



NOTE: Cetylcode-G_Box 2-07
Printer to provide and insert barcode in box provided. Rule does not print.

Ink: PMS 341C Green
Type: Helvetica Neue and Avant Garde
Program: Quark XPress 6.5

Cetylcode-G®

Net contents 32 oz. (946 mls.)

Cetylcode-G®

CONCENTRATE
FOR STERILIZATION AND HIGH LEVEL DISINFECTION
For use in Hospitals, Medical, Dental, and
Other Health Care Facilities

Cetylcode-G must be used with Cetylcode-G Diluent Concentrate. Never use Cetylcode-G alone.

Active Ingredients:
Glutaraldehyde:47.50%
Other Ingredients:52.50%
Total Ingredients**100.00%**

Keep out of reach of children.

Danger

Precautionary Statements

Wear goggles or safety glasses when handling.

Avoid breathing vapor. Use in well ventilated area in closed containers. For additional safety information refer to the product insert and MSDS.

Hazards to Humans and Domestic Animals

Causes severe eye and skin irritation; harmful if swallowed. Avoid contact with eyes, skin and clothing. Avoid contamination of food.

Statement of Practical Treatment

In cases of eye contact, immediately flush with water and continue washing for at least 15 minutes. Obtain the advice of an ophthalmologist urgently. For skin contact, wash contaminated skin with soap and water. If contact has been widespread and prolonged, or if irritation persists, seek medical advice. Contaminated clothing should be washed before reuse. **IF SWALLOWED: DO NOT INDUCE VOMITING.** Do not give anything to drink. Obtain medical advice with urgency. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.



U.S. Pats. No's: 4,923,899; 5,124,359; 5,338,748; 5,344,838
Taiwan Pat. No. 54180 Italy Pat. No. 47682A90
and other U.S. and Foreign Patents Pending

Made in U.S.A.

Rev. 2/07

For use as a high level disinfectant: Immerse instruments in Cetylcode-G Use Solution for 40 minutes at 20°C.

For use as a sterilant: Immerse instruments in Cetylcode-G Use Solution for 10 hours at 20°C. Remove instruments from the solution (using aseptic technique if in sterilant) and rinse thoroughly with water following the rinsing instructions below.

Rinsing: Immerse instruments completely in three separate copious volumes of water (sterile water if taken from sterilant). Each rinse should be a minimum of 1 minute in duration unless otherwise noted by the device manufacturer. Use fresh portions of water for each rinse. Discard the water following each rinse. Do not reuse the water for rinsing or any other purpose as it will be contaminated with glutaraldehyde.

Contraindications: Routine biological monitoring is not feasible with Cetylcode-G Use Solution. Therefore, Cetylcode-G Use Solution should **NOT** be used to sterilize reusable medical devices that are compatible with other available methods of sterilization that can be biologically monitored, e.g., heat, ethylene oxide or peroxide gas plasma. Cetylcode-G Use Solution should **NOT** be used for sterilization of critical devices intended for single use (e.g. catheters).

Storage: Prior to preparation, Cetylcode-G Concentrate should be stored in its original container at room temperature, 15 - 30°C (59-86°F). The C-Tub (or other appropriate instrument tray) containing the Cetylcode-G Use Solution should be stored closed in a well ventilated, low traffic area at room temperature.

Disposal: Discard residual solution in drain. Flush thoroughly with water. Do not re-use empty container. Remove the topmost cap and triple rinse bottle. Dispose of entire container in a sanitary landfill or by incineration if allowed by state and local authorities.

Barcode to be placed here.
Ruled box does not print.
For position only.

Net contents 32 oz. (946 mls.)

Cetylcode-G®

CONCENTRATE
FOR STERILIZATION AND HIGH LEVEL DISINFECTION
For use in Hospitals, Medical, Dental, and
Other Health Care Facilities

Cetylcode-G must be used with Cetylcode-G Diluent Concentrate. Never use Cetylcode-G alone.

Active Ingredients:
Glutaraldehyde:47.50%
Other Ingredients:52.50%
Total Ingredients**100.00%**

Keep out of reach of children.

Danger

Precautionary Statements

Wear goggles or safety glasses when handling.

Avoid breathing vapor. Use in well ventilated area in closed containers. For additional safety information refer to the product insert and MSDS.

Hazards to Humans and Domestic Animals

Causes severe eye and skin irritation; harmful if swallowed. Avoid contact with eyes, skin and clothing. Avoid contamination of food.

