UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Johnson & Johnson Medical, Inc. 2500 Arbrook Boulevard P.O. Box 90120 Arlington, TX 76004-3130

MAY 2 4 1994

Attention: T. M. Wendt, Ph.D., Director Regulatory Affairs

> Paul J. Kruger, Agent for Johnson & Johnson Medical, Inc.

Subject: CIDEX FORMULA 7\* Long-Life Activated Dialdehyde Solution EPA Registration No. 7078-4 Your Amendment Dated April 8, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to revise the product labeling to include a package insert as per FDA 510(k) labeling requirements, has been reviewed by the Agency and found to be acceptable, provided you make the following change.

Amend the submitted product label with the following statement prior to releasing the product for shipment. Immediately under "DIRECTIONS FOR USE" include: "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling." Your release for shipment of the product constitutes acceptance of this condition.

The submitted package insert is appropriate, acceptable, and complies with FDA 510(k) labeling requirements for liquid chemical germicides, as per 21 CFR Section 801.5.

A stamped copy of the product label and package insert is enclosed for your records.

If you have any questions concerning this letter, please contact Doreen Aviado at (703) 305-6554.

Sincerely,

Marshall Swindell

Acting Product Manager-31 Antimicrobial Program Branch

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Registration	Division (7505C)
CONCURRENCES	

EPA Form	1320-1A (1/90)		Printed on Recycled	l Paper	-	OFFICI	AL FILE COPY
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\*U.S. Government Printing Office: 1992 - 620-856/40672

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> ACCEPTED with COMMENTS in EPA Letter Dated:

# MAY 2 4 1994

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the posticide registered under EPA Reg. No.

7078-4

## REUSABLE Sterilizing and Disinfecting Solution

Sporksidal Fundicidal Viruadal Tuberculocida

Reorder No.

2745

Bactericidal Pseudomonauidal



#### long-life activated dialdehyde solution

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EPA REG. No. 7078-4 EPA EST. No. 38128-PH 1

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#### Keep out of reach of children. DANGER: Ser Maria and Party for additional precautionary dations

CIDEX FORMULA 7\* Solution is a liquid chemical sterilant and a high or intermediate level disinfectant, when used according to the Directions for Use.

<u>Sterilant</u>: CIDEX FORMULA 7 Solution is a sterilant when used or reused, according to Directions for Use, at full strength for a maximum of 28 days at 20°C to 25°C with an immersion time of at least 10 hours.

<u>High Level Disinfectant</u>: CIDEX FORMULA 7 Solution is a high level disinfectant when used or reused, according to Directions for Use, at full strength for a maximum of 28 days at 25°C with an immersion time of at least 90 minutes.

Intermediate Level Disinfectant: CIDEX FORMULA 7 Solution is an intermediate level disinfectant when used or reused, according to Directions for Use, at full strength for a maximum of 28 days.

A 10 minute immersion at 20°C to 25°C will destroy all vegetative bacteria, except for large numbers of Mycobacterium tuberculosis, but including Pseudomonas aeruginosa, pathenogenic fungi and specified viruses, as indicated in Section E - Directions for Use - Item 3(c).

A 10 minute immersion at 20°C will kill 89.4% Mycobacterium tuberculosis (Quantitative TB Method).

A 10 minute immersion at 25°C will kill 98.4% Mycobacterium tuberculosis (Quantitative TB Method).

#### 2) <u>Reuse Period</u>



CIDEX FORMULA 7 Solution has demonstrated efficacy in the presence of 2% organic soil and a simulated amount of microbiological burden during reuse. CIDEX FORMULA 7 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 described in Directions for Use. DO NOT rely solely on days in use. Efficacy of this product during its use-life must be verified by the CIDEX FORMULA 7<sup>\*</sup> Solution Test Strip to determine that at least the minimum effective concentration (MEC) o<sup>\*</sup> 1.8% glutaraldehyde is present.

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### 3) General Information on Selection and Use of Germicides for <u>Medical Device</u> <u>Reprocessing</u>

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 process:

#### First, for patient contacting devices, determine whether the reusable device to be reprocessed is a critical, semi-critical, or noncritical 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.
- A noncritical device contacts only intact skin during routine use.

