PM-31 Reg # 46851-2 19-26

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 2 1995

ProChem Company
A Wholly Owned Subsidiary of Cottrell, Ltd.
7399 South Tucson Way
Englewood, CO 80112

Attention: John R. Scoville, Jr.

Subject: Omnicide Liquid Disinfectant
EPA Registration No. 46851-2
Letters Dated July 10, 1995 and July 13, 1995

The container labeling and package insert labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Acts, as amended, are acceptable, provided that you make the labeling changes listed below before you release the product for shipment bearing the amended label.

1. On the Container Labeling:

   a. The "Virucidal" claim must be keyed by a symbol to the paragraph listing the specific tested viruses.

   b. Specify the major areas in which the product is recommended for use (e.g. homes, school, hospitals).

   c. Delete the term "ProCide" wherever it may appear on the label. This is not your product name.

2. According to our records, there is a contradiction concerning the name of this product. The name on file is "Omnicide Liquid Disinfectant" and not "Omnicide sterilization and Disinfecting Solution". Please clarify.

3. You are reminded that the container labeling must meet EPA's current labeling requirements.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COPY

☆ U.S. GOVERNMENT PRINTING OFFICE 1995 619 457

19-26

A stamped copy of the labeling is enclosed for your records. Submit one (1) copy of the final printed label prior to release of the product for shipment.

If you have any questions concerning this letter, please contact Martha Terry at 703-305-6982.

Sincerely,

Marion J. Johnson, Jr.
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

Enclosure

3976

ACCEPTED
with COMMENTS
In EPA Letter Dated:
AUG 2 [illegible]

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 46851-2

OmniCid

Long Life Reusable Activa

Sterilizing and Disinfecti

Sporicidal, Virucidal, Fungic
Bactericidal, Tuberculocidal

Active Ingredient	
Glutaraldehyde	2.4%
Inert Ingredient	97.6%
TOTAL	100.0%

E.P.A. Registration No. 46851-2
E.P.A. Establishment No. 37265-CA-01
E.P.A. Establishment No. 39754-WI-1
(See shoulder of container for E.P.A. Est. No.)

Note: Contents of attached vial must be added to solution before this product is effective. See "DIRECTIONS FOR USE - ACTIVATE"

DANGER: Keep Out of Reach of
See Side Panel for Addition

INTENDED USE

Sterilization: This solution should be used for the sterilization of heat sensitive medical equipment for which alternative methods of sterilization are not suitable. Medical equipment which should always be sterilized is that which is categorized as critical (e.g., used in procedures in which contact will be made with tissue that is normally considered sterile.)

High Level Disinfection: This solution should be used for the high level disinfection of heat sensitive medical equipment for which sterilization is not practical. Medical equipment which should always be subjected to high level disinfection or sterilization is that which will be used in procedures categorized as semi-critical (e.g., used in procedures in which contact will be made with mucous membranes or other body surfaces which are not normally considered sterile).

Intermediate Level Disinfection: This solution should be used for disinfection of medical equipment for which a risk of cross contamination exists. Medical equipment which should always be disinfected is that which is to be used in procedures categorized as non-critical (e.g., used in procedures in which contact will only be made with intact skin).

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Keep Out of Reach of Children. Direct contact may cause eye damage and skin irritation/damage. Do not get into eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling or pouring. Avoid contamination of food. Use in well ventilated area in closed containers.

STATEMENT OF PRACTICAL TREATMENT: In case of contact, immediately flush eyes or skin with copious amounts of water for at least 15 minutes. For eyes, get medical attention. Harmful if swallowed. Drink large quantities of water and call a physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL

Store at controlled room temperature 15°C-30°C (59°-86°F).
Pesticide Disposal: Discard residual solution in drain. Flush thoroughly with water. **Container Disposal:** Do not reuse empty container. Wrap container and put in trash.

NFPA HAZARDOUS CHEMICAL CHART

Health Hazard	Fire Hazard
☑ Irritant	☐ Below 73°
☐ Carcinogen	☐ Below 100°
☐ Toxic	☐ Above 100° And Exceeding 200°
☑ Sensitizer	☐ Above 200°
☐ Flammable Material	☑ Will Not Burn
Physical Hazard	**Reactivity**
☐ Explosive	☐ Water Reactive
☐ Acid	☐ Shock and Heat May Detonate
☐ Alkali	☐ Water Reactive & Oxidizer
☐ Corrosive	☐ Explosive with Water
☐ Use No Water	☐ Oxidizer
☐ Radioactive	☑ Stable

Product Name: OmniCide
Hazardous Chemicals
Glutaraldehyde
Route of Entry
✔ Inhalation
✔ Ingestion
✔ Skin/Eye Absorption
Personal Protection: Rubber Gloves, Goggles or Face Shield