Statement of Practical Treatment

In cases of eye contact, immediately flush with water and continue washing for at least 15 minutes. Obtain the advice of an ophthalmologist urgently. For skin contact, wash contaminated skin with soap and water. If contact has been widespread and prolonged, or if irritation persists, seek medical advice. Contaminated clothing should be washed before reuse. **IF SWALLOWED: DO NOT INDUCE VOMITING.** Do not give anything to drink. Obtain medical advice with urgency. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.



U.S. Pats. No's: 4,923,899; 5,124,359; 5,338,748; 5,344,838
Taiwan Pat. No. 54180 Italy Pat. No. 47682A90
and other U.S. and Foreign Patents Pending

Made in U.S.A.

Rev. 2/07

Directions for Use
Cetylcode-G is an effective high level disinfectant/sterilant only when mixed with the correct dilution (1:64) of Cetylcode-G Diluent Concentrate and used or re-used according to its directions for use at or above the minimum effective concentration (MEC), 2.1 % glutaraldehyde.

Preparation of the Use Solution

- Step 1:** With both caps closed, tilt the bottle forward to fill the measuring chamber.
- Step 2:** Tilt the bottle back using angular pour-back scale to adjust to the desired level (e.g. 1 qt).
- Step 3:** Remove the Pour cap and pour the measured dose into the C-Tub or other receptacle.

For 1 quart: Add 15 mls. of Cetylcode-G Diluent Concentrate (yellow liquid) to 1 quart of water in a C-Tub Instrument Tray or other appropriate container. Then add 63 mls. of Cetylcode-G Concentrate (green liquid) and mix.

For 1/2 gallon: Add 30 mls. of Cetylcode-G Diluent Concentrate (yellow liquid) to 1/2 gallon of water in a C-Tub Instrument Tray or other appropriate container. Then add 126 mls. of Cetylcode-G Concentrate (green liquid) and mix.

For 1 gallon: Add 60 mls. of Cetylcode-G Diluent Concentrate (yellow liquid) to 1 gallon of water in a C-Tub Instrument Tray or other appropriate container. Then add 252 mls. of Cetylcode-G Concentrate (green liquid) and mix. (Fill the measuring chamber to the 126 ml. line twice.)

Record the mixing date on the provided green Use Dilution Label and affix to the container. The glutaraldehyde concentration of the Cetylcode-G Use Solution when freshly mixed is 3.2% and its pH is 6.5-7.8. The MEC of glutaraldehyde is 2.1%.

Reuse: The Cetylcode-G Use Solution can be reused for a period not to exceed 28 days provided the required conditions of glutaraldehyde concentration, pH and temperature exist based upon monitoring. **DO NOT** rely solely on days in use. Refer to the Cetylcode-G insert for information regarding glutaraldehyde monitoring using a test strip. **DO NOT** use beyond 28 days even if the concentration of glutaraldehyde is above the MEC of 2.1 % glutaraldehyde.

Cleaning: Clean instruments thoroughly. Rinse free of all soap before immersion. Clean and rinse the lumen of hollow instruments before filling with solution. Do not use either highly acidic or alkaline detergents as precleaning agents.

For complete instructions and precautionary statements see product insert and MSDS.



Note:
Barcode Human Readable
1.25" Wide x 2.68" High

(01) 1 06 31059 0122 1 X
(where X is a check digit in UCC/EAN-128 Symbology)

Potable Water Rinse

For all other devices a sterile water rinse is recommended when practicable, otherwise a high quality potable tap water rinse is acceptable. A high quality potable water is one that meets Federal Clean Water Standards at the point of use.

When using potable water for rinsing, the user should be aware of the increased risk of recontaminating the device or medical equipment with *Pseudomonas* and *atypical* (fast growing) *Mycobacteria* often present in potable water supplies. A device (e.g. colonoscope) that is not completely dried provides an ideal situation for rapid colonization of bacteria. Additionally, *Mycobacteria* are highly resistant to drying. Therefore, rapid drying will avoid possible colonization but may not result in a device free from *atypical Mycobacteria*. Although these bacteria are not normally pathogenic in patients with healthy immune systems, AIDS patients or other immunocompromised individuals may be placed at high risk of infection by these opportunistic microorganisms. A final rinse using a 70% isopropyl alcohol solution is useful to speed the drying process and reduce the numbers of any organism present as a result of rinsing with potable water.

d. Reusage

Cetylide-G Use Solution has demonstrated efficacy in the presence of 2% organic soil contamination and a simulated amount of microbiological burden during reuse. This solution may be used and reused within the limitations indicated above for up to 28 days after preparation. Do not use prepared solution beyond 28 days. Use the 3M™ Comply™ Cold SteriLog™ 2.1% Glutaraldehyde Monitors reagent test strip to determine that the minimum effective concentration of glutaraldehyde (MEC) of 2.1% is present.