# 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.)
Noncritical Device	Intermediate Level Disinfection recommended when there is a risk of cross- contamination, otherwise Low Level Disinfection acceptable (e.g.: bed pans, blood pressure cuffs, linens, etc.)
Medical Equipment Surface	Same as for noncritical device (e.g.: crutches, oxygen cylinders, 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.

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### 4) <u>Microbial Activity</u>

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The following table indicates the spectrum of activity as demonstrated by testing of CIDEX FORMULA 7 Solution\*\*:

BACTERIA		FUNGI	VIRUSE	VIRUSES	
SPORES	VEGETATIVE Organisims		NON-ENVELOPED	ENVELOPED	
Bacillus subtilis	Staphykeneeus aureus	Trichophyton mentagrophytes	Polkovirus Type 1	Coronavirus	
Clostridium sporcycnes	Salmonella choleraesuis		Rhinovirus Type 14	Cytomegaluvirus	
	Pseudomonas acruginosa		Adenovirus Type 2	Influenza virus Type A [WS/33]	
	Mycohacterium tuberculosis		Vaccinía	HIV-1 (AIDS Virus)	
			Coxseckievirus B-t	Herpes simplex Type 1, 2	

\*\* Testing was done after 28 days of simulated resue using prescribed testing methods.

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#### 5) Material Compatibility

CIDEX FORMULA 7 Solution is recommended for use with medical devices made from the materials shown below. Care must be taken with medical and dental equipment such as anesthesia and respiratory therapy tubing, dental mirrors and burs. These devices may be damaged when cleaned with a highly alkaline detergent, poorly rinsed after disinfection, stored wet or dried at temperatures exceeding 105°F.

#### **METALS**

### **PLASTICS**

Chrome plate<sup>1</sup> Aluminum<sup>4</sup> Anodized aluminum<sup>5</sup> Brass<sup>5</sup> Carbon steel<sup>7</sup> Stainless steel<sup>7</sup>

Polyethylene terephthalate (Polyester)<sup>2</sup> Polyvinylchloride (PVC)<sup>2</sup> Polystyrene<sup>2</sup> Polymethylmethacrylate (Acrylic)<sup>2</sup> Polycarbonate<sup>4,8</sup> Polypropylene<sup>7</sup> Polyethylene<sup>7</sup> Acrylonitrile-butadiene-styrene (ABS)<sup>7</sup> Nylon<sup>7</sup> Cof 15

#### **ELASTOMERS**

Black natural rubber<sup>3</sup> Red natural rubber<sup>3</sup> Polychloroprene rubber (Neoprene)<sup>6</sup> Silicone rubber (Silastic)<sup>7</sup>

#### NOTE:

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- 1 Represents 13 hours of total contact with CIDEX FORMULA 7 Solution over 40 disinfection cycles.
- 2 Represents 20 hours of total contact with CIDEX FORMULA 7 Solution over 20 disinfection cycles.
- 3 Represents 35 hours of total contact with CIDEX FORMULA 7 Solution over 104 disinfection cycles.
- 4 Represents 40 hours of total contact with CIDEX FORMULA 7 Solution over 40 disinfection cycles.
- 5 Represents 144 hours of continuous contact with CIDEX FORMULA 7 Solution.
- 6 Represents 240 hours of total contact with CIDEX FORMULA 7 Solution over 10 sterilization cycles.
- 7 Represents 336 hours or greater of continuous contact with CIDEX FORMULA 7 Solution.
- 8 Triple rinse equipment and dry at room temperature or below 104°F (40°C) to miminize possiblity of stress cracking.

#### 6) <u>Precleaning Agent Compatibility</u>

CIDEX FORMULA 7 Solution is compatible with enzymatic detergents (e.g.: ENZOL\* Enzymatic Detergent) which are mild in pH, low foaming, and easily rinsed from equipment. Detergents that are either highly acid or alkaline are contraindicated as precleaning agents since improper rinsing could affect the efficacy of the CIDEX FORMULA 7 Solution by altering its pH.

#### B) <u>Contraindications</u>

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#### 1) Sterilant Usage

Routine biological monitoring is not feasible with CIDEX FORMULA 7 Solution, and therefore, CIDEX FORMULA 7 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.

