PRODUCT BULLETIN

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Date: **July 29, 2011**

RE: Efficacy of Rapicide® Glutaraldehyde High-Level Disinfectant against *Clostridium difficile* Endospores

Summary: This study measured the rate-of-kill of *C. difficile* endospores inoculated into Rapicide High-Level Disinfectant. After various exposure times (5, 10, 20, and 40 minutes), the number of survivors was determined. At all exposure times, no survivors were recovered. The germicide had effected a >99.9999% or >6.3-log reduction in the number of endospores in 5 minutes at 35°C.

Introduction: *C. difficile* is an intestinal pathogen which can cause severe gastroenteritis, colitis, diarrhea, and even death in humans. The spore-forming stage of the organism can reside undetected in the colon for extended periods of time. It is usually acquired as a nosocomial agent during an in-patient's stay at a hospital. If the patient is taking an extended course of antibiotics for an infection, the normal flora in the intestine will die back, allowing the spores of *C. difficile* to vegetate and grow, releasing a cytotoxin that is responsible for the above conditions. Recently, a more virulent strain has appeared which has heightened awareness of the organism and made effective infection control more imperative. In addition to cases where antibiotic therapy is implicated, *C. difficile* cases are typically found in the elderly or in patients with impaired immunity. When the organism is actively growing (vegetative form) the cells are susceptible to destruction by high-level disinfectants. However, when the organism is in the endospore state, it is resistant to disinfectants and there are a limited number of agents which can destroy the endospores and not damage medical devices, including flexible endoscopes. This group includes glutaraldehydes, peracetic acid-hydrogen peroxide mixtures, and hydrogen peroxide. All of these chemicals have been formulated into high level disinfectants which are commercially available. The present study was designed to evaluate the glutaraldehyde-based product Rapicide for its ability to kill *C. difficile* endospores under the conditions (5 minutes, 35°C) required for high-level disinfection.

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Methods: The organism was grown to a high cell density in right organic medium. The mix of spores and vegetative cells was washed with buffer then treated with alcohol to kill the vegetative cells and produce the spore inoculums used for the efficacy test. Before testing, 5% serum was added to the spore suspension as an organic soil. The presence of the organic soil helps to evaluate the ability of the germicide to be effective on devices that have been cleaned but still have a low residual of bodily fluids. An aliquot of Rapicide was warmed to 35°C and a spore suspension was added. At exposure times of 5, 10, 20 and 40 minutes an aliquot of germicide/spore mix was removed and added to the neutralizer to stop the action of the germicide. The number of survivors at each exposure time was quantified by filtering the neutralizer and culturing the filter on agar medium. The number of cells present in the germicide at time zero (test population control) was determined and the efficacy of the neutralizer was confirmed.

Results: As shown in the table, there were no survivors at any of the exposure times. These data indicate that Rapicide has the ability to kill *C. difficile* endospores (at an endospore population considerably higher than what would be expected on or in medical devices) under the test conditions used in this study.

Rate-of-kill test of Rapicide against *Clostridium difficile* endospores

Exposure time (minutes)	Test population control[a]	Log_{10} test population control	Number of survivors (CFU/ml)[b]	Log_{10} number of survivors	Percent reduction	Log_{10} reduction
5	1.88×10^6	6.274	<1	<0	>99.9999%	>6.274
10			<1	<0	>99.9999%	>6.274
20			<1	<0	>99.9999%	>6.274
40			<1	<0	>99.9999%	>6.274

a: Colony-forming units/ml of germicide/endospores mixture at time zero
b: Colony-forming units/ml of germicide/endospores mixture at indicated exposure time

If you need further assistance please contact Medivators Customer Support at 1-800-444-4729 or contact your local Minntech Representative.