4. Monitoring of Germicide to Ensure Specifications are Met

During the usage of Cetylide-G Use Solution, as a high level disinfectant and/or sterilant, it is recommended that a thermometer and timer be utilized to ensure that the optimum usage conditions are met. In addition, it is recommended that the Cetylide-G Use Solution be tested with the 3M™ Comply™ Cold SteriLog™ 2.1% Glutaraldehyde Monitors prior to each use. This is to insure that the appropriate concentration of glutaraldehyde is present and to guard against an unexpected dilution which may lower the effectiveness of the solution below its MEC. The pH of the activated solution may also be periodically checked to verify that the pH of the solution is between 6.5 and 7.8.

5. Post-Processing Handling and Storage of Reusable Devices

Disinfected and/or sterilized reusable devices are either to be immediately used or stored in a manner to minimize recontamination. Refer to the reusable device-equipment manufacturer's labeling for additional storage and/or handling instructions.

F. Storage Conditions and Expiration Date

1. Prior to preparation, Cetylide-G Concentrate should be stored in its original container at room temperature 15°-30°C (59°- 86° F).

Once the Cetylide-G Use Solution has been prepared, it may be stored in the closed containers in which the immersion for high level disinfection or sterilization is to take place, (C-Tub or other appropriate instrument tray). Closed containers should be stored in a well ventilated, low traffic area at room temperature.

2. The expiration date of Cetylide-G will be found on the bottle and the immediate box.
3. The use period for prepared Cetylide-G Use Solution is for no longer than 28 days following preparation. It should not be used if the MEC falls below a level of 2.1% glutaraldehyde as indicated by the 3M™ Comply™ Cold SteriLog™ 2.1% Glutaraldehyde Monitors, regardless of the number of days of actual use.

G. Emergency and Technical Product Information

Emergency, safety, or technical information about Cetylide-G Use Solution can be obtained from Cetylite Industries, Inc. at 1-800-257-7740.

H. User Proficiency

The user should be adequately trained in the decontamination and disinfection or sterilization of medical devices and the handling of toxic substances such as liquid chemical germicides. Additional information about Cetylide-G Use Solution can be obtained from Cetylite Industries, Inc. at 1-800-257-7740.

I. Disposal Information

Germicide Disposal

Discard residual solution in drain. Flush thoroughly with water.

Container Disposal

Do not re-use empty container. Remove the topmost cap and triple rinse bottle. Dispose of entire container in a sanitary landfill or by incineration if allowed by state and local authorities.

J. Order Information

Cetylite #	Description
0122	Cetylide-G Concentrate 32 oz Bottle (Includes Diluent).
0106	C-Tub Instrument Tray



CETYLITE INDUSTRIES, INC.
3051 River Road
Pennsauken, NJ 08110-3290

Made in U.S.A.

Rev. 4.1/01

Cetylide-G[®]

CONCENTRATE

FOR STERILIZATION
AND HIGH LEVEL DISINFECTION

A. Indications for Use

1. Germicide Level of Activity

Cetylide-G is an effective liquid chemical sterilant and a high level disinfectant when used according to the Directions for Use.

Sterilant: Cetylide-G is a sterilant when mixed and used according to its Directions for Use for a maximum of 28 days at 20°C with an immersion time of at least 10 hours at its minimum effective concentration (MEC) of 2.1 % glutaraldehyde.

High level Disinfectant: Cetylide-G is a high level disinfectant when mixed and used according to its Directions for Use for a maximum of 28 days at 20°C with an immersion time of at least 40 minutes at its minimum effective concentration (MEC) of 2.1% glutaraldehyde.

2. Reuse Period

Cetylide-G can be reused for a period not to exceed 28 days provided the required conditions of glutaraldehyde concentration, pH, and temperature exist based upon monitoring described in Directions for Use. DO NOT rely solely on days in use. Use the 3M™ Comply™ Cold SteriLog™ 2.1% Glutaraldehyde Monitors to determine that the minimum effective concentration (MEC) of 2.1% glutaraldehyde is present. (See Directions for Use-Section E: Monitoring of Germicide to Ensure Specifications are Met.)

3. General Information on Selection and Use of Germicides for Medical Device Reprocessing

Choose a germicide with the level of microbicidal activity that is appropriate for the reusable medical device. Follow the reusable device labeling and standard institutional practices. In the absence of complete instructions, use the following process:

First, for patient contacting devices, determine whether the reusable device to be reprocessed is a critical or a semi-critical device.

