Rapicide® OPA/28

HIGH-LEVEL DISINFECTANT

TECHNICAL MONOGRAPH

Safety, Efficacy and Microbiological Considerations

*For use in the United States

50098-052 Rev B

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Product Description

- Active Ingredient: *ortho*-phthalaldehyde (OPA)
- Concentration: 0.575%
- Minimum Recommended Concentration (MRC): 0.35% OPA
- Use/Reuse Period: Up to 28 days
- High-Level Disinfection Claim: 10 minutes at room temperature (minimum 20°C) for manual reprocessing or 5 minutes at 25°C in an AER
- Dilution Required: None
- Activation Required: None

RAPICIDE® OPA/28 High-Level Disinfectant (HLD) is a ready-to-use disinfectant with an active ingredient of 0.575% *ortho*-phthalaldehyde. RAPICIDE OPA/28 HLD also contains buffers, surfactants, antifoaming agents and deionized water.

Intended Use

RAPICIDE OPA/28 HLD is a high level disinfectant solution for reprocessing of heat sensitive semi-critical medical devices for which sterilization is not suitable. This disinfectant may be used at or above its minimum recommended concentration (MRC) of 0.35% OPA as determined by RAPICIDE OPA/28 Test Strips in manual device reprocessing with an immersion time of at least 10 minutes at a minimum temperature of 20°C for a reuse period not to exceed 28 days. RAPICIDE OPA/28 HLD may also be used in compatible legally marketed automated endoscope reprocessors at or above its MRC as determined by RAPICIDE OPA/28 Test Strips with an immersion time of at least 5 minutes at a minimum temperature of 25°C for a reuse period not to exceed 28 days.

Read and follow the directions for use and precautionary statements contained in the package insert before using.

Safety

In handling RAPICIDE OPA/28 High-Level Disinfectant (HLD), the following precautions should be followed:

- Always wear proper personal protective equipment (PPE) including proper eye protection and protective, chemically-resistant gloves when handling RAPICIDE OPA/28 HLD. Avoid contact with eyes, skin and clothing.
- In case of contact with eyes or skin, flush with copious amounts of water for a minimum of 15 minutes. Seek immediate medical attention in case of eye contact. If clothing is contaminated, remove clothing, wash skin and wash clothing before reusing.
- Avoid breathing fumes or vapors. Use RAPICIDE OPA/28 HLD only in well ventilated areas.
- Harmful if swallowed. If ingested, drink large amounts of water. Do no attempt to induce vomiting. Call a physician immediately.
- Do not store RAPICIDE OPA/28 HLD near or with food.
- Refer to product insert and manufacturer's instructions for reprocessing of medical devices in AER units.
- Refer to product insert for instructions on reprocessing of medical devices manually.

Storage

- Store RAPICIDE OPA/28 HLD in its original container at controlled room temperatures between 15°C - 25°C (59°F - 77°F) in a well ventilated area.
- Once opened, the unused portion of the solution may be stored in its original container and used for up to 75 days.
- Do not store with flammable materials, metals or oxidizing materials.

Neutralization and Disposal

Dispose of this product in accordance with all applicable Federal, state and local regulations. If required by regulations neutralize the solution using a glycine-based neutralizer prior to disposal. A minimum of 25 grams of glycine should be used to neutralize one gallon of RAPICIDE® OPA/28 solution. Discard residual solution into the drain. Flush the drain thoroughly with water.

Do not reuse empty containers. Rinse the container with water and dispose of empty container in accordance with all applicable regulations.

See the Material Safety Data Sheet (MSDS) for additional information.

Efficacy

High-Level Disinfection Summary

RAPICIDE OPA/28 High-Level Disinfectant will disinfect with an exposure time of 10 minutes at room temperature (minimum 20°C) for manual reprocessing or 5 minutes at 25°C in an AER at a concentration equal to or greater than the minimum recommended concentration (MRC) of 0.35% OPA.

Efficacy Testing Summary

RAPICIDE OPA/28 HLD was tested at 0.35% OPA or below under case conditions according to the AOAC methods and other applicable standards for microbiological testing for germicidal efficacy. Tests demonstrated sporicidal, bactericidal, fungicidal, tuberculocidal, and virucidal efficacy (Table 1). The RAPICIDE OPA/28 HLD used for all testing represented worst case stressed material at the MRC of 0.35% OPA.

