

US ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF PESTICIDES PROGRAMS  
REGISTRATION DIVISION (TS-767)  
WASHINGTON, DC 20460

EPA REGISTRATION NO.

DATE OF ISSUANCE

NOTICE OF PESTICIDE:  REGISTRATION  
 RERE-REGISTRATION

(Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended.)

TERM OF ISSUANCE

NAME OF PESTICIDE PRODUCT

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Industries, Inc.  
New York  
New York, NY 10011

SEP 29 1989

**NOTE:** Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusively use that name or to its use if it has been covered by others.

- c. For instrument sterilization/disinfection, add to the back page the directions to include "clean and rinse the lumens of hollow instruments before filling with solution."
- d. On the front panel, provide directions for use in the areas of usage as per item 1 of the label.

ATTACHMENT IS APPLICABLE

**BEST AVAILABLE COPY**

SIGNATURE OF APPROVING OFFICIAL

DATE

- e. Delete the claims for cytomegalovirus and influenza type A viruses, no data were submitted to support the proposed claims.
- f. Under the Mycobacterium tuberculosis claim, revise the wording "in 20 minutes" to read "Mycobacterium tuberculosis in 20 minutes at 20 °C."
- g. Add asterisks to virucidal to the front page to read "Virucidal\*" and to viruses on the back page to read "Viruses\*."
- h. On the back page and following the list of viruses which list 10 minutes contact time, add the wording and revise to read ". . . in 10 minutes on hard, inanimate, surfaces."
- i. Remove the phrase "Wear goggles or safety glasses when handling" and place the phrase under the precautionary statements.
- j. Under Statement of Practical Treatment add the phrases "If swallowed: drink promptly a large quantity of water. Do not induce vomiting. Avoid alcohol. Get medical attention," and "Note To Physician: Probable mucosal damage may contraindicate the use of gastric lavage."

3. Revised Confidential Statement of Formula is not filled out correctly and is not acceptable. Submit revised Confidential Statement of Formula and for each amount that is given in liquid measure tell us pounds per gallon or density. Note that label declarations must be on weight by weight basis.

For guidance please refer to your Confidential Statement of Formula of 10-14-86.

4. Enclosed product chemistry data, manufacturing procedure, and physical and chemical characteristics would be acceptable.

5. Submit 12 month storage and stability data for our review.

6. The net contents must be stated in terms of U.S. measure. There would then be no objection to an additional statement in terms of metric measure. It should be: Net Contents 12.8 oz (380 ml).


7. No data were submitted to support virucidal claims for influenza type A and cytomegalovirus, data generated as per DIS/TSS-7 enclosure should be submitted for a determination.

8. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

**BEST AVAILABLE COPY**

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

John H. Lee   
Product Manager (31)  
Antimicrobial Program Branch  
Registration Division (H7505C)

Enclosures

**BEST AVAILABLE COPY**

PROPOSED FRONT LABEL

Net contents

380 ml.

# Cetylcode-G®

## DISINFECTING AND STERILIZING SOLUTION

Bactericidal, Virucidal, Tuberculocidal, Fungicidal, Sporocidal.

Cetylcode-G® must be used only with use-dilution (1:64) Cetylcode®

### Active Ingredients:

Glutaraldehyde.....47.5%

Inert Ingredients:.....52.5%

Total Ingredients:.....100.0%

Keep out of reach of children

### Danger

Wear goggles or safety glasses when handling

### Precautionary Statements

#### Hazards to Humans

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 case of eye contact, immediately flush with water for 15 minutes, then get medical attention. For skin, flush with water. Wash clothing before re-use.

EPA No. 3150-

EPA Establishment No.

Made in U.S.A.

ACCEPTED  
with COMMENTS  
in EPA Letter dated

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the purpose of  
registered under EPA Act



**CETYLITE  
INDUSTRIES, INC.**  
9051 River Road  
Pennsauken, NJ 08110

**BEST AVAILABLE COPY**

PROPOSED BACK LABEL

**Directions for use:**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**Do not use this product on food or feed.**

Mix use-dilution (1:64) Cetylcide according to directions on bottle: ie., 60 ml. Cetylcide to one gallon tap water. In known hard water areas, use softened, deionized or distilled water.

Per quart of use-dilution Cetylcide, add two pre-measured portions 63 ml. Cetylcide-G. To measure portion, remove cap and seal (if unopened bottle) from Cetylcide-G bottle, gently squeeze lower portion of indented bottle allowing solution to fill the top section of bottle to black fill line. Pour contents of top section into quart of use-dilution Cetylcide. The resulting mixture will be green. To one gallon of use-dilution Cetylcide, add eight pre-measured portions, 252 ml. Cetylcide-G.