- A **critical device** presents a high risk of infection if not sterile. Critical devices routinely penetrate the skin or mucous membranes during use or are otherwise used in normally sterile tissue of the body.
- A **semi-critical device** makes contact with mucous membranes but does not ordinarily penetrate normally sterile areas of the body.

Second, determine the level of germicidal activity that is needed for the reusable device.

Critical Device - Sterilization required (e.g.: products that enter sterile tissue or the vascular system, such as laparoscopes and microsurgical instruments).

Semi-critical Device - Sterilization recommended whenever practical, otherwise High Level Disinfection acceptable (e.g.: GI endoscopes, anesthesia equipment for the airway, diaphragm-fitting rings, etc.).

Third, select a germicide that is labeled for the appropriate germicidal level and is compatible with the reusable device. Follow directions for the germicide.

4. Material Compatibility

Cetylcode-G Use Solution is a glutaraldehyde solution. Such solutions have a long history of compatible use with medical instruments made from a variety of materials without corrosive or other apparent damaging effects. They have been found to be compatible with the following materials:

METALS

- Chrome Plated Metal
- Nickel Plated Metal
- Carbon Steel
- Stainless Steel
- Aluminum

ELASTOMERS

- Black Rubber
- Red Rubber
- Silicone Rubber
- Polyurethane

PLASTICS

- acrylonitrile-butadiene-styrene (ABS)
- polyvinyl chloride (PVC)
- polystyrene
- polyethylene
- polypropylene
- polyurethane
- polymethylmethacrylate (acrylic)
- polyethylene terephthalate (polyester)

Check the labeling of the reusable device for any additional instructions. Cetylcode-G Use Solution is not recommended for use on non-anodized aluminum or for the disinfection of one piece molded, solvent-bonded or sonic-welded polycarbonate equipment due to possible stress cracking after repeated treatments.

5. Pre-cleaning Agent Compatibility

Detergents that are either highly acidic or alkaline are contraindicated as pre-cleaning agents since improper rinsing could affect the efficacy of the Cetylcode-G Use Solution by altering its pH.

B. Contraindications

1. Sterilant Usage

Routine biological monitoring is not feasible with Cetylcode-G Use Solution. Therefore, Cetylcode-G Use Solution should NOT be used to sterilize reusable medical devices that are compatible with other available methods of sterilization that can be biologically monitored, e.g., heat, ethylene oxide or peroxide gas plasma.

Cetylcode-G Use Solution should NOT be used for sterilization of critical devices intended for single use (e.g., catheters).

C. Warnings

HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

DANGER

Keep out of Reach of Children.

1. Corrosive. Causes irreversible eye damage. Causes skin burns. Harmful if inhaled. May be fatal if swallowed. Harmful if absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

Causes asthmatic signs and symptoms in some hyper-active individuals. Do not get in eyes, on skin or on clothing. Avoid breathing vapor. Do not swallow. Wear goggles, protective clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing, and wash before reuse.

2. HARMFUL IF SWALLOWED. If ingested, do not induce vomiting. Obtain medical attention immediately.

D. Precautions

1. Use rubber or nitrile gloves, eye protection, face mask and chemical apron when cleaning and disinfecting/sterilizing devices.
2. Use in well ventilated area in closed containers.
3. Contaminated, reusable devices **MUST BE THOROUGHLY CLEANED** prior to high level disinfection or sterilization, since residual contamination will decrease the effectiveness of the germicide.
4. The user must follow the Directions for Use since any modifications will affect the safety and effectiveness of the germicide.
5. To optimize the effective reprocessing of reusable devices, the user must follow a validated reprocessing procedure for any device disinfected or sterilized in Cetylcode-G Use Solution.

E. Directions for Use

1. Preparation of the Use Solution

(See the How-To-Prepare Sheet for diagrams)

Step 1: With both caps closed, tilt the bottle forward to fill the measuring chamber.

Step 2: Tilt the bottle back using angular pour-back scale to adjust to desired level (e.g., 1 qt.)

Step 3: Remove the Pour Cap and pour the measured dose into the C-Tub or other receptacle.

For 1 quart: Add 15 ml of Cetylcode-G Diluent Concentrate (yellow liquid) to 1 quart of water in a C-Tub Instrument Tray or other appropriate container. Then add 63 ml of Cetylcode-G Concentrate (green liquid) and mix.

For 1/2 gallon: Add 30 ml of Cetylcode-G Diluent Concentrate (yellow liquid) to 1/2 gallon of water in a C-Tub Instrument Tray or other appropriate container. Then add 126 ml of Cetylcode-G Concentrate (green liquid) and mix.

