*For severe stains use additional tablets] [Stabilized] [Excellent for Pools on Chlorine Generators] [Simplify Cleaning] [Simplify cleaning with the drop of a tablet] [Convenient disinfection] [of your home] [Disinfect and clean with 1 tablet] [Disinfect and deodorize] [your] [toilet] [dishwasher] [HE] [washing machine] [with 1 tablet]

[Disinfect and deodorize your disposal] [Kill germs and bacteria with 1 tablet] [EZ Fizzing Bleach Tablet] [Fast Dissolving] [Reinvigorate your spa] [Freshen your spa] [Cleans and disinfects pet areas] [Pastillas desinfectantes de cloro EZ] [=] [EZ BLEACH DISINFECTANT TABLETS]

[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, mop and bucket, H.E} [New!] (To be used for 6 months after the product is released to the market.)

## [HEALTHCARE] [INSTITUITONAL] [INDUSTRIAL] (marketing statements)]

[Effervescent Disinfectant Tablets for Hospitals and Institutional Use]

[This product] {or marketed product name} [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, Hepatitis B virus, Human Immunodeficiency Virus Type 1 (associated with AIDS) or (AIDS Virus), Influenza virus H1N1, respiratory syncytial virus, *, Canine Parvovirus, Newcastle Disease Virus, Pseudorabies, Canine Distemper Virus, Feline Calicivirus, Norovirus, Enterococcus faecalis Vancomycin Resistant, Trichophyton mentagrophytes, and 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.]
- [[Cosmetic], [pharmaceutical], [and] [medical device] [manufacturing facilities], [biotechnology firms], [pharmacies], [and] [compounding pharmacies].]

## [GENERAL CLAIMS (marketing statements)

[This product] {or marketed product name} [is a disinfectant that disinfects pre-cleaned, hard, non porous, inanimate surfaces. This cleaning process 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.]]

# [KLORSEPT]

## KEEP OUT OF REACH OF CHILDREN DANGER

## ACTIVE INGREDIENT:

Sodium dichloro-s-triazinetrione	1%
OTHER INGREDIENTS:	9%
TOTAL:	0%
Refer to dilution chart for Available Chlorine concentrations.	

FIRST AID					
lf in eyes	<ul> <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>				
If swallowed	<ul> <li>Call a 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>				
lf inhaled	<ul> <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>				
If on skin or clothing	<ul> <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>				
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. YOU MAY ALSO CONTACT [1-800-420-9236] FOR EMERGENCY MEDICAL TREATMENT INFORMATION.					
<b>NOTE TO PHYSICIAN</b> Probable mucosal damage may contraindicate the use of gastric lavage.					

See [back] [side] [inside] panel[s] for additional precautionary statements [and first aid].

## 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. [See additional precautionary and first aid statements inside the label]

## **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. General Healthcare disinfectant (479 ppm available chlorine disinfectant solution) is effective against standard gram positive and gram negative bacteria (staphylococcus aureus, pseudomonas aeruginosa and salmonella enterica) and Cold and flu viruses (respiratory syncytial virus, influenza H1N1

[This product is effective as a Healthcare disinfectant for blood borne viruses and animal care facilities when used at level of 958 ppm available chlorine disinfectant solution. It is effective against HIV, Hepatitis B, Feline Calicivirus, Norovirus, Canine Distemper virus, Infectious Canine hepatitis, Teschen/Talfan disease, Avian influenza, Porcine parvovirus, Runting & Stunting virus (tenosynovitis), Actinobacillus pleuropneumoniae, Bordetella bronchiseptica (rhinitis), Brachyspira (Treponema/Serpulina) 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].

[This product is also effective as a Healthcare disinfectant for critical areas potentially contaminated with C.Diff spores when used at a level of 1988 ppm 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]

[This product {marketed product name} is a general disinfectant at 479 ppm available chlorine disinfectant solution effective against staphylococcus aureus, salmonella enterica, pseudomonas aeruginosa and cold and flu (respiratory syncytial virus, influenza H1N1).]