Contact, Ltd.
7398 South Lewis Way
Littleton, CO 80112 USA
1 800 THE EDGE

09529 2000 Rev. 03

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DIRECTIONS FOR USE

IT IS VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

Activation: Activate the ProCide solution by adding the entire contents of the Activator Bottle (which is attached to the ProCide solution container) to the container. Place cap on container and shake well. On activation the solution immediately changes color to blue, thereby indicating solution is ready to use. Record the date of activation on the indicated space below, in a log book or a label affixed to any secondary container used for activated solution. *See package insert for additional instructions and information regarding activated solution.*

Cleaning/Decontamination: Blood and other body fluids must be thoroughly cleaned from the surfaces, lumens, and objects before application of the disinfectant or sterilant. Blood and other body fluids should be autoclaved and disposed of according to all applicable Federal, State and local regulations for infectious waste disposal.

For complete disinfection or sterilization of medical instruments and equipment, thoroughly clean, rinse and rough dry objects before immersing in ProCide solution. Cleanse and rinse the lumens of hollow instruments before filling with ProCide solution. *See package insert for additional cleaning/decontamination instructions.*

Sterilization: Immerse medical equipment/devices completely in ProCide Solution for a minimum of ten hours at 68°F (20°C) to eliminate all microorganisms including *Clostridium sporogenes* and *Bacillus subtilis* spores.

Remove equipment from the solution using sterile technique and rinse thoroughly with sterile water. *See package insert for complete instructions /information on sterilization.*

High Level Disinfection: Immerse medical equipment/devices completely in ProCide solution for a minimum of **45 minutes at 68°F (20°C)** to destroy all pathogenic microorganisms, except for large numbers of bacterial endospores, but including *Mycobacterium bovis* (Quantitative TB Method).

Remove devices and equipment from the solution and rinse thoroughly with sterile water or potable water. The quality of rinse water used is dependent upon the intended use of the instrument/equipment. *See package insert for complete instructions/information on high level disinfection.*

Intermediate Level Disinfection: Immerse medical instrument/equipment completely in ProCide for a minimum of 10 minutes at 68°F (20°C) to destroy all vegetative bacteria, specified viruses and fungi, and 99.99% of *Mycobacterium* strains (Quantitative TB) as represented by *bovis* and *terrae*. *See package insert for complete instructions/information on intermediate level disinfection.*

Refer to package insert for more detailed usage/product data.

Note Dates Here	Expiration Date for
Activation Date	Activated Solution

Check solution upon activation and prior to each use with Test Ink C. Glutaraldehyde Concentration Indicators. This product must be discarded after 28 days, even if the Test Ink C. Glutaraldehyde Concentration Indicator indicates "Pass."

Control Number and Expiration Date for Unactivated Solution on Shoulder

[redacted]

ACCEPTED
with COMMENTS
In EPA Letter Dated:

AUG 2

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 46551-2

Omnicide™ activated dialdehyde solution is a liquid chemical sterilant and a high or intermediate level disinfectant when used according to the **Instructions for Use.**

1. **Germicide Level of Activity:** Omnicide™ can be used at the following germicide levels of activity:

   Sterilant: Omnicide™ is a sterilant when used or reused, according to the Directions For Use, at or above its Minimum Effective Concentration (MEC) as determined by the ProChek G Glutaraldehyde Concentration Indicator Test Strip at 68°F (20°C) with an immersion time of **ten hours** for a use period not to exceed 28 days.

   High Level Disinfectant: Omnicide™ is a high level disinfectant when used or reused, according to the Directions for Use, at or above its Minimum Effective Concentration (MEC) as determined by the ProChek G Glutaraldehyde Concentration Indicator Test Strip at 68°F (20°C) with an immersion time of 45 minutes for a use period not to exceed 28 days.

   Intermediate Level Disinfectant: Omnicide™ is an intermediate level disinfectant when used or reused, at or above itsMinimum Effective Concentration (MEC) as determined by the ProChek G Glutaraldehyde Concentration Indicator Test Strip at 68°F (20°C) with an immersion time of ten minutes according to the Directions for Use in Section E for a use period not to exceed 28 days.

   A ten minute immersion at 68°F (20°C) will destroy all vegetative bacteria including S. aureus, S. choleraesuis, P. aeruginosa, E. coli, all pathogenic fungi, representative viruses and 99.99% of Mycobacterium strains (Quantitative TB) as represented by bovis and terrae.

ACCEPTED
with COMMENTS
In EPA Letter Dated:
AUG ?

