CIDEX® OPA

High Level Disinfecting Solution

TECHNICAL INFORMATION

DESCRIPTION:

CIDEX® OPA Solution is a High Level Disinfectant (HLD) for use in re-processing heat sensitive medical devices. CIDEX OPA Solution is the first new HLD available in the last thirty years with the broad materials compatibility of glutaraldehyde. CIDEX OPA Solution will provide rapid High Level Disinfection in 5 minutes at a minimum of 25° C in a legally marketed automatic endoscope reprocessor or 12 minutes at room temperature (20° C) for manual processing. It is particularly active against mycobacteria, including glutaraldehyde-resistant strains of *M. chelonae*. CIDEX OPA Solution is "ready-to-use", requiring no activation and has minimal odor.

ACTIVE INGREDIENT:

ortho-Phthalaldehyde (OPA) 0.55%

INERT INGREDIENTS:

Aqueous base containing buffering agents,
chelating agents and a corrosion inhibitor.....99.45%

MICROBIOLOGICAL DATA

CIDEX OPA Solution has been extensively tested to demonstrate the excellent germicidal efficacy of the solution. The tests to demonstrate the bactericidal, tuberculocidal, virucidal and fungicidal properties of CIDEX OPA Solution were performed using re-used, stressed solution that was diluted to the Minimum Effective Concentration (MEC), or below.

TESTING RESULTS

BACTERICIDAL TEST RESULTS

The bactericidal activity of CIDEX® OPA Solution against representative types of pathogenic bacteria were evaluated using the AOAC Use-Dilution Test methodology. Results demonstrate that the solution is efficacious when used as directed. A summary of results from the bactericidal tests performed appears below.

Table 1. AOAC Use-Dilution Test Results with re-used and diluted CIDEX OPA Solution at 20°C after a 5-minute exposure time.

Organism Tested	Result
Staphylococcus aureus	No growth - Bactericidal
Salmonella choleraesuis	No growth - Bactericidal
Pseudomonas aeruginosa	No growth - Bactericidal

FUNGICIDAL TEST RESULTS

The fungicidal efficacy of CIDEX OPA Solution was evaluated against Trichophyton mentagrophytes using the AOAC Fungicidal Activity of Disinfectants test method. Results demonstrate that the solution is efficacious when used as directed. A summary of result from the fungicidal test performed appears below.

Table 2. AOAC Fungicidal Activity of Disinfectants Test Results with re-used and diluted CIDEX OPA Solution at 20°C after a 5-minute exposure time.

Organism Tested	Result
Trichophyton mentagrophytes	No growth - Fungicidal

TUBERCULOCIDAL TEST RESULTS

The tuberculocidal efficacy of CIDEX OPA Solution was evaluated against *Mycobacterium bovis* (BCG) using an EPA approved quantitative suspension test method. Results demonstrate the solution is efficacious when used as directed. A summary of result from the tuberculocidal test performed appears below.

Table 3. Tuberculocidal efficacy using quantitive suspension test. Test results with re-used and diluted CIDEX OPA Solution after a 5-minute exposure time at 20˚C.

Organism Tested	Result
Mycobacterium bovis (BCG)	No growth - Tuberculocidal

TOXICITY TEST RESULTS

The toxicological properties of CIDEX OPA Solution have been studied extensively. Results demonstrate that the solution is safe when used as directed. A summary of results from the toxicity tests performed appears below.

Test	Result
Primary Skin Irritation	Non-irritating
Primary Eye Irritation	Moderate Irritant
Acute Oral Toxicity (rat)	LD_{50} > 5000 mg/kg
Acute Dermal Toxicity (rabbit)	LD_{50} > 2000 mg/kg
Dermal Sensitization (Guinea Pig)	Non-sensitizer
Static Acute Bioassay (Fathead Minnows)	LC_{50} > 1000mg/L (Solution neutralized with glycine freebase)

TESTING RESULTS

VIRUCIDAL TEST RESULTS

Virucidal efficacy testing using the EPA Virucide Assay Method was performed with CIDEX OPA Solution. Results demonstrate that the solution inactivated all viruses tested when used as directed. A summary of results from the virucidal test performed appears below.

Table 4. Virucidal efficacy using the EPA Virucide Assay Method. Test results with re-used and diluted CIDEX OPA Solution after a 5-minute exposure time at 20°C.