[Prepare a 479 ppm solution; (refer to Dilution Chart)]. [Add 1 tablet to 1 gallon of water {optional statement to be used only for 6.55g tablet}]. [Add 1 tablet to 1 quart of water {optional statement to be used only for 1.7g tablet}]. [Add 1 tablet to half gallon of water {optional statement to be used only for 3.3g tablet}]. [Add 1 tablet to 2 gallons of water {optional statement to be used only for 13.1g tablet}]. [Apply to pre-cleaned surface with mop, cloth, sponge, brush, wipe, foaming equipment, or coarse trigger sprayer. Allow surface to remain wet for 10 minutes. Allow to air dry. Prepare a fresh solution weekly when using closed containers (spray bottles). Prepare a fresh solution daily when using open containers (buckets) or if solution becomes 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:]

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

*{Number 3 alternate disinfection application.}* 

## [DISINFECTION/VIRUCIDAL DIRECTIONS:

[Prepare a 958 ppm solution; refer to dilution chart]. 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, and rub with brush, sponge, wipe 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. Prepare a fresh solution weekly when using closed containers (spray bottles). Prepare a fresh solution daily when using open containers (buckets) or if solution becomes diluted. All treated equipment that will contact food, feed, or drinking water must be rinsed with potable water before reuse.]

[Kills HIV-1, Hepatitis A, and Hepatitis B viruses on VISIBLY CLEAN ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLYSOILED 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), Hepatitis A virus, and Hepatitis B virus.]

## [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 cleaning process 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 958 ppm 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, Runting & Stunting virus (tenosynovitis), Actinobacillus pleuropneumoniae, Bordetella bronchiseptica (rhinitis), Brachyspira (Treponema/Serpulina) 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 allow to air dry before reuse.]

*{Number 5 alternate disinfection application.}* 

### [DISINFECTION FOR SURFACES CONTAMINATED WITH CLOSTRIDIUM DIFFICILE] [Special Label Instructions for Cleaning Prior to Disinfection against *Clostridium difficile* spores:

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

**Cleaning Procedure**: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the disinfectant product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

**Infectious Materials Disposal:** Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.]

[Prepare a 1988 ppm solution; refer to Dilution Chart)]. [Add 4 tablets to 1 gallon of water {optional statement to be

used only for 6.55g tablet}]. [Add 2 tablets to 1 gallon of water {optional statement to be used only for 13.1g tablet}]. [Add 2 tablets to 1 quart of water {optional statement to be used only for 3.3g tablet}]. Apply to pre-cleaned surface with mop, cloth, sponge, brush, wipe, foaming equipment, or coarse trigger sprayer. Allow surface to remain wet for 10 minutes. Allow to air dry. Prepare a fresh solution weekly when using closed containers (spray bottles). Prepare a fresh solution daily when using open containers (buckets) or if solution becomes 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.}

## [DISINFECTION FOR SURFACES CONTAMINATED WITH CLOSTRIDIUM DIFFICILE IN 4 MINUTES] [Special Label Instructions for Cleaning Prior to Disinfection against *Clostridium difficile* spores:]

[Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.]

**[Cleaning Procedure**: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the disinfectant product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.]

**[Infectious Materials Disposal:** Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.]

[Prepare a 4,311 ppm solution; refer to Dilution Chart.] [Add 9 tablets to 1 gallon of water {optional statement to be used only for 6.55g tablet}]. [Add 9 tablets to 2 gallons of water {optional statement to be used only for 13.1g tablet}]. [Add 9 tablets to 2 gallons of water {optional statement to be used only for 3.3g tablet}]. [Apply to pre-cleaned surface with mop, cloth, sponge, brush, wipe, foaming equipment, or coarse trigger sprayer. Allow surface to remain wet for 4 minutes. Allow to air dry. Prepare a fresh solution weekly when using closed containers (spray bottles). Prepare a fresh solution daily when using open containers (buckets) or if solution becomes diluted. All treated equipment that will contact food, feed, or drinking water must be rinsed with potable water before reuse.]