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 46851-2

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2. **Reuse Period:** Omnicide™ has demonstrated efficacy in the presence of 5 percent organic soil contamination and a simulated amount of microbiological burden during reuse. **OMNICIDE™ SOLUTION MAY BE REUSED ONLY WHILE THE MINIMUM EFFECTIVE CONCENTRATION (MEC) AS DETERMINED BY THE PROCHEK G GLUTARALDEHYDE CONCENTRATION INDICATOR TEST STRIP, PH AND TEMPERATURE MEET THE REQUIREMENTS BASED UPON MONITORING AS DESCRIBED IN INDICATOR DIRECTIONS FOR USE.** Efficacy of Omnicide™ solution during its use-life must be verified by the ProCheK G Glutaraldehyde Concentration Indicator Test Strip to determine that at least the MEC as determined by the ProChek G Glutaraldehyde Concentration Indicator Test Strip is present. The product must be discarded after 28 days.

3. **General Information:** Choose a germicide with the level of microbial activity that is appropriate for the reusable medical device or equipment surface. Follow the reusable device labeling and standard institutional practices. In the absence of complete instructions, use the following guidance:

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

   - A **critical device** routinely penetrates the skin or mucous membranes during use or are otherwise used in normally sterile tissues of the body.

   - A **semi-critical device** makes contact with mucous membranes but does not ordinarily penetrate sterile areas of the body.

   - A **non-critical device** contacts only intact skin during routine use.

   Second, determine if sterilization, high level or intermediate level disinfection is required.

   Critical device: Sterilization is required.

   Semi-critical Device: Although sterilization is recommended whenever practical, High Level Disinfection is acceptable (e.g. GI endoscopes, anesthesia equipment to be used in the airway, diaphragm-fitting rings, etc.)

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with COMMENTS
In EPA Letter Dated:
AUG 2

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 46851-2

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Non-critical device: Medical Equipment Surfaces: Intermediate level disinfection is recommended.

Third, determine the time required to achieve the level of disinfection or sterilization required for the specified medical device.

4. The germicidal activity of Omnicide™ was demonstrated using stressed solutions* in performance, clinical and simulated use testing using the following organisms:

Organisms	Omnicide™ Disinfection Times
Spores	10 hours
• Bacillus subtilis	
• Clostridium sporogenes	
Vegetative Organisms	45 minutes
• Staphylococcus aureus	
• Salmonella choleraesuis	
• Pseudomonas aeruginosa	
• Escherichia coli	
• Mycobacterium bovis	
Fungi	10 minutes
• Trichophyton interdigitale	
Non-lipid Small Virus	10 minutes
• Polio 2	
Lipid Medium Virus	10 minutes
• Herpes simplex	
• HIV-1 (AIDS Virus)	60 seconds at full strength

ACCEPTED
with COMMENTS
In EPA Letter Dated:
AUG 2

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 46854-2

* Testing was performed using Omnicide™ solution which had been diluted to 1.5 percent using 5 percent bovine calf serum.

5. **Material Compatibility:** Omnicide™ solution is recommended for usage with medical devices made from the materials shown below.

polypropylene	vinyl and Tygon tubing**
ABS	nickel plating*
polyethylene*	acrylic bar*
polycarbonate	polyethylene tubing*
black oxide steel*	PVC*
Mylar*	

*represents four weeks of exposure
**represents 13 days of exposure

Following sterilization or disinfection, the sterilized or disinfected medical device should be rinsed according to the Instruction for Use, Rinsing (Section E.4), and dried according to manufacturers instructions.

6. **Pre-cleaning Agent Compatibility:** Omnicide™ is compatible with enzymatic detergents which are neutral in pH, low foaming and easily rinsed from equipment. Detergents that are either highly acidic or alkaline are contraindicated as precleaning agents since improper rinsing could effect the efficacy of the Omnicide™ solution by altering its pH.

B. CONTRAINDICATIONS

1. **Sterilant Usage:** Routine biological monitoring is not possible with Omnicide™ solution and therefore Omnicide™ solution should **NOT** be used to sterilize reusable medical devices that are compatible with other sterilization processes that can be biologically monitored.

Omnicide™ solution should not be used for sterilization of critical devices intended for single use (e.g. catheters).

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In EPA Letter Dated:

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Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 46857-2

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2. **High Level Disinfectant Usage:** Omnicide™ solution should not be used to high level disinfect a semi-critical device when sterilization is practical.

3. **Endoscope Usage:** Omnicide™ solution is not the method of choice for sterilization of rigid endoscopes which the device manufacturer indicates are compatible with steam sterilization.

C. WARNINGS

OMNICIDE™ ACTIVATED DIALDEHYDE SOLUTION IS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS.

DANGER: Keep Out of Reach of Children
Contains Glutaraldehyde

1. Direct contact is corrosive to exposed tissue, causing eye damage and skin irritation/damage. Do not get into eyes, on skin or on clothing.