For 1 gallon: Add 60 ml of Cetylcode-G Diluent Concentrate (yellow liquid) to 1 gallon of water in a C-Tub Instrument Tray or other appropriate container. (Fill the measuring chamber to the 30 ml line twice.) Then add 252 ml of Cetylcode-G Concentrate (green liquid) and mix. (Fill the measuring chamber to the 126 ml line twice.)

Record the mixing date on the provided green Use Dilution Label and affix to the container. The glutaraldehyde concentration of the Cetylcode-G Use Solution when freshly mixed is 3.2%, and its pH is in the range of 6.5-7.8. The minimum effective concentration (MEC) of glutaraldehyde is 2.1%, and the Use Solution should not be used if the level of glutaraldehyde falls below the MEC during the re-use period. Monitor the concentration with the reagent test strip as set out in step 4 below. The pH should remain between 6.5-7.8.

2. Cleaning/Decontamination

Clean instruments thoroughly. Rinse free of all soap before immersion. Do not use either highly acidic or alkaline detergents as pre-cleaning agents.

Blood and other body fluids must be thoroughly cleaned from surfaces, lumens, and objects before application of the disinfectant or sterilant.

For complete high-level disinfection or sterilization of medical instruments, thoroughly clean, rinse and dry objects prior to immersion in Cetylcode-G Use Solution. Clean and rinse the lumens of hollow instruments before filling with Cetylcode-G Use Solution. Refer to the reusable device manufacturer's labeling for additional instructions on disassembly, decontamination, cleaning and leak testing of their equipment.

3. Usage

a. Sterilization (C-Tub or other Instrument Tray)

Immense medical device completely in Cetylcode-G Use Solution for a minimum of 10 hours at 20°C to eliminate all microorganisms including *Clostridium sporogenes* and *Bacillus subtilis* spores. Remove devices from the solution using sterile technique and rinse thoroughly with sterile water following the rinsing instructions below.

b. High Level Disinfection (C-Tub or other Instrument Tray)

Immense medical device completely in Cetylcode-G Use Solution for a minimum of 40 minutes at 20°C to destroy pathogenic microorganisms except large quantities of bacterial endospores but including *Mycobacterium tuberculosis* (Var. bovis). Remove devices from the solution and rinse thoroughly following the rinsing instructions below.

c. Rinsing Instructions

Following immersion in Cetylcode-G Use Solution, thoroughly rinse the instrument by immersing it completely in three separate copious volumes of water (sterile water if taken from sterile). Each rinse should be a minimum of 1 minute in duration unless otherwise noted by the device manufacturer. Use fresh portions of water for each rinse. Discard the water following each rinse. Do not reuse the water for rinsing or any other purpose as it will be contaminated with glutaraldehyde.

Refer to the reusable device manufacturer's labeling for additional rinsing instructions.

Sterile Water Rinse

The following devices should be rinsed with sterile water, using sterile technique when rinsing and handling:

1. Devices intended for use in normally sterile areas of the body;
2. Devices intended for use in known immunocompromised patients, or potentially immunocompromised patients based on institutional procedures (e.g., high risk population served) and;
3. When practicable, bronchoscopes, due to a risk of atypical *Mycobacteria* contamination from potable water supply.

How to Prepare Cetylcide-G Use Solution

(See Insert for Detailed Instructions)



1 Fill C-Tub or other appropriate container with 1 quart, 1/2 gallon or 1 gallon of water, depending on your needs.



2 With both caps closed tilt the 8 oz. Cetylcide-G Diluent bottle forward and fill the measuring chamber.



3 Using the angular pour-back scale, adjust to the amount needed by tilting the bottle back.



4 Hold bottle upright and check the fluid level for accuracy. See step #5 for amounts needed.

5
15 mls. Cetylcide-G Diluent added to 1 quart water, or
30 mls. Cetylcide-G Diluent added to 1/2 gallon water, or
60 mls. Cetylcide-G Diluent (30 mls. x 2) added to 1 gallon water

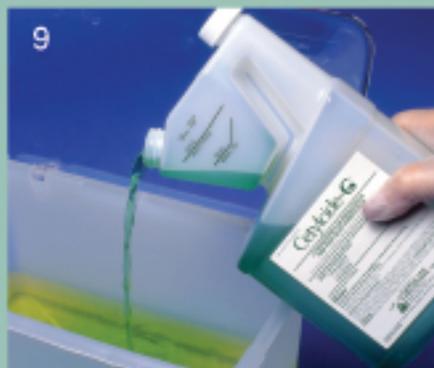


6 Remove the Pour Cap and pour Cetylcide-G Diluent into the C-Tub (or other container).



7 Using the same technique as above, fill the Cetylcide-G Concentrate measuring chamber. See step #8 for amounts needed.

8
63 mls. added to 1 quart of Cetylcide-G Diluent/Water mixture, or
126 mls. added to 1/2 gallon of Cetylcide-G Diluent/Water mixture, or
252 mls. (126 mls x 2) added to 1 gallon of Cetylcide-G Diluent/Water mixture



9 Remove the Pour cap and pour Cetylcide-G Concentrate into the Cetylcide-G Diluent/water mixture. Fill-in and apply the supplied green Use-Solution label to the container.