#### {Number 7 alternate disinfection application.}

## [To Pre-clean Instruments Prior to Terminal Sterilization/High Level Disinfection

[Prepare a 1988 ppm solution] [As a pre-cleaning spray- Place instruments into a suitable container, Spray [Product Name] [this product] onto instruments to thoroughly wet all surfaces. Let stand for up to 10 minutes. Rinse instruments.]

[As a pre-cleaning immersion solution - Fill appropriate size container with a sufficient amount of [Product Name] [this product] to completely submerge instruments. Place instruments into the container of [Product Name] [this product], cover, and allow to soak for up to 10 minutes. Remove and rinse and follow with an appropriate cleaning and disinfecting process. Change solution daily.]

[As a manual instrument cleaner - Thoroughly pre-rinse dirty instruments under running water to remove visible gross debris Immerse pre-rinsed instruments into an appropriate size container filled with [Product Name] [this product]. Scrub instruments using a stiff bristle brush until visibly clean. Submerge instruments while scrubbing Rinse instruments thoroughly Change solution daily. Follow with an appropriate disinfection process. Cleaning of critical and semi critical devices must be followed by an appropriate terminal sterilization/high level disinfection process.] [To Disinfect Non-Critical Pre-Cleaned Instruments - Instruments must be thoroughly pre-cleaned to remove excess organic debris rinsed and rough dried (Clean and rinse lumens of hollow instruments before filling with [Product Name] [this product] or before immersion). Immersion method using a soaking tray immerses instruments into [Product Name] [this product] and let stand for one or 1 minute.

[Change solution for each use Spray method - Spray all surfaces of instruments with [Product Name] [this product] until thoroughly wet. Let stand for one or 1 minute.]]

{Number 8 alternate application.}

## [SANITIZER FOR FOOD AND BEVERAGE PROCESSING AND FOOD HANDLING OPERATIONS

[Prepare a 100 ppm solution; refer to dilution chart for the number of tablets to use] [Prepare a fresh solution weekly when using closed containers (spray bottles). Prepare a fresh solution daily when using open containers (buckets) or if solution becomes diluted. All treated equipment that will contact food, feed, or drinking water must be rinsed with potable water before reuse.]

This product is recommended for sanitizing all types of hard, non-porous equipment and utensils used in food

processing and canning plants, bottling plants, breweries, fish processing plants, meat and poultry processing plants, milk handling and processing plants, stores, restaurant and institutional dining establishments. Use a 100 ppm available chlorine solution [(refer to Dilution Chart)] to sanitize previously cleaned processing and packaging equipment. [Add 1 tablet to 1 quart {optional statement to be used only for 334 mg tablet.}] Allow at least a one minute contact time before draining. Allow adequate draining before contact with beverages.]

## [EGG PROCESSING PLANTS

[Prepare a 100 ppm solution; refer to dilution chart for the number of tablets to use] Clean and destain egg shells prior to sanitizing. To clean egg shells, spray with a 90°F to 120°F solution containing 100 ppm available chlorine solution [(refer to Dilution Chart]. [Add 1 tablet to 1 quart {optional statement to be used only for 334 mg tablet.}] Spray-rinse the cleaned eggs with warm potable water. Only clean, whole eggs may be sanitized. Dirty, cracked or punctured eggs may not be sanitized.

To destain egg shells, immerse the eggs in a 90°F to 120°F solution containing 100 ppm available chlorine [(refer to Dilution Chart)]. After destaining, the eggs must be cleaned by spraying with an acceptable cleaner. Follow with a potable water rinse.

