MEDIVATORS®

RAPICIDE® PA

High-Level Disinfectant

Safety, Efficacy, and Microbiological Considerations

* For use with RAPICIDE PA outside of the USA, Canada and Australia

MEDIVATORS
A Cantel Medical Company

50097-467 Rev C

Contents

PRODUCT DESCRIPTION

RAPICIDE® PA Solutions A and B are combined to produce a single use-solution for High-Level-Disinfection (HLD) of endoscopes and related accessories with peracetic acid (PAA) as the active agent. The characteristics of the single use-solution are:

- Active Ingredient: Peracetic Acid
- PAA Concentration: 1000-1300 ppm
- Minimum Recommended Concentration (MRC): 850 ppm
- Reuse Period: Single use
- High-Level Disinfection Claim: 5 Minutes at room temperature (minimum of 20°C)
- Sterilization Claim: 10 minutes at room temperature (minimum of 20ºC)
- Dilution Required: 1:1 to 48 parts water
- Activation Required: No
- Corrosion Inhibitors: Yes

RAPICIDE PA is a single use liquid chemical germicide solution with PAA in the concentration range of 1000-1300 ppm. RAPICIDE PA also contains corrosion inhibitors and water conditioning agents.

INTENDED USE

RAPICIDE PA is intended for high-level disinfection of endoscopes and related accessories in MEDIVATORS® ADVANTAGE PLUS®, DSD EDGE® or RAPIDAER® automated endoscope reprocessors (AER). RAPICIDE PA is intended for single use at room temperature (minimum of 20°C, may also be used at 30ºC).

In appropriate AER's, RAPICIDE PA High-Level Disinfectant Test Strips may be used to verify that the disinfectant concentration remains above the minimum recommended concentration (MRC). ADVANTAGE PLUS and DSD EDGE AER's contain a sample port where the RAPICIDE PA use solution can be dispensed for monitoring of the MRC. MEDIVATORS RAPIDAER reprocessor utilizes built in monitoring where test strips are not required.

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

SAFETY

In handling RAPICIDE® PA, the following precautions should be followed:

- RAPICIDE PA parts A & B are corrosive. Always wear proper eye protection, and protective, chemically-resistant gloves when handling RAPICIDE PA. 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.
- Avoid breathing fumes or vapors. Prepare and use RAPICIDE PA only in well ventilated areas.
- Harmful if swallowed. If swallowed, drink large amounts of water. Do not attempt to induce vomiting. Call a physician immediately.
- Do not store RAPICIDE PA near or with food.
- Refer to product insert and manufacturer's instructions for reprocessing of medical devices in AER units.

STORAGE

Store RAPICIDE PA at temperatures of 25°C (77°F) or lower. Protect from freezing.

NEUTRALIZATION AND DISPOSAL

Dispose of this product in accordance with all applicable Federal, State and Local regulations. If allowed by federal, state or local regulatory authority, flush spilled solution of RAPICIDE PA (Solutions A & B combined) to the drain using cold water. Run cold water for 15 minutes.

Do not reuse the empty containers. Triple rinse the containers with water and dispose of in an incinerator or in accordance with local, state or federal requirements.

For more information on spills and disposal refer to the RAPICIDE PA spill cleanup and disposal document.

EFFICACY

High-Level Disinfection Summary

RAPICIDE® PA will high-level disinfect with an exposure time of 5 minutes at room temperature (minimum 20°C) at a concentration equal to or greater than the minimum recommended concentration (MRC) of 850 ppm PAA.

Sterilization Summary

RAPICIDE PA will sterilize (>99.9999% reduction of bacterial endospores) with an exposure time of 10 minutes at room temperature (minimum 20ºC) at concentration equal to or greater than the minimum recommended concentration (MRC) of 850 ppm PAA.

Efficacy Testing

RAPICIDE PA was tested at 850 ppm PAA under case conditions according to AOAC methods and other applicable standards for microbiological testing for germicidal efficacy. Tests demonstrated sporicidal, bactericidal, fungicidal, tuberculocidal and virucidal efficacy.