2. Avoid contamination of food.

3. Use in well ventilated area in closed containers.

In case of contact, immediately flush eyes or skin with copious amounts of water for at least 15 minutes. For eyes, get medical attention.

Harmful if swallowed. Drink large quantities of water and call a physician immediately.

Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.

Emergency, safety, or technical information about Omnicide™ solution can be obtained from Cottrell, Ltd. Hotline at 1-800-843-3343, or by contacting Chemtrac at 800-535-5053 or by contacting your local Cottrell, Ltd. representative.

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with COMMENTS
In EPA Letter Dated:
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Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 46851-2

D. PRECAUTIONS

1. Appropriate hand, eye and face protection as well as liquid proof gowns should be worn when cleaning and sterilizing/disinfecting soiled devices and equipment.

   More detailed information regarding the handling of the products along with compatible materials is included in the MSDS sheet attached to the product container.

2. Contaminated, reusable devices **MUST BE THOROUGHLY CLEANED** prior to disinfection or sterilization, since residual contamination will decrease effectiveness of the germicide.

3. The user **MUST** adhere to the **Directions for Use** since any modification will affect the safety and effectiveness of the germicide.

4. The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using Omnicide™ solution.

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with COMMENTS
In EPA Letter Dated:

E. DIRECTIONS FOR USE

1. **Activation**

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the purposes registered under EPA Reg. No. 46854-2

Activate the Omnicide™ solution by adding the entire contents of the Activator Bottle (which is attached to the Omnicide™ solution container) to the container. Place cap on container and shake well. On activation, the solution immediately changes color to blue, thereby indicating solution is ready to use. The solution should then be immediately tested with the Prochek G Glutaraldehyde Indicator Test Strip upon activation and prior to each use to assure glutaraldehyde concentration is above the MEC. Omnicide™ solution is intended for use in manual (bucket and tray) systems made from polypropylene, ABS, polyethylene, glass-filled polypropylene or specially molded polycarbonate plastics. Record the date of activation (mixing date) and the expiration date on the Omnicide™ solution container label in the space provided, as well as in a log book or a label affixed to any secondary container used for the activated solution. Omnicide™ must be discarded after 28 days, even if the ProChek G Glutaraldehyde Indicator Test Strip indicates pass.

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2. **Cleaning/Decontamination**

Blood and other body fluids must be thoroughly cleaned from the surfaces, lumens, and objects before application of the disinfectant or sterilant. Blood and other body fluids should be autoclaved and disposed of according to all applicable federal, state and local regulations for infectious waste disposal.

For complete disinfection or sterilization of medical instruments and equipment, thoroughly clean, rinse and rough dry objects before immersing in Omnicide™ solution. Cleanse and rinse the lumens of hollow instruments before filling with Omnicide™ solution. Refer to the reusable device manufacturers labeling for instructions on disassembly, decontamination, cleaning and leak testing of their equipment.

3. Usage

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

a. Sterilization (Bucket/Tray Manual System)

Prior to immersing medical equipment/devices, test the solution with a ProChek G Glutaraldehyde Indicator Test Strip to assure that the glutaraldehyde concentration is above its MEC.

Immerse medical equipment/devices completely in Omnicide™ Solution for a minimum of **ten hours at 68°F (20°C)** to eliminate all microorganisms including Clostridium sporogenes and Bacillus subtilis spores. Remove equipment from the solution using sterile technique and **rinse thoroughly with sterile water** following the rinsing instructions below.

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In EPA Letter Dated:
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Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 46851-2

b. High Level Disinfection (Bucket/Tray Manual System)

Prior to immersing medical equipment/devices, test the solution with a ProChek G Glutaraldehyde Indicator Test Strip to assure that the glutaraldehyde concentration is above its MEC.

Immerse medical equipment/devices completely in Omnicide™ solution for a minimum of **45 minutes at 68°F (20°C)** to destroy all pathogenic microorganisms, except for large numbers of bacterial endospores, but including Mycobacterium tuberculosis (Quantitative TB Method). Remove devices and equipment from the solution and rinse thoroughly following the rinsing instructions below.

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with COMMENTS
In EPA Letter Dated:
AUG 2

c. Intermediate Level Disinfectant

Prior to immersing medical equipment/devices, test the solution with a ProChek G Glutaraldehyde Indicator Test Strip to assure that the glutaraldehyde concentration is above its MEC.

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 46851-2

Omnicide™ is an intermediate level disinfectant when used or reused, at or above its Minimum Effective Concentration (MEC) as determined by the ProChek G Glutaraldehyde Concentration Indicator Test Strip at 68°F (20°C) with an immersion time of ten minutes for a use period not to exceed 28 days.