Virus Tested	Result
Adeno 2	Pass - Virucidal
Coxsackie Type B-3	Pass - Virucidal
Cytomegalovirus	Pass - Virucidal
Herpes Simplex Type 1 & 2 (HSV1 & HSV2)	Pass - Virucidal
HIV-1	Pass - Virucidal
Human Coronavirus	Pass - Virucidal
Influenza Type A (Hong Kong)	Pass - Virucidal
Polio 1	Pass - Virucidal
Rhinovirus Type 42	Pass - Virucidal
Vaccinia (Wyeth)	Pass - Virucidal

SPORICIDAL TEST RESULTS

AOAC Sporicidal Activity of Disinfectants Tests using bacterial endospore contaminated carriers were evaluated with CIDEX OPA Solution. Results demonstrate that the solution is sporicidal when used as directed. A summary of results from the AOAC Sporicidal Tests performed appears below.

Table 5. AOAC Sporicidal Activity of Disinfectants. Test results with re-used and diluted CIDEX OPA Solution.

Organism Tested	Result
Clostridium sporogenes	Re-used and diluted solution is sporicidal in 32 hours at 20°C and 25°C
Bacillus subtilis	Re-used and diluted solution is sporicidal in 32 hours at 20°C and 25°C

SIMULATED USE TEST RESULTS

Simulated use tests with flexible endoscopes contaminated with approximately 1×10^7 *Mycobacterium terrae*, ATCC 15755 suspended in 5% fetal bovine serum were performed with re-used and diluted CIDEX® OPA Solution. Results demonstrate that the solution is efficacious when used as directed. A summary of results from the simulated use tests performed appears below.

Table 6. Cidex® OPA Solution reused and at MEC 0.3% is effective against *M. terrae* and 5% serum.

Scope Tested	12 minutes at 20°C Mean Log_{10} Reduction	5 minutes at 25°C Mean Log_{10} Reduction
Bronchofiberscope	7.07 Log_{10} reduction	6.93 Log_{10} reduction
Duodenofiberscope	6.85 Log_{10} reduction	7.08 Log_{10} reduction
Colonofiberscope	7.10 Log_{10} reduction	7.05 Log_{10} reduction

Refer to package insert prior to product use for complete instructions.

PHYSICAL DATA

CIDEX® OPA Solution is a clear, pale blue liquid with a pH of 7.5. It contains 0.55% *ortho*-phthalaldehyde in an aqueous base containing buffers, chelating agents and a corrosion inhibitor. It is stable at 15 - 30°C (59 - 86°F) for two years.

DIRECTIONS FOR USE

Device Cleaning/Decontamination

Blood, other body fluids, and lubricants must be thoroughly cleaned from the surfaces and lumens of medical devices before reprocessing in the disinfectant. Blood and other body fluids should be autoclaved and disposed of according to all applicable federal, state and local regulations for infectious waste disposal.

Refer to the reusable device manufacturer's labeling for instructions on disassembly, decontamination, cleaning and leak testing of their equipment.

Before immersion in CIDEX OPA Solution, thoroughly clean devices, including all lumens, using a cleaning protocol or standard, such as the ASTM F 1518 "Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera." Thoroughly rinse and rough dry all surfaces and lumens of cleaned devices.

CIDEX® OPA SOLUTION USAGE

No Activation Is Required

Record the date the container was opened on the container label, or in a log book. After opening, the solution remaining in the container can be used for up to 75 days (providing the 75 days does not extend past the expiration date listed on the container) until used.

Record the date the solution was poured out of the original container into a secondary container in a log book (separate from the one mentioned above), or on a label affixed to the secondary container. The solution in the secondary container can be used for a period up to 14 days. The product must be discarded after 14 days even if the CIDEX OPA Solution Test Strip indicates a concentration above the Minimum Effecture Concentration (MEC).

High Level Disinfection

1. Manual Processing:
Immerse device completely, filling all lumens and eliminating air pockets, in CIDEX OPA Solution for a minimum of 12 minutes at 20°C or higher to destroy all pathogenic microorganisms.

2. Automatic Endoscope Reprocessor that can be set to a minimum of 25°C:
High Level Disinfectant at a minimum of 25°C(77°F). For use in a legally marketed Automatic Endoscope Reprocessor (AER) that can be set to a minimum of 25°C with a minimum immersion time of 5 minutes. As with all high level disinfectants it is critical that temperature is monitored when using CIDEX OPA Solution in an AER at 25°C.