How to use Cetylcide-G Use Solution

For use as a high level disinfectant
Immerse instruments in Cetylcide-G Use Solution for 40 minutes at 20°C.

For use as a Sterilant
Immerse instruments in Cetylcide-G Use Solution for 10 hours at 20°C. Remove instruments from the solution and rinse thoroughly with sterile water following the rinsing instructions.

Rinsing

Immerse instruments completely in three separate copious volumes of water (sterile water if taken from sterilant). Each rinse should be a minimum of 1 minute in duration unless otherwise noted by the device manufacturer. Use fresh portions of water for each rinse. Discard the water following each rinse. Do not reuse the water for rinsing or any other purpose as it will be contaminated with glutaraldehyde.

When using Cetylcide-G Use Solution.



DO NOT TOUCH

DO NOT SPRAY

DO NOT WIPE



CETYLITE INDUSTRIES, INC.
2051 River Road
Pennsauken, NJ 08110-3203
1-800-257-7740



Net contents 32 oz. (946 ml)

Cetylcode-G®

CONCENTRATE FOR STERILIZATION AND HIGH LEVEL DISINFECTION

For use in Hospitals, Medical, Dental, and Other Health Care Facilities

**Cetylcode-G must be used with Cetylcode-G Diluent Concentrate.
Never use Cetylcode-G alone.**

Active Ingredients:

Glutaraldehyde:	47.50%
Other Ingredients:	52.50%
Total Ingredients.	100.00%

Keep out of reach of children.

Danger

Precautionary Statements: Wear goggles or safety glasses when handling.

Hazards to Humans and Domestic Animals

Causes severe eye and skin irritation; harmful if swallowed. Avoid contact with eyes, skin and clothing. Avoid contamination of food.

Statement of Practical Treatment

In cases of eye contact, immediately flush with water and continue washing for at least 15 minutes. Obtain the advice of an ophthalmologist urgently. For skin contact, wash contaminated skin with soap and water. If contact has been widespread and prolonged, or if irritation persists, seek medical advice. Contaminated clothing should be washed before reuse. **IF SWALLOWED: DO NOT INDUCE VOMITING.** Do not give anything to drink. Obtain medical advice with urgency. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage



Manufactured By

**CETYLITE
INDUSTRIES, INC.**

9051 River Road
Pennsauken, NJ 08110-3293

00122

Directions for Use

Cetyl chloride-G is an effective high level disinfectant/sterilant only when mixed with the correct dilution (1:64) of Cetyl chloride-G Diluent Concentrate and used or re-used according to its directions for use at or above the minimum effective concentration (MEC), 2.1% glutaraldehyde.

Preparation of the Use Solution (See the How-To-Prepare Sheet for diagrams)

1. With both caps closed, fill the bottle forward to fill the measuring chamber.
2. Tilt the bottle back using angular pour-back scale to adjust to desired level (e.g. 1 qt.).
3. Remove the Pour Cap and pour the measured dose into the C-Tub or other receptacle.

For 1 quart: Add 15 ml. of Cetyl chloride-G Diluent Concentrate (yellow liquid) to 1 quart of water in a C-Tub Instrument Tray or other appropriate container. Then add 63 ml. of Cetyl chloride-G Concentrate (green liquid) and mix.

For 1/2 gallon: Add 30 ml. of Cetyl chloride-G Diluent Concentrate (yellow liquid) to 1/2 gallon of water in a C-Tub Instrument Tray or other appropriate container. Then add 126 ml. of Cetyl chloride-G Concentrate (green liquid) and mix.

For 1 gallon: Add 60 ml. of Cetyl chloride-G Diluent Concentrate (yellow liquid) to 1 gallon of water in a C-Tub Instrument Tray or other appropriate container. (Fill the measuring chamber to the 30 ml. line twice.) Then add 252 ml. of Cetyl chloride-G Concentrate (green liquid) and mix. (Fill the measuring chamber to the 126 ml. line twice.)

Record the mixing date on the provided green Use-Dilution label and affix to the container. The glutaraldehyde concentration of the Cetyl chloride-G Use Solution when freshly mixed is 3.2% and its pH is 6.5-7.8. The MEC of glutaraldehyde is 2.1%.