4. **Rinsing Instructions**

Following immersion in Omnicide™ solution, thoroughly rinse the equipment or medical device by immersing in two gallons of water. Repeat this procedure a second time with a fresh two gallon volume of water.

For endoscopic instruments with lumens, a minimum of 500 ml of water should be flushed through lumens during each separate rinse unless otherwise noted by the device or equipment manufacturer. Use fresh volumes 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 become contaminated with glutaraldehyde.

Refer to the reusable device/equipment manufacturers labeling for rinsing instructions.

Sterile Water Rinse:

Critical devices which are sterilized with Omnicide™ must be rinsed with sterile water.

Potable Water Rinse:

A sterile water rinse is recommended when practical, for all devices. Alternatively, a high quality potable water (one that meets Federal Clean Water Standards at point of use) may be used.

The use of potable water for rinsing, increases the risk of contaminating the device or medical equipment with Pseudomonades and atypical (fast growing) Mycobacteria that are often present in potable water supplies. The devices (e.g. colonoscope) need to be completely dried, because any moisture remaining 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. A final rinse using a 70 percent isopropyl alcohol solution should be used to speed the drying process and reduce the numbers of any organism present as a result of rinsing with potable water.

F. REUSE

Omnicide™ solution has demonstrated efficacy in the presence of 5 percent organic soil contamination and a simulated amount of microbiological burden during reuse. The glutaraldehyde concentration of this product during its use-life must be verified by the ProCheK G Glutaraldehyde Concentration Indicator Test Strip to determine the solution is above the Minimum Effective Concentration requirement (MEC) as determined by the ProChek G Glutaraldehyde Concentration Indicator Test Strip is present. This solution may be used and reused within the limitations indicated above for up to 28 days after activation. Omnicide™ must be discarded after 28 days, even if the ProChek G Glutaraldehyde Indicator Test Strip indicates pass.

ACCEPTED
with COMMENTS
In EPA Letter Dated:

*Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 46851-2

G. MONITORING OF GERMICIDE TO ENSURE SPECIFICATIONS ARE MET

It is recommended that the Omnicide™ solution be tested with the ProCheK G glutaraldehyde test strip prior to each usage. This is to insure that the appropriate concentration of glutaraldehyde is present and to guard against a dilution which may lower the concentration of the glutaraldehyde below its MEC. During the use of Omnicide™ as a high level disinfectant and/or sterilant, it is also highly recommended that a thermometer and timer be used to ensure that optimum conditions are met. The pH of the activated solution may be periodically checked to verify that the pH of the solution is between 8.0 and 9.0.

H. POST-PROCESSING HANDLING AND STORAGE OF REUSABLE DEVICES

Sterilized or disinfected reusable devices are either to be used immediately or stored in a manner to minimize contamination. Refer to reusable device equipment manufacturers labeling for additional storage and/or handling instructions.

I. STORAGE CONDITIONS AND EXPIRATION DATE

1. Prior to activation, Omnicide™ solution should be stored in its original sealed container at controlled room temperature 15°-30°C (59°-86°F).

2. The expiration date of the unactivated Omnicide™ solution and activator will be found on the side of the immediate container.

3. The use period for activated Omnicide™ is for no longer than as indicated by ProCheK G Glutaraldehyde Concentration Indicator Test Strip or 28 days following activation. Once activated, the solution requires no further dilution prior to its usage.

J. SAFETY INFORMATION

Emergency, safety, or technical information about Omnicide™ solution can be obtained from Cottrell, Ltd. at 1-800-843-3343, Infotrac at 800-535-5053, or by contacting your Cottrell, Ltd. representative.

ACCEPTED
with COMMENTS
In EPA Letter Dated:

AUG 2

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 46557-7

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K. USER TRAINING

The user should be adequately trained in the decontamination and disinfection or sterilization of medical devices and the handling of liquid chemical germicides. Additional information about Omnicide™ solution can be obtained from Cottrell, Ltd. at 1-800-843-3343, or by contacting your local Cottrell, Ltd. representative.

L. DISPOSAL INFORMATION

0.946 L (1 quart), 3785 L (1 gallon), and 9462 L (2.5 gallon) size container must be triple rinsed and disposed of in accordance with local or state regulations.

M. REORDER INFORMATION

Reorder	Description	Case Contains
PC1032	0.946 L (1 quart)	4 x 0.946 L (4 qts/case)
PC1128	3.785 L (1 gallon)	4 x 3785 L (4 gals/case)
PCG660 Strips	ProCheK G Concentration Indicator	60 strips/bottle (6 btls/case)
PCG615	ProCheK G Concentration	15 strips/pkg

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OMNICIDE™ LONG LIFE ACTIVATED DIALDEHYDE SOLUTION
PACKAGE INSERT
ENDOSCOPE REPROCESSING
DRAFT LABELING

A. INTENDED USE/INSTRUCTIONS FOR USE

Omnicide™ activated dialdehyde solution is a liquid chemical sterilant and high level disinfectant for flexible endoscopes when used according to the **Instructions for Use.**

1. **Germicide Level of Activity:** Omnicide™ can be used at the following germicide levels of activity:

   Flexible Endoscopes, when expected to penetrate the skin or mucous membranes or are used in otherwise normally sterile tissues of the body during use are critical devices and therefore, are required to be sterile.