Table 1: Summary of Efficacy Testing of RAPICIDE OPA/28

(10 minutes at 20°C for manual reprocessing or 5 minutes at 25°C in an AER)

TESTS	ORGANISM	RESULTS
Sporicidal (in 32 hours)	B. subtilis	Complete inactivation
Sporicidal (in 32 hours)	C. sporogenes	Complete inactivation
Tuberculocidal	M. bovis	>6 log reduction
Virucidal	Poliovirus Type 1	Complete inactivation
Virucidal	Poliovirus Type 2	Complete inactivation
Virucidal	Herpes simplex virus Type 1	Complete inactivation
Fungicidal	T. mentagrophytes	>6 log reduction
Bactericidal	S. aureus	>6 log reduction
Bactericidal	P. aeruginosa	>6 log reduction
Bactericidal	S. enterica	>6 log reduction
High-Level Disinfection Efficacy		
(Simulated Use)	M. terrae	>6 log reduction
High-Level Disinfection Efficacy		
(Clinical In-use)	Clinical Use	High-Level Disinfection

Material Compatibility

RAPICIDE® OPA/28 High-Level Disinfectant has been shown to be compatible with common materials of medical devices including endoscopes and automated endoscope reprocessing systems, and with common metals, plastics, elastomers, ceramics and adhesives (see Table 2). RAPICIDE OPA/28 HLD is compatible with detergents which are mild in pH, low foaming, and easily rinsed from equipment. Devices may be damaged if cleaned with highly acidic or alkaline detergents, poorly rinsed after disinfection, stored wet, or dried at temperatures exceeding 40°C (105°F).

Table 2: List of Compatible Materials

METALS	PLASTICS	ELASTOMERS
Stainless Steel 17-7	Polyethylene	Buna
Stainless Steel 304	HDPE	EPDM
Stainless Steel 302	Polypropylene	Viton – HK
Stainless Steel 316	PVC - White	Silicone Rubber
Stainless Steel 430	PVC – Gray	Neoprene
Galvanized Steel	PVC – Colored	Nitrile Rubber
Mild Steel	CPVC	Santoprene
Inconnell	Polysulfone	Polyurethane
Hastelloy	Polycarbonate	Ceramic
Nickel-plated Brass	Acrylic	Devcon Adhesive
Naval Brass	ABS	
Copper	Delrin	
Anodized Aluminum 2024	Polystyrene	
Bare Aluminum 6061	Nylon	
Bare Aluminum 2024	PTFE	
Anodized Aluminum 6061	PCTG	
Anodized Aluminum 1100	PVDF	

The compatibility of RAPICIDE OPA/28 HLD has been examined by both running intensive endoscope exposure tests, as well as by doing materials compatibility testing against the chemistry. In addition, biocompatibility testing has been done in order to demonstrate the rinsing of the chemical components from the endoscopes.

Chemical exposure lifetime testing was performed on an endoscope to evaluate the biological effects of germicide residues remaining on an endoscope after reprocessing for 100 cycles. Testing showed that the material is safe for patient contact and staff.

Endoscope Compatibility and Biocompatibility

The endoscope compatibility testing was run using three flexible endoscopes each subjected to a minimum of five hundred (500) high-level disinfection cycles in a MEDIVATORS DSD-201 automated endoscope reprocessor (AER) using RAPICIDE® OPA/28 High-Level Disinfectant at 20°C - 26°C. The three endoscopes used were an OLYMPUS® endoscope model XCF H160AYL, FUJINON® endoscope model EC 530HL, and PENTAX® endoscope model VSB 2990i. The endoscopes were evaluated at the beginning and at the conclusion of the study by Surgical Repair Technologies (Eagan, MN) in order to detect any significant cosmetic changes or any effects on the endoscope operation functions including angulations, control, biopsy, insertion, tub, light guide, suction, light guide connector, eyepiece, image, light illumination, air/water function, and leak testing. No changes were observed in physical appearance or functionality, and the endoscopes passed all leak tests.