To sanitize clean shell eggs intended for food or food products, spray with a solution containing 100 ppm available chlorine [(refer to Dilution Chart)]. The solution must be equal to or warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs that have been sanitized with this chlorine compound may be broken for use in the manufacture of egg products without a prior potable water rinse. Eggs must be reasonably dry before casing or breaking. The solution must not be reused for sanitizing eggs.

Thoroughly clean and sanitize all egg cups, breaking knives, trays and other equipment that come into contact with "off" eggs. First, clean all equipment. Before placing back in use, spray with a solution containing 100 ppm available chlorine [(refer to Dilution Chart)]. Allow surfaces to completely drain before contact with egg product. To sanitize egg freezers and dryers (tanks, pipelines and pumps), use the spray or fog method of treatment (see Sanitizing Application Methods section). This procedure is generally used to sanitize large, non-porous surfaces that have already been cleaned of physical soil.

Prepare a solution containing 100 ppm available chlorine [(refer to Dilution Chart)]. [Add 1 tablet to 1 quart {optional statement to be used only for 334 mg tablet.}]. Heavily apply spray to all surfaces the eggs will touch. Thoroughly spray all treated surfaces, comers and turns. Allow at least a one minute contact time before draining. Allow equipment to drain adequately before contact with eggs.]

## [SANITIZING HARD, NON-POROUS SURFACES, DISHES, GLASSES, FOOD PROCESSING EQUIPMENT AND UTENSILS, DAIRY AND BREWERY EQUIPMENT AND UTENSILS

[[Prepare a 100 ppm solution; refer to dilution chart for the number of tablets to use.] [Prepare a fresh solution weekly when using closed containers (spray bottles). Prepare a fresh solution daily when using open containers (buckets) or if solution becomes diluted. All treated equipment that will contact food, feed, or drinking water must be rinsed with potable water before reuse.] [Add 1 tablet to 1 quart {optional statement to be used only for 334 mg tablet.}] [This product is an effective sanitizing agent. Treatment with this product throughout food and beverage processing and food handling operations can help ensure the quality and safety of the final product.]]

## *{Number 9 alternate application.}*

## [HANDWASHING OF ITEMS

1. Remove all gross food particles and soil by a preflush or prescrape and, when necessary, presoak treatment. Wash surfaces or objects with a good detergent or compatible cleaner, followed by a potable water rinse before application of the sanitizing solution.

2. Prepare a 100 ppm available chlorine sanitizing solution [(refer to Dilution Chart)].

3. Place equipment, utensils, dishes, glasses, etc. in the solution or apply the use solution to surfaces using a cloth, sponge, or coarse sprayer.

4. Allow to stand at least one minute, drain the excess solution from the surface, and allow to air dry.

5. Fresh sanitizing solution must be prepared at least daily or more often if the solution

## becomes diluted or soiled.]

## [MACHINE WASHING OF ITEMS

1. Remove all gross food particles and soil by a preflush or prescrape and, when necessary, presoak treatment. Wash surfaces or objects with a good detergent or compatible cleaner, followed by a potable water rinse before application of the sanitizing solution.

2. Prepare a 100 ppm available chlorine solution [(refer to Dilution Chart)].

3. Add the solution to the feed tank of immersion or spray type machines that can provide at least one minute contact time for sanitizing dishes, glasses, food processing equipment, or utensils. Allow to drain and air dry before use.

4. Promptly use the sanitizing solution. Prepared solutions cannot be reused for sanitizing but may be used for

other purposes, such as cleaning.]

{Number 10 alternate application.}

#### [SHOE AND BOOT BATH SANITIZER

To prevent cross contamination into treated animal areas and the packaging and storage areas of food plants. Shoe and Boot baths containing one inch of freshly made 100 ppm available chlorine [(refer to Dilution Chart)] should be placed at all entrances to buildings, hatcheries, and at all the entrances to the production and packaging rooms. Scrape waterproof [shoes] [and] [boots] and place into solution for at least one minute [60 seconds] prior to entering area. Change the sanitizing solution in the bath at least daily or sooner if solution appears diluted or dirty.]