   Sterilant: Omnicide™ is a sterilant for flexible endoscopes when used or reused, according to the Directions For Use, at or above its Minimum Effective Concentration (MEC) as determined by the ProChek G Glutaraldehyde Concentration Indicator Test Strip at 68°F (20°C) with an immersion time of **ten hours** for a use period not to exceed 28 days.

   Flexible Endoscopes when expected to come in contact without penetration of mucous membranes are semi-critical devices and therefore may be high level disinfected.

   High Level Disinfectant: Omnicide™ is a high level disinfectant for flexible endoscopes when used or reused, according to the Directions for Use, at or above its Minimum Effective Concentration (MEC) as determined by the ProChek G Glutaraldehyde Concentration Indicator Test Strip at 68°F (20°C) with an immersion time of 45 minutes according to the instructions for use in Section E for a use period not to exceed 28 days.

ACCEPTED
WITH COMMENTS
IN FDA letter dated

General Procedure for High Level Disinfection of Flexible Endoscopes

(This procedure is recommended in the absence of specific directions from the device manufacturer)

Trained Personnel

- Personnel involved in the reprocessing of endoscopes should have the ability to read, understand, and implement instructions from manufactures and regulatory agencies as they relate to endoscopic disinfection.

- The person(s) to whom the job of reprocessing endoscopes is given should have the opportunity to become completely familiar with the mechanical aspects of the endoscopic equipment.

- Training should include familiarization with OSHA regulations and in-house policies on how to appropriately and safely handle liquid chemical germicides.

- Training should also include information on the safe handling of instruments that are contaminated with body fluids after use. This should include familiarization with universal precautions.

Cleaning of flexible endoscopes

- **Cleaning at the Examination Room**

Reflux of body fluids from the patient may occur in any of the standard channels. Cleaning of endoscopes and accessories should be performed promptly after removing the endoscope from the patient to prevent drying of secretions.

1. Personnel should donne all personnel protective equipment.

2. Prepare an enzyme detergent (e.g., Pro EZ or Pro EZ Plus) or one recommended by the scope manufacturer.

3. Gently wipe all debris from the insertion tube with a moistened gauze or the like.

4. Place the distal end of the flexible endoscope into the water and enzyme detergent solution and aspirate through the biopsy/suction channel for 5-10 seconds or until the solution is visibly clean. Alternate aspiration of the detergent solution and air several times. Finish by suctioning air.

5. Flush or blow out air and water channels in accordance with the endoscope manufacturers instructions.

6. Transport the endoscope to the reprocessing area.

Cleaning at the Reprocessing Area

1. Attach any necessary water-tight caps to the electrical portions of the umbilicus.

2. Before proceeding with any further cleaning steps, the flexible endoscope should be leak tested. (Refer to manufacturers leakage test instructions). Follow the manufacturers instructions if the instrument appears damaged.

3. Fill a sink or basin with a freshly made enzyme (e.g., Pro EZ or Pro EZ Plus) detergent solution.

4. Immerse the endoscope. All channels should be irrigated with copious amounts of detergent and tap water to soften, moisten, and dilute the organic debris. All detachable parts (e.g., hoods and suction valves) should be removed and soaked in the detergent solution. The insertion tube should be washed with detergent solution and rinsed.

5. Use a small soft brush to scrub all detachable parts.

6. Use a brush to clean under the suction valve, air/water valve and biopsy port openings.

7. Brush the entire suction/biopsy system including the body, the insertion tube, and the umbilicus of the endoscope in accordance with the manufacturer's instructions.

8. Accessible channel(s) should be brushed to remove particulate matter, and the detergent solution must be suctioned or pumped through all channels to remove dislodged material. Channel irrigators may be useful for this step. Fill all channels with detergent solution and soak 2-5 minutes in accordance to the Pro EZ instructions.

Rinse after cleaning:

9. Rinse the endoscope and all detachable parts in clean water.

10. Rinse all channels well with water to remove debris and detergent.

11. Purge water from all channels and wipe dry the exterior of the endoscope with a soft clean cloth to prevent dilution of the Omnicide™ disinfectant used in subsequent steps.