In addition to overall endoscope compatibility testing, biocompatibility testing was conducted to evaluate the biological effects of germicide residues remaining on an endoscope after 1 and 100 reprocessing cycles using RAPICIDE OPA/28 High-Level disinfectant. Following completion of testing in the AERs, there were no toxic residues remaining on the endoscope making it safe for patient and staff contact. The results indicate that the MEDIVATORS DSD-201 Automated Endoscope Reprocessor can adequately rinse RAPICIDE OPA/28 High-Level Disinfectant.

A test was also conducted to evaluate the biological effects of germicide residues remaining on an endoscope after the manual disinfection reprocessing cycle. Following completion of testing, there were no toxic residues remaining on the endoscope, thus making the endoscope safe for patient contact.

Toxicity

RAPICIDE OPA/28 High-Level Disinfectant has been extensively evaluated and tested for potential toxicity to both user and patient.

Summary of OPA Toxicity

Standard toxicological testing data available for OPA was evaluated to assess the possible toxicological effects from inhalation, oral consumption, eye contact, skin contact, dermal irritation, dermal sensitization and genotoxicity (Table 3). Results of the toxicity evaluation support that RAPICIDE OPA/28 HLD is safe for both patients and users when used as intended.

Table 3: Summary of OPA Toxicity Testing

TEST	TEST RESULTS
Acute Oral Toxicity (Rat)	LD50 > 5000 mg/kg
Acute Inhalation Toxicity (Rat)	LC50 > 200 mg/L
Primary Eye Irritation	Ocular irritant
Repeat Dermal Toxicity (Rabbits)	Irritation similar to glutaraldehyde
LD50 > 2000 mg/kg	
Primary Skin Irritation (Rabbit)	May cause dermatitis
Skin Sensitization (Mice)	Potential for induced sensitivity
Development effects	Not known to cause birth defects
Delay fetal development at dose of 40 mg/kg	
Mutagenicity/Carcinogenicity	No reports of possible carcinogenicity
Environmental toxicity (Rainbow trout)	LC50 > 46-160 µg/L (96 hours)

Summary of Patient Toxicity

Testing was performed to evaluate the toxicity of endoscope materials exposed repeatedly to RAPICIDE® OPA/28 High-Level Disinfectant and detergent solution. Samples of bending rubber that are representative of material commonly used on the insertion tube portion of endoscopes was exposed to detergent and the germicide under worst case conditions for both a single cycle and 100 repeated AER cycles. The samples were then evaluated by using a standard cytotoxicity test per ISO 10993-5. Test results showed that the exposed material had no cytotoxic effects and indicate that endoscope materials exposed to RAPICIDE OPA/28 HLD material would be safe for patient contact.

Also, as described above, biocompatibility testing has been performed under worst case conditions to demonstrate the ability of manual and AER rinsing cycles to sufficiently remove RAPICIDE OPA/28 HLD and detergent residues from devices following reprocessing. Test results indicate that RAPICIDE OPA/28 HLD and detergent can be successfully rinsed from devices and any remaining residuals are safe and nontoxic for both the patient and user.

Contraindications

- RAPICIDE OPA/28 HLD should NOT be used to reprocess any instrumentation for patients with known sensitivity to similar OPA disinfectant solutions.
- RAPICIDE OPA/28 HLD should NOT be used to sterilize medical or dental devices and should NOT be used to reprocess devices that routinely penetrate mucous membranes during use or are otherwise used in normally sterile tissue of the body (critical devices).
- RAPICIDE OPA/28 HLD should NOT be used to reprocess any urological instrumentation to be utilized for cystoscopy or other urological procedures for patients with a history of bladder cancer. In rare instances similar OPA based disinfectants have been associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies.

Packaging Configuration

RAPICIDE OPA/28 High-Level Disinfectant is available in the following packaging configuration. One package contains 4 gallons (15.2 Liters) of use solution.

4 bottles per case – each bottle is 1 gallon (3.8 liters)

RAPICIDE OPA/28 Test Strips, used to measure the minimum recommended concentration (MRC) of RAPICIDE OPA/28 High-Level Disinfectant, is available in the following packaging configuration.

2 vials per package – each vial contains 50 strips

Cantel Medical

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