Table 1: SUMMARY OF EFFICACY TESTING RAPICIDE PA 5 minutes at 20ºC

TESTS	ORGANISM	RESULTS
Sporicidal	*B. subtilis*	>4.5 log reduction*
Tuberculocidal	*M. bovis* *M. terrae*	>4 log reduction
Virucidal	Adenovirus type 5	>6 log reduction
Fungicidal	Yeast *C. albicans*	Total Kill
Bactericidal	*P. aeruginosa*	Total Kill
Bactericidal	*S. aureus*	Total Kill
Bactericidal	*E. feacalis* *E.hirae*	Total Kill
Simulated Use	*M. terrae*	>6 log reduction

* >6 log reduction at 10 minutes

MATERIAL COMPATIBILITY

RAPICIDE® PA High-Level Disinfectant is compatible with the following reusable devices and materials: flexible endoscopes, rubber, plastic, many types of metals (such as stainless steel, carbon steel, and aluminum).

RAPICIDE PA High-Level Disinfectant is recommended for use with medical devices made from materials shown in *Table 2* below. These devices may be damaged if cleaned with highly alkaline detergent, poorly rinsed after disinfection, stored wet, or dried at temperatures exceeding 40°C (105°F).

TABLE 2: List of Compatible Materials

Metals	Plastics	Elastomers
Hastelloy	Polyethylene	Aflas
301 Stainless steel	Polyvinylchloride	Silicone Rubber
304 Stainless steel	Teflon (PTFE)	Viton
316 Stainless steel	Polyurethane	Santaprene
Inconnel	Polysulfone	EPDM
	Polyester	
	Polycarbonate	
	Nylon	
	PVDF	
	Polypropylene	
	PETG	
	Acetal	

The compatibility of RAPICIDE PA has been examined both by running intensive scope exposure tests, and also by doing materials compatibility testing versus the "use" solution (as well as the pure part A and part B). In addition, biocompatibility testing has been done in order to demonstrate the rinsing of the chemical components from the scopes.

The endoscope compatibility testing was run using Olympus model TJF-1 and model CF-100l scopes, subjecting them to 500 cycles on the ADVANTAGE PLUS® reprocessor. Each cycle consisted of a 2 minute exposure to detergent, rinsing, a 6 minute disinfection cycle (worst case), followed by rinsing and alcohol. The scopes were inspected before and after the 500 HLD cycle run. The inspection was done by Surgical Repair Technologies (Eagan, MN), involving functional evaluation of angulation, control, biopsy, insertion tub, light guide, suction, light guide connector, eyepiece, image, light illumination, air/water function, and leak testing. No change was observed in physical appearance or functionality, and the scopes passed all leak tests.

We performed chemical exposure lifetime testing on exposed components of the ADVANTAGE PLUS reprocessor. The exposure to the Use Solution (after mixing and diluting the parts A & B to the use dilution) was performed on metal, plastic and elastomer wetted components. The metal components included several types of stainless steel (SS 304, 301, 316), Inconnel springs, ceramic and glass. All components passed the testing. The plastic and elastomer component included EPDM, PETP, nylon, PFA, PP, PTFE, PVC, PVDF, Viton, silicone, santoprene, PS, and proprietary materials such as Iglidur and Gelcoat. All components passed the testing.

Chemical exposure lifetime testing was also performed on materials that would be exposed to Part A alone (undiluted) and also part B alone (undiluted). These materials included stainless steel (316) and Hasteloy, PVC, PP, EPDM and Aflas. All components passed the testing, except for slight effects on two EPDM components (which are part of preventative maintenance and were replaced).

The chemical exposure testing for both the Use Solution and Part A or Part B alone included dimensional, weight, visual and infrared analysis.

In addition to the chemical compatibility testing, a study was done to test the toxicity of rubber components (from Olympus parts) that were exposed to 100 HLD cycles. These materials are from the distal end of an endoscope, which will make patient contact. It was concluded that the RAPICIDE® PA had a non-toxic effect on the rubber parts, based on results of cytoxicity testing after the 100 cycles. This test is governed by ANSI/AAMI/ISO 10993-5:1999.

Biocompatibility testing was also done to examine the residuals on endoscopes after 1 and 100 cycles of HLD exposure. It was concluded that the ADVANTAGE PLUS reprocessor adequately rinses detergent and disinfectant residues from the surfaces of the endoscope, making it safe for both patients and hospital staff.