Manual Disinfection

12. Activate the Omnicide™ Long Life activated dialdehyde by adding the entire content of the Activator bottle which is attached to the Omnicide™ solution container. Recap the container and shake well. On activation, the solution immediately changes color to blue, thereby indicating the solution is ready. Use ProChek G Glutaraldehyde Concentration Indicator Test Strips after activation to determine that the solution is above the Minimum Effective Concentration (MEC) before use.

    Test the activated Omnicide™ solution using the ProChek G Glutaraldehyde Concentration Indicator at 20°C, before each use.

13. Attach channel irrigators/adapters and cover the biopsy port in accordance with the manufacturer's instructions.

14. Pour the activated Omnicide™ into an appropriate sized basin.

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with COMMENTS
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[illegible] registered under EPA Reg. No.
46851-2

15. Completely immerse the endoscope in the basin of Omnicide™. Note: in order to prevent damage to the endoscope, DO NOT soak any other accessory equipment with the endoscope.

16. Inject the Omnicide™ solution into all channels of the endoscope until it can be seen exiting the opposite end of each channel. Assure that all channels are filled with disinfectant and that no air pockets remain within the channels.

17. Cover the disinfectant soaking basin with a tight fitting lid to minimize chemical vapor exposure.

18. Soak the endoscope for 45 minutes. Use a timer to ensure adequate soaking time.

19. Before completely removing the endoscope from the disinfectant, flush all channels with air to remove disinfectant.

Rinse After Manual Disinfection

20. Rinse 1: Fill a basin with two gallons of water (preferably sterile water). Place the endoscope into the basin and thoroughly rinse the exterior of the scope. Attach channel irrigators/adapters to the endoscope and flush with 500 ml of water through the channel irrigator. Empty basin.

21. Rinse 2: Fill a basin with two gallons of water (preferably sterile water). Place the endoscope into the basin and thoroughly rinse the exterior of the scope and flush with 500 ml of water through the channel irrigator.

22. Purge all channels with air.

23. Flush all channels with 70% alcohol until the alcohol can be seen exiting the opposite end of each channel.

24. Purge all channels with air.

25. Remove all adapters and devices.

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Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 46851-2

Storage

26. Dry the exterior of the endoscope with a soft clean cloth. Do not attach detachable parts to the endoscope prior to storage. Storage of endoscopes with the removable parts detached lowers the risk of trapping liquid inside the instrument and facilitates continued drying of the channels and channel openings. To prevent the growth of waterborne organisms, the endoscope and all detached parts should be thoroughly dried prior to storage.

27. Hang the endoscope vertically with the distal tip hanging freely in a well ventilated, dust-free cabinet.

References:

1. ASTM:F 1518-94, Standard for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Visera, Current edition approved May 15, 1994, Published July 1994.

2. Martin, M.A., MD, Reichelderfer, M., APIC guideline for infection prevention and control in flexible endoscopy, Association for Professionals in Infection Control and Epidemiology, Inc., AJIC Am J Infect Control 1994: 22: 19-38.

3. Vesley, D. et. al., Significant factors in the disinfection and sterilization of flexible endoscopes, AJIC, December 1992, pg. 292.

4. Axon, A.T.R., Bond, B., Bottrill, P.M., Cowen, A.E., Fleisher, D.E. and Tandon, R.K., Endoscopic disinfection, Working Party Reports, Blackwell Scientific Publications, 1990, 46-50.

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OMNICIDE™ LONG LIFE ACTIVATED DIALDEHYDE SOLUTION
PACKAGE INSERT
ULTRASOUND TRANSDUCER REPROCESSING
(Endocavity, Endovaginal, Enderectal, Transesophageal, etc)
DRAFT LABELING

(Refer to the device manufacturer's instruction for specific procedures)

A. INTENDED USE/INSTRUCTIONS FOR USE

Omnicide™ activated dialdehyde solution is a liquid chemical sterilant, high level disinfectant and intermediate level disinfectant for ultrasound transducers when used according to the Instructions For Use.

1. **Germicide Level of Activity:** Omnicide™ can be used at the following levels of activity:

   Sterilant: Omnicide™ is a sterilant for ultrasound transducers when used or reused according to the Directions For Use, at or above its Minimum Effective Concentration (MEC) as determined by the ProChek G Glutaraldehyde Concentration Indicator Test Strip at 68°F(20°C) with an immersion time of ten hours for a use period not to exceed 28 days.

   High Level Disinfectant: Omnicide™ is a high level disinfectant for ultrasound transducers when used or reused, according to the Directions for Use, at or above its Minimum Effective Concentration (MEC) as determined by Prochek G Glutaraldehyde Concentration Test Strip at 68°F(20°C) with an immersion time of 45 minutes according to the instructions for use in Section E for a use period not to exceed 28 days.