CIDEX FORMULA 7 Solution should not be used for sterilization of critical devices intended for single use (e.g.: catheters).

#### 2) High Level Disinfectant Usage

CIDEX FORMULA 7 Solution should NOT be used to high level disinfect a semicritical device when sterilization is practical.

#### 3) Endoscope Usage

CIDEX FORMULA 7 Solution is not the method of choice for sterilization of rigid endoscopes which the device manufacturer indicates are compatible with steam sterilization. In general, glutaraldehyde solutions that do not contain surfactants (e.g.: CIDEX\* Activated Diakdehyde Solution) are more appropriate for flexible endoscopes, since glutarakdehyde solutions containing surfactants (e.g.: CIDEX FORMULA 7 Solution or CIDEX PLUS\* 28 Day Solution) are more difficult to rinse from the devices. However, these surfactant containing disinfectants may be used for reprocessing of flexible endoscopes if a validated protocol for rinsing and leak testing is employed.



C) <u>Warnings</u>

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# CIDEX FORMULA 7 SOLUTION IS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS

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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 plenty 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 CIDEX FORMULA 7 Solution can be obtained from Johnson & Johnson Medical, Inc. Customer Relations at 1-800-423-5850, or by contacting your local Johnson & Johnson Medical, Inc. sales representative.

#### D) <u>Precautions</u>

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- 1) Disposable latex gloves, eye protection, face masks, and liquid-proof gowns should be worn when cleaning and sterilizing/disinfecting soiled devices and equipment.
- 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 CIDEX FORMULA 7 Solution.
- 5) The use of CIDEX FORMULA 7 Solution in automated endoscope washers must be part of a validated reprocessing procedure provided by the washer manufacturer. Contact the manufacturer of the endoscope washer for instructions on the maximum number of reprocessing cycles which may be used before refilling with fresh CIDEX FORMULA 7 Solution. Use CIDEX FORMULA 7 Solution Test Strips to monitor glutaraldehyde concentration before each cycle to detect unexpected dilution.

#### E) Directions for Use

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#### 1) <u>Activation</u>

Activate the CIDEX FORMULA 7 Solution by adding the entire contents of the Activator Vial which is attached to the CIDEX FORMULA 7 Solution Container. Shake well. Activated solution immediately changes color to green, thereby indicating solution is ready to use. CIDEX FORMULA 7 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 expiration date on the CIDEX FORMULA 7 Solution container label in the space provided, in a log book or on a label affixed to any secondary container for the act<sup>1</sup>vated solution.

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#### 2) <u>Cleaning/Decontamination</u>

Blood and other body fluids must be thoroughly cleaned from 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 CIDEX FORMULA 7 Solution. Cleanse and rinse the lumens of hollow instruments before filling with CIDEX FORMULA 7 Solution. Refer to the reusable device manufacturer's labeling for additional instructions on disassembly, decontamination, cleaning and leak testing of their equipment.

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#### 3) <u>Usage</u>

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

#### a) <u>Sterilization (Bucket/Tray Manual System)</u>

Immerse medical equipment/device completely in CIDEX FORMULA 7 Solution for a minimum of 10 hours at 20°C to 25°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.

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

Immerse medical equipment/device completely in CIDEX FORMULA 7 Solution for a minimum of 90 minutes at 25°C to destroy all pathenogenic 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.

#### c) Intermediate Level Disinfection (Bucket/Tray Manual System)

Immerse medical equipment/device completely in CIDEX FORMULA 7 Solution for a minimum of 10 minutes at 20°C to 25°C to destroy all vegetative bacteria, except for large numbers of Mycobacterium tuberculosis, but including Pseudomonas aeruginosa, pathogenic fungi, and viruses (Poliovirus Type 1; Adenovirus Type 2; Herpes simplex Type 1,2; HIV-1 (AIDS virus); Influenza Type A [WS/33]; Vaccinia; Coronavirus; Cytomegalovirus; Rhinovirus Type 14) on inanimate surfaces.

A 10 minute immersion at 20°C will kill 89.4% Mycobacterium tuberculosis (Quantitative TB Method).