The above testing indicates the RAPICIDE PA is safe to use on endoscopes and the exposed materials. No effect was observed on the endoscope components or functionality.

TOXICITY

RAPICIDE® PA has been extensively tested for potential toxicity to both user (environmental) and patient.

Summary of Environmental Toxicity

Standard toxicological testing was performed to evaluate the possible toxicological effects from inhalation, oral consumption, eye contact, skin contact, dermal irritation, dermal sensitization and genotoxicity. *Table 3* summarizes the environmental test results.

Table 3: Summary of Environmental Toxicity Tests

Test	Test Results
Acute Oral Toxicity (Rat)	$LD_{50} > 5$ g/kg
Acute Inhalation Toxicity (Rat)	$LC_{50} > 2.1$ mg/kg
Primary Eye Irritation	Corrosive to ocular tissue
Acute Dermal Toxicity (Rabbit)	May produce systemic effects at $LD_{50} > 2$ g/kg
Repeat Dermal Toxicity (Rat)	RAPICIDE PA is not associated with observed signs of toxicity at 1000 mg/kg
Primary Skin Irritation (Rabbit)	Not an irritant
Skin Sensitization (Guinea Pigs)	Not an allergen
Genotoxicity (Ames)	Non-mutagenic

Summary of Patient Toxicity

Standard toxicological tests were performed to evaluate the possible toxicological effects by cytotoxicity, mucosal irritation and hemolysis. *Table 4* summarizes the patient test results.

Table 4: Summary of Patient Toxicity Tests

Test	Test Results
Cytotoxicity (RAPICIDE® PA)	Non-toxic at 1:500 dilution
Cytotoxicity (A-rubber)	Non-toxic
Hemolysis	Non-Hemolytic at 1:1000 dilution
Mucosal Irritation	Minimal irritant
Acute Intravenous Toxicity	$LD_{50} > 5$ g/kg

BIOCOMPATIBILITY

A study was conducted to determine the amount of peracetic acid (PAA) and hydrogen peroxide (HP) residue that remain on endoscopes after reprocessing in an AER with RAPICIDE® PA High-Level Disinfectant and Sterilant, and rinsing with water. The study used RAPICIDE PA at the maximum possible use-solution concentration of PAA and exposed three pediatric colonoscopes to the longest labeled exposure time, a five hour cycle. The pediatric colonoscope was used in the study because it is representative of an endoscope that is most difficult to rinse due to its long narrow channels and large surface area.

Following a five hour cycle in the ADVANTAGE PLUS® AER, the three endoscopes were immediately and exhaustively extracted for 24 hours to remove all PAA and HP residues. This was followed by an additional 4 hour residue extraction.

From the extractions, a worst case of human observable exposure dose was calculated to be 0.9 mg/kg and 1.11 mg/kg for PAA and HP, respectively. The worst case human observable exposure dose limits was compared to the reported rat Repeat Dermal No Observed Effect Level (NOEL) doses of 4.4 mg/kg and 5.4 mg/kg for PAA and HP, respectively. The risk to humans is shown to be close to *five* fold lower than to the rat Repeat Dermal NOEL.

These extractions were performed over a 24 hour period, which is a great deal longer than a typical endoscopy procedure of 15 minutes to two hours. In relating these residual values to realistic patient exposure, we conclude that these PAA and HP levels are not toxic if introduced into the human body.

COMPATIBILITY WITH ENDOSCOPES (500 CYCLES)

An ADVANTAGE PLUS® reprocessor was operated with RAPICIDE® PA in two types of endoscopes for a minimum of 500 cycles. The AER was set to 32º ± 2º C for worst case simulation. At the end of the cycles the endoscopes were examined by Surgical Repair Technologies. No damage was detected, and the endoscopes functioned properly, demonstrating that RAPICIDE PA High Level Disinfectant is compatible with flexible endoscopes (MEDIVATORS QP 201745).

PACKAGING CONFIGURATION

RAPICIDE PA is available in the following packaging configuration. One package contains 20 liters of use-solution.

Packaging:

4 Bottles per Case (20 Liters)

2 Bottles of Part A X 5 Liters

2 Bottles of Part B X 5 Liters
each bottle weighs approximately 10.5 lbs.