Reuse: The Cetyl chloride-G Use Solution can be reused for a period not to exceed 28 days provided the required conditions of glutaraldehyde concentration, pH and temperature exist based upon monitoring. **DO NOT rely solely on days in use.** Refer to the Cetyl chloride-G insert for information regarding glutaraldehyde monitoring using a test strip. **DO NOT** use beyond 28 days even if the concentration of glutaraldehyde is above MEC of 2.1% glutaraldehyde.

Cleaning: Clean instruments thoroughly. Rinse free of all soap before immersion. Clean and rinse the lumen of hollow instruments before filling with solution. Do not use either highly acidic or alkaline detergents as pre-cleaning agents.

For use as a high level disinfectant: Immerse instruments in Cetyl chloride-G Use Solution for 40 minutes at 20°C.

For use as a sterilant: Immerse instruments in Cetyl chloride-G Use Solution for 10 hours at 20°C. Remove instruments from the solution (using aseptic technique if in sterilant) and rinse thoroughly with water following the rinsing instructions below.

Rinsing: Immerse instruments completely in three separate copious volumes of water (sterile water if taken from sterilant). Each rinse should be a minimum of 1 minute in duration unless otherwise noted by the device manufacturer. Use fresh portions of water for each rinse. Discard the water following each rinse. Do not reuse the water for rinsing or any other purpose as it will be contaminated with glutaraldehyde.

Contraindications: Routine biological monitoring is not feasible with Cetyl chloride-G Use Solution. Therefore, Cetyl chloride-G Use Solution should **NOT** be used to sterilize reusable medical devices that are compatible with other available methods of sterilization that can be biologically monitored, e.g., heat, ethylene oxide or peroxide gas plasma. Cetyl chloride-G Use Solution should **NOT** be used for sterilization of critical devices intended for single use (e.g. catheters).

Storage: Prior to preparation, Cetyl chloride-G Concentrate should be stored in its original container at room temperature, 15-30°C (59-86°F). The C-Tub (or other appropriate instrument tray) containing Cetyl chloride-G Use Solution should be stored closed in a well-ventilated, low traffic area at room temperature.

Disposal: Discard residual solution in drain. Flush thoroughly with water. Do not re-use empty container. Remove the topmost cap and triple rinse bottle. Dispose of entire container in a sanitary landfill or by incineration if allowed by state and local authorities.

Use Dilution Label

Cetylcode-G®
High Level Disinfectant, Sterilant

Date Mixed _____

Expiration Date _____

Prepared By _____



NFPA

Rev. 3/00



**CETYLITE
INDUSTRIES, INC.**
8551 River Road
Parsippany, NJ 08110-3293

Net Contents 8 oz. (236.5 ml)

Cetylcide-G[®]

DILUENT CONCENTRATE

For use only with Cetylcide-G[®]
Concentrate to make sterilization and
high-level disinfection Use Solution.

Keep out of reach of children

Danger

See back panel for additional Precautionary Statements

Manufactured By



**CETYLITE
INDUSTRIES, INC.**

9051 River Road
Pennsauken, NJ 08110-3293

Rev. 4.1/01

Made in U.S.A.

Directions for Use

How to prepare Cetyl chloride-G Diluent for Use with Cetyl chloride-G.
(See the How-to-Prepare Sheet for diagrams).

1. With both caps closed, fill the bottle forward to fill the measuring chamber.
2. Tilt the bottle back using angular pour-back scale to adjust to desired level (e.g. 1 qt.).
3. Remove the Pour Cap and pour the measured dose into the C-Tub or other receptacle.

According to your needs, add 1 qt., 1/2 gal. or 1 gal. of water to **C-TUB** or other instrument receptacle.

To each 1 quart of water add 1/2 oz. of Cetyl chloride-G Diluent.

1/2 oz. (15 ml) Diluent Concentrate added to 1 qt. water.

1 oz. (30 ml) Diluent Concentrate added to 1/2 gal. water.

2 oz. (60 ml) Diluent Concentrate added to 1 gal. water. (Fill measuring chamber to the 30 ml line twice).

Pour the appropriate amount of Diluent Concentrate directly into the specified volume of water in **C-TUB** or other instrument receptacle.

This Diluent Solution must then be mixed with Cetyl chloride-G Concentrate (see further instructions on Cetyl chloride-G label) to make Cetyl chloride-G Use Solution.

Storage and Disposal

Do not re-use empty container. Open uppermost cap to triple rinse bottle, then puncture and discard in trash.