A 10 minute immersion at 25°C will kill 98.4% Mycobacterium tuberculosik (Quantitative TB Method).

Remove devices and equipment from the solution and rinse thorougnly following the rinsing instructions below.



#### d) <u>Rinsing Instructions</u>

Following immersion in CIDEX FORMULA 7 Solution, thoroughly rinse the equipment or medical device by immersing it completely in three separate copious volumes of water. Each rinse should be a minimum of 1 minute in duration unless otherwise noted by the device or equipment 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/equipment 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;
- 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.

#### POTABLE WATER RINSE

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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 Pseudonaonads and atypical (fast growing) Mycobacteria often present in potable water supplies. A device (e.g.: colonoscope) that is not completely dried prevides 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 with potable water.

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#### e) <u>Reusage</u>

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CIDEX FORMULA 7 Solution has also 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 activation. Do not use activated solution beyond 28 days. Efficacy of this product during its use-life must be verified by the CIDEX FORMULA 7 Solution Test Strip to determine that the minimum effective concentration (MEC) of 1.8% is present.

#### 4) Monitoring of Germicide to Ensure Specifications are Met

During the usage of CIDEX FORMULA 7 Solution, as a high or intermediate 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 CIDEX FORMULA 7 Solution be tested with the CIDEX FORMULA 7 Solution 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 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 7.5 and 8.1.

#### 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. Note that only terminal sterilization (sterilization in a suitable wrap) provides maximum assurance against recontamination. Refer to the reusable device-equipment manufacturer's labeling for additional storage and/or handling instructions.

### F) <u>Storage Conditions and Expiration Date</u>

1) Prior to activation, CIDEX FORMULA 7 Solution should be stored in its original sealed container at controlled room temperature 15\*-30\*C (59\*-86\*F).

Once the CIDEX FORMULA 7 Solution has been activated, it should be stored in the original container until transferred to the closed containers in which the immersion for disinfection or sterilization is to take place. Containers should be stored in a well ventilated, low traffic area at controlled room temperature.

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- 2) The expiration date of the inactivated CIDEX FORMULA 7 Solution will be found on the bottom of the immediate container.
- 3) The use period for <u>activated</u> CIDEX FORMULA 7 Solution is for no longer than 28 days following activation or as indicated by the CIDEX FORMULA 7 Solution Test Strip. Once activated, the solution requires no further dilution prior to its usage.

#### G) <u>Emergency and Technical Product Information</u>

Emergency, safety, or technical information about CIDEX FORMULA 7 Solution can be obtained from Johnson & Johnson Medical, Inc. Customer Relations at 1-800-423-5850, or by contacting your local Johnson & Johnson Medical, Inc. sales representative.

### H) User Proficiency

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It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. 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 CIDEX FORMULA 7 Solution can be obtained from Johnson & Johnson Medical, Inc. Customer Relations at 1-800-423-5850, or by contacting your local Johnson & Johnson Medical, Inc. sales representative.

#### I) Disposal Information

### Germicide Disposal

Discard residual solution in drain. Flush thoroughly with water.

#### **Container Disposal**

- 0.946 L (One Ouart) and 3.785 L (One Gallon) Size Containers Do not reuse empty container. Wrap container and put in trash.
- <u>9.462 L (2 1/2 Gallon) Size Container</u> Triple rinse empty container with water and dispose of in an incinerator or landfill approved for pesticide containers.

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#### J) How Supplied

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<u>Reorder</u>	Description	<u>Case Contains</u>
2745	0.946 L (One Quart) Container	4 x 0.946 L (4 qts)/box; 4 boxes/case; 16 x 0.946 L (16qts)/case
2750	3.785 L (One Gallon) Container	4 x 3.785 L (4 gals) /case
2753	9.462 L (2 1/2 Gallon) Container	2 x 9.462 L (2 x 2 1/2 gals)/case
2 <b>9</b> 23	CIDEX FORMULA 7 Solution Test Strips	60 strips/btl; 2 btls/case
2928	CIDEX FORMULA 7 Solution Test Strips	15 strips/btl; 2 btls/case

References supplied upon request.

\*Trademark