## [MILK HANDLING AND PROCESSING EQUIPMENT

This product can be used on dairy farms and in plants processing milk, cream, ice cream, and cheese. Rinse milking machines, utensils, and all equipment with cold water to remove excess milk. Clean and rinse prior to sanitizing. To sanitize, spray or rinse all visibly clean cleaned surfaces with 100 ppm available chlorine solution [(refer to Dilution Chart)]. Allow adequate draining before contact with dairy products.

It is important to clean out large deposits of milk or other organic matter before sanitizing. A sharp decline in the available chlorine content of the sanitizer following circulation through milk processing equipment is usually regarded as evidence of inadequate cleaning of the equipment and should be promptly investigated.]

### {Number 11 alternate application.}

## [SANITIZING APPLICATION METHODS

[Prepare a 100 ppm solution; refer to dilution chart for the number of tablets to use]. Prepare a fresh solution weekly when using closed containers (spray bottles). Prepare a fresh solution daily when using open containers (buckets) or if solution becomes diluted. All treated equipment that will contact food, feed, or drinking water must be rinsed with potable water before reuse.] Freshly prepare all sanitizing solutions. Test solutions during use to ensure the concentration does not drop below the recommended level. Keep in properly labeled containers to protect against contamination. Discard unused solutions.]

## [PRESSURE METHOD OF SANITIZING EQUIPMENT

This method is commonly used to sanitize closed systems, such as fluid milk cooling and handling equipment. It is also appropriate for sanitizing weigh tanks, coolers, short-time pasteurizers, pumps, homogenizers, fillers, sanitary piping and fittings, and bottle and can fillers. For mechanical operations, prepared solutions cannot be reused for sanitizing but may be used for other purposes, such as cleaning. For manual operations, fresh sanitizing solutions must be prepared at least daily or more often if the solution becomes diluted or soiled. First, disassemble and thoroughly clean all equipment immediately after use. Remove all gross food particles and soil by a preflush or prescrape and, when necessary, presoak treatment. Wash surfaces or objects with a good detergent or compatible cleaner, followed by a potable water rinse before application of the sanitizing solution. Then place back in operating position. Prepare a solution containing 100 ppm available chlorine [(refer to Dilution Chart)] in a volume equal to 110% of capacity. Pump the solution through the system until it is filled with sanitizer and air excluded. Close final drain valves and hold under pressure for one minute to ensure proper contact with all surfaces. Remove a portion of the cleaning solution from the drain valve and test with a chlorine test kit. Repeat entire cleaning/sanitizing process if effluent contains less than 50 ppm available chlorine.]

## [SPRAY METHOD OF SANITIZING EQUIPMENT

The spray (or fog) method is generally used to sanitize large, non-porous surfaces that have already been freed of physical soil. It is appropriate for batch pasteurizers; holding tanks, weigh tanks, tank trucks and cars, vats, tile walls, ceilings, and floors. Clean all surfaces after use. Prepare a solution containing 100 ppm available chlorine [(refer to Dilution Chart)]. Use pressure spraying or fogging equipment designed to resist chlorine-containing solutions (e.g. rubber-coated, plastic or stainless steel). When using any other kind of spraying equipment, always empty and thoroughly rinse the spray/fog equipment with potable water immediately after treatment. Apply spray or fog heavily to all surfaces the product will touch. Thoroughly spray (or fog) all treated surfaces, corners and turns until wet. Allow at least a one minute contact time before draining. Allow excess solution to drain and air dry then place in service. Vacate area for at least two hours.]

#### [GENERAL RINSE METHOD

Prepare a solutions containing 100 ppm available chlorine [(refer to Dilution Chart)] sanitize plant floors, walls and ceilings, and also control odors in refrigerated areas and drain platforms. Generously flush or swab surfaces with the solution. After one minute contact time allow solution to drain and then air dry.]