Precautionary Statements

Hazards to Humans and Domestic Animals

Corrosive. Causes eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination of food.

Statement of Practical Treatment

Skin and Eyes: In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call physician. Remove and wash contaminated clothing before re-use.

Ingestion: If conscious drink water. Call a physician immediately.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Rev. 4.1/01

CONCENTRATE
DILUENT

Cetylciide-G

Net Contents 8 oz. (236.5 mls.)

Cetylciide-G

DILUENT

CONCENTRATE

For use only with
Cetylciide-G® Concentrate
to make sterilization and
high-level disinfection
Use Solution.

Keep out of reach of children

Danger

See side panels for additional Precautionary Statements

Manufactured By
**CETYLITE
INDUSTRIES, INC.**
9051 River Road
Pennsauken, NJ 08110-3293

4/01a

Made in U.S.A.

0146

Directions for Use
How to prepare Cetylciide-G Diluent for Use with Cetylciide-G.
(See the How-To-Prepare Sheet for diagrams)

- 1) With both caps closed, tilt the bottle forward to fill the measuring chamber.
- 2) Tilt the bottle back using angular pour-back scale to adjust to desired level (e.g. 1 qt).
- 3) Remove the Pour Cap and pour the measured dose into the **C-Tub** or other receptacle.

According to your needs, add 1 qt., 1/2 gal. or 1 gal. of water to **C-Tub** or other instrument receptacle.

To each 1 quart of water add 1/2 oz. of Cetylciide-G Diluent.

1/2 oz. (15 mls.) Diluent Concentrate added to 1 quart water.

1 oz. (30 mls.) Diluent Concentrate added to 1/2 gallon water.

2 oz. (60 mls.) Diluent Concentrate added to 1 gallon water. (Fill the measuring chamber to the 30 ml. line twice).

Pour the appropriate amount of Diluent Concentrate directly into the specified volume of water in **C-TUB** or other instrument receptacle.

This Diluent Solution must then be mixed with Cetylciide-G Concentrate (see further instructions on Cetylciide-G label or Cetylciide-G insert) to make Cetylciide-G Use Solution.

Storage and Disposal

Do not re-use empty container. Open uppermost cap to triple rinse bottle, then puncture and discard in trash.

Precautionary Statements

Hazards to Humans and Domestic Animals

Corrosive. Causes eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination of food.

Statement of Practical Treatment

Skin and Eyes: In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call physician. Remove and wash contaminated clothing before re-use.

Ingestion: If conscious drink water. Call a physician immediately.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Net Contents 8 oz. (236.5 ml)

Cetylciide-G

DILUENT

CONCENTRATE

For use only with
Cetylciide-G® Concentrate
to make sterilization and
high-level disinfection
Use Solution.

Keep out of reach of children

Danger

See side panels for additional Precautionary Statements

Manufactured By
**CETYLITE
INDUSTRIES, INC.**
9051 River Road
Pennsauken, NJ 08110-3293

4/01a

Made in U.S.A.

Directions for Use
How to prepare Cetylciide-G Diluent for Use with Cetylciide-G.
(See the How-To-Prepare Sheet for diagrams)

- 1) With both caps closed, tilt the bottle forward to fill the measuring chamber.
- 2) Tilt the bottle back using angular pour-back scale to adjust to desired level (e.g. 1 qt).
- 3) Remove the Pour Cap and pour the measured dose into the **C-Tub** or other receptacle.

According to your needs, add 1 qt., 1/2 gal. or 1 gal. of water to **C-Tub** or other instrument receptacle.

To each 1 quart of water add 1/2 oz. of Cetylciide-G Diluent.

1/2 oz. (15 mls.) Diluent Concentrate added to 1 quart water.

1 oz. (30 mls.) Diluent Concentrate added to 1/2 gallon water.

2 oz. (60 mls.) Diluent Concentrate added to 1 gallon water. (Fill the measuring chamber to the 30 ml. line twice).

Pour the appropriate amount of Diluent Concentrate directly into the specified volume of water in **C-TUB** or other instrument receptacle.

This Diluent Solution must then be mixed with Cetylciide-G Concentrate (see further instructions on Cetylciide-G label or Cetylciide-G insert) to make Cetylciide-G Use Solution.

Storage and Disposal

Do not re-use empty container. Open uppermost cap to triple rinse bottle, then puncture and discard in trash.

Precautionary Statements

Hazards to Humans and Domestic Animals

Corrosive. Causes eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination of food.

Statement of Practical Treatment

Skin and Eyes: In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call physician. Remove and wash contaminated clothing before re-use.

Ingestion: If conscious drink water. Call a physician immediately.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.