Rinsing Instructions

a) Manual Processing:
Following removal from CIDEX OPA Solution, thoroughly rinse the medical device by immersing it completely in a large volume (e.g. 2 gallons) of water. Use sterile water unless potable water is acceptable. Keep the device totally immersed for a minimum of 1 minute in duration, unless a longer time is specified by the reusable device manufacturer. Manually flush all lumens with large volumes (not less than 100 mL) of rinse water unless otherwise noted by the device manufacturer. Remove the device and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose. Repeat the procedure TWO (2) additional times, for a total of THREE (3) RINSES, with large volumes of fresh water to remove CIDEX OPA Solution residues. Residues may cause serious side effects. THREE (3) SEPARATE, LARGE VOLUME WATER IMMERSION RINSES ARE REQUIRED. Refer to the reusable medical device manufacturer's labeling for additional rinsing instructions.

b) Automated Processing:

Select a rinse cycle on an automatic endoscope reprocessor that has been validated for use with this product. Ensure that the automated rinse cycle selected will thoroughly rinse the medical device including all lumens with large volumes of sterile or potable water equivalent to the reusable device manufacturer's recommendations. Verify that each rinse is a minimum of 1 minute in duration unless the reusable device manufacturer specifies a longer time. Ensure that a fresh volume of water is used for each rinse. Do not reuse the water for rinsing or any other purpose. 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:

Devices intended for use in known immuno-compromised patients, or potentially immuno-compromised patients based on institutional procedures (e.g., high risk population served).

When practical, bronchoscopes, due to a risk of contamination from potable water supply. Although microorganisms in this type of water system are not normally pathogenic in patients with healthy immune systems, AIDS patients or other immuno-compromised individuals may be placed at high risk of infection by these opportunistic microorganisms.

POTABLE WATER RINSE

For all other devices, a sterile water rinse is recommended when practical. Otherwise, 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 microorganisms that may be present in potable water supplies.

Water treatment systems, such as softeners of deionizers, may add microorganisms to the treated water to the extent that microbial content of the water at the point of use could exceed that of the pretreated drinking water. To ensure proper water quality, adherence to maintenance of the water treatment system(s) is recommended.

The use of a bacterial retentive (0.2 micron) filter system may eliminate or greatly reduce the amount of these water-borne bacteria from the potable water source. Contact the manufacturer of the filter or UV system for instructions on preventative maintenance and periodic replacement of the filter to avoid colonization or formation of biofilms in the filter.

A device that is not completely dried provides an ideal situation for rapid colonization of bacteria. As these water-borne bacteria are highly resistant to drying, rapid drying will avoid possible colonization but may not result in a device free from these bacteria. A final rinse using a 70% isopropyl alcohol solution can be used to speed the drying process and reduce the numbers of any organism present as a result of rinsing with potable water.

Special Instructions for Transesophageal Echocardiography (TEE) probe reprocessing

As with all devices, carefully follow all probe manufacturer recommendations such as use of sterile protective sheath when performing TEE. Soaking for a minimum of 12 minutes in CIDEX OPA Solution is required for high level disinfection (HLD).

Excessive soaking of the probes (e..g., longer than an hour) during HLD and/or not rinsing three times with a fresh quantity of water each time, may result in residual CIDEX OPA Solution remaining on the device, the use of which may cause staining, irritation or chemical burns of the mouth, throat, esophagus and stomach.

Reusage for Disinfection

CIDEX OPA Solution has demonstrated efficacy in the presence of organic soil contamination and microbiological burden during reuse. The *ortho*-phthalaldehyde concentration of CIDEX OPA Solution during its use-life must be verified by the CIDEX OPA Solution Test Strips to determine that the MEC of 0.3% is present. CIDEX OPA Solution may be used and reused within the limitations indicated above for up to 14 days. CIDEX OPA Solution must be discarded after 14 days, even if the CIDEX OPA Solution Test Strip indicates a concentration above the MEC.

Monitoring of Germicide

During reuse, it is recommended that the CIDEX OPA Solution be tested with the CIDEX OPA Solution Test Strips prior to each usage. This is to ensure that the Minimum Effective Concentration (MEC) of *ortho*-phthalaldehyde is present.

During the usage of CIDEX OPA Solution as a high level disinfectant, it is recommended that the thermometer and timer be utilized to ensure that the optimum conditions are met.

Monitoring Temperature in Automatic Endoscope Reprocessor that can be set to a minimum of 25°C: As with all high level disinfectants, temperature monitoring is critical for use of CIDEX OPA Solution at a minimum of 25°C for 5 minutes in an AER. If you cannot monitor temperature appropriately in your machine, contact ASP at (888) 783-7723 for further instructions.

Visually inspect the solution during the reuse life for the presence of precipitates which may result from the use of hard water. Discard solution if precipitation occurs.