{Number 12 alternate 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.] [schools], [hotels], [restaurants], [pools] [spas], [hot tubs], [salons], [dairy farms], [farms], [office buildings], [industrial facilities], [homes], [camp sites], [pet areas], [kennels], [marine] [and] [recreational vehicles], [R/V holding tanks], [wells], [kitchen], [bath], [floors], [toilets], [laundry], [washing machines] [shower], [garbage cans] [trash cans], [sinks], [disposals], [tubs], [outdoor uses\* include driveway, fences, decks, patio, garage, siding , and patio furniture][\*DO NOT use directly in pressure washers mix in garden sprayer]

## [Where to Use]

[This product *{or marketed product name}* [is] [are] [a] concentrated multi-purpose bleach tablet[s] 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 ([Prepare a 380 ppm solution; refer to dilution chart for the number of tablets to use]. The tablet will fizz and dissolve, then use a 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.}

[Do not use on any metals or metal surfaces, enamel bathtubs, fine wood surfaces, wool and silk fabrics, man-made, colored, or any fabric with a special finish. Test on inconspicuous area prior to use.]

## [DISINFECTION

[Prepare a 380 ppm solution; refer to dilution chart for the number of tablets to use] [Add 1 tablet to 1 gallon of water {optional statement to be used only for 5g tablet}]. Apply to visibly clean surface [with] [mop], [cloth], [sponge], [brush], [foaming equipment], [or] [coarse trigger sprayer]. Allow surface to remain wet for 10 minutes. Allow to air dry. Prepare a fresh solution weekly when using closed containers (spray bottles). Prepare a fresh solution daily when using open containers (buckets) or if solution becomes diluted. All treated equipment that will contact food, feed, or drinking water must be rinsed with potable water before reuse.]]

## {Number 13 alternate application.}

## [POOLS]

## FOR SUPERCHLORINATION

The pool water should be superchlorinated or shocked every seven days or whenever the combined chlorine level is above 0.5 ppm (mg/L). Combined chlorine is the difference between total and free chlorine, as measured by a suitable test kit. Add a sufficient amount of an appropriate shock product directly to the circulating water to raise the available chlorine level to 5-6 ppm (mg/L), based on test kit readings. If the combined chlorine reading is not below 0.5 ppm (mg/L), repeat the shock treatment described above. For example, the addition of [4 tubs (128 tablets)] {optional statement to be used only for 5g tablet} [100 tablets] {optional statement to be used only for 6.55g tablet} [50 tablets] {optional statement to be used only for 13.1g tablet} [40 tablets] {optional statement to be used only for 17.4g tablet} per 10,000 gallons of water will provide approximately 5 ppm (mg/L) of available chlorine. If the combined chlorine reading is not below 0.5 ppm (mg/L) and the water has not been restored to its normal clarity, repeat the shock treatment described above.]

{Number 14 alternate application.}

[HOT TUBS and SPAS]

[Add 4 ppm available chlorine [(refer to Dilution Chart)]. Using an appropriate test kit, test and adjust the water to the following values: pH: 7.2 - 7.8; total alkalinity: 60 - 100 ppm; calcium hardness: 200 ppm, minimum. Maintain these conditions for proper spa and hot tub operation by frequent testing with a test kit. Do not allow cyanuric acid level to exceed 150 ppm. It is recommended that spas and hot tubs be drained every 60 - 90 days, more often under heavy use.

Consult manufacturer's recommendations concerning the compatibility of chlorine sanitizers with their equipment. Some oils, lotions, fragrances, cleansers, etc., may cause foaming or cloudy water and may react with chlorine sanitizers, reducing their efficacy. Reentry into treated spas/hot tubs is prohibited above levels of 3 ppm chlorine.]

[Start-Up (Freshly Filled)

1. Turn on the circulation system and ensure that it is operating properly.

2. Add 4 ppm available chlorine [(refer to Dilution Chart)]. Check the free available chlorine (FAC) level and, if below 4-5 ppm, repeat as needed.]

