TECHNICAL INFORMATION

ASP™

CIDEX® OPA

DESCRIPTION

CIDEX® OPA Solution is a High Level Disinfectant (HLD) for use in reprocessing heat-sensitive medical devices. 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 reused, 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 reused and diluted CIDEX® OPA Solution at 25°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 reused and diluted CIDEX® OPA Solution at 25°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 reused and diluted CIDEX® OPA Solution after a 5-minute exposure time at 24 ± 0.5°C

ORGANISM TESTED	RESULT
Mycobacterium bovis (BCG)	≥6 Log_{10} reduction

SAFETY DATA 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. For full CIDEX® OPA toxicity and chemical information, please refer to the safety data sheet (SDS).

TYPE	REMARKS
Skin Irritation	GHS Category 1, Slight Irritation
Eye Irritation	Slight Irritation
Acute Oral Toxicity (rat)	

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 reused and diluted CIDEX® OPA Solution after a 5-minute exposure time at 25°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. A summary of results from the AOAC Sporicidal Tests performed appears below.

TABLE 5. AOAC Sporicidal Activity of Disinfectants.

ORGANISM TESTED	RESULT
Clostridium sporogenes	Reused and diluted solution had a 6 Log reduction in 1 hour at 20°C
Bacillus subtilis	No growth after 8 hours at 25°C

SIMULATED USE TEST RESULTS

Simulated use tests with flexible endoscopes contaminated with approximately 1 x 107 Mycobacterium terrae, ATCC 15755 suspended in 5% fetal bovine serum were performed with reused 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	5 MINUTES AT 25˚C MEAN LOG_{10} REDUCTION
Bronchofiberscope	Reused and diluted solution had ≥6 Log_{10} reduction
Duodenofiberscope	Reused and diluted solution had ≥6 Log_{10} reduction
Colonofiberscope	Reused and diluted solution had ≥6 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, as per SGNA Guidelines. 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 Test Strip indicates a concentration above the Minimum Effective 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 five 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 Procedure

1. Manual Processing:
   - Following removal from CIDEX® OPA Solution, thoroughly rinse the semi-critical medical device by immersing it completely in a large volume (e.g. two gallons) of water. Use sterile water unless potable water is acceptable. See sterile/potable water rinse sections on page 5.
   - Keep the device totally immersed for a minimum of one 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. SEE WARNINGS. THREE (3) SEPARATE, LARGE-VOLUME WATER IMMERSION RINSES ARE REQUIRED.
- Refer to the reusable semi-critical medical device manufacturer's labeling for additional rinsing instructions.

2. 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 semi-critical 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 one 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 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).
- 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 or other immunocompromised 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. When using potable water for rinsing, the user should be aware of the increased risk of recontaminating the device or medical equipment with microorganisms which may be present in potable water supplies. Water treatment systems, such as softeners or 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 waterborne 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 waterborne 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 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 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 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	PLASTICS	ELASTOMERS	ADHESIVES
Aluminum	Polymethylmethacrylate (Acrylic)	Polychloroprene (Neoprene)	Cyanoacrylate
Anodized aluminum	Nylon	Kraton G	EPO-TEK 301 Epoxy
Brass	Polyethylene terephthalate (Polyester)	Polyurethane	EPO-TEK 353 Epoxy
Carbon steel	Polystyrene	Natural Rubber Latex	
Chrome-plated brass	Polyvinylchloride (PVC)	Silicone rubber	
Chrome-plated steel	Acrylonitrile/butadiene/styrene (ABS)		
Copper	Polysulfone		
Nickel-plated brass	Polycarbonate		
Nickel silver alloy	Polyethylene		
Stainless steel	Polypropylene		
Titanium	Acetyl		
Tungsten carbide	PTFE		
Vanadium steel	Polyamide		

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

Contraindications

1. CIDEX® OPA Solution should not be utilized to process any urological instrumentation used to treat patients with a history of bladder cancer. In rare instances, CIDEX® OPA Solution has been associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies.
2. CIDEX® OPA Solution should not be utilized to process instrumentation for patients with known sensitivity to CIDEX® OPA Solution or any of its components.
3. 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 (CDC) and the Association for Professionals in Infection Control and Epidemiology (APIC).
4. For complete list of precautions, warnings and contraindications refer to the product IFU.

PRODUCT INFORMATION

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 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 3.785 L)/case
20392	CIDEX® OPA Test Strips	60 strips/btl; 2 btls/case

REFERENCE

Akamatsu T, Minemoto M, Uyeda M. Evaluation of the antimicrobial activity and materials compatibility of orthophthalaldehyde as a high-level disinfectant. J Int Med Res. Mar-Apr 2005;33(2):178-187.

Protecting patients during their most critical moments™

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