Post-Processing Handling and Storage of Reusable Devices

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

Compatibility of CIDEX® OPA Solution with Materials and Medical Devices

CIDEX OPA Solution has been tested for compatibility with a variety of materials and reprocessed devices. The materials tested included metal, plastic, elastomers and adhesives commonly used in the construction of reprocessable medical devices. CIDEX OPA Solution was found to be compatible with a wide variety of materials and was found in many instances, to be less aggressive toward the materials than glutaraldehyde-based products. A list of compatible materials appears below.

METALS [1]	PLASTICS [5]	ELASTOMERS [5]	ADHESIVES [5]
Aluminum	Polymethylmethacrylate (Acrylic)	Polychloroprene (Neoprene)	Cyanoacrylate [8]
Anodized aluminum [2]	Nylon	Kraton G	EPO-TEK 301 Epoxy [8]
Brass	Polyethylene terephthalate (Polyester)	Polyurethane	EPO-TEK 353 Epoxy
Carbon steel	Polystyrene	Natural Rubber Latex	
Chrome plated brass [2]	Polyvinylchloride (PVC) [6]		
Chrome plated steel [2]	Acrylonitrile/butadiene/styrene (ABS)	Silicone rubber [6]	
Copper	Polysulfone		
Nickel plated brass [2]	Polycarbonate [7]		
Nickel silver alloy [2]	Polyethylene		
Stainless steel [3]	Polypropylene		
Titanium	Acetyl		
Tungsten carbide [2]	PTFE		
Vanadium steel [4]	Polyamide		

[1] Exposed to 31 days (744 hours) of continuous contact with CIDEX OPA Solution with no effect unless otherwise noted.

[2] Shows signs of surface discoloration at 7 days or greater.

[3] Most grades tested show no effect. Others may exhibit slight discoloration at 7 days or greater. Stainless steel 440 shows rust at 14 days immersion.

[4] Treated with 500 cycles of CIDEX OPA Solution. Surface breakdown noted after 150 cycles (25 hour total contact).

[5] Exposed 7 days of continuous contact with CIDEX OPA Solution with no effect unless otherwise noted.

[6] Some grades or applications exhibit discoloration.

[7] Some sonic welded parts may exhibit crazing.

[8] Some loss in shear strength but show no signs of severe degradation.

Many devices, including endoscopic, respiratory therapy and anesthesia equipment were tested and found to be compatible with CIDEX OPA Solution.

Contraindications

CIDEX OPA Solution should not be used to sterilize heat sensitive medical devices. When sterilization by a biologically monitorable process is not feasible, high level disinfection of rigid endoscopes is recommended by the Centers for Disease Control and Prevention and the Association for Professionals in Infection Control and Epidemiology (APIC).

SAFETY

Users should follow OSHA Bloodborne Pathogens Universal Precautions when handling and cleaning soiled devices.

When disinfecting devices, gloves of appropriate type and length, eye protection, and fluid-resistant gowns should be used. When using latex rubber gloves, the user should double glove and/or change single gloves frequently, e.g., after 12 minutes of exposure. For those individuals who are sensitive to latex or other components in latex gloves, 100% synthetic copolymer gloves, nitrile rubber gloves, or butyl rubber gloves may be used. Contact with CIDEX OPA Solution may stain exposed skin or clothing.

CIDEX OPA Solution should be used in a well-ventilated area and in closed containers with tight-fitting lids. If adequate ventilation is not provided by the existing air conditioning system, use of local exhaust hoods or ductless fume hoods/portable ventilation devices that contain filter media that absorb *ortho*-phthalaldehyde from the air. See package insert for detailed safety information.

Additional emergency, safety, or technical information about CIDEX OPA Solution can be obtained from Advanced Sterilization Products at (888) 783-7723, or by contacting your local Advanced Sterilization Products sales representative.

STORAGE AND DISPOSAL

CIDEX OPA Solution should be stored in its original sealed container at controlled room temperature 15 - 30°C (59 - 86°F) in a well-ventilated, low traffic area. Once opened, the unused portion of the solution may be stored in the original container for up to 75 days until used. The expiration date of the CIDEX OPA Solution is found on the immediate container.

ORDERING INFORMATION

Reorder	Description	Case Contains
20390	One Gallon (3.785 L) Container	4 gals (4 x 3.785L)/case
20392	CIDEX® OPA Solution Test Strips	60 strips/btl; 2 btls/case
20393	CIDEX® OPA Solution Test Strips	15 strips/btl; 2 btls/case

REFERENCE

Roberts, C.G. and H. Chan-Myers. 1998. Efficacy of Dilute *ortho*-Phthalaldehyde Solutions with Glutaraldehyde-Resistant Mycobacteria. Fourth International Conference of the Hospital Infection Society, Edinburgh, Scotland; September 14, 1998.

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