[Regular Use

Turn on the circulation system and ensure that it is operating properly. Add 4 ppm available chlorine [(refer to Dilution Chart)] to the water. Test for FAC and add additional product, if necessary, to attain 4-5 ppm FAC. Maintain 1-3 ppm FAC while the spa or hot tub is in use. After each use, shock treat with 10 ppm available chlorine [(refer to Dilution Chart)] to control odors and algae. Repeat as needed. Spa or hot tub should not be entered until FAC reaches 1-3 ppm.]

## [Extended Non-Use Period

During extended periods when the spa or hot tub is not being used, with the circulation system running, add 4 ppm available chlorine [(refer to Dilution Chart)] twice a week or as needed to maintain 1-3 ppm FAC.]

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

## PESTICIDE STORAGE

Store in a cool, dry, well-ventilated area at a temperatures below 40°C/104°F. Avoid moisture getting into container **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 HANDLING**

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

## PHYSICAL OR CHEMICAL HAZARDS

STRONG OXIDIZING AGENT: Use only clean dry utensils. Mix only into water. Contamination with moisture, dirt, organic matter or other chemicals (including other chemicals) or any other foreign matter may start a chemical reaction with generation of heat, liberation of hazardous gases and possible generation of fire and explosion. Avoid any contact with flaming or burning material such as a lighted cigarette. Do not use this product in any chlorinating device which has been used with any inorganic or unstabilized chlorinating compounds (e.g., calcium hypochlorite). Such use may cause fire or explosion.

## [WARRANTY

Seller warrants that this product conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with label directions under normal conditions of use, but to the extent consistent with applicable law, neither this warranty nor any other warranty of MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, expressed or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to Seller, and Buyer assumes the risk of any such use.]

## [Manufactured by:

Medentech Ltd. C Whitemill Industrial Estate, Clonard Road 9 Wexford, Ireland] S {for DOMESTIC labels only:}[Tel: 1-(800) 811-2327] {for INTERNATIONAL labels only:}[Tel: 1-(304) 746-3000]

[Produced For: CLEARON CORP. 95 MacCorkle Avenue S.W South Charleston, WV 25303] EPA Reg. No. <u>71847-6</u> EPA Est. No. \_\_\_\_\_\_ Material][Label] No. \_\_\_\_\_\_ NET CONTENTS: \_\_\_\_\_\_ [lbs.][kg.][g.][oz.] [Batch][Lot] No. \_\_\_\_\_

DILUTION CHART								
Tablet size	0.33g	1g	1.7g 3.3			3.3g		
Solution ppm mg/L) Available Chlorine	Tablets per one Quart of Water	Tablets per one Gallon of Water	Tablets Quarts of Water		Tablets	Quarts of Water		
4	1 in 25 qt	1 in 19 ga	1	125	1	250		
10	1 in 10 qt	1 in 7 ga	1	50	1	100		
100	1	2	1	5	1	10		
380	4	5	1	1	1	2		
479	5	7	1	1	1	2		
958	10	13	2	1	1	1		
1988	20	27	4	1	2	1		
4311	45	63	9	1	9	2		

*{Where required the appropriate chart will be used on the marketed label for each tablet size.}* 

DILUTION CHART								
Tablet size	5g		6.55g		13.1g		17.4g	
Solution ppm mg/L) Available Chlorine	Tablets	Gallons of Water	Tablets	Gallons of water	Tablets	Gallons of Water	Tablets	Gallons of Water
4	1	95	1	124	1	248	1	330
10	1	38	1	50	1	100	1	132
100	1	3.8	1	5	1	10	1	13
380	1	1	1	1.30	1	2.5	1	3
479	5	4	1	1	1	2	1	2.5
958	5	2	2	1	1	1	1	1.25
1988	5	1	4	1	2	1	3	2
4311	12	1	9	1	9	2	4	1

ICONS USED FOR KLORSEPT MASTER LABEL (71847-6)