**Label the Cetylcide-G use-dilution with the label(s) provided.**

Clean instruments thoroughly ... rinse free of all soap before immersion.

**For use as a disinfectant, immerse instruments in Cetylcide-G use-dilution for 20 minutes at room temperature.** This will destroy Bacteria in 10 minutes.

Fungi in 10 minutes, Viruses including: Herpes simplex Type I, Herpes simplex Type II, Poliovirus Type I, Poliovirus Type II, Poliovirus Type III, Coxsackie Virus BI, Vaccinia Virus, Adenovirus, Cytomegalovirus, and Influenzae Virus Type A in 10 minutes. Mycobacterium tuberculosis in 20 minutes. Can be re-used as a disinfectant use-dilution for up to 28 days.

**For use as a sterilant, immerse instruments in Cetylcide-G use-dilution for 3 hours at room temperature.** Remove instruments from the solution using a sterile technique and rinse thoroughly with sterile water. If sterile water is not available, use 70% isopropyl alcohol for rinse. This sterilization procedure destroys pathogenic spores. Use-dilution can be re-used as a sterilant for up to 28 days.

**Storage and Disposal**

Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray use mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or your Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. Waste resulting from the use of this product may be disposed of on site.

**Storage**

This product should be stored at room temperature, preferably in a cool place.

**Container Disposal**

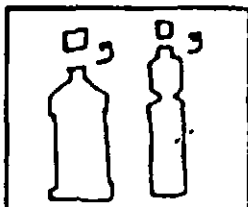
Do not reuse empty container. Triple rinse (or equivalent) top section of the indented bottle, then puncture top section and dispose of entire container in a sanitary landfill or by incineration if allowed by state and local authorities.

Directions

Display this chart on wall directly above mixing area.

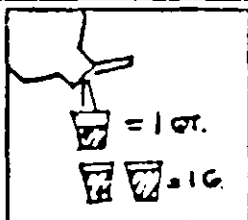
# How to use Cetylcide-G<sup>®</sup>

1



Remove caps from both Cetylcide and Cetylcide-G bottles.  
Cut out inner safety seal (if using previously unopened bottles).

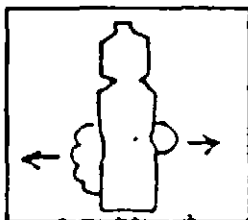
2



Pour 15 ml. Cetylcide into the provided measuring cup to make 1 quart of use-dilution or pour 60 ml. Cetylcide to make 1 gallon of use-dilution.

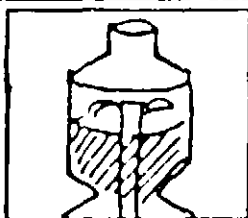
Add the correct amounts of Cetylcide to either 1 quart or 1 gallon of water in a suitable container to make proper use-dilution Cetylcide.

3



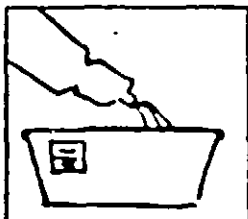
Gently squeeze the lower portion of indented Cetylcide-G bottle until liquid level reaches black fill line in the top portion of bottle.

4



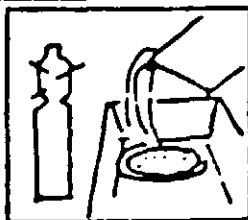
Each squeeze to fill line equals 31.5 ml.

5



Pour two (2) top portions per quart or eight (8) top portions per gallon into the already prepared Cetylcide use-dilution. Affix pre-printed label (provided) to container and fill in date mixed, expiration date (28 days from mixing date) and your name or initials.

6



**DO NOT REUSE Cetylcide-G BOTTLE**  
Triple rinse (or equivalent) top portion of indented bottle, then puncture top portion and dispose.

**As a Disinfectant**

Immerse instruments in Cetylcide-G use-dilution for 20 minutes at room temperature. Can be used as a disinfectant for up to 28 days. The used solution may be disposed of on site.

**As a Sterilant**

Immerse instruments in Cetylcide-G use-dilution for 3 hours at room temperature. Remove instruments from the use-dilution using a sterile technique (lifting the tray or by forceps and rinse with sterile water or 70% isopropyl alcohol). Cetylcide-G use-dilution can be used as a sterilant for up to 28 days.

PROPOSED LABEL

Proposed additional use label for  
inclusion on Cetylcide® container

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**Additional Use**

Can be used as a sterilant when mixed with Cetylcide-G

EPA                      Refer to Cetylcide-G label for use directions.

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