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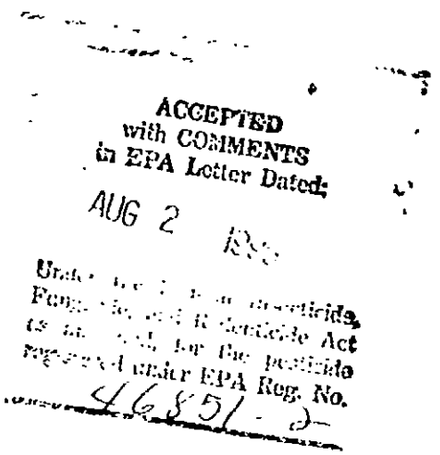
Intermediate Level Disinfectant: Omnicide™ is an intermediate level disinfectant when used or reused, according to the Directions for Use, at or above its Minimum Effective Concentration (MEC) as determined by the Prochek G Glutaraldehyde Concentration Indicator Strip at 68°F(20°C) with an immersion time of 10 minutes according to the instructions for use in Section E for a use period not to exceed 28 days.



General Procedure for High Level Disinfection of Ultrasound Transducers (Endocavity, Endovaginal, Endorectal, Transesophageal, etc.)

(Refer to the device manufacturer's instruction for specific procedures)

Trained Personnel

- Personnel involved in the reprocessing of Ultrasound transducers should have the ability to read, understand, and implement instructions from manufactures and regulatory agencies as they relate to transducer disinfection.

- The person(s) to whom the job of reprocessing Ultrasound transducers is given should have the opportunity to become completely familiar with the mechanical aspects of the ultrasound equipment.

- Training should include familiarization with OSHA regulations and in-house policies on how to appropriately and safely handle liquid chemical germicides.

- Training should also include information on the safe handling of instruments that are contaminated with body fluids after use. This should include familiarization with universal precautions.

Cleaning of Transducers

Cleaning of transducers and accessories should be performed promptly after patient use to prevent drying of secretions.

1. Personnel should donne all personnel protective equipment.

2. Prepare an enzyme'detergent (e.g., Pro EZ or Pro EZ Plus) or one recommended by the transducer manufacturer.

3. Gently wipe all debris from transducer surfaces with a moistened gauze or the like.

4. Immerse the distal end of the transducer into the water and enzyme detergent solution for 2-5 minutes or as recommended by the device manufacturer.

NOTE: Refer to manufacturers instructions for recommended immersion depth.

5. Rinse all surfaces with water and dry by wiping with a soft clean cloth.

Manual Disinfection

Caution: **Omnicide™ may discolor the exterior of some transducers, however, the acoustic or scanning performance is not impaired. Check with the device manufacturers for specific recommendations before proceeding.**

6. Activate the Omnicide™ Long Life activated dialdehyde by adding the entire content of the Activator bottle which is attached to the Omnicide™ solution container. Recap the container and shake well. On activation, the solution immediately changes color to blue, thereby indicating the solution is ready. Use ProChek G Glutaraldehyde Concentration Indicator Test Strips after activation to determine that the solution is above the Minimum Effective Concentration (MEC) before use.

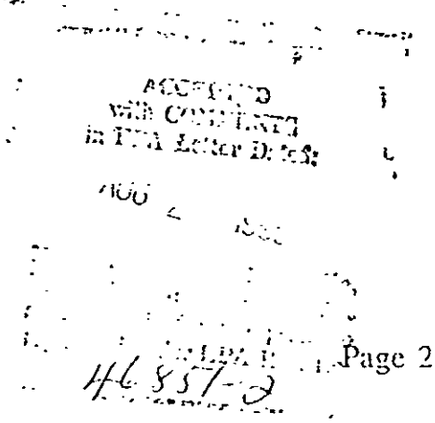
Test the activated Omnicide™ solution using the ProChek G Glutaraldehyde Concentration Indicator at 20°C, before each use.

7. Pour the activated Omnicide™ into an appropriate sized basin.

8. Immerse the distal end of the transducer into the Omnicide™ solution. **Note:** Refer to manufacturers instructions for recommended immersion depth.

9. Cover the disinfectant soaking basin to minimize chemical vapor exposure.

10. Soak the transducer for 45 minutes. Use a timer to ensure adequate soaking time.



Rinse After Manual Disinfection

11. Rinse 1: Fill a basin with a minimum of 1 gallon of water (preferably sterile water). Place the transducer into the water to the recommended depth and allow to soak for 5 minutes. Remove the transducer.

12. Rinse 2: Holding the transducer over the basin, flush with fresh water (preferably sterile water) for one minute.

13. Dry the transducer by wiping with a soft (preferably sterile) cloth.

Storage

Refer to manufacturer's recommendation.